Transcript Details
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Tracking Side Effects of the COVID-19 Vaccines: Is There Room for Improvement?

Dr. Caudle:
As the United States accelerates the distribution of COVID-19 vaccines, there's an urgent need to track possible adverse reactions. But are we, as a nation, doing everything we can to help monitor for those side effects in the most effective way?

Coming to you from the ReachMD studios, this is *COVID-19: On the Frontlines*. I'm Dr. Jennifer Caudle, your host, and joining me in this discussion is Dr. Paul Jarris, Chief Medical Advisor for MITRE Corporation, the federally funded non-profit that created a COVID-19 monitoring tool called "Sara Alert." Dr. Jarris is also the former Vermont State Health Commissioner and he ran the Association of State and Territorial Health Officials during the Ebola Crisis. Dr. Jarris, thank you so much for being here, today.

Dr. Jarris:
My pleasure. Thank you for having me.

Dr. Caudle:
So to start us off, Dr. Jarris, can you set the stage on how the U.S. has been monitoring for side effects of the COVID-19 vaccines and what some of those side effects are?

Dr. Jarris:
Certainly. That's an excellent question, Dr. Caudle, because these are new vaccines and under emergency use, so the public wants to be certain that any potential side effects are being monitored and the adverse effects are being picked up so they are kept safe. Right now, the predominant system being used is something called V-safe. It has been employed by the CDC so that when someone receives the vaccine, they are asked to register on their smart phone for V-safe. They then would report in every day whether they're having any side effects or adverse events. That's daily for a week and then weekly for another several weeks until the second dose and then it goes daily again. What they are asking for are, in many ways, expected side effects, such as muscle soreness, flu-like feelings, slight fever, but in addition, they ask some important questions like, "Are you able to perform your normal activities of daily living?" And they ask, "Have you required healthcare interaction?" And those two questions about are you able to perform your daily living are very important because if you're not, that indicates a level of adverse event that's significant. And have you seen a healthcare provider means it's significant enough to receive healthcare. So that information then is transmitted via your smartphone and a weblink to CDC to the VAERS department, the Vaccine Adverse Event Reporting System. That's the system we've used for years in this country; it's a passive system that you as a physician or someone as a patient might call in if they had an adverse effect. The CDC desk would then call the individual, confirm if they had an adverse event and if so, be entered into the VAERS system for further analysis. So that is the predominant system being used right now and again, it seems to be working well. We aren't, at this point, picking up any significant adverse effects. There were initially a couple of allergic reactions, but those are now screened for and we are prepared for them and they seem to be very rare.

The two potential limitations to the existing system are one, is that it is smartphone-based. About 60% of Americans have a smartphone, that means we've eliminated 40% of Americans from this monitoring system. Those tend to be older people who might not be using the technology of a smartphone or rural people or people living in frontier environments or lower income people who either may not have a smartphone or beyond broadband access or beyond cell phone access. To help accommodate for that, we at MITRE have built a complimentary system that is available to the V-safe system. Our system does not require a smartphone, so that it's available to anyone. In fact, it can call a landline and therefore, in a frontier area or if there's a shared housing situation like a migrant worker might have, we can call a landline and there can be reporting in that basis.

Dr. Caudle:
Excellent. And why is the tracking of those side effects important, and why do this data need to be fed to state and federal public health officials?

Dr. Jarris:
So, it's again important because remember, these are not approved vaccines; these are vaccines that received an emergency use authorization, meaning the full process of going through an approval that would typically happen, if you will "in peace time" and might take years, is simply not possible as we race the pandemic. So the level of certainty has been reached that the vaccines are safe, but it also means we have to do a considerable amount of "post marketing surveillance" in real time. We also know that when you do a study of hundreds or even thousands or even ten thousand people, it's very different than immunizing millions or billions of people across the world. So, very low incident side effects might not show up in a study, but once we're immunizing a broad swath of the population, they may become apparent, so it's really important to look, not only, of course for major side effects, but those low-level side effects which may grow over time that you can only pick up when you're immunizing the full population. So, critically important that we find those things.

One of the challenges, of course, is that every day there are heart attacks, every day there are strokes, every day there are miscarriages and so the challenge here is how do we determine whether an event is really related to the vaccine or was it an event that was going to happen anyway? And that's really where the modeling and the distinguish between the signal to noise ratio, if you will, almost like what's done in the intelligence world, has to be done here in the vaccine world to make sure that there isn't a significant event. So, for example during H1N1, there were a few signals of, Guillain-Barré early. As it turned out, that was background. They weren't related to the vaccine. But you may remember back in, I think it was 1983 or 4, where the "swine flu" outbreak, there was a vaccine campaign launched quickly in the United States and in fact, there was a Guillain-Barré side effect that was related to the vaccine and that campaign was stopped. That wasn't apparent until, in fact, a large part of the population was immunized.

Dr. Caudle:
For those of you who are just tuning in, you're listening to *COVID-19: On the Frontlines* on ReachMD. I'm your host Dr. Jennifer Caudle, and I'm speaking with Dr. Paul Jarris about how we can monitor for side effects of the COVID-19 vaccine.

Now, Dr. Jarris, there are populations in the U.S. that have their own, unique challenges when it comes to monitoring vaccination side effects. Some of these populations include rural communities, veterans, Native Americans, and pretty much anywhere with limited broadband service. So, how can we monitor these populations effectively?

Dr. Jarris:
You know, this is important, and one of the things, of course, we've learned with this pandemic is that so many of the divots in our social fabric are becoming so transparent now, when they might more so than they were during a non-pandemic period and we're already seeing them. And there was a release from the CDC about what's happened to the life expectancy in this country, where in the first six months of 2020, we saw a one year decrease overall in life expectancy in this country. Now, of course, given that we're in the United States, that's not equal across all populations. We've seen a 2.7 year decrease in life expectancy among African Americans, a 1.9 decrease in Hispanic Americans, and a 0.8 year decrease in white Americans, so a disproportion impact. We've also seen the death rate, perhaps, two times higher in the African Americans than our white Americans and 2.3 times higher in Hispanic Americans than white Americans. So, much of the structural and social determinants of health are becoming highlighted in this outbreak and, again, reenforcing the need for us to impact these structural and social determinants of health which are creating these inequities.

The same is true of the vaccine outreach, where it appears that African Americans are being vaccinated at a lower rate than white Americans. And same with Hispanic Americans. So, we have to make sure that we don't structure our vaccine outreach to continue to disadvantage different groups.

Now, having said that, there, as you mentioned, we need to track the side effects of the vaccines and it's very important that we do this for different groups. Overall, we want to know side effects, but are there subgroups -- Native Americans, Latinos, African Americans different age bands -- that may have a disproportionate impact of a side effect or adverse effect? And we really need to know that.

Dr. Caudle:
That's excellent and I really appreciate a lot of the points that you made there about sort of, social determinants of health and so many other things. Very, very important.

You know, if we switch gears a bit here, Dr. Jarris, you actually ran the Association of State and Territorial Health Officials during the Ebola Crisis. Were there any lessons learned from that experience that you're applying to our current global crisis?

Dr. Jarris:

Yes, many. In fact, my career goes back to the original SARS of 2003 when I was Commissioner of Health in Vermont and essentially every public health emergency since, including H1N1. Based upon those collective experiences, last two summers ago, before there even was a COVID-19, I started socializing the idea both with public health people and with engineers about building a tool that would automate the active monitoring of people in isolation and quarantine. Because in Ebola, what we learned was that very few people were coming into the country, they registered at the border, a secure message was sent to a state, which then often downloaded it into a spreadsheet, which sent, faxed, emailed, or electronically transmitted that information to a local health department who might put it on a clipboard, fill it out in pencil and upload it, then message it and it was so inefficient. And so, we recognized that if we ever had a true pandemic like now, we would need to do something at scale and the fragmented system we had could not be scaled. And so, we began discussing this and then as soon as we heard what was happening in Wuhan, China. We said OK, we can't waste a crisis. Now, of course, we had no idea how bad this was gonna be, but we approached the major public health leadership and the public health organizations, the CDC and the states and said, "Look, if we can put an engineering team and public health team together to build a system to scale for managing a pandemic, what would you think?", and they said, "If you could do that, that would be amazing." So, we put a team of public health officials, including some from the National Association of Local Health Officials and epidemiologists and others in a room for a week with engineers and the public health people white-boarded out the process for contact tracing, for isolation monitoring, for quarantine monitoring and the engineers started coding. And then within ten days, we had a prototype, within ten weeks we implemented a system in a U.S. territory and a U.S. state.

And the system actually now has scaled. We're serving 40 million Americans with it across 770 jurisdictions, we've monitored of 2.4 million people that have been in isolation and quarantine and it really takes that very manual process and automates it so an epidemiologist or a public health nurse can monitor far more people than they ever could've without a system like this.

CDC now currently has provided resources for us as a non-profit to make this tool available to any U.S. public health jurisdiction which wishes to use it. It's also been picked up in colleges and universities and is using to monitor students, some municipalities are monitoring their first responders with it, and some health systems are actually monitoring their employees with it. So we're gratified to see that there was a great receptivity for it because it was such a badly needed tool.

Dr. Caudle:
Excellent, and lastly, Dr. Jarris, do you have any key takeaways for our audience?

Dr. Jarris:
Yeah, I think that we need to remember here that of course this is novel. There's much that we don't know about COVID-19. And we will learn as we go and obviously, we'll get some things right, we'll get some things wrong. The real critical thing there is that we fix what we need to get right as quickly as possible. We're rolling out the vaccine, the projection is that we will have 6 million doses by the end of July, but we'll still take several months before those are in arms and we have immunity. So, the important thing is to continue to reinforce the social distancing, continue to reinforce the use of appropriate masks, continue to reinforce the hand-washing, and with the new variants that are coming, we need to remember that if we have someone who's a contact, they need to be quarantined and monitored in a safe environment. If we have a case, they need to be isolated and monitored.

You know, any single approach we have is like that piece of swiss cheese that has a hole in it and it's only when we layer all of these imperfect solutions together that we truly will stop this pandemic.

Dr. Caudle:
Well as the COVID-19 vaccines continue to be distributed across our nation, the swift and accurate monitoring of side effects will become even more important. And I'd like to thank my guest, Dr. Paul Jarris, for joining me today. Dr. Jarris, it was great having you on the program.

Dr. Jarris:
Thank you, Dr. Caudle. I appreciate the opportunity and appreciate the education you're providing us all.

Dr. Caudle:
Of course. We also appreciate you. I'm your host Dr. Jennifer Caudle, and to access this and other episodes in our series and to add your perspectives towards the fight against this global pandemic, visit ReachMD.com/COVID-19, where you can Be Part of the Knowledge. Thanks for listening.