Integrating the Community Voice to Advance Cancer Research: A Message from the President's Task Force

By Karen Winkfield, MD, PhD

Karen Winkfield, MD, PhD, is a nationally recognized expert in community engagement with cancer clinical research with a focus on programs aimed at reducing disparities in health outcomes for racial and ethnic minorities and underserved populations. In November, Dr. Winkfield became Executive Director of the Meharry-Vanderbilt Alliance. Previously, she served as an associate professor of Radiation Oncology at Wake Forest University, and as associate director for Community Outreach and Engagement and director of the Office of Cancer Health Equity at Wake Forest Baptist Comprehensive Cancer Center.

Introducing this issue of the Research Review newsletter, Dr. Winkfield describes the collaborative approach and community-engaged focus that informs initiatives at the Meharry-Vanderbilt Alliance, as well as some tried-and-true practices for amplifying the community's voice.

The Meharry-Vanderbilt Alliance has 20 years of experience in forging connections between two academic institutions—Meharry Medical Center, an historically Black institution, and Vanderbilt University Medical Center, a predominately white institution. Since its inception in 1999, the Meharry-Vanderbilt Alliance has supported the pooling of resources and faculty development, and over the last eight years has begun to develop a robust research portfolio. Community engagement has always been an integral part of the Alliance's work. As the incoming executive director, my job now is to create and disseminate new methods of engaging the community in a meaningful way. At some institutions, the community is only brought in after a research study has been developed; this needs to be flipped on its head. We must engage the community earlier in the process to improve access and uptake. In this issue of the Research Review, you will read about the work of my colleagues in the Office of Cancer Health Equity at the Wake Forest Baptist Comprehensive Cancer Center (WFBCCC), how the voice of the community (both patients and providers) is incorporated into the Wake

[Forest NCORP Research Base](#), recommendations from the Multi-Regional Clinical Trials Center on health literacy in clinical research, and more.

Across the oncology community, there is recognition of the importance of listening to and learning from the community's voice whether it's reflecting issues arising in care delivery or describing clinical trial barriers and challenges. To achieve health and health equity for all of our communities, as health professionals we must also advocate for policies that support sustainable change. On a local level, we can all commit to improving our engagement with the communities we serve. Below are some practical suggestions to help amplify the community's voice in cancer research and care delivery.

Strengthen bidirectional communication. Often what is important to researchers is not what is important to the community. This doesn't mean we can't conduct research focused on moving the needle forward with respect to cancer, diabetes, or other leading health concerns. However, the community may not always have an understanding of the broader picture in terms of population health. Bidirectional communication is key. We can help communities understand the importance of the questions that researchers are interested in, but the flip side of that is that researchers also need to listen to the community. When we listen to the community voice, we learn about things the community is seeing—their health worries and questions—that we're not aware of because we are not in and of that community.

Build lasting connections. To strengthen bidirectional communication, it is important to not only engage with the community when something is needed. Having community members at the table when you are devising a study's research questions not only gives them a voice but also helps to promote investment in the study outcomes. Admittedly, this can sometimes be challenging. It does take some effort. But once you actually train a group of individuals—and this is the importance of the Advocates for Research in Medicine (ARM) program at WFBCCC that you will read about in this newsletter—you have a cohort of individuals who understand the research process. These survivors and/or caregiver volunteers understand the disease that you are interested in; with proper training they can be integrated into research teams so that as research is being developed, the community voice is right there at the table.

Stay in communication with study participants. Another way to elevate the community voice is to stay in communication with study participants during the trial to gauge how burdensome the protocols are for them. As we've had to modify processes during the COVID pandemic, we've learned that maybe we didn't always need multiple tests—sometimes one test was sufficient. Unfortunately, we have not done a good job of integrating simple ways of capturing the participants' real-world burdens and having them reflect these back to us.

Conduct an exit interview with study participants. Often, we don't conduct any sort of exit interview for research participants. Asking questions, such as "Tell us a little bit about how

this study was for you." "Was it burdensome?" "What were some things you think could have been done differently?" would engage study participants in a meaningful way and show that we appreciate the time and effort they put in and that we value their voice.

Better utilize our Patient/Family Advisory Councils. Many cancer programs and practices have a Patient/Family Advisory Council, but how are these volunteers being utilized? While your cancer program might have a council of volunteers in place, you still need someone to facilitate and drive those conversations. For less-resourced programs, even a portion of an FTE's time may not be an option. However, among your post-treatment survivors or family members, you could have an individual who has the needed skillsets and is willing to volunteer to lead the effort. Community practices can leverage the community voice—and literally the community members—to help to build these engaged, bidirectional relationships.

Ask patients: Is there anything you need to continue participation in this study? My hope is that this is not considered innovative anymore. We've been talking about this as a best practice for 20 years. Ask your on-study patients: Is there anything we can do to help? Do you have everything you need to stay in the study? Is there anything else we can help you with? I actually think these are important questions to ask during clinical treatment as well and not just during clinical trial participation. That's why at WFBCCC, we built the population health patient navigation program. For the most vulnerable patient populations—rural, Black, and Hispanic/Latino populations—just getting to their treatment can be a problem. At WFBCCC, by building in resources that helped people get to and stay in treatment, we were able to increase clinical trial participation by 50 percent in each of these underserved communities.

Sometimes providers think that community engagement needs to be very involved and time-consuming. When I was at WFBCCC, we were able show that this doesn't have to be the case. Community engagement can be as simple as giving a talk one or two times a year in a community setting—at a church, a community meeting, or some other event where you can go and share your expertise. Again, the COVID pandemic has shown us how easy this is to do virtually. It's a different kind of connection, but in some ways it's easier for those who are interested in participating. Via online platforms, they can connect from their living rooms. Community engagement can be as simple as doing something you enjoy in the community—running in a 5K, for example. Find something that fits in with the things you love. It doesn't take a whole lot.

If you have patients who are interested in giving back, there are opportunities for community engagement. Leverage their experience. Leverage their relationships. Leverage their capacity. Depending on their interests and your ability to provide training—they can be your community engagement arm and it doesn't cost your program a thing. Just a little bit of time and a little bit of love and that's it.

Patient Resources
- [Cancer Support Community](#)
- [American Cancer Society](#)

For Diverse Communities
- [Latinas Contra Cancer](#) – Their mission is to create an inclusive healthcare system that provides services to the underserved Latino population around issues of cancer.
- [Sisters Network Inc.](#) – A national African American breast cancer survivor organization committed to increasing local and national attention to the devastating impact that breast cancer has in the African American community.
- [The Blue Hat Foundation](#) – Focuses on colorectal cancer with a mission to educate, raise awareness, and provide resources to free screenings for minority and medically underserved communities.
- [Prostate Education Network](#) – Established with the goal to eliminate disparity in prostate cancer in African American men, the Prostate Education Network also advocates for increased overall support and resources for the fight against prostate cancer.
- [The National LGBT Cancer Network](#) – Works to improve the lives of LGBTQI cancer survivors and those at risk through education of the community about cancer risks and prevention; training of the healthcare force to offer more culturally competent, safe, and welcoming care; and through advocacy.

Clinical Trial Support
- [Lazarex Cancer Foundation](#) – In addition to assisting patients with finding trials, the Lazarex Cancer Foundation provides financial support to cover ancillary expenditures (travel, lodging, etc.) for patients enrolled in cancer clinical trials

A Focus on the Community Voice within NCORP

One of the ways community oncology is helping to close gaps in cancer research is through participation in the National Cancer Institute Community Oncology Research Program (NCORP). Through NCORP, participating community-based clinicians offer their patients access to NCI-supported multi-site clinical trials focused in the areas of cancer control, prevention, and care delivery.

The NCORP network makes clinical trials available through a hub and spoke structure. Seven NCORP Research Bases serve as hubs for clinical trial development and research coordination for NCORP studies. Radiating out from these hubs are the nearly 50 NCORP Community Sites (32 Community Sites and 14 Minority/Underserved Community Sites), around which cluster "mini-networks" of local community cancer programs and oncology practices that affiliate in order to participate in NCORP trials. The mini-networks branching from NCORP Community Sites range from small (15 affiliated cancer programs/practices) to large (100 or more affiliates and sub-affiliates at one site).

Of the seven NCORP Research Bases, five are associated with the oncology cooperative groups (Alliance for Clinical Trials in Oncology, COG, ECOG-ACRIN, NRG Oncology, SWOG); two are located at cancer centers (Wake Forest Baptist Comprehensive Cancer Center and University of Rochester Wilmot Cancer Center). The latter two research bases focus exclusively on NCORP studies related to improving symptom management, survivorship, and quality of life and do not lead cancer treatment trials. Additionally, all of the NCORP Research Bases conduct trials that test new approaches to cancer care delivery. The NCORP Research Bases have varying criteria for becoming a member. The Wake Forest Research Base, one of the largest, is willing to work with a site for a single trial.

Learn more and find the NCORP Community Sites and Minority/Underserved Community Sites [here](#).

Kathryn Weaver, PhD, Co-Principal Investigator for the Wake Forest NCORP Research Base, talked recently with ACCC Research Review about current priorities in NCORP research and how the community voice—encompassing both patient advocates and community clinicians—is integrated into clinical trial design and dissemination.

One of the goals of NCORP is to accelerate the implementation of evidence into practice across the cancer care delivery landscape. Dr. Weaver emphasized that community providers play a pivotal role in NCORP's mission—both through enrolling diverse patients from a variety of care settings and through their active participation in NCORP studies. The voice of community—providers and patients—helps ensure that the evidence generated will be relevant to their communities and that the evidenced-based results of these research studies can be integrated into real-world care delivery. Dr. Weaver shared the following Wake Forest NCORP Research Base priorities, as well as priorities that cut across all research areas:

Cancer Control
- Cardiovascular complications of cancer therapy
- Neurocognitive complications of cancer therapy
- Additional cancer and treatment-related symptoms and related outcomes

Cancer Care Delivery Research (CCDR)
- Delivery of comprehensive survivorship care
- Integrating informal or familial caregivers into cancer care
- Integration of evidence-based care in cancer care settings

Cross-cutting Priorities
- Biological mechanisms
- Identify and address determinants of cancer disparities
- Train the next generation of cancer control and CCDR researchers

Within the above areas, the Wake Forest Research Base has set a few specific priorities. "Many of our cancer control trials are focused on cardiovascular complications of cancer therapy and prevention of cardiovascular damage during chemotherapy," Weaver said. "We also have a large observational trial in the field looking at fatigue, exercise capacity, and cardiac function amongst breast cancer survivors receiving a variety of treatments. And one of my current studies is looking at an EHR-based cardiovascular health assessment tool for cancer survivors."

"I think the beauty of NCORP is that it brings the trials to patients in their community. Most of the time those patients are going to be accrued at one of their local participating sites. And patients themselves are able to search by geographic location on the NCORP website to find an NCORP community site that is located close to them."

Integration of the community voice begins at the front-end of trial development at the Wake Forest NCORP Research Base, where the NCORP Committees on Cancer Control and Cancer Care Delivery Research include not only Wake Forest investigators but also community-site investigators. "We rely on them early in the process, the first time that we start looking at a trial to ask the tough questions," said Weaver. "We turn to [the community site investigators] to provide feedback about the importance and feasibility of a trial. They are the experts on their community and their patients."

Community-based clinical research coordinators also join in these calls. "They give us a very 'boots on the ground' perspective on how the trial would work," said Weaver. "Or they might ask: 'Have you thought about this?' Or tell us, 'We've run a similar trial and these are the problems we've run into.'"

Patient advocates serve on these committees, as well. "We do want to hear early on what patients think about a trial," said Weaver. "Is it addressing an important problem? Do they foresee any challenges accruing to the trial?"

The Wake Forest NCORP annual meeting is another venue where the community voice has an impact. "We present our entire portfolio of trials to all of our community-site members, including all the open trials and also our developing trials," said Weaver. "Our partners are great at telling us what they really think and making suggestions for how to improve developing studies and enhance accrual to ongoing trials."

A recent example occurred during the development of a study looking at a supplement to improve fatigue. "Originally, we had proposed to do the study in breast cancer," said Weaver. Unless there was a compelling reason for limiting the study to patients with breast cancer, the community asked that the trial be available to a broader patient population. "We listened and expanded the eligibility criteria for that trial."

Another instance where the community voice helped impact eligibility criteria arose during development of a trial to study a cognitive behavioral treatment for distress in post-treatment cancer survivors. "[The intervention is] delivered by phone, which we think is such an important issue—and how timely given the COVID pandemic," she explained. "We originally proposed that the trial just be conducted in rural survivors and chose a very standard research definition of rural. We opened the trial and we heard feedback from our community that the definition of rural wasn't working for them. They explained that there were populations that they served that were really rural but not eligible [under that definition], and they asked if we could do anything about it."

 "We took that feedback very seriously," said Weaver. The NCORP Research Base team ultimately decided to adopt a more expansive definition of rural and the eligibility was expanded. Recently, the trial was expanded further in response to ongoing community feedback that access wasn't only a problem for rural communities. "Especially at this time, everybody can have problems accessing care," said Weaver. The community spoke up about the real-world challenges facing patients during the COVID pandemic. Community providers had patients they wanted to enroll in the trial. Could it be opened to everyone, not just rural communities? "We thought about it very carefully. We had already accrued a substantial proportion of rural survivors, and we believed we could answer the study question for that vulnerable sub-population. And so, we decided to go ahead and expand the eligibility criteria to include all survivors."

Designed for Dissemination

To achieve the aim of streamlining the path from research-generated evidence to clinical application in the community, NCORP trials must be "designed for dissemination," emphasized Dr. Weaver. "I feel so passionately about this, both because of my work in NCORP and as a public health professional. We want the trials that we do not to die in an academic journal, but ultimately to be adopted in the community where the majority of patients receive care." Thus, when developing interventions, a key piece is thinking about interventions in terms of the resources available in community settings. As an example, Dr. Weaver cited an   intervention that might require every site to have a doctorate-prepared mental health professional for in-person counseling. Most community cancer programs and practices are unlikely to have this clinician on staff. "If this were the model for the intervention, they would never be able to meet that criteria," said Weaver.

To overcome obstacles encountered in low-resourced communities, Web-based interventions are increasingly under consideration, Weaver said. These solutions can provide greater access in areas when scarcity of health professionals is a challenge. While acknowledging that accessibility can still be a barrier, "mobile interventions, Web, telehealth would expand the

ability of sites to ultimately implement interventions, because they don't require that a lot of resources be available at that particular site," Weaver said.

Implementation science, which studies how best to integrate an evidence-based practice into settings of care, is a focus of several new cancer care delivery trials underway through the Wake Forest NCORP. "We just finished a large trial on lung cancer screening practices within the NCORP network to help participants implement evidence-based tobacco cessation for their patients at the point of screening," explains Weaver. "It was such an exciting trial and very well received in the community sites because, for the intervention, we came to them and engaged in a cooperative strategic planning process. We looked at the resources they had available. They told us what was feasible and what was sustainable. Then we worked with them to develop an individualized plan for how they would implement Public Health Service guidelines for offering cessation support."

"That trial is . . . a great example of working with community sites to think through implementation. We have several other trials open now that are hybrid effectiveness-implementation trials, where we are testing an intervention and at the same time collecting implementation data." For these studies, investigators talk to healthcare providers, patients, and key decision-makers in the community and collect data from these stakeholders on questions such as: What barriers do you see to fully implementing this intervention? What resources would be needed to integrate this in your practice? What did you patients and providers think?

Integrating the community voice in clinical trials is important to closing gaps in cancer research and also to reducing disparities. "I am continually impressed by the wealth of knowledge of our community investigators and their research staff. I think the most valuable lesson I have learned is to listen to them. They are experts on their community. When someone discovers something that works really well, we have tried to help amplify their voices throughout the network. The creativity, the passion, and the connection with the community is really inspiring to me as an investigator."

Patient Advocacy in Clinical Research

Carla Strom, MLA, is assistant director for operations in the Office of Cancer Health Equity at Wake Forest Baptist Comprehensive Cancer Center (WFBCCC). She brings more than 20 years of experience in oncology education, research, health policy, and health disparities to this role. Her responsibilities include providing oversight for the office as well as leading grant writing and community capacity building. She is a leader for WFBCCC's community outreach and engagement activities and supports the patient's voice in cancer center research. A two-time young adult cancer survivor, Ms. Strom serves on the NCI NCORP Symptom Management Quality of Life Steering Committee and the Wake Forest NCORP Research Base

Executive Steering Committee. She developed the Advocates for Research in Medicine (ARM) program at the cancer center. Prior to coming to WFBCCC, Ms. Strom spent nine years at the MD Anderson Cancer Center in Houston, TX.

In a conversation with ACCC's Research Review, Ms. Strom talked about how her role as an advocate has evolved and why listening to the community voice early and often in research is vital.

ACCC: How did you become interested in patient advocacy?

Carla Strom: Working formally as an advocate had been on my radar for 9 or 10 years. I'm 14-and-a-half years out from my first diagnosis. It takes a while, I think, to be able to reflect back on the larger experience of having cancer. I spent a lot of time working with non-profits that worked with cancer patients and survivors, because what's really important in being an advocate is that it's not about your story. It's about understanding the bigger perspective of what it means to have been a cancer patient or to be a cancer survivor. I think I was really driven by the work that I had done and continue to do [in oncology]. Also, my first diagnosis was breast cancer—probably one of the first and earliest cancers where advocates showed up as being an important part of the research process. I think The Komen Foundation was one of the first, if not the first, organization to require that researchers involve advocates as part of their research grant proposals.

ACCC: What was your path to becoming an advocate on the Executive Steering Committee for the Wake Forest NCORP Research Base (RB) and as part of the NCI NCORP on Symptom Management and Quality of Life Steering Committee?

Carla Strom: Some organizations have created a formal training program for breast cancer survivors to learn how to be advocates. I had always wanted to participate, but these are week-long programs. I worked full-time the entire time I was a patient and following that, so it wasn't really an option. It took a while for me to find the right opportunity.

Through my professional work, I'm involved in attending, presenting, and submitting work to national organizations. Two experiences helped ready me for the advocacy positions I have now for the Wake Forest NCORP RB and on the NCI NCORP Symptom Management and Quality of Life Steering Committee. Very early on in existence of the Patient-Centered Outcomes Research Institute (PCORI), I served as a survivor/patient stakeholder grant reviewer. That allowed me to formally use my knowledge of grant writing and the research process and couple that with putting on my survivor hat and my knowledge of what the survivorship experience is like and what matters to patients. The second experience was when I joined the [AACR Scientist↔Survivor Program](#) and attended an AACR national meeting to be part of that process. For the Scientist↔Survivor Program, after you've attended the meeting and sessions, you spend time with other advocates and meet one-on-one with scientists. Then, you complete a project. That was really where I started developing ideas around what would become the Advocates for Research in Medicine (ARM) program at Wake Forest. At one of the AACR meetings that I attended, I met a colleague from Oregon Health and Sciences University and learned about what they were doing. They had launched their own version of an advocate in research program. I started to put two and two together that we could do this at Wake.

The Wake Forest NCORP Research Base focuses on supportive care trials, not treatment trials. So, for example, our NCORP trials center around cancer care delivery, symptom management, quality of life, patient-reported outcomes. One of my advocacy/equity colleagues at Wake recommended me and encouraged me to apply for the NCI NCORP subcommittee. I was selected and I've been serving on the subcommittee for a little over two years. NCORP has a number of committees that help review research concepts from investigators that want to run their studies through the NCORP and also help determine priorities within topic areas. It has dovetailed well for me to serve on the NCI NCORP Symptom Management Quality of Life Subcommittee because that is the focus of our Wake Forest NCORP Research Base.

ACCC: One of the many hats you wear in your role at Wake Forest is in Office of Cancer Health Equity.

Carla Strom: Yes, and I think that has really shaped my work as an advocate. I am part of our NCORP RB Executive Steering Committee and the Health Equity Core. I also put my patient advocacy hat on in serving on that steering committee.

In the last 10 years, health equity and disparities have, rightfully so, become an increasing area of emphasis. We are at the point where we are done describing disparities, and now we need to address them.

ACCC: For the Wake Forest NCORP RB committee you are participating in, what is the avenue for the community voice to be heard?

Carla Strom: As an example, I can wear a patient advocate hat on our Steering Committee. We also have individuals on our Steering Committee who can wear the hat of being one of the sites that accrues to our studies. We have an oncologist who accrues to research studies in the community on our Steering Committee. And then, Dr. Weaver has done a lot of work, including in partnership with NCI, at the national level. For instance, there was an NCORP study called The Landscape Capacity Assessment Study that gathered information from all the sites—trying to make sure we understand what the sites look like, what kind of resources they have.

On the NCI Symptom Management and QOL Subcommittee, there is also site representation. We also have researchers whose primary area of focus is disparities, and then we always have patient advocates in addition to experts in the area of symptom management and QOL research.

Locally, through the Wake Forest Advocates for Research in Medicine (ARM) program, we are training a subset of advocates about NCORP so that they can serve as patient advocates for the Wake Forest NCORP RB.

ACCC: Can you share an example of how the process works when, as an advocate, you speak up for the community voice in your work with the NCI committee?

Carla Strom: Patient advocates often speak up about the real-world patient experience. For example, we might say: "You are asking a patient to come in extra every week for six weeks. That is not going to happen. No one is going to sign up for your study." So sometimes, it [the advocacy issue] is something very practical.

Often, we are asked to weigh in on whether the burden on the patients balances out with what they will get out of the trial.

We advocate for ensuring that patients are compensated for their time. To be clear, you do not pay patients for their participation. But if the study asks patients to come in for extra visits—compensation to cover gas or parking costs is important. For a rural patient or a low-income minority patient, compensating their parking or giving them a gas card makes a big difference because, for example, to participate they drove two hours from Virginia for that extra visit needed for the study.

I also speak up as a Hispanic woman. When researchers are choosing validated instruments that are not validated in Spanish—when they could have just as easily chosen an equally acceptable validated instrument that is available in Spanish—I speak up to let them know this

is not OK. It makes a difference in whether or not the overall study could be offered to those Spanish speakers who don't speak English.

Unfortunately, a lot of time patient advocates are involved as a "check box." That's the struggle. It's a requirement, but people aren't really invested in it. So, they do it to say they've done it. Education has to go in both directions. Patients have to be trained to advocate and researchers have to be trained on how to utilize advocates. That really ties into our Advocates for Research in Medicine program at Wake Forest.

But I will say, I've seen the power of advocacy firsthand. After the NCORP subcommittee reviews a [study] concept, the NCI writes a letter reflecting the outcome of the concept review: approved, revise and resubmit, or disapproved. Regardless of the outcome, NCI sends a letter to the team of investigators who proposed the study that outlines anything that the committee is recommending. What was really a turning point for me was when I saw that the NCI had taken the words that I had shared in my review and put them into that letter going back to the investigators of a national study that was going to open across the country.

ACCC: Can you share more about how the ARM program came about at Wake Forest?

Carla Strom: I was serving as the advocate for a lot of the cancer center members we have at the Wake Forest NCORP. But I'm only an N of one, and I'm not always necessarily the best advocacy match for a specific study. So, I started to identify survivors I had worked with—for example, maybe they'd had a career in nursing, and they had a capacity to contribute as an advocate. If I wasn't the best suited advocate for a particular project, I played an informal role in connecting our researchers with additional survivors. This ultimately led to the development of the Advocates for Research in Medicine program, which launched in 2020.

[In developing the program] we wanted to take what has been done at the national level, for example, a one-week, full-time training program for advocates, but we knew that would not be feasible for most people in our catchment area. (Wake Forest serves a largely rural area.) As I mentioned previously, connecting with a colleague from OHSU helped spark my ideas for the program. We developed a curriculum covering what we believed to be key areas in which advocates need to have baseline knowledge. It's important to add: Not every survivor is meant to be an advocate. You have to have an interest in research to serve as an advocate in research, and it's not for everyone.

We started our ARM program with a cohort of survivors. Eventually we plan to expand it to caregivers and individuals at high risk for cancer who have not yet been diagnosed with cancer.

In response to the COVID pandemic, we've had to make some adjustments. We had planned for a combination of some pre-work and then to have the trainees onsite for a day and a half

of core training. Then, participants would be offered continuing education opportunities throughout the year—some from our institution and some from other organizations and non-profits. This would provide a deeper dive on specific topics that would be a match to a particular group of advocates. We've modified the curriculum format to two half-day online sessions and moved some of the core content to the continuing education space. We require advocates to get CITI training because they will be put on the study's IRB. For ARM Part Two, we intend to develop a "reverse" training to help researchers understand the role of advocates, how best to utilize them, and how to facilitate their capacity to improve research and grants.

The ARM core training covers topics such as Cancer 101, Research 101, the Advocate's Role, basics of clinical trials, different types of grant mechanisms, and how to tell your story, which is never really an easy thing to do, but gets easier the more you do it. For 2021, we are developing a subset of ARM that will provide additional training to understand NCORP, because to be a patient advocate on NCORP studies you have to have a certain amount of working knowledge of NCORP. We also have a supplemental grant from NCI that is focused around helping connect researchers with the community. We are piloting this work with our cancer genetics and metabolism scientific program, so we will be training another subset of advocates to have a slightly more in-depth understanding of cancer genetics, precision oncology, and the common terminology around those topics. We can specialize our advocates' training to prepare them so that they are better equipped to provide input on specific research topics.

Health Literacy in Clinical Research–A Two-Way Street

Are you sure your clinical research materials are understandable?

The [Health Literacy in Clinical Research website](#) created through a multi-stakeholder process by the Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's and Harvard can not only help you answer this question, it can also offer you practical steps and resources for addressing health literacy issues facing your patients, your clinical research team, and your cancer program.

Health literacy is now widely viewed as a two-sided (or bilateral) concept. For individuals, health literacy reflects their capacity to understand and use information to make healthcare decisions. For healthcare stakeholders that are communicating health information, health literacy reflects their responsibility to share information that is understandable and communicated clearly.

The imperative is unequivocal. As the MRCT Health Literacy website states: *"Health literacy should be considered a critical component of **all** participant facing clinical research*

*communications created by **all** clinical research stakeholders across **all** points of the clinical trial life cycle."*

Health literacy in clinical research is not only an ethical and justice imperative, the MRCT highlights that the shared responsibility of health literacy is "essential to scientific integrity and the impact of clinical research." Not only does health literacy in clinical research stand to improve study generalizability, proper adherence and follow-up, and data validity, it may lead to cost saving and reduction in liability.

For stakeholders addressing health literacy in clinical research—and in healthcare more broadly—MRCT suggests keeping the following two points top of mind:

Anyone can face health literacy challenges. Recent data finds that only 12% of U.S. adults have proficient levels of health literacy, and 35% of adults in the U.S. have health literacy levels that are basic or below basic. Health literacy barriers can impact anyone, regardless of education level or socioeconomic status. This is especially true when individuals are under stress, receive a difficult diagnosis, are dealing with an unfamiliar area of knowledge, etc.

Do not try to fix everything at once. Rather than attempting a massive overhaul of patient-facing materials, instead consider assessing just the next document or the next process in the clinical research cycle for health literacy. Start the discussion and keep the health literacy conversation going.

The MRCT Health Literacy in Clinical Research website is easy-to-navigate and intuitively structured into four main sections:
- Start Here – Overview of Health Literacy, Principles of Health Literacy in Clinical Research, Putting Health Literacy into Action
- Clinical Trial Lifecycle – Health literacy considerations and resources for all study stages: Discovery, Recruitment, Consent, On Study, and End of Study
- Best Practices – Plain Language, Numeracy, Clear Design, Usability Testing, Clear Design, Glossary, Consent Guide, Case Studies, and more.
- Resources by Role – Includes information for study teams, IRB, study sponsors, and participants and public.

Clear, consumer-friendly information and communications are building blocks for patient and community engagement. Health literacy is an elemental part of fostering partnerships that support community connections and help amplify the patient and community voice in clinical research.

[Access ACCC health literacy resources](#) for cancer programs and patients with cancer. Included are an education video on improving patient communication using the Institute for Healthcare Improvement (IHI) Ask Me Three tool; a gap assessment tool that cancer care

providers can use to identify education needs and target areas in which focused health literacy efforts could improve patient care, links to additional resources, and more.

AACR Cancer Disparities Progress Report 2020

Among the most urgent challenges in cancer clinical research in the U.S. are low rates of participation and lack of diversity among clinical trials participants, according to the AACR Cancer Disparities Progress Report 2020. Examples cited in the report include:

- Recent clinical trials for two new treatments for prostate cancer that ultimately received FDA approval enrolled less than 10 percent of African American men, although this patient population is twice as likely to die of the disease.
- About 20 percent of new multiple myeloma cases occur in African Americans, yet this population represented only 10 percent of participants in the clinical trials for daratumumab, an immunotherapy that received FDA approval for multiple myeloma.
- Hispanic children with cancer are more than 50 percent less likely to enroll in therapeutic clinical trials testing a new treatment than non-Hispanic white children.

While acknowledging the complexity of some of the issues underlying lack of diversity in clinical trial participants, the AACR report notes several actions that can be taken immediately. Research teams need to reach out and collaborate with marginalized, under-represented patient populations. Specifically highlighted in report is the NCI Community Oncology Research Program (NCORP) and its success in offering clinical trials in diverse community settings close to where patients live and work. Second, simplifying and expanding trial eligibility criteria would help in increasing diversity in trial participants. An example referenced is the NCI's recent revision of eligibility criteria opening the door for potential clinical trial participation to those with preexisting conditions such as brain metastases, previous and current malignancies, HIV and hepatitis infections, and organ dysfunction, and the possibility that future further expansion may include those who use medications to manage co-occurring medical conditions. Third, clinical trials should include patient-reported outcomes data to build knowledge and better understanding of the real-world patient experience from diverse populations.

Resource
CancerDisparitiesProgressReport.org [Internet]. Philadelphia: American Association for Cancer Research; 2020. Last accessed Dec. 28, 2020. Available at http://www.CancerDisparitiesProgressReport.org/.

ACCC Webcast: Integrating the Community Voice to Advance Cancer Research

Optimal cancer care delivery changes from place to place. What works best for one location and patient population may not be ideal for another—the same reasoning also applies to cancer research. Understanding the needs of your patient population is critical to trial design and implementation. On **Wednesday, January 27**, expert panelists from Wake Forest will share strategies to incorporate your community's needs and perspective into your research program. Their guidance and experience will help you better understand the burden of cancer in your impact area, present ways to involve and empower patient advocates in clinical research, and discuss strategies for effective trial design and communication. Click here to register.

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.

The **Association of Community Cancer Centers (ACCC)** is the leading education and advocacy organization for the cancer care community. Founded in 1974, ACCC is a powerful network of 28,000 multidisciplinary practitioners from 2,100 hospitals and practices nationwide. As advances in cancer screening and diagnosis, treatment options, and care delivery models continue to evolve—so has ACCC—adapting its resources to meet the changing needs of the entire oncology care team. For more information, visit accc-cancer.org or call

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