Module 4 Week 1

CTI Opening

CP opening Submissions

Witnesses

- 1. Helena Jean Rossiter Member of the CBFFJ UK
- 2. Melanie Newdick obo SCB
- 3. Fiona Clarke obo NI CBFFJ
- 4. Anna Miller Migrant Primary Care Access Group (MPCAG)
- 5. Sam Smith Higgins CBFFJ Cymru
- 6. Ruth O'Rafferty Scottish Vaccine Injury Group
- 7. Kate Scott Vaccine Injured and Bereaved UK (VIBUK)
- 8. Kamran Mallick Disabled People's Organisations (DPO)
- 9. Dr Salman Waqar (Federation of Ethnic Minority Healthcare Organisations)
- 10. Yvonne MacNamara (The Traveller Movement)
- 11. Lara Wong (Clinically Vulnerable Families)
- 12. Matt Hancock (Former Secretary of State for Health and Social Care, UK)
- 13. Professor Heidi Larson (Expert, vaccine hesitancy)
- 14. The Rt Hon Lord Alok Sharma (Former Secretary of State for Business, Energy and Industrial Strategy)
- 15. Clara Swinson (Former DG for Global Health and Health Protection, DHSC)
- 16. Catherine Little (Former Second Permanent Secretary, HM Treasury)

CTI Opening

The UK clinical trial process is also overseen through audits and visits carried out by the MHRA, and each batch of medicine is examined by the MHRA's laboratories independently of the testing carried out by the manufacturer. During the Covid-19 pandemic, to increase efficiency and to progress the regulatory review in a shorter time, evidence in support of these authorisation applications was considered in an expedited and flexible rolling review procedure by the MHRA. This allowed the manufacturers to provide packages of data as they were generated, as opposed to waiting until the conclusion of their trials before submitting all the data in one package. The expert evidence commissioned by this Inquiry is that there was no reduction in the efficacy or safety of any of the vaccines, or the trials, as a result of this process.

Rare or very rare adverse reactions are unlikely to be identified by those trials. Very rare - between one in 10,000 and one in 100,000, doses. Or extremely rare - less than one in 100,000 doses. A reaction or a condition that only occurs in less than one in 100,000 people will simply not be apparent in a clinical trial involving only 30,000 people. It will only become apparent when much higher numbers of people, for example, at a population level, are being vaccinated. The expert evidence that we have commissioned,

suggests overwhelmingly that the UK operated a robust and sophisticated system for ensuring the highest levels of safety.

What is acceptably safe? Almost no active drug, vaccine, or medical procedure is without risk. The term "acceptably safe" means that based on the assessment of the MHRA, the benefits or expected benefits associated with a particular product are considered to outweigh any risks associate with that product at a population level. The question was whether being vaccinated carried fewer risks than being unvaccinated, where there was a high chance of acquiring Covid, and where Covid was a life-threatening disease for many.

By June 2021, Public Health England estimated that over 44,500 hospitalisations and over 14,000 deaths had been averted in older adults. The UKHSA estimated in that by September '21 Covid-19 vaccines had prevented more than 23 million infections and 123,000 deaths in the United Kingdom. The UK has been estimated to be the country in the World Health Organisation Europe region with the highest number of deaths averted due to vaccination.

A severe price was paid unfortunately by some individuals. Side effects may be encountered in any medicine, but serious side effects, whilst very rare, are nevertheless significant and debilitating. Nothing that is said about the rarity of those terrible consequences should be taken to diminish that loss. there is a massive public interest in the maintenance of proper vaccination and immunisation programmes, and for vaccines to have their true curative effect, populations must take them up. It would obviously be damaging to uptake if any belief were allowed to take hold that in the very rare occurrence of vaccine injury, the state has forgotten those who suffered.

How effective were the systems monitoring safety signals? The Yellow Card process, and the system of post-authorisation safety studies. Was safety compromised at all by the virtue of the MHRA's rolling review? How clear was official guidance and the communication of potential adverse effects? Was the degree of skill and scrutiny exercised by the MHRA appropriate and was there was any diminution in the level of safety oversight and regulation of the rolling review.

On 16th June 2021 the Government confirmed that vaccination would be mandatory for staff working in care homes in England with the legislation coming into effect in October. on 9 July, the Welsh Government indicated that it was not consulting on this issue, stating that SAGE had advised that the uptake rate was such that no mandatory vaccination as a condition of deployment was required, because the protection rates were high enough already. The position in Scotland was that a vaccination for workers should remain voluntary and there appears to have been particular concern about the possible impact on staff from ethnic minority backgrounds.

On 9 November 2021, the government announced that the policy for care home staff would be extended to a frontline healthcare and social care workers in England. The announcement was met with concern. In fact the UK Government's own impact assessment estimated that even with mandatory vaccination, only a minority of healthcare workers would comply, resulting in tens of thousands of healthcare workers facing unemployment or redeployment. on 1st March, a month before the policy was due to come into place, the UK Government announced it would be revoked.

AMKC obo CBFFJ UK

Tribute to John Sullivan: John spoke eloquently, authentically, thoughtfully, fearlessly and honestly.

Professor Gilbert's statement is clear: the UK is not well prepared to produce vaccines for the next pandemic. There is no co-ordination and no plan. There is no national capability. We have not invested in vaccine development, the infrastructure is questionable.

It is all too easy for people to forget not only the details and recommendations of inquiries, but that they happened at all. With that collective amnesia, it's then all too convenient, years later, when it becomes politically expedient or when a passing bandwagon needs jumping onto, for people to wring their hands and declare that nothing was done, and why has nothing changed?

We cannot afford for that to happen to this Inquiry. We are all working far too hard on this Inquiry for it not to have a lasting legacy, and it must not fall prey to that curse of collective amnesia in years to come. No one in this room, wants to see a parade of politicians grandstanding and basking in the reflective glory of the research communities in this country and giving themselves a pat on the back accordingly. No one can afford to rest on laurels, particularly laurels that quite frankly most have no business reclining on in any event. What is required are answers and explanations as to why we are in our current position, and why it is not optimum, and how, going forward, we are going to improve that effectively and expeditiously.

Peter Wilcock obo NI CBFFJ

There was no senior medical officer with responsibility for vaccines at the Department of Health in the run-up to the vaccination programme. Significant operational planning and management of the inevitable mass vaccination programme did not take place, until October 2020.

In 2020 Northern Ireland was without a centralised vaccination management system and had no way of centrally managing or evaluating vaccine uptake or distribution. When did those with responsibility note that significant absence and begin to react? What were the consequences of the fact that a VMS had to be developed in real-time during vaccine development and rollout?

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

Claire Mitchell KC obo SCB

Did we properly protect those most vulnerable by making sure they had priority access to vaccines when needed, especially those who had contact with hospitals and care homes, given what was known about hospital acquired infection? Was proper consideration given to the fact that large parts of Scotland are rural and Island, whether asking people to obtain to attend as a family might have assisted with numbers take and minimise financial implications of long travel to get to vaccine appointments individually.

Anna Morris KC obo Vaccine Injured & Bereaved

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

The vaccine rollout put everyone in the UK in a phase four post-authorisation trial. We were the the real world data. This made it imperative for the government and the to ensure that there was an effective system in place that was well organised and signal sensitive to monitor, detect, and treat any adverse effects. Adverse reactions were to be entirely expected. Therefore, it must have been clear when rolling out the vaccine to millions of people that there were likely to be vaccine-related deaths and serious vaccine injuries, however rare on a population level, that would require urgent identification, treatment and care.

Danny Friedman obo DPO

The rollout of the vaccines initially failed to prioritise disabled people, especially those under 65, with learning disabilities. Prioritisation categories did not fully embrace the care system. While there was consensus that frontline health and careworkers needed to be vaccinated early, what was not recognised early enough is that the frontline labour force for disabled people overwhelmingly comprises unpaid carers, informally employed carers, and personal assistants who are not necessarily registered anywhere. As a result, disabled people who lived at home, faced invidious choices about continued support by unvaccinated assistants. Conversely, if their carers also worked in care homes, they could sometimes be vaccinated long before the still shielding disabled person that they cared for.

The approach to prioritisation did not appreciate the triple jeopardy that disabled people faced during Covid.

- 1. that disabled people could die from the virus,
- 2. they could die or be seriously diminished in life expectancy because of lack of access to other healthcare or services, and
- 3. they could otherwise experience inhumane levels of social isolation when confined to their home or that vaccinated carers were not able to safely access them.

The DPO emphasised the need to think through accessibility to vaccines from start to finish, from how to reach out to someone to become vaccinated to what journey they will make to the site, what will happen there, and how they can be supported in their decision making. What instead occurred was the operation of multiple barriers affecting communication, appointments, physical and environmental accessibility, all of which could have been avoided if policies were co-designed with disabled people. Physical and environmental barriers for disabled people existed in accessing vaccination sites, with difficulties in leaving home at all without assistance, thereafter in reaching the sites and entering step free. Once in the environment of the centre, there were queues and waiting, various risk of sensory overload, and for deaf people, the combined problem of no BSL interpreters and staff wearing opaque face masks.

LTKC obo FEMHO

As this pandemic tore through our healthcare system, its heaviest toll fell on those who were already marginalised. It bears repeating: the first ten doctors to lose their lives to the Covid-19 were from the black, Asian or ethnic minority backgrounds. These disparities are not isolated. They are entrenched. It is both unsurprising and deeply troubling to see this same thread woven into Vaccines.

During the pandemic, clinical trials for the major vaccines showed a shocking underrepresentation in minority ethnic groups, for example, over 90% of the participants in the AstraZeneca trials were white. For the Pfizer vaccine phase III trials, almost 83 per cent of the participants were white. And the figure is almost 80% for the Moderna phase III trials, thus leaving significant proportions of our population unaccounted for when assessing the safety and efficacy of the vaccines.

Ethnicity specific data which could have been a vital tool for identifying disparities and tailoring interventions was either absent, incomplete, or inconsistently collected. Without it, governments and healthcare systems were flying blind when it came to understanding the unique vulnerabilities and barriers faced by ethnic minority communities. This failure contributed to the inequitable rollout where pre-existing disparities in healthcare outcomes were not just perpetuated but, in some cases, exacerbated.

Adam Wagner obo CVF

The lower prioritisation of therapeutics and prophylactics very likely caused serious damage and cost lives. Clinically vulnerable and clinically extremely vulnerable people were, rightly, amongst the first to be vaccinated but there were clinically extremely vulnerable people who are not automatically called for vaccination because they had not been recorded as clinically extremely vulnerable. A significant feature of the initial rollout of the Covid-19 vaccine was the use of large vaccination centres which were often not safe for clinically vulnerable people to attend.

Brian Stanton obo BMA

BMA wishes to rebut the criticism that it sought to take commercial advantage of the vaccination scheme. This offensive and unfounded criticism is based on a mistaken view that GPs had sufficient spare capacity within their existing workloads to deliver the largest and most complex vaccination programme in the country's history, right in the middle of a national health crisis. The reality was that the vaccination programme was additional work that general practice, already stretched to breaking point, delivered in the national interest, but which necessitated existing staff working significant numbers of additional hours and the engagement of additional staff, all of which needed to be paid for.

Mr Dixey obo Medicines and Healthcare products Regulatory Agency (MHRA)

MHRA has profound regret that anyone should have suffered adverse effects in association with receiving a Covid-19 vaccine or therapeutic. The MHRA recognises the serious suffering faced by those who now live with long-term injuries and by their families. No vaccine or medicine is without risk.

Estimated to have prevented over 100,000 deaths in the UK

The MHRA adopted a number of regulatory flexibilities that were crucial in facilitating approvals, and this included the rolling reviews of data, as and when they became available. None from these flexibilities compromised the rigour of scientific scrutiny of the evidence of safety, quality, and efficacy the MHRA's scientific standards remained unchanging and were in line with international equivalents. The MHRA's first priority is safety, with a core focus at all times on the balance and of benefits and risks of a medicinal product or vaccine.

Ms Domingo obo National Pharmacy Association (NPA)

Community pharmacy played a vital role in the delivery of the Covid-19 Vaccination Programme. Their teams have delivered over 42 million Covid-19 vaccinations. Community pharmacy should have been involved earlier in the planning, particularly given its years of experience in delivering annual flu vaccinations. It was a missed opportunity to ensure wider public access to vaccinations through the national community pharmacy network, particularly as some patients were being asked to travel considerable distances to receive a vaccine.

Vaccine hesitancy was not appreciated early enough and there was a delay in recognising the positive role that community pharmacy was able to play in addressing this. Approximately 50% of the NPA's membership are from ethnic minority backgrounds. Community pharmacies are trusted healthcare professionals at the heart of their communities and ideally placed to respond to the concerns to their patients, and to address health inequalities and vaccine hesitancy within communities.

Consider whether the creation of mass vaccination centres was a further example of a broader tendency to overlook existing NHS resource and expertise in favour of the creation of expensive temporary systems and services with little lasting utility.

Ms Drysdale obo The Scottish Govt

The limited use of GPs and community pharmacists to deliver the vaccine in Scotland allowed those services to focus on supporting the wider pandemic response and delivering essential primary care services. Rural health boards were able instead to vaccinate across cohorts, sometimes out of priority order, where it would make operational sense. The Scottish Government took the decision to vaccinate care home staff at the same time as care home residents. This led to higher uptake among care home workers in Scotland.

The Scottish Government undertook extensive work to address concerns around vaccine hesitancy while recognising there was a very small minority who would likely refuse any offer of vaccination irrespective of how much work was undertaken to improve vaccine Confidence.

Mr Riffat obo UKHSA

The successful deployment of vaccines against Covid-19 prevented over 100,000 deaths in the UK alone and they allowed for the relaxation of other control measures. NHS England has responsibility for the overall performance of immunisation programmes, including measures to address Inequality.

Four capabilities:

- 1. Sustained investment in research and development.
- 2. Strengthening partnerships between government, industry and academia. The work of the Vaccine Taskforce benefited from the willingness of decision makers to rapidly commit significant resource based on imperfect information and to take risk. Such conditions are unlikely to pertain in peace time and therefore UKHSA seeks to develop and maintain systems which can be scaled up in the event of a future pandemic,
- 3. Routine vaccination work in peacetime provides the bedrock from which to scale in a pandemic.
- 4. Surveillance of the real-world effectiveness of a programme and the presence of a robust system for safety monitoring are vital to both informed future policy and to sustain public and professional confidence in the programme.

Mr Hill obo Dept of Science Innovation and Technology (successor of BEIS)

The VTF was the idea of Lord Vallance, who identified the need for a dedicated expert and operational group with a single point of accountability to work on the vaccine response. It is not possible to have innovation without accepting the risk of failure. The risk was, however, carefully mitigated. The VTF deliberately adopted a portfolio approach to vaccine development to maximise the prospects of achieving its goal. The lesson to be drawn for government is of how to develop informed innovation and risk management in the future.

Welsh Govt

The vaccine rollout in Wales was overall a success. Wales managed to Vaccinate its population efficiently, equitably, and at pace. In order to ensure that vaccines reach the those in the greatest need first, the Welsh Government submits that a needs-based formula (rather than the Barnett formula) is needed to determine the allocation of vaccines in the future. There was simply no realistic possibility for this to be calculated, agreed, and implemented in the time available during the pandemic, but now is the time to revisit this issue as part of our preparedness for the next pandemic. The use of the Barnett formula created the potential for a vaccine shortfall in Wales because Wales had a disproportionately larger share of older people in its population who were a major part of the initial priority groups.

Helena Jean Rossiter - Member of the CBFFJ UK

My son Peter was 39 and was working as a teacher. He had his first dose May 2021. Everything was opening up at this time, people were allowed to gather but he was only then getting his first vaccine despite being a keyworker who was looking after the children of keyworkers who were in contact with the virus and the children were known to be carriers. he only received his 2nd dose 8 weeks after the first. I was really very concerned because the manufacturer Pfizer said the second should be within 3 weeks.

Peter always kept himself fit, and he followed the rules. We all did. And it just seems to us, as parents, is that we did everything right, and yet Peter lost his life still. As did so many of similar families who were in our group, and I believe all of our families really deserve to be heard, and for those cases to be taken into account.

Melanie Newdick obo SCB

We had the situation where people missed their opportunity to get vaccinations because they were in hospital, which seems incredible. If we had another pandemic tomorrow, would our system be able to deliver vaccines at the pace that we did previously? At the minute, the data seems to say that it can't.

In Scotland you cna no longer get your vaccination form your GP. The vaccine uptake in the Highlands is now half the rate comparing it to what it was when GPs provided that service. We raised concerns about having to take vulnerable person to vaccination clinics. The centralised system doesn't work for a remote rural community. Who is going to drive 220 miles to get a vaccine? We need a system that's going to work for the population that it serves and not a central one size fits all policy. Our system in Scotland currently has put an extra barrier for people because they can no longer go to their GP and have a chat with them.

The Scottish Government got in members of the public to talk to them about redesigning the new system. They deliberately excluded anybody that was vaccine hesitant saying that they felt they had nothing to add to the process. If we'd built this this new process around these people, it would have worked for everybody else as well.

Fiona Clarke obo NI CBFFJ

Family members who were vaccinated were not allowed to visit their loved ones in care homes but people who were working there haven't been vaccinated. It was so hard to get my head round that.

There's parts of Northern Ireland that are quite rural, and there are people who are immobile. They should have had a doctor on call to go out and administer the medication, administer the vaccines. It would have been so much more helpful.

Anna Miller - Migrant Primary Care Access Group (MPCAG)

Around 15% of the UK population is foreign born. The precarity of their situation is exacerbated by insecure immigration status that often prevents them from working legally so they end up working in dangerous and exploitative conditions. Digital exclusion is entirely linked to poverty and lack of resources. It's not having enough money to put data on your phone. It's relying on public access open wi-fi networks all the time, which of course, closed during Covid. So the digital poverty that exists in the first place, was enormously exacerbated once public spaces and public wi-fi closed down.

NHS charging decisions are designed to be a deterrent. The risks associated with the policy are high. It's not just that you're going to get a large bill, you also 50% fine for accessing that service. It also carries the risk of being reported to the Home Office which runs the risk that you well be put into immigration detention and for some people it runs the risk that you'll be returned to a country that you fear for your own safety in. The UK is an outlier in terms of the extent to which people are charged and punished for accessing NHS services,

Sam Smith Higgins - CBFFJ Cymru

Father was diagnosed with prostate cancer. Admitted on 5th Jan . I asked there and then if he could have the vaccine, and I was told no. when vaccinations were introduced, the focus was on keeping healthcare workers working. It wasn't about saving lives or saving people like my dad, who were going into what was and still is the most likely place you'll catch Covid, which is a hospital in Wales. He sadly died on 26th January. We received a letter following his death inviting him to attend for vaccination.

Ruth O'Rafferty - Scottish Vaccine Injury Group

The aim is to raise awareness of vaccine injury because there are many people doubt whether the vaccines cause injury. There's an element of fear there that if you speak out against the vaccines you're going against a societal or cultural expectations that the vaccines are wonderful.

Safety was sacrificed for speed. A lot of our members were not given a leaflet until after they'd received their vaccination which means they didn't really give informed consent. They didn't know what they were

consenting to. We now know the level of damage and the breadth of injury that can result and these are not listed in the leaflet.

Vaccine Damage Payment Scheme. How can you prove you're 60% disabled when your condition fluctuates from day-to-day. A lot of us are neurologically impacted so we find it difficult to communicate and we have some people who are so badly injured that they can't actually write so it is difficult to even complete the form.

Kate Scott - Vaccine Injured and Bereaved UK (VIBUK)

Everyone in our group has medical confirmation that their injuries or the death of their loved one was caused by the vaccine. Our central aim is to achieve reform of the Vaccine Damage Payment Scheme (VDPS). The scheme is inadequate and inefficient, it offers too little, too late, to too few.

It is accepted that no vaccine or medicine is a 100%t safe, therefore there should be a fair compensation scheme and the government should have plan for that. Knowing there would be injuries and deaths we should have got the help and support and the financial compensation to be able to continue to live our lives.

Members are deeply concerned about the time taken to process claims. As of 30th November 2024, the 17,519 claims have been submitted to the VDPS.

- Only 194 of those have been notified that they're entitled to the payment.
- 416 people have been told that they are unsuccessful because although causation is met, they are not "disabled enough."
- 1,027 people are still waiting 12 months later
- 438 have been waiting for 18 months
- 126 are still waiting nearly 3 years later for the outcome of their claim.

A percentage disablement is also somewhat offensive. There's no compensation if you fall below that. Someone in our group was told they were only 20% disabled. It took another year to do the mandatory reversal and they were told "Oh, actually, you're 90% disabled, congratulations."

If you did something that the state told you was safe and effective and that wasn't the case, there should be fair and adequate compensation, that's on a sliding scale of the impact.

Earlier action and clearer risk communication could have saved lives. People within our group called ambulances three times to be told it was a migraine, it was only on the fourth when there were seizures they were taken to hospital and that was because the risk and framework had not been communicated to everyone, or you were not even allowed to suggest that vaccines caused injury and bereavement.

Kamran Mallick Disabled People's Organisations (DPO)

22-23% of the population are disabled so we are talking about 14 million people. Yet disabled people are often unseen and unheard, we don't have access to power, we often don't have representation in government. In places where decisions are made where legislation is written, where guidance is designed. And therefore, those spaces have a complete absence of our lived experience of what it's actually like to live as a disabled person in our country. And so without that knowledge and information, decisions get made with ableist thinking. So we have blind people not receiving letters not in braille, people with learning disabilities not receiving letters in easy read, deaf people receiving phone calls etc.

When creating the prioritisation list, they were making decisions based on their medical understanding, but they were taking no account of how someone who had an underlying health condition would be at risk of potentially worse outcomes. Therefore a lot of disabled people weren't included in the clinically extremely vulnerable list who would still have had particularly poor outcomes had they have caught the virus.

People with learning disabilities don't label themselves in that way so they would not know which category they fit into. People with Down Syndrome were at risk of worse outcomes from catching the virus. That was well known but those individuals were not prioritised, and this all comes back to a lack of input from our kind of organisations into the decision-making process.

The cancellation of the Evusheld contract is a particular disappointment because of the success rates that it was showing. The impact is that those individuals who can't have the vaccine have to continue shielding. They, while the rest of the country got out and went back to a level of normality, those individuals' lives couldn't change. They had to continue to isolate but without any of the support systems that may have been available to them during the height of the pandemic.

Dr Salman Waqar (Federation of Ethnic Minority Healthcare Organisations)

There was an inexcusable paucity of accessible communications about the vaccines and how to access them. Much of the misinformation had kernels of truth so how do you disentangle the truth from the misinformation?

We have found it a concerning and consistent issue, that the issue of racism is one that is just not discussed. We seem to skirt around it, we are still quite squeamish about it. Our lack of ability to be at these top tables to make some of these decisions means that we are not able to bring relevant information into those spaces.

Terminology about communities being "hard to reach" externalises the problem that it's not us that needs to do more; it's those communities that need to do more.

Terms like "vaccine hesitancy" when describing a very logical decision. We should be hesitant because of what we've experienced. It's actually an issue of confidence. If you are experiencing bullying, harassment in your place of work because of the colour of your skin, and on top of that you've experienced an excess death amongst your co-workers and every time you raise you voice to ask for more inclusive things for our communities, you're shut down. Then you've decided not to take the vaccine on the basis that you

haven't got the confidence with the trials and concerns about side effects and you're told you're going to lose your job.

Yvonne MacNamara (The Traveller Movement)

The NHS has failed simply these communities because the trust wasn't there, the visibility wasn't there and the communication wasn't there so you can't build the ark when the flood is happening. So if you want to develop those local commissioning services and you are serious about addressing health inequality for a community you have to know who is in your local community, you have to know your local demographics.

Lara Wong (Clinically Vulnerable Families)

Airborne transmission of this virus is a huge problem for us, and it goes into all areas-off life. At vaccine centres we were concerned about the quality of air, the lack of ventilation, and the lack of proper masking.

Evusheld was more similar to a vaccine as it was a prophylactic so preventative rather than post infection treatment. So it would have levelled the playing field for these people who cant have the vaccine. It would have given them the freedoms had other people received through their own vaccination. The consequence of not protecting this group was phenomenal in terms of their mental health, in terms of their social connections, in terms of their general ability to reengage with the rest of the world.

This is a group of people who, through no fault of their own, and through the lack of the government's action to find or procure this treatment, left them essentially locked up without any route out, and these people still live today with these same issues, still with no opportunity and no other thing other than waiting to be infected and then having a treatment and hoping that it's effective for them.

Matt Hancock (Former Secretary of State for Health and Social Care, UK)

Both the vaccine and therapeutic programmes were incredibly successful and saved an enormous number of lives, allowed us to come out of the lockdown. That capability has degraded very significantly since the pandemic. It is hard to know why. think it's a combination of the pressures on the NHS the day-to-day pressures, meaning that the priority of clinical trials is lower when there's so much immediate challenge. There is definitely a funding issue that needs to be sorted,

Many learning difficulties and disabilities are defined educationally, so that becomes a piece of data in a persons' education record, not in their health record. It's a very complicated area and could do with a huge amount of improvement.

We put a huge amount of effort into increasing vaccine update. I kicked off a piece of work in June or July 2020 trying to really understand how you could drive up take-up. The central insight was that you just

can't think of people who are distant from the state as "hard to reach." You have to think of the state being far away from them, you've got to see it from their eyes. There are many communities where there is just not the history of relatively high trust levels. The single biggest determinant of the likelihood of a community who may be more hesitant than the general population to take the vaccine is the ethnicity of the vaccinator. If you put a vaccine centre into the local mosque, then you get the pick-up on the Muslim side.

Professor Heidi Larson (Expert, vaccine hesitancy)

Schemes of vaccinations as a condition of deployment worked in Western Europe for the purposes of driving vaccination rates upwards in the short term. But in the long-term, it was a trust breaker. People did not take the vaccine because they were confident about it, they took it because they wanted to travel, go to that restaurant, to meet with friends. They resented the fact that they had to get it, but they did it because it allowed them to do things they wanted to do. But they resented it and that's where sentiments hardened. That contributes to a general growth in vaccine hesitancy or lack of confidence.

There were protests. It looked like they were against vaccines but they were against the requirement. This mandate hardened some people because they felt like they weren't trusted. They're working 247, and now you don't trust us to make up our own mind. It took a toll. People did leave their jobs because of this.

There are vaccine requirements for some healthcare workers, particularly hepatitis B. I think personally, I think that people who work in settings with very vulnerable person should have their vaccines. I think people sometimes look at the mandates as requiring it for you as an individual when in fact it's about protecting others. It's about putting other people at risk. In terms of human rights and responsibilities, you have your rights and your personal freedoms until they harm other people, and then you start to move into responsibilities. This is not just about you.

It was clear in advance that that there would be issues of vaccine hesitancy and it was something the Govt would have to address. There were clear pre-Covid issues in some of the same groups we were talking about before Covid, and those were predictable as being challenges.

The Rt Hon Lord Alok Sharma (Former Secretary of State for Business, Energy and Industrial Strategy)

The reasons the Vaccine Taskforce worked as effectively as it did, was because Kate Bingham had the right scientific skills but also her private sector knowledge. Secondly, she reported directly to the Prime Minister; that link to the centre was very important. Finally, I think the VTF worked because we were able to make rapid decisions particularly on funding.

Kate Bingham said one of the reasons the VTF worked is because there was a venture capital mindset. I think she's right about that and perhaps we should have more of a venture capital mindset in government. But you don't want everyone in government to have a venture capital mindset because you're talking about public money and the need for accountability. It is very clear that one of the primary drivers for the VTF's success was that their approach to procurement was at risk. They were prepared to tie the government into paying in advance for manufacturing capacity, in advance of the clinical trials.

Vaccine Manufacturing and Innovation Centre, VMIC.

The expectation was that the centre would be built and be opened by June 2021. In December I was asked to approve in principle another £47 million. I delegated that to Nadhim Zahawi, who was the vaccines minister. I supported it. I thought it was very important that we build up manufacturing capacity, not just to deal with vaccine manufacturing during the pandemic but for the future as well. If I had still been in post, I would certainly have asked a lot of searching questions as to whether or not it was right to sell this

Clara Swinson (Former DG for Global Health and Health Protection, DHSC)

We led the preparation for and facilitated the deployment at scale, authorisation and approval for vaccines. On prioritisation we responded to the advice of the independent statutory body, the Joint Committee on Vaccination and Immunisation (JCVI). The JCVI recommendations were concerned with Prioritisation not authorisation. the Secretary of State agreed, to give real weight to anything that the JCVI said on the issue of Prioritisation. JCVI did not consider cost effectiveness because the vaccines had already been procured.

NICE assesses drugs and makes a cost effectiveness judgement and asks the NHS to make them available. RAPID C-19 did that job during the pandemic and recommended which therapeutics should be made available to the NHS.

<u>Authorisation::T</u>he rigour was exactly the same, it was the speed that meant instead of waiting for the entire bundle of information to come which would take weeks or months, the MHRA assesses the information as it was given to them. A rolling review, which meant that by the time the final phase III trials had been completed, they'd already looked at what had come earlier. It was exactly the same level of scrutiny and data required for it's assessment of safety and effectiveness.

The MHRA assessment is both laboratory data and trials in humans. When they come to authorise, they set out any precautions in the patient information leaflet. They also do regulatory checks at the manufacturers, testing each batch of the vaccine before it comes on to the market take sure that what is being provided is as they were set out on paper. After deployment, they do surveillance and monitoring of any side effects that are reported so that they are able to amend any of the conditions under which they've marketed the product.

DHSC did receive advice on the prioritisation from MEAG (the Moral and Ethical Advisory Group). The assessment of the clinical vulnerability was that age was by far the biggest predictor and so therefore for people in different occupations, different settings, they would have access to the vaccine according to age order, unless they had a health condition that put them in priority groups four or six of the JCVI. Care home workers and healthcare workers had been considered and were prioritised in groups 1 and 2 from the start.

Catherine Little (Former Second Permanent Secretary, HM Treasury)

The principles of the managing public money framework were consistent throughout. We didn't change the framework in any way, but we did apply a much higher level of risk taking. It was highly unusual, but our overwhelming advice was that it was right to take a much higher risk approach, because of the benefits to public health and to the economy were so significant, it outweighed any of the initial risks. So we advised the Chancellor to invest in all vaccines that proved to be promising and to explore every single opportunity at this stage.

The Treasury sought explicit ministerial consent in respect of indemnities. We took the view that we had to take exceptional risk in order to secure those commercial arrangements quickly and ahead of global demand. It's highly unlikely that we would have been able to secure those contracts given the pace of demand on a global level, and pace and risk taking were key in the success of the commercial arrangements.