## Just ASK!

How one healthcare system is operationalizing this implicit bias program to ensure equitable access to clinical trials



Ithough the U.S. has realized tremendous progress in diagnosing and treating many types of cancer over the last 20 years, not all segments of society are benefiting equally from these advances. The AACR Cancer Disparities Progress Report 2022 highlights the challenges: "Despite these advances, racial and ethnic minorities and other medically underserved populations continue to experience more frequent and higher severity of multilevel barriers to quality cancer treatment including treatment delays, lack of access to guideline-concordant treatment, and higher rates of treatment-related financial toxicities. The same population groups may also experience overt discrimination and/or implicit bias during the delivery of care."<sup>2</sup>

The COVID-19 pandemic further exacerbated health inequities—as communities most affected by social determinants of health factors lived with a greater burden from the virus both in terms of disease and economic impact.<sup>3</sup>

In the 2022 American Society of Clinical Oncology Education Book, *Strategies to Advance Equity in Cancer Clinical Trials*, Guerra et al. write, "Underrepresented populations—including minority groups, elderly individuals, and rural populations—limit the generalizability of research and prevent clinicians and patients from determining whether new cancer drugs have the same efficacy and safety in these subsets of excluded populations. In addition, exclusion of these populations contributes to delayed enrollment and thus inefficiency of clinical trials."

During the past several decades, research has identified common barriers to patient participation in clinical trials and, specifically challenges to enrollment for medically under-served patient populations. A recent systematic review and meta-analysis by Unger and colleagues posits that with the current complex, intertwined barriers inherent in the U.S. clinical trial enterprise, patients have little opportunity to consider clinical trials as a treatment option. The analysis focused on the rate of participation among adult patients who were offered the opportunity to enroll in a cancer clinical trial. The findings revealed that patients—regardless of race or ethnicity—when asked, agree to participate in a cancer clinical trial more than half the time. In conclusion, the authors write: "Indeed, this finding indicates that perhaps the best way to improve enrollment

"The pursuit of health equity ought to be elevated as the fifth aim for health care improvement, purposefully including with all improvement and innovation efforts a focus on individuals and communities who need them most."

of minority patients to cancer trials is simply to ensure that minority patients are invited to participate. The recognition of this may inform efforts to alleviate potential bias in the provision of healthcare resources by race or ethnicity, including trial offers for eligible patients."<sup>5</sup>

Among the strategies to advance equity in cancer clinical trials suggested by Guerra and colleagues are the following:<sup>4</sup>

- Establish a systemic process to screen all patients for trial eligibility. (Without a standardized process, the authors note, programs adopt ad hoc approaches to screening, which can create opportunity for implicit bias in the selection process.)
- 2. Invite all patients who match trial eligibility criteria to participate.

In 2020, the American Society of Clinical Oncology (ASCO) and the Association of Community Cancer Centers (ACCC) came together in a multi-year collaboration that built on these study findings, publishing a joint ASCO-ACCC Research Statement that outlined specific actions for individual stakeholders in the cancer clinical trial ecosystem to increase diversity in research participation. Among the published recommendations: "Recommendation 1: Clinical trials are an integral component of high-quality cancer care, and every person with cancer should have the opportunity to participate."

On July 25, 2022, ASCO and ACCC released three resources to help cancer programs and practices increase racial and ethnic equity, diversity, and inclusion in cancer clinical trials:

- 1. The ASCO-ACCC Equity, Diversity, and Inclusion Research Site Self-Assessment can be used to identify systemic areas that are known to affect enrollment of diverse patient populations into clinical studies and to gain site-specific recommendations to modify rules and procedures. Completion of the self-assessment helps to identify opportunities for performance and quality improvement across various levels of the organization. The assessment covers the clinical trial enrollment continuum through seven domains that include patient access to the site, screening patients for clinical trials, offering patients clinical trials, and participation and retention in trials.
- The *Just ASK*<sup>™</sup> Training Program addresses the recognized barrier to clinical trial enrollment highlighted in the recent study by Unger and colleagues-i.e., not being asked to participate. The free, interactive training helps research and healthcare staff to better understand the universal nature of implicit (unconscious) and conscious bias, to underscore the imperative to increase diversity in accrual to clinical trials, and to raise awareness of opportunities for change at the individual level. Real-world examples connect underlying challenges with everyday clinical care. The training materials are adapted from a Duke University program pioneered by Nadine Barrett, PhD, Assistant Professor Family Medicine and Community Health at Duke University and Associate Director for Equity and Stakeholder Strategy, Duke Cancer Institute. The adaption process was spearheaded by a steering group composed of leading experts in diversity, equity, inclusion in cancer care. Learn more at https://www.accccancer.org/home/learn/community-oncology-research/ascoaccc-initiative.
- The <u>Just ASK™ Training Facilitation Guide</u> complements the training with guidance for facilitators on how to keep the conversation around implicit biases going once the initial training is completed.

## A Use Case Study

Dr. Marisa Weiss, director of breast radiation oncology and breast health outreach at Lankenau Medical Center, Wynnewood, Pa., is a champion for the Just ASK program. Dr. Weiss has been in clinical practice for more than 30 years. She is also founder and chief medical officer of Breastcancer.org, a global patient advocacy organization providing free expertise and support to individuals with breast cancer in English and Spanish. In both roles, Dr. Weiss is an advocate for equity in cancer care delivery and empowering informed patients to fully participate in their cancer care.

In her dual roles, Dr. Weiss is witness to the collateral damage the COVID-19 pandemic has brought to patient populations that were already medically under-served and she is concerned about the pandemic's persistent negative effect on cancer disparities. Lankenau Medical Center's service area includes West Philadelphia, where the median annual income is about \$35,000 and multi-layered social determinants of health impede health equity.

Through the lens of <u>Breastcancer.org</u>, Dr. Weiss has been immersed in the 24/7 devastation from the pandemic, with the exacerbation of pre-existing health disparities "resulting in delayed diagnoses, treatment disruptions, and dangerous social isolation." Among the medically underserved, "we are slipping and losing precious ground that took decades to obtain," she said. "We've seen the data. Breast cancer incidence [is] still rising in Black women and the death rate has risen at a greater level compared with White women." The American Cancer Society reports that although Black women have a 4 percent lower incidence rate of breast cancer compared to White women, they have a 40 percent higher mortality rate [than White women]. This death rate disparity has been unchanged for the past 10 years.<sup>7</sup>

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Dr. Weiss is acutely aware of "the financial toxicity that compounds every one of the social determinants of health. Further, it constrains a person's ability to get timely quality care. Overall, in the literature, we know that half to three-quarters of people note financial hardship." She cited a recent <u>Breastcancer.org</u> survey where just over half of respondents reported financial hardship, and about 25 percent indicated that they were stretching out their medicines to make them last longer—a step that disrupts the efficacy of their treatment. "We know that financial toxicity ends up being another disease. Maybe your treatment is over, but this disease of financial toxicity with mounting unpaid bills and the threat of bankruptcy lingers on."

Pre-pandemic Dr. Weiss and colleagues at <u>Breastcancer.org</u> had collaborated with Dr. Nadine Barrett and Duke Cancer Institute on health equity research. Through the Lankenau Institute for Medical Research, Dr. Weiss began development of a use case study designed to engage medically under-represented patients to participate in clinical trials, addressing a major barrier to health equity in cancer care. Although the use case study was planned prior to the Just ASK program launch, the study design incorporated recommendations for improving diversity, equity, and inclusion that align with those in the ACCC-ASCO research statement, Weiss said. This included:

- Identifying an urgent study topic highly relevant to the under-served patient population. In this instance, the clinical trial focused on chemotherapy-induced peripheral neuropathy, a common yet difficult-to-treat side effect from the most commonly used chemotherapies, i.e., taxanes and -platins. Chemotherapy-induced peripheral neuropathy is a doselimiting toxicity that disproportionately affects Black patients with cancer treated with neurotoxic chemotherapies and is associated with negative outcomes, Weiss said.
- Making study eligibility criteria as non-restrictive as possible. To appeal to a broad patient cohort, the study was open to people with breast cancer, ovarian cancer, uterine cancer, colorectal cancer, and pancreatic cancer receiving either a taxane or -platin chemotherapy. Except for potential study drug interactions with other medicines and conditions (like a recent heart attack), and preexisting neuropathy, most other co-morbidities were not exclusions.
- Providing a culture of respect and inclusion. Building trust
  with all potential participants was foundational to
  Lankenau Medical Center's study culture including always
  being respectful; full transparency; protecting patient privacy;
  providing as many study visits as necessary, as well as access
  to all members of the team; never rushing any conversation
  or process (like consent); and being accountable for timely
  follow-up on any question or request.
- Making sure that the diversity of the research team represented the diversity of study participants. The main clinical research coordinator was African American and the research assistants were Latina and Muslim.
- *Enabling convenient participation.* The trial design allowed a flexible schedule for study visits with an option for virtual visits when in-person visits were not feasible.
- Designing accessible study materials. Care was taken to design study materials that were "understandable, appealing, inviting, informative, and shareable," Weiss said.
- Identifying and inviting all eligible patients. "We knew we needed to make sure that all people who were able to participate in the clinical trial were asked to participate," Weiss said. As the team learned, this was not a one-step process. First, everyone on the study team was asked to invite anyone who could be eligible to participate in the trial. "But that turned out to be very unreliable," Weiss said. One problem was timing. The study was launched during the early days of the COVID-19 pandemic. Under these extraordinary circumstances, with everyone working at capacity and beyond, this was not a reliable recruitment strategy, Weiss said.

Next, the study team turned to technology, manually querying Epic to identify all patients who would potentially be eligible for the trial. Manual queries were necessary because the hospital does not have an automatic query system in Epic to effectively identify patients eligible for specific trials. This manual query process, conducted daily, ultimately yielded about half the patients enrolled on the trial, Weiss said.

- Identifying and addressing patient barriers to clinical trial enrollment. Once an eligible patient was invited to enroll in the trial, the study team worked with the Lankenau Medical Center social worker and support staff to identify and address social determinants of health barriers with an asset-based approach, Weiss said. This included common barriers such as transportation, food insecurity, housing instability, and medical insurance coverage.
- Collecting and reporting data on patient demographics. Although the study launched in 2020 during the early days of the pandemic, the study achieved 30 percent enrollment by Black individuals, and points to the power of "just asking" all eligible patients to consider clinical trial participation.

"The long-term goal would be systemwide Just ASK training so that everyone in the hospital who touches on the care of a cancer patient could benefit...along with an ongoing commitment to reduce and eliminate any institutional racism."

Despite this success, Weiss emphasized that the years-long COVID-19 pandemic has further exacerbated challenges to equity in clinical trial enrollment. "Under-represented patient populations' participation in cancer clinical trials—already less than 5 percent—saw further declines during the pandemic," she said. "We know the decline in clinical trial participation was multifactorial. Our research program, like many, was shut down for six months in 2020. When clinical and research teams are understaffed and overworked, there is much less time to identify eligible patients and invite them to participate in clinical trials. Then, too, there was an abrupt shift to focus more on the COVID-19 pandemic than on breast cancer clinical trials. Patients' ability to join a trial was further constrained by a greater burden of social determinants of health challenges (due to the pandemic), with associated highrisk of disease and comorbidities. It wasn't just that people couldn't address their breast cancer concerns; they couldn't address other underlying conditions such as diabetes, heart disease, and everything else."

## Aligned to Advance Health Equity

Going forward, Lankenau Medical Center is taking innovative steps to advance equity in clinical trials and leading this effort within the Main Line Health system (of which Lankenau is part). The newly developed RESPECT (Reaching Equitable Standards for Patient Engagement in Clinical Trials) Initiative is one example. This program aims to help grow capacity skills in the community and build bridges between community-based organizations and the Lankenau Medical Center healthcare team that includes social

workers, navigators, nurses, physicians, financial counselors, clinical research coordinators, and other staff, so that Lankenau can improve the quality and continuity of care for the patients it has the honor of serving, Weiss said.

The ASCO-ACCC Just ASK training program is a pillar of the RESPECT Initiative, Weiss said. "It is a beautifully developed and executed program to train our hospital staff with evidence-based information, cultural sensitivity, cogent case examples, and immediately implementable practical solutions." The long-term goal would be system-wide Just ASK training so that everyone in the hospital who touches on the care of a cancer patient—physician, nurse, navigator, social worker, clinical research coordinator, financial counselor, receptionist—could benefit and the health system could advance the goal of improving health equity along with an ongoing commitment to reduce and eliminate any institutional racism, she said.

At present, bringing together leadership across the health system to learn about and experience the Just ASK Training program is yielding key insights into internal foundational steps that must precede system-wide roll out to maximize opportunities for success. Dr. Weiss recommends the following:

- Identify champions in leadership and within each department for the Just ASK training program.
- Publicly acknowledge and reward the completion of Just ASK.
- Establish CME accreditation for any staff completing the Just ASK program
- Ensure that assessment of social determinants of health is done effectively and consistently across the health system.
- Address social determinants of health needs consistently and effectively across the system.
- Enable EHR system(s) to handle clinical trial eligibility queries so that once staff is trained in the Just ASK program, they can follow through as easily as possible.
- Have all clinical trials in a ready-to-access portfolio available at physicians' or clinical research coordinators' fingertips.
- Create a process to track completion of Just ASK training by staff.

Maintaining a focus on health equity across all sectors of hospitals and health systems requires alignment across leadership. Below is a sample of what leadership alignment on health equity at Lankenau Medical Center Main Line Health looks like.

Amanda Patton, MA, is a freelance healthcare writer. She worked as a senior writer and editor for the Association of Community Cancer Centers for more than 15 years.



Katie Galbraith, President and CEO, Lankenau Medical Center

PRESIDENT AND CEO KATIE GALBRAITH assumed her new role at Lankenau Medical Center in October 2022. Previously, she served as president of Duke Regional Hospital and during the past two years as co-incident commander for the COVID-19 response for the Duke Health System. Her tenure at Duke also included an 18-month stint as interim head of community health for the health system.

"Health equity is a critical part of our mission as hospitals, as health systems. We are all focused on improving the health of the communities we serve. We can't say we're improving the health of the communities we serve unless we are improving it for everyone, and part of that responsibility is to really partner and collaborate with our communities to learn what their needs are and to be responsive and to work together in partnership to eliminate health disparities."

"And one of those disparities, of course, has been in access to clinical trials and participation in clinical trials. This is where the Just ASK program is going to be so valuable and has been proven to be valuable already in other settings. Making sure we are doing everything we can to understand implicit bias, to understand and acknowledge the disparities that do exist, and then work together through that knowledge to close the gap and eliminate disparities."

"This is one of the most challenging times in healthcare that we're living through right now. I have had the concern—just broadly—that we could lose our focus on equity if we're not careful. We can't do that. We have to make sure that equity is front and center because it is core to who we are as healthcare organizations. It's core to our mission of caring for our communities and improving the health of the communities we serve. We can't do that if we don't do that through the lens of equity, making sure that we are caring for everyone and valuing every individual for who they are, understanding their unique needs, and then being able to serve those unique needs. Being able to work together to eliminate disparities and make sure that we are providing the very best care and getting the best outcomes for everyone that we are serving."



George Prendergast, PhD, President and CEO, Lankenau Institute for Medical Research

DR. GEORGE PRENDERGAST has served in his role at Lankenau Institute for Medical Research since 2004. This nonprofit, biomedical research institute is located on the campus of Lankenau Medical Center in Wynnewood, Pa. Dr. Prendergast affirms the institute's deep commitment to equity, diversity, and inclusion in clinical research, in accord with Lankenau Medical Center and Main Line Health. The use case study for which Dr. Weiss serves as principal investigator was conducted through Lankenau Institute for Medical Research and is just one example of innovation underway to address diversity in trial enrollment.

Dr. Prendergast describes the ASCO-ACCC Just ASK Training program as an accessible and foundational resource "to prompt clinical trial participation for those who might not otherwise have been approached."

Recently, the Lankenau Institute for Medical Research launched a new population health research center in collaboration with Thomas Jefferson University with oversight from an advisory committee composed of Jefferson and Lankenau Institute for Medical Research experts. A priority for the population research group, Prendergast said, is improving understanding of diversity in research with regard to patient populations within the Main Line Health's catchment area. This includes a focus on data collection on the demographics of patient populations being accrued to clinical trials to better understand how patient accrual demographics compare with those of the catchment area.



Deric C. Savior, MD,
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MEDICAL ONCOLOGIST DERIC C. SAVIOR, MD, previously served as Head of Medical Oncology at Fox Chase Cancer Center at Temple University Hospital. Throughout his career, Dr. Savior has centered his practice on ensuring that all patients, particularly the sickest patients from the local medically underserved community, have access to and receive high quality cancer care.

Dr. Savior completed the Just ASK Training, which he describes as an "accessible and practical" step toward keeping health equity front of mind. He believes the Just ASK training is really important because "it will help us to acknowledge and combat the biases that we have that too often affect the delivery of equitable care and access to research in under-represented populations. It will help also raise awareness about the biases and beliefs that we as providers may harbor and how these beliefs may impact equitable care to all of our population. It helps us acknowledge the bias and gives us strategies to combat it."

"Just asking a patient to participate in a trial will not only potentially help them, but also help the people that come behind them. Something as simple as asking the patient—and that intervention alone kind of levels the playing field, and tells us how far we have to go in addressing our own biases, how we can ask one patient population and not the other—shines a light on the issues we have to address within ourselves as practitioners so that we can make sure all of our patients have equal access to these modalities and interventions."

Amidst the complex, competing priorities of our rapidly shifting healthcare landscape, Dr. Savior is wary of the potential for health equity to become a "check the box" exercise. "It's great to acknowledge these important issues and to discuss them. Thoughtful discussion and analysis are no longer sufficient. It is now the time for effort and action. You have to implement strategies to combat inequities. The Just ASK program does just that. It is one strategy in a multitude of things we need to do, but it's a good starting point.... So many lives hang in the balance. The way technology and innovations are advancing, we have to make sure everybody has equal access to quality care and clinical trials. Otherwise, certain vulnerable populations will be left further behind. It's really imperative that we get this right as soon as possible.



Marisa C. Weiss, MD,
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Chief Medical Officer,
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"TREATMENT DECISIONS ARE OFTEN made between a doctor and a patient in the community setting or in the hospital environment," Weiss said. "To make shared decision-making more equitable, more of a level playing field, more effective, we need to address what is going on in a hospital between a doctor and a patient. I have a clinical practice that gives me the ability to work in a system, Main Line Health, that is a large community hospital system with a strong commitment to equity, diversity, and inclusion in research and to reducing health inequities—starting at the top of the system, there is fierce commitment."

"Health disparity is an urgent public health problem that threatens the lives of precious populations. Their lives are at stake, they are losing ground, requiring immediate action by community-based hospital systems."

"When we learned that Dr. Nadine Barrett's pivotal research at Duke would be scaled through a collaboration with ACCC and ASCO, we thought, 'this is perfect timing.' We can use this well-done, beautifully developed program to train our staff...so that everybody in the hospital who touches on the care of a cancer patient—doctor, nurse, nurse navigator, clinical research coordinator, social worker, financial counselor, receptionist—could all have the benefit of the Just ASK training to empower them to become more effective in their role and to achieve our strong commitment to health equity, including improved access to clinical trial participation by addressing social determinants of health with an asset-based approach."

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