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HELPING COMMUNITY ONCOLOGY TO CLOSE THE GAP IN CANCER RESEARCH
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Training for the Clinical Trials Workforce: A Message from the President's Task Force

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This edition of the ACCC Research Review focuses on issues related to workforce training for cancer clinical research. Whether a cancer program is currently conducting clinical studies or is considering becoming a trial site, the bedrock on which all training rests is an understanding that oncology clinical research is unique in the sphere of medical practice. Although various medical disciplines conduct clinical studies, what sets cancer clinical trials apart is that these are a standard of care whether patients are in a community or academic setting. In fact, clinical guidelines, such as the NCCN guidelines, state upfront in algorithms that when evaluating patients for treatment an available clinical trial represents a standard of care and, therefore, is a potential important choice for an individual.

To start and grow a clinical trials program in the community, establishing a culture of research is essential. This is a culture committed to offering access to state-of-the art therapy in an environment that clearly documents the efficacy of the treatment and places the utmost emphasis on patient safety. Whether research staff are in the laboratory, in the pharmacy, in trial data management, or administration—this must be the mindset and the culture. A research culture is one in which everyone's goal is the best care possible for the individual patient.

Clinical trial personnel needs are another basic consideration. Studies require not only clinical staff but also may require participation of subspecialists and non-oncology providers. Pharmacists, nurses and—increasingly advanced practice providers—are critical members of the team caring for patients on clinical trials. Each clinical staff role, from Principal Investigator to pharmacist to clinical research coordinator to regulatory staff and business manager has specific training needs.

In smaller practice sites, clinical trial staff responsibilities may, by necessity, be combined. For example, a clinical trial nurse may also be tasked with data collection duties or a data manager may also be asked to manage regulatory responsibilities. In such cases, not only must the staff be cross-trained for these dual roles, but there must be oversight to ensure staff is not overwhelmed by the workload. Thus, conduct of clinical trials requires attention to and monitoring of staff workloads, carefully assessing assigned responsibilities so that no staff are overburdened.

Training for clinical research staff is ongoing. A component of conducting research is tracking trial staff training and emerging education needs and requirements. This function is an important consideration

when implementing a management system for clinical trials. Ultimately, the trial Principal Investigator is responsible for conduct of a study. Not only must that individual understand all requirements of a specific clinical trial, but they must also guarantee that all of the responsibilities of the clinical trial site are appropriately executed, maintaining high standards, and, most importantly, the safety of patients.

Resources for training of clinical trials staff are widely available, including from the NCI cooperative groups (for members). Large academic comprehensive cancer centers typically have developed in-house training for research staff specific to the institution. For example, at the Robert H. Lurie Comprehensive Cancer Center at Northwestern University, new employees view a slide series titled Research 101. This covers general information on clinical research such as clinical trial phases, types of trials, personnel involved, and information on the International Conference on Harmonization. Additionally, there are training materials on the NCI's research programs that include an NCTN-ETCTN regulatory overview. In response to the COVID pandemic, Northwestern has employed a slide presentation on COVID Reporting for NCTN trials. The training materials available include, but are not limited to:

- Overview of regulations and standards for conducting clinical trials
- Standard Operating Procedures (SOPs) for clinical trials
- Information on Northwestern's IRB
- Principles of good clinical trial practice
- Discussion of federal regulations pertaining to conduct of clinical trials

Finally, mentoring and continual education strategies are essential in any research environment. Mentoring is embedded in the culture of research at Northwestern, where care is delivered in a disease-team format. For example, the designated research team for GI oncology—including regulatory personnel, data coordinators and managers, and research nurses—meets weekly to review all current studies and all patients on study. Amid the COVID-19 pandemic, this meeting is conducted by videoconference. The robust discussion is not only an opportunity for education but also for mentoring staff. When new staff join the team, they work directly with an experienced colleague to augment the specific essential elements highlighted in the formal training materials. Furthermore, each new clinical trial includes site initiation materials, often in PowerPoint format, that are required viewing for all study team members and are another vehicle to enhance training.

Clinical trial staff training is an ongoing phenomenon. This includes the huge educational aspect of the research study itself whereby research and clinical staff are not only learning about new treatments, they also may gain knowledge about new techniques and methodologies. In clinical research—as in medicine itself—learning is a constant and should be embedded in any practice culture.

Select Training Resources

National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP)
Clinical Trials Monitoring Branch (CTMB)
The Branch sets guidelines and standards for the conduct of clinical trials in order to assure data quality and compliance with regulatory requirements for clinical research. CTMB staff are considered expert resources for dealing with inquiries from both intramural and extramural staff regarding FDA regulations and HHS Office for Human Research Protections regulations.

- Auditor/Monitor Training Modules

- NCI COVID-19 Information for Cancer Researchers

ClinicalTrials.gov

- Training Materials
- Select Publications
- Clinical Trials Trends, Charts, and Maps
- For Researchers
- Investigator's Handbook
- For Study Record Managers

HHS Office for Human Research Protections

- Mini-Tutorials

National Institutes of Health (NIH)

- Training & Resources - NIH Clinical Trial Policies
- Human Subjects Research
- Clinical Trial Requirements for Grants and Contracts

American Society of Clinical Oncology (ASCO)

- Clinical Trial Resources

Association of Clinical Research Professionals (ACRP)

- Staff Training
- Certifications

Collaborative Institutional Training Initiative (CITI)

- Courses

Operational Strategies for Accrual of Racial and Ethnic Minorities to Clinical Trials

A recent article by Regnante and colleagues describes an operational framework for addressing common barriers to clinical trial enrollment for patients from racial and ethnic minority groups. Eight U.S. cancer centers that are successful in achieving greater accrual of patients from all major racial and ethnic minority groups were selected to participate in the study. Selection criteria were developed by the National Minority Quality Forum and the Sustainable Healthy Communities Diverse Cancer Communities Working Group.

During a 12-month period, these cancer centers reported accrual rates of between 10 and 50% for these patient populations. Six of the eight centers are NCI-designated cancer centers; five are ACCC-member programs. For the study, comprehensive interviews were conducted with 14 leaders from these programs to identify operational strategies employed that support clinical trial participation from these under-represented patient groups.

The interviews revealed strategic operational features common to all eight centers:

- A metric collection and reporting approach

- Databases housing racial and ethnic minority population data accessible to research staff
- Deliberate operational standards that support access to healthcare innovation
- Sustainable inclusion standards in cancer research
- Practices that help racial and ethnic minority patients in maintaining their participation for the duration of the clinical trial
- Strategies to shorten recruitment time
- Identification of low-resource strategies for racial and ethnic minority group accrual
- Commitment to support both patients and providers as "key influencers" of patient recruitment to clinical trials.

The article outlines replicable initiatives employed by the cancer centers, in particular, for increased access to precision medicine trials. "This included having the right people, processes, and technological capabilities to ensure inclusion of racially, ethnically and otherwise diverse populations in clinical trials," the authors state. Examples include:

- Hollings Cancer Center is partnering with The Best Chance Network in an initiative that embeds volunteer, breast cancer patient navigators in a mobile health unit enabling immediate support for underserved patients.
- The Henry Ford Cancer Institute, through a partnership with Synapse, is leveraging technology to streamline molecular profiling and precision diagnostic requirements to identify all patients eligible for precision-medicine studies.
- Through its EMR, the Harold Simmons Cancer Center at UT Southwestern Medical Center is capturing race and ethnicity data at the clinic level. These data are integrated with the clinical trials management system so that patient demographics can be tracked, reported, and linked to clinical trials for which individuals may be eligible. The "Count Me In" campaign empowers patients to select "opt in" for potential clinical trial participation through their MyChart patient portal.

Leadership from the eight cancer centers also share a selection of low-resource strategies for accrual of ethnic and minority patients in clinical trials. Read the article.

Increasing Awareness of Implicit Bias

In January 2020, Shantanu Agrawal, MD, MPhil, and Adaeze Enekwechi, PhD, co-authored a *Health Affairs* blog urging that the healthcare delivery system face up to its own contributing role in health disparities. Dr. Agrawal is president and CEO of the National Quality Forum (NQF). Dr. Enekwechi is president of IMPAQ, the holding company of IMPAQ International, Maher & Maher, and ASCEND. Previously, she served as the associate director for health programs at the White House Office of Management and Budget under President Barack Obama.

"It's Time to Address the Role of Implicit Bias Within Health Care Delivery" contrasts factors external to the healthcare system, e.g., social determinants of health, that can be addressed through policy measures with implicit bias, a driver of disparities that is internal to the healthcare delivery system. "Medicine and health care act as if we have no role in producing or promulgating health disparities but instead are simply responding to them," the authors write. The blog is a call to action that outlines

specific short-term and longer-terms steps stakeholders in the healthcare delivery system can take to address implicit bias.

Integrating bias training "in medical, nursing, and other allied health schools, as well as in hospitals and delivery systems," is a critical first, the authors urge. "All clinicians and personnel interacting with patients should receive this training so they are better attuned to their biases and equipped with skills and tactics to address them."

Understanding implicit bias has been the focus of Project Implicit. Founded in 1998 by three scientists – Tony Greenwald (University of Washington), Mahzarin Banaji (Harvard University), and Brian Nosek (University of Virginia) – Project Implicit is a non-profit, international collaboration among researchers interested in implicit social cognition, i.e., thoughts and feelings outside of conscious awareness and control. The project seeks to educate the public about hidden biases while also developing a "virtual laboratory" for collecting data on the internet. Visitors can choose from a series of online Implicit Association Tests (IATs) that aim to reveal implicit biases that may affect perceptions, judgments, and actions. However, the tests are not considered to yield results on an individual's biases and behaviors based on just one test. Learn more.

Practical Approaches for Making Clinical Trials More Diverse

The Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard is hosting the "Leaning In" webinar series on practical approaches to improving diversity in clinical trials. The October 28 webinar focused on Workforce Development, and featured presentations from Racquel W. Bruton, Senior Clinical Operations Lead, Biogen; and Karen M. Winkfield, MD, PhD, Executive Director, Meharry-Vanderbilt Alliance. The discussion covered:

- The opportunities to train clinicians and healthcare providers on cultural humility and implicit bias
- The importance of a diverse participant pool in clinical research
- Strategies to improve workforce diversity
- Tips for clinical trialists on how to use and adapt the MRCT Center's Guidance Document and Toolkit to evaluate and enhance workforce development

Webinar recording and slides are available here.

Research Perspectives: A Conversation with Paul J. Hesketh, MD, FASCO

ACCC's journal, *Oncology Issues,* is featuring a series of articles describing how community oncology is engaged in closing the gap in cancer research. One model, successfully underway at Lahey Health Cancer Institute in Burlington, Massachusetts, is partnering between the Beth Israel Lahey Health system and affiliated hospitals to expand access to clinical trials for patients in their home communities. For an upcoming article, *Oncology Issues* spoke with Lahey Health Cancer Institute Director Paul J. Hesketh, MD, FASCO. Dr. Hesketh is Director of the Sophia Gordon Cancer Center and Director of Thoracic Oncology at Lahey Hospital & Medical Center, and a Professor of Medicine at Tufts University School of Medicine. He is a member of the Executive Leadership Group of the SWOG Lung Committee and chairs a subcommittee focused on community provider engagement. In an excerpt

from the interview, Dr. Hesketh shares his perspective on why clinical trials in the community are critical.

Q: You are a passionate advocate for community engagement in clinical research. Can you share your views on why this is critical?

Dr. Hesketh: We've had some remarkable success stories in recent years in improving our treatment options for our patients with cancer. Clearly, there are a number of factors that have gone into that. One of the most critical factors is our ability to complete key clinical trials, evaluating these innovative treatment approaches. Despite the fact that we've made some progress we still do a relatively poor job of enrolling patients into cancer clinical trials in the United States.

The reality is the majority of patients in the United States treated for cancer are not treated in the bigger, urban academic cancer centers, they are treated in community settings. If we are really going to increase the proportion of cancer patients that get onto clinical trials, we need to figure out a way to successfully reach out to the sites of care where they are getting treated, which, again, for the majority is in the community. This is something that we feel very passionate about at Lahey. It is something that SWOG has been very committed to as well. I'm a member of the Executive Leadership Group of the SWOG Lung Committee, and I also serve as chair of a subcommittee of the Lung Committee that was specifically chartered to better engage community oncologists in clinical trials.

Q: What contributes to successful engagement of community providers in clinical trials?

Dr. Hesketh: The most critical thing in my mind is selecting the right type of clinical trial for the community. Trials that are sponsored by the NCI NCTN groups are really ideally designed to be executed in the community setting.

Q: What is it about the trial design that makes them a particularly good fit for the community?

Dr. Hesketh: Many of the NCI NCTN trials are Phase III trials where you are basically taking a standard of care treatment and then trying to improve upon it with a new agent or a new approach. Trials have become somewhat more complex overtime as increasingly the cooperative groups are partnering with pharma, to evaluate more newer agents. Some of those trials may even lead to registration, so they are more complicated. However, historically they've been less complicated than a pharma-sponsored trial where you often have to do a lot of pharmacokinetics and the data management requirements are much more rigorous. It's been much more difficult to do those kinds of trials in the community setting where you don't have the infrastructure to support that.

I think the NCI NCTN trials by design have really been set up in a way to maximize community-based participation by, if possible, limiting some of the complex issues that make the pharma trials so challenging at times to do.

Q: Would you comment on the impact of the COVID-19 pandemic on cancer clinical research?

Dr. Hesketh: Clearly COVID-19 has had a devastating impact both medically and economically worldwide. It has been a major damper in terms of clinical research. [Despite this] a positive development—from a general care standpoint—has been the ascendency of telehealth.

Of necessity it [telehealth] became utilized to an enormous extent overnight. This technology has made its way into clinical research as well because we realized that a lot of the things, in terms of assessment, that previously required in-person visits could be done remotely. There has been a loosening of some of the very restrictive requirements that NCTN, other government-sponsored trials, and even pharma trials had previously. My hope is that [these changes] will outlast the pandemic, that we'll learn from this experience, and that maybe things can look slightly differently going forward. I think that would be another advance that would really increase the likelihood of success—if we could mandate fewer in-person visits, more virtual visits, and more virtual education about the clinical trials. Maybe that's one positive coming out of this pandemic…that we've learned we can do clinical trials a little bit differently, and perhaps, with fewer logistical challenges.

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.