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Eleven things to facilitate participation of underrepresented groups in headache medicine research

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AUTHOR CONTRIBUTIONS

The principal author takes full responsibility for the data presented in this study, analysis of the data, conclusions, and conduct of the research. The principal author had full access to those data and has maintained the right to publish any and all data independent of any third party.

CONFLICT OF INTEREST

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Keywords

African-American; community-based participatory research; diversity equity and inclusion; health-care disparities; underrepresented populations; underserved populations

INTRODUCTION

Headache is a leading reason for medical consultation and yet remains underdiagnosed.¹ Headache diseases are highly prevalent and disabling. Migraine alone affects 1 billion people and is the second leading cause of disability worldwide.² There still remains a dearth of information surrounding how the headache diseases affect underserved populations and most importantly how this can be addressed. Migraine prevalence studies based in the United States indicate that the prevalence is highest in Native Americans, followed by White Americans, Black Americans, Hispanics, and Asian-Americans.^{3,4} Black Americans are less likely to be diagnosed with migraine, in part because they are less likely to endorse full criteria for migraine, and are also less likely to access the medical system for treatment.^{3,5} Black men receive the least care for headache diseases nationwide and are less likely to present for ambulatory care for migraine compared with Whites.^{6,7} Black patients are less likely to be given pain medications than White patients despite similar self-reports of pain.⁸⁻¹⁰ To our knowledge, there are no examples of headache researchers addressing the challenges to inclusion of diverse populations in headache clinical trials. The authors are aware of only three research studies published that specifically examined for racial health disparities in headache medicine.¹¹⁻¹³ These studies could be classified as first-generation health disparity research.^{14,15} In addition, there is one narrative article that addresses the issues of equity of African-American men in headache medicine.¹ There are frameworks to guide health disparity research found outside headache medicine literature; for example, the National Institute of Aging developed an interactive easy-to-use NIA Health Disparities Research Framework on their website.¹⁴⁻¹⁶

Representation in research begins with research design and recruitment. The National Institutes of Health (NIH) Revitalization Act of 1993 required that NIH-funded clinical trials include participants of diverse race and/or ethnicity and assess outcomes by race or ethnicity due to the observed underrepresentation of Black, Indigenous, and people of color (BIPOC) in clinical trials.¹⁷ The NIH requires planned enrollment tables, which include this information. However, as of 2018, only 13% of published results of publicly funded clinical trials include analysis of outcomes by race or ethnicity.¹⁸ In a systematic review of migraine treatment trials, all the articles reported sex frequency, but only 69.4% reported ethnicity or race.³ No studies examined safety or efficacy stratified by race or sex.³ Headache studies need to account for race and ethnic inclusivity. Although certain sociodemographic factors have been identified as risks for migraine (e.g., low socioeconomic status), headache medicine lacks comprehensive evidence from inclusive populations of study.^{19,20}

Access to research often comes from access to health care. The barriers to accessing care are rooted in a number of factors, including the historical perpetuation of sociocultural

determinants that affect mistrust of health-care professionals (HCPs) and difficulty engaging BIPOC communities.

Once patients access care, they may encounter additional barriers. Implicit biases might affect headache diagnosis, treatment timeline and choice, patient education and support, provider–patient communication and possibly microaggressions.²¹ HCPs must assess their implicit biases in caring for patients of underserved populations. In a study of the role of racial bias in pain assessment and treatment recommendations, 12% of medical trainees (medical students and residents) interviewed endorsed false beliefs about biological differences between Black and White Americans—including statements that claimed the nerve endings of Black people were less sensitive and the skin of a Black person was thicker than that of a White person.⁸ The study found evidence that racial bias in pain assessment was associated with racial bias in pain treatment recommendations.⁸

Data collection and analysis in headache medicine research have to change to reflect culturally inclusive and accurate interpretation. For example, when looking outside the field of headache medicine and into the field of sleep medicine, Dr. Dayna Johnson studied factors contributing to racial disparities in sufficient sleep duration such as neighborhood disadvantages (street lights, noise, population density, poor housing conditions). Racial disparities in sleep duration and efficiency are minimized by residing in similar environments.^{22,23} Such findings have strong implications: racial disparities in sleep also account for some of the racial differences in cardiometabolic disease.^{22–24} We can only postulate how disparities in sleep may affect headache diseases. It is important to note that race or ethnicity as research variables are constructs fraught with issues of inaccurate measurement and lack of standard definitions.²⁵ Racial differences noted in studies warrant further research to assess for the factors that contribute to the observed racial health disparities, including variables reflective of the effects of racism.

The COVID-19 health emergency has further highlighted long-standing racism, social inequities, and health disparities in many ways including disproportionate access to care (including telemedicine), morbidity, and mortality.^{26–28} There is a crucial need for health disparity research in headache medicine. Systemic racism has to be recognized as a cause for racial health disparities.^{29,30} The American Headache Society and American Migraine Foundation made this declaration clear in their published position statement “AHS & AMF Commitment on the Impact of Recent National Events, Racism, and Healthcare Disparities.”³¹ To further their commitment, the American Headache Society has created a Diversity, Equity, and Inclusion Task Force to impact the future landscape of headache care.

Headache medicine research needs to include underserved populations and ensure that the conclusions drawn from that research are accurate reflections of the variables at play. In doing so, this will help address the sociocultural determinants of care to help clinicians deliver thoughtful, equitable, accurate, and efficient headache medicine care. Hence, the aim of this paper is to introduce in Table 1 eleven ways to facilitate participation of underserved populations in headache medicine research and revise research practices to ensure consideration of effects of racism as a variable. We hope Table 1 will be a starting point for discussions, reflections, and collaborations to conduct health disparity research in

headache medicine. Given the limited health disparity research in headache medicine, some of the points in Table 1 are somewhat general and not accompanied by examples specific to the field of headache medicine.

CONCLUSION

Lack of knowledge about headache medicine in underserved populations, false beliefs about pain, biases, and underrepresentation contribute to inadequate access to care and treatment. This article presents important points for consideration to facilitate participation of underserved groups in headache medicine research in the hope for more inclusive and accurate research and, as a result, improved patient care and reduced health-care disparities. Research that focuses on understanding the underlying causal pathways for health disparities in headache medicine is necessary to develop interventions to address those issues.⁷

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Abbreviations:

AA	African American
AHS	American Headache Society
AMF	American Migraine Foundation
BIPOC	Black, Indigenous, and people of color
CBPR	community-based participatory research
HCPs	health-care professionals
NIH	National Institute of Health

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TABLE 1

Eleven ways to facilitate participation of underserved populations in headache medicine research

Research process	Eleven things to consider	Primary barrier	Context	Ways to address
Design	<p>1. Guidelines for headache medicine research and clinical trials to recommend research sample to be representative of the population from a racial, ethnic, socioeconomic, and gender standpoint</p> <p>2. Community members' engagement in research. An Institute of Medicine (now National Academy of Medicine) report recommends "engagement of African American (AA) communities to eliminate health disparities"⁴⁵</p>	<p>Noninclusive guidelines</p> <p>Racism leading to abuse of people of color</p>	<p>• None of the most recent international headache trial guidelines recommend that recruitment be representative of racial and ethnic groups of the affected patients^{3,2-37}</p> <p>• Only the most recent of these, the 2020 guideline for preventive treatment of migraine, explicitly recommends reporting of participant race³³</p> <p>• Long history of medical experimentation and abuse targeting people of color. Dr. Sims performed obstetrics experiments on enslaved women without any anesthesia. The Tuskegee Study was done without informed consent. Participants were not offered penicillin nor allowed to quit the study to receive it. In the 1990s, the Baltimore Lead Paint Study assessed wall abatement and lead intoxication in low-income areas mostly targeting AA children. Participants were misled by the investigators, and many suffered permanent neurological damage. These are only a few select examples of decades of torture, abuse, inhumanity, and racism in medicine^{70,71}</p>	<p>• Future headache research guidelines to (a) encourage participant samples to be representative of the affected patients, (b) invite multisite randomized controlled trials to expand recruitment from specialty clinics to primary care centers, and (c) mirror the NIH policy on race and ethnicity</p> <p>• Journals to require reporting of race and ethnicity commenting on whether the sample is representative of the population, and justification of why if this is not the case</p> <p>• Refer to point 11 regarding additional considerations when analyzing based on race</p> <p>• Involve community members in every step of the research process. Community Advisory Boards might promote participant safety and satisfaction and might lead to positive changes in health behaviors and health policies^{46,47}</p> <p>• Bring community members on the study team as staff to ensure the research efforts meet the needs of the community, considering the structural and socioenvironmental factors at play, and monitor participants' safety</p> <p>• Engage study participants in an open discussion about their knowledge of historical wrongdoings in medical research and their own experiences. Address questions about measures put in place to avoid these wrongdoings from happening again</p>
Design, recruitment, and retention	<p>3. Researchers' engagement in communities underrepresented in research</p>	<p>Mismatch between the researchers' goals and methods and the needs and culture of the community</p>	<p>• Community-based participatory research (CBPR) is an approach focused on a partnership between community members and an academic team who have the mutual goal and shared responsibility in designing and implementing an effective intervention⁴⁸</p> <p>• CBPR improves participant recruitment and engagement^{48,51}</p> <p>• CBPR has proved successful in other disease processes including childhood asthma, infant mortality, and diabetes^{49,50,52-54}</p>	<p>• Ask community members what research interventions are in the best interests of their community and discuss concerns of deception, exploitation, and discrimination⁴⁴</p> <p>• Establish trust and partnership with cultural insiders and key informants^{44,55}</p> <p>• Partner with businesses, religious groups, and community organizations to build outreach programs. Community health workers might provide better education than printed materials alone⁵⁶⁻⁵⁸</p> <p>• Keep the community up-to-date regarding study results</p>
Recruitment	<p>4. Careful choice of the sample population being cognizant of health-care access disparities</p>	<p>Access to care</p>	<p>• AAs report fewer physician visits for migraine care¹⁵</p> <p>• There are many reasons for limited access to care such as lack of health institution outreach in underserved areas, discrimination, health literacy, transportation, language, cultural differences, work demands, childcare, internet access, and economic and insurance factors</p> <p>• Study samples might not reflect the population of interest due to limited access to care by underserved populations. Health-care access disparities might be</p>	<p>• All health-care professionals (HCPs) at the individual and institutional level should seek opportunities to (a) expand care to underserved communities and (b) provide primary community centers in underserved areas with education about headache disorder diagnosis and management</p> <p>• Tertiary headache centers should expand access to care and research for underserved communities by (a) advocating for insurance coverage of telemedicine visits, (b) promoting widely accessible interpreter services, (c) supporting community centers in their referral process to the specialty clinics, and (d) including primary care clinics that serve underrepresented communities in their research projects²⁸</p> <p>• Support advocacy and research efforts aimed at overcoming barriers to care for underserved populations. For example, recent donations were</p>

Research process	Eleven things to consider	Primary barrier	Context	Ways to address
Recruitment and retention	5. Ease the logistics of research participation	Access to research	<p>more pronounced in tertiary than in primary care centers and in online-based research</p> <ul style="list-style-type: none"> Participation in research may be affected by individual constraints such as limitations relating to cost (incidental medical bills, lost productivity from work, childcare), transportation, time away from work and/or care giving, language barriers, health literacy, and education These constraints disproportionately affect people of color and thus hinder their research recruitment and retention³⁸ 	<p>made to the Disparities in Headache Advisory Council (DIHAC) to involve members of Congress serving on underserved caucuses, monitor legislations aimed to improve health care of Black, Indigenous, and people of color (BIPOC) communities, and form alliances with national organizations with similar goals</p> <ul style="list-style-type: none"> Reduce or ease participants' transportation with mobile research units, home visits, virtual visits, taxi vouchers, and bus passes Short research visits on a flexible schedule including weekends and evenings³⁹ Provide childcare resources Invest resources into recruiting non-English-speaking participants (interpreters, patient navigators, non-English research materials such as consent forms)^{40,41}
Recruitment and retention	6. Find the right balance between adequate financial compensation and risk of coercion	Resources	<ul style="list-style-type: none"> Maximize nonfinancial incentives for research participation that would be particularly useful for underrepresented groups Financial incentives should be appropriately calibrated to the participants being recruited⁴² 	<ul style="list-style-type: none"> Consider appropriate compensation for lost productivity and logistical costs (e.g., transport, childcare) due to participation in research study Ensure that the testing is medically necessary and covered Clarify in the consent form that participation or lack of participation in the research study will not affect care; being able to access care only via research participation would be coercive
Recruitment and retention	7. Train investigators in cultural humility and culturally sensitive communication skills	Communication	<ul style="list-style-type: none"> Some standard research practices might not appear ethical to participants. For example, use of placebo or blinding to intervention might be perceived as withholding treatment or withholding information, respectively Inaccurate information regarding medical research is easy to access through less formal forms of media 	<ul style="list-style-type: none"> Attending cultural competency workshops is not enough. Researchers need to engage in the lifelong effort of "cultural confidence." They should carefully assess and regularly re-examine their own implicit and explicit biases^{14,43} Researchers should use communication that effectively educates and empowers participants. They should clearly discuss the following: <ol style="list-style-type: none"> Intent of research (e.g., observational, interventional) Research methods including placebo, blinding, HIPAA Ways study results will be disseminated on its completion Research contact to ask questions Create a diverse research team and a research culture of acceptance and open-mindedness for participants and investigators so that all feel included and safe^{28,44}
Recruitment and retention	8. Ensure continuity in participant-investigator interactions	Lack of rapport with study investigator	<ul style="list-style-type: none"> The already established clinician-patient relationship presents an opportunity for research education and transparency, which creates and maintains trust; it allows for an individualized approach to recruitment When the research team is separate from the clinical team, potential participants are less likely to enroll in studies due to lack of rapport with those recruiting, which perpetuates distrust 	<ul style="list-style-type: none"> Study advertising should contain visuals demonstrating participants representative of the study location's demographic population Promote collaboration between the research and clinical teams. Clinicians who have established relationships with potential participants could personally introduce them to the study with explicit counseling that if participants do not wish to participate it will not affect their care Ensure adequate time for clinician-participant unbiased discussion about study progress and potential concerns Maintain consistency by ensuring participants meet the same research investigator at each study visit
Recruitment and retention	9. Promote representation of underserved populations in medical and research careers	Lack of diversity	<ul style="list-style-type: none"> Underrepresentation of BIPOC HCPs and researchers. AAs represent 13.4% of the US population, only 5% of US doctors, and 7.1% of US medical school matriculants.⁵⁹⁻⁶¹ To our knowledge, the proportion of AA Headache Specialists has not been explicitly reported.⁶² However, the estimated proportion of AA male headache specialists in the 	<ul style="list-style-type: none"> Early exposure and financial aid are major ways to support members from underserved populations in pursuing careers in medicine and research.^{64,65} Examples include the following: <ol style="list-style-type: none"> Medical schools' outreach with professionals from underserved groups at school career days and in K-12 classrooms Pipeline programs and scholarships for underserved youth such as Aetna Health Professions Partnership Initiative (HPPI) summer and ElevateMeD

Research process	Eleven things to consider	Primary barrier	Context	Ways to address
Data collection	10. Recognize that standardization might not always be adequate	Standardization	<p>United States is ~0.5%</p> <ul style="list-style-type: none"> Staff diversity and hence racial and cultural concordance between researchers and participants promotes trust, enhances communication, and conveys cultural understanding⁶⁵ 	<p>(www.elevatemed.org) academic programs</p> <ol style="list-style-type: none"> The International Headache Society offering free membership, short-stay scholarships, and virtual mentoring to trainees in underserved countries The American Headache Society initiatives such as the Diversity, Equity, and Inclusion Task Force, (newly formed) may help spearhead initiatives toward improving underrepresented groups in headache medicine Institutions should promote diversity and inclusion programs by providing some RVU-matched or other compensation to participants for their efforts⁶⁶ <ul style="list-style-type: none"> Adaptation is preferred over translation. However, adaptation is sometimes neither fair nor adequate in which case creating a new test is needed Ensure construct equivalence for the languages and cultures of the participants Ensure new research instruments are validated in diverse populations⁶⁸
Data analysis	11. Take social and structural determinants of health into account when gathering and analyzing data	Biased logic and method	<ul style="list-style-type: none"> Difficulty in standardization of research tools (e.g., recruitment material, questionnaires, cognitive evaluations) in the context of different languages, cultures, and educational levels⁶⁷ Systemic racism has become a health determinant partly due to its relationship to geographic, environmental, and socioeconomic factors 	<ul style="list-style-type: none"> Strictly analyzing data by race might miss the point on the underlying social and structural determinants of health that may be driven by racism⁶⁹ Try to capture socioenvironmental factors that contribute to observed racial health disparities such as contextual (e.g., residential segregation, neighborhood disadvantage), psychosocial (e.g., microaggression, discrimination, financial security, education), and individual (e.g., immigration status, language) factors in the data collection and account for those factors in the data analysis.^{22,23,30} For example, using metropolitan and micropolitan statistical areas might help compare districts and assess potential consequences of redlining Headache journals should encourage the submission of health disparity research articles²⁸