Assessing Strategies for Inclusion of Marginalized Communities in Clinical Trials—What’s the Plan?
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The toll of health inequities is enormous and contributes exponentially to our health care costs and loss of life by historically marginalized communities. In that regard, literature regarding diversity in clinical trials has been increasing, given the heightened awareness of racism, implicit bias, and lack of community engagement and inclusion in research. Historically marginalized communities, defined by race and ethnicity, gender, socioeconomic status, rurality, age, and ability, are less likely to be engaged and enrolled in clinical trials due to lack of convenience and lack of trust in those recruiting, although these marginalized communities are disproportionately represented in chronic and acute disease states. Given that Black Americans and other Indigenous populations and tribal communities were the original unwilling clinical trial enrollees in gynecologic, genetic, and infectious disease studies, one could argue that the lack of trustworthiness of research institutions has contributed to limited enrollment and participation of marginalized communities, which needs to be rectified to improve inclusivity and accurate representation of those affected by disease.

To that end, the study by Florez and colleagues in this issue of JAMA Network Open attempts to address one aspect of inclusion of marginalized communities. The authors performed a survey study that assessed strategies used by researchers to reach out to marginalized populations being recruited to clinical trials from public, private, and academic settings (termed for profit and nonprofit/government). The study is interesting and timely but would benefit from the use of inclusive and up-to-date language (as opposed to disadvantaged) as well as a better definition of “socioeconomically disadvantaged groups,” which one could argue represents social determinants of health as defined by the Centers for Disease Control and Prevention. The authors state that a “working group” of pharmaceutical companies supported the trial and that research sites actively conducting research trials with pharmaceutical companies were recruited, but it is unclear how this list was developed, how sites were recruited, and what the denominator of the study was; although, the authors estimated the response rate to be 7.4%. Florez et al also described using 19 questions in the survey that assessed site demographics, planning, monitoring, recruitment, and access, and developed a “validated survey” that was not validated in a standard fashion. In their analysis, for-profit sites were more likely to offer patient-centered approaches to community participation compared with nonprofit or governmental settings, which was surprising but not unexpected given some of the limitations of federal funding where many academic and public medical institutions receive the bulk of their funding. Finally, the study might have benefited from a multivariable analysis to investigate specific risk factors associated with positive or beneficial outcomes.

In response to the lack of diversity in clinical trials, the Food and Drug Administration (FDA) developed draft guidance for diversity plans to improve enrollment of minoritized populations in clinical trials and industry-sponsored research. Although the FDA focused on racial and ethnic historically minoritized individuals, the FDA defined diversity by race, ethnicity, sex, gender identity, age, pregnancy, and lactation status as well as comorbid conditions. Motivated by a House bill to increase diversity in new drug clinical trials, the recommendations could be used for other marginalized communities as well and includes such measures as (1) offering financial reimbursement for expenses incurred by participants; (2) providing language concurrent information, and (3) developing community-based organization (CBO) partnerships to provide assistance when needed.
Unfortunately, the FDA has not finalized the draft guidance, and there is no current legislation that would help to fund this guidance.

Current literature shows that historically marginalized communities can be engaged to increase enrollment into clinical trials. One example of that comes from the COVID-19 Prevention Network, which showed that 47% of participants were Black, Indigenous and People of Color (BIPOC) individuals and that increasing BIPOC participant enrollment required community and CBO engagement using community-based participatory research principles, increasing diversity in volunteer registry records, targeting various methods of communication, and having a strategy to increase enrollment (faith-based or other targeted outreach). Despite these efforts and fiscal resources, White participant enrollment “outpaced” BIPOC enrollment. Much needs to be done to ensure that diverse groups, which include those with low resourced social determinants of health, are included in clinical trials as advocated by the National Institutes of Health, as well as the FDA and the National Academies.

Considering the FDA's recommendation to develop a plan for inclusion, Congress needs to update laws to motivate researchers, drug companies, and NIH to increase diversity in clinical trials. To that end, Washington State passed legislation that will require the state academic medical institutions to increase diversity in clinical trials. Funding is provided to help with policy change and to engage historically marginalized and minoritized communities. The law requires improvement in the completeness and quality of data obtained by researchers, barriers to clinical trial participation must be identified, demographic data results must be collected in a transparent manner, and clinical trial participants must be offered information in languages other than English if culturally appropriate. The more specific deliverables for academic institutions include (1) adopting a policy that includes better identification and recruitment of underrepresented individuals; (2) providing information to trial participants in languages other than English; (3) provide translation services or bilingual staff for studies and (4) provide culturally specific recruitment materials. Although very difficult, this law is the only 1 in 50 states (to date) that mandates diversity in clinical trials at the institutional level and provides funding for it although CBOs must apply for funding through a separate organization.

Diversity in clinical trials is a timely and important issue. Florez and colleagues' foray into evaluating the baseline of where certain recruitment sites are is a very important and needed first step in that process. We must do more to increase diversity in clinical trials as a research community and need to develop and follow a plan that can model successful engagement of communities at the initiation of research if we want to become trustworthy partners in improving health and diminishing health inequities for all of our communities.

ARTICLE INFORMATION
Published: June 7, 2024. doi:10.1001/jamanetworkopen.2024.13927
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Conflict of Interest Disclosures: Dr Young reported being a site coinvestigator for Vertex at the University of Washington (but no funding of any kind from Vertex).

REFERENCES


