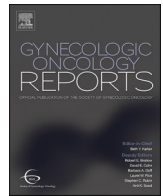




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The time is now: Concrete actions are needed to improve diversity and representation in clinical trials participation

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The gross under-representation of racial and ethnic minorities in oncology clinical trials has been well-established in the oncologic literature and there is overwhelming consensus that trial populations ideally should resemble the affected population (Dignam et al., 2024, Khadraoui et al., 2023). Interventions to combat these disparities remain nascent and are often limited to conceptual frameworks. Concrete plans and evidence-based models are crucial to effectively implement necessary changes and to achieve representative participation in clinical trials.

Lara et al's publication, "Improving clinical trial enrollment in minority racial and ethnic patients with gynecologic malignancy," describes the results of a pilot pre-screening and fast-track initiative to identify and facilitate patients eligible for clinical trials. They demonstrated that multi-disciplinary participation, including financial navigators and clinical trials coordinators, is both feasible and effective at improving screening for eligible Black patients. Fouad et al. (2016) have similarly demonstrated that patient navigation for Black patients improves both enrollment and retention in clinical trials. Other investigations have also found that community-based approaches promote acceptance and enrollment in minority populations. Such interventions are necessary to developing effective infrastructure to make trials accessible to all patients, but particularly the under-served and highest risk.

In that vein, we must also recognize other populations that have limited access to clinical trials and identify and build a more comprehensive approach to address covariates associated with under-representation. For example, rural people experience a disproportionately higher cancer burden and worse oncologic outcomes than non-rural people. Clinical trial participation by rural patients has been demonstrated to have an association with improved survival (Unger et al., 2018) Although interventions such as telemedicine and local lab authorizations improve accessibility for potential trial patients, few tangible accommodations have been incorporated into most protocols and these interventions would likely benefit all populations facing barriers to clinical trial participation.

Racial and ethnic diversity is imperative; there is no doubt about it. However, broadening our conceptualization of diversity and accessibility allows us to recognize the multifactorial barriers to both enrollment and participation that are a lived reality for many patients. Even when patients are successfully recruited to a clinical trial, some ultimately cannot participate due to barriers precluding frequent visits to a tertiary care center. This is a daily occurrence for those of us working

with any under-represented population wherein enrollment is successful but attrition due to transportation barriers, distance and time required for visits, financial toxicity, and other social determinants of health preclude sustained participation in a trial protocol. We must continue to move beyond the phase of identifying disparities and into the phase of implementing programs to decrease them, so must we begin to incorporate a view of diversity that also incorporates the multifaceted structural barriers that prevent patients from the highest quality cancer care.

What concrete actions can all of us take to work toward ensuring all patients have access to clinical trials? National organizations such as the NRG, GOG Partners, and SGO are actively working to prioritize representative participation into clinical trials. For example, the NRG Winter 2024 Education Symposium will focus on IDEA: Inclusion, Diversity, Equity, and Access, with education modules and leadership centered on improving trials diversity. Additionally, NRG Oncology is committed to taking steps to support research that goes beyond surveying the systemic issues within the healthcare landscape. To do this, a two year NRG Health Equity Fellowship, founded by Dr. Joan Walker, co-PI of NRG's National Cancer Institute (NCI) Community Oncology Research Program (NCORP), focuses on training early-stage investigators by means of a structured mentorship experience and focuses on recruitment of researchers from underrepresented groups. Furthermore, the GOG Partners is working with study sponsors for diversity plans in phase 3 trials and incorporating 'IDEA Chairs' on upcoming programs. These efforts are founded from the recent joint statement from GOG Foundation and SGO serving as a call to action and are consistent with the FDA recommendations regarding trials best practices for racial and ethnic diversity (Pothuri et al., 2023; U.S. Department of Health and Human Services, Food and Drug Administration, 2022).

Though these conversations center on racial and ethnic under-representation, an inequity which rightfully deserves maximal attention, there will be room to discuss additional nuances in diversity and accessibility. By broadening our definitions and recognizing the complexity of our patients' barriers to clinical trials, we can improve not only screening and enrollment but ensure equitable participation and receipt of trials-based oncologic care.

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