

GWU's covid-19 clinical trial has met one early goal — getting Black and Latino people to join

By **Fredrick Kunkle**

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Mark M. Spradley searched online for a vaccine clinical trial the way most people go shopping.

Spradley, heeding an inner call to public duty, combed through the National Institutes of Health's website and signed up for a trial underway at George Washington University because he was eager to become part of a massive, accelerated effort to develop a vaccine for the novel coronavirus that causes the disease covid-19.

He did so because friends had become sickened, because he wanted to fight back against a disease that has prevented him from traveling or going out, and because he was curious.

"I trust science," said Spradley, who is African American and a former trustee of Tuskegee University. He said he was also motivated because he knows the stakes are especially high for people of color, both because of covid-19's disproportionate toll and a long history of unethical medical research on minorities. He felt it was important to step up.

"Because it is a pandemic, because it does involve public health, because you are a citizen, you have a responsibility to your friends, your family and your neighbors," Spradley, 66, a financial adviser who lives in Chevy Chase, Md., said in an interview. "That's what public health is, to my mind — a shared responsibility between the healthy, the unhealthy and on and on. It's like all hands on deck. Everyone has a role to play."

GWU is among about 90 sites chosen to participate in Operation Warp Speed, a vast public-private initiative led by the federal government to develop a coronavirus vaccine. The University of Maryland School of Medicine in Baltimore is also taking part.

The clinical trial uses a bioengineered vaccine, developed by Cambridge, Mass.-based Moderna in collaboration with NIH, that teaches the body's immune system to recognize and neutralize the virus by targeting the spike proteins that envelop it and allow it to penetrate human cells. The vaccine, using snippets of genetic coding, triggers the body to produce new spike proteins, prompting the immune system to create antibodies that hunt them down. The nationwide trial is expected to enroll about 30,000 participants. Pfizer also launched the final phase of testing for a coronavirus vaccine on 30,000 volunteers.

A critical goal for the Phase 3 clinical trial is also to ensure that the pool of the vaccine test subjects reflects the nation's diversity, including minorities, older Americans and people with preexisting health conditions. It's all the more important given the disparate impact the pandemic has had on people who are Black or Latino, as well as other racial minorities. A Washington Post analysis of available data earlier this year found that majority-Black counties had three

times the rate of infections and almost six times the rate of deaths as White-majority counties.

In late August, Moderna and Pfizer announced that about half the number of people needed have been enrolled, but only about a fifth of those participants are Black or Hispanic.

But GWU researchers, having reached the midpoint of their overall goal of enlisting 500 people, have exceeded their diversity target, university spokeswoman Lisa Anderson said Thursday. She said about 50 percent of the those who have enrolled so far are people of color, a figure well above their target of about 30 percent. Although recruiting has been swift from the beginning, the pace has increased as the end point, both for GWU's target and the national goal, grows closer.

"We're enrolling people as fast as we can," Anderson said.

Recruiting minorities for clinical trials has long been challenging because of the history of racist abuses in medical research. Many Black people — aware of the infamous Tuskegee study, the "immortal" use of Henrietta Lacks's cancerous tissue in research without her consent or J. Marion Sims's gynecological experimentation on enslaved people — want nothing to do with any medical experiment. Though lesser known than the Tuskegee syphilis study, documented reports of unethical medical research conducted in the 1940s by the U.S. government on unsuspecting people in Guatemala has made people who are Latino wary, too. Recent studies show racial biases persist in health care, showing up in higher rates of death from chronic diseases, unequal access to care and even in assessing and providing treatment for pain.

"It's still been difficult just in normal times to get people of color communities to enroll in clinical trials. And I guess what I like to say is, it's for good reason," said Joseph Betancourt, vice president and chief equity and inclusion officer at Massachusetts General Hospital in Boston. "Now you're talking about a clinical trial on a vaccine for a condition that has absolutely crushed communities of color across the country."

Enrolling minorities in coronavirus vaccine trials has been hampered by uncertainties of the disease and the unprecedented speed with which a vaccine is being developed. Those concerns were magnified, some say, when the public-private vaccine program was named Operation Warp Speed. Conflicting advice early on about the importance of wearing masks has also fed distrust, Betancourt said.

Betancourt, who is Puerto Rican, said it's important for researchers to tap "trusted messengers" in minority communities who can explain the importance of minority participation in clinical trials. These messengers could be local politicians and activists, leaders in the faith community, community-based organizations, or minority physicians and health-care providers.

"Covid-19 is obviously shining a really bright light on issues of inequity, across the board, including these disparities that are related to research participation that have been really long-standing," said Bisola Ojikutu, an infectious-disease physician at Massachusetts General and Brigham and Women's hospitals who directs community-engaged research programs. "You have to work with people who are trusted."

However, the unusually aggressive outreach by coronavirus researchers into traditionally underserved communities has aroused suspicion, said Karen Kotloff, principal investigator in U-Md.'s medical school's part of the Moderna-NIH clinical trial.

“There are many rumors assigning bad motivations to why society would want to be running after these groups,” Kotloff said. To overcome that distrust, her team joined with CASA of Maryland to set up a satellite clinic for the experimental vaccine in a Hyattsville garden-apartment complex where many people who are Latino live.

David Diemert and Marc Siegel, who are overseeing GWU’s vaccine trial, have extensive experience in vaccine development.

Diemert has worked for many years on finding cures for tropical diseases. Both have considerable experience conducting research with an international network designed to prevent the spread of HIV and develop a vaccine against the deadly virus that attacks the immune system — networks that have been pressed into service to develop a vaccine for the coronavirus.

“Obviously, D.C. is a very diverse city and has a large African American population, and I think that’s one of the reasons they saw us as a good site,” Siegel said. He said researchers also have targeted older people and people with underlying health conditions.

To break down barriers to participation, GWU administered the experimental vaccine or a placebo on campus and from a van that visited local neighborhoods. Through these efforts, doctors and researchers attempt to address people’s fears. This includes explaining how the vaccine works and why it’s not possible to contract the disease from the vaccine.

Elmer Huerta, director of GWU’s Cancer Preventorium Clinic, has recruited women and minorities to participate in several clinical trials, including research on the breast cancer drug tamoxifen. A Peruvian immigrant, Huerta also hosts a daily radio show on health issues — “El Consultorio Comunitario,” or Community Clinic — that reaches a large audience of Latino immigrants in the Washington area.

Huerta, who has homes in D.C. and Maryland, said many of his listeners are working people, often with little more than a grade school education, and he addresses their concerns and explains the science in terms they understand. He, too, decided to sign up for GWU’s Phase 3 clinical trial and share his experience with his listeners.

“Many times I have talked to them about the importance of clinical trials,” said Huerta, 68. “So this time, I say, ‘My God, if the doctor is recommending to his listeners and encouraging them to do it, why not do it myself?’ ”

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