



Combating Structural Inequities — Diversity, Equity, and Inclusion in Clinical and Translational Research

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The Covid-19 pandemic has rendered U.S. racial, ethnic, and social health inequities too stark to ignore. In the face of continuing disparities in health risk and staggering inequities in Covid-19

morbidity and mortality, the scientific workforce must confront the structural racism that has shaped not only the pandemic but also centuries of disparate health outcomes. The health crisis and its sociopolitical context have underscored how ill prepared our health care and public health systems are to mitigate inequities. We believe that if the clinical and translational research enterprise is to help resolve current and future health crises and ensure that all people in the United States, including members of historically disenfranchised communities, have the opportunity to live healthy lives, it must shift paradigms and begin to center diversity, equity, and inclusion (DEI) in its work.

DEI has long been acknowledged as a crucial mechanism for broadening the scope, creativity, and innovativeness of research that seeks to solve complex problems and reduce inequities in health and disease. For two decades, the National Institutes of Health (NIH) and other research organizations have been promoting DEI as key

to enhancing the quality and impact of clinical and translational science. Yet we have seen little in the way of racial or ethnic diversification of research leaders, trainees, or trial participants or increases in funding or promotion of research on health equity.

The 2020 U.S. Census estimated that 33% of people in the United States identify as members of racial or ethnic groups that are underrepresented in medicine,¹ but less than 6% of research faculty are members of such groups.² Training programs have not done well in recruiting and retaining diverse scholars; for example, medical school graduates from underrepresented groups receive career development, or K, awards from the NIH at less than half the rate of those from well-represented groups.³ Diverse communities (especially those historically disadvantaged because of race or ethnicity) have limited access to high-quality science education and information and tend to be underinformed about the merits of science.⁴ Clin-

ical trial enrollees also lack diversity: only 4 to 5% of participants in trials of drugs submitted for approval by the Food and Drug Administration (FDA) between 1997 and 2014 were from groups historically underrepresented in medicine.⁵ As a result of these and other systematic inequities, we have failed to rapidly and fully translate impressive scientific advances such as Covid-19 vaccines into equitable health improvements throughout our highly diverse country.

Multiple actors are implicated in these failures. Research centers and academic institutions have not sufficiently altered their recruitment, hiring, promotion, and leadership selection processes or overcome community distrust of the research enterprise — all of which contribute to a lack of DEI among researchers. The NIH and other funding agencies have historically underfunded research focused on improving health and health equity among diverse communities. Insufficient efforts to enhance clinical trial inclusivity have left participant diversity essentially unchanged for decades. We believe it's time for the clinical and translational science enterprise to move from statements of support and documentation of

Goals and Strategies for Achieving Diversity, Equity, and Inclusion in Clinical and Translational Research.

Goals

- Transform the ranks of institutional research leadership, faculty, trainees, and staff to reflect the demographic diversity of the communities their organizations serve
- Fund health equity and community-oriented research at parity with biomedical research
- Build community capacity for research and improve public understanding and trust in science by means of shared investments in research
- Ensure that enrollment for all clinical trials reflects the demographic diversity of people with the health conditions under study

Selected Recommended Strategies from the Clinical and Translational Science Awards National Consortium*

Leadership

- Develop transparent institutional policies, qualifications, and application and selection processes for leadership roles
- Recognize the value of equity work and mentoring trainees in these areas in promotions and recognition processes
- Cultivate and “create space” for diverse leaders and identify diverse leaders in thoughtful succession planning

Training

- Prioritize developing diverse trainee groups at all stages of training
- Develop partnerships and new programs (industry–academic; precollegiate, collegiate, and graduate) to enhance training opportunities and move opportunities upstream to cultivate early careers
- Recognize and reward mentors who support trainees from groups that are underrepresented in medicine
- Develop a culture that values and supports trainees holistically, acknowledging diversity in lived experiences (including race, gender identity, and rural vs. urban background)

Research

- Increase funding for innovative health equity and community-engaged research
- Ensure that a diversity of lived experiences is reflected in funding priorities and on research teams
- Require training in the principles and methods of community engagement for all who conduct research with community members and organizations
- Provide interested community members with opportunities for training in research
- Fund studies that build community health; share funds for research with community stakeholders by hiring diverse community members and through formal agreements (e.g., contracts)

Clinical Trials

- Partner with trusted community organizations in designing data collection and engagement procedures for trials
- Integrate the perspectives of people from marginalized groups in trial design and planning
- Hire research staff from the communities in which research is to be conducted
- Train research teams in cultural humility and effective communication
- Support asset-based (i.e., building on existing community strengths), community-led approaches to trial recruitment
- Embed researchers with expertise in minority health and health disparities in clinical trial teams

* The strategies were developed at the 2020 meeting of the Clinical and Translational Science Awards national consortium.

these inequities to substantive improvements.

Many groups, including the national consortium of the Clinical and Translational Science Awards (CTSAs) (funded by the NIH National Center for Advancing Translational Sciences), have begun stressing this imperative. In a survey conducted at a 2020 meeting of C TSA consortium leaders, 94% of 231 respondents said that they believe DEI in clinical and translational science is “important,” and 86% said they were “committed” to making changes in C TSA processes to improve DEI. During the meeting, panel and breakout sessions identified DEI goals and strategies for clinical and translational research (see box).

These commitments and others by organizations in clinical and translational science are a good starting point but will not be suf-

ficient. We believe that to generate sustained and tangible change, bold and visionary goals must be set. Research institutions must move beyond incremental improvements and take action to align their own demographics with those of the communities they serve. In many places, especially academic training centers, that will mean aggressively recruiting and promoting diverse researchers. Robust funding will be needed for new training programs, including those establishing early pathways (e.g., from pre-high school, high school, collegiate, and predoctoral programs) to science careers for members of groups underrepresented in medicine.

Mentors who invest quality time and effort in supporting such trainees should be recognized and rewarded. Institutions should place as much value on work to improve the health and health equity of

diverse communities as they place on advancing fundamental biologic discoveries. Such a reevaluation requires generating equitable standards for recognizing and promoting faculty and staff who conduct health equity-oriented or community-engaged research, mentoring trainees in these areas, and emphasizing fundraising and endowments to support health equity research. Institutions can target scholars for appointment to institutional research leadership positions and “create space” for diverse leaders using thoughtful leadership succession planning.

The U.S. government, for its part, should increase its funding for health equity-related and community-engaged research to the level of its investments in other areas, with more funds provided to multiple relevant federal agencies (including the NIH, the FDA,

and the Centers for Disease Control and Prevention) to accomplish this mission. These changes could be accompanied by enhanced federal investments in programs to engage diverse community stakeholders in research and to study and target structural mechanisms that have sustained health inequities.

When research institutions receive federal funding, they should share these public investments with local communities to build capacity and demonstrate trustworthiness. Such sharing can be done in transparent ways — for instance, by entering into contracts with community-based organizations and other partners. Furthermore, all clinical trials should be designed to ensure that recruited populations reflect the diversity of the populations affected by the studied condition, and failure to do so should be considered a failure to achieve desired study outcomes.

Many programs that leverage well-established methods to engage diverse populations in clinical research should be moved from the testing phase to full implementation, with funders setting expectations to ensure that contextually tailored approaches to engaging diverse participants are implemented as part of clinical trial design. To enhance public trust in federal funders' commitment to transparency and trustworthiness in research, funders could stipulate that

researchers demonstrate their advancement of DEI goals as a requirement for funding initiation and continuation. Finally, metrics can be developed to assess current DEI in the clinical and translational research enterprise and to ensure accountability for improvements.

Change may be within reach. On January 20, 2021, President Joe Biden issued executive orders prioritizing policies to enhance diversity and equity. On March 1, 2021, NIH Director Francis Collins announced the NIH's stand against structural racism, including a commitment to institute new ways to support DEI and to dismantle policies and practices that could harm science and the research workforce. Collins announced the launch of UNITE, an initiative aimed at ending systemic and structural racism in biomedical research. Eliseo Pérez-Stable, director of the National Institute on Minority Health and Health Disparities, endorsed the NIH's new goal of addressing, managing, and eliminating systemic racism and discrimination embedded in biomedical research policies and practices. And large NIH investments such as the NIH Community Engagement Alliance Against COVID-19 Disparities contributed to greater-than-usual diversity among participants in Covid-19 vaccine trials.

To build on these initial steps, continuous effort will be required to overcome a legacy of racism, disin-

vestment, and societal disadvantage. Sustained and reinforced initiatives from all parties in clinical and translational research — funders, academic institutions, researchers, and others — are needed to develop a diverse, inclusive, and vibrant research enterprise capable of translating biomedical discoveries into health and health equity for all.

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 An audio interview with Dr. Boulware is available at [NEJM.org](https://www.nejm.org)

Research Participation in Marginalized Communities — Overcoming Barriers

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The Covid-19 pandemic has drawn attention to clinical research's critical contributions to disease prevention and treatment. At the same time, ongoing chal-

lenges surrounding vaccine uptake and the use of unproven therapies make it clear that not all research results become widely accepted and change behavior.

Although this gap is often attributed to a general distrust of science, a study's ultimate influence also depends on the level of engagement in the research process