

Q&A: Ochsner PI takes you inside coronavirus vaccine trials

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Marc Zarefsky

Contributing News Writer

Julia Garcia-Diaz, MD, doesn't remember exactly when she first heard of COVID-19, but she confesses that it feels like a lifetime ago.

As the director of clinical infectious diseases research and medical subspecialties at New Orleans' Ochsner Health, Dr. Garcia-Diaz has had a front-row seat to witness the impact COVID-19 is having on the public. As the principal investigator for two different SARS-CoV-2 vaccine trials, she also is deeply involved in the search for ways to stymie the virus that has killed more than 200,000 Americans.

Ochsner—an AMA Health System Program Partner—is one of about 120 sites around the world to participate in the phase 2–3 global study sponsored by Pfizer and BioNTech SE. While 30,000 participants are expected to be involved in the study worldwide, Ochsner has about 230 people from across Louisiana enrolled in the trial. Ochsner was also recently selected to be part of the Janssen (Johnson & Johnson) phase 3 clinical trial—part of Operation Warp Speed. Both trials are attempting to find a way to protect people from the virus that causes COVID-19.

Patients and physicians can learn more about volunteering for SARS-CoV-2 vaccine trials at the COVID-19 Prevention Network, a project of the National Institute of Allergy and Infectious Diseases.

Dr. Garcia-Diaz, an AMA member, recently took some time to talk about the two trials, the realities of vaccine development, how this experience compares with pursuing a vaccine for AIDS, and much more.

AMA: What does it mean for Ochsner to be a part of these two massive clinical trials?

Dr. Garcia-Diaz: In an attempt to end the pandemic, a vaccine will hopefully be a piece. If either or both [of the trials Ochsner is involved with] gets to market, to be part of that and to bring it to our community is something we're very proud of.

AMA: What are the biggest challenges you face as principal investigator for the trials?

Dr. Garcia-Diaz: Being the principal investigator for the trial has a multitude of implications. I'm ultimately responsible for the trial in terms of how it runs, the conduction of the trial, the patients that are being enrolled. I'm responsible for the trial, whether it's good or bad.

The time and the speed with which this has come to fruition has probably been the biggest challenge. It's a little daunting at times to try and turn things around in the amount of time that we were given. Sometimes it takes six months to bring a trial together, or sometimes it can take 18 months. This happened in a matter of weeks.

The speed that we've had to turn things around has been unprecedented, and for us to be able to do that is because I've had huge support from our clinical staff and our research staff.

AMA: How does this experience compare with the AIDS vaccine research you worked on early in your career?

Dr. Garcia-Diaz: I started training in the 1980s when things were really bad, and we had nothing to give those HIV patients. Then we got highly active antiretroviral treatment and all of a sudden, patients were doing better. But that took years.

AMA: From your perspective, what are some of the issues that physicians, scientists and other stakeholders should be communicating to improve public understanding about these SARS-CoV-2 vaccines?

Dr. Garcia-Diaz: The scientific community needs to ensure that when a vaccine gets to emergency use—which is probably the first thing that will happen—we want that vaccine to be safe and we want it to be efficacious. Public safety is first.

There are also still going to be a lot of questions. When you're looking at a vaccine for COVID-19, you're looking at the entire world. There has to be some criteria for who this is going to go to, initially.

Who needs it the most? Even if and when a vaccine is available, those patients [in the vaccine trials] are being followed for a lengthy time. Is the vaccine going to prevent COVID-19 for three months? Six months? Will we need boosters? Will we need to do like we do with the flu vaccine and get it once a year? I don't think we're going to have any of that information available immediately.

It's going to take a while for us to know that and to be able to follow those patients and gather that information. Although we may have something soon, we're going to need some time to be able to determine how well it fairs.

AMA: A growing chorus of experts is raising awareness among the public that even safe and efficacious vaccines will not immediately end the pandemic. What are some things that physicians should be focused on to help their patients protect themselves and their loved ones?

Dr. Garcia-Diaz: It's our goal to educate our patients regarding COVID-19. If each one of us would attempt to teach our patients and try to demystify some of the myths, it would probably go a long way.

There are so many myths about COVID-19. There are still some people who think COVID-19 does not exist. A lot of the patients that we're seeing in the hospital are a lot younger, and they don't understand the social distancing and masking. They continue to do social gatherings. They say they want to get married and have everyone there.

We get that those are life-changing events, but if we can just make people understand that those events have consequences—and you hear that day in and day out. Are we doing enough education to make people not do that? If we could just have everyone mask up, that really does impact transmission.