

### Transcript Details

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Bringing Real World Effectiveness into Influenza Vaccine Monitoring: Expert Clinical and Policy Perspectives

### Announcer:

Welcome to ReachMD. This medical industry feature, titled “Bringing Real World Effectiveness into Influenza Vaccine Monitoring: Expert Clinical and Policy Perspectives” is sponsored by Seqirus. This program is intended for healthcare professionals.

Here’s your host, Dr. Jennifer Caudle.

### Dr. Caudle:

Real-world effectiveness of influenza vaccines varies from year to year, based on several factors such as the match between circulating and vaccine strains, strain drift, egg adaptation, and traits to the individuals being vaccinated. But how is real-world effectiveness actually measured? And what roles do the data gathered from clinical trials have in estimating vaccine effectiveness? These and other questions will be the topics of today’s expert panel.

This is ReachMD, and I’m your host, Dr. Jennifer Caudle, and joining me to discuss and focus on real-world effectiveness and influenza vaccine monitoring are Dr.’s Stephen Pelton and L.J Tan.

Dr. Pelton is a Professor of Pediatrics at the Boston University School of Medicine. Dr. Pelton, it’s great having you with us today.

### Dr. Pelton:

Thank you, Jennifer. It’s a pleasure to be with you, and I look forward to the discussion with L.J and yourself, about real-world data and its critical lead to help us understand influenza vaccine.

### Dr. Caudle:

Excellent. And Dr. Tan is Chief Strategy Officer for the Immunization Action Coalition and co-founder of the National Adult and Influenza Immunization Summit. Welcome to you, Dr. Tan.

### Dr. Tan:

Thank you very much, Jennifer for that introduction. I’m delighted to be here with Steve and yourself as well, and I’m looking forward to this discussion.

### Dr. Caudle:

I’m looking forward to it as well. So Dr. Pelton, we’re gonna start with you. You know, let’s start with a quick refresher on how real-world effectiveness, or RWE is defined with respect to influenza vaccines. What do we need to know about them?

### Dr. Pelton:

So real-world effectiveness refers to the use of real-world data, or data that’s collected after a vaccine is introduced, and analyzed in real time to tell us about the impact of the vaccine following its introduction into the population. It differs from randomized clinical trials, which are the gold standard for licensure of a vaccine, but are often done under very restrictive conditions. The population that can enroll is limited in some way. It might be that immunodeficient individuals are not included in the study, such as those with HIV. It might be that the vaccine is studied during only a brief period of time, like one season, so it might be that the vaccine is licensed for its effectiveness against the strains of influenza that are circulating during that season, but as you already mentioned, influenza is known to mutate year after year, and therefore the antigenic content drifts, and it gives us information about how well the vaccine continues to work, despite those changes in circulating viruses and the new formulations of vaccine that come to us every year. I think indeed the listeners who are our audience is now familiar with this concept because we’ve just heard about the U.K. variant of coronavirus, and whether or not the

vaccines that have been licensed are effective against this new variant, so that it's now a hot topic to understand. Does the virus continue to work as the virus makes minor changes in its antigenic content? And again, this is especially relevant for influenza, because we know that influenza viruses drift in their antigenic content from year to year. It's important to understand. The population that's studied is, larger, is less well-defined, it includes everybody, and then indeed, we have the ability to tailor the specific studies to those with comorbid illness, or those over age 65, or those that are children. And we can make different assessments by evaluating different pieces of the real-world data that's being collected. And this data turns out to be critical to informing us about how the vaccine is working, and indeed, to reassuring the public that the vaccine continues to provide protection year after year.

**Dr. Caudle:**

Okay. And if we extend this research into policy, Dr. Tan, how have real-world effectiveness studies guided or influenced vaccine-related policy decisions?

**Dr. Tan:**

I think it is really important to recognize that after the randomized control trials are all done, it is real-world effectiveness data that will play an important part in not just guiding these recommendations, but also evolving these recommendations, right? So as we get data, we may realize that we need to change some of these recommendations, and it is real-world data that's going to give us the guidance to do that. Indeed, one of the things I like to talk about how important policy is that I actually believe that the infrastructure that we develop to deliver vaccines into the arms of patients – that infrastructure only actually happens when there is a policy recommendation for use that is adopted by a committee such as the ACIP. And if you think about the importance of real-world evidence, I think it's important to recognize that we now have many, many ways in which you can actually integrate, real-world evidence into the health care of our public. So for example, we now use EMRs, electronic medical records – and there's a lot of EMRs out there. And we're also focusing on the bidirectional data exchange between EMRs and the immunization information systems that exist at the states, so that you can get information about who's gotten what vaccine, and so on and so forth.

**Dr. Caudle:**

So Dr. Pelton, let's come back to this theme of putting insights into action. How do you apply vaccine effectiveness data, with respect to the seasonality of influenza?

**Dr. Pelton:**

The critical issue is getting vaccine uptake in the population. And it's a combination of seasonality and the antigenic drift that we've talked about that leads to the result that we have to get influenza vaccine each year. And it has to be reformulated each year. And so, what drives the population to get vaccine and roll up their sleeve every year? It's to believe that they're going to benefit from that. And so what real-world data does – it can help us to understand what the benefits are for individual groups within the population.

In my opinion, in general, what drives people to take the vaccine is the belief that that vaccine will benefit them. And therefore, getting real-world data on how it impacts on different groups – I already mentioned how it did – impacts on the elderly. So we want geriatricians to be advocates. We want the public health system to be advocates for immunizing the elderly, based on data that shows that it reduces the burden of disease and it reduces mortality, and it reduces hospitalizations, and so, indeed, it improves the quality of life. Similarly, in the last few years, we've had ACOG support the immunization of pregnant women with influenza vaccine. Well one, first we needed to demonstrate it was safety. This came from real-world data. Then we had to demonstrate that it actually has an impact on the outcome of pregnancy, that it has a protective effect for young infants who are too young to be immunized. And all of that data coming together then influences pregnant women to say, yes, it's good idea for them to receive the vaccine, and it influences the obstetrical community to promote vaccination in this population. So it's a combination of providing us with safety data and effectiveness data, that then individuals can have trust in our vaccine and can, indeed, see the advantages of being vaccinated, compared to not being vaccinated. And I think that's what drives the uptake in the community, and that's what is so challenging with influenza vaccine, because it has to be a new year. Every year we have to convince people that the new formulation is going to provide the same type of safety and effectiveness that past formulations do, and that only comes by having ongoing evaluation, ongoing monitoring, and ongoing analysis, so that we can say the influenza vaccine was this effective last season, or the season before, and not rely only on trials that might have been done five or ten years ago, to convince the population that the vaccine will provide them with the benefit they are looking for.

**Dr. Caudle:**

And staying on that line of thought, Dr. Pelton, how is the COVID-19 pandemic changing your perspective on how to communicate vaccine effectiveness data, with respect to seasonal influenza?

**Dr. Pelton:**

Well, I think that all of the COVID talk is helping both physicians and the population understand some of the intricacies that really are part of what vaccinology is about. I think we talk about eliciting neutralizing antibodies to COVID. Well, we're trying to elicit neutralizing

antibodies against influenza. We talk about the fact that we're giving an antigen as a vaccine, so we're not giving live virus as COVID. We're not giving live virus in general, as influenza vaccines. We're giving you the killed virus, or recombinant proteins, which don't produce a mild form of the disease. We're talking about our knowledge base, and what we do know, so we do know with COVID that we have short-term protection. That's already been proven from the clinical trials. And again, we know from the clinical trials of influenza vaccine, that we have good levels of protection. We also know that when it gets rolled out for the population, there may be surprises – variants that we didn't expect. In the case of COVID, we're seeing allergic reactions, so there may be variants that – or new information that comes along, and therefore we can't just be in a static place. We have to constantly be getting new data about our vaccines, and new information about their effectiveness, so that we are keeping both our medical community and the population up to date on what we know about the effectiveness of influenza vaccines, from year to year.

**Dr. Caudle:**

Excellent. And turning to you, Dr. Tan, what do you think is needed to better inform public health decision-making on influenza vaccine effectiveness, keeping in mind that influenza vaccines are always changing?

**Dr. Tan:**

I think also to kind of highlight on some of the things that Steve has just talked about also, I think it's important to recognize that there are overlapping risk conditions between influenza and COVID-19. So I think it's important that we continue to protect people from flu. Even as we are launching our COVID-19 vaccination program, we need to make sure that we continue to protect our people against influenza. So Jennifer, back to your question about better public health decision-making, I think first and foremost as we've already said, you know, real-world evidence results in a lot of data. A breadth of knowledge, a breadth of data, some of it we – it could be messy. So it is up to us, as we kind of work through this data, to create consistent, clear and simple messages, right? You know, in fact, what we do know is that if we have recommendations that are confusing, recommendations that leave a lot of interpretations to the provider we don't do well. That's the reason why risk-based recommendations don't generally work as well as age-based recommendation. You know, and so as this real-world evidence generates data on the different indications of vaccine use, drifting strains, different age groups, different risk factors, you know, for example, we're now being able to generate data on cardiovascular disease and the impact of flu vaccine on that, as well as people with diabetes and impact of flu vaccine on that. Right? So, as all that comes out, we need to make sure that we communicate them consistently, clearly, and simply, to our providers as well as, obviously, for our providers to communicate that to their patients as well. I'd like to also put a plug in about helping us understand, when it comes to public health decision-making, that flu vaccine effectiveness is not just about preventing primary infection with flu. It's not about preventing that primary case of influenza. Sure, that's very important, but we also need to appreciate flu vaccine effectiveness beyond that, in terms of what's we've talked about, right? Hospitalization rates, days lost from work, days lost from your family because you're out three to five days with the flu, morbidity and mortality and cost burdens, you know, and quality of life for those over 65. You know, I think those are all really important outcomes that people care about, and real-world evidence gives us the tool to recognize these benefits beyond just preventing primary disease.

**Dr. Caudle:**

Excellent. And lastly, let me open up the floor to you both. Are there any additional takeaways you'd like to pass on to our listeners regarding vaccine effectiveness?

**Dr. Tan:**

I think we need to recognize – and I strongly believe that we need to measure the effectiveness of flu vaccines by more than just prevention of primary disease or infection. I've already said this, and I'm gonna say this again. I think looking at hospitalization rates, looking at the impact of flu vaccination on maintaining quality of life in the aging population – I think those are things real-world evidence gives us an insight into, and by looking at that, we can recognize the benefits of flu vaccine beyond just preventing flu. And as Steve has already said, we need to then educate not just the public, but the providers on these benefits, and that helping folks understand that, yeah, you know what? The flu vaccine in one particular season may not have prevented you from catching influenza, but it sure as heck may have reduced your chances of a severe outcome, perhaps even death. And real-world evidence, when we collect it properly, it gives us the tools to make those messaging statements to the public.

**Dr. Caudle:**

Excellent. Now Dr. Pelton, coming back to you.

**Dr. Pelton:**

Thank you, Jennifer. I'd like to build on the point that L.J just made that is now good data that influenza vaccine even if it doesn't prevent disease, does modify the disease and make it less severe. And so, as L.J was talking about, uh, the quality of life improves, and even if we talk about a vaccine that's 50% effective for preventing disease, it also has a role in making the disease less severe, and therefore less impactful on the individual. I think the second point is that the U.S. has multiple ways of monitoring vaccine safety, and that indeed, vaccine safety is an important aspect of all of the U.S. vaccines, and influenza vaccine, although there may be the occasional, mild

soreness in the arm, even the generalized malaise or muscle aches, that in general, it's a very safe vaccine, and that indeed it does not cause a mild flu. And then lastly, that there are different products that are available for different populations, and that indeed in the last decade, we have focused on preventing disease, especially in those 65 and above, and now we have vaccines that are better able to elicit a strong immune response in that population, and that indeed that population should look for those vaccines, because they will have better effectiveness for prevention of disease.

**Dr. Caudle:**

Well, that's a great way to round out our discussion today on real-world effectiveness trials and their role in improving influenza vaccine monitoring. I'd like to thank my guests, Dr. Pelton and Dr. Tan. It was wonderful speaking with you both today.

**Dr. Tan:**

Jennifer, thank you so very much for this opportunity. I hope we provided some useful information to your audience.

**Dr. Pelton:**

Jennifer, it's always an honor to be able to participate in a program like this, and it's special to be paired with L.J, who is a national figure in advocacy for vaccines.

**Dr. Tan:**

Thank you, Steve. Same to you.

**Announcer:**

This program was sponsored by Seqirus. If you missed any part of this discussion, or to find other episodes focusing on influenza vaccination, visit [ReachMD.com/IndustryFeature](https://ReachMD.com/IndustryFeature). This is ReachMD. Be part of the knowledge.