



Closing the Access Gap: A Message from the President's Task Force

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As we look at how community oncology can close the gap in cancer research, a critical piece of the puzzle is improving access to trials for those living in rural areas. This issue of the Research Review features interviews with oncology providers who are succeeding in making clinical trials an option for patients in rural communities. The challenges are many: geography, health and economic disparities, a lean (or lack of) oncology workforce in many regions, trial eligibility criteria, costs, and provider bandwidth, among others.

The ASCO 2020 Oncology Workforce report snapshot provides a by-the-numbers perspective:¹

- 1 in 6 Americans live in rural areas.
- More than half (66%) of rural counties have no oncologist.
- 32 million Americans live in a county without an oncologist.
- Only 11.6% of oncologists practice in a rural area.

Patients in areas with no oncologist must travel for cancer care. For those seeking access to clinical trials, the travel burden is likely even greater, as is the cost (transportation, lodging, meals) and loss of valuable time from work, loved ones, and family responsibilities. Today, 14% of those in rural areas (in particular, Native American and Hispanic populations) live more than 180 minutes from an NCI-designated cancer center or a satellite of such a facility.² In rural communities that do have an oncology practice, often these are smaller facilities that lack the resources to support clinical trials.

In addition to workforce and geographical constraints, challenges to clinical trial participation in rural areas include:

- Shifting demographics across the U.S. Some minority populations, such as Latinx and American Indian populations, comprise a significant segment of rural health communities. From 2000-2010, the population of rural Hispanics increased by 48% and rural Native Americans increased by 8%.³
- Social, economic, racial, and ethnic disparities in rural patient populations are associated with higher co-morbidities and mortality.⁴ Individuals with co-morbidities may not meet trial eligibility requirements. Variable insurance coverage (i.e., where there is limited provider participation in the health plan) or lack of coverage may also impede trial participation.
- When patients living in rural areas are able to enroll in a study, they are likely to face more transition-in-care obstacles. For example, on returning home between clinical trial treatments, the only option for follow-up care and side effect management may be with a non-oncology provider.

These challenges are daunting but not insurmountable. Some solutions for making clinical trials accessible for rural communities are already underway; others are close at hand. For example:

- Partnering with an academic medical center or large community hospital oncology program to extend clinical trials and clinical trial support to their communities. Because many of the administrative duties are managed centrally, the burden on smaller facilities is reduced. This approach, already deployed through a number of clinical trial networks across the country, could be expanded with additional funding.
- Leveraging telemedicine. The COVID-19 public health emergency (PHE) has demonstrated how telemedicine can be used to resolve a number of the access issues cited above. During the PHE, the NCI and FDA have permitted study treatment visits via telehealth and telephone and e-consenting have been used. Advocacy to allow these practices to continue after the PHE as a strategy for reducing disparities in clinical trial access is essential.
- Continuing trial operations' flexibilities allowed during the PHE. During the pandemic, some examinations for clinical trials have been conducted by local providers rather than study teams. This should also be considered for continued practice post-COVID. Another flexibility allowed by the FDA and NCI during the PHE is permitting oral study drugs to be shipped to patients' homes. This would also benefit rural patients on clinical trials post the pandemic emergency.
- Connecting specialists with primary care providers (PCPs) in rural areas through telemedicine to allow for interprofessional management of patients who are on clinical trials. This could be between an academic and community oncologist or between an oncologist and rural community PCP or advanced practice provider. Another model might be intermittent patient visits to a larger medical center with the local provider conducting interim visits and possibly delivering treatment under the supervision of an investigator and research team located remotely.

- Enabling more virtual reach into rural communities by expanding broadband and access to devices that support virtual care.
- Engaging with local community resources, including community health workers, and partnering to increase support for patients on clinical trials to increase education about and acceptance of clinical trials by rural populations.

Community oncology has an essential role to play in increasing access and diversity in clinical trials. ACCC invites members to share their suggestions for improving trial access in rural areas on the ACCCeXchange online forum.

References

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Improving Access to Clinical Trials in Rural Areas

Over the course of his career in medicine, oncologist Jack Hensold, MD, has filled many roles. Before joining Case Western Reserve University in Cleveland, he was an instructor of medicine at Harvard Medical School and a visiting scientist at Massachusetts Institute of Technology. At Case Western, he served as an associate professor of medicine and ran a research lab funded by grants from the National Institutes of Health, the American Cancer Society, and the Veterans Administration. During his years at Case Western, he became director of the hematology and medical oncology fellowship program and chaired the Scientific Review Board for the American Cancer Society in Ohio. Having studied, lived, and worked in large urban academic medical centers in Chicago; Madison, Wisconsin; Boston; and Cleveland, in 2004, he decided to make a lifestyle change and relocated to southwest Montana. Since that time, Dr. Hensold has been caring for patients at the Bozeman Health Cancer Center in Bozeman, Montana.

Montana is the highest proportion rural state in the Western region of the U.S.; nearly half of the population (43.6%) is rural. The total number of rural residents in the state is slightly less than half a million (442,718).¹

Despite significant challenges, clinicians at Bozeman Health Cancer Center continue to make clinical trials available to their patients.

The biggest issue: Access to an adequate number of trials that match well with the local patient population. “We serve communities as far as 110 miles away and those patients have probably equal opportunity to participate in trials as do the patients who live in Bozeman, per se, even though 110 miles is a good distance. I think patients in Montana have come to accept the fact that they need to travel to get their healthcare. So, they will travel to our center if they need to be on a clinical trial, as well as to get standard therapy. I think the geography, which is daunting, is just an accepted part of life. . . . The bigger part of the challenge to getting patients on clinical trials is the limited access to trials here as opposed to larger cities where there is a much broader range of trials available.”

Despite affiliation with an academic medical center and participation in the [Montana Cancer Consortium](#) through which the practice is engaged with the National Cancer Institute’s Community Oncology Research Program (NCORP), the discrepancy between available trials and eligible patients persists.

“I highly value our association with NCORP,” said Dr. Hensold. One benefit the partnership brings is NCORP’s centralized administration which provides assistance with the myriad administrative responsibilities that are a requirement of clinical research studies. Dr. Hensold is a supporter of NCORP studies. “I think the trials that are offered through the NCORP are well-designed trials asking good questions about how to manage patients clinically. The difficulty, frankly, is that we just don’t have enough trials that are applicable to the general patient population.”

As an example, he describes the challenges faced in matching a breast cancer patient with a trial available in his community. “We see approximately 140 new breast cancer patients a year, and we frequently have no trials available that any of those patients are eligible for . . . So we’re trying but . . . I can’t remember the last time we had a breast cancer patient go on a NCORP trial simply because of the limited number of trials and the strict eligibility, because you’re trying to get a well-defined patient population to ask a really clean question, so it’s just really difficult.”

For Bozeman Health Cancer Center patients currently enrolled in clinical trials, the increased capability to use telehealth during the COVID-19 Public Health Emergency (PHE) has been a boon. “It absolutely has helped the patients we have been able to get on trials,” Dr. Hensold said. “We have greatly expanded our use of telehealth. [During the pandemic] about 80 percent of our clinic visits were via telehealth and that extended to the patients in the rural areas and the patients who were far distant. And to be able to do so, for the limited number of patients we had on clinical trials, did allow us to have that clinical trial visit as telehealth, too. So, it was a great advantage to us.”

When clinicians are able to offer a clinical trial, patients are generally interested, Dr. Hensold said. Often patients want access to the types of cutting-edge treatments that are most often

offered through pharmaceutical trials. However, industry trials require a robust research infrastructure that is costly and requires clinician consensus on making a commitment to conducting research—the process of building such a program takes time. With an increasing number of trials focusing on targeted therapies, identifying patients who meet study eligibility criteria is becoming an even greater challenge.

One potential solution, says Dr. Hensold is to bring together oncology groups in the state that are all trying to offer pharmaceutical trials. “Why couldn’t we do this as a separate consortium? I think that could be part of the answer.” Through this collaboration, a cancer program that is able to offer an industry trial could serve as a single study site but could tap into a larger pool of patients, through the combined groups. “It would increase access to clinical trials for all of us,” says Dr. Hensold. Such a consortium could also provide educational benefits, bringing providers together to discuss research and available trials on a regular basis.

In the context of the present healthcare landscape, Dr. Hensold, who is current president of the [Montana State Oncology Society](#) and recently contributed to a [series of podcasts](#) on rural cancer care, adds a final note of caution. “There’s a movement toward more and more consolidation of cancer care into larger centers which puts it [the care] farther and farther away from rural communities. Doctors who are specialists are much more comfortable working in a large group for many reasons.”

“We are not a big center. We have five oncologists right now. To get to the point that we could support the infrastructure for clinical trials took a while. The ability to offer trials is really going to continue to be focused in larger centers, which by definition are not going to be rural. So now you get into the access to cancer care problem for patients in general, rather than trials specifically. Rural areas suffer from the fact that specialty care is consolidated into larger centers. Clinical trials—where you actually have large numbers of clinical trials—are consolidated into even bigger centers. That amplifies the access problem. If you want to put patients on clinical trials, you need a large number of trials because you need to make sure [that you have studies that match the population of patients you care for]. As we consolidate care from small into medium-sized centers and clinical trials largely into large centers, it amplifies the access problem.”

Reference

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A Focus on Targeting KRAS G12C in NSCLC

A member of the RAS gene family, KRAS G12C is a mutation that occurs in multiple solid tumor types. Of patients with non-small cell lung cancer (NSCLC) in the U.S., about 13% have the KRAS G12C mutation. This cancer-driver is also found in 3-5% of individuals with colorectal cancer and in about 1-2% of other solid tumors.

Developing targeted therapies takes years of work and, as in the case of the KRAS G12C mutation, those years can turn into decades. But results from the CodeBreaK 100 clinical trial [published](#) in the September 24 New England Journal of Medicine and shared in an oral presentation at ESMO 2020 in September, support the promise of the KRAS G12C inhibitor sotorasib, as a potential first-in-class new therapy.

The [CodeBreak 200](#) phase 3 trial of sotorasib compared with docetaxel, in previously treated patients with NSCLC having the KRAS G12C mutation, is currently enrolling patients with a goal to accrue about 650 global participants.

Virginia Cancer Specialists, a large, multisite practice located in Northern Virginia is a study site for the CodeBreaK 200 trial. Medical oncologist Alex Spira, MD, PhD, FACP, Director of the Virginia Cancer Specialists Research Institute, explains why the study is a priority at his practice.

“These are patients with an unmet need. CodeBreaK 100 [the phase I dose finding single arm study], showed some very promising results, but the mandate is still to proceed on with the randomized study to show at least equivalence if not superiority in efficacy and tolerability compared to the standard of care which is docetaxel. Results from the phase 1 trial show that the drug is active and well-tolerated.”

Even though the data presented at ESMO were “phenomenal,” Dr. Spira said that misaligned expectations have created a challenge because some are comparing the data to other targeted therapies such as EGFR mutations treated with osimertinib or ALK translocations treated with alectinib, brigatinib or lorlatinib. This fails to consider that CodeBreaK 100 is data from a “first-in-class drug” in heavily pre-treated patients said Dr. Spira. “The response rates are not as good nor as durable as those other targeted mutations. That was not the expectation. It’s a first KRAS inhibitor of anything and certainly of KRAS G12C. For NSCLC patients with the KRAS G12C mutation, “it’s a huge first step,” he said. “That’s why the randomized study needs to be done to show the efficacy.”

The U.S. study sites for the CodeBreaK 200 trial include a large number of community locations which is exciting Dr. Spira says, “because we’re going to look at much more of a real-world population both in patients that enroll, in ethnicity, and in economic diversity as well. It’s what we should all be striving toward [in terms of] study enrollment.”

Other drugs targeting the KRAS G12C mutation are in the pipeline. Clinical trials are the only way to propel the next generation of these drugs forward. “Three percent of patients nationwide are enrolled into cancer studies. If we increase that by just another 3%, we can double it. That can only happen with non-academic community-based physicians either enrolling or referring patients to enroll in studies and encouraging people to do it,” said Dr. Spira.

When patients on a study have a meaningful response, “there is nothing better than that,” he said. “We’ve seen people travel hundreds of miles to come to our office to get access to—not only this trial but other studies—what is more rewarding than that? To tell somebody that they’ve gotten a drug on clinical study that’s not even FDA approved and 300 people in the United States have gotten—and had a meaningful, durable response. As an oncologist and a researcher, it doesn’t get any better than that.”

What Works Best in the Real World?

Research studies on cancer prevention and screening provide evidence on efficacy of interventions. Clinical guidelines, USPSTF recommendations, and guidance from professional societies establish criteria for whom to screen and when. Implementation science research assesses how best to integrate these interventions into healthcare practice.

Implementation science is something Electra Paskett, PhD, is passionate about. Dr. Paskett is Director of the Center for Cancer Health Equity at the Ohio State University Comprehensive Cancer Center (OSUCCC). She is the Marion N. Rowley Professor of Cancer Research; Director, Division of Cancer Prevention and Control, Department of Internal Medicine, College of Medicine; Professor, Division of Epidemiology, College of Public Health; Associate Director for Population Sciences and Community Outreach at the OSUCCC.

The Center for Cancer Health Equity is the community outreach and engagement arm of OSUCCC. The 17-member staff, which includes patient navigators and community health workers, are matched demographically to the different populations served by the cancer center, which include underserved, minority, and marginalized populations. Center staff establish connections in the community and collaborate with more than 240 community-based organizations across the state to conduct outreach, education, screening, and provide continuum of care navigation. This provides support for patients from cancer prevention education through the screening process and includes help overcoming any economic and/or logistical barriers to receiving the recommended screening test(s). If there is an abnormal finding, the care continuum navigation process follows the patient through follow-up and treatment. “It’s a very close tie between the navigator who is at our center and the community health worker who works out in the community,” explains Dr. Paskett.

An overall population health concern is the ripple effect that the COVID-19 public health emergency (PHE) has had on cancer screening rates. In an editorial published in *Science*, NCI Director Norman E. Sharpless, MD, warned of the potential downstream consequences of

the delays and decline in cancer screenings (due to COVID-related priorities for imaging services and healthcare staff, reduced schedules during Phase 1 closures, flatten-the-curve restrictions, and other factors):

There already has been a steep drop in cancer diagnoses in the United States since the start of the pandemic, but there is no reason to believe the actual incidence of cancer has dropped. Cancers being missed now will still come to light eventually, but at a later stage (“upstaging”) and with worse prognoses. . . . There can be no doubt that the COVID-19 pandemic is causing delayed diagnosis and suboptimal care for people with cancer.¹

Further, the racial and ethnic populations that have experienced a disproportionate burden of COVID are also the populations that often are not having recommended cancer screenings. According to the recently-released American Association of Cancer Research (AACR) Cancer Disparities Progress Report 2020: “People who are not up to date with recommended cancer screenings are disproportionately found among segments of the US population that experience cancer health disparities, including racial and ethnic minorities.”²

In the context of the COVID PHE, moving the needle on cancer screening rates for Black and African Americans, Hispanic and Latinx populations, and other racial and ethnic minorities is more critical than ever. Cancer screening can help reduce cancer incidence, reduce incidence of advanced disease, reduce treatment-related toxicity and adverse events, and reduce cancer mortality.²

The AACR report concludes: “Identifying strategies to increase cancer screening awareness, access, and uptake among those for whom screening is recommended is an important step toward achieving health equity.”²

At the Center for Cancer Health Disparities, Dr. Paskett and colleagues design and conduct community-based participatory research studies with an implementation science focus. In a recent conversation with ACCC’s Research Review, Dr. Paskett described three studies: a large comparative effectiveness study of education on breast cancer screening that is nearing completion; a multi-year ongoing study underway with the University of Kentucky, West Virginia University, and the University of Virginia that focuses on cervical cancer prevention in Appalachia; and a study launching in October that aims to address higher death rates from breast cancer in African American women.

Nearing completion is the large CER study which recruited women from every rural county in Ohio and Indiana. Because all recruiting was done virtually, through Facebook, the COVID PHE did not slow the recruitment process. The study recruited women in need of breast, colon, or cervical cancer screening. “We recruited women 50 to 74 years of age, doing eligibility screening over the phone. We sent them a questionnaire to fill out and a medical release form. We got that back in the mail, and then contacted the clinic to get validated in-

formation on if they were up to date with screening. If they needed any combination of those three tests, they were randomized to one of three [study] arms. Group one received usual care. Group two received a DVD to take home and watch. The DVD provided education so that the participants could identify the test(s) needed and listen to vignettes from women from rural areas who faced similar barriers to obtaining screening. Group three received the DVD and a phone call from a navigator. For this group, the navigator, who was from a rural area, provided barrier counseling to identify and address the obstacles the women faced in completing the screening needed. The study is looking at which intervention was the most effective for the women.”

An ongoing, multi-year project will deploy implementation science research learnings to address cervical cancer prevention in the Appalachia area of Virginia, West Virginia, Ohio, and Kentucky. For this large grant-funded project, researchers are working with nearly 40 Federally Qualified Health Centers (FQHCs). “The first year we were doing some qualitative work, informant interviews, and finalizing our interventions,” Dr. Paskett explains. “We’re about ready to kick off our programs in the clinics next month. We’re now having to do all this virtually. We will be introducing three programs into the clinics that focus on cervical cancer prevention. The first one will be a program to help the clinics increase the uptake of the HPV vaccine. The second focuses on smoking cessation. The third is on cervical cancer screening including, for women who won’t come into the clinic for cervical cancer screening, mailed self-test kits.”

The three programs will be rolled out sequentially over one year, followed by teaching the clinics how to bundle all three into a cervical cancer prevention program. Half the clinics will participate this year, and the remainder will launch the process next year.

In October, the center will launch an initiative, funded by the American Cancer Society, Pfizer, and Pelotonia, focused on 12 counties in Ohio that have high death rates for African American women with breast cancer. The project will engage community partners and several interventions including the use of telephonic navigators to assist women in obtaining genetic testing counseling, accessing genetic testing, and mammograms. The OSUCCC Center for Cancer Health Disparities will provide education for the FQHCs on effective ways to focus on breast health and who, as well as how, to refer for genetic counseling and testing (if needed), mammography, and how to follow-up when a positive finding is reported.

Applying implementation science research to disparities in cancer screenings begins to address some of the barriers to coordinated care endemic in the fragmented U.S. healthcare delivery system. The AACR Cancer Disparities Progress Report 2020 notes that:

Increasing cancer screening rates alone will not eliminate cancer health disparities. We need to ensure that individuals whose screening tests show an abnormality receive follow-up testing and care in a timely manner.²

As Dr. Paskett explains, implementation science offers evidence-based practices for helping healthcare providers understand the next steps, make the linkages, and adopt or adapt best practices for integrating these into existing workflows “The clinics we’re working with, they want to provide the best care for their patients. They care about their patients. They want them to live a long time. But nobody teaches them how to do this.”

Reference

1. Sharpless NE. Science. June 2020;368(6497):1290. DOI: 10.1126/science.abd3377.
2. American Association for Cancer Research. Disparities in Cancer Screening for Early Detection. In AACR Cancer Disparities Report 2020. Available at <https://cancerprogressreport.aacr.org/disparities>.

Related Resources

Joining *All of Us*

The National Institutes of Health (NIH) ambitious [All of Us study](#) launched in May 2018. The study framework grew from the final report of the Precision Medicine Initiative Working Group. The mission: to accelerate health research and medical breakthroughs and further enable individualized prevention, treatment, and care across all of the U.S. population. The aim: to enroll 1 million participants in the U.S. [Read the study protocol](#).

This large-scale observational cohort study is building a diverse database that researchers can access to inform their work across healthcare disciplines and diseases. One of [the study’s core values](#) is diversity. People from all walks of life, all areas of the country, and of varying health status are encouraged to participate. The program has been shaped with guidance from 22 community partners. To date, more than 80% of participants are from groups historically under-represented in biomedical research, according to the NIH.

Just one example of how All of Us participants are already helping advance knowledge is by completing the [COVID-19 Participant Experience \(COPE\) Survey](#), which will aid researchers in understanding of how the pandemic is affecting individual physical and mental health, daily activities, and communities.

A [special report](#) in the March 15, 2019 New England Journal of Medicine describes the study, which is intended to run for 10 years or more. People interested in joining the study can also self-enroll. Read about a just-announced [funding opportunity for new engagement partners](#).

Reducing Disparities in the Oncology Workforce

When it comes to cancer research, equitable access and representation are not just issues for

patients. Only one-third of oncologists are women,¹ and racial and ethnic minorities and women continue to be underrepresented in leadership and medical school faculty positions.²

To encourage greater representation of women in the oncology workforce, Dell Medical School at the University of Texas at Austin has launched a work experience program that reaches out to rising juniors and seniors at Title 1 schools in the Austin area. Created in collaboration with the Livestrong Cancer Institutes, the [Summer Healthcare Experience \(SHE\)](#) immerses young women in a weeklong program to learn about the oncology profession and how to navigate being female in a predominantly male workforce.

Referencing the aforementioned statistics in a keynote presentation at the ACCC 37th [Virtual] National Oncology Conference, Nick Smith Stanley, MBA, Associate Director of Administration and Strategic Planning, Dell Medical School, said, “I want you to be uneasy about the statistics, I want you to be uncomfortable about the stories, because uncomfortable is good. It allows us to start having a conversation, and these conversations can lead to real change.” [Watch his presentation here.](#)

On a recent episode of the CANCER BUZZ podcast, ACCC spoke to two of the young women who participated in the SHE pilot program in 2019, Ximena Cruz and Korena Martinez, about the value of their hands-on experience. Kristen E. Wynn, Senior Administrative Program Coordinator, Livestrong Cancer Institutes, also shared how this collaborative program came to be and steps that programs around the country can take to improve the representation of women in the oncology workforce. [Listen to the show here.](#)

Reference

1. ASCO. Key Trends in Tracking Supply of and Demand for Oncologists. August 2020:8.
2. American Association of Medical Colleges. *Diversity in Medicine: Facts and Figures 2019*. Available at <https://aamc.org/data-reports/workforce/report/diversity-medicine-facts-and-figures-2019>.

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 acc-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 25,000 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 acc-cancer.org or call 301.984.9496. Follow us on [Facebook](#), [Twitter](#), [LinkedIn](#), and [Instagram](#); read our blog, [ACCCBuzz](#); and tune in to our podcast, [CANCER BUZZ](#).