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Confronting Vaccine Concerns: Mandates, Diversity, & More

Announcer:
Welcome to *VacciNation* on ReachMD, sponsored by Moderna. On this episode, we're joined by from Dr. Cynthia Leifer, a Professor of Immunology at Cornell University, who will take a look at ethical considerations associated with mRNA vaccines. Here's Dr. Leifer now.

Dr. Leifer:
How diverse are the populations that we're including in clinical trials, especially for vaccines? And generally, what we can say from the two major trials that were done for Pfizer's vaccine, and Moderna's vaccine is that first of all, Pfizer's included over age 12. And Moderna's included over age 18. That tells you that we have different age distributions in those two. But the Pfizer vaccine was a multisite worldwide, clinical trial, and it had an overall diversity of the inclusion of the participants of 42 percent, which is really, really good for a clinical trial. Now, it's not perfect. Certainly, we can, do a better job of diversifying our clinical trials.

In fact, a study that was recently published in the *Journal of American Medical Association Network*, did a cross-sectional study to look at 230 different clinical trials for vaccines. And overall, it looked at about 219,000 participants in these 230 clinical trials. And what they showed was that there was a definite underrepresentation of Black and African American, American Indian, Alaskan Native, Hispanic, and Latinx individuals in those clinical trials. So, we know that we're not, in general, having the diversity in the clinical trials that are representative of what we see in the population.

Now, what's the importance of that? The importance is that if we have less diversity in our clinical trials, one we could miss some differences in outcomes, so different efficacy in different populations. That's one thing. And the other thing is if these individuals from these diverse backgrounds know that they're not represented in those clinical trials, they may be less likely to try these newer investigational drugs.. It's something we definitely need to work on overall in our clinical trial design.

I think one of the major groups of people we need to worry about are elderly or disabled individuals who can't get to the locations to get the vaccines as easily as some of the other people. Now, some of the other things that we need to worry about are, for example technological barriers. So people who aren't so facile with using a smartphone might not be able to sign up to get their vaccine as easily as the people who are younger and able to sign up really easily online.

Another barrier is providing information and access in the languages that the people speak. So, we have pockets in communities where they may not have access to the information on how to sign up or the safety and efficacy information. We need to make sure that we're distributing the information in a way that everyone can get that information and take advantage of it.

And then the last thing is we need to partner with communities and churches to be able to get to individuals who might have more difficulty accessing. And that's important, because if we look at the overall demographics that are reported, it looks like we're doing a really good job. When we look at the percentage of people who are getting vaccinated that fall into these different demographics, it's pretty close to their overall percentage of the population, when we look at the census data. So it looks like we're reaching them. However, when we have pockets of individuals in communities that are all not getting it, then we have a group of entirely susceptible individuals. And they could get and spread this or any other infectious disease, for that matter, more broadly, if their community gets infected.

Are there long-term effects? And what we can say is that for every other vaccine we've ever made the vast majority of reported effects happen within the first few weeks to one to two months post vaccination, for any serious effects from any vaccine we've ever developed, regardless of the platform. So in general, vaccines are one of the safest and most effective and least expensive medical interventions that we have. That said, people are worried about mRNA-based vaccines and lipid nanoparticles because this is a quote unquote, new

technology. When in reality we've been using nanoparticles and mRNAs for various different medical applications for years. The first drug that was approved using a nanoparticle was in 2018. These are FDA approved. They've been used in lots of patients and we haven't seen negative effects. There was a vaccine trial, in fact, for an mRNA-based vaccine for rabies in 2013.

Still raises the question about mandates. We will hear arguments that people should have free choice. And that's true, except for when we think about public health. This is not just an individual. We're talking about a population. A lot of our vaccine requirements are to do certain things. Like children have to have vaccines to attend school. We may have things like that in place. Employers can require vaccines if they choose to, if they're a private employer. And governments can choose to mandate vaccines. It's not unheard of to imagine that there could at least be partial mandates for some of these vaccines, and I don't particularly see a problem with from my own personal opinion.

Announcer:
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