Friday, 31 January 2025

(10.00 am)

LADY HALLETT: Mr Wagner.

Closing statement on behalf of Clinically Vulnerable Families by MR WAGNER

MR WAGNER: Good morning, my Lady. I appear for Clinically Vulnerable Families, together with Hayley Douglas and Lameesa Iqbal. I am instructed by Kim Harrison and Shane Smith of Slater and Gordon.

I am going to use my time today to focus on five key points, which have an overarching theme which I'll come to at the end.

First, the therapeutics programme was the poor relation to the vaccine programme, and that wasn't good enough.

One of our main submissions in opening was that the vaccines were prioritised over therapeutics. Perhaps the better way of putting it, now that we've heard the oral evidence in this module, is that the vaccination programme was given the highest possible priority, independence and funding. And whilst the programme had its flaws, it could be said that Dame Kate Bingham, Clive Dix and others demonstrated the gold standard of independence and impact.

But the contrast with the therapeutics programme was

stark. Although there were some successes, there was none of the world-beating vim and vigour of the vaccines programme. The therapeutics programme slower, it was more bureaucratic, and it was more limited in its results. And that meant that the people who could not benefit from the vaccine programme, notably the immunosuppressed, were left behind. And this is the very same group who were among the highest risk of Covid-19.

And we say that is a failure.

An important question for this module is why, and what could have been done differently, if things had been done better?

Dame Kate Bingham is an independent and trusted voice. She has no reason to defend decisions on therapeutics that were not the right ones, and she is also well placed, as well placed as any witness, to identify what a successful programme would have looked like. She said she absolutely felt that the issue of prophylactic development was left behind. She said, "The government was following a very clear two-tiered strategy, where the clinically vulnerable, immunocompromised patients were being deprioritised in favour of those who were able to receive vaccines."

She said she felt that was manifestly wrong, both

ethically and morally, but also, it simply did not follow the goals that we'd been set, which was to protect the entire population.

She said there was zero appetite in the Department of Health to actually consider how those patients would be treated, and that it was cheaper to let those clinically vulnerable individuals, who were already shielding, to stay shielding at home, and then if they were to be infected they would be treated with drugs.

A two-tier strategy, cheaper to leave them shielding at home without an exit plan. CVF says this is a damning analysis.

Clive Dix agreed. He said that the Vaccine Taskforce had a very entrepreneurial way of going about things and very much getting things done, but on therapeutics, there was less enthusiasm, particularly for the procurement of antivirals, even though those are aimed at the most vulnerable, high-risk groups.

The chair of the Antivirals Taskforce, Eddie Gray, spoke of his frustration with the process for getting funding approved for oral antivirals identified by the taskforce, both in terms of the time it took, and the fact that the volume approved was significantly less than he had recommended.

Sir Sajid Javid gave similar evidence. He says by

the time he came to the Department in June 2021, finding a vaccine that worked had been successful, the focus then was more shifted on vaccines, and getting them delivered, because they were broadly working. And he felt there was less focus on, including from the Treasury, having something other than vaccines.

He also gave evidence of the difference in funding propositions in vaccines which he described as having an almost unlimited budget, and antivirals, which had no overarching budget at all. And so he had to get specific approval from the Treasury for the procurement of antivirals, only to have the clinical case for antivirals questioned by Treasury officials.

Of course, there were therapeutic success stories, but -- and the Antivirals Taskforce ultimately succeeded in procuring two oral antivirals, but CVF is concerned that this masks the true picture for clinically vulnerable and immunosuppressed people.

In her evidence, the founder of CVF, Lara Wong, reminded us that some of the therapeutics procured are not suitable for many clinically vulnerable people, notably Paxlovid, which cannot be taken along with the kinds of medications that immunocompromised people commonly take.

Sir Munir Pirmohamed agreed in his oral evidence

that one of the learning points is that it's important to develop a diverse portfolio of vaccines and antivirals so that vulnerable people can take them.

The grim reality is that to this day, no prophylactic treatment for Covid-19, that is one that can be taken in advance of symptoms, has been procured by the government. And there are huge problems in accessing those life-saving antivirals in practice.

We say that if the same creativity, independence, and appetite for risk had been applied to therapeutics, as was applied to vaccines, things might have been different.

Sir Chris Whitty said that antivirals is an area where we are much weaker than we are on both vaccines and antibodies and other antiparasitics. We should be asking why.

It might be said that this was something of a dismissive view, particularly when he said that there would have been some niche benefits to the procurement of Evusheld, and I'll come to that.

My second point is that the system for accessing therapeutics did not work properly, and still doesn't. Despite its importance, the Covid-19 antiviral pathway was, and remains to this day, fraught with access issues and barriers, which have prevented many vulnerable

people from receiving the treatment they need.

It's significantly more restrictive when compared to other medications like influenza antivirals, which can simply be prescribed by a GP.

Lord Bethell gave memorable evidence about the need for swift delivery of antivirals. He said you need to get them very, very quickly, for instance on a motorbike. The moment people test positive, you need to test and treat, because the medication can't get in early enough.

And he reflected that: within the NHS we could have been more creative about Test, Trace and Treat. And we agree.

We can now order takeaway food and practically anything else on our phones, and it's delivered 20 minutes later. Why can't the clinically vulnerable report Covid after a positive lateral flow test and have antivirals delivered to their door 20 minutes later?

CVF members report that getting therapeutics is a bit like the Goldilocks story. The triaging system decides that you're either too ill, you're too far gone, or not ill enough.

And it shouldn't take another pandemic to come up with some creative solutions. A simple point might be simply pre-flagging clinically vulnerable people who

will be given early access and easy access to therapeutics when they need them, rather than having to go through all these bureaucratic hoops every time, and they can then be delivered those therapeutics using nothing more advanced than the technology which allows millions of people to get a curry delivered to them in 20 minutes.

Going forward, considering recommendations, CVF is concerned that people deemed high risk by NICE a year ago after the PANORAMIC trial still can't access treatments because of an 18-month funding variation. These are the kinds of issues which arose during the pandemic and they continue to this day.

A third point. Vaccination was a huge success, but there were gaps which the clinically vulnerable sometimes fell through. Many CVF members, particularly the clinically vulnerable, reported confusion around their eligibility for priority vaccination.

Chris Whitty and Emily Lawson candidly acknowledged, as they did in Module 3, that there were very significant problems of combining data from different systems, particularly within the first few months of the pandemic. And it's no surprise that by the time it got to offering the vaccination in December 2020, that some of those problems remained.

CVF remains concerned that the ever-changing eligibility for vaccine boosters caused significant confusion amongst clinically vulnerable people whom the boosters were intended to protect, and also within the health services providing those vital doses.

Clinically vulnerable people who are not immunosuppressed will be prevent from accessing the vaccines from the autumn of this year and this will remove protection for millions of people who remain vulnerable to Covid-19.

Another concern for clinically vulnerable people is the safety of vaccination centres. Put simply, too many people, too little ventilation. There were good examples, such as drive-in centres, but generally there were problems. And Dr Ben Kasstan-Dabush gave straightforward evidence of how this might be dealt with in the next pandemic: by planning, by doing what wasn't done in this pandemic, which is pre-planning to protect the clinically vulnerable.

And we agree with that.

Fourth point. Vaccination of children was a missed opportunity to protect the clinically vulnerable, both clinically vulnerable children and clinically vulnerable households. Lara Wong explained in her evidence:

"The risk to children impacts on clinically

vulnerable households, but there are also clinically vulnerable children who are very often we did not hear about. There was a suggestion in the media that clinically vulnerable children did not exist, to an extent, or that children were not at risk, and there were children who were at risk and there were children who died, and it's really important to understand that."

We say that there was a delay in the decision-making around children, and that was combined when children were offered the vaccination with a sort of half-offer; "You can come and get the vaccine, but don't worry too much about it", in effect. And we say that that led to lower uptake amongst children, and there should have been more consideration of the indirect effect that the vaccination of clinically vulnerable children would have on the households they were in.

Fifth and final point: Evusheld was an important missed opportunity for a very vulnerable group: the immunosuppressed.

CVF does not agree with the evidence of Sir Chris Whitty and Jonathan Van-Tam who suggested that Evusheld became less important once the vaccine started to work. Simply put, the vaccine doesn't work for immunocompromised people. And we say there's an element of motivated reasoning, looking back, to say: well, it

wouldn't have worked anyway, so it turns out the decision we made was the correct one.

We say you should prefer the evidence of Dame Kate Bingham, who said the fact that the vaccine rollout had been effective doesn't stop people without an immune system getting infected.

Clive Dix said: "I actually felt most of those" -- as in, the reasons given by the decision makers -- "are excuses, and the actual reason that it wasn't purchased was cost."

Chris Whitty said: "If Evusheld had been available it would have had at least some niche use."

One of 38 people or 2.6% of the population is hardly niche.

In conclusion, my Lady, I have focused on five points this morning: the therapeutics programme was the poor relation of the vaccines programme; the system for accessing therapeutics did not work properly, still doesn't; the system for accessing therapeutics did not work properly and still doesn't; vaccination of children was a missed opportunity; and Evusheld was also a missed opportunity.

There is an overarching theme which connects this is five points: that the clinically vulnerable were often overlooked, their needs underappreciated, and their

voices not heard.

Lord Bethell said frankly that there was no plan for the immunocompromised at the beginning despite it being clear enough that they were going to be particularly gravely impacted by a virus that affected the immune system. And it was already known, it was already known at the beginning of this pandemic, that the likely vaccine candidate would be the one which relied on a person's immune system to fight back against Covid-19. And so which would not work well for immunocompromised people.

But the lack of a plan was only part of a distressing picture; for some clinically vulnerable people, freedom day never came. How can we ensure clinically vulnerable people's needs are not overlooked again? We'll set out our proposed recommendations in our written submissions, but our umbrella point is that clinically vulnerable people need to be identified as a particular group or protected characteristic under the Equality Act. And this would go some way towards embedding their protection in law, and in decision-making, and reduce the risk of them being relegated to the second tier of a two-tier strategic again.

CVF is grateful, my Lady, for your care and

attendance throughout this important Module.

Thank you.

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

Ms Morris.

Closing statement on behalf of UK CV Family, Scottish Vaccine Injury Group and Vaccine Injured and Bereaved UK by MS MORRIS KC

MS MORRIS: Thank you, my Lady. I, alongside Mr Weaver and Mr Bradley, instructed by Mr Terry Wilcox of Hudgell Solicitors, represent three core participant groups: VIB UK, UK CV Family and Scottish Vaccine Injured Groups.

My Lady, can I say at the outset that the bereaved appreciate being Core Participants in this important Module. This Inquiry has provided an important space for the voices of the vaccine injured and bereaved to be heard away from the distortion and the noise of the baseless vaccine conspiracy theories.

In their oral and written evidence, Ruth O'Rafferty, Kate Scott and Charlet Crichton have provided you with multiple individual examples of the experiences which speaks to the breadth and depth of the vaccine injured and the effects of the Covid-19 vaccines. They're not statistics; they're real people.

By being engaged and visible in this public Inquiry, our groups have been able to raise awareness and there

are now more people who have contacted them, who are now no longer suffering alone.

We'd also like to give the group's formal thanks to Hestia, who have provided incredible and ongoing support, both to members attending court and those watching the hearings remotely.

The Inquiry has received hundreds of pages of witness statements from the groups, and we trust the Inquiry will read them carefully. Please remember that those statements were pulled together by real people, injured people, who are the experts in their own experiences and their own conditions.

Those I represent have appreciated being asked some questions of witnesses in this module, but the Inquiry hasn't addressed all of their questions. And we hold the Inquiry to their undertaking that they will read every page of the written statements and seek to answer all of our questions in the evidence of the Inquiry -- or the Inquiry's reports.

The vaccine injured and bereaved are the best resource, and should be involved with the Inquiry and government in developing any recommendations that flow from this Inquiry. This must be the beginning of an honest and transparent dialogue with those who have suffered the adverse effects of the vaccines.

And significantly, my Lady, this Inquiry is the first time that those I represent have been looked in the eye and been told by the UK, Scottish, Welsh and Northern Irish governments that they acknowledge that there were those who were injured or killed by the Covid-19 vaccines.

Before I move on, I must address some of the military language that's been used by witnesses and advocates in this module. We are repeatedly being told that we are now in peacetime. If there was a war, it was a war against the Covid-19 virus, and vaccines were heralded as the world's most effective weapons against that virus and they were deployed in that conflict.

Scientists and public health officials have repeatedly acknowledged, in evidence, that no vaccine, and, in fact, no medicine, is without risk. And that for these novel vaccines, there were likely to be adverse effects that were not identified by clinical trials, but that would likely occur when the vaccines were rolled out to millions of people. Despite this, no one within government or public health planned for how to treat any casualties of the war on the Covid-19 virus.

Each of us who was vaccinated with these novel vaccines was a soldier in that war. Some of us were

also vaccinators, doctors, and pharmacists.

The key difference is that if soldiers die or are injured in active service, their loss and their contribution to the struggle is acknowledged. Their service is recognised in the context of the furtherance of the national interest. There is wide recognition that the loss of every life is a tragedy and that must also happen here.

In the impact film, my Lady, you heard about a pharmacist who didn't want to speak about his injury for fear of discouraging others from taking it. He identified himself as being "collateral damage".

This Inquiry must understand that mass vaccination schemes are a form of social contract. Individuals who get vaccinated put themselves at a risk, however rare, of injury following vaccination, for the wider benefit of our communities.

In order for that contract to be fulfilled, this risk needs to be acknowledged and affected individuals must receive address if it materialises.

Restoring that social contract now is not only the just and right thing to do but it also restores trust, which as we've heard, plays a key role in reducing vaccine hesitancy.

Moving forward, the key issue that we ask the

Inquiry to address in its report in its simplest terms is: where was the safety net for those who suffered adverse effects from the Covid-19 vaccines?

The Inquiry heard from Dame Bingham and Lord Sharma that the government was quick to secure a safety net for the pharmaceutical companies indemnifying them against the risk of litigation arising from adverse effects amounting to billions of pounds, but what was the safety net for members of the public who were exposed to that risk and those who suffer those adverse effects?

This question has three parts. What were the communications on risk that would allow people to make an informed choice about the vaccine? What were the ways in which those that were injured or bereaved report their injuries in order to receive support and care? And what was the care and financial support available to them, once they'd made that report?

Dealing first with the topic of communications and public messaging on risk and how they can be improved, in our submission, during the pandemic, speed and simplicity were prioritised over transparency. The government's central messaging promoted vaccine confidence but delayed updates on risks, leading to preventable deaths due to vaccine injury.

Communicating vaccine safety must go beyond

reassurance: it must empower individuals to accept the vaccine with informed consent and enable them to quickly report adverse events, confident they'll be able to access care and redress. So we urge the Inquiry to recommend the development of an authoritative, dynamic information source on efficacy, risks, and adverse effect reporting, improved patient information access beyond printed leaflets, including multilingual and accessible formats, including audio and Easy Read versions for those with additional needs and, specifically, we ask the Inquiry to look at a module like the WHO COVAX scheme whose communications integrate benefits, risks, and reporting mechanisms.

Next topic. How do you reform vaccine safety reporting systems to detect all relevant safety signals? Rare and severe reactions may have been difficult to detect in trials. You've heard that the MHRA treat approval as a milestone, not an endpoint. Yet in our submission, post-rollout safety reporting mechanisms were inadequate.

The Yellow Card system was poorly known about, even amongst healthcare workers, and in 2021, in the midst of the pandemic and six months into the vaccine programme rollout, not even the Health Secretary, Sir Sajid Javid, knew about it.

Our groups report the Yellow Card reports were often ignored, forcing individuals to chase responses. Barriers also included it not being sufficiently available in multiple languages or in accessible formats and by the reluctance of doctors to acknowledge vaccine-related conditions.

In addition, a lack of pairing of information about efficacy and risk, as I've outlined above, was a missed opportunity to incentivise and support the public to make reports.

We therefore urge the Inquiry to recommend there should be what Professor Evans called in his written report a high suspicion index when it comes to reporting suspected injuries. This is clearly a scientific approach and a vital approach during an unprecedented rollout, at speed, of three novel vaccines.

Dr Richardson told the Inquiry that the Yellow Card only works in peacetime and needs more active surveillance during a pandemic.

We say that alongside the pairing of nuanced public information with safety reporting information, public health workers must be trained and primed to identify adverse effects and safety signals. Dr Richardson supported earlier safety signals to clinicians which would assist them in identifying adverse events and

emerging patterns earlier.

But you can improve data and improve self-reporting, but you still need a culture in which those reports are recorded as signals and not stigmatised.

Professor Evans says that medical notes should be the main source of information for reports of adverse effects, but they're only as good as the information that's recorded within them. Doctors are the gatekeepers and the information and training they have impacts on their ability to effectively identify vaccine injury. Those professionals also need to be able to feel able to report injuries without consequences to them.

Next, a few important words on specialist care pathways. Of those witnesses who have given evidence to this Inquiry, only two have said anything about the care and treatment of the vaccine injured and bereaved. May I remind you of Professor Evans' words. He said: "As a community, we have to acknowledge that it does happen, in extremely rare cases, and that such people need to be looked after properly and their relatives and those who are bereaved need proper treatment."

We say this must extend not just to those who have had the connection between their condition and the vaccines confirmed, but include support for those who

continue to struggle to have their conditions recognised as vaccine related and to access support. For all I'm about to say about the VDPS, there are still many people who continue to feel that they are shut out of any form of treatment or redress.

Dr Richardson eloquently made the case that vaccine injuries should be treated like highly contagious infectious diseases. The key to that recommendation is that a patient classified as having an HSID, are then referred to specialist treatment centres.

She also highlighted that another benefit of pooling expertise in centres of clinical expertise is the rapid identification and treatment of anything that could be an adverse effect which will in turn help clinicians to learn more about treatment and management of those injuries.

In short, my Lady, if you want to incentivise people to report, there has to be a benefit to the reporter. If people think they're going to receive care and support, they are more likely to report.

We urge the Inquiry to recommend the development of centres of clinical expertise for the treatment and care of those injured by the Covid-19 vaccines, the development of specialist care pathways to provide specialist support for the wide range of physical and

neurological injuries that they are suffering from, the development of bespoke support pathways for the emotional and mental health of the vaccine injured and bereaved, in recognition of the continuing trauma they endure, which has been compounded by the years of dismissal and stigmatisation of their experiences.

My final topic, the Vaccine Damage Payment Scheme.

Sarah Moore and Kate Scott of VIB UK have told the Inquiry that the VDPS was currently too little, too late for too few. The Department of Health and Social Care appears to have accepted the moral case for changes to VDPS during the pandemic. The Inquiry has a memorandum provided by former Health Secretary Matt Hancock in 2020 that proposed the option of a bespoke scheme in reflection of the novelty, speed and size of the vaccine rollout.

In her evidence, Clara Swinson identified a second proposal made in 2022 under Mr Javid's tenure. He told the Inquiry that he himself had recommended a more generous financial award that should be made more quickly, but again his recommendation wasn't acted on.

So that is two Health Secretaries, and all those since, that have not acted on clear policy recommendations. In fact, nothing at all has changed in terms of the amounts payable, or the criteria that is

applied, the decision-making under the VDPS.

It has been pointed out repeatedly that the VDPS is not a compensation scheme. This is because it was always envisaged to be an interim and not a final payment scheme, and so an award could not preclude making any claims against the pharmaceutical companies.

However, as Sarah Moore told the Inquiry, the harsh reality is that a combination of barriers exist to litigation, that any medical confirmation of an injury, lack of funding for claims, the high cost risk, and the three-year limitation period have left many without viable recourse through the courts.

The effect of all of these barriers is that there remains no proper redress at all for the vaccine injured and bereaved.

This lack of redress has resulted in a breach of the social contract. The trust of the vaccine injured and bereaved has been broken. There is now powerful and cogent evidence before the Inquiry from victims, lawyers, senior public health officials and even former secretaries of state that the VDPS needs to be reformed urgently.

The status quo cannot be allowed to continue for another month, another year. My Lady, the vaccine injured and bereaved now to look to you to recommend

urgent redress and urgent reform.

The Inquiry will be aware of many other groups of bereaved and injured people who have had to wait 10, 20, 30, or even 50 years for redress, and only after a public inquiry has identified failings. Those I represent have already waited for over 4 years and they cannot wait any longer.

In his second interim report of the Infected Blood Inquiry, Sir Brian Langstaff recognised that the failure of politicians to resolve the issue of compensation to victims had led to significant personal psychosocial consequences on top of those caused immediately by their injuries. He said that he could not, in all conscience, contribute further to that harm in delaying what he had to say about compensation. That is why he took the unusual step of issuing his recommendation about compensation and redress in advance of all other recommendations.

So we now urge you, my Lady, to issue an interim report containing an urgent recommendation that consultation begins between the government and the Covid vaccine injured and bereaved to develop a bespoke scheme of redress and a separate programme of reform of the VDPS.

We ask you to include in your interim recommendation

that there is consideration of urgent interim payments to update awards for those who have already been awarded payments under the scheme, to uplift inflation, ensure that those who have already had a confirmed diagnosis of injury or bereavement should have a payment made without delay. We also ask you to recommend an urgent review of the VDPS, to recommend again, in full and transparent consultation with the vaccine injured and bereaved, a scheme is developed -- to quote from Dr Richardson -- which is "empathic understanding, accessible and timely".

We recommend that the VDPS removes the disability threshold and instead examines physical and mental injuries, both permanent and temporary, in a more flexible way. And we endorse the evidence of Sarah Moore on how the UK has plenty of other schemes to draw upon.

Now, those in academia, at the universities of Oxford, Essex and Durham, who have expertise that you and the government can draw upon to assist with recommendations, and we will address you further on this, my Lady, in our written submissions.

Nothing I have said here should detract away from the reform that I have already mentioned that is required to provide proper diagnosis, medical and

emotional support for those who still suffer after many years to even access redress schemes.

My final words then, my Lady, on how you repair trust.

Despite the promotion by all state Core Participants of the success of the vaccine programme, one of its uncomfortable legacies is a decrease in vaccine confidence since the pandemic. This Inquiry can take the first steps in repairing that trust by acknowledging the reality of the vaccine injured and bereaved in order to reduce stigmatisation and discrimination that still exists.

It can repair that trust by being clear about the scale and severity of their lived experience. Our health service can repair that trust by responding to those injuries with belief, care, and treatment. Our governments can repair that trust by providing a safety net to those who are impacted via urgent compensation and reform of the VDPS.

My Lady, this repair can't wait until the next pandemic hits. We must repair the trust of the vaccine injured and bereaved in peacetime to decrease vaccine hesitancy.

Each of the groups I represent will lose members through their physical or mental health conditions

before your full report on this module comes out. We now urge the Inquiry to act now to save lives. My Lady.

LADY HALLETT: Thank you very much indeed, Ms Morris.

Mr Friedman, have you had time to catch your breath or shall we go to -- I think I've got Ms Palmer on her feet.

MR FRIEDMAN: My Lady, I'm in your hands. I am sorry I was delayed.

LADY HALLETT: I think Ms Palmer was primed so we'll go to Ms Palmer.

MR FRIEDMAN: Thank you very much.

Closing statement on behalf of NHS England by MS PALMER

MS PALMER: Thank you, my Lady.

My Lady, I make these submissions on behalf of NHS England [inaudible -- microphone not switched on].

We are again grateful to the Inquiry for the (unclear) work done to facilitate these constructive and focused hearings [unclear as microphone is not on].

LADY HALLETT: I am not sure the microphone -- I can hear you because you are able to project your voice --

MS PALMER: My Lady, is that working now?

LADY HALLETT: That's it.

MS PALMER: Would you like me to start again from the beginning?

LADY HALLETT: Yes, you'd better.

MS PALMER: Thank you.

My Lady, I make these submissions on behalf of NHS England. We are, again, grateful to the Inquiry for the substantial work done to facilitate these constructive and focused hearings.

NHS England has listened to all the evidence and submissions. We would like to thank all of those who have come forward to share their personal experiences in this module. All of the perspectives shared translate beyond the next pandemic, and we are carefully considering the points raised.

Whilst it is right to acknowledge that the vaccine programme and the work done to trial and secure life-saving therapeutics and antivirals were a success, it is important to know why things went well, to inform your assessment of what lessons can be learned and recommendations made. It is this we seek to address orally.

In undertaking your task we ask that you keep in mind three things: first, to ask how well did the system do against reasonable expectations? In context: the ongoing pandemic, the pre-existing deep-rooted societal inequalities, the scale and complexity of the task, and the impacts upon the NHS and its staff, already stretched, who were being asked to do even more.

Second, what has already been learned? Therapeutics and vaccines are not only about a pandemic response; they were, and continue to be, an important part of public health, and are addressed in the current vaccination strategy.

Thirdly, on recommendations: to consider the wider health ecosystem and to ask whether recommendations on deployment can be operationalised.

My Lady has five additional detailed statements from NHS England: on vaccines, two corporate statements from Stephen Russell, national director for vaccines and screening; on therapeutics from Gareth Arthur, then director and SRO of antivirals deployment; and Professor James Palmer, national medical director for specialised services; and Dr Keith Ridge, the then Chief Pharmaceutical Officer, on both topics.

On vaccines, the problem posed to NHS England was the operational delivery of a mass vaccination programme like never before aimed at every adult in England, in the first instance.

NHS England, which, as my Lady knows, is not the same thing as the NHS in England, was responsible ultimately for the successful deployment of vaccines, including supply chains, operating procedures, security, governance, reporting and deployment of the workforce.

Planning required developing options for a novel and fragile vaccine, within the JCVI prioritisation criteria, to deliver on day 1, and then in scaling up when it was possible to do so.

The programme was led and developed centrally with clear and directive protocols meeting regulatory requirements, putting safety first, and ensuring systems were not rolled out before they were ready.

Security and limitations on supply rightly influenced early decisions. That model meant that on 8 December 2020, the first Covid vaccine outside a clinical trial was delivered in England at 6.31 am. From the authorisation of the Pfizer vaccine to this world first was six days.

By 15 December, 116 GP-led primary care sites delivered the vaccines. From 16 December a pilot in care homes, with vaccine delivery from the 20th. By Christmas, the national protocol was approved, enabling delivery to be planned for non-healthcare settings. On 9 January the new national booking system went live, built from scratch, complemented by a telephone service 119 for those who could not or did not want to use the digital system.

The first community pharmacy delivered a vaccine on 14 January, and smaller pharmacies could apply from

mid-February if they could deliver 400 doses where there were significant benefits to patient cohorts.

By 21 January, vaccinations started in novel places that worked for local communities. The first mosque, cathedral and cinema. Within 60 days, there were 1,650 sites nationwide, all hospitals, particularly to vaccinate staff, 90 vaccination centres, and 1,293 local vaccination centres.

By day 69, the target of offering a first dose to everyone in the top four priority groups was met, and 12.9 million first doses administered.

Additional capacity followed at speed, increasing convenience and seeking to address barriers. There are hundreds of examples of local NHS working with local authorities and voluntary organisations, of locally-led clinics stood up to meet the needs of local communities in areas with health inequalities, including using vaccines as a broader health intervention.

National help included securing £4.2 million of funding to be spent using local judgement and amplifying local trusted voices.

Communities with slower vaccine uptake saw significant increases over the programme, but it took effort and time. It was vital to do different things in different areas for different communities, and to allow

people to come forward when they were ready.

By the end of the relevant period, 125.6 million doses were delivered; an extraordinary achievement.

So why was it successful? In short, because it was simple, sought to maximise uptake nationwide, and had enormous political and public support. In addition, I highlight six points.

First, the NHS itself was critical to the process. NHS England built on and adapted existing NHS systems, at national, regional and local levels, using routine immunisation experience, and established ways of working. It built new systems when needed, brought in expertise, adapted and innovated, much of which has been retained today.

Second, because of the initial central co-ordination and leadership by NHS England and Dame Emily Lawson.

Third, teamwork was key. Local partnerships played an invaluable role identifying sites and tackling inequalities, with the RDCs acting as a two-way bridge to the centre. Specialist expertise, whether from the army or externally on the supply chain, frontline staff, clinicians, including pharmacists and volunteers, and many more.

A team of teams working together with a single purpose.

Fourth, it was agile, as demonstrated by the introduction of the 15-minute observation period in less than 24 hours, and the turning around of the system in days when the dosage interval was changed.

Fifth, data insights played a central role in improving and adapting the programme. Data was reviewed daily and shared with local systems to facilitate decision making. The vaccine equalities tool enabled an intersectional approach to data by age, deprivation and ethnicity, and it was instrumental in driving uptake and understanding where additional resources or local initiatives were required.

However, data was also challenging. NHS England acknowledges there were gaps and took steps to address this, to find workarounds. There was substantial engagement with clinicians and NHS England leveraged existing relationships to improve data, and used the data that it had.

Sixth, there was substantial innovation which has created a blueprint for future ways of working.

Turning to therapeutics. NHS England's role in therapeutics and their delivery is addressed in detail in the written statements. Some highlights, if I may.

NHS England was instrumental in the establishment of RAPID-C19 and contributed to its consideration of

evidence for therapeutics. It led on developing clinical policy, monitoring uptake, and assessing where stock was needed.

In the case of dexamethasone, RAPID-C19 was closely engaged with researchers running the RECOVERY trial and received early data enabling NHS England to prepare clinical policy in advance. The usual timeframe between a successful clinical trial and clinical change is measured in years. The result of this novel approach to therapeutic trial monitoring was that on the same day the RECOVERY clinical trial results were published, dexamethasone was able to be provided across the NHS. This was extraordinary innovation at speed, saving lives and reducing the numbers in intensive care.

Covid Medicines Delivery Units, or CMDUs, were another example of NHS England's operational focus and ability to leverage existing systems to develop innovative ways of responding to the pandemic.

NHS England worked with NHS Digital to identify those whose health records suggested they might qualify, proactively contacted those identified, and offered access to the relevant therapeutic. Notwithstanding the technical data and logistical obstacles presented, over 110,000 treatments were provided through CMDUs to patients from the highest risk cohorts by June 2023.

Significant work was undertaken to improve data, to facilitate access to more patients, and reduce health inequality, although we acknowledge there is more to be done.

Dame Bingham rightly noted the life sciences industry was critical to trialling and identifying effective therapeutics. So too was the culture of research and recruitment in the NHS that makes it an attractive setting for running those trials.

As with vaccines, NHS England's successes owed much to the strength of the NHS and its people.

The use and adaptation of existing infrastructure, innovation and collaboration with partners, and responding operationally at pace and at scale.

Pandemic-specific measures such as RAPID-C19 and CMDUs and the use of clinical trials across the NHS are examples of how NHS England can stand up new initiatives to support the health system response during the next pandemic, albeit adapted as necessary.

Turning, then, to recommendations. As we submitted in Module 3, there needs to be a response in place which is as resilient as possible. But any response must also be flexible and agile to adapt to uncertainties, and we must acknowledge that no response will be perfect.

Throughout the deployment programmes, NHS England

continually improved, adapted, and learned, reviewing insights from data, listening to the experience of those on the ground, and sharing best practice. The system in England was, we submit, rightly built around the NHS in England, its existing delivery systems, and expertise.

You will likely be considering how much do we need to have ready now, and the implications of doing so, versus knowing how to build it when it's needed.

We know too that the Inquiry will carefully consider what changes have already been made. In particular I highlight NHS England's current vaccination strategy published in December 2023. This brings the Covid vaccination operating model alongside more longstanding vaccination and screening programmes.

We welcome the experts' acknowledgement that the new strategy builds on learning, engaging more closely with local communities, and places an emphasis on outreach and opportunistic delivery. The strategy's mission is to reduce morbidity and mortality by increasing vaccination uptake and coverage. To do so by high-quality, convenient access to services, tailored to the needs of local people, supplemented by targeted outreach to increase uptake in under-served populations, delivered in a joined-up way by integrated teams across the NHS and other organisations.

Specifically, that means improving convenience by retaining the national booking system, and extending it to flu and RSV, continuing to use multiple pathways, GPs, and pharmacies, mass centres, and pop-ups.

Improving information accessibility: now a standard 28 languages, Easy Read, braille and audio, taking a digital-first approach but maintaining the 119 telephone service.

On outreach, work is ongoing to forge links with communities with low uptake, with a continuous engagement offer, extending to blood pressure and diabetes checks, mental health and eating well services, to make every contact count, with campaigns to highlight what vaccination can do for public health, to reduce hesitancy and build confidence.

As the experts acknowledge, a robust ongoing programme will help in any future pandemic.

Notably, in the recent national MMR campaign, the largest coverage increases were consistently seen in people from African, Arab, other black, and white Gypsy and Irish Traveller ethnic groups. However, more needs to be done. We agree that initiatives need to be evaluated. Data was shared throughout the pandemic and there were some evaluations, but NHS England continues to work with academics to evaluate initiatives.

Secondly, on data --

LADY HALLETT: I'm afraid you're running over rather, Ms Palmer.

MS PALMER: I'm so sorry, I'm just coming to it.

LADY HALLETT: I have been tough on others, so --

MS PALMER: No, of course. I'm just coming to the end.

So the Inquiry recognises the extreme complexity of health data which requires careful public engagement. The Sudlow review was commissioned by NHS England amongst others, and work is ongoing to deliver a single-patient record and an engagement campaign to have their say on using data.

Just finally, the Inquiry has highlighted the vital public health role that vaccination plays and that vaccinate a population level is overwhelmingly beneficial. It is hoped that the Inquiry, having listened to and having engaged with the understandable concerns, your report will have a positive impact on vaccinations, tackling mis- and disinformation, responsibly addressing vaccine hesitancy, and building trust.

Finally, we say thank you and pay tribute to everyone that played their part in the pandemic. We look forward to your recommendations and I'm terribly sorry for running over.

LADY HALLETT: I'll let you off.

Thank you, Ms Palmer.

Mr Friedman?

Closing statement on behalf Disability Rights UK, Disability Action Northern Ireland, Disability Wales, and Inclusion Scotland by MR FRIEDMAN KC

MR FRIEDMAN: We act for four national Disabled People's Organisations, or DPO, run by and for disabled people.

My Lady, for disabled people, the possibility of successful pharmaceutical release out of the pandemic required them to negotiate an arc of exclusion. There were problems of need, trust and access.

On need, according to ONS figures, by March 2023 a higher proportion of adult disabled people in England, regardless of the extent of their impairment, had received a vaccine, compared to non-disabled people. This 2023 data indicates that disabled people were, by then, able to take up the vaccine in substantial numbers.

As with other aspects of the pandemic, there are problems with the data, particularly with how data was collected in real time. But the overall result is important. It indicates that despite barriers to accessibility, disabled people, by their actions, expressed their need to vaccinate, that given risk to

life and the impact of continuing lockdown, it was less open to disabled people to be hesitant.

The data shows that disabled people acted in great numbers to overcome the odds.

Our second point concerns trust. The relatively higher vaccination numbers by March 2023 were reached notwithstanding that disabled people often have good grounds to mistrust aspects of healthcare. As Kamran Mallick framed it: "We are often done to, told that others know best what's best for us, that we're not experts in our own lives and our own conditions that we live with day in, day out."

For the DPO it was foreseeable that features of disabled people's needs would be overlooked in the delivery of vaccines; that bright line rules on prioritisation would be drawn up with disabled people on the wrong side of them; that competency and compliance in the field of reasonable adjustments would be assumed and not properly monitored; that administrative systems would be set up to do things to disabled people rather than be in dialogue with, and accountable to, them.

My Lady, in the crisis of a pandemic, where there was no plan at the outset, and the state had to make hard choices and put in place mass systems, disabled people had good reason to fear exclusion.

Our third point is access, which for disabled people, has a fundamentally more expansive and dramatic dimension than for people who spend most of their lives not having to think about it. Access is the ever-present basis for disabled people's exclusion to operate and accumulate, and here it arose at multiple stages: in prioritisation, delivery, antivirals, and for those injured in the Vaccine Damage Payment Scheme.

Prioritisation means unequal access. In the first phase of scarce supplies, it was necessary to discriminate by categorising who needed favoured vaccine status. What complicated prioritisation was the complex decisions about categorisations which did not fully work through what they needed to recognise, and they failed to properly address certain critical needs of disabled people in an informed way, of which we ask the Inquiry to consider primary care housebound patients who could die of a non-Covid disease without support; disabled people living at home, but requiring personal assistance for basic sustenance and mobility, and the real-world viability of adopting that label, "severe and profound learning disabilities". Once decided upon, the flaws in those bright line categories became especially problematic, given the limited avenues for legal challenge, the extent of ministerial discretion in this

area, and the decision to defer to what the JCVI advised, even though government was not legally bound to do so.

Clara Swinson referred in her oral evidence to operational discretion for local vaccine providers to vaccinate a carer at the same time as the person they were caring for.

My Lady, discretion to that end was never written into the Green Book or any standing operating guidance, or any communication to the public.

There are examples of individual NHS clinical commissioning groups, like Leicester and Kent, that unilaterally amended cohort 6 for learning disabled people beyond the unreliable category of "severe and profound" before government did, but it is not clear upon what legal basis this happened, or that regulations existed at any stage that permitted cohort rearrangements in this way.

Given the range of hard choices, which were not resolvable using a purely clinical calculus, and given the nature of the power at stake, we say it was axiomatic that ethical and broader social reflection was required.

Lord Bethell's evidence to the contrary is, indeed, candid but it overlooks, with respect, that integrated

ethics and analysis would have been a safeguard fulcrum at the heart of the most difficult type of public service decision making. Perhaps because Ms Swinson knows that to be the case, she believed in her evidence that the Moral and Ethical Advisory Group carefully considered the issues on different cohorts, whereas records of MEAG, as it was known, make clear that prioritisation was discussed in May 2020, and then not again until March 2021.

It was obvious too that decisions about what constitutes a frontline social care worker, and how learning disabled people would be identified for vaccination by local services needed the input of social care and other specialists with the benefit of dialogue with representative groups, including DPO, not least because Minister Whately established that JCVI was making decisions about these matters when no one there was a specialist in the area.

My Lady, the absence of ethical analysis and broader social advice informed by the input of DPO exposed JCVI's approach to mistaken assumptions and lack of due regard, to the lived experience of disabled people.

With the benefit of that engagement, it would have become clear at an earlier stage that learning disabilities were neither practically nor consistently

coded in records and registers, and that there were several unconsidered aspects of employed and unpaid domiciliary care that were unaccounted for in the cohorts, that could place certain disabled people in serious jeopardy.

On delivery of vaccines, the DPO urged caution about the summary position put to Dame Emily Lawson in her evidence, which she agreed with, that vaccination centres were systemically accessible to disabled people.

My Lady, accepting the overall challenges that NHS and the wider health system faced, we do say that as a summary position on that issue, it is not correct. It doesn't match with the accounts across the country that DPO and the Inquiry have received, and from an overall systems point of view, it assumes too readily that accessibility was adequately addressed. Here are five system problems.

First, despite the 2023 ONS findings of how things turned out in the end, disabled people were considerably more likely to be unvaccinated in the earlier period. Concern to that effect was highlighted by the Disability Unit in March 2021.

Second, that new National Immunisation Management System suffered a design flaw, as it did not record disaggregated data on disability. The consequence was

that the system had no real idea how it was doing on accessibility, and whether it was a success. In fact, the slower initial uptake and the results from the ONS opinions and lifestyle surveys in 2021 indicate that it was not.

Third, the Vaccine Equalities Committee created by government in January 2021 did not consider disabled people's access to vaccines, and had no disability-focused membership, let alone structured engagement with DPO, including funding, to enable DPO and other groups to co-design and monitor accessibility of local vaccine programmes.

Fourth, the standard operating procedures, or SOPs, for vaccination centres were woefully minimalist about disabled people. Under the heading "Access" there was no guidance on physical access and environmental issues, nor reference to the NHS Accessible Information Standard.

The RNIB noted in Module 2 that appointment letters in braille for a first vaccine dose to those who hadn't received it were only introduced in July 2022, more than 18 months after the rollout began, and I'm bound to say, just two years short of how long -- double the time -- of how long it took to create a vaccine, being ten months.

Fifth, in conflict with an assumption that the health system had sufficient institutional knowledge and procedures to handle these matters, the Inquiry has evidence of the exercise at Epsom race course in October 2020 that, according to Dame Emily's witness statement, formed the core participatory work on how to create a vaccination centre. The exercise identified that policy around disability needed to be clear and form part of a cross-cutting patient experience. It recommended planning, involving staff training, model design, booking arrangements and all communications.

The template for the SOPs developed in November, informed by this very exercise, did not mention these matters, and they did not form part of the subsequent SOPs.

Finally, on the lack of pharmaceutical alternatives to vaccines, and especially what happened with Evusheld. The accounts of ministers, advisers and civil servants, and the competing positions based on priorities, costs and available clinical evidence have been heard, and heard in a way that possibly only an Inquiry like this could enable. What is missing, because there was no role given to it at the time, is ethics.

It should be striking to everyone, as it was to Dame Bingham, that moral and ethical values were at

stake, but those values were never explained or justified because ethical analysis in relation to this matter, like prioritisation, was not integrated in decision-making. The result is that a million-plus people are excluded from the national solution to Covid-19, and the clinical cost and ethical analysis of what is to be done is incomplete.

My Lady, we've talked about exclusion. Can we end on solution.

Trust optimises outcomes, whether it is planning for the pandemic needs of the future, or acknowledging the needs of those who have been injured and are seeking justice for the pandemic just passed.

The observations in realtime by DPO and others with what was essential to both trust and equitable outcomes was for governments to see people and representative organisations as a resource and to look for solutions from bottom-up, not just top-down.

Something of the depth of the issue arose in Mr Keith's exchange with Dr Kasstan-Dabush, and we thank them both for it. Counsel, in his role as investigator, asked whether system accountability to community groups, including disabled groups, was bureaucratically necessary if a local vaccination programme were getting on with the job and getting it done anyway, or, and I'm

going to quote: "Is that not just a heightened unnecessary degree of administrative process?"

To which the answer came back: "It's crucial to ensure that changes happen when they're needed, to learn from past limitations, let us say, or failings, and to create an agenda for change in partnership with those groups."

As the doctor later added, the question from Mr Keith, why accountability to the groups mattered, was an important question to address, because it is quite clearly a life or death matter, and it has to be said.

My Lady knows, from evidence across the modules, that the qualities of participatory policy building include co-production at the design stage, integration of representative organisations and their local networks into a two-way pipeline of ideas, information and action, dialogue, especially around difficult matters, and facilitation of representative groups, such as DPO. They are to participatory community engagement what Kate Bingham's business sector leaders are to ambitious vaccine development.

Disabled people's complex access to Covid pharmaceutical solutions shows that we are not there yet, but we could be.

Thank you, my Lady.

LADY HALLETT: Thank you very much, Mr Friedman.

Ms Naik, would you like to take us up to the break? Where are you? There you are, behind Mr Friedman.

MS NAIK: Can I just confirm you can hear me?

LADY HALLETT: I can, thank you.

Closing statement on behalf of Migrant Primary Care Access Group by MS NAIK KC

MS NAIK: My Lady, as you are aware, I represent the Migrant Primary Care Access Group, and, my Lady, you'll recall that you granted Core Participant status to my clients as distinct from the Gypsy, Roma, Traveller community precisely because you rightly identified that migrants were deserving of their own focus and examination in the Inquiry and of their needs in the context of and access to vaccines and therapeutics within primary healthcare.

And this was by reference to the cross-cutting health inequalities of race and racism, social isolation and deprivation, as well as their migration status.

No other group fears accessing state healthcare because it's not clear to them, or those administering the system, whether they are entitled to that healthcare. No other group lack, by virtue of not being born in the UK, an NHS number which is otherwise assigned at birth, and which is a key requirement for such access.

No other group risks being charged for healthcare through a series of complex regulations, which is clearly a deterrent, and indeed an intended deterrent, to accessing healthcare. And no other group risked being reported to the Home Office to have their immigration status checked and a risk of consequent enforcement action as a result of accessing treatment for Covid-19.

No other group faced hearing daily anti-migrant rhetoric in addition to experiencing racism.

I pause here to note that throughout these hearings, there has been much discussion around those that my clients represent, which has been deeply technical and policy driven, but I just want to remind the Inquiry this is still about real people and real lives. On the first day we saw that very moving impact video, and yet our clients were not invited to share a story, and their voices, we say the voices of migrant communities for whom we stand, were missing from that narrative.

And so one example that my client Kanlungan know of is an individual who we're calling Elvis -- it's not his real name -- and he died following several days of suffering severe Covid-19 symptoms. He was an undocumented individual and he feared that if he sought help from the NHS, he'd be reported to the authorities

and charged thousands of pounds for treatment, so he didn't seek the help that he desperately needed and that may have saved his life.

So I want to begin by recognising people like him, for him and many others, that lives were lost and others put at risk to the detriment of the whole community, not just because of the virus alone but because of the acknowledged and deeply entrenched fear that prevented them from seeking medical care that they needed.

Migrants are just the same as all the rest of us, mothers, fathers, brothers, sisters, neighbours, and friends. Among them were healthcare workers, delivery drivers and carers who made a critical contribution during the pandemic, risking their own lives for the safety of us all and we remember them, and we deeply hope that lessons are learnt from the hardship and sacrifices they endured.

And so it's against that backdrop that we ask the Inquiry to examine whether, in practice, there were very real barriers to migrant access to healthcare from a public health perspective, and we say the evidence points in one direction, and that central to the task of the Inquiry is to examine the government's actions and, in particular, inactions by reference to first identifying the root causes of the barriers to vaccine

uptake, and identifying whether any or any adequate steps were taken to remove those barriers in order to shape the Inquiry's final recommendations.

We invite the Inquiry to adopt our five core recommendations, which will have a tangible public health impact for migrant communities, we say, and that nothing we've heard over the last few weeks has undermined any of our submissions. Rather, in fact, we say they're strengthened.

I just wanted to say something about scope at the outset, my Lady, because we maintain that barriers to public health, including the NHS charging regime, and the data-sharing practices which are Department of Health and Social Care policies, do fall squarely in scope for consideration, of their impact on migrants, by the Inquiry in this module. There can be no doubt the official terms of reference require the Inquiry to consider the public health response, including in the areas of immigration and asylum, and the evidence shows that these policies undermine the understanding of access to primary care by migrants and their confidence do so, which cannot be disentangled in practice, and was not addressed during the pandemic, which goes to the heart of the scope of this module.

It means that the impact on migrants, also as

a matter of legal obligation, should have been at the forefront of government decision making where, as has been acknowledged, there were such barriers to uptake, and that it should have been monitored under the scrutiny of the Equalities Minister, Kemi Badenoch, and the Equality Hub within the Cabinet Office, and we say that from the evidence this is clearly not the case.

So whilst, of course, the topic of immigration is politically charged, in this context, the chair, my Lady, you're looking at barriers to primary healthcare access faced by migrants through the public health lens, policies operated by the Department of Health and Social Care, which we invite the Inquiry to engage, and on that basis we then make five sort of headline points.

The first is that GP registration and the lack of an NHS number was a practical barrier to access. Policies that restrict or undermine migrants' registration with GP services in non-pandemic times limit opportunity for their access to vaccination in a pandemic scenario, so said the experts Kasstan-Dabush and Chantler.

The British Medical Association highlighted in their opening that not having an NHS number became a barrier to vaccine uptake for vulnerable migrants, and early in the pandemic, our clients raised both of those issues

with the government, and despite that, the earlier vaccine rollout was dependent on GP registration, based on that exclusionary model, and we heard that planning for the expected vaccine commencement was around October 2020, but the government's attempts to inform and communicate public health providers and the public that vaccines were accessible without an NHS number only took place from February 2021.

Second, we say that the impact of data sharing between the NHS and the Home Office is not simply about better communication of access to primary care for all, but the complexities of addressing the impact of those intersectional barriers to that access that -- placed by governments that were well known to them at the outset, and our clients' experience of the migrants that they encountered and assisted during the pandemic, demonstrated substantial and objectively reasonable fears, and concerns in accessing the Covid-19 vaccine on account of their immigration status, whether they were insecure or undocumented, which means whether they were lawfully present or not, for fear of being charged or their data being shared with the Home Office.

The Home Office can't claim and don't claim that they were unaware of this, so the critical question is whether enough was done to remove the impact of those

known barriers.

The NHS charging for secondary healthcare and the data sharing by healthcare providers with the Home Office and the risk of this has been directly identified as a barrier of access to primary healthcare by both the two main expert witnesses from the Inquiry and our own witness, Ms Miller.

The experts explain that data sharing can "result in a fear of immigration enforcement", and their view that the evidence indicates this does not only affect people's insecure status but implications for migrants and people from other ethnic minority communities, more broadly, who have been subject to racial profiling in NHS settings.

And in her oral evidence, Dr Chantler already expressly referred to the Home Office Windrush Scandal as an example of the impact of Hostile Environment health policies on those with or perceived to have insecure immigration status. So this is not a fanciful risk of denial of access to healthcare or confidence in accessing healthcare, but rather a real and exclusionary risk.

And, indeed in his evidence, his oral evidence, Chief Medical Officer Chris Whitty, when addressing the issue of health data, said that people were "very

nervous about their data being shared" and "you have to be able to absolutely guarantee the security of data" and this, we say, must clearly extend to patient confidentiality for all.

But during the pandemic, there were no guarantees of confidentiality when accessing the vaccines or therapeutics that could have been made unless mandatory data sharing provisions under the NHS Charging Regulations had been suspended or repealed completely. Neither of that occurred.

And let us not forget the evidence of Ms Miller, that the UK is an outlier in Europe using healthcare data to support immigration enforcement.

When my clients ask for the confirmation that patient data collected as part of the vaccine programme would not be shared with the Home Office, Public Health England were unable to provide that guarantee.

Turning, third, to the charging exemption, much has been made of the Covid-19 charging exemption being a sufficient solution, but the Covid exemption never covered hospital treatment of any subsequent or secondary illness caused by Covid, and critically, Chris Whitty didn't agree that the exemption went far enough. His advice to the Department of Health and Social Care, as early as April 2020, in the following terms in an

email, which is actually -- I'm going to give you the INQ000068816. That advice couldn't have been clearer.

He says, "I would encourage that we don't charge for Covid-19 treatment or treatments that arise as a result of Covid-19."

That advice is only relevant to migrants. Only those who are liable to charging. It unequivocally supports our clients' primary position as to the impact of charging on migrant health policy. No government witness has explained why this critical advice was ignored.

My Lady, you've heard from our witness, from Doctors of the World, Ms Miller, that people present with symptoms, not diagnoses, and those symptoms are rarely static. And her evidence was that people seeking treatment for symptoms would clearly be at risk of being unable to draw that distinction, so how does a person know whether they're going to go into hospital for Covid-19 treatment rather than an acute asthma attack unrelated to Covid, for example? How can they know that their exempt treatment for Covid wouldn't turn into non-exempt treatment for a secondary condition? And those risks were too grave for many to take.

Moreover, there has been a call, throughout this module, for more data in primary and secondary care in

order to make the vaccine access more effective and able to be monitored, including, for example, from Dr Emily Lawson. You heard from the BMA that improved data sharing is essential to providing safe and high quality healthcare and to enable healthcare services to respond to a future pandemic.

And although they emphasise also the importance of doctor-patient confidentiality, Mr Jacobs from the Traveller Movement promoted the use of handheld health records. But we say as to both, that without a data firewall to ensure confidentiality between the NHS and the Home Office, this will only and very seriously exacerbate the existing challenges in practice, diminish trust, and reduce vaccine uptake, and put the lives of migrants at risk and public health more broadly.

That takes us to our fourth, my fourth point, which is that public health must be divorced from immigration policy. There needs to be clarity and confidence within the healthcare system in order to make it essential that the most widely-effective public healthcare policy can only be achieved through the decoupling of health and immigration policies.

Again, Kasstan-Dabush and Chantler put it in their report: policies that enmesh access to healthcare in immigration enforcement are counterproductive to health

protection.

It couldn't have been more clear.

Mr Zahawi told the Inquiry that the vaccination of all migrants, including those with precarious immigration status, was in the country's interests of public health. But this required effective action to deliver it, given the Hostile Environment policies, and we say that didn't happen.

You will also recall the evidence to the Inquiry of Ms Badenoch, then the Equalities Minister operating from the Equality Hub in the Cabinet Office, that we cannot adjust our health system to undermine borders and border security, that's something we just have to accept.

That statement is an outlier and clearly inconsistent with the stated right of access of all to primary healthcare.

So we say that we need long-term policy change to create and embed real and unequivocal clarity that seeking access to healthcare and seeking healthcare will not expose anyone to financial penalty or immigration enforcement.

Fifth, we say messaging can't remedy substance. There was a clear inference that the issue was about the failure to take steps to communicate exemptions to migrant groups, and we say that if -- to conclude that

that was the reason for low vaccine uptake, and that it could simply have been remedied by improved communication, would clearly be misplaced and not based on the evidence, when it comes to the messaging: "I can get the vaccine for free, but if I fall ill from the virus, I may get treatment for that that's free, but if my illness becomes secondary to Covid, I'll be charged, and if I can't or don't pay them, my data will be shared by the Home Office, and I may be getting at risk of not getting my immigration status if I owe a debt to the NHS, or I may be removed from the UK."

How can any effective public health campaign communicate that to promote access to vaccine and Covid care?

So we say while we encourage effective communication between government and migrant communities, it also requires the government to take the experience of those on the frontline seriously, including the intended and the unintended but foreseeable consequences of Hostile Environment policies.

So, finally, we say that trust cannot be built in a day. Building trust in a migrant community needs to recognise the historic and current context of racism and anti-migrant sentiment. That is key. In the climate of fear, rectifying that mistrust requires a long-term

policy change and addressing the link between racism and hostility, and that must begin during peacetime.

The evidence from the former government ministers to the Inquiry has disclosed, at best, a lack of awareness about migrant issues and concerns, and, at worst, the dismissal that they're not even deserving of equal access and protection in a public health emergency.

We say that despite what Mr Hancock said, that no stone was left unturned, that in fact the evidence shows the opposite, and that the prioritisation of health over immigration policy is not an unrealistic ambition.

We have Dr Richardson, stated in her evidence to the Inquiry, that Wales never subscribed to the Hostile Environment policies. Clinical data was never shared and there was never a requirement to be registered with a GP or have an NHS number to obtain a vaccine, and that Wales was declared a nation of sanctuary.

We say in conclusion, my Lady, that doing nothing, maintaining the status quo, or allowing for greater data collection without hard-edged patient confidentiality safeguards will mean that more migrants will not access vaccines, will contract the virus, and will die as a result when, as Jonathan Van-Tam said, the racing certainty of a future pandemic occurs.

Thank you, my Lady.

LADY HALLETT: Thank you, Ms Naik.

I think I'm going to be generous to the stenographer, given that it's tough transcribing submissions, so I shall return at 11.35.

(11.21 am)

(A short break)

(11.36 am)

LADY HALLETT: May I apologise to everybody. Having said I was going to be generous, I was then mean. My maths has failed me at the last hurdle. So, sorry.

Mr Block.

Closing statement on behalf of His Majesty's Treasury

by MR BLOCK KC

MR BLOCK: Good morning, my Lady. As you may recall, I represent His Majesty's Treasury together with Mr Steven Grey instructed by Robyn Smith of the Government Legal Department.

My Lady, we hope you've had the assistance of a detailed corporate witness statement from Catherine Little and a state from the Right Honourable Steve Barclay MP who received as the Chief Secretary to HMT from 13 February 2020 to 15 September 2021.

You have also had the benefit of hearing brief oral evidence, less than an hour, from Catherine Little, and was recognised by Counsel to the Inquiry, it was only

possible to touch briefly on some of the core themes in the evidence at that time and indeed the same applies to me today but we hope to highlight a few matters that may be of assistance to you when you come to look at the evidence.

Briefly, because I have outlined this before, the role of His Majesty's Treasury is that it's the government's economic and finance ministry responsible for maintaining sound public finances, delivering sustainable economic growth, and maintaining a macroeconomic and financial stability.

In relation to vaccines and therapeutics, HMT had four main objectives: first, delivering the best possible health outcomes; second, maintaining value for money for taxpayers, avoiding waste and driving efficiency; third, supporting ministers and accounting officers to ensure government spending operated with regularity and propriety at all times; and fourth, supporting the government's wider economic considerations.

As the evidence in this module clearly shows, HMT acted flexibly and pragmatically so as to ensure that the United Kingdom could secure and deliver an appropriate supply of vaccines and therapeutics, in particular by accepting a significantly higher level of

risk than is usual regarding public spending.

HMT's approach to funding the vaccines programme. We consider it's important to highlight that the vaccines programme was extremely unusual in the context of public spending control. It was very difficult, especially in the early stages of the pandemic, to forecast spend accurately, and it was therefore extremely challenging to set an accurate budget for the programme.

As a result, HMT adopted a much higher risk and more flexible approach than usual to spending very large sums of public money, and this was considered an appropriate and proportionate approach to take because of the huge potential benefits to society of securing a successful vaccine.

I give a few examples, three. First, given the uncertainties around what would be required and to provide maximum flexibility, HMT agreed in the summer of 2020 to provide a three-year funding commitment to the Vaccine Taskforce, with the VTF given full flexibility to deploy that funding across the different financial years: £5.3 billion initially in the summer of 2020, rising over time to a total of £9.35 billion.

That approach permitted the VTF to operate with significant freedom and pragmatism, and was, as

Ms Little described in her evidence, absolutely unheard of outside of a spending review or in normal spending practice.

Secondly, HMT sought and obtained ministerial consent to agree contractual indemnities with vaccine developers. Whilst HMT did not agree to provide developers with blanket indemnities and the agreements did permit developers to be held to account in specific circumstances, HMT's approach did result in the Exchequer bearing a much higher share of the risk than would ordinarily be the case. HMT took this exceptional approach to enable the VTF to secure those commercial arrangements quickly and ahead of global demand. As a result, the UK's access to invaluable vaccines was maximised.

And thirdly, HMT increased the limit to which it delegated authority to BEIS to spend without specific prior approval from £70 million to £150 million for the vaccines programme. Again, this increased the ability of BEIS to act quickly and flexibly.

In addition, and as referred to by a number of witnesses, the governance arrangements around spending approvals were adapted through the establishment of the VTF ministerial panel which met for the first time on 27 August 2020.

HMT agreed to streamline and collapse the usual sequential ministerial approval process into a single collaborative process, a move described as "fantastic" by Dame Kate Bingham in her oral evidence. And as Ms Little said in her evidence, this worked well in the pandemic and should be repeated if a similar situation arose.

HMT acknowledges that some criticism was made by Dame Kate Bingham of the pace at which HMT provided approval for the future funding of the Vaccine Taskforce, and that was the subject of a business case submitted in July 2020, the final version being submitted nine days later.

However, HMT remains firmly of the view, as Ms Little explained, that a written business case was appropriate for that very significant request, £5.23 billion over three years. As Ms Little said, that equates to a penny on Income Tax, and careful scrutiny of the proposal as well as a written record that the decision-making process were both essential.

The CST approved the £5.2 billion on 31 July 2020, that's two days after the final version of the business case.

Approval for further administrative costs was requested on 31 July and it was approved about four days

later. There were further negotiations regarding conditions, and final approval was communicated to the VTF in late August 2020, the final settlement letter prepared and sent in early September of that year. However, no one should be under any misapprehension, we submit, that this process of scrutiny stalled the VTF's work.

Whilst that request for £5.23 billion was considered, HMT continued to receive and approve specific funding requests. As Ms Little explained in her evidence, at that time, HMT was often signing off significant public spending within 48 hours of receiving a complex written case. HMT teams worked round the clock to make sure that resources were available where required, in this instance for the VTF.

Whilst considering the VTF's request in the summer of 2020, HMT signed off £1.3 billion of additional specific approvals to ensure the VTF could maintain its momentum and pace of work.

In her oral evidence, Ms Little explained to the Inquiry why the HMT's Green Book guidance on investment appraisal for the public sector is helpful, when a spending request as substantial as that made by the VTF is made. The Green Book guidance, considered to be one of the most longstanding and mature sets of guidance

in this area, doesn't set out a prescriptive approach but, instead, provides a toolkit of methodologies to be used when quantifying risks and uncertainties, plainly highly pertinent to the VTF's business case, as Ms Little explained.

The Green Book is also clear that evidence and data should be used throughout and there should therefore be no need for a separate scientific case.

It was open to the VTF to deploy as much scientific evidence as they considered appropriate in support of their business case.

My Lady, HMT of course recognises, to pick up on your observations at the end of Mr Gray's evidence, the need for peacetime processes to be expedited in an emergency, but decisions on this scale do need a proper framework within which to be made and understood. Due process cannot be dispensed with altogether. It's a balance which we believe was achieved.

HMT's role in the procurement of the seven vaccines, including the booster vaccines, that ultimately formed the VTF's vaccine portfolio, is set out in detail in Ms Little's witness statement at paragraphs 56 to 82.

HMT consistently supported BEIS and the VTF to secure supplies of promising vaccines at scale, whilst seeking to ensure value for money. And similarly, HMT

consistently worked, including agreeing to provide funding in advance of regulatory approvals, to help vaccines be deployed and administered as swiftly as possible, including in respect of the booster campaigns in 2021 and 2022. And that's, for your note, at paragraphs 133 to 144 and 158 to 167 of Ms Little's statement.

In addition to funding and supporting the VTF, the resilience and capability of the UK manufacturing sector for vaccines was also a priority for HMT. It invested in a range of initiatives to support that manufacturing resilience and capability, including the Vaccine Manufacturing Innovation Centre, and the Centre for Process Innovation, as well as providing funds to BEIS to invest in manufacturing resilience.

Again, that's set out in detail in Ms Little's witness statement at paragraphs 103 to 132.

Therapeutics and, in particular, antivirals, are dealt with by Ms Little at paragraphs 170 to 205 of the statement, and in relation to these, as she explained her oral evidence, HMT always saw them as having a critical role in response to the pandemic, especially for clinically vulnerable groups, and those who couldn't have the vaccine.

That is why it approved £621.5 million of funding

sought in the Antiviral Taskforce's business case in May 2021, as well as very substantial additional funding.

My Lady, however, it is right to acknowledge that a number of significant challenges then arose in connection with antivirals, including three examples, firstly the price of the Project Arrow doses increased 50-fold. Secondly, an insufficiency of evidence that antivirals would have the positive impact on hospitalisations and wider public health assumed by DHSC. And thirdly, the emergence in November 2021 of the Omicron variant which led to a request for additional funding for antivirals that would ultimately not have been developed and deployed until the second half of 2022/23.

We accept that this raised challenging questions at various stages about -- sorry, that we raised challenging questions at various stages about the potential benefits of antivirals, but this wasn't HMT seeking to override clinical advice or to step into the arena of clinical assessment. It was HMT discharging its core function of managing public money by scrutinising the available evidence in order to assess value for money.

In the event, whilst funding for additional

antiviral procurement was agreed, need turned out to be far lower than anticipated by DHSC and 4.98 million doses costing over £3 billion went unused.

It would be wrong, therefore, to say that there was a lack of supply as a result of unwillingness on the part of HMT to fund antivirals, and similarly, HMT supported the procurement and deployment of monoclonal antibody therapies to combat Covid-19 amongst those who were ineligible or unable to receive a vaccine, along with those who did not produce a significant immune response after immunisation -- around 1.7 million people in the United Kingdom.

Funding was approved by the Chief Secretary and the ministerial panel before approval by the MHRA, enabling the UK to access supplies that were highly sought after globally, especially as a result of Omicron.

My Lady, if I may just briefly turn to lessons learned.

Firstly, given the huge uncertainty at the outset, of the pandemic, HMT considers the delivery of the UK vaccination programme to have been a very significant success, and this module has highlighted many positive elements of the response to the pandemic, which the Inquiry will no doubt be keen to see embedded in any future response to a pandemic.

Regarding HMT, Ms Little highlighted in her oral evidence three particularly positive areas. First, explicit use of risk-based judgements and risk management techniques to support a very high-risk approach to its decision making. Second, the flexible use of the spending framework to enable rapid decision making, and in particular, thirdly, the significant time saved by governance, consolidation via the ministerial panel.

However, notwithstanding the many successes, HMT is also keen to learn lessons in connection with this module and it's already begun to do so, as Ms Little set out in paragraphs 206 to 229, and also, in particular, in the Chief Secretary's letter to the Chair of the Treasury Select Committee in April 2021.

In her oral evidence, Ms Little identified the following areas where there is potential room for improvement. Firstly, the use of data. Our Module 2 submissions set out the various steps HMT has taken to improve its data and modelling capabilities since the pandemic.

Secondly, the raising of commercial and STEM skills across the Civil Service, and thirdly, embedding the Cabinet Office and HMT upfront into large programmes which seemed to work well for vaccines but could be done

more consistently, and HMT has also identified ways in which accounting officers could be better supported.

My Lady, we hope that that's been of assistance to you in your upcoming deliberations, and because I've gone at such pace, whilst we are not intending to put in large written submissions, we will send you the speaking note, just as an *aide memoire*.

LADY HALLETT: Thank you very much, Mr Block.

Mr Dixey? There you are.

Closing statement on behalf of Medicines and Healthcare products Regulatory Agency by MR DIXEY

MR DIXEY: My Lady, on behalf of the Medicines and Healthcare Products Regulatory Agency, may I begin by thanking your Ladyship and the Inquiry legal team for the care and attention which this important Module has received. The MHRA will be providing written closing submissions in due course; however, I wish briefly to address some of the findings which we invite your Ladyship to make, and to highlight certain matters which it may be felt usefully to inform your recommendations for the future, as this module offers a key opportunity for the agency and others to learn and strengthen its systems.

As I explained in our opening statement, the MHRA recognises the importance of external scrutiny,

especially in the context of vaccination, where misunderstanding, misinformation, or disinformation are prevalent.

The module has provided that scrutiny, not least through the opinions of the independent experts.

The evidence shows that the MHRA responded quickly and adeptly to the pandemic. The adapted its working practice it is and utilised its regulatory flexibilities, including through the use of rolling references of data. The result was that the MHRA was the first regulator in the world to authorise for use a vaccine against Covid-19.

No other regulator reached a materially different conclusion, with the result that millions of lives have been saved worldwide.

Notwithstanding the significant challenges and pressures which the pandemic presented, the agency robustly maintained its independence throughout, and did not compromise on the rigour with which it approached and assessed patient safety and benefit-risk.

In that endeavour, the MHRA's expertise and experience was supported and enhanced by the independent scientific advice of the Commission on Human Medicines, and its expert working groups.

We invite you to accept the evidence of

Professor Evans that the authorisation process which the MHRA adopted for vaccines and therapeutics were appropriate. They were in line with other international regulators, and they did not impact on the scientific assessment of the safety of the vaccines, which was in line with international standards.

Indeed, as Professor Evans explained, the processes meant that the scrutiny afforded is likely to have been greater than would normally have been the case.

As to clinical trials, the expert evidence is that the oversight mechanisms were robust and consistent with pre-pandemic standards. These well-designed and appropriately-sized trials generated considerable amount of data from studies in different countries, reflecting different demographics and ethnicities.

Professor White has raised important questions about how some clinical trials were run and regulated. In particular, whether steps should be taken to improve the effectiveness of phase II trials to ensure that they are not underpowered. The opportunity to have those discussions will arise with the forthcoming implementation of the new clinical trials legislation. Regulations amending the Medicines for Human Use Clinical Trials Regulations 2004 have been laid before Parliament in December of last year.

In respect of post-authorisation surveillance, we invite you to accept the evidence of Professors Evans and Prieto-Alhambra.

First, the MHRA's strategic approach to post-authorisation monitoring, of Covid-19 vaccines, was reasonable, and was built upon tried and trusted methods of analysis.

The Yellow Card Scheme worked well, as the main source of signals although it was not the only means through which the MHRA identified signals. Second, the MHRA evaluation of those signals was done well. The MHRA consulted with and drew upon the independent expertise of the CHM and its expert working group.

Third, the system responded effectively to safety concerns which emerged following the authorisation of the Covid-19 vaccines.

The response to the emerging signals of myocarditis, pericarditis and thrombosis with thrombocytopenia syndrome was appropriate and consistent with other comparable international regulators.

The Inquiry has received into evidence statements from Dame June Raine, the MHRA chief executive, who also gave evidence to the Inquiry in person on 22 January.

In her principal statement at paragraphs 796 to 859 she set out various reflections on what went well and

where improvements could be made for future pandemics.

We highlight three in particular today. First, access to data. A topic which has been frequently raised throughout this module as a key enabler. Data generation is essential to robust benefit-risk profiles.

There is clear potential to use real-world data more effectively in support of robust and timely regulatory decisions.

Better data linkages between healthcare datasets, in particular, offer the opportunity to move closer to realtime signal detection. It will be important to further consider how signal detection can be done in large clinical datasets using all the tools that are now available, including AI.

Second, representativeness in clinical trials. The Inquiry has heard about the challenges of ensuring genuinely representational clinical trials. More, however, can and should be done to promote greater diversity within those trials.

The new clinical trials legislation which is now being introduced offers a generational opportunity to herald a new area of truly representative studies. This is important not just to get more robust data, but as others have pointed out, to assist in reassuring all users of medicines and vaccines, that an authorised

product has been tested in someone like them.

Third, ensuring the scientific expertise, capacity, and capability of the regulator.

During the pandemic, the MHRA relied on the extraordinary skills and efforts of highly skilled staff, who were able to be redeployed to review complex information at pace, to produce high-quality approval and safety processes for vaccines and therapeutics for the UK.

It is vitally important that there is continued investment in the MHRA's capability for pandemic preparedness. It is equally important that the agency is able to stay competitive with industry as an employer, in retaining and recruiting people with the types of skills and expertise needed in the best interests of patients and the public.

My Lady, the Inquiry has heard moving evidence from those who have been injured or bereaved following receipt of a Covid-19 vaccine. It is right that their voices have been heard. Anyone who has suffered as a result of playing their part in a vaccine campaign of such societal consequence should be properly supported in the very rare event of a serious adverse effect.

It is the MHRA's firm hope that what patients and families in turn have heard here has demonstrated the

agency's unwavering commitment to patient safety, and to continually strengthening the ways in which it protects the public's health.

My Lady, unless I can be of any further assistance, those are my submissions on behalf of the MHRA.

LADY HALLETT: No, thank you very much indeed, Mr Dixey, I am very grateful.

Housekeeping matters

MR KEITH: My Lady, may I raise just a couple of housekeeping points.

Firstly, as you're aware, a great many documents have been put up on the screen in the course of this hearing, as well as references made to other Rule 9 witness statements.

The Module 4 team is preparing a list of documents to which you may wish to have regard when you come to writing your report following this module, and that list will comprise documents which references have been made but which have not been put up on the screen, other Rule 9 witness statements and other documents to which you may have regard. We hope to have that list compiled in the next couple of weeks.

Most importantly, perhaps, it will take account of any documents to which the Core Participants refer in their written closing submissions so that, of course,

you've got them available for the purposes of the report writing.

May I also mention the fact that you have made, today, a general restriction order on the publication of material under section 19 relating to that information, documentary information, which was redacted from documents provided to the Core Participants on the grounds of irrelevancy or sensitivity or public interest grounds, and also documentary information which may have been published on the Inquiry's website as part of the general disclosure of the documents given to the Core Participants and to this hearing.

My Lady, that concludes the module.

Remarks by THE CHAIR

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

As he has just said, we have now completed Module 4. I should like to thank everyone involved in ensuring that Module 4 has reached a successful conclusion in just three weeks. I know it has been a hard slog for an awful lot of people. We have heard from 48 witnesses, a third, I think, of the selection of the witnesses who provided statements, so just obtaining the statements, analysing them, and working out the questions must have taken a great deal of effort.

We have also obviously received written submissions,

and shall be considering all the written statements, all the written submissions, as well as the oral evidence before reaching any conclusions, and I am extremely grateful to all those who have assisted me to date, and I know will continue to assist me in that task.

There are so many people to thank, it's hard to start without sounding like an Oscar winner but I'd like to thank all the material providers, the witnesses, some of whom are becoming regular visitors to the Inquiry; the Core Participants and their legal teams; the efficient team -- the Inquiry team who make sure the hearings here in the hearing centre run smoothly and look after people; the support team were already thanked by Ms Morris earlier, Hestia; our technical wizards who seem to have -- so far, we seem to have coped with virtually no technical hitches; the Inquiry legal team obviously, but also the wider Inquiry team who do things like policy and research, and the paralegals who support the Inquiry team.

So I'm very grateful to everybody. There will be some hearings in February, but I shall conduct them remotely and the next substantive hearings in this hearing centre will begin on 3 March and it's Module 5, Procurement.

So thank you, everybody. I hope those who have been

working so hard get some kind of break before the next instalment of the Inquiry. Thank you.

MR KEITH: Thank you, my Lady.

(12.04 pm)

(The hearing for Module 4 concluded.)

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