



Trustworthiness before Trust — Covid-19 Vaccine Trials and the Black Community

Rueben C. Warren, D.D.S., Dr.P.H., M.Div., Lachlan Forrow, M.D., David Augustin Hodge, Sr., D.Min., Ph.D., and Robert D. Truog, M.D.

The only way out of today's misery is for people to become worthy of each other's trust.

— Albert Schweitzer

As the race to develop a vaccine for Covid-19 has reached phase 3 clinical trials, concerns are increasing about the low rates of trial participation in important subgroups, including Black communities. Recent data show that although Black people make up 13% of the U.S. population, they account for 21% of deaths from Covid-19 but only 3% of enrollees in vaccine trials. This problem threatens both the validity and the generalizability of the trial results and is of particular concern in vaccine trials, in which differences in lifetime environmental exposures can result in differences in immunologic responses that could affect both safety and efficacy. Despite long-standing calls from the Food and Drug Admin-

istration (FDA) and the National Institutes of Health (NIH) to improve the participation of underrepresented subgroups in drug trials, the problem persists.¹

What are the barriers to greater participation of Black people in Covid-19 trials? Although they are multiple, a critical factor is the deep and justified lack of trust that many Black Americans have for the health care system in general and clinical research in particular. This distrust is often traced to the legacy of the infamous syphilis study at Tuskegee, in which investigators withheld treatment from hundreds of Black men in order to study the natural history of the disease. But the distrust is far more deeply rooted, in centuries of well-documented examples of

racist exploitation by American physicians and researchers.²

How can these long-standing barriers to trust be overcome? The presidents of Dillard and Xavier Universities, two of the 104 historically Black colleges and universities (HBCUs) in the United States, recently wrote to their communities saying that they themselves were participating in one of the vaccine trials and asking their students, faculty, and staff to consider doing the same. The pushback from parents of some students came quickly. One wrote on Xavier's Facebook page, "Our children are not lab rats for drug companies. I cannot believe that Xavier is participating in this. This is very disturbing given the history of drug trials in the black and brown communities."³

Presidents of the four historically Black U.S. medical schools recently called for measures to increase the participation of Black

patients in clinical trials, correctly arguing that without such involvement, “there will be no proof that our patients should trust the vaccine.” The presidents added that “Black doctors are the best way to build trust in our communities” and called on other HBCUs to join the effort to “foster trust in communities throughout the country.”⁴

Though we applaud these efforts, we fear that once again the responsibility for addressing the sequelae of centuries of racism is falling on Black people themselves. Our country has yet to comprehend adequately that overcoming racism is not primarily the responsibility of Black people; the racist ideas and practices that constitute today’s “structural racism” were created, and have been sustained, primarily by White people. It would be wrong, as well as ineffective, to ask Black communities to simply be more trusting. Clinicians, investigators, and pharmaceutical companies must provide convincing evidence — sufficient to overcome the extensive historical evidence to the contrary — that they are, in fact, trustworthy.

What can we do to earn and deserve increased trust?

First, trial sponsors and regulatory agencies can ensure that the informed-consent process is exemplary, including ensuring that all relevant aspects of the design and conduct of the clinical trials are maximally transparent.

Second, all clinical research depends on people who are willing to accept the risks posed by trial participation in order to improve health for the people who come after them. Black participants who agree to enroll in these trials have a right to expect and trust that Black communities will

have fair access to vaccines once they become available. The recent guidelines from the National Academy of Sciences (NAS) are notable in this regard, recommending that priority be given to “people who are considered to be the most disadvantaged or the worst off,” as defined by measures such as the Social Vulnerability Index created by the Centers for Disease Control and Prevention.⁵ Though this approach would not directly target people in specific racial or ethnic groups, it is functionally antiracist in that it prioritizes people who have suffered from the social determinants of poor health that are unfortunately prevalent in many Black communities.

Third, politicization of the vaccine trials has engendered widespread mistrust among the general public. The joint pledge by nine pharmaceutical companies that they will “stand with science” and not submit a vaccine for approval until it has been thoroughly vetted for safety and efficacy is welcome, but earning trust will require credible evidence that this pledge is being honored. Just as important, however, is that the evidence must not only be convincing to the general public, but — in the words of the NAS guidelines — also be perceived as convincing “by audiences who are socioeconomically, culturally, and educationally diverse, and who have distinct historical experiences with the health system.”⁵

Fourth, to earn and deserve trust from prospective trial participants, we must ensure that they will receive appropriate medical care if they are injured as a result of receiving an experimental vaccine. In addition to often lacking access to health care, Black people are also disproportionately

likely to be uninsured, and pharmaceutical sponsors in the United States are not required to provide compensation to people who experience research-related injuries. Even when participants have insurance, there is no guarantee that they will be covered for such injuries. In many cases, injured participants will be forced to rely on the tort system for compensation — a situation that is morally indefensible, especially for participants who lack the means to engage in this time-consuming and expensive process. One way to demonstrate trustworthiness would be for the pharmaceutical companies sponsoring these trials to establish a fund to guarantee health care coverage and death benefits to patients and families as compensation for serious vaccine injuries or possible deaths.

When Covid-19 vaccines are eventually approved by the FDA, their success in Black and other communities will depend on whether members of these communities not only trust that they are safe and effective, but also believe that the organizations offering them are trustworthy. Trust could be earned more quickly by a collaboratively designed Operation Build Trustworthiness that matches the seriousness and scope of Operation Warp Speed. To be effective, this effort would need to be firmly grounded in grassroots involvement of individuals and organizations with solid, well-earned reputations for trustworthiness in Black and other minority communities, including respected elected representatives, trusted local and national faith leaders, community advocates, and others. Active, ongoing, and fully bidirectional collaboration, learning, and communication will be

essential. Time is running short, and trustworthiness, not trust, must be our first and most urgent priority.

Disclosure forms provided by the authors are available at [NEJM.org](https://www.nejm.org).

From the National Center for Bioethics in Research and Health Care, Tuskegee University, Tuskegee, AL (R.C.W., D.A.H.); and the Center for Bioethics, Harvard Medical School, Boston (L.F., R.D.T.).

This article was published on October 16, 2020, at [NEJM.org](https://www.nejm.org).

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DOI: 10.1056/NEJMp2030033

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