

Advancing Equity in Cancer Research: Opportunities for Sponsors, Institutions, and Investigators

Nadine J. Barrett, Kenisha Bethea, Leigh Boehmer, Kimberly S. Johnson, Daniel Carrizosa

Numerous studies have documented patient-level barriers to research participation that are often connected to social determinants of health. As described in this paper, significantly moving the needle toward greater diversity and inclusion in cancer research will take a full commitment to integrating an equity lens across the cancer research ecosystem, specifically among sponsors, institutions, and investigators.

Introduction

Lack of intentional commitment and accountability to research equity compromises the rigor of oncology clinical trials and their impact on health outcomes and cancer disparities [1]. In the United States and in North Carolina, cancer is the second leading cause of death, and racial and ethnic disparities in cancer outcomes are substantial. Specifically, minoritized racial and ethnic populations have higher cancer incidence, prevalence, and mortality compared to their White counterparts, yet are grossly underrepresented in cancer clinical research and trials, which exacerbates inequities [1-3]. For example, Black men are significantly more likely to get prostate cancer and two times more likely to die from the disease compared to any other race or ethnic group, yet less than 3% participate in clinical trials [4]. Essentially, underrepresented race and ethnic populations, who carry the greatest burden of cancer, do not get equitable opportunities to participate in potentially life-saving or life-enhancing clinical research and trials, and in general do not equitably benefit from current therapies and interventions available across the cancer continuum [1-2, 5].

Approximately 70% of all clinical research studies funded by the federal government never meet their diversity recruitment and retention goals; despite data showing that 80% of patients with cancer would consider participating in a clinical trial, less than 5% do so [1, 5-6], and rates are especially low among minoritized and marginalized populations. Reasons for low participation are multifaceted and include structural, systemic, attitudinal, and clinical barriers [4-5, 7]. Specifically, patients are frequently not asked to enroll, which may be due to unconscious bias and stereo-

types held by research teams and providers regarding the suitability or willingness of patients from underrepresented groups to participate, and too often research teams do not adequately focus on diversity in recruitment plans and goals. Further, numerous studies have documented patient-level barriers such as mistrust in research stemming from well-documented injustices and factors connected to social determinants of health, including lack of insurance, transportation, language and cultural barriers, poverty, and low health literacy [8, 9].

Although attention to these longstanding issues is important, ongoing efforts are required to move from describing the problem to identifying culturally relevant, patient- and community-informed interventions that can be replicated and scaled to increase access to cancer research [8, 10]. However, there has been historically slow uptake of equity-driven commitment and accountability to the application of rigorous practices, processes, and policies in the recruitment and retention of diverse research participants. To significantly move the needle, it will take a full commitment to integrating an equity lens across the cancer research ecosystem, specifically among sponsors, research institutions, and investigators [8].

The Perils of Inadequate Representation in Cancer Research

Equitable representation in cancer clinical trials advances the development of interventions and therapeutics that are relevant to diverse patient populations. However, an analysis of manuscripts published in a national peer-reviewed journal found a substantial number of studies lacked adequate inclusion of underrepresented race and ethnic groups [11]. The results of these studies can add to the harms of racism in research and further exacerbate gaps in health disparities and equity in cancer health outcomes. For example, in a

Electronically published January 8, 2024.

Address correspondence to Nadine J. Barrett (Nadine.Barrett@duke.edu).

N C Med J. 2024;85(1):13-19. ©2024 by the North Carolina Institute of Medicine and The Duke Endowment. All rights reserved. 0029-2559/2024/85107

prostate cancer study examining the effects of apalutamide plus abiraterone and prednisone on progression-free and overall survival for patients with metastatic prostate cancer with a sample of 492 participants (365 White men [74%], 19 Black men [4%], and 69 Other [16%]) found some improvements in progression-free survival, but no improvement in overall survival. Essentially, the combination of apalutamide and abiraterone lacked superiority over abiraterone alone [12]. Despite the large sample size, and the racial disparities in prostate cancer where Black men carry the greatest burden in both incidence and mortality, no analyses were conducted by race due to inadequate representation. Recent studies have underscored the significance of having diverse representation in the studies, noting racial differences that would not be observed without adding a racial equity lens to their research questions and recruitment strategies that allow for race and ethnic analyses [13-16]. For example, a recent study explored the effects of a novel combination of hormonal therapies, Apalutamide and Abiraterone plus prednisone in patients with castrate-resistant prostate cancer and hypothesized that Black men may benefit more than White men [13]. Ninety-three participants (43 Black men [46%], 50 White men [54%]) were enrolled. Study authors found that Black men doubled the median progression-free survival at 15 months versus 30 months for White men, and had less than half 24-month mortality at 14% versus 33% of White participants [13]. Ensuring equity in cancer research furthers our understanding and ability to address the mechanisms and underlying factors at the societal, institutional, individual, and ancestral levels that contribute to health outcomes and disparities.

Applying an Equity Lens and Framework

Understanding the context of inequities in research participation requires an equity framework that arms those in the research environment and ecosystem with the questions that both define the problem and seek actionable solutions with a focus on equity, anti-bias, and anti-racism [8, 17]. The 5Ws framework provides guidance for sponsors, institutions, and investigators to apply a racial equity lens to ask critical “who, what, where, when, and why” questions to uncover opportunities for equitable practices and policies in research. This framework centers patients, particularly those from marginalized and minoritized groups. 5Ws requires asking deeper questions to help find solutions that ensure programs, services, and policies are designed and implemented from an equity lens, leading to advances in equitable access to research participation and better interventions and therapies [17].

“I wanted to learn about clinical trials when I was diagnosed with cancer, but my provider never mentioned it. I asked him and others on the team about research, and he said there were no studies here, and I have two options, surgery or radiation. I was still interested so a local community organization I belong to, the Durham County Department of Public Health

Men’s Health Council, connected me to a national organization for Black men with prostate cancer called PHEN. They helped me find two trials, but they were only available in another state. I was glad to learn and know about the trials, and may have considered participating in it, or other studies, if the place I was getting my care spoke to me about the possibility of research.”

— Mr. Bradley Long, an African American Patient with Prostate Cancer

Mr. Long was eager to learn about research studies, specifically asking the provider and his team about potential opportunities. His experience highlights some key opportunities with implications for sponsors, institutions, and investigators to advance equitable access to cancer clinical trials.

Sponsors/Funders

Applying the 5Ws framework, trial sponsors and local/national research-funding agencies can begin looking at their portfolios and ask: Who are we funding? Who are we defining as experts? Who are we consulting to ensure we are developing and implementing our research and funding programs with an equity-driven lens? What groups are we missing? How can we do things differently to urgently advance cancer equity? Funding is needed to support collaborations between community-based organizations/nonprofits and academic health centers, community clinics, and other entities to heighten access to oncology clinical research. With these types of collaborations, Bradley would have been able to identify clinical trials that worked for him and discuss them openly with his provider and care team. Moreover, he may have become aware of other clinical research studies available at his institution, or in the vicinity. Serving as research partners, national organizations like the Prostate Health Education Network (PHEN) and the Durham County Department of Public Health Men’s Health Council are incredible leaders in engaging minoritized and marginalized populations in meaningful conversations about clinical research and trials participation. These types of collaborations can address commonly cited barriers to recruitment and retention of minoritized populations, such as administrative burdens and time constraints in large academic health centers and community clinics [18].

Sponsors/funders can contribute to normalizing and integrating research participation by promoting and supporting collaborations with national and local community health worker and public health education programs, as well as mobile outreach and screening programs [19, 20]. These organizations are ideal partners because of their innovative programming in urban, rural, and minoritized communities where they are well trusted. Supporting the development and integration of research in these areas broadens the platform for mass campaigns, outreach, and coordination to support research education and participation in underserved and minoritized communities. Many of these organizations were instrumental in increasing access to COVID-19 clinical trials,

and once the pandemic became less of a threat the funding for these organizations quickly disappeared. Addressing cancer, and particularly cancer disparities, is critical and should be met by local and national funders with the same urgency as COVID-19 [21].

Sponsors and funders are in a unique position to promote and advocate for the decentralization of cancer clinical trials by supporting robust collaborations and capacity-building studies with clear metrics to assess lessons learned and identify best practices [8]. Funding programs can prioritize engaging primary care providers, rural and urban cancer centers, local community pharmacies, clinics, patients, caregivers, and survivors by promoting the opportunity to partner with other entities that can make processes more efficient and accessible [1,5].

On a state level, the North Carolina Department of Health and Human Services Cancer Control Branch develops a cancer control plan every five years with a descriptive report of the state of cancer by county [3]. The branch also convenes academic health centers, National Cancer Institute-designated cancer centers, clinics, and numerous nonprofit community organizations and partners from across the state to promote collaborations and support education, outreach,

and advocacy efforts. State-level funding in North Carolina could be used to foster these partnerships and support other initiatives, such as culturally sensitive education programs, the increased use of community health workers in the context of research, and outreach and screening programs that integrate the importance of clinical trials and promote equitable access [19-21].

Institutions and Systems Change for Equity in Cancer Research

Systems—whether small clinical sites or large academic cancer centers—have significant opportunities to promote equity in research by addressing the institutional practices and policies that limit access to research, particularly for underrepresented populations. Applying the 5Ws framework, systems can explore where facilitators and barriers to research participation exist, identify key touchpoints, and prioritize actionable equity-driven solutions. Key questions include: Who is benefiting from policies and practices? How does our environment benefit some while further disenfranchising minoritized patients and communities? Who is being invited to participate and who is not? What expertise do we have to incorporate and assess what needs

to change to promote equitable access to clinical research and trials?

Fostering a culture of research as an extension of improving health outcomes for patients with cancer is important to the success of recruiting underrepresented populations to participate in studies. Clinics where providers, nurses, and other members of the team do not embrace research as part of their practice can be more challenging environments for recruiting patients, particularly those from underrepresented communities [22]. Other studies highlight implicit bias and not being invited to participate as a key reason that African American/Black and Latino/x populations are underrepresented in cancer clinical trials [7]. Despite the lack of African American and Latino/x representation in cancer trials, there are studies that suggest they are interested in participating and in some cases are more likely to participate compared to their White counterparts [6, 23].

Training and education programs in clinics, academic and community oncology centers, and across teams within these sites have the potential for significant impact. These groups can benefit from training programs like Just ASK™ Increasing Diversity in Cancer Clinical Research, which is

designed to help research teams cast an equity lens on their work; learn strategies to mitigate barriers to research participation, including implicit bias; and increase diverse representation in cancer trials [24]. This type of training should be incorporated at the institutional, sponsor, and investigator levels to integrate equity into all aspects of the research process and ecosystem.

Lastly, institutional Review Boards (IRB) and Cancer Protocol Committees (CPC) are in a unique position to promote diversity in clinical trial participation. These entities have the opportunity to engage investigators at the key touchpoints of study review, new protocol submissions, continuing renewals, and amendments. IRBs can initiate a referral process by leveraging institutional resources (Clinical and Translational Science Institute [CTSI], Cancer Center Support Grants [CCSG], or community advisory councils) to support and bolster equity in cancer clinical trials and support equitable practices in clinical trial recruitment and retention. Moreover, as CPCs address studies that are not meeting accrual goals, more institutional policies can be implemented to equally address studies that are not meeting diversity and retention goals [25].

Investigators and the Research Team

Investigators and research team members should integrate an equity focus at all steps in the research process, including idea generation, study design, implementation of study protocol, and dissemination of study findings [8, 17]. Incorporating perspectives of community partners and diverse patients with equitable compensation for their expertise, teams should apply the 5Ws framework to ensure critical questions are driving equitable opportunities for diverse participation. For example, beyond providing feedback on the content of advertising and education materials, community partners and patients from minoritized populations can provide expertise and insights across the research spectrum and recommend innovative methods to maximize recruitment and enrollment processes. Clinical research studies have successfully recruited and enrolled African American and Latino/x populations by conducting clinical research in church-based settings and through community-based mobile outreach programs, both trusted environments [20, 26]. This requires establishing relationships and

building trust by engaging patients, community members, and leaders from minoritized populations as partners in the research. Working with community partners to establish mutual goals, plan recruitment strategies, identify study measures, and provide feedback throughout the course of the research will facilitate diverse representation of study participants and ensure relevance of work to populations disproportionately affected by cancer.

Investigators and research teams should set explicit goals related to recruitment and retention of minoritized groups into the study. These goals should include systematic strategies for identifying and screening potentially eligible patients. Some studies have applied specific strategies to integrating diversity as a daily part of team meetings; applying the 5Ws framework, teams address critically important questions that align with the recruitment and diversity goals of the study. Recruitment goals should be tracked and discussed regularly throughout the study with modifications to current strategies when needed [27].

Investigators should examine use and representation of race and ethnicity in their studies to ensure the interpreta-

tion and recommendations are appropriate and not biased. Questions to consider include: Does the sample adequately reflect the diversity of the community to ensure equitable representation and generalizability of study findings? Are the research questions or study conclusions making assumptions based on prior studies that lacked adequate diversity? Does the sample make reference to those carrying the greatest burden of the disease? Are eligibility criteria reviewed regularly to ensure they are not based on unfounded or cut-and-paste criteria, including comorbidities that may disproportionately impact underrepresented race and ethnic groups? Likewise, given the lack of diverse representation in the clinical research workforce, does the research team reflect the diversity in the community or catchment area? How can the team tap into resources to ensure a diverse candidate pool when seeking to fill positions?

Integrating Equity: Sponsors, Institutions, and Investigators

Unequal access to cancer research and clinical care has been linked to implicit bias and lack of intentional efforts to apply an equity lens across organizations and teams [7, 8]. Advancing cancer health equity across the research ecosystem requires continual training of all constituents involved in cancer care and research. Sponsors/funders, cancer care institutions, and investigator/research teams should engage health equity experts and strategists to support equity-focused planning and implementation to make meaningful gains in inclusive research. Ensuring diversity within the research workforce that reflects the broader community is an ongoing challenge requiring innovative, mutually beneficial efforts and partnerships with organizations such as Historically Black Colleges and Universities (HBCUs) and community colleges. Last, community engagement and partnerships to promote inclusive research participation must deepen engagement beyond reviewing flyers and study materials and expand to informing and guiding funding priorities; identifying and shaping system and organization practices, policies, and culture toward equity; and serving as community colleagues, advisors, and leaders throughout the research process.

This paper is not meant to be exhaustive. There are many opportunities to advance equity in cancer research and outcomes. However, these recommendations highlight the importance of asking equity-leading questions that result in equity-driven solutions. As policy expands to set expectations and accountability, we emphasize opportunities and strategies that have the potential to make significant gains toward equitable access to cancer research in North Carolina and nationally. NCMJ.

Nadine J. Barrett, PhD Senior Associate Dean, Equity in Research and Community Engagement; Chief Community Engagement Officer, Atrium Health/Levine Cancer Institute Service Line, Maya Angelou Center for Health Equity; Professor of Public Health Sciences, Department of Social Science and Public Health Policy, Wake Forest School of Medicine;

Associate Director, Community Outreach and Engagement, Wake Forest Comprehensive Cancer Center; Winston-Salem, North Carolina.

Kenisha Bethea Project Planner II, Duke Clinical and Translational Science Institute, Duke School of Medicine, Durham, North Carolina.

Leigh Boehmer, PharmD Chief Medical Officer, Association of Community Cancer Centers, Rockville, Maryland.

Kimberly S. Johnson, MD, MHS Professor of Medicine, Division of Geriatrics, Center for the Study of Aging and Human Development, Duke University School of Medicine; Geriatrics Research Education and Clinical Center, Durham Veteran Affairs Health Care System, Durham, North Carolina.

Daniel Carrizosa, MD, MS Associate Professor of Hematology and Oncology, Wake Forest School of Medicine; Assistant Director of Community Outreach and Engagement; Medical Director for Disparities and Outreach, Levine Cancer Institute Campus, Wake Forest Baptist Comprehensive Cancer Center, Winston-Salem, North Carolina; Associate Program Director, Hematology/Oncology Fellowship at Levine Cancer Institute, Charlotte, North Carolina.

Acknowledgments

The authors would like to thank Mr. Bradley Long and the Durham County Men's Health Council, and Bishop Godbee and the River Church, for their insights and partnership to advance equity in access to care and clinical research.

Disclosure of interests. Nadine J. Barrett, PhD, is the inventor of Duke University's Just ASK™ Training Program. Leigh Boehmer, PharmD, provides consulting services for EMD Serono and Merck. No further interests were disclosed.

References

1. Bibbins-Domingo K, Helman A, eds. *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups*. National Academies Press (US); 2022.
2. American Association for Cancer Research Cancer Disparities Progress Report, 2022. Accessed November 1, 2023. <https://cancerprogressreport.aacr.org/disparities/>
3. *North Carolina Comprehensive Cancer Control Plan, 2020-2025*. CDC. Accessed November 14, 2023. <https://ftp.cdc.gov/pub/publications/cancer/ccc/north-carolina-ccc-plan-508.pdf>
4. Lillard JW Jr, Moses KA, Mahal BA, George DJ. Racial disparities in Black men with prostate cancer: a literature review. *Cancer*. 2022;128(21):3787-3795. <https://doi.org/10.1002/cncr.34433>
5. Unger JM, Cook E, Tai E, Bleyer A. The Role of Clinical Trial Participation in Cancer Research: Barriers, Evidence, and Strategies. In: *American Society of Clinical Oncology. American Society of Clinical Oncology educational book. Annual Meeting*. 2016;35:185-198. https://doi.org/10.1200/EDBK_156686
6. Unger JM, Hershman DL, Till C, et al. "When Offered to Participate": a systematic review and meta-analysis of patient agreement to participate in cancer clinical trials. *J Natl Cancer Inst*. 2021;113(3):244-257. doi: 10.1093/jnci/djaa155
7. Niranjan SJ, Martin MY, Fouad MN, et al. Bias and stereotyping among research and clinical professionals: perspectives on minority recruitment for oncology clinical trials. *Cancer*. 2020;126(9):1958-1968. doi: 10/1002/cncr.32755
8. Chaiyachati KH, Beidas RS, Lane-Fall MB, Rendle KA, Shelton RC, Kaufman EJ. Weaving equity into the fabric of medical research. *J Gen Intern Med*. 2022;37(8):2067-2069. doi: 10.1007/s11606-022-07450-3
9. Baptiste DL, Caviness-Ashe N, Josiah N, et al. Henrietta Lacks and America's dark history of research involving African Americans. *Nurs Open*. 2022;9(5):2236-2238. <https://doi.org/10.1002/nop2.1257>
10. Ford CL, Airhihenbuwa CO. The public health critical race methodology: praxis for antiracism research. *Soc Sci Med*. 2010;71(8):1390-1398. <https://doi.org/10.1016/j.socscimed.2010.07.030>
11. Rhodes RL, Barrett NJ, Ejem DB, et al. A review of race and ethnicity in hospice and palliative medicine research: representation matters. *J Pain Symptom Manage*. 2022;64(5):e289-e299. doi: 10.1016/j.jpainsymman.2022.07.009
12. Saad F, Efstathiou E, Attard G, et al. Apalutamide plus abiraterone acetate and prednisone versus placebo plus abiraterone and prednisone in metastatic, castration-resistant prostate cancer (ACIS): a

- randomised, placebo-controlled, double-blind, multinational, phase 3 study. *Lancet Oncol.* 2021;22(11):1541-1559. doi: 10.1016/S1470-2045(21)00402-2
13. Ramalingam S, Humeniuk MS, Hu R, et al. Prostate-specific antigen response in black and white patients treated with abiraterone acetate for metastatic castrate-resistant prostate cancer. *Urologic Oncol.* 2017;35(6):418-424. doi: 10.1016/j.urolonc.2016.12.016
 14. George DJ, Halabi S, Heath EI, et al. A prospective trial of abiraterone acetate plus prednisone in Black and White men with metastatic castrate-resistant prostate cancer. *Cancer.* 2021;127(16):2954-2965. doi: 10.1002/cncr.33589
 15. George DJ, Halabi S, Fleming MT. A prospective trial of apalutamide and abiraterone acetate plus prednisone in Black and White men with metastatic castrate-resistant prostate cancer. *J Clin Oncol.* 2023;41(Suppl 16):5015-5015. doi: 10.1200/JCO.2023.41.16
 16. Bitting RL, Goodman M, George DJ. Racial disparity in response to prostate cancer systemic therapies. *Curr Oncol Rep.* 2020;22(9):96. doi: 10.1007/s11912-020-00966-z
 17. Bentley-Edwards KL, Jordan Fleming P, Doherty IA, Whicker DR, Mervin-Blake S, Barrett NJ. The 5Ws of racial equity in research: a framework for applying a racial equity lens throughout the research process. *Health Equity.* 2022;6(1):917-921. <https://doi.org/10.1089/heap.2022.0042>
 18. Niranjana S, Wenzel JA, Martin MY, et al. Perceived institutional barriers among clinical and research professionals: minority participation in oncology clinical trials. *JCO Oncol Pract.* 2021;17(5):e666-e675. doi: 10.1200/OP.20.00970
 19. Raghavan D, Wheeler MS, Doege DL, et al. Initial results from mobile low-dose computerized tomographic lung cancer screening unit: improved outcomes for underserved populations. *Oncologist.* 2020;25(5):e777-e781. doi: 10.1634/theoncologist.2019-0802
 20. Rodriguez EM, Saad-Harfouche FG, Miller A, et al. Engaging diverse populations in biospecimen donation: results from the Hoy y Mañana study. *J Community Genetics.* 2016;7(4):271-277. <https://doi.org/10.1007/s12687-016-0275-3>
 21. Loewenson R, Colvin CJ, Szabzon F, et al. Beyond command and control: A rapid review of meaningful community-engaged responses to COVID-19. *Glob Public Health.* 2021;16(8-9):1439-1453. doi: 10.1080/17441692.2021.1900316
 22. Barrett NJ, Ingraham KL, Vann Hawkins T, Moorman PG. Engaging African Americans in research: the recruiter's perspective. *Ethnicity & Disease.* 2017;27(4):453-462. <https://doi.org/10.18865/ed.27.4.453>
 23. Hagiwara N, Berry-Bobovski L, Francis C, Ramsey L, Chapman RA, Albrecht TL. Unexpected findings in the exploration of African American underrepresentation in biospecimen collection and biobanks. *J Cancer Education.* 2014;29(3):580-587. <https://doi.org/10.1007/s13187-013-0586-6>
 24. Barrett NJ, Boehmer L, Schrag J, et al. An assessment of the feasibility and utility of an ACCC-ASCO implicit bias training program to enhance racial and ethnic diversity in cancer clinical trials. *JCO Oncol Pract.* 2023;19(4):e570-e580. <https://doi.org/10.1200/OP.22.00378>
 25. Eliminating Racial Health Inequities: An IRB's Antiracist Intervention. The Hastings Center. Published July 11, 2023. Accessed October 5, 2023. <https://www.thehastingscenter.org/news/eliminating-racial-health-inequities-an-irbs-antiracist-intervention/>
 26. Crankshaw S, Butt J, Gierisch JM, et al. The Durham Initiative for Stomach Health (DISH): a pilot community-based Helicobacter pylori education and screening study. *BMC Gastroenterol.* 2020;20:261. <https://doi.org/10.1186/s12876-020-01405-w>
 27. Hamm RF, McCabe MG, James A, Parry S, Levine LD. A simple intervention to improve equity in obstetric research. *Health Equity.* 2023;7(1):692-698. <https://doi.org/10.1089/heap.2023.0073>