Building Trust in COVID-19 Vaccines and Beyond Through Authentic Community Investment

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OVID-19 vaccine development has advanced at lighting speed. Research that would normally require years has been completed in months. As a result of this unprecedented effort, two vaccine candidates, mRNA-1273 (Moderna, Cambridge, MA) and BNT162b2 (Pfizer, New York, NY), have been found to be safe and more than 90% effective in preventing symptomatic COVID-19 shortly after vaccination. These vaccines are extremely promising and will eventually be distributed widely. Unfortunately, as the science of vaccine development has swiftly progressed, the equally important science of community engagement, which should guide the establishment of mutually beneficial partnerships and promote eventual vaccine uptake, has lagged behind. Research methods focused on the development of effective public health interventions place communities groups with shared culture, norms, beliefs, or language—at their core and emphasize the primacy of community ownership as essential for uptake and

sustainability. 1 Yet, communities of color (i.e., Black, Latinx, and Indigenous communities), who remain at highest risk for infection, have been peripheral, not central actors in the pursuit of COVID-19 vaccines. Instead, the tripartite relationship between industry, government, and academia has dominated the research enterprise related to COVID-19.

The peripheral position of community has been evident since early in vaccine development. Notably, initial trial recruitment consisted of short-term community outreach, and more detailed plans for longer-term community engagement to support enrollment and eventual vaccine uptake commenced late in phase III trials. Such a critical oversight may be the Achilles' heel of this unprecedented effort. Deeply rooted mistrust bred by centuries of well-documented, abusive medical experimentation and ongoing structural racism impedes racially and ethnically diverse individuals' participation in clinical trials and threatens the uptake of future COVID-19 vaccines, particularly among Black individuals.

This history may be overcome by reimagining how industry, government, and academic institutions partner with marginalized communities. COVID-19 vaccine development offers an opportunity to shift from transient outreach to true investment in communities of color, which may mitigate mistrust, improve vaccine uptake, and have far-reaching effects beyond COVID-19.

TRUSTWORTHINESS AND VACCINE DEVELOPMENT

Vaccine development is a continuum, from clinical trials to allocation plans to distribution and eventual uptake. If any stage of this continuum fails to build trust and to demonstrate the trustworthiness of those involved, the overall effort will be undermined. For example, as phase III trials began, concerns were raised regarding lack of transparency in reporting participant demographics and suboptimal enrollment of diverse populations. Given the threefold higher rates of COVID-19 infection among Black, Latinx, and Indigenous individuals compared with non-Hispanic Whites,² the National Institutes of Health recommends that these groups be represented in COVID-19 vaccine trials at higher rates than their population proportion.3

Pfizer reported participation rates of Black and Latinx individuals of 10% and 13%, respectively, in its vaccine trial,⁴ which is lower than the proportion of these two groups in the US population. Suboptimal diversity in clinical trial participation may translate into low vaccine uptake. As several vaccine candidates entered phase III trials in the United States, anticipated acceptability decreased significantly—from 54% to 32% among Black and from 74% to 56% among Latinx individuals.⁵ Although the

National Academy of Science, Engineering, and Medicine has proposed a comprehensive allocation framework for vaccine access,⁶ without diversity in clinical trials, complete transparency, and clear demonstration of the trustworthiness of all partners, skepticism surrounding COVID-19 vaccines will continue to grow.

CURRENT OUTREACH AND ENGAGEMENT APPROACHES

We believe that efforts to end the pandemic through vaccination will be hampered because of an overemphasis on short-term strategies, such as community outreach, delayed community engagement, and absent investment in at-risk communities. For clarification, community outreach is the act of connecting with stakeholders or groups in communities to provide information and is often used for clinical trial recruitment. By definition, community outreach is temporary, unidirectional, and focused on limited goals. By contrast, community engagement is the longer-term process of working collaboratively with groups of people to address issues affecting the well-being of those people. Public health research and practice have increasingly employed community engagement to build trust and improve overall health outcomes. Although community engagement in COVID-19 vaccine trials has been initiated, it began after the studies were designed and, in some cases, already under way.

Neither short-term community outreach nor post facto community engagement will contribute to building a foundation of trust. Conversely, these approaches may further exacerbate mistrust and raise questions regarding the motivations of researchers, industry, and policymakers. For example, when stakeholders are asked to recruit participants after trials have been initiated, they are rarely able to address community needs, which may limit study participation. A more authentic community engagement process would begin earlier (i.e., during study development) and result in raised awareness of barriers to participation and study redesign if needed. In the end, we have created "outreach fatigue" among many stakeholders (i.e., exhaustion related to interactions with researchers with little foreseeable benefit to the communities themselves) and doubt regarding the trustworthiness of engagement efforts.

AUTHENTIC COMMUNITY INVESTMENT

Decades of systematic disinvestment and structurally racist policies have resulted in deficits in material resources in many communities of color. As a result, partnerships with external entities, such as academia and industry, are inherently unequal. Meaningful community investment would acknowledge the need for capacity building that would

Selected Investment Strategies to Support Communities of Color as Partners in COVID-19 Vaccine Research and Beyond

Invest in community-based organizations and institutions.	Provide direct, longitudinal financial investment in community organizations that partner in clinical research.
	Engage community organizations for participant recruitment "plus" (e.g., for vaccine education, deployment, distribution), and fund interventions to increase vaccine uptake (e.g., vaccine educators).
	Provide in-kind resources, including technical expertise, mentoring, and clinical and nonclinical resources to help strengthen and build capacity in community organizations.
	Provide development resources to minority-owned businesses that are engaged in research-relevant work.
Invest in community participation in research.	Cover the cost of adverse events for study participants who do not have insurance or are underinsured.
	Establish a seamless system to access care if participants become infected.
	Guarantee that all trial participants have access to an approved vaccine, even if from a different trial.
Invest in building trust.	Increase transparency of government contracts for manufacturing and distribution.
	Require that industry establish contracts with minority-owned businesses in proportion to the public dollars invested.
	Engage a nongovernmental "honest broker" organization to monitor vaccine access, community investment, and investment in minority-owned businesses.
Invest in community education and research leadership.	Establish programs to improve health and science literacy in communities of color, and increase funding to support the development of careers of racial and ethnic minority investigators who are committed to the study of vaccines and other public health approaches to mitigate pandemics.

lead to more equal partnerships in defining and achieving shared priorities, such as ensuring the uptake of safe and effective COVID-19 vaccines. Investment strategies would contribute to the establishment of partnerships between communities of color, industry, academia, and government that build on assets in each entity and ensure mutual and bidirectional benefit. Drawing on the principle of shared-value creation, as Porter and Kramer propose,7 community investment involves creating economic value in a way that also supports societal needs and challenges. For example, providing direct, longitudinal financial investment in stakeholder organizations now may lead to more collaborative research and intervention development in the future.

Furthermore, community investment may build trust and shift the perception of a COVID-19 vaccine from a guestionable intervention to a trustworthy, collective good from which all will benefit. To our knowledge, there is no systematic effort to invest in communities in ways that will change the fundamental nature of the relationship between communities of color, industry, academia, and government. Given the enormous investment of federal funds in the public-private partnership to develop candidate COVID-19 vaccines, the inclusion of communities of color who are at highest risk in this partnership is warranted. To that end, community investment could be promoted by a series of systematic strategies, examples of which are provided in the box on p. 367.

CONCLUSIONS

With many COVID-19 vaccine candidates still under study, the race to find effective and safe options is far from over. Therefore, we must consider relevant

ways to maximize the return on the extensive public investment in COVID-19 vaccine development and ensure equity in access. We would be well served if these recommendations were routinely integrated into the conduct of clinical trials and intervention development so that investment in communities of color is an ongoing process. The pandemic has not created health inequities: it has amplified those that have long been tolerated. We have an opportunity to create new and innovative approaches to the long-standing problem of ensuring participation among diverse groups in clinical trials, to improve broader health literacy, and to enable communities to be robust partners in the research enterprise. Let us learn from this crisis to create a new normal, one that uses public investment and leads to true public good. AJPH

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CONFLICTS OF INTEREST

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