Module 4 Week 3

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Darius Hughes (General Manager, Moderna Biotech UK)

Clinical trials for the Moderna vaccine, had to meet the same requirements and approvals as if conducted in non-pandemic circumstances. No safety concerns were identified. There has been no unexpected serious adverse reactions during the trials. The stringency was as it was for any other application. Myocarditis and pericarditis were monitored as adverse events within the clinical trials because it's a known risk of vaccines, but it was not observed.

As of May 2021 there were 19 reported cases of myocarditis among people who received the Moderna vaccine, and an additional 19 cases of pericarditis. That was out of a total of approximately 20 million doses of the vaccine that had been administered by that point.

Assessing the safety signal in relation to myocarditis and pericarditis is complicated by the fact that Covid-19 can cause those conditions itself. Product information was updated in relation to Moderna on 25th June 2021 to state that myocarditis and pericarditis were noted as "very rare." "Very rare, may affect up to one in 10,000 people.

Rt Hon Kemi Badenoch (former Minister of Equalities)

Being in the Treasury at the same timed I was equalities minister was quite helpful because I could use some of the Treasury levers which I would not have had if I'd just been in a totally separate department. Should we have had someone who was exclusively focused on equalities and that nothing else? I think that the disadvantage would be they would have no levers. They would purely be in an advisory role.

Data was the biggest challenge. You didn't know whether there was something to see, and we couldn't find it, or there was nothing to see. Then there was the issue of people having data, but not wanting to share it. Trying to find out the ethnicity of people who had been dying, especially the frontline ethnic minority workers in the NHS. We didn't have that.

I had very real concerns about the VCOD policy, I had meetings with the BAME Communities Advisory Group, where they were concerned about people leaving the workforce rather than taking a vaccine. That would have been quite damaging for social care settings in particular, because we needed those people to carry out the work. there was also a concern that if people were not vaccinated, they would be at more risk of getting Covid and passing to it very vulnerable groups. So, it was about balancing those two very serious risks and working out what the best outcome would be.

Rt Hon Nadhim Zahawi (former Minister for Covid-19 Vaccine Deployment)

The PM wanted me to lead on vaccine deployment if a vaccine became available. An enormous amount of work had taken place, and a deployment strategy was pretty much in place. We always knew the challenge was that we had limited supply. How do you make sure that you have fair equity and protect as many people as quickly as possible? the JCVI looked at every factor that the virus impacts on the human body, and the evidence is age was the dominant factor as to whether you get severely impacted.

The mRNA vaccine needed storage at minus 74 degrees, and when it was broken into smaller packs to get to the frontline, the fragility and the ability to store, and therefore deploy, was a huge constraint.

We were building the plane while we're flying it. data sharing became better, but if you're going to try and design a data system by engaging with everyone whilst you've got a virus ripping through the nation, you just don't have time.

Dame Emily Lawson (Senior Responsible Officer for the Covid-19 Vaccination Programme, NHS England)

We had to transport the vaccine at minus 70. Minus 70 is not a standard way to transport medicine so there wasn't an established supply chain to do that. The only place we knew in mid-November that had minus 70 freezers were hospitals, but JCVI had defined the cohort most at risk were care home residents.

At the middle to the end of November it became clear the national vaccine appointment booking system would not be ready until January so we would have had no way of booking people into a mass vaccine centre. Also, the national protocol would not be ready until around Christmas Eve. Vaccination centres could not have safely vaccinated without the national protocol.

On 8th December, two incidents of anaphylaxis were reported via the Yellow Card system. Anaphylaxis was a serious but not unexpected reaction to a vaccine. A decision was made that it was safe to continue the programme, but that we should introduce the 15-minute wait post-vaccination to ensure if something was going to happen, it happened on site, not when somebody was travelling home.

No one appears to have been clear on who should be offered a vaccine on account of suffering from a learning disability because there was a lack of data. The registers for reporting learning disability were not entirely accurate, and no one appears to be quite clear as to what degree of learning disability one would have to suffer before one would even get on to the register. We were lucky in England that we had a Learning Disability Register to start off with. I don't think that was the case in the DA's. Down's syndrome moved from cohort 6 to cohort 4 because further data on morbidity came through. Had we had the complete register to start with, we'd have been in a better position, but I think we had a decent starting position, and we worked really hard to improve it.

We didn't start using pharmacies in Vaccine Taskforce to start with for scale and complexity reasons. By the end of the relevant period just under, 21% of the Covid vaccines were delivered in pharmacy. The role that pharmacy played in vaccination, particularly in areas which are underserved by both primary and secondary care are absolutely vital.

Derek Grieve (Senior Responsible Officer for the Covid-19 Vaccination Programme, Directorate for Health and Social Care of the Scottish Government)

We didn't use primary care (pharmacists or GPs) extensively, because of some of the constraints with the vaccine. They came in large trays of 975 doses and in Scotland and none of the GP practices had the ability to use them all within the very limited amount of time that the Pfizer vaccine in particular had to be used, without a high level of wastage.

Decision made not to offer vaccination to all over 80 years old in the first phase with the the exception of those who are care home residents. We had a policy of vaccinating care home workers at the same time as the care home residents. It was a very pragmatic decision and made sure there was minimum wastage. There were times where we weren't sure the JCVI understood the complexity of differences in Scotland eg a different academic year. Carers may be another example.

There was no single register of unpaid carers and local data was patchy. There were some unpaid carers who were in receipt of benefits, and we used that data to identify and target them for invitation. Those who were not in receipt of disability benefit or benefits, then there was no way for us to immediately identify them and so we move to a self-identification model.

There is not a Learning Disability Register in place in Scotland. JCVI advised that we should, but I don't think we have one yet. We took a liberal definition of "Learning disability".

Professor Dr Gillian Richardson (Senior Responsible Officer for Covid-19 Vaccination Programme, Welsh Government)

We had our own Vaccine Clinical and Prioritisation Group so that if the JCVI guidance needed further interpretation to operationalise it, that group could be consulted. We also sometimes made our own decisions on vaccine safety, for instance we did not suspend the 15-minute waiting interval for clients under 16 and with learning disabilities or those in whom there may not be capacity to understand an anaphylactic reaction.

There was an inequity gap in uptake between people who lived in the most deprived communities in Wales compared with those who lived in the least deprived communities. The vaccination uptake gap was even starker in those from Black, Asian and other ethnic groups. These disparities were foreseeable, because we had seen them with our influenza programme for adults as well.

Building up trust outside of a national crisis is a precursor to good healthcare. It's very difficult to fix in a crisis what is damaged in peacetime, because you do not have the luxury of time to build up relationships. So we tended to use our trusted community leaders and networks, our disability forums, our black and ethnic minority engagement groups and out of that grew the Vaccine Equity Committee.

We decided to take a permissive approach. Our minister was at pains that no one was to be left behind, and it was very difficult to strictly define who was severe or profoundly learning Disabled. It captured anyone that we could identify as having a learning disability, and we knew that even for those with mild to moderate, there were much poorer health outcomes, for instance, just generally in terms of their healthcare.

Yellow Card Scheme works in peacetime. I think in a crisis, we needed a more enhanced active surveillance. The problem is that many members of the public are not aware of the Yellow Card Scheme, and junior doctors in training are told about it but may not be experienced in its use.

Dr Naresh Chada (Senior Responsible Officer for Covid-19 Vaccination Programme, Northern Ireland DCMO)

Supplies were coming in slowly, so we were focusing on targeting those that were most vulnerable, particularly the residents of care homes and the staff that were working there.

We did not have a single Vaccine Management System in Northern Ireland so that had to be commissioned and put together at pace, which we did. We are in a better position now. It was operational from day one of our program on 8th December.

Peter WIlcock on behalf of NI CBFFJ

Q: Clear contradiction in allowing unvaccinated care home workers in care homes whilst refusing visits from vaccinated family members?

As SRO for vaccine delivery, the visiting policy was outside my remit. Every attempt was made for the visiting policies to be as humane as possible and to consider not only the care of the visitors but also the need for that social contact to be there for the residents.

Dr Tracey Chantler and Dr Ben Kasstan-Dabush (Experts, vaccine delivery and disparities in coverage)

There was a limited supply chain, particularly at the beginning so it had to be guided by the severity of risk. Guidance was indicating risk increased with age. That's why they had to be the priority cohorts. There might be lessons to learn from other jurisdictions that did do this based on occupation, but I think the age descending approach was the most appropriate and responsible course of action.

In England ultimately the Learning Disability Register was used as one resource but obviously that is not in operation in the same way across all four nations. The social care system in England is incredibly fragmented, broken up across lots of different services and sectors, so the ability to identify a cohort of social and care workers wasn't there.

In Scotland a different approach was taken of offering care home residents and their carers working their vaccination at the same time which has real operational benefits for protecting two priority cohorts. There's lots of learning on that approach. Northern Ireland took a very novel twin-track approach whereby different priority groups could either go to the trust or to the GP surgery at the same time.

In the white population groups, we were up to 97% vaccination. We did not reach that threshold level in all marginalised communities. We cannot be complacent. We must be continuously promoting uptake of vaccinations.

Sarah Moore (Solicitor re VDPS)

The Vaccine Damage Payment Scheme is not fit for purpose so people who are vaccine injured and bereaved are now being forced to take on the might of vaccine companies and the British Government. The scheme was intended to provide prompt support, but people have been waiting 12, 18, 24 months.

Obtaining medical records has been a problem that the medical assessment panels have experienced. Some of the people making these applications to the Vaccine Damage Payment Scheme are bereaved so they are making this application with the benefit of a confirmed death certificate which will say that the vaccine has caused the death. It's very difficult to understand why somebody should be waiting 18 months for a medical assessment panel to decide about causation. In the UK the acceptance rate of claims is 2% which is the lowest in the world.

Lord James Bethell (former Minister for Technology and Life Sciences)

The success of the vaccines programme is something that we can celebrate but the therapeutic programme didn't have the same profile because it wasn't on TV every night. I think it's an unsung success for the UK in many ways. The fact that it wasn't on the front pages of newspapers doesn't mean that it wasn't focused on by the government and the NHS.

We were one phone call from disaster; we just needed to know about a clinical trial that had gone badly wrong, and then we would have to go to plan B, so the therapeutics were very much seen as plan B. Secondly, the vaccine might not have worked for everyone, so for some people, therapeutics and antivirals were going to be very important.

I fear that clinical trials in the UK have fallen back in quite a worrying way since that moment of energy.

The big problem with antivirals is you need to give them to people before they show symptoms, the moment they test positive. I felt that within the NHS we could have been more creative about test trace and treat, giving people antivirals prophylactically and having them available for moments of outbreak. There are ways of trying to use data and home diagnostics to spot people much earlier on, and to knock it out before the symptoms emerge. That is the way that medicine is going. For our health system to be up to date and ready for the next epidemic, it's worth us thinking today about how we put in place those kinds of mechanisms.

We didn't have a 'What do we do with the immunocompromised' plan at the very beginning so we were putting these things together after the fact.

Cost did not arise as an issue. We were given everything that we needed to fight the virus. Recommendations from the CMO and others were based on clinical evidence, not on economic evidence. That said, cost isn't just a pound, shilling and pence. There's an opportunity cost in terms of how do you prioritise healthcare resources, which were extremely limited? So I wouldn't say that resources in the broad sense weren't a consideration.

The Therapeutics Taskforce did not have a blank chequebook. It was the big distinction between the Vaccine Taskforce and the therapeutics. One of the reasons for that is the therapeutics and antivirals work in different ways in different circumstances. Putting taxpayers' money at risk for that complexity of procurement wouldn't have made sense.

Frustratingly, I think we are in worse shape today than we were 5 years ago. The NHS is clearly under a huge amount of pressure in terms of capacity, the workforce is under pressure and there's been a drop-off in recruitment. International surveillance of viruses is not where it could or should be. UKHSA, should be a national agency with heft and resources, and I'm disappointed that it has been denuded in the way it has been. Local Resilience Forum remain a shadow organisation rather than something with strong local reach. There is a dozen of these areas where we should have learned the lesson, but we simply haven't moved forwards.

Eddie Gray (former Chair of the Antivirals Taskforce, DHSC)

A very early position was adopted that if you could find effective vaccines, as a population intervention, they were likely to be the most effective response to the pandemic. With antivirals, there are different ways in which they can be employed. You can utilise them in a broad population basis, possibly prophylactically, where the goal is to interrupt transmission, to clear them of the virus and to stop them passed it on to other people. Alternatively, you can hold it back for certain people in the population who are more badly affected by the virus.

I was approached in March but not appointed until June. That delay was 25% of the available time. I found out afterwards that the Permanent Secretary at the time was advocating not to have an external chair.

There was a mechanism for approval of financial decisions but the speed at which we were moving and buttressing up against what I think was a poorly calculated initial budget, meant that we moved to different mechanisms of trying to get decisions made. The frustration I was starting to feel was about the decision-making process. I was concerned that the process of constant reiteration meant there was a potential trade-off between public health goals and affordability goals and decisions ended up being made by junior civil servants. I was observing a clear power imbalance. I could see officials in the Department of Health and Social Care starting to undermine their own argument for the recommendation we were making before we'd ever had the proper discussion at the right level. The only way to sort that was to step out of the system, bypassing the normal practice to get right to the people to make the decision.

Professor Sir Munir Pirmohamed (Chair, Commission on Human Medicines)

The Pfizer vaccine had been authorised on 2nd December and rolled out on the 8th. On that first day there were two reports of anaphylaxis. Anaphylaxis is an adverse event which occurs very soon after the administration of the medicine such as a vaccine. We felt that the vaccine was probably responsible, so we changed the drug label, the product information the patient information leaflet and introduced the 15-minute waiting time after Vaccination. That was done overnight.

When you have a 15-minute waiting time you need more space in the waiting room, and your throughput goes down. We discussed all the risks associated with that 15-minute period, particularly with people in a small waiting room, and the increased risk of transmission, but also the reduction in throughput. We felt it was important for the safety of the people who were being vaccinated. As we got more data, we were able to relax those 15 minutes.

in February 2021, the MHRA first started to receive Yellow Card reports of suspected thrombosis and associated thrombocytopenia. those reports were associated with the AstraZeneca vaccine. This is extremely rare condition that occurs. Covid itself can cause thrombosis, thrombocytopenia and both together. So, it was important to be able to understand whether it was truly vaccine related or related to the underlying disease.

Austria, Norway, Iceland, Italy, Estonia, Latvia, Luxembourg, and Lithuania all suspended the deployment of AstraZeneca. The vaccination practices were different in those countries, compared to the UK. They were vaccinating different age groups. We were focussing on the vulnerable groups, whereas some of the European countries were using AstraZeneca in the younger population. Some of the EU countries which were able to stop the AstraZeneca vaccine will have looked at what other vaccines were available to continue the vaccination of the population.

Professor Nicholas White (Expert, Therapeutics)

Overall, the UK was very strong in clinical research. The weakest part was measuring whether it works in people. There was a large number of small, inconsequential trials, which could never have answered did the drug work or not? We needed a better method and that was not developed. When you have a very large benefit, you do not need many people to be studied to show that very large benefit. But when you have a relatively small benefit, for example a reduction in the death by 20%, you need very many people to show that with confidence. In general, the clinical trials are too small.

The science of trying to understand how much of a drug needs to be given is one of the weakest parts of the drug development. It requires innovation, and, in in general, the regulatory authorities who ultimately make the decision whether a drug should be registered, are fairly conservative.

Diversity is a very important point. When you go to the larger, definitive phase III trials, you do need to proactively engineer diversity. But in the context of a rapidly evolving pandemic which is killing lots of people, speed is paramount, and that speed benefits the diverse population. Getting to an answer more quickly, is more important than having diversity which might slow down the recruitment to the trials.

Helen Knight (Director of Medicines Evaluation, National Institute for Health and Care Excellence)

Role of the centre is to undertake evaluations of new medicines and review of the clinical effectiveness and the cost effectiveness and to provide guidance to the NHS. A standard appraisal usually takes about 44 weeks.

We adapted established RAPID-C19 in April 2020. That stands for research to access pathway for investigational drugs for Covid. RAPID-C19 process didn't consider cost effectiveness. Ultimately, it was for DHSC to decide whether to actually go ahead and provide access to the drug.

The main concern with Evusheld was whether it was effective against the Omicron variant. Although the trial data would show there's clinical protection, we couldn't be sure whether the same level of protection would be seen in clinical practice when different variants were circulating. We were very aware that we were discussing a prophylactic medicine for patients who had a high unmet need but were also very clinically vulnerable and were shielding at the time. We wanted to make sure that we had a high confidence that the treatment would protect this clinically vulnerable group and we didn't see the evidence to say that it would. At no point did we consider the cost effectiveness in our advice to the CMO.

Dr Clive Dix (former Chair of the Vaccine Taskforce)

The UK didn't have any infrastructure or thinking to build a vaccine portfolio at the start of the pandemic. Right from the outset, Kate and I sat down and talked about how can we be the first? What's it going to take to make the vaccine industry come here rather than go to America, for instance?

The UK is in a weaker position now than it was prior to the Covid-19 pandemic. We have less resilience now and have failed to learn the lessons from the pandemic.

VALNEVA Contract

It was cancelled because trial data suggested the Valneva vaccine would be ineffective as a booster dose. The data they used to make that decision was poor. It wasn't a full study, and it was done in a rush to get booster data because they wanted to boost by the end of the year. It was putting a vaccine through a test that was going to be negative. A phase III study of 6000 people was about to report. That study showed the Valneva vaccine was better than the AZ vaccine. I don't believe any experts were part of that analysis. I know all the experts, because I worked with them, none of them were consulted. The people that knew the vaccines inside out and were part of the people that you would consult when you made big decisions, and none of them were ever consulted on this decision.

<u>VMIC</u>

VMIC was sold in April 2022, and that's subsequently been mothballed. That had a serious negative impact on the UK's ability to develop and manufacture vaccines at speed in the face of a future pandemic.

The UK Government does not have to invest in manufacturing. What we need is the ability to have really good relationships with the pharmaceutical industry, show them what the UK can offer, and encourage them to come here and do their research, development, clinical trials, and then have manufacturing as part of their remit in the UK. Then you've got manufacturing, but it's run by them, it's paid for by them, and the government can just be there incentivising and understanding it, not trying to run it.

I do share a concern that others have about an overreliance on mRNA technology when it comes to vaccines. It's far from a perfect vaccine, the cold chain is terrible and storage is difficult. The duration of these vaccines isn't great, after six months it seems to wane. Resilience for a pandemic will not come from just having mRNA. We don't know what virus is coming but if it's a virus that we haven't done a lot of background research on, an mRNA vaccine won't work.

The reason we had Valneva is that it is a live, inactivated virus. If a virus comes along that we don't know a lot about, all we've got to do is grow it, then we can start manufacturing it as a whole virus and then just inactivate it. It may not be a future sexy technology, but it works. There's nothing wrong with it, it's just old fashioned and people don't like old-fashioned, but it works.

EVUSHELD

I feel most of the reasons given for not going ahead with it are excuses, and the actual reason that it wasn't purchased was cost. The argument about shelf life is an error. You don't get a medicine of any type into your hands until it's approved. And once it's approved, you agree a delivery schedule to have it at the rate that you can use it. So that just isn't an argument.

The argument about having to give it over and over again is wrong. This anti-body protected people for six months, and we were talking about buying enough to give people two doses to get them through this early stage of the pandemic and free them from a lockdown. There were some discussions about it being difficult to deliver to the patient and they needed specialist clinics. It was intramuscular; it was an injection into the bum. So these arguments sound great, but I honestly don't believe they're valid at all.

Our members of the Vaccine Taskforce were asked to participate in podcasts and Zoom meetings with various ethnic groups to help disseminate understanding of vaccines. This was frowned upon by HMG comms [the government communication centre] and eventually stopped. In my opinion, this was wholly short sighted. There wasn't a national reason. It was paranoia, I think.