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

By Randall A. Oyer, MD

Clinical trials need to be more inclusive of Black and African American, Latinx, and older adult patients, as well as other historically under-represented groups. Equitable representation in and access to cancer clinical trials is essential to truly closing the gap in cancer research.

ACCC has its finger on the pulse of our U.S. oncology community. Top of mind for all of us now are COVID-19, health equity, and expanding the clinical research that continues to improve oncology care for our patients. Based upon the needs and interest of our members, ACCC has selected this year' president's theme: *Community Oncology Can Close the Gap in Cancer Research: Here's How.*

Your ACCC Board of Directors quickly appointed the President's Taskforce to help inform, guide, and plan our approach to improving cancer care for all people. Taskforce participants are the following ACCC members Nadine J. Barrett, PhD, MA, MS, Director, Office of Health Equity and Disparities, *Duke Cancer Institute*; Al B. Benson III, MD, FACP, FASCO; Associate Director for Cooperative Groups, *Robert H. Lurie Comprehensive Cancer Center of Northwestern University*; Jennie R. Crews, MD, MMM, FACP, Medical Director, *SCCA Network & Community Sites, Seattle Cancer Care Alliance*; Una Hopkins, RN, FNP-BC, DNP, Director of Research, *Montefiore Medical Center*; Ali McBride, PharmD, MS, BCOP, Clinical Coordinator, Hematology/Oncology, *The University of Arizona Cancer Center, Department of Pharmacy*; Larry Wagman, MD, Regional Medical Director, Inland Empire, *City of Hope National Medical Center*; and Laura Zitella, MS, RN, ACNP-BC, AOCN, *University of California, San Francisco*.

Your ACCC volunteer group of clinical trials, health equity, and population health experts note that Black and African American, Latinx, and other minority and underserved populations are disproportionately affected by COVID-19. Additionally, our individual and collective work exposes systemic and structural inequities in our healthcare system and our society. In terms of public health, a stark example of this is the lack of consistent race and ethnicity data collection during the initial months of the public health emergency.

As healthcare providers, professionals, and caregivers, you understand that strong and reliable data must inform the evidence-based guidelines that guides the care we deliver in our practices, our programs, and our institutions. Much of the data needed rests in our patients, notably the care they receive and the outcomes of their care. It is our shared responsibility to provide our patients the opportunity to have their data included in research trials so that individuals and populations can benefit from improved knowledge and improved care.

Black and African Americans, Latinx, and other ethnic and racial minorities continue to be underrepresented in clinical trials despite many years of study and effort to improve this serious inequality. To close the gap in cancer research, communities must focus on real inclusion opportunities and results for Black and African Americans, Latinx, geriatric patients, sexual minorities, and others in the world we live in.

ACCC's focus on health equity, one example of which is improving inclusion of under-represented people in clinical trials, has dynamically commenced and will surely take more than one president's term in office. We want you to know how we are laying the foundation for sustained work, and we will keep you closely updated so that you are aware of your opportunities to participate and to learn new approaches with us.

Please communicate with us! ACCC will produce a monthly research newsletter—you are reading the inaugural issue now. Please consider helping! ACCC will highlight a series of clinical trials vetted by the President's Taskforce, including reasons why you should strongly consider opening these trials to your patients.

Please connect with us! ACCC will develop a series of webcasts on research-related topics of interest to our members. Learn more about the inaugural webcast below.

Let us remember that successful reform efforts begin with collaboration. ACCC is building this collaborative with partnering organizations like the American Society of Clinical Oncology (ASCO). And the value of ACCC is its collaborative and interactive membership. Be part of our work. Be the change you want to see. Make clinical cancer advances available to all. Your patients and your communities will thank you. And I thank you for your consideration.

Featured Clinical Research Trial: The ASCO Survey on COVID-19 in Oncology (ASCO) Registry

To date, more than 100 programs are participating in a registry study to collect information that closes the COVID-19 and cancer data gap. Help us analyze disease burden, understand outcomes and treatment efficacy, and share how your operations are affected by the pandemic.

ACCC strongly supports and recommends ASCO's important registry trial designed to close the COVID-19 and cancer data gap. We strongly urge ACCC members to help ASCO, ACCC, and the greater oncology community gather, capture, and analyze critical data that:

- Analyzes distribution of symptoms and severity of COVID-19 among people with cancer.
- Examines the impact of COVID-19 on cancer treatment and outcomes.
- Documents how cancer care delivery has been affected by the pandemic. For example, what steps and processes did cancer programs take to protect patients and staff?

The registry is collecting both patient and practice data. Patient data includes the number of patients with a confirmed COVID-19 diagnosis AND 1) initiating treatment for new cancer diagnosis, OR 2) with clinically evident cancer receiving anti-cancer treatment, OR 3) with clinically evident cancer receiving supportive care only, OR 4) disease-free but receiving adjuvant therapy within 1 year after surgical resection.

Practice data includes:

- Number of confirmed COVID-19 cases
- Use of telemedicine
- Modifications of infusions and other treatments
- Screening and triaging processes
- Physical changes to clinic workflows
- Drug and PPE shortages
- Staffing changes.

Participation is easy. First, execute a research participation and data use agreement with ASCO. Second, submit your data to ASCO via web-based REDCap forms (ASCO will de-identify and provide data back for your own use) OR collect data locally using a “cloned” REDCap project and upload data to ASCO monthly.

Special note: the ASCO Registry qualifies as a HighWeighted Practice Improvement Activity under the Merit-based Incentive Payment System (MIPS). Interested programs and practices can find agreement and data capture forms online at asco.org/asco-coronavirus-information/coronavirus-registry.

Deliverables from the ASCO Registry include:

- Periodic reports on estimates of disease severity, treatment modifications, and clinical outcomes of patients
- Data summaries to participating programs
- Publicly available reports to inform patients and clinicians
- Scientific manuscripts for peer-reviewed publication
- Registry data in ASCO Data Library that will be available to qualified researchers

As of the time of this newsletter:

- More than 100 programs were currently in the approval process
- 33 practices in 21 states were fully enrolled
- Data has been collected on more than 100 patients
- 80% of those enrolled and/or currently enrolling are ACCC member programs

Initial results:

- 20 sites from 17 programs across 15 states are reporting data
- 90% have reported new use of telemedicine (85% conducted some or all routine visits for patients not in active therapy by telemedicine; 15% delayed some routine visits)
- 60% allow lab collection closer to the patients’ home
- 40% experienced staffing reductions and/or changes due to reassignment, COVID-19, and reduced scheduling of patient visits.

“All Power to the Patient: Achieving Cancer Health Equity”

The FDA's Oncology Center of Excellence hosted a webcast on how the oncology community can improve cancer care for minority and underserved patients. Read five key takeaways for eliminating the systemic inequities that these patient populations face.

In February, as part of Black History Month, the Food and Drug Administration's (FDA) Oncology Center of Excellence (OCE) hosted a webcast titled "All Power to the Patient: Achieving Cancer Health Equity." Four months later, the death of George Floyd and nationwide protests brought America's institutional, structural, and systemic racism to the front of the public consciousness. As these issues plague our country and lead to inequities that impede access to equitable and quality care for underserved communities, this informal conversation between a group of six Black and African Americans offers the oncology community gems of wisdom that bear repeating.

First, **healthy equity remains a priority for many in the oncology community**.

Radiation oncologist and ASCO President-Elect, Lori Pierce, MD, said that ASCO has long had an interest in improving the cancer care of minority patients, and that "Health Equity" would be the theme of her Presidency.

Healthy equity is also a priority of the American Cancer Society Cancer Action Network (ACS-CAN). "We are on a mission to improve the social determinants of health that are critical to reducing the burden of cancer," said Felicia L. Woods, Esq. "Cancer affects everyone, but it does not affect everyone equally."

The FDA has done much work in the field of health equity, although, when polled, many in the audience were unaware of the agency's efforts. "Our vision is to create a future where health equity is a reality for all," said Jovonni Spinner, MPH, senior public health advisor in the FDA Office of Minority Health and Equity. "We are creating programs, resources, and materials that resonate with our diverse communities." Spinner stressed the importance of tailoring education linguistically and culturally so that people see themselves reflected in these materials to help patients make informed health decisions for themselves and their loved ones.

Second, **navigation is one solution to improving health equity.**

Navigation can help level the playing field for underserved patients who often come into a cancer diagnosis with a deficit of information, said Lisa Simms Booth, Executive Director, Smith Center for Healing and the Arts. Sharing information about the robust navigation services offered at her program, Simms Booth continued, "Navigation is really what health equity is about. Meeting people where they are, but also making sure that we treat the whole person and meet all of their physical, social, mental, and spiritual needs."

Third, **community engagement is key**.

"We need to have a thoughtful approach to health equity," Simms Booth recommended. "There have been too many times when organizations 'swoop' into a community and say we are going to do this, or we are going to do that, and then leave. We need to be thoughtful about who is engaging and [recognize] the importance of a sustainable relationship."

"Communication needs to be authentic and genuine," Woods urged. We must seek out principal investigators who look like the patients we are trying to accrue to our clinical trials. Our goal, she said, should be to "keep clinical trials within the community and run by providers from that community."

When going into an underserved community, Thelma D. Jones, Founder of the Thelma. D. Jones Breast Cancer Fund and an 11-year breast cancer survivor, advised to first ask what assets these assets are already there, and how can be utilized. “Work with the people who live there. The faith-based institutions who serve there. Engage and involve the people in the community. [Seek out the] ones who are willing to help you move the needle forward and remove barriers to equitable care.”

Jones went on to say that provider and other healthcare organizations going into communities to offer education and information around clinical trials need a paradigm shift in their approach. “These people do not know you or why you are there. They want to know why you want this information, and what you are going to do with it,” Jones said. Her most important piece of advice: listen. “If you want to help people, you first have to know how they feel. Between your knowledge [of cancer and cancer treatment] and what they are saying is where some type of communication can occur.”

Finally, Jones warned that even after all this effort “the community may still resist you. And you cannot blame them. Just go back to the drawing board and keep trying.”

Fourth, **to improve health equity, we must first listen to the people we are trying to help**.

Having patient advocates share their cancer experiences in their own communities is critical, said Woods. People who have gone through a clinical trial and are willing to talk at churches or community centers can be powerful ambassadors. “These messengers are key to getting conversations about clinical trials started in the community,” advised Woods.

These first-person stories from those who live in the community and who have participated in a clinical trial can help others “become more empowered about having conversations with their physicians,” Spinner agreed.

Patients feel more comfortable proactively initiating discussions about clinical trials instead of waiting for their physician to bring it up. Jones spoke powerfully about the importance of cancer survivors being their own advocates. “We cannot just leave it to our doctors and others to know what is best for us. We must be willing to speak up.” But she admitted that is often a challenge for people of color. Born and raised in the south, Jones said, “My parents taught me not to challenge adults. And certainly not to challenge a white man in a uniform or a white coat.”

Jones went through the Navigation Program at the Smith Center for Healing and the Arts and said that patient navigators can help break down the fear, intimidation, and lack of trust in the healthcare system that still exists for many minority patients.

Patient advocate and prostate cancer survivor Robert Carey suggested that support groups are one avenue to meet and hear from the people you are trying to educate about clinical trials and that “support group members can be excellent community ambassadors.”

Dr. Pierce agreed that this kind of bi-directional education is key to improving health equity. She went on to say that providers and others need to ask our underserved patients “What help do you think you need and what can we learn from you?” She concluded by urging that “we not go into communities with the message that we are here to rescue you. There may be some healthcare needs in this community, but there are also lessons we [providers] can learn.”

Finally, as current events have reminded us, **health equity is not going to be solved by one organization and it is not going to be solved overnight.**

“When you are working with an issue like health equity, you are not going to be able to snap your finger and have a result,” warned Smith. The panel agreed that to improve health equity, organizations have to be in it for the long haul and [work] in tandem with partners that are trusted by those who live in the community. “We can’t keep putting a band-aid on a gaping wound. We need buy-in from every stakeholder if we are to truly achieve health equity.”

An important initiative that ASCO is working on with the NCI, FDA, and the Friends of Cancer Research looks to increase the eligibility criteria for trials. “When you become too narrow in focus, you stifle diversity. If [clinical trials] are too prescriptive, they will not be inclusive,” Dr. Pierce stated. In addition to making clinical trials more inclusive, Dr. Pierce says the focus must be in decentralizing clinical trials.

The FDA has a Diversity in Clinical Trials Initiative with a wide range of print and digital materials that focuses on language and culture to break down barriers for the country’s diverse patient population, but Spinner says that stakeholder engagement remains at the crux of the agency’s efforts. Working with other organizations to synergize health equity efforts and create consistent messaging is key. “[The FDA] recognizes that one person or one organization cannot do it all,” admitted Spinner. Instead the agency focuses on building collaborations and ensuring that “multiple voices are heard.”

One key area of FDA focus is diversity in clinical trials, which aligns well with the ACCC 2020-2021 Presidential Theme discussed earlier and may be an avenue for future collaboration between the two organizations.

A Focus on Precision Medicine

Each month, we’ll be asking an ACCC member to share their expertise in a specific area of research concentration. In this inaugural issue, we’ve asked Michelle Shiller, DO, AP/CP, MGP, member of ACCC’s Board of Trustees and co-medical director of the Division of Molecular Medicine and Pathology at Baylor Sammons Cancer Center in Dallas, Texas, to highlight the necessity of integrating Pathology into the multidisciplinary cancer care team and some practice impactful precision medicine clinical trials.

While most of the work conducted in precision medicine and molecular oncology has been done at academic medical centers, the decreasing cost of sequencing, adoption of commercial next generation sequencing (NGS)-based testing, and emerging technologies like clinical decision support tools are likely to make the use of NGS-based tests in the community-oncology setting standard of care for patients with metastatic cancer.

Engaging Pathology, particularly pathologists with subspecialty-training in molecular genetics, is pivotal to the success of bringing highly efficacious targeted therapy to your cancer program. These providers have expertise in the characteristics and nuances of the many platforms that support these highly complex tests, which ultimately drive therapeutic decision-making for oncology patients.

Access to these subspecialists can be challenging, however, in community oncology practices and programs. Numerous papers support the cost savings potential in implementing panel-based approaches to testing. These tests not only guide the selection of the right therapy for the right patient at the right time, but also reduce adverse events. Comprehensive molecular profiling has revealed many different oncogenic drivers in non-small cell lung cancer (NSCLC).

Guidelines now recommend broad molecular profiling in advanced or metastatic disease to help determine targeted drug therapy or to appropriately counsel patients regarding the availability of clinical trials. A few actively recruiting NSCLC trials gaining a lot of traction at present include Keynote-158 (ClinicalTrials.gov Identifier: NCT02628067) and Keynote-495 (ClinicalTrials.gov Identifier: NCT03516981). Data from Keynote-158 was recently cited in the FDA's decision to grant accelerated approval to pembrolizumab for adult and pediatric patients with unresectable or metastatic tumor mutations burden (TMB)-high solid tumors, as detected by an FDA-approved test in at least the second-line setting.

Keynote-495 is investigating the utility of biomarker-based triage (gene expression profile and TMB) for participants with advanced NSCLC without prior systemic therapy. Pembrolizumab is similarly used, in combination with one of three additional agents (MK-1308, MK-4280, or lenvatinib). There's never been a more critical time for making sure precision medicine is reflected in your clinical trial portfolio. As the number of pan-tumor indications increases, the value of panel-based testing continues to become more evident. Optimization of the promise of precision medicine, which involves appropriate test selection, discussion regarding the findings, and tissue stewardship, requires a multidisciplinary cancer team care that includes a pathologist.

References

1McKenzie AJ, et al. Should next-generation sequencing tests be performed on all cancer patients? *Exp Rev Mol Diagn. 2019;19(2):89-93.*