Tuesday, 14 January 2025

(10.00 am)

Opening remarks by THE CHAIR

LADY HALLETT: Good morning.

The Inquiry completed the oral hearings for Module 3, healthcare systems, in December 2024, and work has already started in earnest on drafting my report and recommendations for Module 3.

Today we begin the first set of hearings for 2025, and it will be a very busy year. First, we have the module that we begin today on vaccines and therapeutics. That will be followed by modules dealing with procurement, test and trace, the care sector, children and young people, and the economic response.

As each set of hearings conclude, work begins in earnest on drafting the report for that module and any findings and recommendations I make. So, for the Inquiry, 2025 will involve six sets of hearings and the drafting of reports for Modules 2 to 9. So we have a great deal of work to do to fill my terms of reference.

Beginning vaccines and therapeutics today, we would normally begin with an impact film. For reasons entirely beyond the control of the Inquiry, the film needs last-minute editing. Work has already started on

that, and as soon as it is ready it will be played, and that should be later today.

I am sorry for the delay -- it is not the fault of the Inquiry, I wish to emphasise -- and I know that there will be many people here and possibly following online who are anxious to see it, but we will play it today. So I'm sorry for the delay.

At this stage, then, instead of playing the impact film, I will call on Mr Hugo Keith KC, Counsel to the Inquiry, to set out the issues that this module will be investigating.

Mr Keith.

Opening statement by LEAD COUNSEL TO THE INQUIRY for MODULE 4

MR KEITH: My Lady.

As with all statutory inquiries under the Inquiries Act (2005), this Inquiry, your Inquiry, is bound by and must address the issues and matters identified in the terms of reference to which you have referred already.

Included in your terms of reference is the obligation to consider and report upon the response of the health and care sector across the United Kingdom, including the development, daily living, and impact of therapeutics on vaccines. So this module, Module 4, is concerned with the important topic of vaccines and

therapeutics, and in particular I emphasise the systems and processes for their research, manufacture, trialling, safety, authorisation, and delivery.

As is very well known, on 2 December 2020, following a recommendation from the Medicines and Healthcare products Regulatory Agency, the UK regulator, and on advice from the Commission on Human Medicines (CHM) and its expert working groups, a UK minister licensed the first Covid-19 vaccine for use in the United Kingdom. This was the Pfizer BioNTech vaccine, brand name Comirnaty.

This vaccine was authorised for use under the temporary authorisation procedure provided for by what is known as Regulation 174 of The Human Medicines Regulations 2012. This is a UK legal provision that permits authorisation on a temporary basis, as opposed to the direct application of EU law, which was then applicable in the United Kingdom, and in fact which continued to apply until 11 pm on the night of 31 December 2020 at the end of the transition period.

I need to start this opening by saying something about the trial and authorisation process that led to that decision, because that process applies in general terms to both vaccines and therapeutics. As will be examined in the course of this module, but now in

summary outline only, companies which develop new medicines, including vaccines, first need to obtain an authorisation to run clinical trials in the United Kingdom.

Authorisation to use the medicine clinically can then only be granted following the successful completion of a rigorous pre-clinical and clinical trial process. Clinical trials are conducted via a series of phases, phases I, II and III, to test the safety and effectiveness of the trial medicine. In the case of the United Kingdom Covid-19 vaccines, the phase III trials were well powered trials of between 20 or so thousand to 43 or so thousand human volunteers. Equivalent, in fact, to other large-scale clinical trials required for the licensing of other vaccines.

The manufacturer then submits to the MHRA the results of those clinical trials as well as data on the safety, quality and effectiveness of the medicine, including data that is available both for and against the product. All safety data for the medicine must be provided, regardless of where in the world the trials took place.

The UK clinical trial process is also overseen through audits and visits carried out by the MHRA, and each batch of medicine is examined by the MHRA's

laboratories independently of the testing carried out by the manufacturer.

During the Covid-19 pandemic, to increase efficiency and to progress the regulatory review in a shorter time, evidence in support of these authorisation applications was considered in an expedited and flexible rolling review procedure by the MHRA. And in effect, this allowed the manufacturers to provide packages of data as they were generated, as opposed to waiting until the conclusion of their trials before submitting all the data in one package.

The expert evidence commissioned by this Inquiry is to the effect that there was no reduction in the efficacy or safety of any of the vaccines, or the trials, as a result of this process.

As with all clinical trials, the MHRA also requires the manufacturer to report what is known as any suspected unexpected serious adverse reaction, a SUSAR, within the clinical trials. It is an adverse event, a condition or a reaction which is assessed to be unexpected, serious, and as having a reasonable possibility of a causal relationship with the drug being studied.

Where in the case of a specific vaccine, the clinical trials were conducted globally by the

manufacturer across multiple sites, but with at least one site in the United Kingdom, the MHRA required the reporting of any SUSARs occurring anywhere in the world.

My Lady, because clinical trials can only study a finite number of patients over a defined period, rare or very rare adverse reactions are unlikely to be identified by those trials. The serious conditions for which there now exists published evidence suggesting an association with a Covid-19 vaccine were all either very rare, that is to say between 1 in 10,000 and 1 in 100,000, doses; or even rarer, described in places as extremely rare, that is to say less than 1 in 100,000 doses, and a reaction or a condition that only occurs in less than 1 in 100,000 people will simply not be apparent in a clinical trial involving only 30,000 people. It will only become apparent when much higher numbers of people, for example, at a population level, are being vaccinated.

It is worth remembering that during the first two days of vaccine rollout in the United Kingdom, more people had been vaccinated than in all the clinical trials in the United Kingdom up to that point.

For this reason, and because certain groups such as those with underlying chronic conditions or those who are immunocompromised or pregnant women, did not take

part in the clinical trials, a crucial part of the regulatory process is the system of post-authorisation surveillance of the safety of the medicine in clinical use. Obviously, as clinical usage of the medicine expands, more and more real-world data on the safety of that medicine, in this particular case vaccine, becomes available, and this must of course be closely examined.

The manufacturer is therefore legally obliged to keep under review the safety of the medicine, and the MHRA and other bodies are obliged to carry out safety monitoring so that the benefit/risk of that medicine can be constantly reassessed and prescribers, patients, and the public can be kept informed.

Without going into the detail at this stage, manufacturers are required to submit a number of documents and a great deal of data and information to the MHRA. They provide safety surveillance data, the submission of UK as well as non-UK individual case safety reports, periodic safety update reports, risk management plans, and what is known as post-authorisation safety study protocols, and at the same time, one of the major ways in which healthcare professionals and the public may be kept informed about safety is through the product information that accompanies every authorised medical product specifying

the conditions of use and details of any risk minimisation measures. And there are two principal documents which relate to the provision of that information: the summary of product characteristics and the patient information leaflet.

In addition, there are a number of important elements to how the MHRA operated its post-authorisation surveillance system. Again, it is not necessary to set them out in detail in the opening, but these four pillars, as they were known, comprise, firstly, the Yellow Card scheme through which the MHRA scientists and clinicians examined the process by which professionals and the public could report any suspected side effects or adverse drug reactions. And the MHRA published weekly summaries of the Yellow Card reporting as well as online drug analysis profiles for the vaccines.

Secondly, the MHRA examined trends and events through what is known as rapid cycle analysis, that's to say analysing pre-defined events and monitoring trends to see what the reaction in the population cohorts consists of.

Thirdly, there was targeted active monitoring through the Yellow Card Vaccine Monitor scheme, which entailed the sending out to a very large number of people, I think one and a half million people in all,

invitations inviting them to allow themselves to be followed up to see whether or not they encountered any suspected adverse reactions.

And then finally, they carried out a series of studies, formal epidemiological studies, involving evaluation of electronic health records, published medical reports, and other national data sources.

My Lady, I set all this out immediately and at this stage because the evidence before this Inquiry, particularly the evidence from the expert evidence that we have commissioned, suggests overwhelmingly that the United Kingdom operated a robust and sophisticated system for ensuring the highest levels of safety. But it will be, of course, for you to assess the accuracy of that proposition, and therein lies one of the most important purposes of this module.

The overall process by which the MHRA ensured that the Pfizer vaccine, and indeed all of the vaccines authorised under that regulation, Regulation 174, were effective and acceptably safe, was no different in substance to the process that would have applied had those applications been made pre January 2021 for full marketing authorisations under the then EU regulatory scheme, or after 1 January 2021 under the English or British UK scheme that replaced it.

I've said "acceptably safe". What is acceptably safe? Almost no active drug, vaccine, or medical procedure is without risk. And indeed, some, such as major surgery or chemotherapy, carry substantial risks. The term "acceptably safe" means that based on the assessment of the MHRA, the benefits or expected benefits associated with a particular product are considered to outweigh any risks associated with that product at a population level, and that the risks are acceptable in the context of the expected benefits.

My Lady, the public health benefit of vaccination generally is beyond argument. But the issue which arose, and it's the issue which lies at the heart of this module, was whether the MHRA properly assessed whether the benefit of a particular product -- of course the vaccines -- outweighed the risk.

In the context of those vaccines, the question was whether being vaccinated carried fewer risks than being unvaccinated, where there was a high chance of acquiring Covid, and where Covid was a life-threatening disease for many.

I should also emphasise that this approach is also broadly similar to that applied by overseas regulators such as the European Medicines Agency and the US Food and Drug Administration. Indeed, many of the most

important thresholds for aspects of this regulatory process, such as the need for randomised controlled trials, and ascertaining what level of vaccine efficacy would be considered acceptable, were in fact agreed with other major national regulators in other countries.

And so, on 8 December, the UK launched its Covid-19 vaccination delivery programme, and 91-year-old Margaret Keenan became the first person in the world to receive a Covid-19 vaccination outside the setting of a clinical trial.

By December 2023, three years later, many more vaccines had been authorised by the UK Minister, formally known as the Licensing Minister, on the recommendation of the MHRA. But the three vaccines that were actually deployed in the United Kingdom during the time period being looked at by this module were as follows: first, there was the Pfizer BioNTech vaccine, Comirnaty, to which I've already referred, which was given to Margaret Keenan.

My Lady, this vaccine is known as a messenger RNA, a ribonucleic acid, vaccine. A messenger RNA vaccine is one that carries, hence the name "messenger", an RNA molecule as opposed to part of a piece of bacteria or a virus, and this molecule causes cells in the body to produce protein that corresponds to the spike protein on

the outer membrane of the coronavirus SARS-CoV-2. That spike protein having been produced, the body then produces antibodies to attack it, thereby giving the body protection against the virus in the event of infection.

At the time of the authorisation decision for Pfizer BioNTech, clinical safety data was available for more than 43,000 trial participants, of which more than 19,000 had been followed up for at least two months post second dose. Those Pfizer BioNTech trials took place in the United States, in Europe, Turkey, South Africa and South America. Approximately 42% of those global participants and 30% of the US participants had racially and ethnically diverse backgrounds. The trials reported no SUSARs. The SUSARs are the reports that I described earlier of serious unexpected suspected adverse reactions.

As you know, authorisation for use in 12- to 15-year-olds was subsequently granted and after that in December 2021 and then in December 2022, authorisation was granted for the use of smaller doses for 5- to 11-year-olds, and then six months to 4-year-olds.

The United Kingdom Government ordered a very large number of doses in July 2020, by way of advanced purchase, 40 million doses in all, and many more

millions subsequently for primary and booster campaigns.

The second vaccine was the Oxford -- is the Oxford AstraZeneca vaccine, brand named Vaxzevria. This, my Lady, is a vaccine known as an adenoviral vector vaccine, and I describe the science and the technology underpinning these vaccines because it forms an important part of the evidence that you'll hear in due course, about the technological consequences or observations that might be drawn from their use.

The technology involves using another virus from the family of viruses known as an adeno virus to carry the vaccine, hence the name vector. The adeno virus is modified, however, so itself cannot cause infection. It's then modified so that when it enters the body, it can enter the body's cells carrying the vaccine contents, the vaccine parcel. That parcel contains, again, the genetic blueprint of the spike protein from the coronavirus target which the cell then starts to make and then, again, as with the mRNA, the body's immune system is triggered to make antibiotics to attack the spike protein, and that technology has been around for a while. It's used in vaccines for flu, the Zika virus, the tropical disease chikungunya, as well as the respiratory syndrome MERS and has since been approved in the United Kingdom for an Ebola vaccine.

That Oxford AstraZeneca vaccine was evaluated in clinical trials internationally and in the United Kingdom, involving more than 23,000 participants.

The MHRA approved pre-authorisation clinical trials to be conducted in the United Kingdom in March 2020 for phase I and II and then for phases II and III in May.

The AstraZeneca trials took place in the United Kingdom, in Brazil, and South Africa. And in relation to diversity of those trials, the non-white ratio in the UK phase III trial was 7.1%, reflective in very general terms of the ethnic make-up of this country; in Brazil, 31.4%, and in South Africa, 87%.

That vaccine, the Oxford AstraZeneca vaccine, was authorised by the MHRA on 30 December 2020, again under Regulation 174, and for use in patients aged 18 and older. It was first deployed, as you will recall, on 4 January 2021. But no authority, for reasons we'll come to, was later given for younger age groups.

In May 2020, by way of advanced purchase, 100 million doses were ordered by the United Kingdom Government.

Third, but by no means least, and last, there is the Moderna vaccine, brand name Spikevax. It is, like the Pfizer BioNTech vaccine, a messenger RNA vaccine. It was evaluated in clinical trials involving more than

30,000 participants. There were no pre-authorisation trials in the United Kingdom, but no SUSARs were in any event reported from any of the overseas clinical trials. It was authorised on 8 January 2021 for use in patients aged 18 and older.

Insofar as the ordering was concerned, some 17 million doses were ordered in November 2020 and a further 60 million were subsequently ordered. It was deployed in April 2021 and its authorisation was subsequently extended for younger age groups in August 2021 for 12 to 17-year-olds, April 2022 for 6 to 11-year-olds, and in May 2023 for those aged six months to 5 years old.

My Lady, those three vaccines are what I've called the UK Covid-19 vaccines. But there were, as I've said, other vaccines, which are required to be mentioned. Although the Novavax and the Sanofi-GSK vaccines received conditional marketing authorisations in February 2022 and December 2022 respectively, they weren't actually deployed during the time scope of this module, which ends, in its review, in June 2022.

Similarly, although doses were ordered of the Janssen vaccine, the Johnson & Johnson vaccine, in August 2020, and it too received a conditional marketing authorisation in May 2021, it also was not in fact

deployed in the United Kingdom during the relevant period. So my Lady, for those reasons those three vaccines are not the subject of specific scrutiny in the course of this module, but since, insofar as they are concerned, the focus of this module is on the systems and processes for the development, research, manufacturer, authorisation, safety and so on, of vaccines, little turns on the fact that we're not looking at those three in particular.

We are, however, looking at the process surrounding the Valneva vaccine, 60 million doses of which were ordered in September 2020, because its contract with the UK Government was terminated in September 2021, and because the circumstances surrounding that termination are not without controversy, it will be looked at.

My Lady, the figures are illuminating. The Pfizer BioNTech, Oxford AstraZeneca and Moderna vaccines made up the vast proportion of vaccinations administered in the United Kingdom during the pandemic. By the time the Vaccine Taskforceclosed its operations in September 2022, over 150 million doses of those three vaccines had been used in the United Kingdom. The number of Covid-19 doses given to people of all ages was approximately, as at September 2022, 131 million in England, over 13 million in Scotland, roughly

7.7 million in Wales, and almost 4 million doses in Northern Ireland.

We have a slide, or a number of slides, but one of which shows the weekly take-up for each of those three vaccines.

Slide 3, please.

And you can see there, over the general course of the pandemic up to June 2022, how doses of each vaccine were given weekly. And you can see, therefore, of course, how it is that use of particular vaccines ebbed and flowed during the passage of time. But by the end, AstraZeneca was in very little use, Pfizer was in the greatest use, followed by Moderna.

The next slide, slide 4, shows the cumulative total of doses given of each vaccine between December 2020 and June 2022. So again showing that, overall, many more Pfizer vaccine doses were administered by comparison to AstraZeneca and Moderna.

Those three vaccines also account for amongst the most used vaccines in the world, calculated by the number of countries which have deployed them.

It is of the utmost importance that I emphasise that by the particular metric of the need to protect, at a population level, against the SARS-CoV-2 virus, the vaccine programme succeeded.

The JCVI, the Joint Committee on Vaccination and Immunisation, estimated that the nine cohort groups who were vaccinated in phase I of the programme, that is to say the priority groups comprising residents in a care home or care home workers in priority group number 1, and then a series of groups defined by age and vulnerability to morbidity and mortality thereafter, that together they constituted 99% of preventible mortality from Covid.

The numbers of those vulnerable people protected by the vaccines amounts to some 27 million people in England and around about 33 million across the whole of the United Kingdom.

The UK Covid vaccines delivery plan noted at the time that best practice in existing vaccination programmes is two-dose vaccination of 75% of the total population cohorts.

By the end of the relevant period under consideration in this module, late June 2022, approximately 87.6% of the UK adult population had been vaccinated with two doses, so well above that planning assumption.

Nearly nine in ten people in the United Kingdom aged 12 and over received two doses.

And if we could have slide 1, please, I'd be very

grateful.

Slide 2 shows the percentage in each nation of over 12-year olds who had received at least two doses by 30 June 2022. In Wales, 89.8%; Scotland, 85.7%; England, 83.7%; Northern Ireland, 81.1%.

Those figures differ slightly from the figures that we looked at earlier because these are calculated by reference to persons aged 12 and over, as opposed to adults 18 and over, but the broad message in all these figures is of a very high take-up.

In England, all the priority groups were offered vaccination by 12 April, in Scotland by 7 May, in Wales by 4 April, and for Northern Ireland, although there's no exact comparable data, very shortly thereafter.

The breakdown by age and ethnicity of those who had two doses in England is at slides 5 and 6, and obviously we will look at these figures with much closer attention in due course, and in greater detail during the course of the evidence, but slide 5 shows the cumulative percentage of adults, so segregated by age, with reference to their take-up between January 2021 and June 2022, and as is perfectly obvious and plain, those who were older tended to have, of course, a higher degree of take-up because they were most at risk.

Slide 6 shows very broadly the age-standardised

percentage of adults receiving two vaccinations up to June 2022 by ethnic group, and a great deal more will be said about these figures through the expert evidence in due course.

My Lady, by June 2021, Public Health England estimated that over 44,500 hospitalisations and over 14,000 deaths had been averted in older adults.

Lest it be thought that that was just Public Health England's take on the matter, a World Health Organisation study found that between December 2020 and November 2021, an estimated 22,000 deaths were directly averted through the vaccination programme in Scotland.

The United Kingdom Health Security Agency further estimated in September 2022 that by September 2021, a year earlier, nine months after the rollout had begun, the Covid-19 vaccines had prevented more than 23 million infections and 123,000 deaths in the United Kingdom.

My Lady, empirically, it is beyond argument that vaccinated people were far less likely to get Covid-19 with symptoms. They were even more unlikely to get serious Covid, to be admitted into hospital, or to die from it.

Vaccinated people were also less likely, although the figures are much harder to interpret, to pass the virus to others.

In mid-July 2021 and late October 2021, the number of Covid cases in England were broadly equivalent to the levels that had been seen in December 2020 and mid-January 2021, so the virus was circulating in the population at the same broad level, yet the number of Covid-related deaths and hospitalisation cases were far lower in July 2021 and October 2021 than they had been for those earlier periods.

The absolutely clear expert opinion of the leading pharmacoepidemiologist instructed by the Inquiry, Professor Prieto-Alhambra, from whom of course we will hear in due course, is that the vaccines, those three Covid-19 vaccines, were entirely effective. He reaches four main findings.

Firstly, he says the initial estimates on how well vaccines protected against Covid came from large randomised phase III clinical trials which had involved tens of thousands of people. Although of course there were differences in location, in study population (because they involved different nationalities and different ethnicities) and in the choice of placebo, all the trials consistently showed high protection against Covid.

Secondly, when the vaccine campaign started and the vaccines began to be rolled out and increasingly

a number of people were vaccinated, the effectiveness of the vaccines was able to be tested in real-world conditions and it was monitored by multiple academic groups and multiple agencies, such as the UKHSA, Public Health Scotland, Public Health Wales, the Public Health Agency in Northern Ireland and so on. They included studies to establish the effectiveness of the vaccines in the general population as well as in subgroups of people who had not been included in, or who had been under represented in the phase III trials.

Although precise figures varied, they did consistently show that vaccines were effective to substantially reduce the risk of symptomatic, severe and fatal Covid in real-world conditions. Moreover, all ethnic groups benefited from vaccination, as did those populations who had been underrepresented in trials, such as clinical risk groups.

Thirdly, he concludes that numerous studies were conducted to understand the impact of Covid vaccination on Covid-related and all-cause mortality. Those show without any doubt that vaccination had a substantial beneficial impact on the course of the pandemic.

And lastly, he says the effect of the approved vaccines on reducing transmission was not studied in the trials, of course, and measuring transmission through

observational research and modelling studies is challenging, but there is nevertheless moderate to high quality data to show that the UK Covid-19 vaccines were also effective in reducing both the likelihood of infection, that is to say that a person who is vaccinated is less likely to catch the virus, as well as infectiousness, ie the likelihood of passing it on.

In summary, the evidence suggests overwhelmingly that the UK Covid-19 vaccines successfully protected the people of the United Kingdom against a virus that was killing and liable to kill hundreds of thousands of people.

Indeed, the UK has been estimated to be the country in the World Health Organisation Europe region with the highest number of deaths averted due to vaccination, and of course, the success of the programme enabled the relaxation of other control measures facilitating socioeconomic recovery.

My Lady knows that it was, however, not a foregone conclusion that the United Kingdom or indeed any country would find and develop an acceptably safe and effective vaccine, especially as no one had ever made and trialled an effective vaccine for a human coronavirus before.

Historically, success rates for developing vaccines against viral infectious diseases are low. There is

only around a 10% probability of progressing from phase II trials to licensing within 10 years. And as you know, for HIV, the last pandemic with a global impact, a vaccine has still not been developed, over 40 years since the virus was first identified.

In the early days of the pandemic, there were believed, in fact, to be around 200 or so vaccines in early development across the world to deal with the challenge posed by coronavirus. But the chances of any one vaccine candidate being effective and safe were remote, and the Vaccine Taskforce's own programme business case estimated that the likelihood of any individual vaccine being safe and effective varied between 5% at the most pessimistic scenario, and 10% on the most optimistic scenario.

That Vaccine Taskforce met more than 80 times between April and December 2020, and secured access to a portfolio of seven vaccines for the United Kingdom. We'll hear much more evidence in due course, including from the chair of the Vaccine Taskforce, Dame Kate Bingham, but essentially, the taskforce succeeded. Firstly because it had agreed an enormous 5.2 billion programme business case with the Treasury to fund interventions; it applied a portfolio approach under which it tried to secure access to as many available

vaccines as it could; and it procured at risk, that is to say it invested in manufacturing of vaccines before data on their safety and efficacy was available.

I emphasise, they invested in manufacturing before that data became available. That is by no means to say that there was authority given for the vaccines to be administered before that data was available.

It's important, my Lady, that I emphasise also that the foundations of that success were built on decades of global research and preparation benefiting from previous work to develop prototype vaccines for SARS-CoV-1 and MERS coronavirus, and decades of research to develop mRNA vaccines, many of which were conceived as cancer vaccines. It was also built on the United Kingdom's formidable science and clinical research infrastructure.

Ultimately, that success could not have been achieved without the remarkable collaborative and collective effort of dedicated administrators and regulators, scientists and researchers, clinicians and epidemiologists, public health professionals, academics, universities and external professionals, as well as, of course, the commercial entities that developed and manufactured the vaccines.

And also, my Lady, you would wish me to make mention, I know, of all those members of the public who

volunteered for vaccine clinical trials in the community.

And credit must also be given to the bodies and organisations, particularly the national health and social care bodies, the public health agencies and local authorities and, where they were engaged, the military and charitable and voluntary community groups who made this unprecedented population vaccination possible.

So, my Lady, that is the starting point for the scrutiny of vaccines.

I now want to say something about non-vaccine medicines because they were also a critical part of the response to the pandemic, and this module will be focusing on therapeutics, non-vaccine medicines, with the same degree of scrutiny as it will be focusing on vaccines.

At the beginning of the pandemic, my Lady knows there were no drugs and no vaccines. Patient management was symptomatic, the provision of oxygen and, if necessary, respiratory and other vital organ support in hospital.

The benefits of therapeutics and prophylactics are obvious in the context of a pandemic. The process of discovering, developing, testing, manufacturing and distributing vaccines takes time, if it is possible at

all. Drugs, therefore, play a vital role in prevention and treatment, particularly of the elderly, the frail, and the immunocompromised, whilst waiting for a vaccine to be deployed. And even if a vaccine does become available, there will be people who cannot take a vaccine for medical reasons, or for whom the vaccine does not mount a sufficiently protective response.

So the drugs can be used to treat them, to treat vaccine breakthrough infections, or the unvaccinated and vulnerable groups.

My Lady, very briefly, there were four main types of medicine.

In the context of the Covid pandemic, we'll be looking at small molecule antivirals which stopped the virus from multiplying.

Secondly, neutralising monoclonal antibiotics, such as sotrovimab, which was approved in the second year of the pandemic, these are antibodies engineered to help block the ability of the virus to invade cells, and they help the body to recognise and destroy infected cells.

The importance of those monoclonal antibiotics is they can be used prophylactically in advance of infection, and they turned out to be less effective against variants of the coronavirus.

Thirdly, there are anti-inflammatories. These help

to treat the inflammatory complications in the body's immune system caused by Covid. The most important life-threatening complication of Covid was inflammation in the lungs, caused by the body's excessive response to the preceding viral infection, and this happened to be the main cause of hospitalisation and death.

Lastly, and only in very general terms, there were medicines used in the treatment of complications caused by the disease, such as blood clotting.

My Lady, the view of the therapeutic expert instructed by the Inquiry, Professor White, who is a professor of tropical medicine at the University of Oxford and at Mahidol University in Bangkok, is that, in general terms, the speed of the clinical research response therapeutically in the United Kingdom in 2020 was at admirable.

This was due, he says, to primarily the UK's strong record in the science and in the conduct of clinical investigation and clinical research, and the fact that many government bodies and entities, the DHSC, the then business -- Department for Business, Energy & Industrial Strategy (BEIS), the Office of the Chief Medical Officer, the Government Chief Scientific Adviser, then Sir Patrick Vallance, and the main research funding structures, such as the National Institute for Health

Research and the UK Research & Innovation, and its Medical Research Council, all responded very rapidly indeed.

Within days of what was called an urgent public health process being announced on 4 February, UK researchers submitted applications for research to be set up at hospitals, in GP practices and non-NHS settings such as schools, prisons, and care homes.

That body, the National Institute for Health Research and its Clinical Research Network, received over 1,500 applications for research. Some hundred or so studies were badged with what is known as the "Urgent Public Health process", and over a million participants were recruited in thousands of sites.

Hundreds of candidate therapeutics were proposed in the first days and weeks of the pandemic and I want to mention a number of bodies and entities that played a hugely important part, from the UK Covid-19 Therapeutics Advisory Panel, which considered potential Covid treatments to be proposed for nationally/publicly-funded clinical trials; two, the Prophylaxis Oversight Group, the NERVTAG Therapeutics Subcommittee; and the Research to Access Pathway for Investigational Drugs. All played a vital role in ensuring that research was commenced speedily and

effectively.

My Lady, I needn't, I think, set out the detail of many of the other committees that were involved in this important process, but you will hear many references to the role of RAPID C-19, the multi-agency entity which monitored emerging trial evidence and the effectiveness of therapeutics. Also, the Therapeutics Task Force, which was established in April 2020, and then was followed, in April 2021, by the Antiviral Task Force, and in April 2022, the Antivirals and Therapeutics Taskforce.

To give you, my Lady, some idea of the scale of the endeavour, over 700 new drugs were researched or explored in some shape or another. The UK Government secured 5 million courses of oral antivirals to treat Covid. They were Paxlovid and molnupiravir, and some 80% of those courses were procured after in fact the emergence of Omicron.

But, my Lady, and this is something we will be looking at in much greater detail, there were significant issues with the procurement of antivirals generally and with one neutralising monoclonal antibody cocktail, Evusheld in particular, as well as some delay. Many believe that there could have been greater therapeutic procurement, which is an issue to which you

will have to return in the course of the evidence.

There were, in addition, real concerns about whether there were too many trials, some were underpowered, and many of them were ultimately inconsequential.

Nevertheless, in general terms, the UK stood out in the pandemic for conducting very high-quality and impactful therapeutic studies. My Lady, those trials and the research benefited Britain and it benefited the whole world.

One large hospital-based platform trial, a multicentre trial, because it tried a number of different therapeutics, was organised with remarkable speed. This was the UK's phase III RECOVERY trial, the acronym is for the Randomised Evaluation of Covid-19 Therapy.

My Lady, this trial was funded by the UK Research and Innovation's Medical Research Council and the National Institute for Health Research in March 2020. It was co-led by Professor Sir Martin Landray and Professor Sir Peter Horby and supported by the University of Oxford.

It recruited some 50,000 patients ranging in age from less than six months to over 100 years old, one-third of whom were female, and one-sixth of whom were black, Asian or minority ethnic background.

It spread across 195 hospital sites were patients were receiving drugs clinically. It commenced within six weeks of being funded and grew to become the world's largest clinical trial into treatment for Covid.

A second important community trial was PANORAMIC. This was sponsored again by Oxford, and funded by the National Institute for Health and Care Research. It recruited around 30,000 participants over around 70 sites and it looked, importantly, at whether patients at home could be treated with a drug called molnupiravir, an antiviral treatment, and also Paxlovid which was ritonavir-boosted nirmatrelvir and is now the most effective currently available antiviral drug against SARS.

A third important UK trial was the PRINCIPLE trial. This was launched in March 2020. It recruited participants online from anywhere in the United Kingdom, as well as across a thousand GP practices and it became the world's largest Covid-19 treatments trial for recovery in the community.

My Lady, I intend no discourtesy if I don't mention all the many other trials -- they are no less important. They included the REMAP-CAP trial which carried out trials in over 8,000 patients at over 250 sites worldwide, and the World Health Organisation SOLIDARITY

trial which involved 14,000 or so hospitalised patients across 50 countries.

The most significant results, my Lady, were, however, obtained, in the main, from the RECOVERY trial. And it is important that I set them out because this provides the forensic basis for the examination of why some other drugs were not tested through and then authorised in due course.

The first main finding from the RECOVERY trial was that it showed that certain repurposed drugs which were looked at particularly at the beginning of the pandemic, because of course, the researchers and the clinicians and the administrators and regulators looked first at those drugs which were already in existence and had been authorised for other conditions, and whether they could be repurposed.

So RECOVERY looked at whether lopinavir, in combination with another therapeutic ritonavir, and another therapeutic, azithromycin, an antibiotic, worked against SARS. They showed in fact that they didn't reduce mortality in Covid patients but even a negative outcome of course has a beneficial impact because it shows what isn't therefore worth spending time and money on pursuing, and of course it will drive the trial on to try to find beneficial outcomes through other

therapeutics.

Secondly, the RECOVERY trial showed that hydroxychloroquine had no beneficial effect on patients hospitalised with Covid. There were other trials, however, I emphasise, which did provide evidence that it was moderately effective at preventing symptoms, that is to say as a prophylactic, and you'll hear evidence about hydroxychloroquine and its research and development but because that is a somewhat contentious issue.

Thirdly, the RECOVERY trial produced evidence about the remarkable impact of dexamethasone. My Lady, this a cheap and readily available corticosteroid. It was the first drug to improve survival in Covid because it reduced deaths by about one-third in ventilated patients and by one-fifth in other patients receiving oxygen only.

My Lady, following the publication of the clinical trial results in June 2020 the Chief Medical Officer, then Professor Sir Chris Whitty, issued what is known as a Covid-19 therapeutic alert advising immediate use in the United Kingdom.

A number of studies estimate that dexamethasone saved the lives of around 22,000 patients in the United Kingdom, and globally around a million lives by March 2021. It was the single-most important

therapeutic research result of the entire pandemic.

Fourthly, RECOVERY was concerned with an anti-inflammatory intravenous drug which is used to treat rheumatoid arthritis called tocilizumab. This was the second therapeutic that had its treatment, or the treatment with it, added to the authorisation by the MHRA.

Fifthly, the RECOVERY trial showed that the monoclonal antibody cocktail, that is to say the combination of two monoclonal antibodies, casirivimab and imdevimab, reduced the relative risk of mortality by 20% in hospitalised patients with Covid who had not yet mounted an antibody response of their own. That cocktail is known as Ronapreve which was developed by Regeneron and Roche.

It also looked at baricitinib, which is an anti-inflammatory treatment licensed for use in rheumatoid arthritis which had considerable beneficial impact because it reduced the risk of death when given to hospitalised patients. And it also looked, finally, at natural antibodies obtained from the plasma of convalescent patients.

In the event, the MHRA authorised a supply of six new medicines for Covid treatment in the United Kingdom: remdesivir (Veklury), which was the therapeutic which

was looked at primarily by the WHO SOLIDARITY trial. They authorised the use of casirivimab and imdevimab, the Ronapreve cocktail, although that was subsequently withdrawn from use because it turned out eventually to not to be quite so effective against Omicron, or not effective against Omicron.

Thirdly, they authorised molnupiravir which was a therapeutic which was the subject of advanced purchase. They also authorised sotrovimab, again the subject of an advanced purchase. And they authorised the Paxlovid therapeutic, nirmatrelvir and retonivir. And finally, they authorised the new medicine Evusheld, to which I will return in a moment, and about which you will hear a great deal of evidence, which is the combination of tixagevimab and cilgavimab as a pre-exposure prophylactic.

My Lady, two previously authorised therapeutics, that is to say two drugs which were already authorised for other use, were also approved by the MHRA and they were dexamethasone, which was the repurposed drug to which I have already referred, the outcome of the RECOVERY trial, and also tocilizumab, RoActemra, which was the result of the REMAP-CAP trial.

My Lady, I have emphasised that detail and I have set it out there because it means that we needn't spend

any time at all in the course of the evidence setting out what the outcome was forensically in terms of the trialling and the authorisation process, those are the drugs that were repurposed or authorised afresh.

My Lady, the therapeutics programme was not of course, and how could it ever have been, an unalloyed success. There were very real problems with, in particular the co-ordination and management of some of the trial phases, phase II, and many have suggested that there was insufficient focus on the pursuit of antivirals and prophylactic drugs, and in particular, whether certain particular medicines should have been procured prophylactically or for treatment, and that is where we become engaged in the issue of Evusheld.

But again, like the vaccine programme, the evidence overwhelmingly suggests that the therapeutic programme was a success.

My Lady, is that a convenient moment?

LADY HALLETT: Certainly, if it's convenient for you, Mr Keith. It is now coming up for 11, I shall return at 11.15.

(10.57 am)

(A short break)

(11.15 pm)

LADY HALLETT: Before you recommence, Mr Keith, I just want

to say about the impact film. I am hopeful, not entirely confident, but hopeful that we will be able to play it at the close of your submissions, so before the Core Participants make their submissions.

MR KEITH: Thank you very much, my Lady.

So, my Lady, given the many successes of both the vaccine and therapeutics programmes, some may immediately ask why, beyond the fact that these topics are mandated for our examination by our terms of reference, the Inquiry is enquiring into them. My Lady, that question is easily answered.

First, as the written submissions from the Covid-19 Bereaved Families for Justice UK group in particular put it, it is important to recognise achievements and best practice that worked, as well as why other things did not work. This is of course because lessons may be learned from both.

Lessons can be learned as to whether the innovative ways of working utilised during the pandemic can be embedded in peace time and replicated in future. It may also be asked whether the undoubted successes of the programmes relied in fact over much on the UK's many undoubted strengths and the scientific research development regulatory fields as opposed to having its genesis in proper resourcing, proper planning, and

efficient and administrative data systems.

There are number of questions that need to be asked. Is the United Kingdom's scientific and biomedical research centre sufficiently robust and resourced to continue experimental research of vaccines and therapeutics, for example, in relation to Disease X, the as yet unknown pathogen that might cause a future pandemic? To what extent do we need to focus more on prototype diagnostics, therapeutics and vaccines to treat pathogenic classes of the greatest pandemic potential?

Ultimately, although it is entirely a matter for my Lady and the evidence has not yet of course been heard, you may conclude that the UK demonstrated an impressive ability to research, procure, produce and deliver multiple vaccines and therapeutics, but can the systems that were utilised for the setting up and delivery of clinical trial platforms and the large-scale platform trial process, and the provision of health-related data be improved upon?

There were notable data highlights in vaccines and therapeutics such as the SIREN Study involving the testing of over 45,000 healthcare workers. Public Health Scotland's EAVE II study, the SAIL databank in Wales, and the OpenSAFELY data process in England, but

it is not clear that those studies could be replicated swiftly or effectively in the future.

There are also doubts, many of which are well known, as to how well embedded the UK's research and development facilities now are. In May 2020 the government announced it was further investing in the Vaccine Manufacturing and Innovation Centre in Oxfordshire to broaden its capacity as a vaccine manufacturing centre. But in April 2022, the board of that company took the decision to sell itself to a multinational company. You will be hearing evidence about what the plans are for that centre.

The Vaccine Taskforce invested millions of pounds in the Cell and Gene Therapy Catapult centre in Braintree in Essex, to fund a state-of-the-art manufacturing innovation centre. What is the state of those investments?

The Inquiry will also look at the current state of play concerning the deployment facility at Oxford Biomedica, as well as government support for the Centre for Process Innovation in Darlington, and also the government's strategic partnership with Moderna, and the building of the new mRNA research facility at Harwell and AstraZeneca's investment in its own manufacturing site in Speke in Liverpool.

My Lady knows that very recently the House of Lords Science and Technology Committee wrote to the Chancellor of the Duchy of Lancaster to express concerns of the UK's ability to manufacture vaccines in a future pandemic.

Turning to procurement processes, how efficient and properly resourced were they? Why was it necessary to establish new structures such as the VTF and the TTF in the course of the pandemic?

Were the NIHR's hibernated sleeping research contracts, which were set up after the 2009 pandemic, the right ones? Is more public-private collaboration required between scientists, industry and government?

What is the nature of the UK's participation in the 100 Day Mission, the global initiative to better prepare the world by driving the development of new diagnostics, therapeutics and vaccines?

We also need to look at the liability and indemnity arrangements that were entered into by the government, and the cancellation of the Valneva contract.

Turning specifically to therapeutics, how effective and wide-ranging was the clinical research into therapeutic medicines and the systems for their authorisation and eligibility for access, particularly antivirals and prophylactics? Were the trials

sufficiently diverse? Was there proper quality data capture of protected characteristics in those trials?

Pregnant women have traditionally been excluded from randomised drugs trials due to fears about drugs causing foetal abnormalities but this left them with very little by way of evidence-based treatments. What is the position for them?

To what extent was clinical research undermined as our expert posits it may have been by obstructive bureaucracy, overly-burdensome process requirements, and limited funding?

Professor White, our therapeutic expert, also addresses two other important but separate issues: the issue of AstraZeneca's Evusheld, to which I have already referred, that's the cocktail of the two neutralising monoclonal antibodies, tixagevimab and cilgavimab. The government decided not to purchase it in advance of trials and then in light of later data decided not to make a post-trials purchase either.

Also, what was the position with hydroxychloroquine? Trials in the United Kingdom were paused following the publication in The Lancet of a report of an observational study that made a claim of a serious adverse effect. By the time the trials restarted, the first wave of infections had receded, and it was

believed there was therefore less need for a moderately effective chemo prevention. But from the standpoint of vulnerable groups who needed that drug, and couldn't benefit or receive benefit from or receive the vaccines, the failure to proceed with Evusheld and hydroxychloroquine was obviously of the greatest importance.

To the question of why, there is a second answer. It is that even more importantly, lessons can be learned for the benefit of those who were not able to benefit from the vaccination or therapeutic programmes. This was for a number of different reasons, such as because they could not be vaccinated for medical reasons, or because vaccination was of markedly less benefit, for example the immunosuppressed, or because they weren't vaccinated quickly enough, or they had no proper access to vaccination, or were not eligible for therapeutics, or because they suffered from Long Covid, the condition that neither programme could completely prevent.

And even more tragically, a number of people, very small in the overall scale of the vaccination programme, but of no less importance individually, or to our examination, did suffer serious harm. Alongside the vast majority of the population who did have access to the beneficial effects of vaccines, a severe price was

paid, unfortunately, by some individuals. Those side effects may be encountered in any medicine, but serious side effects, whilst very rare, are nevertheless significant and debilitating.

I must emphasise the rarity, more often the extreme rarity, of the serious adverse effects that were suffered, and the fact that the figures demonstrate beyond any doubt that the life-saving benefits of the UK Covid-19 vaccines vastly outweighed the very rare risk of a serious side effect. Nevertheless, my Lady, they did occur. And for those who did suffer serious side effects, and even worse, for the very small number of people whose loved ones died as a result, it was of course a complete tragedy, and nothing that is said about the rarity of those terrible consequences can be taken or should be taken to diminish that loss.

It's important that I emphasise that you have expressly assured, for a number of reasons, that the general issue of vaccine injury must be examined by this Inquiry. It is why you gave a number of representative groups Core Participant status. Let me seek to explain why.

It is in principle right that a public inquiry examining matters of public interest and public harm should include those who were harmed by the vaccines

through no fault of their own, and where their individual vaccination was carried out in furtherance not just of their own good but also that of the wider public.

Through the giving to that group of Core Participant status, the Inquiry therefore acknowledges the experiences of those who have suffered and hopes that their involvement in this Inquiry process will assist in countering the stigmatisation they have undoubtedly also had to bear.

Wider than that, my Lady, the long-recognised fact that vaccines can very rarely have serious side effects is also intimately bound up with the issue of public confidence in vaccines. For vaccines to have their true curative effect, and there is a massive public interest in the maintenance of proper vaccination and immunisation programmes, populations must take them up. It would obviously be damaging to uptake if any belief were to take hold and were to be allowed to take hold that in the unhappy and very rare occurrence of vaccine injury, the state has forgotten those who suffered.

So turning to the third issue of safety. No proper inquiry into the development and use of vaccines and therapeutics could possibly dispense with the obligation to ensure that critical aspects of the safety systems

worked properly and were effective. So we will scrutinise the diversity and rigour of the pre-authorisation clinical trials as well as the post-authorisation studies.

How effective were the systems for monitoring safety signals, in particular the Yellow Card process, and the system of post-authorisation safety studies? Was safety compromised at all by the virtue of the MHRA's rolling review?

How clear was official guidance and the communication of potential adverse effects?

The Inquiry intends to call Professor Stephen Evans, whose many distinguished qualifications and posts include being honorary professor of medical statistics, professor of pharmacoepidemiology and emeritus professor at the London School of Hygiene and Tropical Medicine. Important issues that he will address in evidence include whether the clinical trials in the United Kingdom were done to the usual high standards and sufficiently extensive; why the Regulation 174 legal process was adopted, whether the skill and degree of scrutiny exercised by the MHRA was appropriate and whether there was any diminution in the level of safety oversight or regulation by virtue of the fact that there was a rolling review.

He will look at the diversity of clinical trials, the nature and effect of the post-marketing surveillance, the effectiveness of the system for informing people about suspected adverse events and also whether the departure from the EU EMA data system and the EU database, EudraVigilance, adversely affected the United Kingdom's scrutiny.

The fourth reason why this module is necessary relates to the fact that in relation to the issue of vaccination take-up, the overall figures for vaccination in fact hid notable problems.

Disparities between population groups were profound, with lower uptake recorded in particular among people from minority ethnic backgrounds and migrant and Gypsy, Roma and Traveller communities.

Ethnic minority groups in England in particular had lower age-standardised rates of vaccination coverage compared with the white British population. By April 2021, just 65.6% of black African people aged over 80 were vaccinated in England, compared with 97.4% of white British people. Given that being 80 or more constituted the second priority group, you will recall, due to the severity of the risk of serious illness or mortality, that disparity is a matter of major health concern.

By April 2021, 62.2% of all adults, those aged 18 or over, of black African ethnicities, had been vaccinated compared to 93.2% of white British and 87% of people of Indian ethnicities.

The level of coverage broadly across black African ethnicities did not reach 75% until June 2022.

Rates of coverage were also lower in the most deprived areas of the United Kingdom. The difference between the percentage of adults aged 18 or more in the least and the most deprived areas who had received two doses was particularly sharp in England.

Looking at geographical spread, the number of adults who had received two doses was lowest in London in all age groups by June 2022. Uptake among child cohorts was also lower in London than the rest of England, and there was consistent undervaccination.

The Joint Committee on Vaccination and Immunisation (JCVI) advised, as you will recall, that the first priority for the vaccination programme had to be the prevention of mortality, through that age-focused approach, and the protection of health and social care systems, with secondary priorities then focusing upon the vaccination of those at increased risk of hospitalisation through stratified age cohorts.

So a number of questions arise for consideration in

relation to that prioritisation. Was the process through which those decisions were made effective? Was the prioritisation right? Were decisions clearly communicated?

Nine priority groups were identified, and the JCVI estimated that, taken together, they represented, as I've said, around 99% preventable mortality. But what was the process for deciding on eligibility for those cohorts, and how workable was that system?

Did it work, in particular, for unpaid carers, disabled people, especially learning disabled people, the clinically vulnerable, pregnant and breastfeeding women and children?

How effective were the devolved delivery and rollout procedures in each of the Four Nations?

How well were the well-known barriers to take-up addressed particularly amongst ethnic minority, disabled, migrant and Gypsy, Roma and Traveller communities?

We've been greatly assisted by the written representations from the Core Participant groups. They largely acknowledge that some measures were implemented, but they maintain that they were either delayed or superficial or overly generic, and often not specific to the needs and often the unique barriers to vaccine

uptake that their clients faced.

Bluntly, they say the measures adopted in each nation failed to address the systemic and root causes and the barriers that their clients acutely experienced when trying to get access to vaccines and therapeutics.

The Disabled People's Organisations suggest there was no dedicated forecast on disability. The JCVI and the UK Government's Vaccination Equalities Committee had no dedicated focus on disability by comparison to the Vaccine Equity Committee established in Wales.

Pregnant women were another group which had needs which were not, it is said, sufficiently met. Changing government advice led to confusion amongst those who were pregnant or those who were considering pregnancy about whether they should take the vaccine, and it wasn't until April 2021 that the government offered the vaccine to all pregnant women and were able to confirm its safety.

My Lady, the Inquiry has commissioned, as you know, an extremely comprehensive report from Dr Ben Kasstan-Dabush, assistant professor in public health and policy at the London School of Hygiene and Tropical Medicine, and Dr Tracey Chantler, associate professor of public health evaluation, again at the LSHTM.

Their report on Vaccine Delivery and Disparities in Coverage gives an overview of the vaccine prioritisation and rollout processes across the United Kingdom, including the key characteristics and procedures that were adopted.

My Lady, there is no need for me to summarise or attempt to summarise what they say in their report, and indeed there will be no need to call evidence about this, because they provide, in a readily accessible format, a summary of the coverage across the entirety of the United Kingdom and each of the four nations. They provide the figures for coverage broken down by age, sex, ethnicity, geographical regions, socioeconomic status, coverage amongst health and social workers, coverage in black and black Caribbean communities, disabled people's organisations, and so on.

And what they say is that whilst vaccine delivery was generally very successful and unprecedented in its scale, the fact remains that some groups simply did not have proper access.

And they identify the common practical barriers to vaccination, such as lack of awareness, thorough poor communication of eligibility and options for vaccination. They identify the issues of distance and accessibility, cost, and pre-existing inequalities and

past experiences of racism which have led people from ethnic minority groups in particular to have a lack of trust in the NHS and the government.

The evidence before you is clear that the stark disparities of Covid coverage, which is what they were, amongst minority ethnic groups, were rooted in inequality rather than difference, that is to say because there were different clinical aspects to those groups.

Access barriers, rather than refusal, was obviously the primary barrier to vaccination for many of those communities, and so the authors of the report outlined the various strategies that were deployed to address uptake amongst, in particular, ethnic minority backgrounds.

It is obvious that significant efforts to mitigate disparities were made and the authors refer to the work done by the JCVI, by SAGE, by the establishment of a Vaccine Equalities Committee in England, a Vaccine Equity Committee in Wales, a vaccine equalities and inclusion team and the vaccination directorate in Scotland, and a Covid-19 Vaccine Low Uptake Working Group in Northern Ireland.

You'll also be told about the evidence and reminded of the evidence, because you'll recall from Module 2 we

looked at these reports, the reports from the Race Disparity Unit and the Cabinet Office, which produced four quarterly reports which investigated and addressed disparities.

But what the evidence appears to show is that, notwithstanding all these efforts, issues of trust and misinformation remained for some populations, and disparities across the United Kingdom persisted.

Moreover, those became increasingly apparent across all the nations as delivery progressed through the dissenting priority groups.

So their view is that whilst pandemics differ in their epidemiological risk, the vaccination programme in the United Kingdom for Covid offers profound learning for future preparedness. And they make a number of recommendations, too many for me to summarise in my opening, but they focus on the need to strengthen the routine immunisation deployment systems.

Key to this, they say, is closing gaps in routine programme delivery. They say much more must be done to address more aggressively barriers to access, to engage proactively with under-served communities and by training healthcare providers to confidently recommend vaccination.

They also say that national communication campaigns

had not prepared the ground for vaccine hesitancy. Minority communities with entrenched feelings of neglect and disenfranchisement remained unlikely to engage and more steps should have been taken to deal with them, and to prepare them for rollout.

Thirdly, they say that health partners simply can't expect to see high coverage by acting only during a public health emergency. Long-running and entrenched inequalities need to be tackled.

There also needs to be a better process of consultation through the setting up of a vaccine equity taskforce in each nation. There needs to be better identification of priority risk groups, for example people with conditions that aren't recorded in GPs' notes, and unpaid carers. There needs to be a learning disability register in all four nations that is comprehensive.

They also address issues concerning whether or not there should be an expanded vaccination force, consisting perhaps of health visitors, and whether the next pandemic may place children at greater risk.

They focus also on how each UK nation produced and managed its own vaccine coverage data but how there were differences in how data was approached. They recommend a better comparison of figures across all four nations

and the possibility of integrating or coordinating data management systems.

And, my Lady, that then leads on to the general topic of vaccine hesitancy, which is the further reason why this module is mandated to investigate into the topic of vaccines and therapeutics. The Inquiry must examine what more can be done to instill vaccine confidence and to overcome barriers to vaccine uptake, structural inequality of access, and the impact of misinformation.

On this topic, the Inquiry has instructed the preparation of an expert report by a team of authors, led by Professor Heidi Larson, professor of anthropology at the London School of Hygiene and Tropical Medicine, and greatly assisted by Alexandre De Figueiredo, assistant professor in the Department of Infectious Disease Epidemiology. Her view, Professor Larson's view, is that vaccination in the United Kingdom in the decades preceding the pandemic revealed a largely positive picture for routine immunisation, despite the two notable vaccine controversies concerning the pertussis vaccine and MMR.

However, there has been a general decline in routine childhood immunisation levels, particularly in London, and Professor Larson and her co-authors are clear that

vaccine hesitancy is brought by the number of complex factors: sociocultural and political influences, trust and distrust, past experience of the vaccines, understanding and perceptions of risk and benefits, societal norms, and practical barriers.

And they say that those barriers include obvious matters such as information and language barriers, a lack of familiarity with the UK's health system, financial concerns, but also an understanding or a perception that people have been treated badly by the UK health or government systems and therefore have a large degree of mistrust in the whole vaccine process.

She reports that despite an initial high level of vaccine confidence when the rollout began, from April 2021 there was a gradual decline in trust in the vaccines, and in the UK health systems in general. She identifies the main causes of this as follows: firstly, the issue of inequalities. She says that the pandemic has highlighted and exacerbated those inequalities.

Perceived institutional structural discrimination weighed heavily against vaccine confidence, particularly in the black community. Barriers were created by lack of information. For migrants, there were additional barriers to accessing vaccines due to what are called "hostile environment" policies. And notably, those who

felt disconnected were then more likely to rely upon the word of mouth or social media, which then led, through poor understanding or translation, to heightened exposure to misinformation, thereby fueling, in a circular way, further mistrust and hesitancy.

My Lady, it is obvious that a number of false narratives emerged throughout the pandemic ranging from tropes concerning the effectiveness of vaccines, their chemical constitutions, certain side effects, to more grandiose claims that vaccine-related deaths were being concealed, or that vaccines could alter one's DNA, or that Covid-19 itself was deliberately caused as a pretext for mass vaccination.

It is not necessary to enquire into why such false narratives were created and promoted, although Professor Larson posits some causes, but it is obvious that this was contributed to by low trust in the government, in scientists and medics. And that lack of trust appears to go hand in hand with high reliance on social media, high distrust about vaccine safety and high levels of vaccine hesitancy.

So, my Lady, we have asked number of organisations, the DHSC, NHS England, UKHSA, to explain how the government, the UK Government, tackled Covid vaccine mis- and disinformation, and we will be looking at the

work of the Counter Disinformation Unit and the Rapid Response Unit. What did they do to address these real problems?

We have also obtained evidence from the social media platforms as to how the government interacted with them, and we will be hearing from the Permanent Secretary at the DCMS about the processes for identifying and acting on such material.

My Lady, that brings me on to the subject of mandatory vaccination, which is a highly contentious topic. As you know, national guidance in the United Kingdom strongly recommends rather than requires certain vaccination for some healthcare workers with patient-facing roles, such as vaccination for hepatitis B. So an important issue for debate is the extent to which vaccination as a requirement of deployment is required to be deployed or whether it impermissibly undermines the autonomy of the person being vaccinated and their right to assess themselves and the associated risk.

Support for mandatory vaccination in the United Kingdom was generally quite low but the government held a public consultation exercise between April and May 2021 on a proposal to make proof of vaccination a condition of employment in care homes. On

16 June 2021, it confirmed that vaccination would be mandatory for staff working in care homes in England, with the legislation coming into effect in October.

But on 9 July, the Welsh Government indicated that it was not consulting on this issue, stating that SAGE had advised that the uptake rate was such that no mandatory vaccination as a condition of deployment was required, because the protection rates were high enough already. VCOD was not implemented in the other home nations other either. It was not imposed in Northern Ireland, where the Department of Health instead sought engagement and support from professional bodies and unions to help encourage staff to take up the offer of vaccination.

The position in Scotland was that a vaccination for workers should remain voluntary, and there appears to have been particular concern about the possible impact on staff from ethnic minority backgrounds.

My Lady, there is considerable evidence to the fact that VCOD may not be necessary in any event, but because the levels of uptake in the care sector were at a relatively high level anyway. In addition, it has been estimated that the policy led to large numbers of staff leaving the sector.

There was then a further consultation period for

frontline health and social care workers. On 9 November 2021, the government announced that the policy for care home staff would be extended to frontline healthcare and social careworkers in England. The announcement was met with concern by the unions and a number of ethical and practical issues were raised, and in fact the UK Government's own impact assessment estimated that, even with mandatory vaccination, only a minority of healthcare workers would comply, resulting in tens of thousands of healthcare workers facing unemployment or redeployment.

Then, in the event, on 1 March, a month before the policy was due to come into place, the UK Government announced it would be revoked.

So Professor Larson comments upon this as well as many other issues related to vaccine hesitancy, and on the public interest and public health importance of maintaining confidence.

She says maintaining and improving the infrastructure for routine immunisation is fundamental to mitigating potential harm from a future pandemic. High confidence in routine immunisation must be retained. If there is one overall central lesson to be learnt about vaccine hesitancy, it is the critical importance of trust in the government and related

authorities and institutions, the NHS, and in vaccines.

Because the high level of trust in the vaccination programme has since diminished, it is vital that steps are taken to reverse that decline.

She makes a number of practical recommendations which will be put to her in the course of her evidence, dealing with, for example, building more robust and better tailored communication and outreach strategies, a peacetime taskforce dedicated to maintaining links with community organisations, better educational initiatives, greater use of trust and community figures, better capture and coding of data, the standardisation of ethnicity and disability data collection across all four nations of the United Kingdom, and specialist training for health workers to improve education about vaccines, and instill confidence in the population from childhood.

My Lady, we will also be looking in Module 4 at the topic of the Vaccine Damage Payments Act 1979 and the no-fault Vaccine Damage Payment Scheme for which it provides. This scheme has given rise to very considerable public concern and to, understandably, remarkable distress on the part of those who have sought to utilise its provisions.

My Lady, it is obvious that having an effective

vaccine payment scheme is vital. It acknowledges the impact on individuals of vaccine damage and bereavement and a scheme which commands confidence is an important part of the system for countering vaccine hesitancy. Under the existing system, entitlement is based on being able to establish before independent medical assessors that the person has suffered severe disablement to the extent of 60% or more and that on the balance of probabilities the vaccine caused the injury or death alleged.

My Lady, these are not straightforward thresholds, and the maximum award, last revised in 2007, is £120,000, which may, it may be thought, not go very far in the event of lifelong injury or disablement.

The matter is not free from difficulty, because the scheme has a statutory foundation and an Act of Parliament would be required to amend it. It is also a scheme that is concerned with the payment of money from the public purse, and some claims arising from the pandemic have already been paid with many thousands more under active consideration. It is, nevertheless, a scheme which you are mandated to examine.

Mention must also be made of the Every Story Matters process, which has allowed tens of thousands of people across the United Kingdom to share their experiences of

the vaccines and therapeutic programmes with this Inquiry.

My Lady, through an online form, also through listening events and virtually held events and through in-depth interviews and discussion groups, the Every Story Matters team had been able to gather over 34,000 stories relating to the subject matter of Module 4. Those accounts have been analysed and collated into a report, as you know, and that report has been disclosed to the Core Participants, and on your instructions will be published today on the Inquiry's website.

I need to emphasise that the Every Story Matters process is of course not a survey or a comparative exercise. Those accounts cannot be representative of the entire population and were not designed to be, but they nevertheless span the whole range of the list of issues to be examined in this module, and they are extremely valuable because they allow us to see what issues have been of the greatest concern to the population of the United Kingdom, and they raise issues such as public messaging, the nature of government advice for particular sectors of the population, such as disabled people, pregnant or breastfeeding women, children and young persons and members of ethnic

minorities, the role of social media, the reasons for lack of vaccine confidence, prioritisation, societal employment pressure to vaccinate, the position of the immunosuppressed, the clinically extremely vulnerable, and lastly and certainly not least, the issue of safety and the predicament of those who suffered harm.

Those broad issues are reflective of the fact that Module 4 has, despite commentary in certain quarters, in fact an extremely wide and ambitious scope.

But there are some areas into which we cannot go, and I need to make plain that it remains beyond the scope and the ability of this Inquiry to enquire, for example, into how the issues to which these questions give rise translated into real-world effects in individual cases.

No inquiry, however well resourced or lengthy, could enquire into, let alone resolve, how individuals fared as a result of the vaccination and therapeutic programmes. It would be an impossible task and one that the public does not expect and would not warrant. But I want to make plain that we have, nevertheless, been greatly aided by the receipt of the statements from the Core Participant groups representing the bereaved and vaccine injured, as well as those representing other various groups of people who were particularly adversely

affected by the vaccines and therapeutic programmes, such as minority ethnic healthcare workers, disabled people and migrants, as well as those who believe that the vaccine programme did not go far enough and did not bring them the succour and help to which they were otherwise of course entitled.

All those witnesses will give evidence, as in earlier modules, of their own experiences, give a summary of the issues and matters that impacted their group members and recount their dealings with government and appropriate bodies.

Those accounts are deeply informative as to where the processes and systems may not have worked, and where they may require improvement.

Another vital area in terms of identifying -- it's not a vital area, but it's not an area that this Inquiry can go into, as it is outside the scope, but we cannot make determinations as to whether a specific vaccine is or is not safe in absolute terms, nor can we determine matters of causation in specific cases of injury. In other words, this Inquiry cannot reach an empirical view on whether, pharmacoepidemiologically, any of the conditions which undoubtedly have come to be believed to be associated with the UK vaccines, were in fact caused by them, let alone whether they were so caused in an

individual case.

It is obvious, and it is well known, that it is very difficult to determine whether a serious condition that emerges in the days or weeks following vaccination was caused by the vaccine as opposed to the Covid virus itself, or was entirely coincidental.

Lastly, identifying precise risks or safety margins of specific vaccines and therapeutics would be an impossible task, it would take years and engage the Inquiry in highly complex and disputed scientific analysis that it is ill equipped to carry out.

But in any event, my Lady, you may think that the exercise of pronouncing the last word on the commerciality or efficacy and safety of specific vaccines may serve little purpose. Who is to say whether those vaccines will be of any use in the future, perhaps a non-coronavirus pandemic?

It is for all those reasons that the evidence will focus on the systems and processes concerned with the safety. But you have directed that an expert team of pharmacoepidemiologists led by Professor Prieto-Alhambra carry out a most important task.

What he and his team have sought to do is to consider in fact the main serious adverse events which were observed during the vaccine rollout, and to which

the UK regulatory agencies responded in a variety of ways, and carry out a comprehensive review of all the most relevant scientific and medical literature in order to be able to tell the Inquiry whether that material at least suggests an association between the conditions which have been identified by the Core Participant groups, and one or more of the vaccines.

They consulted hundreds of published and available reports. The list, and we'll just have it up on the screen, of the conditions which they have looked at, is in the expert report at page 3, you'll see at the bottom quarter of the page the particular serious adverse events to which they have paid regard and which they have researched from myocarditis, pericarditis, blood clots, Guillain-Barré syndrome, Bell's palsy, transverse myelitis, thrombocytopaenia -- TTS, that is -- and over the page, ADEM, and anaphylaxis.

The team of experts has more specifically considered the quality of the evidence that suggests an association between those serious adverse events and one or more of the vaccines, and what they've done is they have asked themselves whether there is good evidence to support an association so that the true position may be known. Also, where there is little or poor evidence to suggest an association, whether further research or analysis is

required.

Those experts have looked at the details of the frequency or rarity of the event, whether in fact the evidence suggests that it may be caused by Covid itself or whether it appears to have been coincidental, and therefore whether it is Covid, not the vaccines, which appears to pose the greater risk.

I emphasise that they must necessarily be limited to looking at what the existing material appears to demonstrate, because they cannot, and nor can you, reach a determinate view on what pharmacoepidemiologically the position is in reality.

But this way the Inquiry and the public will know with respect to each of these conditions whether there appears to be a genuine issue, and what the scale of the problem is, and that will provide a forensic foundation for your recommendations.

Professor Prieto-Alhambra has also looked at the long list of conditions and health outcomes revealed across the entirety of the Core Participant group statements, and he has considered on a high-level literature review, the degree of quality of the evidence and the reports which might suggest or might not suggest an association. That list is at page 56 of his report, INQ000474703, paragraph 5.119. You will see the very

long list of conditions to which he and his team have had regard.

If you could take that down, please.

Many of those conditions are very rare, or appear to have had multiple contributing causes which makes it challenging to investigate them for causality.

Professor Prieto-Alhambra was able, however, to find some material to suggest that some of those conditions simply do not establish an association with the vaccines. But in respect of other conditions, there is some material which may warrant further enquiry.

My Lady, reverting to the identification of areas into which this module cannot go, although the Inquiry will examine the nature and efficacy of the regulatory regime, the considerations that underpin decision making, the operation of the post-approval monitoring system, it cannot examine the scientific analysis that underpinned the data upon which authorisation was granted.

Also, we can neither call orally nor scrutinise in the course of this three-week hearing more than a proportion of the witnesses whose statements you have obtained. About 170 witness statements have been procured along with 18,000 or so documents. But such a course is, of course, not necessary. The hearing is

only one part of the Inquiry's work. For the purpose of drafting the report and recommendations, all of that large body of material will of course be considered by you and taken into account. The hearing is, in truth, only part of the forensic iceberg, and it must focus on the most important matters.

We will not be spending time traversing every area identified on the list of issues, or on recreating forensically what actually took place between January 2020 and June 2022, let alone describing each of the bodies and entities that played their valuable roles in this complex procedure. The hearing must focus on identifying the most significant systemic features that worked or which did not work, and thereby identify what needs to be embedded and what needs to be improved.

I need also say that the Module 4 legal team has gone through every single one of the Rule 9 statements from all 12 of the impacted Core Participant groups, amounting in fact to over 1,000 pages of descriptions of events. We have noted the many hundreds of questions, issues and concerns that have been raised, and we have deliberately checked that all those points that lie within the proper scope of this module will be addressed one way or the other by the written material, by the oral evidence, or through the Rule 10 questioning which

you have permitted through the Core Participant groups.

Finally, there's a final point to be made by way of introduction concerning the fact that this is a UK module. The module will of course examine the position in all four nations, but that doesn't mean that every issue that arises can or needs to be looked at through a national lens. Procurement of medicines is usually a devolved competency under current devolution arrangements, meaning Scotland, Wales and Northern Ireland buy their own medical supplies such as vaccines for seasonal flu. But in respect of Covid, the UK Government and the devolved administrations reached agreement that in the pandemic, the Vaccine Taskforce would act on behalf of all four nations in pursuit of a vaccine.

A number of the activities undertaken by the Vaccine Task Force, the Antivirals Task Force and Antivirals and Therapeutics Taskforce, were conducted on behalf of the whole United Kingdom and that of course included procurement. But also organised by the UK bodies on behalf of all four nations, and then applied jointly or through agreed adoption by the devolved administrations, were the support and funding of research, the authorisation of clinical trials, regulations, safety monitoring, eligibility for and prioritisation of

vaccines and therapeutics.

And so, that is why, my Lady, many of those issues can only be looked at through witnesses who necessarily played their part in the United Kingdom Government.

By contrast, public communication and messaging, delivery and rollout, were matters for each devolved administration, and that is why we're deliberately calling, in respect of each of the devolved administrations, the official or the senior responsible owner responsible for the Covid-19 vaccination programme in each country.

My Lady, that I hope gives some explanation of why we have gone about the undoubtedly complex forensic task that we have before us in the way that we have.

My Lady, that concludes my opening. And my Lady, as you said earlier, we can now turn to the playing, I believe, of the video. May I have your permission to say one word about it, before we hear it?

I think in the public interest it is important that I seek to emphasise that the references in this video to the obvious and well-known fact that in very rare cases, vaccination has serious side effects, as indeed do all medicines, must not be used as a platform to seek to undermine the vital public health role that vaccination plays in keeping people safe from disease,

or to try to seek to argue that at a population level, vaccination is not overwhelmingly beneficial.

My Lady, I have just been told that in fact we are not ready.

LADY HALLETT: We are ready now.

MR KEITH: Oh no, we are ready. We are ready.

LADY HALLETT: It has been changing. I am told -- I hope I can say with some confidence -- that we have now done what we can to edit the impact film in the time available, and we shall be playing it shortly.

I understand there may be those who feel it does not fairly reflect the experience of the vaccinated members of the UK population as a whole, and I understand those concerns. It consists of accounts from a number of people who were affected by the vaccination programme and the pandemic, including those who suffered the rare and very rare side effects which Mr Keith has mentioned.

I wish to emphasise three things. First, the film is not evidence. Second, it is not intended to be representative of the experience of the vaccinated population of the United Kingdom. And third, it does not reflect my views. I will reach my findings on the evidence, and the evidence will explore in detail the overall benefits of the vaccination programme as well as any problems it faced, or it created.

So the film lasts about 15 minutes now. It explores physical and mental health, bereavement, and suicide. Anyone who wishes not to see it should leave the hearing room now, or if they are following online, please press pause.

No one seems to wish to leave the hearing room so can we please play the video and keep our fingers crossed the audio is working.

(Video played)

LADY HALLETT: I'm extremely grateful to all those who contributed to the film. I don't think anyone left the hearing room, so I think we can probably start, I think Ms Munroe KC, you're on your feet.

Submissions on behalf of Covid-19 Bereaved Families for Justice UK by MS MUNROE KC

MS MUNROE: Good afternoon, my Lady.

My Lady, before I start on my opening submissions I know that you've been notified that there is just a short announcement I wanted to make on behalf of our team.

LADY HALLETT: Indeed.

MS MUNROE: My Lady, you will recall only a few weeks ago John Sullivan, a member of this group whom I represent, gave evidence before you in Module 3. Sadly, over the course of the Christmas period, we were informed by his

family that John had passed away. My Lady, I'm sure you will join us in sending our deepest condolences to John's family.

John was one of the people that I referred to in my closing submissions for Module 3 as speaking truth to power. He spoke eloquently, authentically, thoughtfully, fearlessly and honestly, reminding us of the power of lived experiences, and anecdotal evidence.

John, along with others from our group, fought passionately for this Inquiry to come into fruition and believed in the work that the Inquiry is doing. We are extremely grateful that John was able to give his oral evidence to you in that last module, and along with his family, we hope that what you took from John's evidence, my Lady, has and will assist you in formulating answers and strong recommendations. That, we say, would be a very fitting and lasting legacy to John's memory.

LADY HALLETT: Thank you, Ms Munroe, I certainly join in sending my condolences. In fact I shall be writing separately.

I will never forget Mr Sullivan's evidence; it was very moving, it was very powerful and everything else you said it was.

MS MUNROE: My Lady, thank you very much.

My Lady, then turning to this module. My Lady, you

will have seen our detailed written opening and I would highlight in particular our paragraphs 4 and 5 which set out eight questions, not an exhaustive list, which our families feel are particularly germane to this module. In the time available this morning, I am not going to be able to address you at length on all of those so will concentrate on three points. Those I do not mention are of equal importance, and we do not resile from those in any way.

There was much to be praised about securing a vaccine in the UK, and Mr Keith KC in his opening this morning has taken us through much of that, but, as with all things, the picture is rather more complex and nuanced than at first blush. There is the good, the bad, and whilst not necessarily ugly, the somewhat unsightly and troubling, and it is particularly the last two aspects which require closer scrutiny in this module.

So my three topics I want to highlight, firstly, planning and delivery. The Inquiry Module 1 finding with regard to the overall state of preparedness in 2020 included the finding that there was "a damaging absence of focus on the measures, interventions and infrastructure required in the event of a pandemic."

Those comments equally apply to this module, we say.

A central question must be: was the success due to pre-pandemic government having identified, understood, and grasped the importance of vaccines and therapeutics and ensure sufficient resourcing and planning, or was it due to the excellence of our research scientists in the laboratories, and happenstance?

As we say in our written opening submissions, it is vital to go beyond the headlines and properly evaluate the UK's response. The Inquiry also noted in its Module 1 report that proper preparation for a pandemic costs money. Applying those principles to this module, research, development, and manufacturing, all require proper funding.

Professor Wendy Barclay, who I will refer to a number of times this afternoon, makes some very trenchant remarks in her statement, including:

"The funding that supports research into new vaccines and delivery vehicles that is essential to be carried out carefully in peace time, was and remains suboptimal and fragmented."

That's in her statement, INQ000474315, at paragraph 26.

That must be a source of extreme concern requiring serious and urgent government intervention.

The government taskforce, did that achieve its

goals? The objectives were broad securing vaccines for the UK but also seeking to promote equitable distribution of vaccines around the world and to promote long-term resilience for the UK in dealing with future pandemics. And whilst many have been rightly praised in respect of the first aspect, with regards to the longer-term goals, the picture was rather more bleak.

Again, turning to Dame Kate Bingham, she says, characterising the progress made in securing equitable access to vaccines across the world as "modest", and expressing the view that the UK "donated too few vaccines to countries overseas".

Same citation, at paragraph 47.9.

The Vaccine Manufacturing and Innovation Centre, VMIC, the infrastructure that never was. We invite the Inquiry to scrutinise the government's actions and decision making in respect of the VMIC, and we share, again, Dame Kate Bingham's view that the VMIC "had reduced our resilience" -- and the sale of the VMIC -- sorry -- "has reduced our resilience and capability to be prepared for a future pandemic" and "could have been used to help with the innovative side of vaccine development and bulk manufacturing".

Professor Pollard also expressed a view that the VMIC could have filled some of the gaps in capability

for small- to medium-scale production and allowed more rapid innovation in vaccine in the UK post-pandemic. That's at his statement, INQ000474399, paragraph 28.

Whilst Professor Gilbert notes that:

"The UK had no national capability in vaccine manufacturing which VMIC could, and would, have provided."

INQ000474278, paragraph 57.

These are all rather ominous and somewhat depressing observations that should give rise to urgent concerns and immediate remedial action. We ignore these at our peril.

Therapeutics and antivirals. It is heartening to hear this morning that this will be prioritised in this module. This is vitally important because of course the vaccines have not been able to prevent the spread of Covid-19 and do not fully protect against such things as Long Covid, reinforcing the importance of therapeutics and antivirals.

Sir Jeremy Farrar in his statement at INQ000496107 says and observes that we do not have the balance right at present "between investment in and development of therapeutics on the one hand and vaccines on the other."

So, my Lady, that clearly is a very right area to be considered in this module.

Clinical trials. Again, this was identified as a key area of strength, yet in the written evidence disclosed thus far, again, some concerns have been highlighted that there remained limitations in respect of clinical trials in phase I and II, see the clinical technical report, and again, calling upon Sir Jeremy Farrar's statement, he notes that our old friend, lack of data, remains a stubborn and unwelcome guest.

So from that brief look at some of the aspects of planning and preparedness, it is clear that it will be imperative that the Inquiry examines the narrative critically and addresses the fundamental question: where do we stand now?

Professor Gilbert's statement is clear: the UK is not well prepared to produce vaccines for the next pandemic. There is no co-ordination and no plan. There is no national capability. We have not invested in vaccine development, the infrastructure is questionable. Both professors Evans and Alhambra highlight the negative impact of leaving the EU. We are falling behind our European counterparts.

All the research brilliance in the world will be limited without infrastructure, funding, and manufacturing, and the ability to progress vaccine discoveries. Those Eureka moments in the laboratory

will need to be translated into vaccine rollouts for all of the population.

Point 2, the experience of the deceased. Our member Helena Jean Rossiter, my Lady, is due to give evidence, oral evidence, tomorrow and she will tell the Inquiry about the sad loss of her son Peter.

We have said before and I reiterate again, one cannot underestimate the importance of the evidence of the bereaved and those with firsthand experience of the matters under discussion. I have here just three short examples that are illustrative, perhaps, of some of the issues under discussions in this module. Some people might find some of the details distressing.

Conflicting messaging and vaccine rollout guidance. One of our members, Mr and Mrs Inderjeet Girn, neither were vaccinated. This couple were about to embark upon a journey to try for a third baby and of course asked their GP whether it would be advisable to be vaccinated. The GP recommended that they did not have the vaccine and, indeed, the health -- midwife told them to follow the GP's advice.

Mr Girn was concerned about contracting the virus via work and decided he should be vaccinated, but as the nearest appointment could have been at least an hour-and-a-half from home, he decided to wait. Sadly,

he contracted Covid and was hospitalised.

Mrs Girn states that she received conflicting information at the hospital, with doctors saying that he should have been given his jab.

Mr Girn was 38 when he passed away. He was fit and healthy. He had no underlying health conditions. He left behind his wife and two very young children. He was unvaccinated.

Secondly, access to, and prioritisation of, vaccines. Children. Another of our members, Sara Meredith, her son Daniel passed away from Covid-19 aged just 7. Daniel had complex needs and throughout the pandemic his mother advocated for children who were vulnerable to have access to the vaccination as early as adults. She spoke to MPs and members of the House of Lords, and was constantly met with the response "Children are not adversely affected."

Tragically, Daniel was exposed to Covid from his sister, who worked as a teaching assistant and cared for a child who, unknowingly to her, had Covid. Daniel was in the Children's Hospital for two weeks and sadly passed away on 27 April 2022.

At that time, he had received one dose of the vaccine. His sister and mother are left with so many unanswered questions, and the thought: why were they not

listened to?

Thirdly, key workers. Prioritisation bands began with age, but what happened thereafter? By the summer of 2020, occupational risk was clearly a relevant factor. Our member, Emma Renshaw's sister Helen was an essential worker for TfL at Charing Cross Station. She worked throughout the pandemic doing her own shifts, even doing other people's. She believe she contracted the virus whilst covering a shift at Piccadilly Circus from a colleague who wasn't wearing a mask properly. She contacted her GP numerous times and attended A&E twice, and was admitted on her second occasion due to difficulties in swallowing and taking fluids.

She was at one point going to be discharged and sadly she passed away on 1 March 2021 whilst in hospital. She was unvaccinated. She was an essential worker, but she was not eligible for the vaccine for at least a year.

A rather sad PostScript to her story is that Helen was a carer for her mother who was suffering from Alzheimer's and subsequently in a care home. At the time of her passing, Helen was advised that unless she was receiving Carer's Allowance for looking after her mother, she was again not eligible to be vaccinated on the basis of being a carer of a vulnerable person,

something her family now believe may not have been the correct advice.

My Lady, those are just three examples of the stories that are replicated throughout the four nations of the lack of prioritisation, poor communication and access to the vaccine. This cannot be allowed to continue and must be addressed as a matter of urgency.

Point 3, vaccine scepticism, ethnic minorities, the Roma community, economically deprived areas of the UK. Language is important, and I use the phrase "vaccine scepticism" for a reason. The term "vaccine scepticism" suggested by FEMHO in their written document is one that we would also adopt. Our Bereaved Families from black, Asian and minority backgrounds very much resile from the use of the term "vaccine hesitancy", it transfers the issue onto their shoulders. It is their hesitancy, their problem. That is not right, fair or true. Further, the term fails to acknowledge the barriers these groups face in vaccine uptake.

Some of these have been addressed this morning by Mr Keith KC in his opening, and we will no doubt look at those in detail during the course of the module. But we know historically that those from black and minority communities were more at risk of contracting Covid. The statistics were there, we have come across them in

earlier modules: 34% of the people admitted in ICU in April 2020 were from BAME backgrounds, the first ten doctors who died from Covid-19 were from BAME backgrounds, and 63% of the healthcare workers who died in June 2020 from Covid were from BAME backgrounds. So the information was there.

Migrant workers, they continued to undertake work on the front line, often on zero-hour contracts or cash-in-hand jobs, living in poor or overcrowded housing. In the UK, migrant workers had a 22% higher chance of infection during the second wave of the pandemic as opposed to UK-born population.

We commend to the Inquiry the observations made by FEMHO and on behalf of the migrant workers group, and adopt and endorse their written oral submissions and, in anticipation, the oral submissions that will be made by counsel.

It is against that backdrop that one should consider the issue of vaccine uptake. The government conflated vaccine hesitancy with low vaccine uptake under such headings as confidence, convenience and complacency. This failed to address the real barriers to vaccine uptake by ethnic minority and deprived groups.

The SAGE ethnicity subgroup identified some of these barriers to vaccine uptake. They included perceptions

of risk, low confidence in the vaccine, distrust, access barriers, inconvenience, sociodemographic context and lack of endorsement, lack of vaccine offer or lack of communication from trusted providers.

The SAGE ethnicity subgroup report also cautioned that the failure to understand the views, needs and barriers to vaccine uptake risks exacerbating pre-existing inequalities. That's in their report at INQ000250215.

Vaccine uptake amongst migrant communities was also affected by the hostile environment and laws and policies designed to deter and prevent migrants accessing healthcare, as well as the socioeconomic barriers.

And whilst the initial vaccine rollout was largely age based, and that rationale is understandable, the fact that this approach to vaccine priority was taken resulted in significant numbers of the population from ethnic priority and migrant groups being excluded from early vaccination priority.

My Lady, we would commend to the Inquiry the report *"Not by choice – the unequal impact of the COVID-19 pandemic*" on disempowered ethnic minority and migrant communities produced by the Race Equality Foundation in 2023. They noted that whilst on the one hand the

over-representation of BAME workers within the care sector may have benefited in a positive way in terms of they being -- accessing a vaccine, on the other hand, ethnic minority groups were underrepresented in the care homes themselves and in the older population over 80. Amongst nursing home residents, black, Asian and mixed race ethnicities were under-represented compared to their prevalence in the general population, while in the over-80s, only 3.2% were ethnic minorities, meaning that almost 147,000 people from ethnic minority groups were eligible for vaccination as part of the initial 4.6 million over-80s.

The families considered that the government's failure to engage with and address known and pre-existing barriers to vaccine uptake among ethnic minorities and migrant groups in its pre-planning, development and rollout, is consistent with structural and institutional racism and we urge the Inquiry to consider this as a systemic issue rather than placing blame on marginalised people themselves, which in itself is a manifestation of structural discrimination.

We welcome the instruction of a team of experts on this, and on other matters. And pausing there, it should be noted that the quality of experts instructed in the Inquiry to date has always been very high, and

their reports have often been comprehensive, informative, and extremely persuasive.

My Lady, thus, in conclusion, we are now starting Module 4, and we will be hearing from a vast array of witnesses in the next three weeks, but it occurs to me that the recent discourse in social media and in Parliament concerning another inquiry, the child abuse inquiry, overseen by and the subsequent report by Professor Jay, reminds us that it is all too easy for people to forget not only the details and recommendations of inquiries but that they happened at all.

With that collective amnesia, it's then all too convenient, years later, when it becomes politically expedient or when a passing bandwagon needs jumping onto, for people to wring their hands and declare that "Nothing was done" and "Why has nothing changed?"

We cannot afford for that to happen to this Inquiry.

Perhaps these words are more directed outside of this room than to those within.

Your Ladyship, the CPs in this room, CTI, STI, are all working far too hard on this Inquiry for it not to have a lasting legacy, and it must not fall prey to that curse of collective amnesia in years to come.

For Module 4 we will have quite an array of

witnesses, many of whom will not be making their first appearance before you. Our families, indeed no one in this room, wants to see a parade of politicians grandstanding and basking in the reflective glory of the research communities in this country and giving themselves a pat on the back accordingly. No one can afford to rest on laurels, particularly laurels that, quite frankly, most have no business reclining on in any event.

What is required are answers and explanations as to why we are in our current position, and why it is not optimum, and how, going forward, we are going to improve that effectively and expeditiously. We need to be well placed now so that we are ready for the future.

My Lady, those are our submissions.

LADY HALLETT: Thank you very much indeed, Ms Munroe, I'm very grateful. As you know well, but newcomers to the Inquiry may not know as well, I don't need people to recite their written submissions, I'll take them all into account, and I'm grateful to you for summarising those important aspects of them.

MS MUNROE: Thank you.

LADY HALLETT: Thank you.

I think probably, given we started again after the break at 11.15, we need to break now. I shall return

at 1.45.

(12.45 pm)

(The Short Adjournment)

(1.45 pm)

LADY HALLETT: Mr Wilcock KC.

Submissions on behalf of Northern Ireland Covid Bereaved Families for Justice by MR WILCOCK KC

MR WILCOCK: My Lady, I represent the Northern Ireland Covid Bereaved Families for Justice which exists to ensure that the voices and experiences of the Covid bereaved in Northern Ireland are heard and properly considered throughout this Inquiry, and these, as your Ladyship knows, are made up of members who have lost loved ones, both old and young, to Covid-19.

We adopt but will not repeat the submissions you have just heard from Ms Munroe KC.

Throughout the proceeding modules we have sought to highlight a range of systemic and structural failings within the political and health systems of Northern Ireland that rendered it both so ill-prepared and ineffectively run to be able to properly react to a global health emergency. You have heard and will hear of the resultant pain and frustration of our members as they experienced the impact of a chronically overstretched and ill-equipped health system run in the

context of a political vacuum or repetitive instability.

In terms of this module however, the Inquiry will want to scrutinise whether although, perhaps inevitably, Northern Ireland relied on the UK's greater scale, research capacity and purchasing power in terms of the development and supply of the Covid vaccines, its decision makers, scientists and representatives might have better participated at all stages in the development and supply of Covid vaccines, not least to ensure timely communication, but also to improve understanding, and by extension, to ensure that the needs of the people of Northern Ireland were fully considered from the earliest possible stage.

Perhaps, just as in society as a whole, the Northern Ireland Covid Bereaved Families for Justice has a range of different views on the issues being considered in this module of the Inquiry. Many, most, perhaps the vast majority, of our members shared a commonly held belief that the development, regulatory approval, procurement, and rollout of the vaccine was one of the comparative success stories of the response to Covid, and recognise that it is at the heart of the UK's ability to bring the pandemic under control.

I say success story. However, our group doesn't see success in this context in absolute terms, measurable

simply by comparing performance to that of neighbouring states. On the contrary, the approach we urge upon the Inquiry is to examine whether the vaccine rollout could have been improved as far as Northern Ireland is concerned, and we suggest a number of questions may arise for consideration.

One, given the early recognition throughout the world that only a mass vaccination programme was likely to provide a route out of the pandemic, did Northern Ireland act with sufficient speed and impetus to lay the groundwork for that rollout?

In this context the Inquiry will note that there was no senior medical officer with responsibility for vaccines, at the Department of Health in the run-up to the vaccination programme, a familiar refrain you've heard in other contexts in earlier modules. Indeed, it appears that significant operational planning and management of the inevitable mass vaccination programme did not take place, until Patricia Donnelly was appointed head of the Covid vaccination programme on 5 October 2020.

On top of that the Inquiry will note that in 2020 Northern Ireland was without a centralised vaccination management system, the VMS, and had no way of centrally managing or evaluating vaccine uptake or distribution.

How could this be? When did those with responsibility note that significant absence and begin to react? What were the consequences of the fact that a VMS had to be developed in real time during vaccine development and rollout? Is it correct that the VMS was not fully operational and did not evaluate vaccine uptake until May 2021?

These are Northern Ireland-specific questions, which your Ladyship will want to consider.

Once the vaccination programme became a reality, the Inquiry might want to ask, did the Northern Ireland administration and health sector devise the necessary means to ensure maximum uptake was achieved?

My Lady, we say that if scope for improvement in any of the questions that the Inquiry feels fit to ask in this question are identified, then the Inquiry is enjoined to identify this in order to inform future responses when the next pandemic surely hits our shores.

So what are the possible areas of improvement within the Northern Ireland context? Well, given the evidence the Inquiry has heard in other modules, your Ladyship will not have been surprised to read in our written submissions and hear me repeat now, that one area where the vaccine rollout most obviously could be improved lies in the collection and the ability to collect data

on vaccine rollout and uptake, and whether this hindered the effectiveness of the programme in Northern Ireland and the ability to evaluate that effectiveness.

My Lady will note that in the expert reports commissioned for the Inquiry, Dr Kasstan-Dabush and Dr Chantler highlighted that effectively the absence of data in this area meant that we rely almost exclusively on the self-report of the Northern Ireland CMO for any evaluation or analysis of the rollout.

But, my Lady, the disadvantages of not having timely access to detailed data of, at the very least, vaccine uptake, age, geographical coverage and ethnicity, are obvious. In any mass vaccination programme, success depends on reaching the widest range and number of people. As we have set out in our written submissions, if vulnerable sections of the community are overlooked, then the potential for the virus to proliferate among them is clear and the danger to everyone who is unvaccinated is plain.

My Lady, in addition to the vulnerable groups that Ms Munroe mentioned, as far as Northern Ireland is concerned, we ask the Inquiry to consider particularly those who give unpaid or informal care and thus fall outside the protection -- professional care sector. My Lady, may have been surprised to read that in

Northern Ireland they amount to some 12% of the population, 12% of the population providing unpaid care for those they love.

Given the extremely high numbers involved, we suggest the Inquiry should consider what impact the absence of a central carers register, or any otherwise reliable individual data, had on the vaccination programme in Northern Ireland. Did it hinder access to an appropriate priority group for the 220,000 potentially eligible individuals? What has been done about creating a carers register in the years since the Covid vaccination programme concluded? These are all Northern Ireland-specific matters which we would ask you to consider.

But, my Lady, there is an overarching issue at the heart of this Inquiry, and the Inquiry will hear tomorrow from Fiona Clarke, one of our lead representatives, who, like many of our members, is understandably haunted by the thought that, given AstraZeneca was approved in December 2020, had it been made available to her mother, Margaret Lusty, a few weeks before she received the first dose on 7 January, then she may not have contracted Covid on the 12th and died in the heartbreaking circumstances you know of in Antrim Area Hospital on 17 January.

That is one example of the experience of our members. And it is an indication of Fiona's compassion and the generosity of spirit within the organisation that I represent that despite her own experiences, including suffering Long Covid, Fiona nevertheless acknowledges that although she personally did not know of anyone who had been caused harm by the vaccine, she is aware of other members of our group who have had different experience and therefore concerns about the vaccine.

For that reason, she has drawn your attention to the case of William Wilson, who suffered organ failure after receiving the Pfizer vaccine. And thus, he, like other bereaved members of the group I represent, has a different experience of the vaccine rollout than perhaps Fiona Clarke does, and the vast majority of our members do.

And that experience requires us to ensure that the Inquiry equally considers concerns that the desire, the understandable desire, for speed of mass vaccination was not over-prioritised over vaccine safety, and your Ladyship will, I know, be looking at that.

Accordingly, in acknowledging the speed of the vaccine development and deployment between early March and December 2020, we simultaneously asked the Inquiry

to consider both whether preparedness could have been better, so as to allow for even more rapid deployment, whilst, in the words of the written submissions of the Vaccine Injured and Bereaved UK, quote "not forgetting the uncomfortable truth for many that vaccine injury and death are also part of the pandemic story".

My Lady, rightly or wrongly, there are those within our campaign and society at large who have deep concerns about whether the true picture as to the safety of vaccines was or is being imparted to the public.

It is plainly axiomatic that confidence in the vaccine will only be diminished, it can only be diminished, if information about vaccine safety is either inaccurately or not fully publicized, and that, we applaud the Inquiry's attempts to try to give a neutral analysis insofar as a legal inquiry possibly can on this issue.

My Lady, we are therefore grateful to Mr Keith KC for his outline of the UK clinical trial process and the post-authorisation surveillance of the vaccines that he outlined this morning. And all of our families look forward to the Inquiry investigating the experiences of those within the Vaccine Injury Groups and considering whether the evidence on vaccine safety was in fact sufficiently robust and sophisticated as we all in this

room hope that it would have been.

On a related subject, my Lady will hear tomorrow that even though William Wilson, of whom I spoke a few minutes ago, suffered organ failure after receiving the Pfizer vaccine, and spent a significant time in hospital -- and I'm not using this because the Inquiry can do anything about the individual case; I'm using it as an example of the issues that are being raised -- that even though he suffered what might be thought extremely serious consequences and life-changing injuries, he was deemed not to meet the relatively high criteria of severe disablement or 60% disablement when he applied for compensation under the vaccine damage payment which Mr Keith mentioned this morning.

My Lady, you will no doubt be looking carefully at whether this scheme remains appropriate in today's world, or whether the Vaccine Injured and Bereaved UK and other CPs are right to describe it as inadequate and inefficient. And Mr Keith KC was quite right to say this morning that a scheme which commands confidence is an important part of the system for countering what he called vaccine hesitancy but which may more appropriately be called vaccine scepticism, and it's only if there is confidence in the compensatory regime that there will be full confidence in those issues.

My Lady, one aspect of the Northern Ireland experience of delivery is the consequence of Northern Ireland being a largely rural area. And, my Lady, you will have read of the experiences of one of our members, Michelle Reid, whose father tested positive and he was eligible for the vaccine but was immobile and housebound and thus unable to attend his GP, and was told by the GP that at that time there was no mandate from the Department of Health to allow them to administer vaccine in his home. And Michelle and her family were not alone in this experience, and we ask the Inquiry to consider whether sufficient consideration was given to ensuring access to the vaccine by those who were, for whatever reason, marginalised.

In a future pandemic, reaching those who are unable to leave their homes, wherever they live, must be do quickly and without bureaucratic hurdles.

My Lady, the group I represent is also concerned about the vaccine condition of deployment issue which Mr Keith raised this morning. You heard one view in the impact video this morning from Anne Marie O'Neill but there are others. Many of our group questioned, for example, why in June 2021 the Executive concluded that it was not necessary to make vaccination compulsory for care homes, and that family members and other visitors

were required to be vaccinated before spending time in care homes with loved ones, whilst those caring for their loved ones around the clock were not, appeared to many of my members to be, at best, incongruous.

My Lady will appreciate that although the effect of the pandemic and care homes is to be dealt with in Module 6, it is that issue which lay at the heart of the foundation of the group I represent, and we would ask your Ladyship to consider the adequacy of the various public responses that are set out in the statements you will hear tomorrow.

My Lady, moving to a close, thus far I've only addressed the issue of vaccines. Plainly, you will want to consider the issue of therapeutics. One complication of this issue is of course the word "therapeutic" means different things to different people depending on your knowledge of the issues involved. Your Ladyship will have read within the statement how many of the people I represent believe that their loved one did not receive the appropriate therapeutical treatment in relation to their care. Either way, we share the view of the clinically vulnerable families that it is important that the issue of therapeutics does not "fall through the cracks" and we were therefore reassured by Mr Keith's assurance that that will not be the case in his outline

of the issues this morning.

My Lady, I come to a close. It's really this: so much to do, so little time. We ask the Inquiry to apply its usual rigour to the evidence it receives in this module, and as far as Northern Ireland is concerned, to try to ensure that at the very least, a more nimble and data-driven approach might be pursued in the likely event of another pandemic requiring mass vaccination.

My Lady, that ...

LADY HALLETT: Thank you very much indeed, Mr Wilcock, I'm very grateful.

Ms Mitchell KC.

Submissions on behalf of Scottish Covid Bereaved by DR MITCHELL KC

DR MITCHELL: I appear as instructed by Aamer Anwar on behalf of the Scottish Covid Bereaved. The Scottish Covid Bereaved are, once again, grateful to play a part in ensuring that important and relevant questions are asked of our experts, our politicians, our scientists, to help obtain evidence to provide a basis for making recommendations.

We thank Counsel to the Inquiry Mr Keith KC this morning for a comprehensive and detailed opening statement which sets out a helpful framework for the Scottish Covid Bereaved to understand the scope of this

module and provide a blueprint against which we can proceed with obtaining relevant evidence.

There are very many questions the Scottish Covid Bereaved have about vaccines, and between this module and the next we highlight the following six.

One, what were the barriers to enable the rapid development and production of vaccines, and how were they removed? And what changes to systems and processes have been put in place since?

Two, how was the vaccine rolled out in Scotland, including an assessment of who was eligible to obtain a vaccine as a key worker and who was not?

Three, what lessons can be learnt from the rollout? Did we properly protect those most vulnerable by making sure they had priority access to vaccines when needed, especially those who had contact with hospitals and care homes, given what was known about hospital acquired infection?

Four, was proper consideration given to the fact that large parts of Scotland are rural and island; whether asking people to attend, for example, individually for vaccines was the best methodology, whether vaccinating families might have assisted with uptake and minimise financial implications of long travel to get to vaccine appointments individually.

Was vaccine hesitancy properly addressed? I note the phraseology used of "vaccine scepticism" and that will be something given consideration by the Scottish Covid Bereaved, although "vaccine hesitancy" indicates a pause, "vaccine scepticism" may indicate a doubt, and there may be yet a third term which can encapsulate all those matters together.

Was sufficient consideration given to meeting misinformation and challenging disinformation, debunking theories which had no evidential basis, particularly in social media?

Six, was sufficient information given to people, particularly the vulnerable, about the possible effects of the vaccine?

Behind these questions our people, families who have lost loved ones and want answers. These answers won't help protect their loved ones but the answers will ensure that families in the future may better protect their loved ones, our loved ones. They want to know how we can best prepare their vaccine systems and procedures for Disease X.

In this module we would urge two things: firstly, that those who come to give evidence before this Inquiry do it understanding that their answers ought to be given truthfully and in a straightforward manner without

agenda.

Secondly, that the press who, in certain areas, have been critical of this Inquiry, give proper consideration to how unwarranted criticism plays into disinformation narratives surrounding Covid, and could undermine critical confidence not only in the recommendation process, but in relation to vaccines themselves.

Recent events in the UK serve to remind how important the media and social media is in forming narratives.

As the Scottish Covid Bereaved made clear in Module 1 and continue to say, an attack on the work of this Inquiry is an attack on the families who lost loved ones in the Scottish Covid Bereaved group.

As ever, we approach this module keen to help the Inquiry come to a view about the best recommendations possible to ensure any and all lessons that can be learned so that Disease X meets a population ready to roll out suitable vaccines, efficiently and fairly.

These are the submissions of the Scottish Covid Bereaved.

LADY HALLETT: I'm very grateful, Ms Mitchell. Thank you very much indeed.

Mr Jacobs, are you back there somewhere? Oh, right in the corner. I don't know if you could get further

away from me, Mr Jacobs. I don't know if you're switched on. Is the green light on?

No. I think the problem is getting you to the transcriber. Rob? Okay, he's on it. Try again.

No. I usually find kicking helps but I'm not recommending that. It's not my equipment.

I was going to say is there anyone ... are we confident that you're moving to one that works? I'm afraid audio today is -- no.

MR JACOBS: Should I come --

LADY HALLETT: That's it!

Submissions on behalf of the Traveller Movement by MR JACOBS

MR JACOBS: I'm back. Thank you.

I appear for the Traveller Movement. We represent the Roma, Gypsy and Traveller groups, and Traveller Movement is a registered charity and the largest representative body engaging with these groups. Our CEO, Ms MacNamara, will give evidence before you on Thursday.

My Lady, the GRT communities have been part of our society for at least 500 years. Sadly, they have always been, and remain, the subject of suspicion, hostility, and marginalisation. Indeed, the first official recognition of their presence in England was the 1530 Egyptians Act, which sought to remove them from the

country.

In 2014, the Office for National Statistics found that the recorded number of GRT were likely to be seriously underestimated and that there was evidence that there may be 300,000 GRT in the UK. Other sources put that number as high as 500,000. So, my Lady, we say significantly this accounts for between 0.5 and 1% of the UK population.

It's TM's primary position, as borne out by much of the evidence in this Inquiry, that these communities were largely ignored in the Covid-19 Vaccination Programme.

John McCarthy, an Irish Traveller in his mid-sixties, has asked us to convey his reflections, and he says:

[As read] "It was a disgraceful abandonment. We were left to fend for ourselves, invisible to those who were meant to protect us."

We spent much time considering the evidence that has been disclosed by the Inquiry in the build-up to this module, for which we are grateful, and we say that the following three conclusions have emerged from that evidence.

Firstly, it appears that GRT were the highest unvaccinated group within the UK population. The

Inquiry's own experts have referred to a June 2022 report by Public Health Scotland, and the reference for that is INQ000147517, and it's also referred to in Dr Kasstan-Dabush and Dr Tracey Chantler's report at paragraph 184, INQ000474623.

And that report shows that GRT were 55.1% unvaccinated. This is the only group for which over half of its population did not receive Covid vaccines. The same Public Health Scotland report confirms that Traveller communities, when measured against 15 other minority groups, were shown to be the least likely to have received at least one vaccine dose.

Secondly, the evidence from the University of Glasgow for August 2023 shows that the GRT population also showed faced a higher risk of hospitalisation and death from Covid than white Scottish groups.

And thirdly, government and medical institutions knew about the problem of lower vaccine uptake in the Traveller communities, or ought reasonably to have known, we say. We have stated in our written submissions which are before you that well regarded health journals such as the European Journal of Public Health and the BMC Public Health journal said in 2017 and 2018 -- importantly, that's two to three years before the Covid vaccination rollout -- that there were

a number of barriers to vaccine uptake in relation to Travellers, which include discrimination and poverty.

The Traveller Movement say that it should always have been obvious to government and medical institutions that the GRT communities would have difficulty in accessing vaccines. For example, and we stated this, you may recall, at the preliminary hearing in May 2024, around 10,000 GRT are forced to live on unauthorised sites as a result of failure by local authority to meet their spatial planning duties. These people are unable to provide addresses to register with GPs, or access the vaccine programme through medical authorities, and there is evidence from Friends, Families and Travellers, a charity, to the effect that 74 out of 100 GP surgeries appeared to break NHS England guidance by refusing to register a nomadic patient in March and April of 2021.

Furthermore, it's well known that GRT people face literacy and Internet access issues, digital exclusion, and that made registering for vaccinations and attending appointments significantly more difficult.

So it should have been obvious also that GRT communities were at higher risk from Covid-19 through their inability to self-isolate due to living arrangements.

My Lady, we say that above all, the primary barrier

to vaccine uptake is the discrimination suffered, year in, year out, by these communities, and this discrimination directly feeds into levels of trust and the authorities.

And marginalised groups, all marginalised groups, will necessarily take a more circumspect or sceptical view of the official messaging around vaccination than those whose lives are not blighted by discrimination.

We highlighted at a preliminary hearing back in May that the experience of many Travellers during the pandemic was, instead of receiving any guidance or assistance, their only interaction with the authorities took the form of heavy police presences at funerals, in circumstances where the number of officers were often greater than the number of mourners. They were seen as problems to the law enforcement agencies and not as a vulnerable community in need of support and help.

More recently we've read in the evidence disclosed by the Inquiry that critically ill Travellers died because ambulances were not allowed onto Traveller sites until the police had arrived to accompany paramedics. These are not isolated examples and we understand from our client that there are many further examples of pandemic measures which exacerbated the very discrimination that has contributed so greatly to

scepticism and low vaccine uptake.

My Lady, it is important for the Inquiry to understand that there were solutions to the problems of vaccine hesitancy or scepticism -- I'll adopt that term from earlier on today -- in the GRT communities, and that these solutions were put forward prior to the vaccine rollout.

We've referred in our written submissions to a study from the Journal of Public Health from July 2020, that's INQ00474820, entitled *"Improving immunization uptake rates among Gypsies ... and Travellers: a qualitative study of the views of service providers*" -- Roma as well, sorry, I missed that.

In that report, research was undertaken in four UK centres where six Traveller communities were based. Those were Bristol, Glasgow, London and York. 39 service providers were interviewed and four major themes emerged from the evidence that had been gathered.

Firstly, service providers in all four cities spoke about the importance of building trusting relationships with Traveller families, and the need to understand community concerns regarding specific vaccines. There was a need for individual care providers and face-to-face engagement, and specialist health visitors for Travellers were highly valued in all four cities for

their strong relationships with families and knowledge of Traveller culture.

Secondly, it was reported that Traveller families often were not registered with GPs. Having a large family and many children often increased difficulties with booking or attending appointments and these factors led to lack of uptake of immunisation appointments.

Thirdly, there were concerns raised -- and this is an important concern -- around lack of data collection on Traveller ethnicity, such as GP practices not recording ethnicity at registration, and child health information systems not recording this information. And starkly, even now, NHS systems, do not include GRT ethnic categories for staff to complete.

Fourthly, the 2013 NHS reforms in England, which resulted in responsible for health protection and immunisation programmes being moved to Public Health England, then a new organisation, were regarded as having had a negative impact on the ability of service providers to improve uptake of immunisations in Traveller communities. The consequences of those reforms included loss of organisational memory, and led to reduced funding for awareness campaigns or staff training, and created a situation whereby specialist health visitor posts were sometimes no longer available.

So the key themes are maintaining trust within Traveller groups locally, and specialist health attendances on GRT, and high-quality data.

And the Traveller Movement maintains that policymakers had no record or indeed interest of how many GRT there were in the UK, so no meaningful steps were taken to assist them, protect them, or vaccinate them.

My Lady, it is a constant complaint by those who I represent that the GRT communities are not visible. Even though the problems and potential solutions to GRT vaccine hesitancy and low uptake were known about prior to rollout, the GRT communities were effectively overlooked and that's a situation that continues even today.

Now, earlier this morning at 10.30 am, Mr Keith KC, in his opening submissions, took the Inquiry to a document entitled "*Introductory Charts, Statistics on Vaccines*", and slide 6 within the presentation shows nine ethnic groups and the percentages of those groups who received two doses of vaccine. But there was no reference in that slide to GRT, even though, as I've previously stated, this group comprises half to 1% of the UK population and are recorded by Public Health Scotland as being the highest unvaccinated group and the

group that was the least likely to have received at least one dose.

We can assume that GRT are represented in the "Any other ethnic group" category within slide 6.

My Lady, when you come to consider that evidence and that slide, you will note it bears a strong resemblance to figure 5 in the report of Dr Kasstan-Dabush and Dr Chantler, which also excludes GRT, and seems to only relate to England.

You will also note that GRT was not recorded as a relevant ethnic group in the data recorded by the National Audit Office, which records 15 ethnic groups, many of which have an equivalent UK population to GRT.

The reference for that is INQ00065228(?), see figure 21.

The slide presentation would, no doubt, have been uncomfortable for my client watching this on the live feed. Yet one suspects the reason for the omission of GRT in the Inquiry's presentation is not, of course, that the Inquiry is disinterested in those who I represent, but that data collection in England was deficient insofar as GRT were concerned, and this is one of the many matters that we wish the Inquiry to consider.

We've noted with some regret that the evidence

proposals of the witnesses don't touch very much on GRT issues, and we propose to address this as we're entitled to do of course through the Rule 10 process, and we have submitted and will submit Rule 10 questions for every witness who may be in a position to answer questions relating to what steps, if any, government and healthcare institutions took to identify the size and location of the GRT population in any particular area, so as to ensure that this group was adequately considered during the vaccination programme.

We have also asked whether -- what actions were taken to address the impact of the vaccination programme on the GRT community, whether government agencies and medical authorities worked closely with local authorities, for example, which held data on caravan sites, whether digital exclusion and literacy issues were considered, and who, if anybody, was charged with addressing potential vaccine hesitancy or low uptake in relation to this group.

My Lady, we accepted that the timetable in this module might be somewhat demanding, but it's important that time is taken for the putting of these key questions to witnesses so that they can throw light on the failure of institutions to properly address the issues of vaccine hesitancy and low uptake by GRT in the

Covid pandemic.

My Lady, to conclude, your counsel has told you this morning that the Inquiry must examine what more can be done to overcome barriers to vaccine uptake, structural inequality of access, and the impact of misinformation.

We say that the Inquiry must look closely at the position of every minority group if it is to fulfil its TORs, its terms, and the Inquiry cannot disregard the Roma, Gypsy and Traveller groups simply because other institutions have done so and continue to do so. It is no longer acceptable that GRT remain invisible to policymakers. The reality is that the GRT communities exist in large numbers across the UK, and they suffer from the most extreme marginalisation problem, more than any other minority, in a number of areas, including from access to healthcare and of course access to vaccines.

Finally, it is hugely important to my client that the Inquiry takes all possible steps to ensure that the mistakes of the Covid-19 pandemic in relation to vaccination of GRT are not carried forward into any future pandemic or vaccination programme. That can only be done if the Inquiry looks closely at the evidence in relation to this group, and it goes on to make robust findings and recommendations.

Unless I can assist further, then those are my

submissions.

LADY HALLETT: Thank you very much indeed, Mr Jacobs, I'm very grateful.

Ms Morris, I think you're over there this time.

Submissions on behalf of the Vaccine Injured and Bereaved UK (VIBUK), UK CV Family and the Scottish Vaccine Injury Group by MS MORRIS KC

MS MORRIS: Thank you, my Lady.

My Lady, I, alongside Mr Weaver, Mr Mark Bradley and Mr Wilcox of Hudgell Solicitors represent three groups who together are recognised by the Inquiry as the Covid Vaccine Adverse Reaction and Bereaved Groups.

These three groups are the UK CV Family, the Vaccine Injured and Bereaved UK, and the Scottish Vaccine Injury Group. You will hear powerful evidence from Kate Scott, Charlet Crichton and Ruth O'Rafferty on behalf of these three groups during your Inquiry.

The thousands of people that these three groups represent present what is an uncomfortable truth for many: that vaccine injury and death are part of the pandemic story. These are men, women and children who were otherwise healthy, who followed public health advice and voluntarily attended to receive their vaccine. They include doctors, healthcare professionals, carers and parents who accepted the

vaccine thinking not only of themselves but of their patients and those who they cared for. Those I represent are neither anti-science nor are they anti-vaccine. They are real people with real experiences.

My Lady, this Inquiry must recognise and acknowledge the real experiences of the vaccine injured and bereaved, and their need for real treatment, real care, and the need for real change in the way that vaccine injuries are reported and addressed. For too long they have been ignored by the government, public health bodies and the media.

The Covid Vaccine Adverse Reaction and Bereaved are not just an unfortunate statistic or collateral damage of the government's vaccination strategy. They are individuals and families calling upon the health service and the government for urgent help.

So, my Lady, what does the Inquiry need to understand about the Covid Vaccine Adverse Reaction and Bereaved in this module? First, the Inquiry must understand the decisions that were made around the production, regulation, and rollout of the Covid-19 vaccines.

The groups I represent question what was a so-called acceptable risk of the Covid-19 vaccines to them, and

were those risks communicated in an effective way which meant that members of the public were able to provide informed consent to vaccination?

There was clearly a political drive for the UK to be seen at the forefront of global vaccine development, and we ask the Inquiry to interrogate whether political pressure created an environment in which the assessment and the regulation of the safety of vaccines was not as robust as it should have or could have been, or whether a focus on vaccination meant the alternatives, such as therapeutics, were overlooked.

We understand, for example, that the Inquiry will hear evidence that the UK Government agreed to pay AstraZeneca in advance for the supply of a potential vaccine and that the government also agreed to indemnify them and the other pharmaceutical companies, such as Moderna and Pfizer, in respect of any losses from certain third-party claims. The purpose and the impact of this indemnification needs to be fully understood. Was this standard practice? Or was this a recognition by the government and the pharmaceutical companies that there was a safety risk in the development and distribution at such speed which required special indemnification?

The Covid Vaccine Adverse Reaction and Bereaved

Groups also want to understand the data available to the companies from their clinical randomised trial data and how this information was presented to the UK regulators. Where vaccines were scaled up from those tests in clinical trials, were the regulators presented with accurate safety data for the products that were in fact rolled out to the public? We also ask how do the MHRA and the JCVI scrutinise data, particularly with regard to those who commenced but did not complete the trials?

Second, my Lady, the Inquiry must understand the post-rollout surveillance and monitoring of the vaccines. Although the desire for a vaccine at speed may have been understandable, the fast-track process for the development and rollout that followed meant that the stringent post-authorisation surveillance and monitoring was essential, as was public education and information on how to identify and report any adverse reactions to the vaccine.

Essentially, the vaccine rollout put everyone in the UK in a phase IV post-authorisation trial. We were the real-world data that Mr Keith KC referred to this morning. This made it imperative for the government and the NHS to ensure that there was an effective system in place that was well organised and signal sensitive to monitor, detect, and treat any adverse effects.

My Lady, adverse reactions were to be entirely expected. As acknowledged by Mr Keith KC this morning, any statistical probability on a population level of serious side effects such as thrombosis, thrombocytopenia, myocarditis, Guillain-Barré syndrome and other serious, haematological, neurological, immunological, and musculoskeletal injuries does not undermine their severity when they occur to individuals. Therefore, it must have been clear, when rolling out the vaccine to millions of people, if the planning assumption was that 75% of the population were to be vaccinated, that there were likely to be vaccine-related deaths and serious vaccine injuries, however rare on a population level, that would require urgent identification, treatment and care.

Many of us were vaccinated by our GP or our local healthcare provider. The BMA estimates that in England this was by over 75% of those vaccinated. We ask, were GPs also provided with sufficient information and training in relation to how to spot and report vaccine injuries? Many of us were vaccinated in mass vaccination centres and received multiple doses across different settings and from different manufacturers. We ask, were those who were vaccinated and vaccinating always advised of the latest information surrounding

known risks? Was the patient information leaflet always up to date and available to those being vaccinated?

Where changes were made to a safety profile, the Inquiry must question whether public health messaging was early enough or clear enough in order that individuals could properly assess the risk to them?

Also, was there a full understanding of whether multiple doses would impact any risk of injury or further compound any existing vaccine injury?

As Professor Stephen Evans points out in his written report to the Inquiry, it could be said that safety is always provisional, in the sense that with rare events, it may take some time to be detected. The logic to this statement is that vaccine risk assessment and risk management must retain an open mind to the occurrence of adverse events, what Professor Evans calls a degree of individual or a system's index of suspicion.

Our groups question whether the UK Government, regulators and the NHS had a sufficiently high index of suspicion to identify vaccine-related deaths and to treat vaccine injuries when they occurred. For example, given that it was known that there would be adverse affects from the vaccine, some of which might not arise immediately, why were the public and healthcare professionals not alerted to the possibility of delayed

onset adverse reactions or the potential for adverse reactions of an unknown nature?

My Lady, you've heard from those in the impact film and you'll hear from the witnesses from the groups tomorrow who detail the experiences of those whose vaccine injury symptoms were dismissed, ignored, and misdiagnosed, sometimes resulting in catastrophic escalation of the injury or in fact death.

It is likely that much of the Inquiry's evidence from the government and public health bodies will highlight the Yellow Card scheme and the additional Yellow Card pathway introduced for the Covid-19 vaccines as the most effective way of identifying adverse effects or safety signals. But medical and emergency staff should have been given training and directives requiring them to identify any conditions arising after vaccination and to immediately report them. This would have been crucial both for ensuring appropriate treatment and for collecting data on emerging side effects. For example, why was there no guidance stipulating that medical professionals should ask patients who attended hospital or medical appointments with new symptoms, whether they've been recently vaccinated, similar to the way in which questions are routinely asked about smoking, other medication and drug

use as part of a standard health examination?

Those in our groups have experienced disbelief and sometimes hostility by medical professionals when reporting their symptoms. Doctors and coroners have refused to accept that injuries or deaths were caused by the vaccine. Suddenly losing a loved one following a, quote, "safe and effective" vaccination is a massive trauma. Then being told that the cause of death is not related at all to the vaccine adds indescribable distress.

Members of our groups continue to fight for the true cause of death to be recognised, leaving them unable to find closure over the loss of their loved ones.

But we say the problem goes further than a lack of training or a lack of suspicion. The Inquiry must have the courage to examine how the public messaging and narrative in the context of the vaccine rollout created a hostile environment for the reporting of Covid vaccine-related deaths and injury.

The Inquiry will recall the mantra of "follow the science" from Module 2. In Module 4 our groups question whether that mantra and that mindset contributed to a culture of political and public pressure which dictated that vaccines were inherently good, and that there would be no adverse reactions expected.

My Lady, scepticism and challenge are all valuable parts of scientific analysis but sadly those within our groups were likely to be branded by those designing public health messaging as being anti-science or even anti-vax. The vaccines were consistently reported as safe, with members of the public being told in messaging: you must have them. Everyone's personal freedoms, ability to travel, go to work, or to visit loved ones often depended on being vaccinated.

The government also provided healthcare providers with financial incentives to maximise vaccinations within their communities. This must have contributed even unconsciously to a mindset that the vaccine must be delivered at all costs. The Inquiry should be quick to identify any development of vaccine bias within healthcare settings which could have impacted on healthcare providers' ability to properly identify symptoms of vaccine injury.

Within our groups, there are also numerous doctors within the NHS who had their own concerns about the vaccine, but were instructed to keep those concerns from the public, including their own patients. We should all find this form of cultural censorship deeply troubling.

Thirdly, my Lady, the Inquiry must understand the stigma and censorship attached to the vaccine injured

and bereaved and how that is preventing them from accessing the treatment and the care that they need. One of the biggest issues that they have faced up until this point is being stigmatised, discriminated against, and censored when they've used their voices to speak about their experiences of bereavement or life-changing injuries, husbands, wives, mothers, fathers, sons and daughters who have been killed, or severely injured by the Covid-19 vaccine. Each death or injury has placed considerable emotional and practical strain on families, with some members having to become carers, leave their jobs, lose their homes, rely on food banks and face many other devastating consequences.

During the early months of the vaccine rollout those who experienced adverse reactions found it nearly impossible to access information about the vaccine injuries in the mainstream media. When they were eventually covered, the stories were often framed with an emphasis on the rarity of such reactions, the safety of the vaccine, the millions of lives it had saved.

Having been disbelieved by healthcare professionals and ignored by the mainstream media, those injured or bereaved by the vaccine turned to each other for recognition and support. They used social media to connect with each other, to share stories, and express

their grief.

A poll of all UK CV Family members reveal that 74% had been censored when talking or posting about their adverse reaction to the vaccines on social media.

One member of a group posted his experience on developing blood clots and other debilitating symptoms following his vaccination. His post was removed and described as false and harmful.

Unfortunately, this censorship has continued years after the pandemic and into our engagement with this Inquiry. YouTube removed a video featuring my legal submissions to you, my Lady, on 13 September 2023, and despite requests for a thorough review, YouTube cited a violation of its "medical misinformation policy" as grounds for removal.

Given the speed and novelty of the vaccine rollout and the pandemic, the UK should have created an environment in which safety signals around adverse effects could be spontaneously reported and data collected. It should have been recognised that when the Yellow Card system was not or was not able to capture all the signals, that social media was a rich source of information and support for those concerned that they were injured.

Instead, the strategy that seems to have been

deployed in relation to posts about vaccine bereavement or injury was simply to remove them from social media, to silence their voices. There does not appear to have been any effective attempt by the government or public health officials to use social media or even traditional media to meaningfully increase awareness of vaccine injury reporting schemes or to offer support and access to compensation for those who had suffered.

Could a reason for the rise in trust of social media have been that people were able to find information about the adverse effects they'd experienced from the vaccine at times when the government and official sources were silent on these matters?

The psychological and emotional impact of those suffering from adverse effects of the vaccine coupled with the silencing and discrimination against them is likely to contribute to future vaccine hesitancy if not adequately addressed by this Inquiry.

Fourth and finally, my Lady, the Inquiry must urgently address the inadequacies of the Vaccine Damage Payment Scheme. The government knew at the time of the vaccine rollout that very rare adverse effects of Covid-19 vaccine will only be observable when there had been a large-scale rollout. Therefore, it was clear, we say, that there would have been a need for an efficient

system to address vaccine injury that could satisfy the moral duty of the government to act in a way that was just towards individuals who had suffered a disability or death as a result of engaging in a government-run health protection scheme.

The Covid Vaccine Adverse Reaction and Bereaved Groups are clear that the VDPS is not fit for purpose. Their calls for urgent reform have been supported by Parliamentarians in both houses and legal academics. They have highlighted the moral and social duty underscoring the VDPS and underlying the fact that if there is no reform, there are likely to be significant implications of vaccine confidence, something that Mr Keith KC recognised himself in his observations to you this morning, my Lady.

The DHSC itself acknowledged in its impact assessment for the expansion of the VDPS to include the Covid-19 vaccines that, quote, "all citizens gain from the knowledge that the government would award financial assistance if they were severely affected".

My Lady, you will hear tomorrow some harrowing stories from those who have had to wait inordinate amounts of time to have their claims resolved, often only on appeal, causing significant and compounding further distress for them and their loved ones when they

need support the most. No one who has watched this morning's impact film can be left in any doubt of the level of distress that the VDPS rejection can cause to those who are vaccine injured or bereaved.

Many individuals experienced severe injuries that required urgent and protracted medical treatment, sometimes taking months. It was only after this point that doctors would acknowledge or confirm that the injury was caused by the Covid-19 vaccine. Many of these individuals were only able to make an application to the scheme when they were well enough to do so. They then faced 18 months to two years of delays in processing their claim and receiving payment.

Mr Keith has touched upon the disablement criteria, but the notion of a 60% disablement criteria is not one generally recognised in UK personal injury law and is attributed to a pre-war pension scheme and industrial injuries. We agree with the evidence before the Inquiry in writing from Duncan Fairgreave KC that the current system is unfair and we say it needs urgent reform.

It must now be clear that reform is urgently required and that the current system has not met the needs of the injured and bereaved. There have been promises made by the previous and current government to look at the VDPS, but here we are, four years after the

first vaccination, and there has still been no action taken.

My Lady, your Inquiry, like the many others before it, will be judged on the implementation of its recommendations. The imperative for you, therefore, my Lady, we say, to assist the effective implementation is to thoroughly investigate the evidence with a view to making urgent, clear and meaningful recommendations, we say via an interim report, combined with a robust monitoring framework to deliver the long-awaited support to those who have suffered and those who continue to suffer the adverse effects of the vaccine.

This will not wait until 2026 or 2027, action is needed now.

Importantly, as Mr Keith acknowledged this morning, effective support and care for the vaccine injured and bereaved is inextricably linked to vaccine hesitancy. If the status quo is allowed to continue, public confidence in future vaccination programmes will be affected, as those that are asked to engage in vaccination can no longer have the confidence that there is any effective safety net for their physical/mental health or financial needs should they need it.

In conclusion, my Lady, of course the groups I represent are grateful for being granted participant

status in this Inquiry but our simple presence at this Inquiry is not enough. What we trust the Inquiry will hear loud and clear from these submissions, and those we have made on previous occasions, is that the voices of the Covid Vaccine Adverse Reaction and Bereaved will not be dismissed or ignored.

Their experience with Every Story Matters and the report that has been produced has not given the vaccine injured and bereaved groups confidence that the Inquiry has yet fully understood their lived experience, but we hope that Mr Keith's words this morning reflect the Inquiry's ability to listen during these evidence hearings.

The Inquiry must now listen to their voices and reject the stigma that has so far been attached to their stories in order that the truth can be acknowledged. Only then can the Inquiry propose meaningful change to benefit future pandemics.

We raise significant questions, and make substantive proposals which we -- and we ask this Inquiry to break with the failings of the past and demonstrate what can be achieved by way of recommendations when the bereaved and injured are listened to.

My Lady, those are the opening submissions on behalf of the Covid Vaccine Adverse Reaction and Bereaved

Groups.

LADY HALLETT: Thank you, Ms Morris.

Mr Friedman, I think you're next.

Mr Friedman, I appreciate that the likes of you, Mr Thomas and Mr Stanton have all moved from top right to back left.

I have asked if arrangements can be made, if everybody is agreeable, for those of you who are likely to ask more questions and therefore need to be closer to me and to the witness, to see if we can do some swapping around so I appreciate -- forgive me for the next two days, but that's the plan.

MR FRIEDMAN: Ah, so it's -- can you hear me now?

LADY HALLETT: Yes.

Submissions on behalf of the Disabled People's Organisations (DPO): Disability Rights UK, Disability Action Northern Ireland, Inclusion Scotland and Disability Wales by MR FRIEDMAN KC

MR FRIEDMAN: Thank you very much, and thank you for what you've just said, my Lady.

As you know, we act for Disability Rights UK, UK Inclusion Scotland, Disability Wales and Disability Action Northern Ireland. They are national disabled people's organisations, or DPO, run by and for disabled people.

The Inquiry is about to consider a narrative that the way in which government, science and industry carried out pharmaceutical interventions during the pandemic is something that the UK did well.

Whatever value is placed on that narrative, for disabled people, it is complicated by a tendency to judge success by non-disabled standards. It declares how pharmaceutical interventions allowed society to reclaim its normality without sufficiently acknowledging that there is a plurality of different norms or appreciating the features of the endeavour that were problematic for disabled people.

As we set out in written submissions, the problems that disabled people encountered with the vaccines were foreseeable, but too often overlooked because of the way government works.

This has adverse implications for disabled people, especially for prioritisation and accessibility of the vaccines, as well as profound and continuing exclusion for a sizeable part of the population for whom vaccination was not a medical option.

Starting with foresight. As the Inquiry has established in its Module 1 report, due to long-term failure to plan, the system of government, including the resilience of its health and care sector, were deeply

vulnerable to a pandemic.

For disabled people, the position was one of distinct precarity, and government knew that was so, not least because they had been repeatedly warned as such by domestic and international DPO and human rights bodies. For reasons that the DPO have articulated across different Inquiry modules, government is not set up well to give forethought dynamically to the interests of disabled people.

But by the late summer of 2020, the foreseeable consequences of the pandemic for disabled people's mortality, morbidity and social exclusion were unavoidably demanding of recognition. Statistics counted disabled people as six out of ten Covid fatalities. Death rates of those with learning disabilities were 30 times higher for younger people. Disabled people were profoundly isolated without access to care, or at risk from catching Covid from their carers.

This was the context in which government rushed to find pharmaceutical solutions, but with awareness of its considerable shortcomings in planning and capability to protect disabled people.

There is indeed a particular moment, we suggest, when the disconnect between vaccine planning and

disabled people's marginality might have come into focus. It was October 2020, when Michael Gove, as the chair of the Covid-O meeting, alerted departments by letter that "time [was] running out [for disabled people] for the second wave", and that fundamentally more ambitious programmes were needed.

The Disability Unit of the Cabinet Office responded in November 2020 with proposals, and we say the date is relevant. First, a data commission "to understand the factors driving increased mortality risk".

Second, a national panel for disabled people to quote, "create a channel to hear voices of lived experience and feed these into [government's] Covid policy".

And, third, a national centre for digital access, to, quote, "improve digital access ability for disabled people".

All these proposals, my Lady, were essential, practical means for a targeted and effective rollout of vaccines to disabled people being planned there and then, but none of the proposals were developed.

What my Lady is about to see is a consequence of their actions, which brings us to the role of the government.

DPO used the Social Model of Disability to reflect

the extent to which much of the experience of being disabled is socially determined.

As this Inquiry progresses it becomes clear that the social model is important as a method for evaluating government decision making, because, one, policies tend to be designed to accommodate non-disabled people, causing recognition of disabled people to be an afterthought, and, two, disabled people are under-represented in government, not prioritised in the structure of government machinery, and consequently made politically vulnerable in their capacity to influence the production and design of policy.

The problem was no less relevant to vaccines and therapeutics. With matters which are repeatedly described in the statements and the exhibits as "clinical" and "medical", there was even greater risk that consideration of disabled people would be limited to consideration of medical conditions. This not criticism of medical science or the necessary role of experts in decision making, but without social considerations, questions of risk categorisation and prioritisation were treated as ethically neutral and essentially a matter of natural science, when these matters are far more complex.

Neither is the creation of a pharmaceutical product

and the prioritisation of different cohorts the sum total of a successful policy. Whatever cohort a disabled person was in, vaccination needed to be accessible to them.

The DPO's criticism in this module is that government failed to engage disabled people at each stage of its pharmaceutical interventions, from development to prioritisation, to delivery and accessibility. And the reason why that happened is because government is not structured, educated, or culturally committed to work that way.

Problems came to the fore because vaccine prioritisation decisions, particularly in phase I, were not informed by the social model, and ethical reasoning did not play a significant role at all.

In consequence, the rollout of the vaccines initially failed to prioritise disabled people, especially those under 65 with learning disabilities, when prioritisation was due, because of what was known about the risk of premature death to that category of population.

Even when cohort 6 was expanded to include those categorised as having "severe and profound learning disabilities", change was made without acknowledging that there is no generally accepted definition of this

term, it was not consistently coded on the GP and other databases, and learning disabled people and those caring for them do not necessarily self-define that way.

In addition, prioritisation categories did not fully embrace the care system. While there was consensus that frontline health and careworkers needed to be vaccinated early, what was not recognised early enough is that the frontline labour force for disabled people overwhelmingly comprises unpaid carers, informally employed carers, and personal assistants, who are not necessarily registered anywhere or identifiable by reference to deployable data held by the DWP or local authorities.

As a result, disabled people who lived at home faced invidious choices about continued support by unvaccinated assistants. Conversely, if their carers also worked in care homes, they could sometimes be vaccinated long before the still shielding disabled person that they cared for.

The approach to prioritisation was also not ethically robust, because its laudable concern to save lives did not appreciate the triple jeopardy that disabled people faced during Covid: not only, one, that disabled people could die from the virus, but, two, they could die or be seriously diminished in life expectancy

because of lack of access to other healthcare or services, and, three, they could otherwise experience inhumane levels of social isolation when confined to their home or that vaccinated carers were not able to safely access them.

My Lady, there may be counter arguments, and I'm not trying in a short speech to rewrite a policy, but what is apparent on current disclosure is that this type of ethical discussion did not take place in government in a structured and transparent way, and it certainly did not take place with the involvement of DPO. Instead, the JCVI decided at the outset that it would not consider ethics. In practice, ministers deferred to their advice, government resisted the moral and ethical advisory group suggestion that there should be a published ethical framework, and that ethics group did not scrutinise the JCVI approach to prioritisation at any time until March 2021.

Which brings us to the problems with accessibility. The DPO emphasised the need to think through accessibility from start to finish, from how to reach out to someone to become vaccinated, to what journey they will make to the site, what will happen there, and how they can be supported in their decision making. What instead occurred was the operation of multiple

barriers affecting communication, appointments, physical and environmental accessibility, all of which could have been avoided if policies were co-designed with disabled people.

To mention just two areas, first, physical and environmental barriers for disabled people existed in accessing vaccination sites, with difficulties in leaving home at all without assistance, thereafter in reaching the sites and entering step free. Once in the environment of the centre, there were queues and waiting, various risk of sensory overload, and, for deaf people, the combined problem of no BSL interpreters and staff wearing opaque face masks.

Second, disabled people who were cautious about taking a new and relatively untested vaccine enjoyed far less accessible information and communications to support them in both their decisions and the practicalities of getting vaccinated.

There should have been heightened emphasis on accessible and effective communication from initial contact, followed up with supported decision making, and an opportunity to understand the implications, if any, of the vaccines for pre-existing conditions.

What disabled people got were singular formats for letters, briefings without BSL interpretation, deaf or

hearing impaired individuals receiving phone calls, letters without Braille were sent to those who were visually impaired, booking processes predominantly comprised online systems when it was known that disabled people were less likely to have essential digital access skills or internet access.

In any event, websites were often not high contrast, there was an adequate easy to read versions or telephone options for those unable to book online or who otherwise wanted support or further discussion.

Our final point concerns those disabled people who, for reasons of being immunocompromised, either could not take the vaccine or for whom the vaccine would not be fully effective. We are told that this could be over 1 million people, who have not been able to return to normal life and are still shielding. The incompleteness of the research and ethical discussions about the urgent need for alternative kinds of prophylaxis, such as antivirals and monoclonal antibiotics, is one of the problems of everyone else, so to speak, returning to their normality.

For the DPO, the situation is neither smart nor kind. There is no certainty that vaccines will work for any of us next time round, but until then, the political will of the crisis and the heightened market incentives

for big pharma have gone away, and a sizeable part of the disabled population have been consigned to exclusion.

My Lady, when pandemic inequalities became a major political issue, as they did later in 2020, disabled people did not enjoy significant recognition in that politics. New structures and policies were brought into being, but disabled people were not empowered as the co-designers of planning for the second wave and the vaccine rollout. The Disability Unit and the Minister for Disabled People could not be relied on to amend the policies in the design stage, and neither could anyone else in government.

For the next pandemic, establishing why this was so and how things could be different is probably the most important thing this Inquiry could do for the now 16.1 million disabled people in this country who make up 24% of its population. The module is an important case study. What many disabled people experienced was a relatively non-negotiable set of options with little agency in design and delivery, and a burden on DPO and others in devolved nations and the third sector to correct deficiencies after the fact.

This is not how government claims it wants it to be. But after several modules of evidence, one must ask how

to describe a system that causes patterns of repeated disadvantage on a widespread scale to a particular group of people. An unavoidable word for that system is "discrimination". What to call this aspect of the way disabled people are governed is important, not because we are in a court of law, but because the inequalities of the pandemic response were not inevitable. They require more open and adequate reckoning with the choices involved, and the changes that need to be made.

Once again, the Inquiry is about to see why.

LADY HALLETT: Thank you very much indeed for your help, Mr Friedman, I'm very grateful.

That takes us conveniently to 3.00 and I'm particularly grateful to all the advocates who are keeping to time so beautifully. I shall return at 3.15.

(3.00 pm)

(A short break)

(3.15 pm)

LADY HALLETT: Mr Thomas.

PROFESSOR THOMAS: Restful break.

JUDGE: Yes -- I can hear you, sorry -- restful break, did you say?

PROFESSOR THOMAS: Yes, I did.

LADY HALLETT: Thank you.

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

PROFESSOR THOMAS: My Lady, as you know, I represent FEMHO.

"The time is always right to do what is right."

These words from Dr Martin Luther King Junior deeply resonate today, reflecting one of the most pressing and moral practical challenges of our time, ensuring that no one is left behind in healthcare.

These words remind us that in moments of crisis doing what is right requires urgency, courage, and clarity of purpose. You see, my Lady, as this pandemic tore through our healthcare system, not caring who it touched, its heaviest toll fell on those who were already marginalised. We've said it before and it bears repeating: the first ten doctors to lose their lives to the Covid-19 were from the black, Asian or ethnic minority backgrounds.

This is of no coincidence.

It's a harrowing testament to the systemic inequities ingrained in our healthcare system. As we've examined in the first three modules of this Inquiry, these disparities are not isolated. They are entrenched. It is both unsurprising and deeply troubling to see this same thread woven into Module 4 on vaccines.

For members of FEMHO, these numbers are not abstract statistics; they represent colleagues, friends, family, who were the backbone of the pandemic response, but bore the heaviest burdens of risk, illness, and death. Our members, standing at the intersection of race and healthcare, lived these realities daily. They are uniquely placed to illuminate not just what went wrong but why, why it went wrong, and to share learnings as to how matters may be improved from both their professional and lived experience.

Module 4 on vaccines provides a crucial opportunity to ask bold questions and draw meaningful lessons. Were vaccine strategies designed with equity at their heart? Did they tackle mistrust rooted in systemic racism? Did the government meet its obligations to dismantle barriers, or did it inadvertently deepen them? You see, we approach this Inquiry with both the weight of the past failures and the hope for a future that learns from them. FEMHO is here to assist, in ensuring that the mistakes of this pandemic are not repeated and that reforms we pursue are bold, inclusive, and lasting.

My Lady, FEMHO is not simply here to highlight failures. We hope we are here to drive solutions, our members being professional, and bring professional expertise and their experience, that it will illuminate

what went wrong, and how we can ensure that these mistakes are not repeated.

Let me come to a main theme. Trust and communication. You see, trust is the foundation of any successful public health strategy, yet during the pandemic it became a fault line.

Trust is not an intangible concept; it's the bedrock of public health. Yet during the pandemic, trust was systematically eroded for many minority ethnic communities, not because of their reluctance, but due to institutional failures to engage with them meaningfully. Trust simply cannot be assumed. It must be earned through transparency, cultural sensitivity, and consistent engagement.

You see, it's crucial to understand that the challenge was not simply about communities being reluctant to accept vaccines; instead the failure lay in how these policies and initiatives were communicated, or, I should say, inadequately communicated to them.

For ethnic minority communities, trust in public health policies was already fragile, eroded by decades of systemic inequalities and underrepresentation, and my Lady, I pause there and come off script just to note that the impact video that we saw this morning with the doctor touching on this very issue with members of her

community.

The pandemic only deepened this divide from the perceived lack of transparency of safety and the expedited approval processes, misinformation spreading unchecked, to poorly communicated vaccine policies. We saw the devastating impact of a failure to engage communities in ways that resonated with their lived experience. The problem, as I say, was not a lack of willingness but a lack of trust in the system, often overlooked or undervalued these communities.

For example, the absence of culturally competent communication left many ethnic minority individuals alienated and uncertain. Simple yet critical concerns, for example "Are the vaccines halal? Do they contain alcohol in the ingredients?", conflicted with other cultural practices, which was not adequately addressed in the initial rollout.

This failure contributed to what has been described as vaccine hesitancy, not out of defiance, but out of a lack of trust in the system, which seemed blind to their needs. This module offers an opportunity to reframe the conversation. This module must confront the reality that trust cannot be built retrospectively. The lesson here is clear: inclusive communication strategies that actively engage communities are not optional; they are

essential.

Building trust requires active listening, culturally sensitive outreach, and communication strategies that are informed by and designed in partnership with the communities they seek to serve. Rebuilding trust is not just a moral imperative; it's a public health necessity, and it must be a continuing process.

Let me turn to the next theme, structural inequalities and data gaps. Systemic inequality isn't just a historical wrong. It is a present and persistent barrier to equity in healthcare. Nowhere is this more evident than in the glaring and longstanding issue of the lack of diversity in vaccine trials. During the pandemic, clinical trials for the major vaccines showed a shocking underrepresentation in minority ethnic groups. For example, over 90% of the participants in the AstraZeneca trials were white. For the Pfizer vaccine phase III trials, almost 83% of the participants were white. And the figure is almost 80% for the Moderna phase III trials, thus leaving significant portions of our population unaccounted for when assessing the safety and efficacy of the vaccines.

This oversight reflects not just the failure to prioritise diversity, but also a failure to uphold basic principles of equity in science and medicine.

Equally troubling is the persistent data deficit that plagued decision making during the vaccine rollout. Ethnicity-specific data which could have been a vital tool for identifying disparities and tailoring interventions was either absent, incomplete, or inconsistently collected. Without it, governments and healthcare systems were flying blind when it came to understanding the unique vulnerabilities and barriers faced by ethnic minority communities.

This failure contributed to the inequitable rollout where pre-existing disparities in healthcare outcomes were not just perpetuated but in some cases exacerbated.

Vaccines as a condition of deployment. The introduction of vaccines as a condition of deployment was, on the face, a policy aimed at protection but it was poorly communicated and in practice disproportionately burdened ethnic minority healthcare workers, the very people who carried out our healthcare system through the crisis. This policy was a blunt tool which erroneously overlooked the historical and cultural barriers to vaccine uptake in these communities, compounding workforce challenges and deepening divides.

The lack of engagement and consultation with staff exacerbated concerns, and fostered a culture of fear and coercion.

Safety surveillance in the Yellow Card scheme. The Yellow Card Scheme was intended as a safeguard, a mechanism to ensure vaccine safety and build public confidence. Yet, for many ethnic minority communities it became yet another symbol of mistrust. How could they have faith in a system that for many, unknown, and for others, barely understood. The lack of proactive measures such as providing options in multiple languages, utilising local pharmacies and community leaders and raising awareness in communications about how the scheme worked, particularly around addressing adverse reactions, left a vacuum of misinformation, readily filled.

You see, if we're to rebuild trust, such schemes must be transparent, accessible, and embedded in culturally competent outreach that resonates with all communities.

Next theme: vaccine confidence. Vaccine confidence is not a measure of individual trust, but a reflection of systemic effectiveness. The barriers that undermine vaccine competence and uptake among ethnic minority communities were not born in these communities; they were the product of government failure to meet them where they are, in language, in culture, in shared trust, and we submit that given the data and existing

knowledge from previous vaccine programmes, a lower uptake and confidence levels amongst ethnic minority communities ought to have been anticipated and mitigated against from the outset.

Misinformation spread like a second pandemic, my Lady, preying on historical mistrust and amplifying fears. Communities already marginalised by systemic inequities found themselves left behind by public health messaging that failed to resonate or address their legitimate concerns. For example, cultural fears, as I've already indicated, about the ingredients.

Accessibility also played a critical role. Vaccine sites and public health campaigns often failed to cater for non-English speakers or adapt their messages to cultural norms and values. Culturally sensitive outreach was often an afterthought, rather than an embedded practice, compounding existing hesitancy and leaving those most vulnerable without clear and trusted information.

I've nearly finished, my Lady. I just want to move on to some lessons because I want to be forwarding thinking.

Lessons for future preparedness. As we consider the lessons of Module 4, one truth becomes undeniable: our preparedness for future pandemics. It must look

profoundly different from the past. Equity cannot be an afterthought, it must be a foundation. The preparedness plans must embed equity as a core principle ensuring that diverse voices are present at every table where decisions are made.

My Lady, let me leave you with a vision. Imagine a healthcare system where every vaccine developed and deployed is a testament to fairness and equity. A system where clinical trials reflect the rich diversity of our population ensuring that vaccines are tested and proven effective across all ethnicities, ages and backgrounds. Picture a vaccine distribution strategy that not only reaches every corner of our communities but does so with sensitivity and cultural competence. Envision a public health campaign that resonates deeply because they're co-created with communities they serve, messaging that's delivered in languages that people speak. Addressing their fears, their concerns, and delivered by leaders they trust.

Imagine a vaccine centre designed to accommodate cultural needs where accessibility is not a hurdle but a given, where misinformation is drowned out by a chorus of trusted, inclusive voices. In this reform system, vaccine confidence flourishes not because it is demanded, but because it is earned. Trust is built

through transparency, inclusivity, and respect, ensuring that no community is left behind.

This is the vision we must collectively strive for, for a healthcare system where inequities of the past are lessons for a better, more just future, where vaccines are not just life saving, but trust-building tools for every individual regardless of their background.

LADY HALLETT: Thank you very much indeed, Mr Thomas.

As ever, very grateful.

Now I think it is Ms Naik KC? Yes.

Submissions on behalf of the Migrant Primary Care Access Group by MS NAIK KC

MS NAIK: Ah, yes, we're on now. Thank you, my Lady.

We represent Doctors of the World, the Joint Council for the Welfare of Immigrants, the Kanlungan Filipino Consortium and Medact, who formed a collective in this Inquiry known as the Migrant Primary Care Access Group. And during the pandemic, those organisations, through their collective knowledge and experience, emerged as key experts on the health consequences of Covid-19 for migrants in the United Kingdom, given their years of working with and supporting migrant communities in health and migration policy.

And in our Rule 9 statement, to which Anna Miller from Doctors of the World will speak tomorrow on behalf

of all four organisations, we clearly and without doubt identify barriers to vaccine delivery and healthcare inequality that prevented access to the Covid-19 vaccine and therapeutics for a significant proportion of migrant communities.

Well, in real terms, what that means is that some migrants contracted Covid and died as a direct result of failure by government to address and dismantle those barriers that prevented them from accessing the vaccine on account of their immigration status, barriers which the government knew about from the outset, and which had been deliberately put in place to deter people from coming to the UK and remaining here. And despite public health requiring those barriers to be removed in the context of this unprecedented health emergency, they were maintained.

This evidence shows that immigration policy was prioritised, and continues to be prioritised, over public health, to the detriment of all of us.

What is crucial to highlight at the outset is that the independent expert reports commissioned by this Inquiry, and which Mr Keith identified this morning, on disparities in vaccine coverage and vaccine hesitancy, overwhelmingly corroborate our evidence by identifying that the same persisting barriers to vaccines for

migrants exist as an obstacle.

The government's failings exacerbated those pre-existing inequalities in healthcare access and outcomes, which without doubt led to avoidable illness and death amongst migrants. Many migrants occupy an intersectional space as being both black, Asian and minority ethnic individuals, and of course being amongst the most socioeconomically deprived, to which other Core Participants have spoken today, including Ms Munroe KC and Mr Thomas KC just now.

The statistics with which Mr Keith opened this morning clearly show that there was a demonstrably lower uptake of the vaccine amongst all ethnic minorities. But that is not the whole story, and it is the task of this Inquiry to scrutinise the reasons why, and in particular how and why, immigration status was a factor in that unequal uptake.

We know from your Ladyship's initial report in the preparedness and resilience of the UK from Module 1 that the government's approach to risk assessment was fundamentally flawed, and that the planning focused on dealing with the impact of the disease rather than prevention, and this included a failure to appreciate the range of people who might be vulnerable in the pandemic.

When those conclusions were examined in the context of this module, the government's failure to adequately plan for vulnerable groups is stark when considering the impact on migrants in relation to the vaccine.

Migrants as a class feature a disproportionate number of individuals who faced both increased exposure to contracting Covid-19 and an increased risk of experiencing severe symptoms and fatalities caused by the virus, and as such they were deserving of particular care and consideration in government planning to facilitate access to the vaccine and to prevent individual harm, and in the interests of wider public health.

They didn't get it. Instead, they faced significant and interwoven barriers to access, embedded by decades of immigration policy, structural racism and socioeconomic inequalities that all contributed to deep-rooted mistrust of authorities and an inability or reluctance to access healthcare during the pandemic.

But the most pernicious barriers to vaccines and healthcare were government-created, specifically designed to enmesh access to healthcare with immigration control. They include the NHS charging regime and data sharing practices between the NHS and the Home Office. Those barriers and the harms they caused to public

health were well known and well documented prior to the pandemic. For years, experts in the field, including the four organisations that we represent, called on government to remove those barriers to protect wider public health, but those warnings went unheeded. And although we acknowledge the government did take some reactive and short-term action during the pandemic, for example by adding Covid-19 to the schedule of exemptions for NHS charging, the evidence is unequivocal: the measures were ineffective and failed for being too little and too late.

The fear and mistrust caused by the longstanding hostile environment policies cannot be switched on and off in times of natural emergency. The only evidence based on credible recommendations to ensure effective and meaningful removal of those barriers to healthcare, in the interests of wider public health, including vaccine uptake, both now and in future pandemics, is for those hostile environment policies to be permanently repealed. From a public health perspective, anything less would be ineffective.

So, ultimately, prioritising the saving of lives of all individuals in the UK, regardless of race and immigration status, is the only way to effectively protect us all, and discriminatory denial of access to

healthcare harms everyone.

Our clients would like to highlight the following five governmental failings from our opening submissions and witness statement, which we won't repeat in detail. Our recommendations derive from those core propositions. Delays or refusing to implement the changes that we propose until we're in the midst of a future healthcare crisis will be too late and would once again put migrant lives and consequently all of our lives at risk.

First, there's an ineffective approach to exempting Covid-19 from NHS charging. The NHS charging framework is extraordinarily complex and frequently misunderstood and misapplied by NHS Trusts, and this results in migrants being denied healthcare, erroneously charged for healthcare, and/or pursued for unpaid debts that they cannot afford.

From late January 2020, the government included Covid-19 as an exemption from healthcare -- from NHS charging. However, from that time and to date charges continue to apply to treatment for Long Covid or other health complications caused by the surrounding NHS charging regimes, and there was no clarity as to what might be charged, and chargeable, and what was not.

Throughout the pandemic, NHS staff, royal medical colleges, and migrant organisations, formed a unified

voice in calling for effective action to suspend the most harmful exclusionary healthcare policies, but those calls were ignored.

Second, the data sharing. The NHS is required by law to share information with the Home Office on patients' immigration status and unpaid hospital debt and this, unsurprisingly, has caused many migrants to view the NHS and healthcare workers with suspicion, fear and profound mistrust. It was well known and long recognised by the Department of Health and Social Care that data sharing between the NHS and the Home Office deters many migrants from accessing healthcare due to fear of immigration enforcement action. During the pandemic, many who feared such personal data being shared avoided accessing the vaccine, and critically, at no stage during the pandemic was there a data-sharing firewall implemented between the NHS and the Home Office to reassure migrants, and that refusal to respect patient confidentiality on grounds of immigration status is a serious public health concern with serious consequences.

Third, the vaccine access model was based on a model that directly excluded the most vulnerable and at risk migrants. The government's approach to vaccine invitation and booking only captured those with an

active GP registration and an NHS number.

The issue of GP practices routinely refusing to register migrants, including on account of their immigration status or lack of documentation, was widely reported and well known to government prior to the pandemic, yet it persisted unaddressed.

As a result, when the pandemic struck, many migrants didn't feature in primary healthcare records and they didn't have an NHS number. Belated government efforts to communicate that vaccines could be administered without such a number were inadequate.

Four, there was a clear failure to identify or prioritise migrants in high risk settings. Despite urging social distancing and isolation, the government procured several former military barracks as asylum accommodation sites, where overcrowding and shared facilities significantly increased exposure to the virus, but at no stage did the government identify or prioritise these sites as being high risk and eligible for vaccine priority, and the evidence suggests that this was on account of it being politically unpalatable. And again, this was a failure to put public health first as a priority over immigration policy.

Fifth, there was a failure to collaborate with specialist frontline migrant NGOs and consider their

recommendations. So even where barriers to access to healthcare and, in turn, vaccine uptake were repeatedly identified, and in particular by our clients, the government failed or refused to take the necessary and timely action that that evidence showed was necessary to seek to ensure access.

So, my Lady, this Inquiry now presents a pivotal and critical opportunity to make robust evidence-based recommendations that restate the fundamental and inalienable right to equality, dignity and access to healthcare for all. The importance of ensuring the universality of access to healthcare has never been more vital when addressing the issue of vaccine delivery and barriers to uptake. The impact of the government's deliberate policy choices and the pre-occupation with immigration undermined the health and safety of the entire population. Public health at its widest and in the context of a pandemic hinges entirely on achieving widespread and inclusive vaccine uptake.

One of the expressed overarching stated terms of reference of this Inquiry is to consider any disparities evident in the impact of the pandemic on different categories of people, including those relating to protected characteristics under the Equality Act 2010, and in Module 4, one of the terms of reference is

specifically of course to examine unequal uptake, the potential causes of such unequal uptake, and the government response.

The evidence before this Inquiry demonstrates that the Covid-19 pandemic -- during that, the government persistently failed to address the fundamental question necessary to design and implement effective interventions aimed at ensuring equitable access to the vaccine: namely, what were the root causes of the barriers to vaccine uptake by migrants? This question was simply not properly posed or considered by key government departments and therefore those barriers and health inequalities were significantly widened as a result, as the statistical evidence clearly demonstrated.

This failing was squarely identified by the Inquiry's own experts to Module 4 to which Mr Keith has referred to this morning in the Kasstan-Dabush and Chantler report on vaccine delivery and disparities in coverage, which identified that national policy and particularly immigration policy had an adverse impact on vaccine delivery strategies during the pandemic.

Now, this strongly underscores and reinforces our client's central position advanced at this Inquiry. Although the hostile environment policy agenda and

overarching legislation was introduced by the Home Office to deter migrants, the NHS charging regime now sits squarely within the remit of the Department of Health and Social Care. They laid the regulations underpinning the charging regime and they are responsible for its operations, but key elements of the charging regime remained fully operational throughout the pandemic, including data sharing provisions that mandate the NHS to undertake immigration checks with the Home Office and report unpaid hospital debt directly to the Home Office.

None of the key decision makers in the relevant central government departments, including Matt Hancock and Sajid Javid, the former ministers for the Department of Health and Social Care, Nadhim Zahawi, the then Vaccine Minister, Kemi Badenoch, the then Minister for Equalities, have identified or referred to, either by name or in substance, the NHS charging regime or the data sharing as barriers to vaccine delivery or uptake or at all, and the very narrow reference to historic suspension of data sharing by the Home Office in their witness statement fails to address the ongoing data sharing between NHS and Home Office under the charging regime throughout.

The government, we say, failed cross-departmentally,

to address the impact of those policies on migrant access to healthcare. This wholesale government omission is stark. The failure to acknowledge even the root causes of those low uptakes obviously means that the barriers could not be and were not mitigated or removed. At best, this is a failure by those departments to identify and address the impact of the hostile environment immigration healthcare policies. At worst, it amounts to a wilful and deliberate reluctance to prioritise public health over immigration control, even during a national emergency.

The failure to properly identify those barriers is deserving of criticism from the Inquiry, commensurate to the harm and the risk of harm it caused, and if maintained, this approach will cause such harm in the next public health emergency. The Department of Health and Social Care now in their opening written submissions to this Inquiry acknowledged that more could have been done, and earlier, and that there's much to be learned with respect to tackling inequalities in relation to ethnic minorities, but there is no reference to migrants as a subset and no reference to the impact of immigration policy.

So in closing, my Lady, we say that this necessitates robust recommendations from the Inquiry

that restate the priority of public health over immigration policy as a clear lesson to be learned. As Counsel to the Inquiry stated, the Inquiry must focus on identifying the most significant systemic features to identify what needs to be embedded or improved. And in line with your Ladyship's recommendation from Module 1, the radical reform, we invite the Inquiry to make bold and impactful overarching recommendations. And by adopting those recommendations, the Inquiry will send a clear and committed message that truly Every Story Matters, and by ensuring that everyone, regardless of their immigration status, will have access to the healthcare that they need.

Thank you very much, my Lady.

LADY HALLETT: Thank you. Very grateful.

Mr Wagner.

Submissions on behalf of Clinically Vulnerable Families by MR WAGNER

MR WAGNER: Good afternoon, my Lady.

I act for Clinically Vulnerable Families, which are referred to as CVF. I act together with Hayley Douglas, who sits to my left, and Libby Sague Bell(?), and I'm instructed by Kim Harrison, who sits to my right, and Shane Smith of Slater and Gordon.

CVF is a grassroots organisation born of the

pandemic and it represents the clinically vulnerable, the clinically extremely vulnerable, the immunosuppressed and their families.

The first issue I will address is vaccines versus therapeutics. CVF remain concerns that although the Inquiry has said that Module 4 will examine vaccines and therapeutics in parallel, as is in the Module 4 list of issues, the examination of therapeutics will ultimately fall through the cracks. In the ten weeks of hearings in Module 3, despite therapeutics apparently being split across the two modules, the topic was barely mentioned in oral submissions.

We are grateful for the indication by Mr Keith KC this morning that non-vaccine medicines were also a critical part of the response to the pandemic, and this module will be focusing on therapeutics, non-vaccine medicines, with the same degree of scrutiny as it will be focusing on vaccines. We really are grateful for that indication, and trust that that will allay our concerns.

But we do identify that a number of witnesses, for example Dame Kate Bingham, have said to the effect of "I do not know why a different approach was taken to vaccines on the one hand and therapeutics and antivirals on the other" in relation to the pandemic itself. And

CVF makes an overarching submission that the low prioritisation or lower prioritisation of therapeutics and prophylactics very likely caused serious damage and cost lives, and that's why we've said a number of times it's important that the Inquiry doesn't repeat that mistake. But we do appreciate the indication.

Prioritisation and eligibility and communications. And I'm referring to issues in the issues list.

Clinically vulnerable and clinically extremely vulnerable people were, rightly, amongst the first to be vaccinated, but many of CVF's members reported confusion around their eligibility for priority vaccination. There were clinically extremely vulnerable people who were not automatically called for vaccination because they had not been recorded as clinically extremely vulnerable.

Many more clinically vulnerable people who were not clinically extremely vulnerable were never officially identified and were therefore left doubting their own eligibility.

Without the knowledge that they were eligible for priority vaccination, clinically vulnerable people were understandably less likely to advocate for themselves. And CVF are concerned the result was that clinically vulnerable and clinically extremely vulnerable people

were simply not aware of their status or not aware enough, and therefore did not receive the protection of the vaccine as early as they should have. We urge the Inquiry to investigate how that played out in the early months of the vaccine programme.

Our next topic is vaccination of children. This is important to CVF because of two points: first, the impact on clinically vulnerable children, who were at higher risk of severe outcomes of Covid-19, of not being able to access the vaccine. And, secondly, the impact on households, that is non-clinically vulnerable children who lived with clinically vulnerable parents or siblings or household contacts.

CVF was concerned by the slow rate of expansion of the Covid-19 Vaccination Programme to children. So, for clinically vulnerable families, there was a very long delay between the rollout of the vaccines to adults in December 2020 and the eventual vaccine offer to healthy 12-15-year-olds in September 2021, and to 5-11-year-olds even later, in February 2022. We say this had a detrimental impact on those families.

It led to some CVF members, who could afford to, travelling internationally to get vaccines for their children.

The vaccination has never been offered to healthy

children under 5 years old, despite other vaccines being offered to that group.

CVF submits that the decision making around the vaccination of children was too cautious, too slow, and out of step with the approach taken by other countries.

We also say that the JCVI's singular focus on the potential risks from the vaccine versus the potential benefits of the vaccine to the individual child was too narrow. We say more about this in our written submissions but essentially we say they should have taken a broader view, looking at not just the impact on the children but the impact on their families of the children not having access to the vaccines, particularly in clinically vulnerable households.

Once the vaccine was eventually offered to 12 to 15-year-olds in September 2021, CVF members experienced difficulties in actually accessing the vaccine for their child. And we submit that it's likely that delays in decision making around children, combined with discouraging language and communication used once the vaccines were approved for children, in stark contrast to the language, the positive language, used for adults, contributed to the lower uptake amongst children.

Our next issue is barriers to vaccine uptakes, and particularly accessibility to vaccines. This has been

mentioned by a number of Core Participants this morning, such as the disability groups and others.

A significant feature of the initial rollout of the Covid-19 vaccine was the use of large vaccination centres, which were often not safe for clinically vulnerable people to attend. The CVF are concerned that patients who were eligible for vaccination didn't come forward or didn't obtain a vaccination as early as they could have done because of their valid concerns about the risks of such centres.

For example, there was often severe overcrowding, a lack of ventilation and poor air quality in the buildings used, as well as staff and others regularly removing their masks, and this simply not fit for purpose in a pandemic involving an airborne virus.

Clearly, there had to be a balance between what was available and what was achievable, but we do say, in terms of future planning, that needs to be thought through more carefully for an airborne pandemic.

This is reflected by the Inquiry experts, Dr Kasstan-Dabush and Dr Chantler, who say that mass vaccination sites were not always suitable and possibly not safe for a number of vulnerable cohorts, and in the JCVI prioritisation list, including people in older age groups, clinically extremely vulnerable, and people who

had physical or learning disabilities.

And this was, of course, in addition to the risk of contracting Covid-19 if you had to travel long distances to get to the vaccine centres, which for some people was the reality. That meant using public transport or being driven by someone who was potentially infected.

Next, I want to talk about therapeutics. We do not, with respect, entirely agree with Counsel to the Inquiry's statement that, like the vaccine programme, the evidence overwhelming suggests the therapeutics programme was a success. Helen Knight, the chief executive of NICE, said in her written evidence that the system as a whole would need to do more to develop therapeutics for the highest-risk patients in the event of another pandemic.

CVF invites the Inquiry to investigate why it took until October 2021 for a procurement decision to be taken on oral antivirals, with the first patients receiving treatments in December 2021, one year after the vaccine rollout began.

Was this because of insufficient or unequal priority being afforded to the programme for therapeutics as compared to vaccines?

And we ask the Inquiry to consider whether a better approach could be adopted in future.

Eligibility. CVF is concerned that the list of people eligible for therapeutics has been and continues to be particularly limited, especially given the underlying conditions and age profile of the people admitted to hospital, and sadly dying of Covid-19.

We submit that there should be an urgent rollout to those identified as eligible by NICE a year ago, in January 2024, who have no access to the therapeutics to date. That 18-month delay, until summer 2025, when the drugs will apparently be available, leaves vulnerable people exposed to unnecessarily high risks, including during, of course, the current quad-demic during the winter of 2024.

Deployment. Sir Sajid Javid, amongst others, emphasises in his evidence that the entire focus of the procurement of antivirals was to help those in high risk groups, and particularly for those who could not be vaccinated but were still at particular risk or would not achieve the results of vaccination that others would achieve.

But despite the importance, the Covid-19 antiviral pathway was, and remains to this day, fraught with issues about access and barriers which have prevented many vulnerable people from receiving lifesaving treatment they need. It's significantly more

restrictive compared to other medications, like influenza antivirals, which can simply be prescribed by a GP. And many vulnerable people to this day are still not aware of their eligibility for those antivirals.

Professor Nicholas White has told the Inquiry in his written evidence that antiviral drugs were most effective as soon as people felt ill or were diagnosed with Covid-19 in the community. But in practice the burden has been on the patient, who has to go through a series of administrative and bureaucratic hoops to get those antivirals, and we detail that in our written submissions.

Finally on the Inquiry issues, non-vaccine prophylactics. For those who are immunosuppressed and unable to mount an effective response to vaccination, prophylactic treatment was, in effect, their vaccine, you could take it in advance before you got the virus and it would help you, but there were very significant barriers, again, to receiving those treatments.

There will be some evidence, and Mr Keith KC has already referred to Evusheld, but in short we agree with Dame Kate Bingham's conclusion on the decision not to approve Evusheld. By far, she says, the most significant harm was caused to hundreds of thousands of immunocompromised members of the UK public. The effect

was the UK was the only Western country not to protect its immunocompromised people using long-acting antibodies. It was very plausible that this decision cost lives and condemned many more people to suffer through long-term shielding. And we agree.

Before I conclude, I want to make a brief point about the impact film. We appreciate your statement, my Lady, about the impact film not being evidence and not representing your Ladyship's views, and we of course accept that.

We also know how hard the Inquiry team has been working on every aspect of this module, including the film, no doubt having to balance many, often competing, perspectives.

However, the impact film is an important piece of public communications, and any films produced by the Inquiry should be produced carefully to ensure accuracy, proportionality, and representation of the issues identified by the expert witnesses to this Inquiry, who have all now reported. That approach helps to reduce the risk of spreading misinformation or disinformation which is crucial for safeguarding public health.

The film in its final form was 14 minutes long and it devotes as much time to people who say they or their relatives suffered adverse reactions to the vaccines as

those who gave a positive perspective. Only just over five of the 14 minutes are devoted to the positive impact of the vaccine. Another two and a half minutes features those who were bereaved by Covid but it doesn't make clear what the link, if any, of those stories has to the vaccine.

One of the purposes of this module is to identify what went wrong with the vaccine development and rollout. And this includes listening to people who had adverse responses to the vaccine. CVF entirely supports that. Their voices are as important as others who have suffered as a result of the Covid-19 pandemic. Indeed, the CVF membership group includes a small number of people who were vaccine damaged, but thankfully, and as Mr Keith KC very clearly pointed out this morning, this is a relatively small group of people compared to the tens of millions who took the vaccine and had a good outcome. The tens of millions who were protected from the worst impacts of Covid-19, including many clinically vulnerable people.

CVF's concern, and I hope that this is taken in the constructive way it's proposed, is that the impact film focuses too heavily on negative views, and members of the public watching may reasonably get the impression that a significant majority of people who had negative

vaccine -- had negative vaccine experiences, which would be wholly the wrong impression.

As you will be aware, Covid-19 has been surging this winter and the vaccination programme is and remains central to protecting people against that surge, as well as for many other viruses such as flu. But meanwhile, the ONS reports that around 1 in 20 adults, 4%, report negative sentiment towards the coronavirus vaccine.

The Inquiry, as a highly trusted public authority, with good reason, has a duty to ensure that it does not, even inadvertently, encourage a disproportionately sceptical view of the vaccination, and one of the immediate negative impacts of the curation of this film was that two clinically vulnerable people withdrew consent to be in the video and had to be edited out at the last minute, which led to almost no mention of being made of the two key focuses of this module, antivirals and therapeutics.

LADY HALLETT: I'm sorry, Mr Wagner, I'm going to stop you there. It was not the Inquiry's fault that the clinically vulnerable people who had contributed withdrew, and they withdrew with very late notice, which left the Inquiry with very little option to produce the film that it did, and I have already acknowledged that there may be those who considered it wasn't a fair

reflection of the experience of the UK population.

So, I'm sorry, I don't take these criticisms of the Inquiry in the constructive way you say. It was forced upon us.

MR WAGNER: Well, they will probably say it was forced upon them, my Lady, and I don't speak for them because they're not my clients but that's -- that's all I can say on that.

Look, to be very practical, I will finish here, we request that the Inquiry consider, before it posts the video online, adding context, by way of text or additional footage in order to ensure the film does not have the negative public health impact we fear it will.

To conclude, CVF's concerns are linked by a common theme: that the clinically vulnerable were often overlooked or their needs underappreciated when it came to the response to Covid-19. In this module, this is clear from the comparative lack of focus on antivirals and therapeutics which are crucially important for the clinically vulnerable people as compared to vaccines. It is for these reasons that CVF considers it is essential that the clinically vulnerable are identified as a specific group or protected characteristic, under the Equality Act 2010, and the Inquiry's equalities and human rights statement, to ensure that they receiver the

vital protections that they deserve, and that they can no longer be switched on and off at the whim of public officials. CVF is grateful for your care and attention throughout this important module.

LADY HALLETT: Thank you, Mr Wagner.

Ms Murnaghan, I think you are going next, aren't you, because you have a plane to catch?

MS MURNAGHAN: Yes, my Lady, good afternoon. Thank you very much.

LADY HALLETT: You are hiding.

Don't worry, I can see you on the screen.

Submissions on behalf of Northern Ireland Department of Health by MS MURNAGHAN

MS MURNAGHAN: Yes, I'm hiding, my Lady.

My Lady, I make this opening statement on behalf of Northern Ireland's Department of Health which I refer to in the course of my submissions as "The Department".

At the outset of Module 4 the Department would like to emphasise that its overriding priority during the pandemic was always to protect the population of Northern Ireland, to minimise the loss of life and to support all efforts to contain the spread of the virus. The loss of life and the individuals and families who were affected must remain, we say, at the forefront of everyone's thoughts throughout this Inquiry. And to

that end, my Lady, the Department would like to offer its sincere condolences again to all of those who were bereaved as a result of Covid-19 and extend its sympathy to the wider public who suffered as a result of the effects of the pandemic.

The Department recognises the grief caused by Covid-19 is an ongoing matter and its effects are still being felt by many individuals as well as by the wider health and social care system.

Equally, my Lady, the Department would like to thank those who responded to the pandemic. That includes, of course, those who worked in hospitals, care homes and the community, members of the charity and the volunteering sector, staff in the Department, and throughout all of the Northern Ireland Civil Service.

We would also like to -- wish to acknowledge the efforts of those who volunteered and participated in clinical trials of drugs and vaccines, from -- those trials from which so many others, both in Northern Ireland and the rest of the UK, benefited. Ultimately, it was only through the effective treatment and the Covid-19 Vaccination Programme that our path out of the pandemic was provided, and we were able to gain the normality with which we had previously been so familiar.

It is undoubtedly the case that the link between

infection and severe outcomes was progressively weakened by the identification and development of effective drug treatments and vaccines.

These factors created the circumstances in which Northern Ireland could move away from the need for our non-pharmaceutical interventions and the more restrictive measures and so limit the damaging impact to the health and wellbeing of the population and wider society.

The Department is grateful to the expert scientific advisory committee, the Joint Committee on Vaccination and Immunisation, that's the JCVI, which advised the four UK health departments throughout the pandemic on all matters relating to vaccination, including eligibility and prioritisation.

While the Covid-19 vaccines have been effective in helping to protect us all, especially those considered most at risk from the impact of the virus, we acknowledge that unfortunately, in some rare cases, individuals may have been injured as a result of vaccination.

As with all medicines, vaccine side effects need to be continuously balanced against the benefits in preventing illness. To this end, we fully support and appreciate the work of the Medicines and Healthcare

products Regulatory Agency, who continue to closely monitor and review the effectiveness and impact of the Covid-19 vaccines.

This work we consider is necessary to ensure that the benefits of the vaccines continue to outweigh any possible side effects.

My Lady, despite the Northern Ireland health and social care system already being under severe pressure prior to the pandemic, the collaboration of all of those involved ensured, in our view, the successful implementation of a vaccination programme. It was only through the collaborative and collective effort which was required, and was supported by dedicated clinicians, public health professionals, scientists and academics, that we were able to achieve such success. Their tireless endeavour whose work in the trial, development and rollout of effective drug treatment and vaccines, undoubtedly, in our opinion, saved many lives.

In Northern Ireland, much innovation and many challenges were addressed, both in the rollout of the Covid-19 vaccine and in the new Covid-19 treatment programmes, through collective commitment and the collaborative approach taken by many, and to name just some, we cite the primary care general practice teams, the community pharmacies, the health and social care

trusts, the Public Health Agency, the Health and Social Care Board, patient representative groups, and professional bodies and organisations.

The Department worked tirelessly to develop highly productive and effective relationships with a wide range of stakeholders. We include trade unions, care home providers, schools, local government, sports bodies, businesses, et cetera.

It's important also, in acknowledging those local sectors, to emphasise the significant collaboration and co-ordination across the United Kingdom in the rollout of Northern Ireland's programme at all levels, which included, of course, the collective efforts of the four senior responsible officers and their teams.

This approach, my Lady, of joint working facilitated, in our opinion, a solution-based approach to the many inherent challenges that arose.

Joint working permitted the Department to offer access to routine health and social care treatment and support services, as well as other public services, whilst at the same time rolling out an entirely new vaccination programme.

This was possible notwithstanding the challenges inherent in the new protocols and procedures, and the significant logistical challenges which were occasioned

by that vaccination programme.

Those same challenges arose again when the new Covid-19 drug treatments were identified in clinical trials. The Department reacted to the imperative to rapidly translate the findings of those trials into clinical guidelines, protocols, and access pathways, for those who were most likely to benefit.

The Department reacted quickly to adapt and change the guidelines as new data and information became available.

The reflection, my Lady, in all of this is that while there were no easy or straightforward answers or solutions to many of the challenges, the collective endeavour of all ensured that, through research, innovation and operational logistics, the delivery came together in what was an unprecedented national and Northern Irish effort.

The Covid-19 vaccination programme was the largest and most challenging vaccination programme in the history of the Northern Ireland Health Service. The first Covid-19 vaccine was administered in Northern Ireland on 8 December 2020 and within one year, almost 3 million doses had been administered.

That figure has now arisen to over 5 million doses as we continue to follow the advice of the JCVI, and

offer the vaccine to those who are currently considered by it to be most at risk.

The vaccination delivery model in Northern Ireland was designed to be flexible. GPs administered the majority of vaccines with community pharmacy teams and HSE trusts playing extremely important roles in making the vaccine readily available throughout Northern Ireland.

Mass vaccination centres came into operation at an unprecedented speed, and health and social care staff adapted quickly to change and reorganise at pace to deliver that programme.

This programme saw leisure centres and other facilities converted to mass vaccination centres, which administered more than 1.5 million doses between them. Together with GP and community pharmacy teams, these centres helped to protect and save the lives of many people in Northern Ireland.

My Lady, deployment of novel vaccines was complicated by the unique challenges posed by the physical characteristics of the vaccine products, including storage at ultra-low temperatures and restrictions on transport and handling. In the early days of the programme, the Department worked collaboratively with the medicines regulator, the

Medicines and Healthcare products Regulatory Agency, to ensure practical solutions were devised to enable the programme to be rolled out whilst at the same time complying with medicine regulatory requirements, and the relevant summary of product characteristics, as approved by the relevant medicine regulatory bodies.

Additionally, the Department ensured the programme continued uninterrupted by working closely with the Vaccine Taskforce, the UK Health and Security Agency, and the MHRA, to identify and address any potential issues which may have arisen from regulatory divergence between Northern Ireland and Great Britain, due to the introduction of the Northern Ireland protocol on 1 January 2021, which was -- we were concerned, could have potentially impacted our vaccine rollout.

The Department has discussed how Northern Ireland was unique amongst the UK countries in that it is the only part of the United Kingdom with a land border with an EU country, namely Ireland. As a result, there were several issues that Northern Ireland had to address that other UK nations did not. The vaccination programme in Northern Ireland, for example, was launched several weeks before a similar vaccination programme began in Ireland whose initial rollout was slower due to vaccine availability constraints.

My Lady, with regard to new therapeutics and the repurposing of existing medications, much detail has been provided on the role played by the Department in these developments. This includes the Department's role in the deployment of Covid-19 therapeutics to vulnerable groups, including those deemed clinically extremely vulnerable. The Department has fully supported the role of the MHRA in post-approval monitoring and surveillance of Covid-19 therapeutics, including for side effects and changes in effectiveness due to the evolution of new variants, and has encouraged professionals and the public to report any suspected adverse effects to the MHRA by way of the Yellow Card Scheme.

To conclude, my Lady, of course this opening statement can only allude to the level of detail that has already been provided to your Inquiry, in preparation for this hearing. We have provided numerous documents and witness statements which have been lodged by several key professionals.

We hope, my Lady, that the evidence submitted by the Department illustrates the work involved to implement the Covid vaccine programme in Northern Ireland. The Department recognises, of course, that the Inquiry is uniquely placed to identify learnings and recommendations that should help shape future responses.

It is for these reasons that the Department places the utmost importance on this Inquiry. As such, the Department reiterates its firm commitment to the Inquiry and stands ready to assist in any way that it can. Given, of course, the potential for another pandemic, it is essential, in our view, that lessons are identified and fully learned across health and social care, and in all parts of government, both in Northern Ireland and the United Kingdom.

Thank you very much, my Lady.

LADY HALLETT: Thank you very much, Ms Murnaghan, very grateful.

Mr Stanton.

Submissions on behalf of the British Medical Association by MR STANTON

MR STANTON: Thank you, my Lady.

The opening statements of the British Medical Association is as follows. The BMA views the Covid-19 vaccination programme as one of the biggest successes of the pandemic response, in large part due to the immense efforts of doctors, particularly GPs, and their practice teams, the wider healthcare workforce, and volunteers.

The unprecedented scale of the vaccination programme saved millions of lives globally.

A study by the World Health Organisation of

54 countries in the European region found that those countries that implemented vaccination programmes early, such as the UK, saw the greatest benefit in terms of numbers of lives saved overall through vaccination.

And the authors of this report estimate that Covid-19 vaccinations in the UK reduced mortality by approximately 70% in adults aged 25 and over, which is among the best outcomes across the European region.

Vaccination also changed the context of the pandemic, and allowed governments to move towards reopening society as Covid-19 became less of a risk for most of the population.

The PMA proactively made the case in England that the Covid-19 Vaccination Programme should be delivered by GP practices, given their expertise in delivering vaccinations, such as the annual flu vaccination programme, their proximity to local populations, and their ability to respond to any concerns regarding vaccination.

By the end of October 2021, 71% of vaccines in England had been administered by GPs and their teams, and community pharmacies, compared with 21% by vaccination centres and the remaining 8% in hospitals or other settings.

And this significant contribution, which is well in

excess of planning assumptions, was made alongside the delivery of other Covid and non-Covid care.

GPs also made significant contributions in the devolved nations. As of spring 2024, 47% of vaccines in Northern Ireland had been delivered by GP practices. In Wales, where health boards were responsible for the delivery of the vaccination programme, there were nevertheless some 51 GP practices involved in the delivery of vaccinations by July 2021.

And in Scotland, where over two-thirds of all vaccine doses were delivered using either mass or community vaccination centres, general practice administered the second largest proportion of doses, at approximately 13%.

GPs were also involved in efforts to increase vaccine uptake amongst their patients, and many GPs personally contacted individual patients from at-risk groups to encourage uptake.

However, despite its success, the vaccination rollout was not without its challenges. The pre-pandemic understaffing of health services as well as the pressures of the pandemic and insufficient consideration given to workforce planning meant that GPs and their teams were required to work even longer hours, while already overstretched, to deliver the vaccination

programme and maintain non-Covid and Covid care in parallel.

These pressures resulted in medical professionals reporting stress, burnout and fatigue, for example a GP from Northern Ireland who reported:

"We have been stretched so thin covering COVID centres and also delivering vaccine programmes, this has had a huge impact on our staff."

Issues with the vaccine supply chain also presented a challenge for vaccination delivery. Calls for improvement to the vaccine supply chain were made at various stages of the programme, and the BMA raised concerns that the approach to delivery and availability of vaccines had created uncertainty amongst GPs and healthcare teams regarding what they were able to provide to their communities and when.

Regarding prioritisation, the BMA's position was that those most at risk of illness or death from a Covid-19 infection, together with frontline healthcare workers, should be prioritised for vaccination.

Frontline health and social care workers had a far greater risk of exposure to infection due to their work caring directly and intimately for patients with Covid-19, and it was imperative that doctors and other frontline staff be protected so they could continue to

provide these services, particularly in the face of a severe workforce shortage.

However, there were differing experiences across the medical profession during the rollout, and groups that reported particular difficulties in accessing vaccination included resident doctors, GP locums, and doctors working in private practice.

There were also indications of vaccine hesitancy amongst some healthcare staff, and in July 2021, research published by UK reach found that healthcare workers were more likely to be vaccine hesitant if they were younger, female, pregnant, or had already experienced an infection.

The research also found that healthcare workers from ethnic minority backgrounds were more likely to be vaccine hesitant than their white British colleagues.

The BMA strongly urged doctors and frontline healthcare workers to be vaccinated, and uptake was high amongst doctors. For example, results from a February 2021 BMA survey found that, at the time, 93% of respondents had received the first dose of the vaccine.

However, the BMA voiced concerns about the policy put in place in England that made vaccination a condition of deployment among staff in older adult

care homes, and the proposed expansion of this policy to the wider health and social care sector. Not least because it led to the loss of significant numbers of care home sector staff and exacerbated the existing workforce crisis.

The BMA's view was that vaccination should be voluntary, based on the principle of informed consent, being respectful of individual rights and liberties, and that any move away from the existing voluntary model would need to be properly justified and proportionate.

The BMA's priority was to support doctors and other healthcare workers getting vaccinated whilst listening to and addressing any concerns that staff may have, emphasising that vaccinations are safe and effective in protecting against the disease.

In the general population, while the overall uptake of the vaccine programme was also high, the BMA expressed concern that progress was not equal across the UK and that an overall high rate of vaccination masked significant disparities in uptake, particularly along the lines of deprivation and ethnicity.

Lower rates of Covid-19 vaccine uptake amongst some people from ethnic minority backgrounds was seen across the UK, and throughout the different stages of the vaccination programme, again with vaccine uptake highest

amongst those from a white ethnic background.

Disparities in vaccine uptake were also seen along deprivation lines. As referenced in the BMA's fifth Covid-19 review report, data from 2022 showed that across England Scotland and Wales, vaccine uptake was higher in areas of greater affluence and gradually decreased along deprivation lines.

Pregnant women were also another group which had needs that were not sufficiently met in relation to the vaccines. Changing government advice led to confusion amongst those who were pregnant about whether they should be taking the vaccine. This confusion should have been avoided as pregnant women were at higher risk of severe disease from Covid-19.

There were also concerns among people who were considering pregnancy fuelled by misinformation about the vaccine adversely impacting fertility.

The BMA believes more could have been done to identify the needs of vulnerable and minority groups ahead of the vaccine programme's delivery, particularly in light of the well known pre-existing health inequalities and knowledge that vaccine uptake was lower in marginalised and minority groups, not least because of a history of struggle racism.

This significant disparity in uptake cannot be

ignored and the barriers to vaccination must be addressed if the UK is to be prepared for any future pandemic.

In the BMA's view there were several key barriers to uptake of the Covid-19 vaccine. First, there were physical barriers to accessing vaccination sites, such as difficulties reaching the sites, for example some vaccination centres were a considerable distance from people's homes or workplaces and could not be accessed via public transport routes.

The cost of transport, as well as having to take time out of work to travel, were also issues, especially for those on lower incomes.

Accessing the vaccine was also challenging for those who were unable to leave home easily, such as elderly or disabled people, and for those who were clinically vulnerable, many of whom had an understandable fear of leaving home and catching Covid-19.

Second, not having an NHS number became a barrier to vaccine uptake for many people in the homeless population as well as for vulnerable migrants. And despite there being no need for a fixed address to access the vaccine, there were reports that some people still faced this barrier.

Third, communication barriers for people who could

not understand or access all the relevant information about having the vaccine, for example in a linguistically or cultural only appropriate way.

Fourth, a significant cultural barrier amongst some ethnic minority communities was a lack of trust in health services and, by extension, the vaccine. People from ethnic minority and deprived communities also had worse health outcomes before the pandemic, and with this in mind, and as already mentioned, there should have been greater consideration of these groups when planning the vaccine rollout.

Fifth, misinformation about Covid-19 vaccinations and anti-vaccination messaging in the press and on social media also likely added to vaccine hesitancy and the BMA called on the UK government to take more action to tackle this information online.

Finally, a discrete issue that the BMA wishes to raise within this opening statement is to rebut the criticism that it sought to take commercial advantage of the vaccination scheme. This offensive and unfounded criticism is based on a mistaken view that GPs had sufficient spare capacity within their existing workloads to deliver the largest and most complex vaccination programme in the country's history, right in the middle of a national health crisis. The reality was

that the vaccination programme was additional work that general practice, already stretched to breaking point, delivered in the national interest, but which necessitated existing staff working significant numbers of additional hours and the engagement of additional staff, all of which needed to be paid for.

Despite these challenges, vaccinations administered by GPs were delivered at significantly lower cost than the planning assumptions made and at significantly better value than at vaccination centres.

The strain placed on general practice at this time was made clear by the BMA in a letter to government in September 2021, stating:

[As read] "... there are simply too few GPs and practice staff in under resourced premises to meet the huge surge in demand that practices are currently experiencing, which will be exacerbated by the Covid vaccination booster programme ... It will be GPs and their practice teams who will be leading this additional work and, given the magnitude of delivering millions of vaccines over the coming months, together with the increased patient demand during winter, it is vital that the public are made fully aware of just how much strain practices are under."

My Lady, in conclusion, and as outlined in this

statement, while the vaccine rollout was an undoubted success, it was not without the need for improvement.

The BMA invites the Inquiry to consider the inefficiencies within the supply and delivery of vaccines around the country, to reflect the strain that the vaccination programme placed on general practice and the healthcare workforce, to acknowledge the detrimental impact on the workforce of vaccination as a condition of deployment, and to make recommendations that address the disparities in vaccine uptake and access to healthcare more broadly, which the BMA says requires urgent improvement by governments across the UK.

Thank you, my Lady.

LADY HALLETT: Thank you very much, Mr Stanton.

Mr Dixey, I think you have difficulties tomorrow; is that right?

MR DIXEY: Yes.

LADY HALLETT: Ms Domingo, can you be back tomorrow?

MS DOMINGO: Yes, that's no problem.

LADY HALLETT: That's no problem for you?

MS DOMINGO: Yes, I can be here tomorrow.

LADY HALLETT: That's really kind of you, thank you, because I think for the stenographer it's been quite a long afternoon and a long day for many people.

So if it suits you, Mr Dixey, as it obviously does,

we'll take you next.

Submissions on behalf of Medicines and Healthcare products Regulatory Agency by MR DIXEY

MR DIXEY: My Lady, I make this opening statement on behalf of the Medicines and Healthcare products Regulatory Agency.

The MHRA welcomes the opportunity to take part in Module 4 of the Covid-19 Inquiry to ensure that its role and actions are fully understood and to play its part in supporting the Inquiry to make findings and recommendations which will ensure that the United Kingdom and global community are better prepared for future pandemics.

At the outset of these submissions the MHRA wishes to publicly record its condolences and sympathies to all those who were affecting by the Covid-19 pandemic.

In particular, and in the immediate context of Module 4 of this Inquiry, the MHRA wishes to publicly acknowledge its profound regret that anyone should have suffered adverse effects in association with receiving a Covid-19 vaccine or therapeutic.

The MHRA recognises the serious suffering faced by those who now live with long-term injuries and by their families. No vaccine or medicine is without risk, and the MHRA is committed to finding out as much as possible

about those risks, and to ensuring that no effort will be spared to further strengthen its systems to identify and to act to minimise risks, however rare they may be.

It is, however, important to acknowledge the many deaths which were prevented as a result of the Covid-19 Vaccination Programme. It has been estimated from 1 January to 8 December 2021 Covid-19 vaccines prevented between 14.4 million and 19.8 million deaths from Covid-19 in 185 countries and territories, and by September 2021 it was estimated that the UK vaccination programme had prevented over 20 million infections and over 100,000 deaths.

The Inquiry will also have in mind the extraordinary context in which unprecedented decisions and actions were taken. The authorisation and subsequent rapid and wide-scale deployment of Covid-19 vaccines prevented the loss of many thousands of lives, and allowed the UK and the global community to return to some degree of normalcy much quicker.

My Lady, as you've heard, the MHRA is the UK's regulator for medicines, including vaccines and therapeutics, medical devices, and blood components for transfusion. The MHRA is responsible for ensuring their safety, quality, and efficacy.

Its mission is to enhance and improve the health of

millions of people in the UK every day, through the effective regulation of medicines and medical devices, underpinned by science and research.

The Inquiry will hear from the MHRA's chief executive Dame June Raine, who has provided a detailed witness statement.

In summary, and by reference to the provisional list of issues in Module 4, the MHRA was involved in the development of Covid-19 vaccines, including through the authorisation of clinical trials, the authorisation of such vaccines, post-marketing surveillance of those vaccines, and communication of the results of that surveillance to clinicians, the public, and others, and to the development, clinical trials, and authorisations of therapeutics.

The MHRA is not responsible for procurement or deployment decisions. In respect of the latter, decisions on which vaccines and medicines were deployed and who might receive those vaccines and medicines, those decisions were taken by the Joint Committee on Vaccination and Immunisation, or the devolved health authorities.

The pandemic was a profoundly challenging time for everyone, including for those public servants who were at the forefront of the national response effort,

traditional ways of working were adapted, including by the MHRA. As is well known, the Pfizer BioNTech vaccine was the first vaccine for Covid-19 that was authorised for use by the MHRA, and was the first vaccine against Covid-19 authorised worldwide.

In subsequent weeks, regulators in other jurisdictions followed suit with no significant differences in terms of their approvals. It was administered in the UK on the morning of 8 December 2020, a pivotal moment.

As of December 2023, the MHRA had authorised nine vaccines for use against Covid-19 with a further four strain-adapted vaccines. Six new medicines were authorised for Covid-19 with two previously authorised therapeutics approved by the MHRA to treat Covid-19.

The MHRA adopted a number of regulatory flexibilities that were crucial in facilitating these approvals, and this included the rolling reviews of data, as and when they became available.

None of these flexibilities compromised the rigour of scientific scrutiny of the evidence of safety, quality, and efficacy. The MHRA's scientific standards remained unchanged and were in line with international equivalents.

An understandable focus of much of the evidence in

Module 4 will be on the safety of Covid-19 medicinal products. The MHRA's first priority is safety, with a core focus at all times on the balance of benefits and risks of a medicinal product or vaccine. As already stated by others, no medical product is completely risk free. All have the potential to cause side effects. This module will examine the benefit risk decision making by the agency, in particular through clinical trials and the data which was obtained.

Medicinal products are authorised by the MHRA with a requirement that manufacturers operate a robust post-authorisation surveillance system, through which the benefit/risk balance can be revised, as real-world data becomes available and as clinical usage expands.

A feature of the post-marketing surveillance is the Yellow Card Scheme to which others have referred. The Inquiry will hear evidence about the Yellow Card Scheme and the understanding of the adverse reaction associated with particular vaccines. The Inquiry will consider in particular how the MHRA detected, evaluated, and responded to the risk of thrombosis with thrombocytopenia syndrome associated with the AstraZeneca vaccine and the risk of myocarditis and pericarditis associated in particular with mRNA vaccines.

My Lady, the MHRA seeks to be an organisation which learns and improves through that learning. It recognises the importance of external scrutiny, especially in the context of vaccination, where misunderstanding, misinformation, or disinformation are prevalent.

It seeks to act transparently and, for example, during the pandemic, published vaccine safety updates and information to keep the public and healthcare professionals informed.

Little could be more corrosive to public confidence in vaccines and other medicinal products as secrecy or obfuscation. The MHRA comes to this Inquiry with a willingness to assist in establishing the facts, and to enable lessons to be learnt, so that it can continue to strengthen its systems and processes, particularly in the likely event of a future pandemic.

My Lady, those are our opening submissions.

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

Very well. I think that is probably sufficient for today.

Sorry about that, Ms Domingo, you'll be on first thing tomorrow, I promise.

In which case that will be Ms Domingo at 10.00 tomorrow.

MR KEITH: Thank you, my Lady.

(4.39 pm)

(The hearing adjourned until 10.00 am the following day)

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