Inclusion of Racial and Ethnic Minorities in Cancer Clinical Trials: 30 Years After the NIH Revitalization Act, Where Are We?

FAITH MUTALE, DNP, CRNP

From Abramson Cancer Center, Hospital of the University of Pennsylvania, Philadelphia

Correspondence to: Faith Mutale, DNP, CRNP, Perelman Center for Advanced Medicine, 3400 Civic Center Boulevard, Philadelphia, PA 19104. E-mail: faith.mutale@pennmedicine.upenn.edu

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Abstract

The lack of diversity in cancer trials is a multifaceted, decades-old problem that has remained persistent despite efforts to increase the number of participants from underrepresented racial and ethnic backgrounds. This lack of meaningful improvement is a problem that continues to perpetuate inequities in cancer care. For optimal generalizability of clinical trial results, populations that are likely to be treated must be adequately represented. Beyond consensus statements, policy enactments, and federal mandates, strategic collaboration with at-risk underrepresented communities is critically necessary to improve the accrual of minorities to cancer clinical trials. As such, the clarion call is for advanced practitioners in oncology to take a keen interest in this issue and seek to develop population-specific strategies to bridge and eliminate the disparity gap and improve outcomes in these groups.

Improving diversity in cancer clinical trials is critically important to improve patient outcomes. The lack of diversity in clinical trials continues to be a concern among policymakers, including stakeholders such as trial investigators, advocacy groups, and consensus groups like the Oncology Nursing Society (ONS) and the American Society of Clinical Oncology (ASCO). However, in a recent congressional hearing deliberating on diversity in clinical trials, Lucy Vereshchagina, PhD, Vice President, Science and Regulatory Advocacy Pharmaceutical Research and Manufacturers of America (PhRMA), argued that a regulatory mandate to include racial and ethnic minorities in industry-funded trials leads to "unfeasibly large and long studies, delayed access to medicines, or disincentives for industry to invest in highly risky therapeutic areas" and may result in "serious unintended

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consequences of reenforcing rather than overcoming known barriers to participation for patients."

These efforts by industry leaders to push back on a federal mandate are disingenuous and highlight the priorities of industry where market attractiveness and the potential for profit dictate decisions. This is not in any way meant to indict industry sponsors of clinical trials who must make a profit. Rather, the idea that the inclusion of minorities into trials will adversely impact work on "risky therapies and delay access to therapies" is absurd and an affront to good clinical trials practice, because the same group is willing to support moving trials into communities. What is evidently clear is that, until recently, industry sponsors have not made diversity in cancer trials a priority and have not been keen on prioritizing this issue.

PARTICIPATION IN CANCER CLINICAL TRIALS

Cancer remains the second leading cause of death in the United States. However, less than 20% of adults diagnosed with cancer participate in clinical trials, with White middle-class men making up the majority at roughly 85%. Although African Americans and Hispanic Americans constitute 13% and 16% of the US population, less than 5% and only 1% of these respective populations participate in clinical trials (Cory Booker, 2020). In 1993, Congress enacted the National Institutes of Health (NIH) Revitalization Act, which requires mandatory disclosure of the gender and race of clinical trial participants in order to receive federal funds. In the decade following, there was a modest improvement in enrollment rates, especially among White women who currently make up 50% of trial participants. However, similar gains have not been seen with patients from minority racial/ethnic groups. In fact, there has been a steady decline in trial participation rates among these groups.

Today, nearly 30 years after the NIH Act, diversification remains a concern in virtually all cancer trials despite legislation aimed at improving trial diversity, including the 2010 Affordable Care Act, the 2012 Reauthorization of the Prescription Drug User Fee Act, the 2016 21st Century Cures Act, and the 2017 NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. As of 2018, reporting of clinical trial enrollment and outcomes had not improved as these policies largely do not apply to industry-sponsored trials (Brigham and Women's Hospital, 2022). In fact, a study published in 2021 demonstrated that many researchers were not adhering to NIH policies with respect to the reporting of trials (Fain et al., 2021). The lack of a federal mandate requiring industry-funded trials to report on the racial composition of those trials continues to be a challenge and serious obstacle to improving minority participation in clinical trials, especially given that a significant proportion of clinical trials are industry sponsored. For example, between 2006 and 2014, 6,550 cancer trials were industry funded compared with 1,048 NIH-funded trials (Llamas, 2022). Additionally, in 2012, only 17% of patients who enrolled in industry-funded trials were of a minority background and less than 5% of NIH-funded trials reported on participants' race (Woods-Burnham et al., 2021).

ADDRESSING THE PROBLEM

In 2018, ProPublica published the racial composition of trial participants spanning a decade prior (Chen & Wong, 2018). In two thirds of these trials, less than 5% were from a minority background and no Alaskan natives (who account for 2% of the US population) were included. The lack of diversity is prevalent in both prevention and therapeutic trials, with a participation rate of < 10% (Guerra et al., 2021). This begs the question of whether industry sponsors have a genuine commitment to improving diversity in clinical trials, and absent a federal mandate, will anything change?

Consider the problem of inappropriate hospital readmission rates, where the Centers for Medicare and Medicaid Services (CMS) had to institute penalties and design a value-based purchasing program that decreases reimbursement to hospitals with disproportionately high readmission rates (commonly known as the Hospital Readmissions Reduction Program) to address the problem (Boccuti & Casillas, 2017). As expected, everyone got on board. Perhaps a similar program to penalize industry sponsors is required for the industry as a whole to change its stance on the diversification of participants in clinical trials and for meaningful improvements to occur. It is perhaps time for industry sponsors to make good on improving diversity in cancer trials.

CONCLUSION

The lack of diversity in cancer trials limits the generalizability of outcomes of clinical trials. The goal of the NIH Revitalization Act as it was envisioned has yet to be realized. Given the importance of clinical trials in drug development and the generalizability of results, it is essential for cancer clinical trials to reflect populations likely to be treated. Therefore, it is time for Congress to extend a similar mandate that applies to all cancer clinical trials, including those with industry sponsors.

The potential lack of knowledge among advanced practitioners regarding disparities in cancer clinical trials likely and inadvertently perpetuates disparities. For meaningful improvement to occur, advanced practitioners must acquire appropriate knowledge to ensure cogent and evidence-based strategies that will likely improve the accrual of racial and ethnic minority patients into cancer clinical trials.

Oncology advanced practitioners must be intentional in presenting clinical trial opportunities to all potentially eligible patients and seek to collaborate and engage with minority communities in an effort to foster trust and inclusion.

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