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Examining Real-World Evidence on Flu Vaccine Effectiveness

Announcer Introduction

You're listening to *VacciNation* on ReachMD, and this episode is sponsored by CSL Seqirus. Here's your host, Dr. Charles Turck.

Dr. Turck:

This is *VacciNation* on ReachMD, and I'm Dr. Charles Turck. Joining me to discuss real-world evidence on flu vaccine effectiveness is Dr. Darvin Scott Smith, who's an infectious disease consultant of Public Health Works, LLC in Northern California. Dr. Smith, welcome to the program.

Dr. Smith:

Thank you, Dr. Turck. Glad to be here.

Dr. Turck:

So if we start with some background, Dr. Smith, would you tell us about the benefits of using real-world evidence to assess vaccine effectiveness?

Dr. Smith:

Sure. Real-world evidence is an approach for understanding vaccine effectiveness, especially in the context of flu vaccines, and it uses really a broader representation of the population. So we're looking at people who are getting vaccinated or not getting vaccinated within a population and how they respond. The other thing about the real-world example is larger sample sizes can be studied, and so we're looking, for example, at electronic health records for HMOs or other sources like registries or observational studies. And it's actually an advantage to have these larger samples in a real-world setting to better assess the response and effectiveness of the vaccine. And you can do a little bit longer-term follow-up as well with this type of observational study, and, of course, it's real-world conditions and you can understand the vaccine impact with this approach.

Dr. Turck:

Now in clinical trials, a lot of times we're lucky if we're talking about sample sizes on the order of hundreds or thousands. What sort of sample sizes are we seeing in these real-world evidence studies?

Dr. Smith:

Yeah, that's a great point because in real-world evidence studies, those sample sizes are much, much greater, and it'd be on the scale of millions since that's how many people might be in an HMO closed health system where the observations can be made.

Dr. Turck:

And would you tell us a little bit about the metrics that are used to measure vaccine effectiveness in these studies?

Dr. Smith:

Sure. So there are several metrics, and these might be thought of as endpoints for understanding the effectiveness of the vaccine. So a high-level endpoint might be laboratory-confirmed influenza, and so you would do a lab test to see yes/no, if somebody had influenza, and maybe even what kind of influenza if you're studying it to that level. And then another metric that we typically use would be

influenza-like illness, so ILI, I-L-I. That's a broader metric that's used to assess the effectiveness of flu vaccine in preventing asymptomatic illness, maybe resembling flu. But as you can imagine, laboratory-confirmed influenza is hard to do because you have to get the person to the lab in a timely way, and whereas with the influenza-like illness assessment, it can be a little bit broader and more inclusive, although many of the cases of influenza-like illness may not represent the actual flu or even the flu that's included in the vaccine. And then lastly, and this is very important, the hospitalizations and severe outcomes are a good metric for understanding the effectiveness of the vaccine because if somebody's hospitalized or dies with influenza, we want to capture and understand that within a large system to assess the effectiveness of flu vaccines.

Dr. Turck:

For those just tuning in, you're listening to *VacciNation* on ReachMD. I'm Dr. Charles Turck, and I'm speaking with Dr. Darvin Scott Smith about the rationale of using real-world evidence to assess flu vaccine effectiveness.

So with that background in mind, Dr. Smith, let's zero in on the influenza vaccines. What does the real-world evidence say about their effectiveness?

Dr. Smith:

That's a great question. The effectiveness of vaccines are measured in different ways. So, for example, you could imagine one metric would be looking at the efficacy in older adults. So, with real-world evidence, you might just gear the data that you're assessing to adults 65 and older, who have been vaccinated or not vaccinated. And you might look at the adjuvanted or higher dose vaccine versus the standard-dose vaccine, to assess effectiveness of the vaccine. And then another metric, which is very important for younger and working people, is missed work, for example. So if somebody calls in sick – we don't even know what the sickness was – but you could look and see if that influence of the influenza vaccine having been taken by the person calling in sick or not had an impact on missed work. And indeed, that's been shown in flu studies to be a measurable outcome, thus translating or showing the efficacy of the vaccine.

Dr. Turck:

And how have these data shaped the vaccine recommendations from the Advisory Committee on Immunization Practices, or ACIP?

Dr. Smith:

So overall, these data help make recommendations about who should be vaccinated and what to do in the context of shortage of vaccine, therefore how to prioritize who gets vaccinated.

The other thing that's being reported is strain-specific effectiveness. So you can see with respect to what strain is circulating and what people are getting in studies where that data is being measured. For example, at Public Health Labs, you can also get a breakdown of which strains have which efficacies, and therefore what might be used in the future, and then the ACIP will take that into consideration for impact of the vaccine.

Dr. Turck:

Now bringing us back to real world evidence, I was wondering how it's played a role in impacting patient care.

Dr. Smith:

Probably a number of ways. It's improved our understanding of the effectiveness of influenza vaccines by doing these studies, and it's shown us how to prevent illness, hospitalization, and death just by observations within the system and what we're doing on a public health level. So it also may help identify new treatment options for flu and how to use them. So with the real-world evidence studies, we're able to evaluate that effectiveness and then apply that to the utilization of antiviral medications and how to use them in treatment. So if there's an outbreak in the community and somebody is exposed, you might have a lower threshold during that outbreak to more readily use those medications for prevention purposes.

Dr. Turck:

Lastly, Dr. Smith, do you have any final thoughts you'd like to leave with our audience today?

Dr. Smith:

The most important thing is that vaccines are extremely important and they do prevent illness, and we really need to use them as a cornerstone of our approach to managing influenza in our communities. And many people might think that vaccine decisions are being made for themselves and they're making a personal decision, but I would really like to emphasize that it turns out we are a community, we're a collective, and we're all connected. And so our individualistic decisions may harm or help people around us, and getting a

vaccine is actually a good idea. And according to the CDC recommendations now, everyone 6 months and older is recommended to get a vaccine for flu. So I think that we really need to feel lucky that we have vaccines, that they work, and to use them, not only for ourselves to prevent illness but also thinking of the community at large.

Dr. Turck:

Well with these final thoughts in mind, I want to thank my guest, Dr. Darwin Scott Smith, for joining me to discuss real world evidence on flu vaccines. Dr. Smith, it was great having you on the program.

Dr. Smith:

Thank you so much, Dr. Turck. It's always a pleasure.

Announcer Close

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