ACCC Research Review
HELPING COMMUNITY ONCOLOGY TO CLOSE THE GAP IN CANCER RESEARCH
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A Message from the President's Task Force

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This issue of the ACCC Research Review provides support, perspectives, and resources for follow through on the imperative to make clinical trials more inclusive, diverse, accessible, and representative of our patient populations in communities across the country.

While this task can seem overwhelming, let us consider the fact that as oncology professionals, change drives the work we do. Improving rates of screening and early diagnosis, advancing treatments, eliminating health disparities, and reducing the burden of cancer on society—these overarching goals all demand intentional actions and sustained commitment to achieve change.

We know that without systemic change to enable more inclusive, diverse, and equitable participation in cancer clinical trials:

1. Studies may not accrue and retain the diversity of patients needed to fully answer research questions with scientific validity and rigor.
2. Patient access to clinical trials will be constrained by a number of a factors such as where they live, the language they speak, and their race and ethnicity.
3. Under-representation of minority participants in trials will limit the generalizability of study results to the broader patient population.
4. A large segment of our population will not get access to cutting-edge treatment that can benefit the larger community and has the potential to extend or enhance quality of life.

It may seem counterintuitive at a time when our healthcare system is in the midst of urgent, unanticipated change in response to the COVID-19 pandemic—however, the reality is that this pandemic has brought to national attention the systemic racism and bias inherent in our healthcare system that contributes significantly to health disparities. Now is the time for us to focus on this issue with commitment and urgency. It is the time to be resolved on effecting change in cancer research and trials so that study designs engage diverse participants that reflect our society, including racial and ethnic minorities, marginalized populations, people in rural underserved communities, and the elderly. It is our responsibility and the moral and ethical thing to do.

Included in this newsletter are practical resources and tools: the opportunities are here. What is needed is unwavering intention and relentless attention to actionable steps and measurable progress.

A Focus on the Importance of Collaboration Between Community Groups & Academic Institutions

Each month, we ask an ACCC member to share their expertise in a specific area of research concentration. In this issue, we asked ***Sanford E. Jeames, DHA,*** *Adjunct Faculty member at Huston Tillotson University in Austin, Texas, and Chair-Elect of the ASCO Health Equity Committee to highlight the importance of community engagement in cancer research. Dr. Jeames is also a member of American Association for Cancer Research (AACR) and the Society of Urologic Nurses and Associates (SUNA). His research interests are in community-based research, cancer prevention, survivorship, and health disparities.*

Studies have linked an increasing number of cancers—as well as other leading chronic conditions such as cardiovascular disease and diabetes—with modifiable risk factors related to smoking, lack of physical activity, poor nutrition, and excess weight. A 2017 study from the American Cancer Society reported that 42% of newly diagnosed cancers are associated with lifestyle-related risk factors including smoking, excess body weight, physical inactivity, and diet.[1] Making accessible health information, screenings, and resources available and actionable across all communities in the U.S. is a foundational step toward realizing health equity and eliminating the health disparities. Community-Based Participatory Research (CBPR) has a critical role to play in affecting these conditions.

CBPR is a collaborative approach to research between academic researchers and communities that builds on the strengths and assets of the partners and engenders trust between them.[2] In working with vulnerable populations to reduce racial and ethnic disparities in health, research has shown that CBPR is the preferred model.[2] CBPR begins with a research topic of importance to the community with the aim of combining knowledge and action for social change to improve community health and eliminate health disparities.[3] CBPR comes with challenges; some of which are related to ensuring that the academically-based community collaboration is truly a partnership, that the goals and objectives are the same on both the community and academic levels, and that there is an open and honest two-way communication that takes place throughout the research.[4] Lastly, the most important aspect of CBPR is communication; effective communication through community-based initiatives helps both the community and the academic partner with outreach and data collection.

The Men of Color Health Awareness (MOCHA) program is one example of CBPR strategy that contributes to lifestyle change for health improvement. Formed in 2010, MOCHA is led by men from the community who serve as community health advocates and messengers in Springfield, Massachusetts. MOCHA has utilized and benefited from significant contributions from its target population. This collaboration has strengthened MOCHA's presence in the general community and throughout the Commonwealth of Massachusetts.

An active fitness initiative with a community-based focus, MOCHA programs' results have shown potential to positively impact the overall physical and mental health level of their participants. MOCHA's overarching goal is to help reduce health disparities among men of color. The program consists of effective and meaningful partnerships among community members and the University of Massachusetts Amherst. The academic partner continues to collaborate with MOCHA on effective ways to show outcomes of their active fitness component. These collaborative partnerships enable structured assessment across the program's operations and in return MOCHA provides data and results.

Although academic institutions, hospitals, and community agencies have employed a variety of methods to address disparities, gaps still exist among the various populations.[4] The reasons for these gaps are layered and multi-factorial and cannot be attributed to a single cause. However, a contributing factor could be the existing modes of engagement used by many academic institutions when undertaking research in the community. Most often, contributions from the community on the research design are non-existent, and this omission frequently leads to lack of trust between communities and researchers.

Hundreds of individuals have participated in the MOCHA program to date, and participant results are indicative of weight loss, reductions in body fat, increase in strength training and endurance, and decreased levels of stress. MOCHA represents an active fitness initiative that provides a community-based focus and its results have shown potential to positively impact the overall physical and mental health level of its participants.

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Featured Clinical Research: Barriers to Clinical Trials Participation

There is no debate: clinical trials are essential to advancement of treatments for cancer and improving patient outcomes. Despite the fact that cancer treatment trials are standard of care and offer patients access to leading-edge therapies, that a clinical trial may be a patient's only treatment option but also their best option—enrollment in clinical trials is persistently low. Among the consequences of insufficient or slow accrual are trials forced to close due to insufficient enrollment and studies that take so long to complete that their results become less timely.

Numerous studies have explored obstacles to clinical trial participation, often with a focus on patient- and/or physician-related barriers. A recent study by Joseph M. Unger and colleagues looks at barriers from a different vantage point.[1] By conducting a systematic review and meta-analysis, researchers examined the "magnitude" of three different, overarching domains of barriers to trial participation [i.e., structural (trial availability), clinical (eligibility), and patient/physician domains]. The study asks how these domains stack up in terms of impeding clinical trial participation. The review and analysis encompassed 13 previous studies (9 in academic and 4 in community settings) totaling 8,883 patients using a standard framework to characterize and quantify the three domains along the trial decision-making pathway. The accrual period across the 13 studies covered 1997-2012.

Study results revealed that overall structural and clinical barriers accounted for more than three out of four patients (77.1%) not enrolling in clinical trials. More than half the time (55.6%) a trial was not available for patients at their institution. Another 21.5% of patients did not meet inclusion criteria for an available trial. Although trial enrollment rates in academic settings differed from those in community settings (15.9% compared to 7.0%, respectively), rates of trial unavailability, ineligibility, or non-enrollment did not. The authors conclude that "these findings emphasize the enormous need to address structural and clinical barriers to trial participation . . . One focus should be to improve access to available trials." Some progress is being made, the authors note. In particular, the study calls attention to the NCI-sponsored network of cancer research groups that makes their trials available to all through a centralized participation pathway, the Cancer Trials Support Unit (CTSU), and has specifically reached out to community oncologists and their patients. They also point to collaborative efforts of oncology stakeholders, including the American Society of Clinical Oncology, Friends of Cancer Research, and the U.S. Food and Drug Administration, to update and make less restrictive clinical trial eligibility criteria.

The authors acknowledge patient- and physician-related barriers to engagement in clinical trials; however, in discussing the study findings, they point out that ". . . the influence of patient-related factors and patient choice—which occurs only at the end of an extensive decision-making process—comprised only a small portion of barriers to trial participation overall." The only way to achieve a substantial increase in cancer clinical trial participation is to address structural and clinical barriers, the authors conclude. Read the full study, *Systematic Review and Meta-Analysis of the Magnitude of Structural, Clinical, and Physician and Patient Barriers to Cancer Clinical Trial Participation*.

Reference

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AACR Panel on Racism and Racial Inequalities in Cancer Research: Let It Not Be in Vain

At the American Association for Cancer Research (AACR) Virtual Annual Meeting in June a special session hosted by AACR President Antoni Ribas, MD, PhD, FAACR, brought together a distinguished panel of leaders from academia, government, industry, and the patient advocacy community for a frank conversation on racism and racial inequities in cancer research. Persistent disparities exist across the cancer research enterprise. From the health professional standpoint, there continue to be disparities in the numbers of faculty, clinicians, researchers, and allied professionals from racial and ethnic minority populations. Representation at the C-Suite level is rare. From the patient and caregiver perspective, disparities in access to cancer clinical trials, accrual to clinical trials, and in health outcomes are pervasive.

The panel discussion took place in the midst of unfolding national trauma—the murder of George Floyd in late May and emerging epidemiologic data revealing the disproportionate impact of the SARS-CoV-2 virus on Black, Latinx, and Native American people. These same populations continue to experience disparities in access to care, health outcomes, and an unequal burden of cancer.

Panelists talked openly about psychological, emotional, and physical pain resulting from the murder of George Floyd, the recent deaths of Breonna Taylor, Ahmaud Arbery, and other tragedies. Throughout the conversation, panelists expressed personal and professional commitment to ensuring these events will not have happened in vain.

The intersection of lethal racism and a highly contagious life-threatening viral pandemic has made the inequities in U.S. society and in the U.S. health system transparent. During the AACR session, panelists shared their views on action needed at every level—individual, in academia, institutional/systemic, and in society—to vanquish racism and achieve equity.

The following summarizes key points from the discussion.

What Individuals Can Do

Acknowledge racism. Individuals often do not recognize racist behaviors in themselves. As with a chronic disease, such as alcoholism, acknowledgment that a problem exists is a first step to change. "We have to get to a point where people can begin to feel comfortable recognizing racism," said John D. Carpten, PhD, Professor and Chair of Translational Genomics; Director, Institute of Translational Genomics, USC Keck School of Medicine. "Racism is a hard word. We tend to want to use [the words] diversity and inclusion, because it sounds better and people are more comfortable with that. But we've really got to become uncomfortable if we're going to move the needle and see racism dispelled in America."

Speak up. Change will require more than being an ally to minority colleagues. Russell J. Ledet, PhD, emphasized the need for individuals who are not part of a marginalized group to speak up about racism. "We need disruptors," he said. "We need people who will shake up conversations that they know are racist instead of being complicit at the dinner table. And it starts at the dinner table because a lot of our psychological thinking, the way we frame the world is built at a dinner table . . . in every realm, the people who are being marginalized can't be the people to solve the problem. It's the people doing the marginalizing that have to solve the problem." Dr. Ledet is president and co-founder of The 15 White Coats and a third-year medical student in the MD/MBA program at Tulane University School of Medicine.

Call out racial bias. Distinct from overt racism, racial bias reflects an implicit attitude or mindset. For example, a mindset that implies people of color, racial and ethnic minorities, are not quite up to par, or that their achievements are not quite as legitimate as those of others. Whether minority individuals succeed or fail, this attitude paints the work of the marginalized individual or group as inferior. "I think calling out that mindset and recognizing how prevalent it is, is a big part of countering it," said Levi A. Garraway, MD, PhD, Chief Medical Officer and Executive Vice President, Head of Global Product Development, Roche/Genentech.

Look in the mirror. Greater awareness and knowledge of existing disparities and inequities can spur individuals to assume personal responsibility for change. Hannah Valantine, MD, MRCP, Chief Officer for Scientific Workforce Diversity and Senior Investigator, National Institutes of Health (NIH), was moved by an editorial by *Science* Editor-in-Chief, Holden Thorp, PhD, "Time to Look in the Mirror," that urges researchers, clinicians, and scientists across disciplines to reflect on disparities and inequities within their specialties. "What this [editorial] means to me is this: racism exists everywhere, including science . . . In looking in the mirror I began to reflect on the programs we have and to the extent we could be even more successful," she said, emphasizing that NIH is committed to increasing the number of Black scientists in the pipeline and at the faculty level.

Be anti-racist. "It is no longer okay just to say you are not racist: be anti-racist," said Robert A. Winn, MD, Director, Virginia Commonwealth University Massey Cancer Center; Professor, Division of Pulmonary Disease and Critical Care Medicine.

What Industry Can Do

Engage the community. Kenneth C. Frazier, JD, Chairman of the Board and CEO, Merck & Co., Inc., described Merck's commitment to research around the world in countries with "diverse populations including people of varying age, race, ethnicity, gender and other characteristics." Merck applies multiple approaches to understand what matters to patients, including patient advisory panels, consultations with experts, and more. "Community engagement has been especially helpful to increase awareness and education," he said. "It's really critical to build trust and help people regarding the importance and benefits of clinical trials. When people don't see people *like them* conducting these clinical trials, they are not so sure whether we are doing something *for* them or doing something *to* them." [emphasis added]

Begin equity training at the C-suite. Genentech and Roche have ongoing efforts to address racial bias, with a "large effort in inclusive research," said Dr. Garraway. Equity training begins with the C-Suite at his organization, he said. Calling out and countering implicit bias when members of marginalized groups are not in the room is critical to creating a culture that does not allow racism to flourish. "This is something where everyone has to own the issue. You can't just have a diversity office and expect these issues to go away," he said.

Set measurable goals and report back. Lola A. Fashoyin-Aje, MD, MPH, Acting Deputy Director, Division of Oncology 3, Office of Oncologic Diseases, FDA, challenged her fellow panelists with leadership roles in industry to commit to developing and implementing an action plan to achieve more diverse racial and ethnic representation in clinical trials over the next 1 to 5 years. "I emphasize the action part of this because I think we need to see results. I think we've studied the issue extensively, and I think we just need to take bold action in order to really put some weight behind commitment to providing equitable access to clinical trials and generating data on racial and ethnic minorities. I think this is really what's going to improve health outcomes for our patients, and our patients deserve this." Both Mr. Frazier and Dr. Garraway accepted the challenge on behalf of their organizations.

What Academia Can Do

Recruit talent. Pointing to existing programs that are succeeding in bringing Black, Latinx, and other minority students into the sciences, medicine, and the cancer research pipeline, Dr. Winn argued that we know what needs to be done. What is needed is consistent, focused, relentless prioritizing of what has already been shown to work. Simply put, the institutional "will" to do what needs to be done.

Knowledge of how to reduce the gap in minority healthcare professionals has been demonstrated by programs such as those conducted by Dr. Sanya Springfield and Dr. Valantine, Dr. Winn noted. "They already have programs, and programs been validated. Some of them 20 years ago. It's not the issue that we don't know. It's the issue of the will."

Teach the history of medical experimentation. Medical students, residents, and faculty should be educated on the history of Black people and medical experimentation in the U.S. and around the world, urged Dr. Ledet. An understanding of these past abuses is integral to recognizing that these are a source of much of the distrust of medicine, doctors, research, and the healthcare system for Black individuals.

Close the funding gap for minority researchers and ESIs. Panelists pointed to the need to address disparities in research funding for minority investigators. A chilling effect due to implicit bias often occurs at the study section level, noted Dr. Carpten. "That needs to continue to be explored and those processes and approaches need to be modified and changed . . . so we can see more diversity on study sections, minority scientists can feel more confident that studies are judged on the contents of the science and not the race of the investigators."

What Healthcare Institutions Can Do

Provide support for staff. Judith S. Kaur, MD, Professor of Oncology; Medical Director, Native American Programs, Mayo Clinic Cancer Center, shared a process underway at her institution in response to recent events. They've been holding "everybody in" conversations that bring staff together to "try to address these unspoken fears, racism, concerns, attitudes within ourselves." Racism in healthcare can surface in all settings. "One of my hematology fellows came to me recently and was disturbed by a patient who was very offensive to one of our female Muslim fellows," said Dr. Kaur. "So, we involved the leadership. We involved the attending physicians. We stand firmly on what we tell our patients that that is not allowed. If they abuse a team member, then the team can choose not to continue care for a patient who violates those basic values that we all hold necessary."

Fill the pipeline. While education remains key, several panelists pointed to disparities at the faculty level as a disincentive for those entering the field. "We recognize it's a vicious circle. If we are not successful in increasing the faculty-level diversity, in particular Black scientists, we will not make a difference: first, in the demographics; secondly in inclusion; and [third] in health disparities," commented Dr. Valantine.

What Society Can Do

Immediate action: support hospitals and essential workers. Panelist Marcia R. Cruz-Correa, MD, PhD, AGAF, FASGE, raised immediate and mid-term action steps in response to the COVID-19 pandemic.

1. Support hospitals caring for minority populations. Ensure resources are provided for those hospitals caring for marginalized populations that are suffering a disproportionate burden of the SARS-CoV-2 pandemic.
2. Provide Medicaid coverage for essential workers. Immediate action is needed so that essential workers (the majority of whom are African American and Latino) and those who have been laid off or have lost jobs can access care.
3. Double down on cancer screening and prevention for underserved populations. Once the pandemic starts to ease, don't forget cancer prevention and early detection. "Minorities are by far the groups that present with cancer at advanced stage. And it's usually a direct response to not having the right test at the right time. We cannot forget once this is moving forward, we need to go back to cancer screening, cancer prevention."

Dr. Cruz-Correa is Director, GI Oncology Division, Oncologic Hospital; Professor of Medicine, Biochemistry & Surgery; Affiliated Investigator, Cancer Biology, University of Puerto Rico Comprehensive Cancer Center.

Promote economic inclusion. Lack of economic inclusion is a primary driver of health disparities, Mr. Frazier noted. "I think it's important that we recognize that health disparities and access to cancer research and the promise of that research won't really have an impact until we improve the economic inclusion among people of color which is the most important root cause of many of the disparities in our society," he said. "We're all contending with the COVID-19 pandemic, and I think what that has revealed is the stark inequities in our society that have led to a disproportionate impact on people of color." Many of the structural elements of racism are not just occurring in the medical field, he noted. "Economic inclusion is a critical issue for African Americans all throughout the country. As leaders, scientists, researchers, academics, as business people—we need to prioritize economic inclusion."

Panelists agreed that some progress has been made in addressing racism and racial inequities in cancer research, but that much remains to be done. AACR is committed to realizing social justice and equality for all Black and other racial and ethnic minorities, both nationally and globally.

Closing out the panel discussion, Dr. Winn said, "Let's not let these recent events go in vain. Let's reclaim our best selves. In that best self, we will do better, we will impact real lives. I think we are being called now to become and reclaim who we know we should be and that is our best selves."

Access the AACR June 23 panel discussion on Racism and Racial Inequities in Cancer Research on the AACR Virtual Meeting II website at https://www.aacr.org/meeting/aacr-annual-meeting-2020.

Guidance for Achieving Diversity, Inclusion, and Equity in Clinical Research

In August, the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) released guidance for "Achieving Diversity, Inclusion, and Equity in Clinical Research" along with a companion Toolkit consisting of practical resources to facilitate change.[1] The guidance outlines a principled, multi-stakeholder approach to optimize the inclusion of diverse populations in clinical research.

The impetus for development of these new resources was a Bioethics Collaborative convened in 2017 to discuss the lack of diverse participation in clinical research and explore the data, barriers to inclusion, and failure to recruit and retain under-represented and underserved populations in research. The collaborative discussion led to the creation of the MRCT Center "Diversity Workgroup" to advance the goals of diversity in clinical research.

Approximately 50 individuals—from industry, academia, patients and patient advocates, regulatory authorities, clinical research organizations, and other entities—participated in the workgroup, which met regularly to:

- Explore why diverse representation has not increased despite evidence of the need
- Identify the barriers that limit diverse participation and why
- Develop and disseminate resources such as guidance materials, tactical strategies, and tools to advance required changes to conceptual, organizational, and operational challenges.

In an executive summary to the guidance, the imperative for increased diversity in clinical research is made plain:

> In addition to the biological importance of heterogeneity of treatment effect, there are reasons of health equity and social impact to support and promote appropriate inclusion of diverse populations in clinical research. As an important ethical principle,

> justice and fairness in distribution of the opportunities and potential benefits of participation in research drive an affirmative commitment to diverse inclusion. Further, there are considerations of health equity, in which all persons should have access to equal opportunity for participation, given the utility and potential benefit of the knowledge gained for the population as well as the possibility of direct benefit to the individual. Finally, it is a matter of public trust.[2]

The guidance framework is organized into Parts and Chapters; each Chapter focuses on different areas in clinical research where interventions might be effective. In addition to addressing barriers to inclusion of diverse populations in clinical research, in Parts C through F, the guidance outlines potential approaches and solutions to increase diversity.

Among specific areas of interest:

- Value of partnerships with community, public, and patient participants (Chapter 8) and the importance of these partnerships from the pre-planning stage to execution of the trial.
- Workforce development, including efforts to diversify the workforce as well as training in implicit bias and cultural competence of the current workforce (Chapter 10).
- Approach to data analysis (Chapter 12) including the limitations of traditional approaches, potential innovative methods to consider, and the role of real-world data.
- Accountability for promoting diversity in clinical research (Chapter 17), divided by each stakeholder as well as cooperative and interrelated responsibilities.

The authors are forthright in stating "an initial investment to address diverse inclusion is necessary," but anticipate that this will decrease over time as diversity becomes "normalized." Further, although different stakeholders may bear different costs in this investment, the authors make clear that "all stakeholders, individually and collectively, have responsibility for change."[2] Required actions for achieving diverse enrollment: planning, support, and accountability.

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At-a-Glance Tools from ASCO's Research Community Forum

Among the many effects of the COVID-19 pandemic has been disruption of cancer clinical research. In response the American Society of Clinical Oncology (ASCO) Research Community Forum is providing tools to help support prioritization of cancer clinical trials as hospitals and health systems move forward. Released in May 2020, *Making the Case for Oncology Clinical Research* outlines a four-step approach for driving home the benefits and potential impact of research for patients, the oncology program, and the broader community: engagement, awareness and impact, collaborations, and creating a culture of research. Download here.

Released in August 2020, *Basic Steps to Building a Research Program* is a concise look at key considerations, tips, and best practices for addressing the challenges to getting a research program off the ground. Download here.

View more tools in the ASCO RCF clinical trials resources.

The **ACCC Research Review** newsletter is developed as part of the 2020-21 ACCC President's Theme. Its goal is to help bring research opportunities into community practices/programs to ensure that all Americans may benefit equally from cancer research. For additional resources and to learn how your cancer center can become involved, please visit accc-cancer.org/president-20-21.