

Take Charge Of Your Health Today. Be Informed. Be Involved.

COVID-19 vaccine trials must include Black community

This month, the "Take Charge of Your Health Today" page discusses vaccine trials and their relationship with Pittsburgh's African American community. The current COVID-19 pandemic has increased pressure for the medical community to develop a vaccine to combat COVID-19. The development of a new vaccine means that clinical trials will eventually begin to recruit participants. We must ensure that COVID-19 clinical trials will include African American participants. Systemic racism in the United States is responsible for the medical mistrust among African Americans and could be part of the reason for their historically low participation in clinical trials.

In my role as codirector of the Community PARTners core at the University of Pittsburgh's Clinical and Translational Science Institute (CTSI) and as president and CEO of the Urban League of Greater Pittsburgh, I have made a commitment to inform and educate people about how they can take charge of their health. State-sanctioned violence has been perpetuated against African Americans in the name of medicine since the United States' inception. The "Tuskegee Study of Untreated Syphilis in the Negro Male," a United States' Public Health Service-led research study from 1932 to 1972, intentionally infected African American males with syphilis without their consent. The study's participants were not adequately treated, and, in some cases, not treated at all, even by 1947 when penicillin was commonly used to treat the disease. We may not have any unethical historical precedents like Tuskegee in our city or universities; however, the pub-



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lic health's sector failure to establish trust keeps the Tuskegee stigma alive.

The Community PARTners core and the Urban League are vigilant and hold our medical system accountable, ensuring Pittsburgh's African American community that this will never happen again.

In a 2015-16 Food and Drug Administration report, of the women who participated in cardiovascular trials in the United States, only 3.2% identified as African American, while 78.7% of participants identified as white. The racial makeup of these studies does not reflect the 13.7% of African American women in the country. This does not seem to be an adequate sample of African American women and raises red flags on the accuracy of treatment outcomes for all women. Because we want studies of the current coronavirus pandemic to apply to all of us, African American participation in clinical trials is essential. African Americans make

up 25% of all COVID-19 cases in Allegheny County (according to the Allegheny County Health Department), yet only make up about 13% of its population. We can't afford not to be included in the COVID-19 vaccine clinical trials.

In order to gain footing in research-inclusive spaces, it is my hope that studies include opportunities for community input on topics like the value of participation. What is in it for community members who are asked to share their lived experiences? What is the plan for returning results, including closing the loop on the work in and with communities—particularly black and brown communities that have been historically marginalized—to ensure that researchers are doing the work they set out to do? Accountability in research environment means so much. When possible, thinking about offering both day and evening hours to participate in the research, providing childcare and offering inroads to break down definitions and ethical considerations and exploring safety and privacy in ways that all participants understand, are critical to making research inclusive.

I have two recommendations for researchers who want to increase African American participation in clinical trials. Be mindful that these suggestions are not a complete list and are only intended to initiate the dialogue.

Include us throughout the entire research process. Hiring a research recruiter that looks like us does not help to overcome the barrier of mistrust. Even if the recruiter can connect with the African American community, that relationship ends after the recruit-

ment phase. African American participants are then typically interacting with an all-white research team. This could lead to lower retention rates. Including African Americans throughout the entire process looks like garnering input around recruitment and retention plans, protocols and the dissemination process.

Establish pipelines for researchers from the community. African Americans are usually an afterthought when conducting research studies. Most researchers who are receiving funding to study our communities often decide on a research question based on surface knowledge. However, we know that this is not an equitable process. Researchers are instead contributing to the medical mistrust by doing research on African American communities instead of with them. The Urban League of Greater Pittsburgh has been partnering with CTSI for more than 14 years now. In that time, I have learned so much from CTSI leaders like Dr. Steve Reis and my friend Dr. Elizabeth Miller. In turn, they have also learned a lot from the African American community. This reciprocal relationship between our two organizations has helped to build a pipeline between researchers and the African American community. I am extremely proud of the mutual trust and respect our organizations have built. I look forward to what we will continue to accomplish together.

Thank you, readers. Please join the Take Charge of Your Health page next month when we talk about food insecurity, with particular insight into access during the COVID-19 pandemic.

Pittsburgh vaccine trials at forefront of COVID-19 research

In the late 1940s and early 1950s, people in the United States were afraid of contracting polio, a highly contagious, disabling and sometimes deadly disease. It hit children especially hard. At its peak in 1952, the virus infected 60,000 children. Some parents kept their children indoors and isolated during the summer, a season when the virus seemed especially rampant. Only a vaccine could protect people from the disease.

University of Pittsburgh researchers Jonas Salk, MD, Julius Youngner, ScD, and colleagues had been working for years on a polio vaccine. Children in Pittsburgh participated in the first small study of a potential vaccine. In 1955, after a larger, nationwide trial, the vaccine was proved safe and effective. It was widely considered to be a monumental achievement in public health that led to the eventual eradication of new polio cases from the United States.

During the COVID-19 pandemic, we are, again, keeping our distance from each other and waiting for a vaccine. Many different vaccines are in development around the world, including at the University of Pittsburgh. Drs. Alejandro Hoberman and Judith Martin have conducted vaccine research in the region for 20 years through their Clinical Trials Unit. Now Pittsburghers will have another chance to participate in studies that could change lives for the better worldwide. The unit is preparing to conduct a COVID-19 vaccine study in the region. The effort begins with creating a registry of people who may be interested in participating in such a study.

Creating a registry of interested people will lay the groundwork for when a vaccine trial is ready to begin. Research studies are a multi-phase, rigorously monitored process. The first phase of a trial is a safety study, according to Judith Martin, MD, professor of pediatrics, University of Pittsburgh School of Medicine and codirector, Pittsburgh Vaccine Trials Unit.

"A phase-one study isn't looking at whether the vaccine works," she says. "Phase one is when we're just making sure the vaccine is safe and doesn't cause harm. Phase two of the study is where we know the vaccine is safe, but we're trying to figure out the dose and make sure it would be effective. Phase three builds on the findings of the previous phases. We know the vaccine is safe, and we're fairly confident it's going to work. Phase three studies are large scale with hundreds, if not thousands, of participants."

Currently, there are more than 100 vaccines in development around the world. To bring a COVID-19 vaccine trial to the area, the Pittsburgh Vaccine Trials Unit must evaluate each vaccine to see which is the safest



JUDITH MARTIN, MD

and the best fit for the community. The unit is multidisciplinary, with people from internal medicine, pediatrics, family medicine, infectious diseases, vaccine development companies, Pitt's Clinical and Translational Science Institute and from the community.

"Our job as scientists is to digest what we learn about each of the vaccine options and bring to the community the one we think has the best chance for success," says Alejandro Hoberman, MD, Jack L. Paradise Pro-



ALEJANDRO HOBERMAN, MD

fessor of Pediatric Research, University of Pittsburgh School of Medicine, professor of clinical and translational medicine and codirector, Pittsburgh Vaccine Trials Unit.

When the vaccines are ready for phase three clinical trials, Drs. Martin and Hoberman want to hit the ground running. To do that, they say they first need to understand the needs of the community and what people's concerns are. Then, people will be asked to go to the online registry

and indicate their interest in being a part of the phase-three study so that the community is prepared for when the study begins.

As with any study, Drs. Martin and Hoberman say it is necessary for the COVID-19 vaccine study to include people of any race, gender, sex or ethnicity. The more diverse a study population is, the better the chance is that the vaccine will be effective for everyone.

Researchers are learning more about COVID-19 every day. Dr. Hoberman says that while we cannot yet know when a vaccine will be available, the different phases of the vaccine trials are progressing quickly. But when it is time to conduct phase-three studies of vaccines, Drs. Martin and Hoberman want Pittsburgh to be in on it.

"We want our community to have the advantages of a COVID-19 vaccine," says Dr. Martin. "I see it as the best of both worlds: We're bringing something to the community that's potentially going to protect them, and they can benefit from it earlier than the rest of the population. This is going to be another opportunity for Pittsburghers to demonstrate that they can contribute to scientific progress."

Check <https://www.chp.edu/our-services/mobile-medical-clinic/schedule> for the most up-to-date

locations and dates this summer!

All clinics run from 10AM – 2PM

Neighborhood	Location	Dates
Chartiers	Chartiers Early Childhood Center 3799 Chartiers Ave, Pittsburgh, PA 15204	June 8 th & 10 th
Clairton	Family Dollar 533 Miller Ave, Clairton, PA 15025	June 4 th
Coraopolis	Cornell School District 1099 Maple St, Coraopolis, PA 15108	August 31 st
Homestead/Munhall	Steel Valley Middle School 3114 Main St, Munhall, PA 15120	July 27 th & 29 th
Homewood	Homewood-Brushston YMCA 7140 Bennett St, Pittsburgh, PA 15208	June 25 th & July 23 rd
Natrona Heights	Allegheny Valley YMCA 5021 Freeport Rd, Natrona Heights, PA 15065	July 2 nd & August 6 th
New Castle	New Castle Jr/Sr High School 300 E Lincoln Ave, New Castle, PA 16101	July 20 th & August 19 th
New Kensington	Valley Points Family YMCA 800 Constitution Blvd, New Kensington, PA 15068	June 22 nd & July 16 th
North Side	Children's Museum of Pittsburgh 10 Children's Way, Pittsburgh, PA 15212	June 17 th & July 15 th
Penn Hills	Penn Hills Family Care Connection 10 Duff Rd, Penn Hills, PA 15235	June 18 th & July 31 st
Wilksburg	Wilksburg School District 718 Wallace Ave, Pittsburgh, PA 15221	June 19 th & July 13 th

Don't let your child fall behind on their needed immunizations.

UPMC Children's Hospital of Pittsburgh, UPMC Children's Community Pediatrics, and Ronald McDonald House Charities of Pittsburgh and Morgantown are partnering to bring needed vaccines, safely, to western Pennsylvania communities.

Look for the Ronald McDonald Care Mobile in your community.

Have questions or need more information? Contact the Care Mobile at 412-352-1059. | Check www.chp.edu for more dates and locations this summer.