

EDITORIAL

How Diversity, Equity and Inclusion are Changing Clinical Research

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“Medical journals will force clinical trial designs to be more inclusive.

Trials need to include more women and minorities.

Clinical research needs to be more patient-centered.”

Renato D. Lopes

Clinical research must be translated into changes in clinical practice. One of the difficulties faced by physicians is how to apply results of randomized clinical trials to patients with different profiles from those enrolled in the studies. So, one common question is: Is it appropriate to use clinical trial results in my patient? It is not easy to make clinical decisions based on results from clinical research that does not consider racial identity, ethnicity, age, or gender of patients. One important initiative in science is to promote diversity, equity and inclusion in clinical research in order to produce more reliable data.¹

Women are historically underrepresented in cardiovascular disease trials, despite sex-determined differences that lead to different forms of clinical presentation and therapeutic management. In cardiology, clinical presentation, risk stratification, prevention, treatment, and outcome parameters are gender sensitive, and this should be taken into account when designing clinical trials.² Recently, the American College of Cardiology’s Cardiovascular Disease in Women Committee Leadership Council pointed out the low rates of women enrollment in cardiovascular

research: the rates of women across coronary artery disease, acute coronary syndrome, and heart failure trials were 27.3%, 26.9% and 28,6%, respectively.³ Sex-specific data concerning therapy is essential because women may respond differently than men and may even have adverse effects from some drugs at the same dosage that are beneficial to men.³ To being with, part of this small participation of women in cardiovascular (CV) clinical trials can be attributed to the limited diversity in the leadership of these studies: only 10% of members in leadership committees of CV clinical trials are women. A similar number of 10% of CV trials published have a woman on the first or last author position.⁴ Women need to be included, respected, empowered, and adequately represented in clinical research to guarantee the applicability of the results to their gender. Recently, the International Journal of Cardiovascular Sciences endorsed SAGER guidelines to improve the reporting of sex and gender in research while creating an environment able to integrate equity of sex and gender into manuscripts as an integral part of the editorial process.^{5,6} As women, minorities also have been underrepresented in CV clinical studies. Some minority populations have shown disproportionately higher rates of certain diseases such as hypertension, heart failure and cerebrovascular disease.⁷

Poverty, marginalization, and inequity, that are very common among minorities are added risk factors for morbidity and mortality from many diseases, including CV diseases.⁸ The COVID-19 pandemic is one example of this situation. The COVID-19 pandemic has had a great economic impact, especially in Latin America where the number of poor people has increased substantially. Despite markedly higher rates of COVID-19 infection, hospitalization and deaths in racial and ethnic minority groups, these groups were significantly underrepresented in COVID-19 clinical

Keywords

Ageism; Cardiovascular Diseases/therapy; Clinical Trials as Topic; Gender Diversity; Equity; Women, Inclusion.

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DOI: <https://doi.org/10.36660/ijcs.20220131>

trials.⁹ In the United States of America some measures have been taken to fill this gap like a federal law (Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2) and policies such as the National Institutes of Health (NIH) policy NOT-OD-18-014 that mandates the inclusion of minorities in NIH-funded research.

To fight against the lack of diversity in clinical trials it is crucial to understand and address the needs of minority communities, including the costs for participating in a clinical trial. In Brazil, the patient has the right to be reimbursed for the expenses (eg. food and transportation costs) related to the participation in the trial. Other important barriers that must be tackled to promote more inclusive trials are poor health literacy, lack of information, disinformation, science negation, language barriers, lack of diversity of principal investigators, limited accessibility, and biases against minorities.⁹ Another possible way to increase inclusion is to promote patient and public involvement (PPI) in trial decisions. For example, PPI is very useful in designing clinical questions and primary objectives that address their needs, developing the clinical protocol, interpreting results; and disseminating results for communities.¹⁰

How can a medical journal foster diversity, equity and inclusion in clinical research? This question is key in our times. Figure 1 includes some actions that can be taken by the editors. The first step is to understand and to measure the lack of diversity in CV trials. Secondly, to adopt policies focused on diversity, equity and inclusion that can be easily translated into actions such as endorsing guidelines promoting equity such as SAGER, including minorities in editorial and reviewer boards, and promoting diversity publicly (webinars and symposia).^{6,11} Finally, some high impact journals are promoting an increase in transparency of data concerning minorities. Since January 1, 2022, the New England Journal of Medicine has demanded that authors prepare a supplementary table that provides background information on the disease, problem, or condition and the representativeness of the study group, to be posted with the article.¹ Demanding clarity and transparency in trials design, patient selection and representativeness of study participants is another step to promote more inclusive clinical research. These actions can contribute to a healthier future, reducing inequalities and promoting equity.

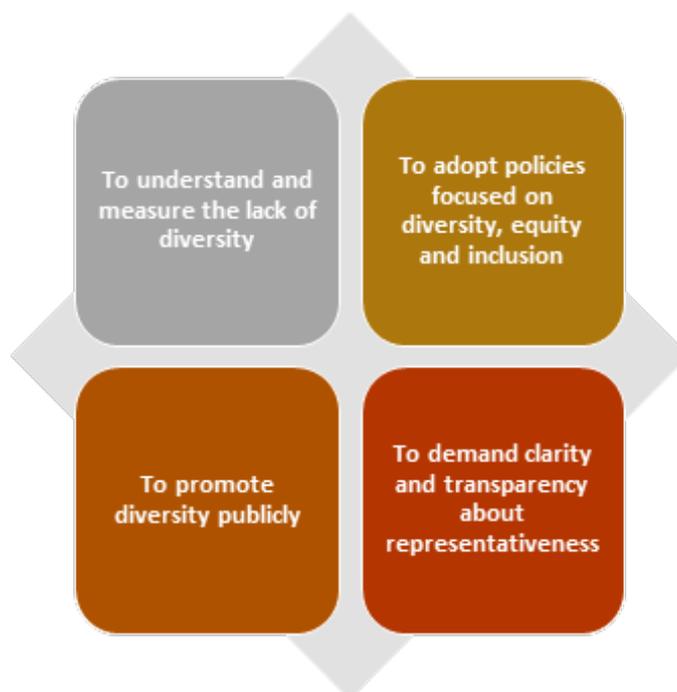


Figure 1 – Medical journals actions to promote diversity, equity and inclusion in clinical research.

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