

Boosting diversity in COVID-19 vaccine clinical trials

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Reverend Debra Hickman, founder and CEO of Sisters Together And Reaching, is aiding in recruiting Black volunteers for COVID-19 vaccine trials to help ensure its efficacy across populations. Credit: Chris Hartlove

From the pandemic's earliest days, the coronavirus has hit hardest in Black, Latinx, and Native American communities. The mortality rate among these groups is more than twice that of whites, according to the Centers for Disease Control and Prevention. Many explanations have

been given: Minorities are more likely to work at riskier, frontline jobs for grocery stores, public transit systems, or warehouses; live in multigenerational households; and be impacted by systemic health care inequities leading to more comorbidities and less access to care.

Rev. Debra Hickman doesn't need to read the statistics or explanations; she lives them.

Her first encounter came when she gave a graveside service for a [coronavirus](#) victim. "Now, I know a lot of folks with family members that have passed on from COVID," says Hickman, an assistant pastor at the City Temple of Baltimore Baptist Church, in the city's Bolton Hill neighborhood.

Hickman wears her mask. She practices physical distancing. She knows how the virus spreads and what behaviors to avoid. Still, at rare times, she sees so much heartbreak and loss that she is "reminded of our humanity" and bends the rules.

"Sometimes I might take a risk just to hug a person," she says, "if they seem that they really need that hug."

But hugs won't end this scourge, as Hickman well knows. She shares a commitment to faith and health as founder and CEO of Sisters Together and Reaching, a nonprofit health care organization providing support, direct health services, and prevention education to underserved Baltimore communities, with an emphasis on Black women living with HIV and their families.

Faith leaders and small community organizations like hers may be playing a big role in curbing the greatest health crisis of our age.

Ending the pandemic will require a safe and effective COVID-19

vaccine. And the best and most ethical way to create one is to make sure the most vulnerable populations are well represented in clinical vaccine [trials](#). That means Black, Latinx, and Native American volunteers must, literally, roll up their sleeves and join Phase 3 [clinical trials](#). Hickman and groups like hers are now helping to spread this message amid a process that is happening at "warp speed."

Scientists want to test a vaccine candidate's efficacy in different populations because they want to make sure it works in the groups most affected by COVID-19, says Anna Durbin, principal investigator at the Johns Hopkins Center for Immunization Research. For a large AstraZeneca trial, which has a national goal of 44,000 participants, the center is charged with signing up around 500 people this fall, mostly recruited from Baltimore with some from the Eastern Shore and southern Pennsylvania. CIR has also nearly completed enrolling just over 100 volunteers so far for a Pfizer/BioNTech trial. The overall goal is to have these trials be at least as racially diverse as the country itself, with individual recruitment sites reflecting local demographics. In Baltimore, that means signing up some 300 Black residents for the AstraZeneca trial alone.

But the effort faces headwinds in minority communities, including a general mistrust in medical research and big pharmaceutical companies as well as fears of becoming guinea pigs in a rushed, politicized process. Some undocumented Latinx residents worry that participating in a trial could somehow expose them to immigration authorities. And then there are the challenges of the pandemic itself.

"This kind of outreach takes time and effort, but things are happening very quickly," says Durbin. She adds that building trusting relationships with communities is best done in person—through shoe leather and handshakes. However, COVID restrictions require reaching out remotely over Zoom.

Since churches and mosques are among the anchor institutions for Black and Latinx Baltimore, researchers launched a series of listening sessions with faith leaders, says Chris Beyrer, an epidemiology professor and senior scientific liaison for the CoVPN. "Basically, we want to ensure that they have the information and the expertise they need to then speak to their constituents, to their communities, to their congregations about this effort," Beyrer says.

Researchers are also leveraging existing connections with community partners like Generation Tomorrow, which trains health workers in HIV and hepatitis C screening in Baltimore. "The good thing is that we have people that we have worked with and know us, and we can now translate that relationship over into COVID-19," says Risha Irvin, an assistant professor at the Johns Hopkins School of Medicine and the organization's founder and director.

To persuade the skeptical and those who have been confused by mixed messages around COVID-19, Irvin emphasizes the primacy of science. It will dictate the timeline and the messaging around a vaccine, she says. Another dimension of community's experience, she adds, also must be addressed: "We need to make room for discussions about systemic racism and the distrust that may exist, and not try to hide from those issues," Irvin says.

"Historically, [medical research](#) has not treated these populations well," says Kawsar R. Talaat, a CIR investigator and assistant professor in International Health. "The Tuskegee [syphilis study] comes up in pretty much in every conversation that we have. It is still very fresh on the minds of people, and it's something that we have to address—the huge mistakes and huge abuses."

Talaat's strategy is to acknowledge past errors while emphasizing that it's a new era with institutional review boards and other oversight

mechanisms.

Another challenge for researchers: Physical distancing and strict sanitizing protocols require that the vaccine trials be conducted at a Hopkins facility instead of in the field, making it more harder for participants. The AstraZeneca double-blind trial requires participants come in for two separate injections and make as many as six follow-up visits over two years. They will be compensated \$860 for their time. To increase Latinx participation, a mobile medical unit will be deployed to reach a largely Latinx workforce at a meat processing plant in Pennsylvania. Such plants have accounted for more than 45,000 COVID-19 cases and 214 deaths, according to the nonprofit Food and Environment Reporting Network. At least 20 poultry plant workers on Maryland's Eastern Shore have died.

Researchers understand that one way to achieve an urgent short-term medical goal is to wrap it within the larger aim of building a lasting health care relationship and chipping away at inequities. "We make a point to say that we aren't just coming in do a trial and then leaving," Durbin says. "So we ask, what can we bring to the community besides these trials that is going to last? How can we help with getting people engaged in health care?" Durbin's team, for example, is working with the regional Latinx and immigrant advocacy group Casa de Maryland to beef up their COVID-19 testing program and to assist them with diabetes and blood pressure screenings.

Such deeper relations can only help when the next great public health campaign rolls out: encouraging people to get immunized once a COVID-19 vaccine is available. That may not easy. Nearly half of Black American adults might refuse a COVID-19 vaccine based on fear and mistrust, according to an October poll by news website The Undeclared and the Kaiser Family Foundation. Such fears may have been reinforced when the FDA paused the AstraZeneca trial in September across the

U.S. after a UK trial participant experienced a "serious adverse event."

"It's like a double-edged sword," says Irvin. "It's exactly what should happen until they figure out the causes. That's good science. But then for individuals seeing on the news that it's been stopped, it can also add to their fear or hesitancy."

Will the local clinical trial recruitment efforts be enough? In early September, Moderna slowed enrollment in its vaccine trial to focus on bolstering diversity; when enrollment completed, Black people accounted for 10% of participants. By early November, 10% of Pfizer's U.S. trial participants were Black and 13% Latinx.

"While I am encouraged by a more concentrated and intentional effort to increase COVID-19 clinical trial diversity, enrollment of diverse participants is still lagging overall," says Aletha Maybank, vice president and chief health equity officer of the American Medical Association. "It will be key to ensure that equity inclusive of an anti-racism lens remains a strategy and a goal for all vaccine trials, as well as when it comes time to actually disseminate a vaccine."

For her part, Rev. Hickman is on board. Her team is armed with the information they need to discuss the vaccine trials in Baltimore neighborhoods. "In our African American community, there is a huge need for us to participate at this hour," Hickman says. "I think it's time for us to move away from the drama and negative pathways that have been created in America and create pathways where people are simply saying, "I really need to get the information I need so that I can do my part.""

Hickman knows the suffering is far from over, but she keeps the faith.

"We will get through this," she says. "That's what we have to get up on

every day and go to sleep on every night—we will get through this."

Provided by Johns Hopkins University

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