The Lack of Representation in Medical Research: How DEI is the Solution

Benjamin Adubofour
University of California Los Angeles

Karime Montaño
University of California Los Angeles

Nishel Narajos
Glendora High School

Ava Schreier
Dartmouth College

Abstract

Incorporating diversity, equity, and inclusion (DEI) is a founded necessity in modern scientific studies and is imperative to improving the health outcomes for people of all genders, ethnicities/races, sexual orientations, identities, etc. Some may see DEI as unnecessary to clinical trials and would rather allocate the time to pursuing the research rather than implement diversity into the patient sample. However, the results of the trial(s) are significantly skewed when neglecting to represent the whole population in the study. After researching three specific clinical trials, it is very likely that DEI is necessary for the further advancement of medicine.

Introduction

Imagine an African American woman is denied healthcare because of the color of her skin. She is in physical distress because she is in labor. Her pain is unbearable, yet she is seen as “last priority” because of her physician’s false belief that African Americans have an increased pain tolerance. She then passes away. This is not merely an imagined situation, but a veritable and experienced risk. A study conducted by the Department of Psychology at the University of Virginia reported that “50% of medical

students endorsed [similar], false beliefs related to Black pain tolerance" (Hoffman & Trawalter & Axt et al. 2016, p. 4296-4301). These beliefs are reinforced by the lack of representation in a significant number of scientific studies. Consequently, doctors and scientists have incorporated societal misconceptions and biases into their practices.

Why is it so significant that individuals of all identities and backgrounds are included in research studies and clinical trials? The answer lies in the conclusions that scientists and physicians draw from the results of their studies, and the subsequent application of these results in their treatment procedures. To not only avoid bias, but accurately represent the diverse communities frequently overlooked by scientific research and clinical trials, scientists and physicians should implement diversity, equity, and inclusion (DEI) in their studies. DEI is defined as the promotion and participation of different groups of individuals, including people of different ages, races, ethnicities, cultures, religions, abilities and disabilities, genders, and sexual orientations (Barney & Rosencrance, 2023).

Body

A foundational aspect of addressing the lack of representation in clinical trials is understanding what a clinical trial fundamentally entails. According to the World Health Organization, "clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes" (WHO, 2020). There is a severe equity problem when it comes to representation in these studies, primarily regarding racial/ethnic background and gender (NIH, 2024) which is highlighted throughout this paper, drawing evidence from previous clinical trials conducted without these groups in mind. Underrepresentation in these trials is often the result of bias. Some clinical trials implement bias, either implicitly or explicitly, while others give rise to it. Examples of this include researchers failing to accommodate for the hidden costs of participating in studies (Schoch, 2023), and medical practitioners limiting the treatment options of patients based on race (Apeles, 2022). Understanding that an accurate clinical trial must be able to represent people of all identities, the promotion of diversity, equity, and inclusion (DEI) should be adopted to ensure that the results of scientific research are accurate.

Historically, in the United States, minorities have been disproportionately underrepresented in medical research studies. A specific instance of this can be noted in 24 U.S. clinical trials for

cardiovascular drugs, examined by physicians Siliang Chen and Jiarui Li. This study found that "83.1% of subjects [amongst the 24 trials] were white, while only 2.9% were Black" (Chen & Li, 2021). This is greatly concerning considering that Black and white Americans are nearly equally susceptible to cardiovascular disease, at "23.5% for Black Americans, and 23.7% for white Americans" (Web MD Editorial Contributors, n.d.). The severe underrepresentation of Black patients in these trials poses a substantial risk for African Americans who suffer from cardiovascular disease. This is because the results of clinical trials that largely exclude racial minorities may give rise to conclusions that underestimate or overstate adverse health effects for these groups. For example, racial minorities that were underrepresented in the trial would be more likely to experience adverse reactions to the cardiovascular drug, as the limited sample may fail to capture critical variation in drug response. The insufficient data on racial minorities that is available to work with could potentially be harmful when these cardiovascular drugs are available for prescription.

Another occasion of a clinical trial failing to produce results representative of a diverse patient population is Roche's Crenezumab drug in Alzheimer's disease. The anti-amyloid drug, tested internationally in 2020, supposedly planned to assess the "rate of change in cognitive abilities or episodic memory function in cognitively unimpaired persons at risk for Alzheimer disease" (Meglio, 2022). However, the clinical trial was terminated due to failure in generating results that improved the condition of the participants. A colossal error on Roche's part of the trial was not acquiring a substantially diverse participant group. In 2020, the race demographics of its phase 2 drug trial showed that out of the 813 participants, 712 (88%) were white. With only 12% of the entire participant group composed of people of color, and less than 1% of participants being African American, many underrepresented groups and variations in treatment responses are left unaccounted for (Hoffmann-La Roche, 2016). The irony in this is that "among people ages 65 and older, African Americans have the highest morbidity of Alzheimer's disease (13.8 percent)." Hispanics follow at 12.2% (CDC, 2018). This lack of representation in Alzheimer's research limits our understanding of how treatments for the brain disorder would impact diverse groups. This clinical trial was not approaching their testing with the idea that all races will use their product. The repercussions of unvaried research are severely detrimental to those racial minority groups excluded from clinical trials, especially those with senile dementia. Given that "the number of older

adults with Alzheimer's disease is projected to increase from 230,000 in 2020 to 260,000 in 2025", it is imperative that pharmaceutical scientists take action to ensure that the subjects of their research are culturally diverse to provide accurate results (Suneson & Byrnes, 2020).

The lack of representation in clinical trials extends not only to race but to gender as well, creating additional barriers in medicine. Due to its unprecedented nature, the COVID-19 pandemic incited a global demand for medical attention, necessitating extensive research on its severity and long-term effects. Clinical trials and research began on this virus quickly, to bring information to the public, as we knew nothing about COVID-19. In December 2020, there were 45 randomized controlled trials that had been reported. The trials were performed quickly, likely to provide reassurance amidst crises. However, when these trials were closely examined, only eight out of the 45 had reported details on the different impacts the virus had on gender. Understanding the different impacts of COVID-19, depending on the gender, is important since "for every 10 COVID-19 intensive care unit admissions among women, there are 18 for men; for every 10 women who die of COVID-19, 15 men die" (O'Grady, 2021). Having insight into the data surrounding the death rate of COVID-19 not only shows how different people are affected but shows the importance of taking a dive into how medical attention should change to fit the necessities of a person's conditions and identity. When different aspects such as how a disease affects a person are recorded in clinical trials, people are less subject to fitting into one generalized group. This then becomes dangerous when everyone is treated the same, regardless of any factor that may play a part in their specific medical needs.

According to Ana-Maria Šimundić's study on bias in research, "It is immoral and unethical to conduct biased research. Every scientist should thus be aware of all potential sources of bias and undertake all possible actions to reduce or minimize the deviation from the truth" (Šimundić, 2013). As illustrated in each case presented, scientific studies need to prioritize greater outreach to minority groups to ensure more comprehensive, reliable findings. Additionally, scientists and physicians should prioritize including participants of all social characteristics that are relevant to their research.

In the case of the 24 cardiovascular trials discussed above, the lack of African American subjects despite their nearly equal susceptibility to cardiovascular diseases, poses serious risk as cardiovascular disease is the leading cause of death in America (CDC, 2022). If Americans of all backgrounds are not represented in research regarding the treatment of a

threat to America's health as ubiquitous as cardiovascular disease, the death toll will continue to rise disproportionately.

Similarly, the Crenezumab drug for Alzheimer's needed a drastic increase in its participation of people of color. Claiming the lives of more than 135,000 in the United States alone and rapidly growing, a treatment for this ailment must ensure to prove effective in all individuals affected (CDC, 2018). Broadcasting DEI is essential for fair and accurate medical research as it "promotes a more accurate understanding of minority participation in clinical trials [and] has significant public health implications. [This is] because it relates to efforts to eliminate disparities and achieve equality through clinical research" (Fisher & Kalbaugh, 2011). Roche's Crenezumab drug in Alzheimer's disease lacked an equitable clinical trial, resulting in insufficient results. Racial inequality in scientific studies not only increases the number of studies leading to failure, but indirectly increases the mortality rate of those diseases.

Understanding the importance of implementing diversity would allow the medical world to be fit for all people. Addressing the lack of representation and diversity in the medical field involves reexamining policy, education, and institutional priorities. Medical students should receive the training and education needed to be able to treat everyone equitably. Policies that uphold the values of diversity and representation need to be implemented in order to make a change. The lack of DEI in clinical trials stems from all of the wrongs in the policies and systems that encompass the medical field. In order to move forward with a much more diverse and inclusive medical field, it is important that clinical trials not only become more open, but also implement policies that uphold trials to report how different genders perform in the study. Furthering clinical trials into reporting gender performance ensures patient safety and the availability of patient information. Given that clinical trials offer crucial information and ensure the safety of treatments, it is vital that each aspect is evaluated thoroughly to ensure proper medical care that meets the needs of all patients.

From a policy standpoint, efforts to mandate that scientific research and clinical trials incorporate a diverse pool of subjects have come into fruition. In April of 2022, the U.S. Food & Drug Administration released a draft guidance which "recommends that sponsors of medical products develop and submit a Race and Ethnicity Diversity Plan" before supporting the clinical testing of a medical product (FDA, 2022). An additional example of an effort to increase diversity, equity, and inclusion in scientific studies can be seen in the National Institute of Health's

Revitalization Act. The act was signed into law in 1993, and "establish[ed] guidelines for [the] inclusion of women and minorities in clinical research" (NIH Editorial Contributors, 2001). The act intended to ensure that women and people of color were included in clinical research by setting guidelines as to when the inclusion of women and minorities as clinical research subjects was inappropriate, how trials including underrepresented groups were to be carried out, and how to account for differences in data from the testing of underrepresented groups. It is imperative that legislation and policies are enforced, as the issue of underrepresentation continues to persist in the United States. In order to ameliorate the detriment that results from unrepresentative clinical research, a precedent of conducting equitable, accurate research must be set amongst scientists and physicians.

While the term "diversity, equity, and inclusion" in medicine strives for healthcare that is equitable and accessible for all individuals, the idea may seem unimportant to some. Opponents to the idea may view the emphasis on DEI as an impediment to medical advancement, drawing attention away from the research. However, recognizing the impact of research directly can produce results more successfully for all people, not just a targeted group. A factor as to why clinical trials have a lack of diversity in their studies is because of convenience. The initial question of why clinical trials are not representative of the population they serve is because of the requirements which patients must fulfill for the study. The design of exclusive studies are in part "a result of stricter eligibility criteria in early studies, and is also due to clustering of phase 1 trial centers in urban locations that are less accessible to patients in rural or underserved areas" (Chaudhry, et al., 2022). A diverse sample of patients is often lacking in phase 1 trials through the belief that the issue can be solved by phases 2 and 3. However, this further pushes the detrimental effects of a lack of inclusivity such as immorally ostracizing minority groups in scientific studies.

Moreover, implementing bias and underrepresenting the diverse communities which make up the public is not only immensely unethical and unfair, but also leads to misconceptions about gender and race derived from inadequately conducted studies, seeping into the way students are taught, and into their future practices as doctors or as scientists. Beliefs of biological differences between America's racial groups have deep historical roots. In events such as the Yellow Fever Epidemic in late 18th century Philadelphia, the bias of "white physicians and lay people [led them to] erroneously think that Black people were immune to yellow fever

because of their race" (Hogarth, 2019). Beliefs of biological differences between America's gender groups can be affiliated with biased Colonial America where "boys learned additional skills so they could go into business, farming, or trade, while girls learned household skills" (National Geographic Society, 2022). From these examples, physicians and scientists, knowingly or unknowingly, implement these antiquated ideas into practices of their own.

As the field of science continues to evolve, while continuing to fail at focusing on DEI, underlying bias proceeds, stemming from ideas of the past. This contributes greatly to the lack of diversity, equity, and inclusion in obstacles we've consistently faced as a society. To steer from racial prejudice and gender conformity, we need to actively examine the unconscious (and continuous) biases we all have, as part of being human in an (unfortunately) unequal society.

Conclusion

We'd like to close with a quote, "Whether you are motivated by the goal of producing the highest quality science, by pursuit of fairness and equity in how science might translate into better health for our patients, or by the enormous economic toll of health disparities in the U.S., I hope you embrace the urgency of improving representation and inclusion in clinical research," wrote UCSF physician, teacher, and leader in health equity, Dr. Kirsten Bibbins-Domingo.

Race and gender are far too often overlooked in scientific research and clinical trials. The effects are being felt even beyond traditional medicine into the way patient care is being delivered in analysis of data, delivery of mental health online and machine learning. To not only avoid bias, but to also accurately represent these social characteristics, scientists and physicians should more effectively implement diversity, equity and inclusion (DEI) in their studies. Remediating unfair practices when it comes to increasing the ethnic and gender mosaic in science begins with advocacy. The world is progressively yearning to spread awareness about how detrimental inequality really is and how we can amend it. If we all advocate for implementing DEI in science, people from all walks of life could not only be accurately represented, but would also be provided with equitable, quality care. Using the information presented, the African American mother in the paper's onset is a realistic example of the vital changes that must be made to the medical landscape. With increased implementation of DEI policies in medical research, she could be holding her child today.

References

Apeles, L. (2022, 1 18). Race-Based Prescribing for Black People with High Blood Pressure Shows No Benefit. UCSF. Retrieved 11 27, 2024, from https://www.ucsf.edu/news/2022/01/422151/race-based-prescribing-black–people-high-blood-pressure-shows-no-benefit

Centers for Disease Control and Prevention. (2018, September 20). U.S. burden of Alzheimer's disease, related dementias to double by 2060. Centers for Disease Control and Prevention. https://www.cdc.gov/media/releases/2018/p0920-alzheimers-burden-double-2060.html

Centers for Disease Control and Prevention. (2023, January 17). FASTSTATS - Alzheimer's disease. Centers for Disease Control and Prevention. https://www.cdc.gov/nchs/fastats/alzheimers.htm

Centers for Disease Control and Prevention. (2023, January 18). FASTSTATS - leading causes of death. Centers for Disease Control and Prevention. https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm

Chaudhry, M. S., & et. al. (2022). Myths about diversity in clinical trials reduce return on investment for industry. Nature Medicine, 28(8), 1520–1522. https://doi.org/10.1038/s41591-022-01858-4

Chen, S., & Li, J. (2021). Participation of Black US Residents in Clinical Trials of 24 Cardiovascular Drugs Granted FDA Approval, 2006-2020. In JAMA Network Open (Vol. 4, Issue 3, p. e212640). American Medical Association (AMA). https://doi.org/10.1001/jamanetworkopen.2021.2640

FDA. (2022, April 13). Diversity plan to improve enrollment of participants in clinical trial. U.S. Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations

Fisher, J. A., & Kalbaugh, C. A. (2011). Challenging Assumptions About Minority Participation in US Clinical Research. In American Journal of Public Health (Vol. 101, Issue 12, pp. 2217–2222). American Public Health Association. https://doi.org/10.2105/ajph.2011.30027

Grant, K. (2022, May 5). Why do clinical trials still underrepresent minority groups?. Medscape. https://www.medscape.com/viewarticle/973500

Hoffman, K. M., Trawalter, S., Axt, J. R., & Oliver, M. N. (2016). Racial bias in pain assessment and treatment recommendations, and false beliefs about biological differences between blacks and whites. In Proceedings of the National Academy of Sciences (Vol. 113, Issue 16, pp. 4296–4301). Proceedings of the National Academy of Sciences. https://doi.org/10.1073/pnas.1516047113

Hoffmann-La Roche. (2016, February 1). A study evaluating the efficacy and safety of crenezumab versus placebo in participants with prodromal to mild alzheimer's disease (AD). - study results. A Study Evaluating the Efficacy and Safety of Crenezumab Versus Placebo in Participants With Prodromal to Mild Alzheimer's Disease (AD). - Study Results - ClinicalTrials.gov. https://www.clinicaltrials.gov/ct2/show/results/NCT02670083?view=results

Meglio, M. (2022, June 20). Roche's Crenezumab Fails to Meet End Points in Autosomal Dominant Alzheimer Disease. Neurology Live; HCP Live Network. https://www.neurologylive.com/view/roche-crenezumab-fails-meet-end-points-autosomal-dominant-alzheimer-disease

National Geographic Society. (2022, May 19). Women and children in Colonial America. Education. https://education.nationalgeographic.org/resource/women-and-children-colonial-america/

NIH. (2024, January 12). Diversity & Inclusion in Clinical Trials. National Institute on Minority Health and Health Disparities. Retrieved November 27, 2024, from https://www.nimhd.nih.gov/resources/understanding-health-disparities/diversity-and-inclusion-in-clinical-trials.html

O'Grady, C. (2021). COVID-19 affects men and women differently. So why don't clinical trials report gender data? In Science. American Association for the Advancement of Science (AAAS). https://doi.org/10.1126/science.abk2837.

Rosencrance, L., & Barney, N. (2021, March). What are Diversity, Equity and Inclusion (DEI)? SearchHRSoftware. https://www.techtarget.com/searchhrsoftware/definition/diversity-equity-and-inclusion-DEI

Sagar, V. (2022, June 17). Roche's potential Alzheimer's drug crenezumab fails in Phase 2 clinical trial. NS Healthcare. https://www.ns-healthcare.com/news/roche-crenezumab-fails-trial

Simundic, A.-M. (2013). Bias in research. In Biochemia Medica (pp. 12–15). Croatian Society for Medical Biochemistry and Laboratory Medicine. https://doi.org/10.11613/bm.2013.003

Suneson, G., & Byrnes, H. (2020, August 10). Alzheimer's disease to affect 7.1 million Americans by 2025. Here's the expected increase by state. USA Today. https://www.usatoday.com/story/money/2020/08/10/alzheimers-disease-states-where-cases-will-rise-most-by-2025/42187567/

U.S. Department of Health and Human Services. (2001, October 9). NIH policy and guidelines on the inclusion of women and minorities as subjects in clinical research. National Institutes of Health. https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm.

World Health Organization. (n.d.). Clinical trials. World Health Organization. https://www.who.int/health-topics/clinical-trials/ [Original source: https://studycrumb.com/alphabetizer]