

Racial and Ethnic Disparities in Physical and Mental Health Care and Clinical Trials

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istorically, in the United States, scientific racism has been used to justify differential treatment of Black, Indigenous, People of Color (BIPOC) populations compared with the White population.¹⁻⁴ Discrimination toward BIPOC populations by the medical community^{5,6} has contributed to racial and ethnic disparities in health care that persist to this day.⁶

At the 2022 American Society of Clinical Psychopharmacology Annual Meeting, a panel of 5 experts from the areas of academia, advocacy, and clinical research discussed racial and ethnic disparities in mental health care. This ACADEMIC HIGHLIGHTS summarizes and expands on that discussion by tracing the history of scientific racism from the colonization of the US to present-day health inequities, illustrating the ongoing problem of low diversity in clinical trials, and outlining solutions through community engagement.

Although the references we reviewed used a variety of different terms to describe races and ethnicities, for consistency we chose the following: American Indian/ Alaska Native (AI/AN), Asian, Black, Hispanic/Latino (H/L), and White. We acknowledge that there are many terms in use related to race and ethnicity but have adhered to the US Census Bureau terminology where possible. In a few instances the terminology was adjusted based on the reference, such as using "Native American" rather than AI/AN regarding land seizure by colonizers before Alaska became part of the US.

ROOTS OF RACIAL AND ETHNIC DISPARITIES: HISTORIC INEQUITIES

US Colonialism and Slavery

The US was ostensibly founded on principles of equality and liberty, yet inequities in physical and mental health care for BIPOC populations compared with the White population are embedded in the fabric of the nation.^{5,6} The social construct of race was used to justify the White European colonization of the Americas and the Atlantic slave trade in the 16th century.^{7–12} More than 12 million African people were enslaved, with approximately 33% dying during the forced transit to the West and another 10%–30% dying in their first 3 years in slavery due to harsh

Clinical Points

- Compared with White people, Black, Indigenous, People of Color (BIPOC) populations are less likely to have health insurance and access health care less (including mental health services). Additionally, BIPOC populations have higher rates of infant mortality and have been harder hit by the COVID-19 pandemic.
- Racial and ethnic disparities are also widespread in clinical trials and a major ethical and medical concern.
- Diversity in clinical trials can be enhanced through community engagement efforts, an important step toward eliminating racial and ethnic disparities in health care.

living conditions and lack of medical care.^{5,13,14} On US plantations, enslaved Africans endured malnourishment, forced labor, family separation, physical punishment, rape, excessive salt loss from sweating and diarrheal diseases, suicide, inferior medical treatment, and medical experimentation.^{6,13–16} Simultaneously, 2.5 to 5 million Native Americans were enslaved in the Americas in what historian Andrés Reséndez describes as a "parallel system of bondage as degrading and vast as African slavery."^{17(p1)}

Racism was enshrined in the US Constitution in 1788 with the "Three-Fifths Clause," which determined a state's congressional representation by counting White people each as a whole person, counting enslaved Black people as three-fifths of a person, and not counting Native Americans at all.¹⁸ The US also enacted the Indian Civilization Act of 1819, which began 150 years of forcing Native children from their homes and systematically suppressing their culture in residential facilities where widespread abuse occurred.^{19,20} This treatment of BIPOC populations was condoned by the scientific community.

Scientific Racism in the 1800s in the US

Scientific racism—a pseudoscience purporting without evidence that perceived human physical and behavioral differences are due to race⁴—was used to justify the enslavement, segregation, land seizure, and genocide of BIPOC populations.^{2,4,21} Scientific racism was taught in medical schools, while science journals described experiments of burning and starving enslaved people, and pervasive scientific racism led to unethical medical studies and differential treatment by the biomedical community.^{5,6}

In the 1830s and 1840s, physicians such as Samuel Morton and Charles Caldwell measured skulls from Native Americans and concluded that stealing their land was warranted because they were "slow" and that enslaving Africans was acceptable because their skulls demonstrated "tamable-ness."⁴ Physician Samuel Cartwright argued that slavery was the natural state of Black people, and in 1851 he described 2 alleged mental illnesses, drapetomania and dysaesthesia aethiopica, as "diseases" that caused enslaved people to run away, perform subpar work, and not feel pain from physical punishment.^{22,23} He suggested liberty was the cause of these diseases and proposed whipping and other forms of cruelty as treatments.²³

Racism was not only prevalent in scientific literature but also codified into health care institutions. The first psychiatric facility was founded in 1773, and its superintendent implied that enslaved people were acceptable forms of payment in exchange for receiving treatment.²⁴ The American Psychiatric Association, founded in 1844, has recently acknowledged that since its creation, practitioners (including American Psychiatric Association members) have discriminated against, abused, experimented on, and victimized BIPOC communities in the name of science.^{24,25} Until 2015, its logo featured the face of Benjamin Rush, known as the "Father of American Psychiatry,"1,26,27 who believed that healthy skin was light colored and black skin was a form of leprosy that could be acquired through birth or interracial marriage.^{26,27} White physicians regularly conducted painful experiments on enslaved people in front of audiences, wrote about the enslaved people they used for experimentation in dehumanizing ways, performed gruesome and unethical surgeries, practiced on their corpses,28 and used psychiatry to validate slavery with false claims such as that insanity rates increased the further north that Black people lived (where slavery was less prevalent or absent).27,29

Scientific Racism in the 1900s to Today in the US

Although slavery was abolished in 1865, the Black Codes and Jim Crow system legalized discrimination and continued to limit Black people's freedom^{9,30} and their access to health care long after. In 1900, the average life expectancy for White Americans was 49.6 years and 30-32 years for Black Americans.⁵ Certain demographic data are not available from this period due to lack of tracking. For example, the US Census Bureau reported that the population in 1900 was 87.9% White, 11.6% Black, 0.3% AI/AN, and 0.2% Asian and Pacific Islander, while Hispanic people were not systematically counted until the 1970 census,^{31,32} limiting discussion of racial and ethnic disparities in the early 20th century. Despite the absence of this historical data, there is ample evidence of scientific racism during this time. Psychiatrist James Woods Babcock contended that emancipation removed all "healthy" restraints from Black people, causing a rapid increase in rates of insanity.9,27 The first president of the American Psychological Association, G. Stanley Hall, published a textbook in 1904 describing AI/AN and African people as akin to impulsive, immature children.9 A subsequent president, Robert Yerkes, organized an effort to test the intelligence of 1.7 million army recruits and published his conclusion that recruited people of color had a "striking inferiority in intelligence."33 Carl Jung,

the founder of analytic psychiatry, worried that the mental and moral problem of "racial infection" would occur wherever White people were outnumbered by BIPOC populations, whom he described as "primitive."⁹

These racist beliefs fed into the eugenics movement that began in the late 19th century, and eventually 31 US states passed sterilization laws.34 Between 1930 and 1960, an estimated 60,000 individuals (people of color, those with mental illness, and those with disabilities) in the US were forcibly sterilized to purportedly improve the genetic composition of the human race.^{5,27,29,34,35} The sterilization rate of women of childbearing age in Puerto Rico in the 1960s rose to over 35%-more than 10 times the rate as the rest of the US^{34,36}—and the phrase "Mississippi appendectomy" was coined to describe the common practice of sterilizing hospitalized Black women.^{5,29} North Carolina sterilized Black women at > 3 times the rate of White women and > 12 times the rate of White men.37 Of those sterilized in federally financed programs in 1970, 43% were Black Americans, and in the 1970s 40% of AI/AN women were sterilized.34

The treatment of marginalized communities in the health care system paralleled that in the US biomedical research community, which conducted numerous unethical science experiments in the twentieth century. One such experiment was the government's testing of mustard gas in the 1940s on 60,000 Americans to determine whether Black, Japanese American, or Puerto Rican soldiers differed in susceptibility to the gas compared to White soldiers.³⁸ Scientific belief in biological racial differences drove these painful experiments, which many of the soldiers participated in because they were ordered to, or because they thought it was their patriotic duty.³⁸ Many soldiers experienced long-term health issues after these experiments, such as problems with their eyes and lungs.38 Some of the Japanese American soldiers had been drafted directly from the US government's internment camps.³⁹ An infamous example of scientific ethical misconduct targeting BIPOC communities is the US Public Health Service's Syphilis Study at Tuskegee, an experiment that ran from the 1930s-1970s by investigating syphilis in hundreds of poor Black men without informed consent, while withholding medication from them for nearly 30 years after penicillin had become standard treatment.^{29,40,41}

In 1951 Henrietta Lacks, a poor Black mother farming the same land her ancestors were enslaved on, arrived at The Johns Hopkins Hospital with cervical cancer.⁴² Without her knowledge or consent, doctors cultured her cervical tissue cells and shared them widely. Although her cells revolutionized medicine, have been included in > 134,000 publications, and continue to be sold for profit today, her family has still not been compensated despite ongoing lawsuits (Lacks died from cancer in 1951).^{42,43} Lacks's story is just one of many exemplifying the mistreatment of BIPOC populations during this time period.

Mistreatment of BIPOC populations by the medical community continued through the civil rights movement; The American Psychological Association president during that time, Henry Garrett, organized scientific opposition to the movement,33 and Black people who fought for racial equality were labeled as schizophrenic to rationalize hospitalizing them.^{26,44} Planned Parenthood of San Antonio, Texas, sponsored a 1968 study in which 70 low-income H/L women were told they would all receive contraception, but in fact half were given a placebo without being informed of that possibility.36 Prejudice and biases also impacted medical diagnoses. Research from the 1970s and 1980s indicated that White therapists often misdiagnosed H/L clients due to lack of cultural awareness, and evaluated their Black clients as more psychologically impaired than their Black peers did.45 Psychiatrists often labeled frustration as neuroticism in White patients but as schizophrenia in non-White patients, and when presented with clinical vignettes, they diagnosed schizophrenia more often in Black patients than White patients.²⁴ Snowden and Cheung (1990) pointed out that diagnostic bias was also likely happening to Asian and AI/AN patients but had not been given the same level of attention.⁴⁶

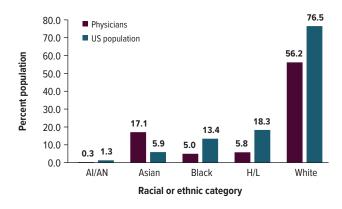
When the deinstitutionalization of mental health care began (a push to move patient care from state psychiatric institutions to community settings), White patients benefited more than BIPOC patients. Between 1970 and 1986, inpatient hospitalization rates dropped 54% for White patients but only 20% for BIPOC patients.⁴⁵ Researchers in the 1980s found that Black and H/L patients with bipolar disorder were more often misdiagnosed with schizophrenia than White patients.⁴⁵ The health care system has been slow to change; throughout the 2000s researchers have continued to find that Black, Asian, and H/L people are diagnosed with schizophrenia at significantly higher rates.⁴⁷

Throughout the second half of the 20th century, psychologists continued publishing racist pseudoscience. Raymond Cattell, known for his work in multivariate personality research, promoted eugenics in his system of "Beyondism" and argued into the 1980s that the interbreeding of different groups of immigrants contributed to high crime and mental illness rates.33,48 Richard Herrnstein and Charles Murray (authors of The Bell Curve, a book steeped in scientific racism), as well as Philippe Rushton, argued that Black people are inherently less intelligent than White people.4,49 In the present day, psychologists still publish papers claiming that differences in behavior and intelligence are due to race,⁵⁰ and Black physicians work in an environment where the word *slave* is used repeatedly in peer-reviewed medical journal articles and surgery rooms to refer to supportive parts of medical devices.51

At the end of the 20th century, differential treatment by the medical community continued to be associated with stark disparities in health and financial wellness for BIPOC

Figure 1.

Racial and Ethnic Makeup of the Physician Workforce Versus the General Population in the US^a



^aData from references 68 and 69. Categories are not mutually exclusive, and not all categories are displayed.

Abbreviations: Al/AN = American Indian/Alaska Native, H/L = Hispanic/Latino, US = United States.

populations compared with the White population. In the 1980s, the average median net worth was \$43,279 for White, \$4,169 for Black, and \$5,524 for H/L renters and homeowners.⁵² During this period, compared with White Americans, H/L and AI/AN Americans had higher rates of end-stage renal disease,^{53,54} and Black Americans had 2 to 3 times higher rates of very low birthweight, infant mortality, maternal mortality, deaths from diabetes, and deaths from kidney disease.⁵ These disparities continued into the early 2000s, with Black and H/L patients receiving less health care than White patients, including fewer mental health visits, mammograms, and flu vaccinations.^{55,56}

To this day, people who are H/L, AI/AN, or Black are far more likely to live in poverty in the US and less likely to have health insurance than White people.^{57–59} BIPOC children have higher rates of infant mortality, low birth weight, premature birth, obesity, and asthma than White children,⁶⁰ and Black newborns die at nearly 3 times the rate as White newborns.⁶¹

A study of > 600,000 Americans' health care use from 1963 to 2019 indicated that White people accessed health care more than Black people every single year during that nearly 6-decade period and that inequities have broadened in the last 5 years to reach a record high.⁶² Use of mental health services is also substantially lower for BIPOC populations than for the White population.^{56,57,59,63} Further, rates of youth antidepressant usage,⁵⁹ high school suicide attempts,⁶⁴ and completed suicides differ by ethnicity (eg, AI/AN females aged 15–19 years completed suicides at a rate nearly 4 times higher than White females).⁵⁸

Compared with the general population, Black Americans are offered evidence-based psychotherapy or medication less frequently,⁵⁷ and those with mental health

conditions are imprisoned more frequently than Asian, H/L, or White Americans.^{57,65} Between 2016 and 2020, there were 116,722 excess premature deaths related to mental and behavioral health among BIPOC populations in the US, costing \$278 billion (ie, from office and emergency room visits, hospitalizations, medications, and loss of life).⁶⁵ These data do not even include the billions of dollars in mental and behavioral health excess costs arising from unhoused and incarcerated populations, where BIPOC populations are overrepresented.⁶⁶ The COVID-19 pandemic has further highlighted health care inequities; compared with rates for non-Hispanic White Americans, COVID-19 hospitalization and death rates are higher for AI/AN (2.8 and 2.1 times higher, respectively), Black (2.2 and 1.7 times higher, respectively), and H/L (2.1 and 1.8 times higher, respectively) Americans.67

Racial and ethnic disparities in health care are reflected by the lack of diversity in the associated workforce. In 2018, the proportion of H/L, Black, and AI/AN physicians was much lower than that of the general US population (Figure 1).^{68,69} This result is problematic for numerous reasons, not the least of which is that physician-patient racial discordance is linked to worse communication, with shorter visits and lower levels of information-giving, satisfaction, and participatory decision-making.⁷⁰ The mortality rate of Black newborns is reduced by 53% when a Black infant is cared for by a Black doctor versus by a White doctor.⁶¹ Addressing both the shortage of Black physicians and the ongoing racial and ethnic disparities in the health care system is a crucial need.

PERSISTENT SYSTEMIC INEQUALITIES

Terminology for Discussing Racism

Racial and ethnic disparities in physical and mental health care persist today, as does the structural racism that maintains them.^{10,11} In 2021, the American Psychiatric Association acknowledged that the discrimination "embedded within psychiatry" has contributed to BIPOC populations receiving poorer quality of care historically and to this day.^{24,25} Racism within psychiatry contributes to mental health disparities, misattribution of the causes of those disparities, scientific racism, and underrepresentation of marginalized populations in mental health research and treatment.^{11,71} Addressing racism in mental health care requires change from the individual to societal levels.⁷¹

Structural racism refers to a system where institutional practices, public policies, laws, ideologies, and customs work together to maintain inequities between racial and ethnic groups.^{12,72,73} In the US, structural racism is reinforced by inequitable systems and resources such as housing, education, wealth, employment, nutritious food, legal justice, and health care, with differential access for BIPOC and White populations.^{60,73,74}

Interpersonal racism happens at the individual level as microaggressions and discrimination intentional or unintentional.^{10,73} The vast majority of AI/AN, Black, H/L, and Asian Americans report having faced interpersonal racial discrimination (eg, slurs, harassment, threats, violence).⁷⁵

Internalized racism occurs when an individual accepts and incorporates racist stereotypes and ideologies into their worldview; this self-stigmatization can lead to depressive symptoms and diminished well-being.⁷³

The Connection Between Historical and Contemporary Inequities

BIPOC communities are systematically oppressed in the US, from where they live and their medical treatment to how they are policed and imprisoned. Many of the inequities that have historically occurred in the US continue today, including those stemming from redlining, racism in health care, slave patrols, and the leasing of people who are convicted.

After the Great Depression of the 1930s, the US government established the Home Owners' Loan Corporation program to save homeowners from mortgage default.⁷⁶ The program ranked city neighborhoods by lending risk, using racial demographics as one of the factors to compute risk; low risk areas were assigned the color green, and "hazardous" areas, the color red.⁷⁶ Areas with BIPOC populations tended to be rated as higher risk and were described with terms such as "thoroughly blighted."77,78 Today, many of the redlined areas (74%) in the US are still designated as low or moderate income, have a majority of BIPOC residents (64% of neighborhoods), and are associated with worse air pollution, less greenspace, higher temperatures, pre-term birth, delayed cancer diagnosis, and higher rates of poor physical and mental health.76,79,80

In addition to housing discrimination, BIPOC populations still experience discrimination in the health care system. The myth that Black people do not feel pain as much as White people-once used to validate performing surgeries without anesthesia on enslaved Black people⁴-persists in the current health care system, whereby doctors provide less pain medication to Black children than to White children for acute appendicitis and broken bones60 and National Collegiate Athletic Association medical staff believe Black athletes feel less pain than White athletes.⁸¹ Blackness was pathologized during slavery (eg, drapetomania, leprosy),^{22,26} and that continues today, as evidenced by recent studies that confuse race with genetic ancestry and imply that racial differences in health are biological rather than normal responses to systemic racism, oppression, exploitation, and trauma.7 As Opara and colleagues (2021) aptly stated: "Racism, not race, is the vector of disease and health disparities."7(p226)

Historically, Black Americans have also been treated differently in the criminal justice system. The slave patrols of the early 1700s (formed to capture people attempting to escape slavery and to prevent revolts by people who were enslaved) grew into modern-day police forces in the US,75,82 with Black Americans often the targets of police violence. More than half of Black, H/L, and multiracial children report having been followed by a security guard in a store, and one-third have reported unfair treatment by a police officer.⁶⁰ Police use force 3.6 times more often with and fatally shoot nearly 3 times more Black Americans than White Americans; they arrest proportionally more Black men than White men by age 23 (48.9% vs 37.9%); and they fatally shoot Black teens at 21 times the rate of White teens.^{82,83} On any given day in 2015, approximately 1.6% of White men, 3.9% of Hispanic men, and 9.1% of Black men aged 20-34 years were incarcerated.83

Convict leasing, whereby the majority Black prisoner population was forced into manual labor, historically funded the judicial system and US state economies (eg, in 1898, convict leasing accounted for 73% of Alabama's revenue).⁸⁴ The US continues to profit from prison labor. Although slavery has been banned, the 13th Amendment makes an exception for people convicted of crimes⁸⁵; the US prison population, in which Black, AI/AN, and H/L people are heavily overrepresented,^{86–88} produces more than \$11 billion annually in goods and services while unprotected by minimum wage laws, overtime, or workplace safety measures.⁸⁵ The average maximum wage in prison is \$0.52 per hour, and those incarcerated who refuse to work can be punished.⁸⁵

Thus, historical discrimination in housing, medical treatment, policing, and incarceration of BIPOC communities has directly led to present-day inequalities. Systemic racism still permeates the nation, with drastic health consequences for BIPOC populations.⁷⁵

Inequities in Clinical Trials

As with the broader US health care system,^{62,63,67} clinical trials are rife with racial and ethnic disparities, in terms of both their participants and the researchers who conduct them.^{89,90} Lack of diversity in clinical trials is both an ethical and a medical issue,⁹¹ and addressing this disparity was a primary motivator for the panel and this publication.

Participant diversity is crucial for trial results to be generalizable and trustworthy.^{90,92} Low participant diversity contributes to skewed clinical data⁹¹ and can exacerbate existing health disparities.^{92,93} For example, the predictive power of genetic data for complex traits is far lower for H/L, Asian, and African populations than for those of White European descent,⁹⁴ giving them less access to accurate health information for making important clinical decisions.⁹⁵ The pharmacokinetics and pharmacodynamics of medications can differ across patient populations, and the efficacy and safety profiles of a drug may vary for different races and ethnicities.^{91,96} Approximately 10%–21% of US Food and Drug Administration (FDA) newly approved drugs have known differences in terms of safety, efficacy, dosing, pharmacogenetics, or pharmacokinetics for various racial or ethnic groups.^{97,98} Despite this knowledge, most drugs approved by the FDA have been tested in clinical trials consisting primarily of White participants.⁹⁵ The danger of this lack of diversity was demonstrated in clinical trials for 5-fluorouracil to treat cancer, in which study investigators missed the medication's increased risk of toxicity in Black participants due to the low participant diversity in these trials.⁹² Because of such underrepresentation, BIPOC populations have benefited less from biomedical advances than White people in the US.⁹¹

In 2018, only 41% of the 213 clinical trials that reported results included race and ethnicity data from all 5 commonly reported groups (AI/AN, Asian, Black, H/L, White).⁸⁹ In studies that did report racial and ethnic demographics, White participants were overrepresented and H/L, Asian, and AI/AN participants were all underrepresented.⁸⁹ Despite underrepresentation in most clinical trials, Black people are overrepresented in trials that use the FDA's exceptions from informed consent (EFIC) process.99 EFIC trials conduct research on people without decision-making capacity due to having life-threatening conditions with inadequate treatments; a systematic review of EFIC trials found that 29% of the participants were Black and the overwhelming majority of the experimental treatments were not effective.⁹⁹ Black people are overrepresented in clinical trials of schizophrenia drugs100 and in psychiatric drug trials in general (45% of participants), while Asian (1.24%) and AI/AN (0.45%) people are underrepresented.¹⁰¹ In fact, just 0.17% of clinical research funded by the National Institutes of Health (NIH) from 1992 to 2018 focused on Asian American, Native Hawaiian, and Pacific Islander individuals.93 In randomized clinical trials of depression treatments, these individuals had the lowest rates of enrollment.¹⁰²

To improve diversity in clinical trials, the FDA issued draft guidance in April 2022 recommending that sponsors submit a diversity plan to enroll participants from racial and ethnic populations in numbers that represent their proportions in the US.¹⁰³ In 2018, the racial and ethnic makeup of the psychologist-based workforce indicated underrepresentation of Asian (4% vs 6%), Black (4% vs 13%), and Hispanic (6% vs 18%) psychologists versus the general US population.^{68,104} Similarly, at all levels of the psychiatry-based workforce, there are significantly fewer people from historically underrepresented populations among residents (16.2%), faculty (8.7%), and practicing physicians (10.4%) than in the general population (32.6%).¹⁰⁵ NIH grant applications submitted by Black investigators are discussed at a lower rate (44% vs 57%) and funded at a lower rate (11% vs 18%) than

those by White investigators.¹⁰⁶ Although the NIH has attempted to address this disparity, researchers have argued that the efforts have been inadequate.¹⁰⁷ Another factor driving racial and ethnic inequality in clinical trial populations is that some doctors have implicit biases that prevent them from discussing clinical trials with BIPOC patients, including believing these patients are less trustworthy, less compliant with treatment, mistrustful of the medical establishment, and overall poor trial candidates.¹⁰⁸ However, one of the most effective methods for improving clinical trial recruitment of marginalized populations is community engagement.⁹⁰

ADDRESSING DISPARITIES VIA COMMUNITY ENGAGEMENT

Defining Community Engagement

Since disparities in health care are rooted in socioeconomic inequality, the key to addressing them is partnering with individuals, agencies, and institutions in the community.¹⁰⁹ Community engagement is "the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people."^{109(p7)} Through a two-way exchange of information, researchers learn the needs of the community, and the community learns the rationale of the researchers—both groups partner in designing, executing, and communicating the results of a study.^{3,90}

Figure 2 shows one example of how community engagement can be implemented. It starts by building relationships with community stakeholders (eg, local health care providers [HCPs])¹¹⁰ and establishing one or more community advisory boards (CABs).¹¹¹ A CAB is a formal group consisting of individuals from academia and/or the government (eg, researchers, policymakers) as well as the community (eg, patients, HCPs, social service agencies, community groups) who reflect the target research population, share their expertise, and advise researchers during each step of the clinical trial process.^{110,112}

Next, researchers collaborate on the study design with the CAB, including revising inclusion/exclusion criteria, implementing changes to ensure participant safety and comfort, adapting the study protocol, and engaging patients (eg, sharing patient newsletters, birthday cards, thank you notes).¹¹¹ After conducting the trial, clinical trial staff meet with community stakeholders to discuss trial findings and identify which are most relevant for disseminating to the community.¹¹⁰ Researchers can also meet with the CAB to discuss which findings would be of most interest to various stakeholders and tailor the content to specific audiences (eg, community forums, continuing education trainings).¹¹⁰ Staff then present findings to the community with interactive presentations that incorporate personal stories and show how community feedback was implemented in the study.¹¹⁰ Following the presentations, the staff schedule in-person and remote meetings with the community to further strengthen relationships.¹¹⁰ The goal is to cultivate an enduring synergistic relationship between researchers and the community.⁹⁰

How the Community and Sponsor Benefit From Collaboration

Although community engagement takes time and resources from both the community and researchers, the many benefits outweigh the costs.¹⁰⁹

Communities can benefit from community engagement by shaping the study to align with community needs and by gaining new skills, knowledge, and sustainable resources.^{109,113} Furthermore, communities benefit by participating in the study more easily, receiving financial compensation for their involvement, growing their network, increasing transparency of the research, understanding the pros and cons of participating in research, helping to develop programs in culturally appropriate ways, and becoming empowered.^{109,113} Community engagement is an effective tool for combating racial and ethnic disparities in clinical trials by increasing recruitment and participation of marginalized populations.¹¹³

Trial sponsors can benefit from community engagement by gaining access to funding sources that require community engagement as part of the research proposal, improving their study design and intervention through increased understanding of the community and the area of research, and identifying and resolving ethical problems that may arise (such as with consent).¹¹⁴ Sponsors can further benefit by broadening the impact of their results¹⁰⁹ and laying the groundwork for recruitment for future studies.¹¹³ When the community is informed about a clinical trial and involved in it (such as by helping finalize consent forms), recruitment is enhanced (eg, by speeding up the process, recruiting more participants, increasing diversity).^{109,115}

Implementing Solutions: New Approaches to Engaging With Communities

There are numerous barriers to increasing diversity in clinical trials; however, each has its potential solutions. Table 1 provides examples of how these strategies have been implemented in clinical trials.

One barrier to diversifying recruitment for clinical trials is lack of public awareness. Only a small proportion of patients are offered participation in clinical trials, but over half of those who are offered do enroll.¹²⁷ Racially marginalized populations are as likely as non-Hispanic

Figure 2.

Illustration of the Cycle of Community Engagement in Clinical Trials

Engaging the community in clinical trials

Etablish a CAB Build relationships with community stakeholder Wet with the community afterwards to storegithen relationships Present findings to the community with community with thereactive presentations Wet with CAB to tailor the content to specific audiences

Abbreviation: CAB = community advisory board.

White populations to consent to participating in a clinical trial if given the opportunity; however, BIPOC populations are often not informed about clinical trials.^{108,128} This obstacle can be overcome by supporting and training HCPs in recruiting BIPOC participants, as well as offering patients information about clinical trials directly with online tools designed to educate and enroll racially and ethnically diverse participants.¹⁰⁸

Another factor contributing to the lack of diversity among clinical trial participants is a similar lack of diversity among the researchers conducting the trials.⁹⁰ Researchers do not always understand the communities they are recruiting from.^{120,122} Some White researchers are uncomfortable approaching people from marginalized populations, while others believe it is not even possible to increase diversity in research.¹²¹ Yet, it is crucial to integrate social and cultural factors when building research processes to ensure strong health outcomes.¹²⁹ Fortunately, trainings have been designed for clinical trial research teams and HCPs to learn about including marginalized populations in clinical trials.^{108,120} To better understand the communities they are recruiting from and to ensure communication with culturally sensitive terminology,^{3,122} researchers have also interviewed community members and asked for their help identifying respectful language to use in consent forms and communications.^{3,114} There is a learning curve involved in building relationships

Table 1.

Barriers to Diversity in Clinical Trials and Real-World Solutions

Barriers to diversity in clinical trials	Potential solutions to barriers	Real-world examples
Implicit bias of HCPs ^{92,108,116}	 Deliver diversity training for HCPs¹¹⁶ Build a trusted therapeutic alliance between the HCP and patient¹¹⁶ 	 Several states have passed laws requiring some categories of HCPs to undergo implicit bias training¹¹⁷
BIPOC populations not being informed about clinical trials ¹⁰⁸	 Build relationships with local physicians to increase their readiness to recruit patients for clinical trials¹⁰⁸ Train HCPs in using participant-centered communication to be culturally sensitive and build trust, which is important for enrollment¹⁰⁸ 	 A day-long intensive communication course for doctors improved their discussions with patients about clinical trials¹⁰⁸ An interactive online tool for patients was created to improve awareness and understanding of clinical trials for marginalized populations¹⁰⁸
Lack of diversity among clinical researchers ⁹⁰	 Recruit and mentor more researchers from marginalized backgrounds¹⁰⁸ Diversify the clinical research workforce and increase diversity in leadership of clinical trials⁹⁰ 	 Publications from heart failure clinical trials with female first or senior authors enrolled significantly more female participants¹¹⁸ Before 2007, The Ohio State University had not trained any cardiologists from marginalized populations, but since then has successfully instituted a program to intentionally recruit and support trainees from these populations¹¹⁹
Researchers not understanding how to engage with marginalized communities ^{120,121}	Educate researchers on methods of recruiting and retaining marginalized populations in clinical trials ¹²⁰	A massive open online course has been developed to train research teams about recruiting marginalized populations for clinical trials ¹²⁰
Researchers not understanding the community from which they are recruiting ^{110,122}	 Conduct interviews in the community to learn their unmet needs and discover potential data gaps, use that data to inform decisions¹¹⁴ 	 Responding to the COVID-19 pandemic, CTSA-funded institutions learned about community needs through surveys in multiple languages, focus groups, working with local organizations, and developing registries to track health and financial outcomes; they used this information to create new testing sites, increase health care accessibility, and gain a better understanding of the communities¹¹⁴
Researchers communicating with insensitive terminology ³	 Involve community members in identifying respectful language to use³ 	 Elected and non-elected leaders helped inform language choices (eg, older adult vs elderly, priority population vs target population) for the COVID-19 vaccine trials³
Physical inaccessibility of clinical trials ^{90,123}	 Reach participants where they are: expand clinical trial sites to new geographic areas and non-traditional sites within communities, and use technology to decentralize clinical trials through remote data collection^{90,123} 	 Barbershops were used to recruit and deliver an intervention to improve hypertension in Black men⁹⁰
Financial inaccessibility of clinical trials (eg, lack of access to transportation, childcare, health care, and adequate health insurance) ¹⁰⁸	 Financially compensate participants for their involvement,¹⁰⁹ including medication and procedures from the trial as well as indirect costs such as gas, hotels, and any time missed from work¹¹⁶ 	 Participants in the IMPACT study with a household income below a certain amount were eligible for reimbursement for indirect costs such as gas, parking, tolls, rideshare, lodging, and travel costs for a companion¹²⁴
Trial design inaccessibility ^{90,121}	 Make participation requirements in trials more inclusive, such as not requiring proficiency in English¹²¹ Use digital health tools to collect data remotely, reducing the burden of participation⁹⁰ 	 Fully remote clinical trials have been implemented successfully using digital health technologies, achieving higher diversity than typical^{125,126} (eg, among participants enrolled in a clinical trial for COVID-19 treatment with remote cardiac monitoring, 17.4% were Al/AN and 29.8% were H/L)¹²²
Community mistrust of research and medical institutions due to historical and ongoing mistreatment ^{90,110}	 Acknowledge historical wrongdoing⁹⁰ Put time and effort into earning trust⁹⁰ Adhere strongly to ethical standards¹⁰⁹ Educate the community about any possible risks¹⁰⁹ Involve the community in all aspects of the trial³ Be receptive to feedback from the community and implement it¹¹⁰ Be transparent and use plain language³ Use personal stories to communicate why the area of study is important to the researchers¹¹⁰ Be transparent about data for drug efficacy in diverse populations, including gaps in data⁹² 	 To circulate information about COVID-19 and the vaccine trials, researchers partnered with trusted community organizations (eg, social service agencies, advocacy groups, media, faith-based organizations serving BIPOC communities)³ For the COVID-19 vaccine trials, researchers and the communities discussed the role racial disparities in health care play in mistrust for biomedical research, providing new insight and leading to additional data collection¹¹⁴ To increase enrollment of diverse populations in the COVID-19 vaccine trials, researchers convened expert panels for each priority community (eg, Al/AN, Black/African American, H/L, older adult/veterans), consisting of scientists and community leaders from those populations. These efforts led to decisions to reimburse participants for study costs, implementation of mobile clinics, and researchers working with Tribal nations to develop contracts together³
Community misinformation and misperceptions about trials ³	Use community-based participatory research approaches ³	 Educational materials were developed for the COVID-19 Prevention Network–sponsored vaccine trials, with input from the CAB, including a website, a toll-free call center, and a Dropbox with infographics, videos, animations, and social media posts, all available in English and Spanish³ With the help of trusted organizations and celebrities, a multimedia campaign to address concerns about vaccine trials was launched and disseminated with an advertising buy focused on Black and Latino adults³ In response to the COVID-19 pandemic, CTSA-funded institutions communicated accurate information to the public through town halls, social media, infographics, webinars (in Spanish and English), local ethnic media, and guides on how to evaluate news stories¹¹⁴

Abbreviations: Al/AN=American Indian/Alaska Native, BIPOC=Black, Indigenous, and People of Color; CAB=community advisory board; CTSA=Clinical and Translational Science Award; HCP=health care provider; H/L=Hispanic/Latino; IMPACT=IMproving Patient Access to Cancer clinical Trials.

with the community, but many studies have reported on their approach to this process, which is critical for building culturally appropriate interventions.¹²⁹

Researchers need not only diversity training, but also to increase the diversity of the clinical research workforce by making it a priority to recruit, support, and mentor more researchers from marginalized populations, offering targeted professional development and tailored recruitment activities.^{90,108,119} Increased researcher diversity has been linked to increased participant diversity in clinical trials-one example is that published heart failure studies with female first or senior authors had a higher enrollment of female participants.¹¹⁸

Another barrier to diversity in clinical trials is the mistrust of medical research due to the past and present inequities and mistreatment experienced by BIPOC communities in the name of medical advancement, detailed earlier.90,110 Efforts to build trust through community engagement that have been implemented include acknowledging historical wrongdoing and current gaps in data,^{90,92} communicating plainly, being transparent, 3,92 and implementing community feedback.110 Before asking for something from the community, researchers should first give to the community.¹³⁰ After asking how to help the community, when conducting a trial, it is important for researchers to honestly share their intentions, honor their word, and alert the community to any changes in planning.¹³⁰ The Resource Centers for Minority Aging Research achieved their goal of improving trust and relationships between 3 of their university sites (in California, North Carolina, and Colorado) and specific BIPOC communities through community engagement efforts such as hiring members of the community, integrating cultural practices with research protocols, and communicating trial results to the community.131 Another essential aspect of trust building is time. "Helicopter researchers" fly into a community, collect data, and leave; however, researchers should devote time to being continuously and actively engaged in not only their research but also their partnerships with the community.130

Accessibility and inclusivity are additional challenges to increasing diversity in clinical trials. Researchers should aim to ensure trials are physically and financially accessible and include participants from marginalized populations.^{90,108} For instance, researchers have expanded trial sites to non-traditional locations (eg, barbershops, community clinics),90,123 used digital health tools to collect data remotely,90 reimbursed participants for both the direct (eg, medication, procedures) and indirect (eg, gas, lodging, time off work) costs of participating in a trial,^{109,116} and removed barriers to participation such as requiring English proficiency.121 Community engagement practices have been implemented for decades and were successfully used to recruit representative samples of BIPOC participants to clinical trials for vaccines against COVID-19, illustrating that equitable enrollment is achievable.3

CONCLUSION

Human genetic diversity is far greater within than between populations, with continuous, extensive gene flow for hundreds of thousands of years showing all humans have a single evolutionary lineage.^{132–134} Despite lacking a meaningful biological basis, 10,12,21,132,135 race is a real sociopolitical construct with drastic consequences in the US.^{8,10,18,136} From the time the Americas were first colonized to the present, racism has systematically disadvantaged BIPOC populations in the US,^{11,12} which has created a public health crisis.137 Clinical researchers can help to address this crisis by understanding how systemic racism creates and maintains racial and ethnic disparities in health care.^{11,12} The education process includes reading, reflecting, receiving training on providing culturally informed health care, cultivating friendships with people from different backgrounds, concentrating on social determinants of health, and participating in interventions aimed at institutional change.^{11,12} Moreover, supporting community engagement efforts is vital for increasing diversity in clinical trials,³ repairing the relationship between the biomedical community and the marginalized populations it has mistreated and exploited throughout history, and eliminating the pervasive racial and ethnic disparities in health care.

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