Heart of the Matter

People living with HIV are crucial to clinical trials related to the virus.

June 24, 2024 By Jay Lassiter

Alicia Diggs, MPH, is a busy woman. Currently wrapping up her PhD in public health education, she’s driven by a desire to improve the health care system for women and people of color.

A Philadelphia native now residing in Burlington, North Carolina, Diggs splits her time between her academic pursuits and cutting-edge scientific collaborations with some of the most brilliant doctors and clinicians in the game.

Along the way, she’s helping change the status quo that gives rise to race- and gender-based disparities in the American health care system.

In the past decade alone, Diggs has participated in “roughly a dozen” research studies and clinical trials. Diagnosed HIV positive in December 2001, she participated in her first research trial in 2007.

“It’s important that we—we, meaning women—are in these studies,” says Diggs. “Years ago, when HIV treatment started to come out, there weren’t many women in a lot of those clinical trials—[it was] predominantly just white men. Medications were being developed, but we were not in those studies, especially Black women. So we’re taking medications but aren’t sure how the side effects are going to affect us differently than our male counterparts.”

She also notes the historical medical trauma women and people of color have faced—for example, the infamous Tuskegee experiment in which Black men with syphilis were left untreated so physicians could study the progression of the sexually transmitted infection.

Diggs also cites J. Marion Sims, long considered the “father of gynecology” in America.

“He was a Caucasian physician back in slavery times doing experiments on Black women and children with no anesthesia,” Diggs says. “These women were in pain. And this continued. Some women died. Some children died. But the experiments were being done on Black bodies with no anesthesia.”

This history helps explain why recruiting more women, especially Black women, for clinical trials can be an uphill battle.

Alicia Diggs Natalia Weedy

"But today, we have a voice that researchers and scientists would like to hear from," Diggs says. "There are a lot of consent documents that are in place to protect us. You can sign up for a study and then in the middle of it decide you don't want to do it anymore. And that's OK."

Diggs cites "free health care" as the best reason to sign up for clinical trials. (Most clinical trial costs are covered by the trial sponsor.) She's also keen to propel science forward for humanity, which she says is "rewarding and meaningful."

"I'm not there for the $50 gift card," she quips. "It is not about the money. It's about making sure that there's a diverse population participating. It's to make sure that there are people who look like me taking part."

Clinical trials are useful for examining gender-based health care disparities.

The Randomized Trial to Prevent Vascular Events in HIV (REPRIEVE) study demonstrated that women living with HIV face a higher risk for adverse cardiovascular events than HIV-negative women. REPRIEVE was a randomized trial studying the heart health of participants living with HIV. Diggs was a participant in the REPRIEVE study.

Markella V. Zanni, MD, of Harvard University, was one of REPRIEVE's lead researchers.

"There were 7,769 participants overall, among whom 2,419 (31%) had female sex at birth," says Zanni.

"REPRIEVE results suggest that traditional risk calculators may underestimate heart disease risk among women with HIV," she says. "For this reason, it's important for women with HIV to discuss their heart disease risk with clinical care providers and strategize about ways to reduce risk." That's the bad news.

The good news is, neither a cure nor a vaccine are needed to address the disparities revealed by REPRIEVE. For instance, we already know that diet and exercise can mitigate the increased heart disease risk that HIV-positive women face. There's also medication.

"Through REPRIEVE, we learned that statin therapy reduces heart disease events to the same extent among women with HIV as among men with HIV," Zanni says. All it took was a clinical trial that prioritized female participation to achieve this very consequential conclusion. (For more on the REPRIEVE trial, please see “Give it a Try.”)

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In general, the misconceptions that Black people face when seeking care are extensive, says Diggs. These include the belief that Black people’s skin is actually thicker than white people’s, that Black people’s blood coagulates differently and that Black people’s nerve endings are less sensitive than those of their white counterparts. None of these are true, but the myths endure and affect how clinicians perceive and treat Black people. Especially when it comes to treating Black people in pain.

“So for us as, Black and brown communities, especially women, when we go to the doctor and we say that we’re in pain, we’re not treated like our white counterparts when it comes to that pain,” Diggs says.

What’s more, Black women confront health care disparities, especially during pregnancy and childbirth, even after controlling for factors such as income and access to care.

Diggs cites as an example Serena Williams, arguably the greatest champion in the history of tennis. Williams won the 2017 Australian Open while 10 weeks pregnant. She is one of the most physically gifted humans ever to wield a racket. And yet she nearly died during childbirth.

More recently, the Olympic gold medal–winning sprinter Tori Bowie died last year during childbirth. Once quite literally the fastest woman on the planet, Bowie went into labor early and died at home, alone, from childbirth complications. Her premature child was stillborn.

Does Diggs find these examples demoralizing? Quite the contrary. “It makes me work harder. It makes me stay in the fight. It truly makes me stay in the fight,” she says.

Diggs knows she’s fighting HIV stigma. She’s also fighting to get more women—in particular, women of color—into clinical trials, which starts by setting an example.

“This work around HIV advocacy can be stressful,” she explains. “It can be tiring. It is hard. It is heavy. But when you know there are other people dealing with unfair treatment or unfair access or lack of access, it makes you want to continue to fight. Because I am the person that I am—someone who speaks up because I have a voice—I think about those who haven't found their voice yet. I truly feel like it is my duty to stand up for and represent my peers who don't have the same access or who don't have the same voice as I do."

Diggs says clinicians also have a duty to communicate better with trial participants as well as those who aren't selected for trials.

"Researchers need to explain to the participants clearly why they can't participate," Diggs says. "People feel like they're being rejected because of race and gender. I hear women say, 'Well, I was rejected from a study, and I know it's because I'm Black, and I'm a woman.' But what I've learned over time is if there are other health issues going on, it is safer for the person to not participate versus participating. Like if you have anemia, it's not good to be in a study that has large blood draws. Years ago, people were rejected because of race or gender, but now it is primarily about safety for the participants."

A far cry indeed from the days when unethical medical experiments on vulnerable populations were common.

When we do have a representative number of women enrolled in clinical trials, we learn interesting and important things, such as that HIV-positive women are at greater risk for heart health issues than women who are HIV negative.

According to Diggs, the first step in encouraging others to participate might be acknowledging the cultural and systemic barriers women of all races—especially mothers and caregivers—face.

"Most times, women are not focusing on themselves because they're taking care of other family members or they're working," she explains. "Transportation could also be a huge issue. There are so many different factors and barriers for women."

Zanni, the REPRIEVE researcher, says her colleague Sara Looby, PhD, was "instrumental in developing and launching the "Follow Your Heart" campaign to recruit more women into clinical trials and research studies."

The number of women in the REPRIEVE study, roughly a third of participants, might seem low considering women make up half the population. But women constitute slightly less than a quarter of America's HIV-positive population. So in this instance, women were in fact robustly represented.

Diggs says the trials she’s involved with usually have a patient advisory board, something she strongly recommends joining.

“Being a part of the advisory board consisted of just listening to some of the new writings that the researchers were doing to get our opinion, especially on screening questions,” Diggs explains. “When some of the questions or the surveys were being generated, we had buy-in. It was really just asking us as a community to make sure that they were delivering in a way that was equal, if you will.”

Community advisory boards help craft eligibility questionnaires to be more culturally competent and relevant so that future studies don’t just enroll a cohort of white men.

“It’s really important that our voices are there so that we have input and changes can be made that are favorable for us,” Diggs says. “A lot of times I am encouraging my peers to at least understand research studies and get a little bit more information and talk to your physician, social worker or someone who is involved with these studies and trials to get more information.”

Diggs also advises would-be participants to connect with others who are involved and who have success stories. “Such as myself,” she says.

Alison Rodger, MD, of University College London, echoes the sentiment that gender parity is a must. Rodger’s groundbreaking research underpins the Undetectable Equals Untransmittable message (U=U), which states that people on effective HIV treatment don’t transmit the virus via sex. (Go here for a profile of Rodger.)

“We know that sex and gender are major determinants of health outcomes and responses to medical treatments and vaccines,” Rodger says. “The REPRIEVE study demonstrated yet again that it is critical to ensure adequate recruitment of women to clinical trials to be able to effectively inform evidence-based care.”
