HOUSE OF LORDS

Childhood Vaccinations Committee

Corrected oral evidence

Monday 22 June 2026

3.15 pm

Watch the meeting

Members present: Baroness Walmsley (The Chair); Baroness Andrews; Baroness Browning; Baroness Cass; Lord Dholakia; Baroness Freeman of Steventon; Baroness Hodgson of Abinger; Baroness Neuberger; Lord Randall of Uxbridge; Baroness Ritchie of Downpatrick; Baroness Wyld.

Evidence Session No. 16 Heard in Public Questions 184 – 193

Witnesses

I: Professor Wei Shen Lim, Chair, Joint Committee on Vaccination and Immunisation; Professor Shareen Doak, Deputy Director, Benefit-Risk Evaluation I, Medicines and Healthcare products Regulatory Agency.

USE OF THE TRANSCRIPT

1. This is a corrected transcript of evidence taken in public and webcast on www.parliamentlive.tv.

Examination of witnesses

Professor Wei Shen Lim and Professor Shareen Doak.

Q184 **The Chair:** Welcome back to today's meeting. This is the 16th oral evidence session as part of the committee's inquiry into childhood vaccination rates in England. Thank you very much to Professor Wei Shen Lim and Professor Shareen Doak for attending today to give us evidence.

The session is open to the public. It is broadcast live and will subsequently be accessible via the parliamentary website. A verbatim transcript will be taken of the evidence and published on the parliamentary website. In order to get it absolutely correct, a few days after this session our witnesses will be sent a copy of the transcript to check for accuracy. It would be very helpful if you could both advise us of any corrections as quickly as possible after today. If, after this evidence session, you would wish to clarify or amplify any points you make during your evidence or have any additional points that you would like to send us, you are very welcome to submit supplementary written evidence.

I am going to ask the first question. How safe and effective are the vaccines in the routine childhood vaccination schedule in England? What is the evidence on links between routine childhood vaccinations and any adverse events? How does the safety of routine childhood vaccinations compare to other medicines and vaccines, and to people who have not been vaccinated?

Professor Shareen Doak: Thank you, Chair and members of the committee, for the opportunity to provide evidence today. I am a Deputy Director in Benefit-Risk Evaluation, which sits within the safety and surveillance function of the MHRA, which is the Medicines and Healthcare products Regulatory Agency. By way of background to the MHRA, we are responsible for ensuring that all vaccines used in the UK meet robust standards of safety, quality and effectiveness. That includes vaccines that form part of the routine childhood immunisation schedule.

We regulate vaccines across the whole life cycle. That goes from providing preclinical scientific advice during development phases of vaccines through to providing regulatory approval of clinical trials for new vaccines in the UK. We also undertake rigorous assessment of safety, quality and effectiveness for vaccines as part of that licensing process. Prior to those licensed products reaching the market, we will also test vaccine batches, independent of the manufacturer, to ensure that they meet the quality that is necessary. Finally, we will provide continuous safety monitoring of vaccines, even once they are in use, through schemes such as yellow card reporting.

To your question about how safe and effective vaccines are, routine childhood vaccines that are used within our immunisation schedule are absolutely safe and effective. All vaccines in the UK must meet very strict standards that are set by the MHRA. To give you a flavour of that, there are several vaccines that offer protection against a range of infectious

diseases, with about 11 brands available. These have been used globally for many years, ranging from five to 26 years depending upon the brand, with millions to hundreds of millions of doses given. That means that they have very strong and well-established safety records in place.

We could comfortably say that childhood vaccines are among the most extensively studied and closely monitored medical products that are used in children. They remain the most effective way of protecting children from serious and potentially life-threatening illnesses. Our role is very much central in terms of ensuring that the vaccines are safe and effective, as well as assuring their high standards.

As with all medicines, vaccines can cause some side effects, but most of those side effects are mild and short lived, so for example pain or redness at the site of injection, fever or elevated temperature, and some body aches. That is to be expected, because vaccines work by introducing a safe or weakened part of a virus or a bacterium, which cannot cause the disease itself but helps the immune system learn how to recognise and fight those infectious agents. As the body builds that protection, that is when people may experience some of those mild side effects, which should usually go away within a few days. They are normal signs that the immune system is responding as it should do.

Serious side effects can occur, but they are rare. We continuously monitor for them. The risks are very well characterised by us at the MHRA and we include that in information that is given to healthcare professionals as well as patients and caregivers. We very carefully take those risks into account as we are continuously assessing the overall benefit versus risk of vaccination.

Childhood vaccines are probably among the most closely monitored products in use, because, ultimately, they are administered to healthy children and therefore the regulatory standards that we have in place for safety are particularly high. None the less, for those vaccines that are in use currently within the childhood programme, we have extensive safety records extending over several decades and, as I have mentioned, millions of administered doses worldwide. We are really quite clear that the overall benefit of routine childhood vaccination outweighs the known or potential risks of side effects for the vast majority of children.

The Chair: Is there any evidence that they are more or less safe than any other medication that you might give to a child when they are ill?

Professor Shareen Doak: I would not say that we necessarily make comparisons like that. For each vaccination, or for each medicine even, we take into account benefit versus risk in the context of what is being treated. For example, if you had a medicine that was to treat cancer as a condition, a higher level of risk would be acceptable in those considerations because of the benefits that the individual would receive from having that medication.

As I say, with regard to childhood vaccinations, we are providing these to healthy children, so that benefit-risk question is very different from other medicines. We have to be very confident in terms of the safety of those vaccines in order to support both their approval and their continued use.

Q185 **The Chair:** Professor Lim, could you answer the same question, please?

Professor Wei Shen Lim: I am a Consultant Chest Physician in Nottingham and my other role is as Chair of JCVI—the Joint Committee on Vaccination and Immunisation. As regards your question on safety and efficacy, I want to start by saying that healthy people, in general, do not take medicines. However, healthy people take or receive vaccines in order to remain healthy, and that means that any criterion or threshold of safety that is applied to medicines and vaccines would be very stringently applied to vaccines in particular, because they are given to healthy people to keep them healthy. The public and clinician tolerance of safety is such that we would expect higher standards to be applied by MHRA and every other regulator. That is the baseline starting point.

Another bit that may be helpful in framing the question of vaccine safety is how we use the word "safety". Often, we put safety together with tolerability and report them as one. What I mean is something that Professor Doak mentioned just now. When somebody is jabbed with a needle into the skin, you would expect some pain. Both the administrator and the person receiving the needle jab would expect some pain, and that is a natural response. Vaccines create natural responses, such as pain and swelling. Although we describe those as safety indicators, they are natural responses. They are not necessarily unsafe and most people would not say having a bit of pain when they have a needle jab meant that the vaccine was unsafe.

That compares to other adverse events or reactions, which may indeed represent a safety signal, so something untoward or unexpected that is not a natural response. An example might be that, during the Covid pandemic, we had a report of very unusual or rare occurrences of myocarditis—that is inflammation of the heart muscle—potentially because of the vaccine. That would be considered a true safety signal.

In that situation, whether something is acceptably safe or not is read in the context of the disease, as has been just mentioned. A comparison, for instance, with Covid-19 was made. The incidence of this rare complication as a result of the disease itself—Covid-19 infection—was about four times higher than the effect if you had the vaccine. Even though there was a safety signal identified related to the vaccine, the same problem was arising because of the disease at a higher rate. One would say that therefore the benefit and risk in that situation was such that one might describe the vaccine as acceptably safe in the context of how it was being used. Those are important in terms of thinking about tolerability and safety.

Then you mentioned efficacy. Not too long—I think two years—ago, WHO celebrated 50 years of the expanded immunisation programme. To

celebrate the 50 years of childhood vaccines being supplied to the global world, an estimate was done regarding how many lives were saved. The estimate was that, of all the improvements in childhood mortality over 50 years, 40% was down to vaccinations. The estimate in terms of numbers was that 150 million children's lives were probably saved. Each life saved represented, I think, 66 healthy life years. Therefore, in total, 50 years of childhood immunisation across the world saved over 10 billion healthy life years.

That is the efficacy of these childhood vaccines across the world. These are the same vaccines that we use in the UK and many other countries. They have been proven time and time again not just to be safe, tolerable and acceptable, but also to be highly efficacious in saving millions of children. That also needs to be put in context.

The Chair: Professor Lim, given your particular role at JCVI in recommending the schedule of numerous childhood vaccinations, can you say how the safety of putting a number of vaccines together and at what age they are given to the child is established?

Professor Wei Shen Lim: There are two parts to that question. One is which vaccines to introduce to a programme. In the second I think you are implying combination vaccines or how you mix and match vaccines.

The Chair: Yes, and the age when they are given to the child.

Professor Wei Shen Lim: To decide whether a vaccine should be implemented in the UK, for instance, there are broadly three categories that we need to consider. The first is the burden of the disease and, in particular, the age spectrum, if it is relevant. The second is the vaccine product itself, so how tolerable, safe and efficacious the vaccine might be. The third, which is a very important part of what JCVI does, is the cost effectiveness of the vaccine for the UK or England.

If we think about the meningitis B vaccine, because that is in the news quite a lot, it was introduced into the UK childhood schedule in 2015. That was offered at eight and 16 weeks, with a booster later on in life. One reason for choosing eight and 16 weeks is related to when meningitis B affects children, when there is a peak in incidence. We want to give the vaccine before the peak incidence of disease occurs. There would be less point in giving the vaccine later on in life if that is after the peak of maximum incidence. That is one of the ways in which vaccine age is determined. When is the peak of infection and how can we prevent the most number of cases? That would also help with the cost effectiveness if you prevent the most number of cases.

Obviously, if we want to give a vaccine at a certain time to prevent disease happening later on, we need to know that it works if given to younger infants, and at what dose schedule. In the case of the meningitis B vaccine, although the initial trials were using three doses, there were other trials that showed that two doses to start with were good enough,

with an eight-week gap between them. Hence we started with eight weeks, followed by 16 weeks for the second dose.

The reason for bringing up the meningitis B infant vaccine programme is that there has been a later development, as you know, in that we have moved the second dose from 16 weeks down to 12 weeks. The reason for that move is that, having introduced the meningitis B programme, it was found that the peak of incidence of meningitis B disease in infants had moved from five to six months down to one to three months. Because of the vaccine programme, the peak incidence of disease had moved. Therefore, there was a desire to introduce the second dose before that peak, so, rather than waiting until 16 weeks, bringing the second dose to 12 weeks in order to capture the now new peak of disease in infants.

In order to help with the scientific decision for that move, a clinical trial was performed in the UK, specifically testing what happens if we move the second dose earlier. By reducing the dose interval between the two doses, we may lose vaccine efficacy. As some of you may remember, there are some data that suggest that, if you have a wider dose interval, one might get a better immune response.

The question was whether we can reduce the dose interval and still get a good immune response. The second question was whether, if we move that second dose, will we get more adverse events or tolerability problems? The third question was whether, if we move the dose interval, might we want at the same time to move the pneumococcal vaccine, which was being given at eight weeks[1], up to 16 weeks, so a little juggling around of the programme to avoid too many needles at any one point? Giving too many needles to any person at any one point reduces the acceptability of the programme, so we want to reduce the needle jabs at any visit.

The trial was conducted in the UK and showed that it was not only safe but useful to move the second dose from 16 to eight weeks[2]. There was greater acceptability in terms of tolerance, so that was a bonus, and no degradation in the immune response. You will find now that the meningitis B programme has indeed changed since it was first introduced. It has changed because of good surveillance that tells us when the peak of disease is and good clinical trial scientific data to tell us that we can do this safely, on good scientific grounds. Those are just some of the examples of how one decides on a vaccine programme and how that then impacts on the schedule. It is all these things put together really.

The Chair: Thank you for that example of post-introduction monitoring and response. That was very helpful.

Q186 **Baroness Hodgson of Abinger:** I am really interested in what you have had to say. There is no doubt that vaccinations overall are of great benefit. I have three bits to my question. The first one is how you test

[1] Note from witness: The correct figure is 12 weeks rather than eight.
[2] Note from witness: The correct figure is 12 weeks rather than eight.

batches for safety monitoring.

The second one is around the childhood vaccines. Twenty-three doses by 18 months seems to me a very heavy load. When people talk about benefit versus risk that always worries me, because, when you are the one in a million where the risk goes wrong, it is very devastating. I noticed that Professor Doak emphasised that they are given to healthy children. When would you consider a child not healthy and not suitable for the vaccine? Are they screened for that? How does that happen?

The third bit of my question is that there is obviously a trust element to this. When I hear Professor Lim talk about the Covid vaccines, that concerns me. There is the heart inflammation. I do not have the right medical words; I am not medical. I do not remember hearing about that at the time when people were being vaccinated. People need to know the risk and might not have chosen to have the vaccine and get this infection. I understand what you are saying about it being much worse if you had the actual Covid, but people might decide to completely isolate themselves and avoid the vaccine. It is the whole thing about information. How much information is out there? If things went terribly wrong, would you ever tell us or would it all be squirreled away?

The Chair: Who would like to go first on that very challenging question?

Professor Shareen Doak: I am happy to jump in first, because there are probably quite a number of areas that fall to the MHRA there. I will work through those questions one at a time. I hope I capture them all. In terms of the first part of the question about the batch testing, all licensed vaccines are subject to independent control testing before they can be used in patients. This is a legal requirement and applies to every vaccine batch that is used in the UK childhood immunisation programme. The MHRA has a statutory responsibility for testing and quality assurance, and that is delivered by our control testing team, which sits within the biological laboratories at the MHRA.

What happens there is that we perform independent quality and safety checks, separate from the manufacturer's, on every batch of vaccine. This is a piece of work that is critical in terms of maintaining trust, because it is that independent evaluation of those vaccines before they go into use. The process includes review of the manufacturer's data as well as targeted laboratory testing of key parameters such as the vaccine's potency, so how well they work, their identity and their purity. The whole testing programme operates under really robust assurance frameworks. That is the first part of the question.

On the second part, in terms of the benefit-risk evaluation, this is something that we do on a daily basis for every medicine, but it may be helpful if I just explain what is involved in that, because it might help to set the scene a little. Much of that benefit-risk evaluation happens before licensing, as well as afterwards.

Before licensing, we will collect a whole range of data. It will be data from non-clinical studies that are conducted in laboratories, and data generated through clinical trials. We will look very carefully at all of that information in order to understand all safety aspects that are known at that particular point in time, as well as how well that medication or vaccine is working, so ensuring that it provides the protective effects that it should. The clinical trials are designed that they are quite broad. They will involve up to tens of thousands of patients to help us understand how different individuals will respond.

Once a vaccine is authorised, it does not stop there in terms of measuring that benefit-risk, because we have ongoing safety monitoring where we continuously gather information from a wide range of sources, including yellow card reports, to understand whether there are any issues that we may need to take into consideration and evaluate. We will draw data from a wide range of sources. I have mentioned yellow card reports, but we will have access to clinical databases, data from our partners in both the NHS and the UK Health Security Agency, and international information through contacts with other regulators.

We will gather all of that information and then sift through it, because we have to distinguish between real signals and background noise, if you like, because many health events would happen in the population anyway. We have very experienced scientific and clinical assessors who will undertake robust statistical analyses and evaluate the strength and the patterns of the associations between the vaccination and any health effects that may be seen in order to work out whether it is a real effect or background noise.

Within that, because of the breadth of data we are collating and collecting, we will have information on individuals with wide-ranging health and demographic backgrounds. That is all taken into consideration when we are weighing up that benefit-risk evaluation, as we call it.

If we identify any issues that we need to raise awareness about, we are very proactive in that. We have to be transparent with providing an understanding of exactly what we understand and know, and those things that we may need to gather more information on as well.

We will issue communications when we identify any new things that we need to inform people about through a wide range of sources, the idea being that we target healthcare professionals, patients themselves, as well as their parents and carers, so that they are able to make informed decisions about the vaccines available.

Those communications will take a number of different forms so that we reach as wide a network as possible. That might be through updated product information or press releases. We will also use partners to amplify our messaging as well as social media.

We do have very robust monitoring systems in place that allow us to identify meaningful safety signals, despite high and quite noisy data

volumes that we receive, in order to inform our regulatory approach. I am hoping I have answered most of your questions.

Baroness Hodgson of Abinger: You emphasised that these were given to healthy children, so do you have a cohort of children who you would take out of the vaccine programme until they had improved? How would you screen a child for not being healthy enough to have a vaccine?

Professor Shareen Doak: In essence, within the clinical trials phase in particular, they are healthy children who would be included within that. The clinical trials that are approved by the MHRA are done so under stringent conditions, to ensure that patients are well protected through that programme of work too.

There will be some cases where specific groups, for example, are not advised to receive a particular vaccine, and that is also something that we would look at very carefully. That is often identified during those clinical trial phases, and is reflected very early on in the licence and the product information, where that might be the case. One example might be for individuals who have a suppressed immune system because of a pre-existing condition that they may have, and it might be suggested that they should not receive a vaccine.

Typically, it is in the clinical trials phase that we would identify that. Occasionally, something may be observed through wider rollout through our post-market surveillance. In those cases, we would identify a signal rapidly through that process of post-market surveillance that I have just described by reviewing the data from multiple sources. Should we see anything where we need to update the information or provide additional guidance in terms of whether individual groups should or should not be advised to receive a vaccine, we can provide that information rapidly, as needed, through our updated communications.

Q187 **Baroness Freeman of Steventon:** The benefit calculation is going to change depending on the prevalence of the disease that it is protecting against and on the uptake of the vaccination. How often do you re-evaluate the benefit calculation on that?

As a cheeky second question, who funds the clinical trials? Do you require a clinical trial to be non-industry-funded on each vaccination? Do you weight the evidence from industry-funded trials differently from the weighting on a non-industry-funded trial?

Professor Wei Shen Lim: Before I go to that, I would just make the point to say that JCVI is an independent scientific advisory board. Many of us are clinicians. My day-to-day job is to look after patients. I work for the benefit and optimisation of health for our patients and for the public. Therefore, the idea that we would know about a safety signal and hide it away is something that none of us would contemplate or do, and the committee would not allow that anyway. We do not work for the Government. We do not work for manufacturers. We declare all our conflicts of interest. We are as independent as we can be, and it is our

patients who are at the heart of our service. I just want to make that very clear at the outset.

In terms of how frequently we review cost effectiveness, one thing to state is that the cost effectiveness models at the start of any immunisation programme are fairly rigorous. They take months to put together. They are not done on the back of one spreadsheet. They take into account vaccine uptake or coverage, and these are usually modelled based on either observed data, if there are such observed data, or expected estimates. There will be a range of sensitivity analyses, as they are called, to cover different estimates and assumptions. Those are integral to the models at the start.

We often have two models, which are independent, from two non-industry-funded academic groups. Industry may commission models, and those may be published independently, but they are not part of the JCVI process for evaluation.

How frequently these models are updated depends on the vaccine programme, whether the product changes in cost and so on, so there are a number of features that would warrant a change or an update in the model. As an example, in terms of the flu vaccination programme, I cannot remember when the first model was done, but we are re-looking at the model later this year. We have re-looked at the Covid-19 vaccination model because the epidemiology of Covid-19 has been changing ever since 2020 and has required an update to the model. It depends on which programme we are talking about and how the disease has changed over time.

Are all studies funded by industry or are they sometimes funded by academics? The answer is both. There are studies that are funded by industry, and Professor Doak can probably say more about those because they fall more in the remit of the MHRA, but there are also many independent studies that are funded by academic groups or public health bodies.

Professor Shareen Doak: What Professor Lim has just outlined is quite right. Funding for clinical trials comes from a number of sources, including industry funding and grant funding that could be academic in origin, for example. The MHRA does not get engaged or involved with the funding side of the clinical trials.

I would also highlight that we have a very stringent conflicts of interest policy in place. That covers conflicts of interest not only for our staff, but also for those external experts who we have on our advisory committees that support some of the evaluation work that we undertake. We cannot hold direct financial interests in the industries that the MHRA regulates[3]. We are very open about declaring any relevant interests on appointment or when they may arise on a regular basis, so that we can either discuss or mitigate that.

[3] Note from witness: "We" in this context refers to Staff at the MHRA.

We receive data from industry, because that is part of our process. The companies that are undertaking the clinical trials and that would ultimately hold the licence are legally required to carry out and provide us with safety data continuously. This is in part because it is their responsibility to oversee the safety of their medicine, but they also have access to and are able to draw on very large global datasets, because they have direct linkage into the different worldwide avenues in which their medicines are being used. That is a strength for us too, because it means that we can access information across multiple countries quite readily and quickly.

It is probably important to also stress that we do not rely on that data alone. We are an independent regulator and so we do draw on a wide range of other sources. That includes data coming from within the healthcare systems, but also academic studies, and international partners and other regulators globally who use the same products as we do.

Q188 **Baroness Browning:** Professor Doak, could we talk about the clinical trials and licensing of these vaccines? You mentioned that the children, for example, at the clinical trial stage are healthy. How age-appropriate are they for the vaccines to be given? What would be the strengths and weaknesses of the whole process right through to licensing? How could those processes be improved?

Professor Shareen Doak: Thank you for that question. All vaccines are subject to a very rigorous MHRA-led process of development—the clinical trials testing as well as subsequent regulatory review. With regard to the clinical trials themselves, they are specifically designed to assess safety, the immune response and effectiveness, and will typically involve thousands to tens of thousands of participants before a vaccine is authorised.

The trial design is overseen by us to ensure that it provides the data and information that we need to be assured of those things. Each trial would be considered independently with regard to its own outcomes or expected outcomes, so it can be quite a complex process, and those trials will go through several phases. An initial trial may be much smaller, and then, depending on the outcome of that, it will grow in size to cover wider groups. Authorisation is granted only where the MHRA would determine that those benefits clearly outweigh any potential side effects. It is based on the totality of evidence at that given time.

However, there are limitations to clinical trials—even large ones. For example, they may not detect very rare adverse events because, for those, you need to have hundreds of thousands to even millions, in some cases, of individuals who would be vaccinated, and they are limited in terms of scale. They may also not fully represent the diversity of our wider population and all population groups—particularly, for example, those who have a rare medical condition. The other limitation is that trials are typically conducted over a finite period, which limits detection of longer-term effects.

These are all limitations that we are very aware of, and so we mitigate this through that robust post-authorisation safety system that we have in place. That is an essential part of our vaccine safety assessment. That includes our yellow card reporting scheme, as well as clinical data analyses that, as I mentioned, we work closely on with partners in the NHS and the UKHSA to help identify any emerging risks that may arise in a larger and more diverse population. It is that ongoing monitoring that really provides the additional safeguards.

With regard to improvements, the MHRA sees vaccine regulation and safety monitoring as a continually evolving system. We always strive to respond to and take into consideration advances in science and in data analyses, as well as in public health need, and to introduce those into our processes in as timely a manner as possible.

This year, for example, we had new clinical trials regulations that came into force with a view to streamlining approvals processes and making them more flexible, incorporating innovative trial designs with a view to helping accelerate patient access to safe treatments, but, at the same time, maintaining those robust standards of safety, transparency and oversight that are really central to our function. An area for improvement that is very much on our radar is how to increase participation from more diverse populations in clinical trials generally.

With regard to our surveillance model, we have a very robust surveillance process in place, but there are always opportunities for strengthening oversight and assurance. One of those is through continuing to enhance our international collaboration, which is really quite important in detecting and evaluating those rarer events more rapidly by having access to broader and larger datasets.

Another area of improvement that we are looking at is an ambition to move away from more passive safety monitoring to a more fully integrated, data-enabled system, so that we have what we call an always-on surveillance approach. The way to do that is by improving the integration of healthcare with vaccination data. It is enriching the data that we have ready access to. Advances in data science and things such as the electronic health records may really help us improve our ability to identify rarer safety signals and assess outcomes in specific populations—for example, to allow us to effectively monitor in near real time.

Those sorts of system-wide improvements would be helpful in providing us with linked, high-quality data that would enable us to identify some of those risks earlier and act more quickly where possible to protect.

Baroness Browning: What about the age-appropriateness of the clinical trial stage? We give vaccines to very young babies. How do they select which babies will be in that very small cohort at the beginning of a trial before they build it up? What is the process there?

Professor Shareen Doak: I would have to take that question away just in terms of the selection process behind the patient cohorts that are

included. As I say, they will be quite trial-specific. None the less, we do have very strict operating processes that the clinical trials team that is involved in conducting those approvals will work towards. I am quite happy to gather that information for you and to provide you with specific examples and case studies in writing afterwards, if that would be acceptable.

The Chair: Thank you very much. We would welcome that.

Baroness Browning: Thank you. Professor Lim, do you have anything else that you want to add to that?

Professor Wei Shen Lim: If I understand your question correctly about the age-specific selection of volunteers into trials, they are obviously volunteers.

Baroness Browning: I hope that they are parental volunteers, because I do not think that young babies are going to be in a position to say whether they want to be part of this.

Professor Wei Shen Lim: Yes, indeed. Trial units in the UK have relationships with their patients and with the communities around them. They will generally invite people to participate in a trial. This would be done depending on who they want to include in the trial. It could be done by radio, by newspaper or by all sorts of means. If somebody is interested, they are given the correct information.

The most robust trials are those that are randomised, so the participant would be voluntarily agreeing to be included in one or the other arm of a trial, if it was a two-arm trial, and nobody would pre-select which arm they are entered into. It would be done at random. The hope is that, by having an open process that invites as many people as possible, one gets a representative response, and so the participants in the trial would be representative of the community that was invited to participate in the trial.

This is the bit that Professor Doak has mentioned. An improvement we want to make generally, not just in vaccine trials but in any trial, is to increase participation from the whole of the population across all communities and neighbourhoods. Unfortunately, while some communities may say, "We want to see more people represented in the trial", if they do not volunteer or understand how to volunteer, or do not have access to the process of participating, they will be underrepresented as a neighbourhood or a community. That is an effort that needs to be made in terms of communication, even at the clinical trial stage.

Baroness Browning: With Covid, we saw the development of the AstraZeneca jab, which was one of the first off the starting block. The blood clotting side effect seemed to affect younger people more than older people. Is that correct? I realise that Covid was something rather different because there was a real pressure to get that out ASAP, but, as they start to pick up serious side effects, what work is done to identify whether it is specific groups of people, whether by ethnicity, age or

certain health conditions, who perhaps should be looked at especially?

Professor Wei Shen Lim: The information that informs a product—not only a vaccine but also a medicine—may not come from just one country. Trials are often multinational, and so they come from other countries with other ethnicities and other geographic or demographic changes or differences. It is an understanding of how these differences might affect the product when it is being tested that gives us an idea of how applicable it is for use in the general population.

If any product is tested in more settings, you have a better idea of how it will work if it is deployed in a multicultural, multi-ethnic, multi-societal and layered country. Those are part of the strengths of international collaboration. It is not just one trial or one country that does this.

Q189 **Baroness Neuberger:** I ought to declare an interest, as I chair University College London Hospitals, and we do run a lot of trials. On the precise point made by Baroness Browning, can you give us information—and please feel free to send it afterwards—about how much of the testing is done on, if you like, adult healthy volunteers, and how much on the small babies who are going to be the people who receive the vaccines? There is something quite important about the extent to which we know the effects on babies, and then you come back to the point that you have both made very well about different ethnicities and groups, but it would be very helpful to have some more evidence on that.

Professor Wei Shen Lim: The licensing is often based on the group that will receive the product, so an infant vaccine would be tested on infants. The clinical trial will be in the target group to receive the product. The licensing for an adult vaccine would not simply be transported and suddenly given to children.

Baroness Neuberger: But there are questions about how you then recruit the parents of the infants who receive the vaccines, and that has a great implication for ethnicity and social grouping. You have already made that point, and it is really quite an important one, so we do need to know any evidence you can give us.

Baroness Hodgson of Abinger: I have a very similar question. How do you get people to put their small babies forward for trials on vaccines?

The Chair: Is there a difficulty in recruiting enough people who put their babies forward for a clinical trial?

Baroness Hodgson of Abinger: Are they paid? Do you give incentives?

Professor Shareen Doak: I am afraid it is not a question that I could answer at this time, but I can certainly take that away. Generally, and certainly in the UK, we struggle to recruit for clinical trials, and that is across the board. We have difficulty with that, and it does mean that there may be delays in clinical trials for that reason.[4]

[4] Note from witness: This comment was made in the specific context of the discussion. The MHRA

To the specific question around how you recruit, much of that does go back to the team that would undertake the clinical trial. That is part of their process. It is not necessarily something that the MHRA would dictate in any way, if you like, but we would have a role in looking at the study design and commenting on that. I can come back with further information if that is okay.

The Chair: Thank you. We would be grateful.

Q190 **Baroness Ritchie of Downpatrick:** This is a question first to Professor Lim. I have two and a half questions. First, what are the strengths and weaknesses of JCVI processes for assessing and recommending changes to the routine childhood vaccination schedule, and how could these processes be improved? I am aware that MHRA approved the PCV20 vaccine for paediatric use in 2024. However, two years on, the JCVI is yet to make a recommendation. Why is that the case?

What is the relationship between changes to childhood vaccination uptake and JCVI recommendations about the vaccine schedule—for example, the recommendations to move the second dose of MMRV to the age of 18 months? How did JCVI inform the Government's recent decision to run a one-off MenB vaccination programme for young people? How and why was that different from normal practice?

Professor Wei Shen Lim: It is going to take about half an hour to answer all of those.

The Chair: Be as brief as you can, Professor Lim, please.

Baroness Ritchie of Downpatrick: If there are issues that you feel that you want to write to us about afterwards, that would be very useful.

Professor Wei Shen Lim: I will make a start. I might need to supplement this later on. I will start with the example of PCV20 because that may help answer some of the other things anyway. PCV is the pneumococcal conjugate vaccine covering 20 serotypes or serogroups of pneumococcus. There are about 100 serogroups of pneumococcus that cause disease. This covers 20 and was approved by MHRA, as you say, two years ago, in 2024. It has been used in some other countries in their infant programmes. In the UK, we have been looking at PCV20 and how it might be used in the UK programme. In fact, in two days' time, we have a pneumococcal sub-committee to review PCV20's use in the UK immunisation programme.

Part of the process of working out whether to use a new product involves those three points that I mentioned before, which are the burden, what the vaccine is like, and the cost effectiveness. In the case of pneumococcal vaccines, this is particularly difficult. As you know, we have pneumococcal vaccine programmes for infants, as well as one for adults.

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is responsible for the approval of clinical trials, whereas responsibility for participant recruitment and ensuring adequate enrolment rests with the trial sponsor and/or investigator.

The nature of pneumococcal disease is that the pneumococcus is carried in the back of children's throats, and is then transmitted or spread and can cause disease in adults. That means that, if we give a vaccine to children where the vaccine is able to block or reduce carriage of the pneumococcus in their throats, it can have a protective effect, which is called herd protection, in adults. If we removed all the carriage in children, we would have a reduction in disease in adults, and that would then impact on the adult vaccine programme.

A difficulty with PCV20 is that the amount of carriage reduction in children might be different compared to its previous product, PCV13, which is the one we are using currently. Those differences in how much it affects carriage will impact on how much adult disease may be protected and, in turn, how that affects the adult programme.

This interaction between the children and the adult makes the modelling extremely difficult. It is the modelling process that has taken quite a long time before we can come up with something that says whether this is cost effective, bearing in mind that there are, in this particular field, many new PCV products that are being rolled through the regulation process over the next two three years. It is this process that is taking time and making the recommendation difficult.

You asked me about the weaknesses and strengths of the process. The strengths are that it is highly robust, that it is based on scientific data and not on opinion, generally, and that it takes into account very seriously the modelling and the cost effectiveness, because that is what we are tasked to do.

The weakness is that the modelling capability and resource can be quite restricted sometimes. These models take many months to build and to run. Just changing one or two assumptions in the model can take weeks for the output to be read. Having enough capacity and resource to run the models is important. Particularly as we have more and more vaccines coming down the line, we have more and more models that need to be run, and there is a certain limit to the modelling capacity in the UK.

One of the other questions was about the one-off MenB offer that was just announced a few days ago. JCVI was involved in the advice on the response to the Kent meningitis B outbreak in March of this year. If we think back to those three things that JCVI advises on, we looked at who the people most likely to be affected were. We were able to advise DHSC which vaccines are available and whether they would cover the outbreak strain. In this case, it would, which is good. We were able to provide some advice regarding what the likely clinical effectiveness might be—for example, the number needed to be vaccinated to prevent one case.

What we did not do in terms of the one-off advice—and this is an important difference—is that we did not provide advice on cost effectiveness. We were not asked to and did not do so. We provided what we could, and the decision was, as they always are, made by the policy team and by Ministers.

The Chair: Do you have anything to add, Professor Doak?

Professor Shareen Doak: I do not have a lot to add to that one, to be honest, primarily because our role is quite distinct to that of JCVI.

The Chair: It was a bit specific to Professor Lim, was it not?

Q191 **Baroness Freeman of Steventon:** We have heard how important communication is. Especially post Covid, there seem to be more people wanting to have a conversation and to hear about the benefits and the risks. During Covid, the advice did change on who should be receiving what vaccines, and that may have had an effect on people's perceptions about the vaccine programmes.

How effectively do you think the safety and efficacy is communicated to the public by the various actors within the system, such as the JCVI, the MHRA, the UKHSA and the NHS, and how do you think it could be improved?

Professor Shareen Doak: Communication is really quite key in terms of improving uptake. It relies on a system-wide approach as well, because each of our agencies releases communications. Certainly from the MHRA's perspective, we publish quite a wide range of information including patient-facing information, which is the product information that goes alongside the vaccinations. We will release safety updates.

We have also started to try to be a bit more proactive in terms of how we communicate, and have taken steps to release vaccine fact sheets, which we have put up on the GOV.UK website. Within that whole process of generating the vaccine fact sheets, we worked very closely with our partners, particularly UKHSA, to make sure that the messaging that we were including was cohesive and connected, and that we were saying the same things. The UKHSA and the NHS have information sources available on their various public platforms as well, so that effort of working together to make sure that our messaging was consistent was really quite important.

Within those fact sheets, we also included information on how to report potential side effects through the yellow card scheme, so that we could link up awareness around that. There was a series of fact sheets. We had a general one on vaccines, plus a series of others that came out on specific vaccinations.

Looking ahead, we are certainly planning to build on this further, so that we can have that closer collaboration with partners across the wider health system to really ensure that that consistent messaging and the release of trusted, evidence-based messaging, which is quite important, reaches patients as well as healthcare professionals to support their discussions.

Professor Wei Shen Lim: The importance of communication cannot be overestimated. Usually, changes in advice occur because of important changes in science or epidemiology. This was as true for Covid as for any

other situation. The difference in the pandemic was the pace of change. As scientific information increases, it may well be that scientific or medical decisions need to change, and they need to be communicated.

Unfortunately, the communication regarding why some advice changes over time may not always come across to all sectors of the community, such that it is well understood that the change has occurred because evidence has changed, not because the same evidence has suddenly been looked at with the left hand and we did not know what the right hand was doing. It is about making that clarity better understood, which is one of the challenges with communication.

You might come on to how to improve uptake later on. Uptake and communication are both highly dependent on an understanding of what local communities and neighbourhoods are thinking. Part of communication is being able to listen and hear what people are concerned about, and listening to how to communicate, because different people listen in different ways. Trying to get all those points right is difficult, particularly in a pandemic. When anything changes rapidly, there is always the chance that something will be dropped in that listening process and, therefore, the communication process.

Baroness Freeman of Steventon: When we are talking about changing schedules, I remember, during the pandemic, Jonathan Van-Tam going on television to explain why there was a change to the AstraZeneca vaccine recommendations. Who do you think is the best person to be doing communications about changing schedules? What do you think it is important that they say to allow people to understand why that changes and to keep trust in the whole system?

Professor Wei Shen Lim: I was sitting next to Jonathan during that broadcast, as was June Raine from MHRA at the time. We need a consistent message when advising on change, but it is also important to have different voices, who are seen by different people as being trusted voices, saying the same thing. That gives the strongest impact.

If I stood up and said something, and it was only my voice, for example, there would undoubtedly be some people who would not want to listen to what I had to say, but would prefer to listen to what Jonathan Van-Tam had to say. More voices being able to deliver a consistent message in different ways will help understanding and will help people listen correctly. That is my view.

Professor Shareen Doak: I am in agreement. It very much is that system-wide response that is needed. We probably also have to recognise that different parts of our society gather information from different places too, so being mindful of that and ensuring that we are sending those same messages but via multiple channels to reach all of those different communities is important. It is a challenge but something that needs to be looked at, regardless, because it is how trust can be built to tackle issues such as misinformation.

Q192 **Baroness Wyld:** Good afternoon. Thank you so much for your time. You have given us a huge amount of information. As I have the last question, could I just ask you to sum up for us? When we have taken all our evidence, the committee, as you know, will make recommendations to the Government about how to improve uptake, as you said, Professor Lim, of childhood vaccinations and how to reduce disparities. Could you talk about what you think your own organisations and the Government can do to help achieve that aim?

Professor Shareen Doak: The conversation that we have just had about communication is really quite key. It is essential that we have that clear, consistent and accessible communication coming from trusted bodies that is really grounded in evidence. Certainly, from the MHRA's perspective, we are very keen on being a key part of that effort, with the Government and the committee's support, because we have a role to play there in terms of cross-government approach.

Another thing that would certainly be important to the MHRA is looking at how we can also improve use of data to more comprehensively identify safety issues and ensure that we have that wide coverage across the UK. As I mentioned a little earlier, we do have lots of mechanisms for gathering information and data, but anything that we can do to increase the speed of that and just move it more towards real-time access to data from across care settings would really be helpful for us, because that would allow us to make sure that we are identifying any potential safety issues as rapidly as possible. That real-time approach would really be helpful for us too.

Professor Wei Shen Lim: I want to raise two things, but, before I do, I just want to mention that, in October 2023, JCVI noted the decreasing coverage of childhood immunisation and commissioned the four nations to form a forum and to identify and investigate ways and means of understanding both why deployment was being reduced and what factors could be taken into account. That report was published with the JCVI October 2025 minutes, and I think that the report has been submitted to the committee for review, so I just wanted to mention that to you.

There are two things that I want to raise, partly out of the report. First, access has been repeatedly identified as the most important factor. It is difficult for somebody who has many children to find the time or take time off work and organise childcare, and then have the vaccine and deal with the crying child afterwards. That takes a huge amount of effort, and we can improve access to support for vaccination. That makes the biggest difference, based on the reports that have been coming out. That is so important.

Part of improving access is to be able to offer vaccination at any and every appointment where this is available, so opportunistic identification of vaccine opportunities. You heard earlier from WHO, and there was mention about school-based catch-up programmes. Again, that is a very useful time to check on vaccination schedules and to be able not just to check but also to offer catch-up vaccines. This requires the school

programmes to be adequately resourced and funded so that they can offer catch-ups.

These things, where we can reduce the barriers to access to vaccinations, will be so important. School vaccination programmes are less subject to socioeconomic biases, because people enter school and are offered a vaccine. It is less about having to travel two miles, two buses or two hours to get to a vaccine clinic.

The second point is education. As you have heard time and time again, nurses and doctors are the most trusted voices when it comes to advice. What would be good would be for every health professional—nurse, midwife, physio, social worker or medical student, it does not matter—to be reasonably trained in vaccination and comfortable to discuss vaccination with everybody else. It should not be left just to the practice nurse who does vaccines. Everybody can have a share in supporting vaccinations. It is a public health programme and it should be for the public to understand.

That education can be in schools and universities, or in antenatal clinics so that the would-be mum understands why she needs a vaccine and, later on, why her child might need a vaccine. All of these are really important, so I would stress early education for all health professionals as the next step.

The Chair: Thank you very much. That is very helpful. We have a tiny, short final question from Baroness Hodgson.

Q193 **Baroness Hodgson of Abinger:** You are so right about having a crying child who does not want needles. Is there any research being done into delivering more vaccines without needles?

Professor Wei Shen Lim: There is quite a lot of research into different vaccine platforms. There are some vaccines that are more stable and can be delivered through microneedle patches, for example. These are in development. They will be particularly useful in low and middle-income countries where the cold chain and needles may be more difficult to sustain, but they apply across the world, really. These are all things that the scientists are trying to help us with.

The Chair: Thank you very much. That is very helpful. I would like to thank both of you very much for all the information you have given us this afternoon. You have given us plenty of food for thought and, perhaps I can say, support for some of the recommendations that were beginning to crystallise in the minds of the committee already as we reach the end of our oral evidence sessions in a few weeks' time. Thank you both very much. That is the end of the session.