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4 Increasing Clinical Trial Accrual Through Implementation of a Clinical Trials Navigator

Adding a clinical trials navigator to this practice team required a business case that demonstrated return on investment. After a successful onboarding, this navigator is now the point person to help identify patients appropriate for clinical trials and to help busy clinicians with enrollment criteria and trial selection.

By Alexander Spira, Mitul Gandhi, Marcy Sullivan, and Carrie Friedman

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Extending Our Conversations Beyond Live Meetings

BY MARK LIU, MHA

Recently had the opportunity to attend two oncology conferences: the 2023 Academy of Oncology Nurse and Patient Navigator Midyear Conference and the Getting Our Fair SHARE 2023 Conference to End Health Disparities. I enjoyed connecting in-person with those in the room and with others virtually about how to make greater impact and reach more patients among the diverse populations we serve. The energetic dialogue and inspiring stories are exactly why I know I have found my calling working in oncology. Reflecting on what I learned at these two meetings and how it aligns with the 2023-2024 ACCC President’s Theme, (Re)building the Oncology Workforce to Deliver the Next Generation of Cancer Care, it is clear that patient navigation is key to helping us deliver care that is more person-centered, more coordinated, and more equitable.

Meanwhile preparation for the ACCC 40th National Oncology Conference (#NOC), Oct. 4-6, in Austin, Texas, is well underway. It is a meeting I always look forward to and this year is no exception. Several sessions have already caught my attention, for example, the work that 2023 ACCC Innovator Award Winners Rochester Regional Health - Lipson Cancer Institute is doing to embed counseling in oncology and patient care clinics and Orlando Health Cancer Institute is doing to leverage technology to improve patient triage and evaluation. From my own organization, Mount Sinai Health System, another 2023 ACCC Innovator Award winner, I look forward to hearing from radiation oncology leaders about the creation of the first advanced practice radiation therapist role in the United States and how that fits into a new model of inpatient care.

While few dispute the value of attending these types of meetings, most are asked about return on investment (ROI). A key ROI indicator is when important conversations are extended beyond the In-person meeting. And ACCC is doing just that in this edition of Oncology Issues.

The “Trending Now in Cancer Care: Part I” article, pages 11-30, summarizes all the great conversations and ideas from the deep dive workshops this past March at the ACCC 50th Annual Meeting & Cancer Center Business Summit (#AMCCBS). These facilitated discussions and the resultant ideas will help us all in our short- and long-term strategic planning.

Continuing the topic of trends, the chemotherapy drug shortage is a critical challenge facing the oncology community right now. On June 14, ACCC released an official statement on this issue, “encouraging members to report any drug shortages to the FDA. The more reports the agency receives, the better understanding it will have of where these shortages are occurring. Shortage notifications and updates may be reported to the FDA at drugshortages@fda.hhs.gov.” Meanwhile, as we look for long-term solutions, also in June, ACCC partnered with the Hematology/Oncology Pharmacy Association and the Association of VA Hematology/Oncology in a virtual round table where experienced pharmacists explored the management of drug shortages, offered valuable perspectives, and shared actionable plans to tackle these shortages. If you missed this event, watch the recording at: https://www.youtube.com/watch?v=tPHFiJIooDQ.

As our organizations continue to be agile in evaluating and navigating the current drug shortage, I want to thank all pharmacists for their monumental efforts. Remember: we are in this together and should continue to share resources and strategies with each other through venues like ACCCeXchange. ACCC’s member-only listserv at accc-cancer.org.
Investing in Our Oncology Workforce

OLALEKAN AJAYI, PHARMD, MBA

We live in a time of great progress in the field of oncology. Advances in research and development are leading to cutting-edge treatments that are allowing people with cancer to live long and healthy lives. Yet, this complex and evolving field is also one of the biggest challenges facing the oncology workforce. New treatments and new technologies mean that oncology professionals need to constantly learn and adapt to provide the best possible care for their patients. In addition to keeping up with the latest information on new treatments and technologies, oncology professionals must also be familiar with other factors that significantly impact patient care, including reimbursement models and regulations, restrictive payer policies, and sociodemographic barriers, such as transportation and food insecurity.

Another challenge facing the oncology workforce is the lingering impact of the COVID-19 pandemic, which has led to increased workload, stress, and burnout. In addition, delayed access to cancer screening during the pandemic means more patients are presenting with advanced cancers, placing further strain on the oncology workforce.

To overcome these challenges, we must reimage how we deliver care and invest in a workforce that is equipped and ready to provide quality patient care.

There are several steps we can take to prepare our oncology workforce for these challenges. First, we must invest in education and training. With new drugs and treatment modalities approved with increasing regularity, healthcare workers must learn how to effectively manage information. We must develop and operationalize innovative approaches that help cancer care teams navigate a vast amount of information and resources and ensure that they receive the right information at the right time.

Second, we must embrace technology to help us manage the administrative burdens that come with cancer care. For example, technologies, such as artificial intelligence, are proving vital in automating repetitive tasks and in providing clinical and business decision support. Smart use of technology promises to reduce the workload of cancer care teams and help these professionals work at the top of their licenses and capabilities.

Third, we must support our oncology workforce. This support means providing the resources these professionals need to do their jobs. It also means providing the mental health services that these professionals need to cope with the emotional challenges of working in oncology.

Finally, we must develop a new generation of leaders who can help build systems and think creatively about clinical and operational models that improve communication, collaboration, and the quality of life of our oncology workforce.

Under the auspices of my 2023-2024 Association of Community Cancer Centers (ACCC) President’s Theme: (Re)Building the Oncology Workforce to Deliver Next Generation Care, ACCC will be developing tools and resources to support all these efforts, including a new track devoted to workforce development at the ACCC 40th National Oncology Conference, October 4-6, 2023, in Austin, Texas. Sessions will address topics like developing an oncology pipeline, improving your recruitment efforts and processes, keeping up with compensation best practices, taking your recruitment program to the next level, hardwiring the employee relationship through effective leadership, and more.

I hope to see many of you in Austin because—despite the challenges facing the oncology workforce—it is a time of hope and optimism. The lessons we have learned from the COVID-19 pandemic provide unique opportunities to rebuild a stronger and more nimble oncology workforce. I am excited to be a part of this journey. I am excited to be a part of reimagining the oncology workforce. I am excited to be a part of the future of oncology.
Increasing Clinical Trial Accrual Through the Implementation of a Clinical Trials Navigator
Virginia Cancer Specialists, PC, is a large, multidisciplinary, community-based oncology practice in Northern Virginia, with expertise in medical, surgical, and radiation oncology. The practice’s footprint spans 9 offices throughout the region, anchored by a central cancer center in Fairfax, Virginia, and is strategically positioned to meet the growing needs of the community. Currently, there are more than 35 physicians and advanced practice providers (APPs) on staff, as ongoing recruitment and expansion efforts continue to achieve the practice’s goal of delivering cutting-edge, world-class cancer care to patients close to home.

Critical to this effort is the Virginia Cancer Specialists Research Institute—one of the largest research programs on the East Coast. This clinical trials program investigates novel agents across the full spectrum of solid tumors and malignant hematologic diseases, spanning from early phase and first-in-human studies to late-phase protocols. The research institute was founded in 1997 under the supervision of Nicholas Robert, MD, a founding partner of Virginia Cancer Specialists. The first activated clinical trial was AOR 97-001, which looked at using 2 doses of gemcitabine as a second-line treatment for metastatic non-small cell lung cancer. At the time of its inception, the research institute comprised 3 team members—a clinical research coordinator, data coordinator, and regulatory coordinator. Alexander Spira, MD, PhD, then assumed the directorship of the Virginia Cancer Specialists Research Institute in 2007 and was tasked with growing it based on the foundations laid by Robert. Spira’s passion for research and continuous desire to provide better care to patients are evident in the program he has nurtured, which now includes 71 full-time research staff members and more than 170 clinical trials (about half are phase 1 studies).

Additionally, the Virginia Cancer Specialists Research Institute is a key member of US Oncology Research, the research arm of The US Oncology Network, allowing our patients to participate in national and international studies and our providers to collaborate with leading cancer research institutes across the country. Parallel to its size, the scope of the research institute has widened, with incredible diversification of studies across different malignancies and increased inclusion of tumor-agnostic, molecularly driven protocols. In 2021, Mitul Gandhi, MD, joined the research institute as a codirector, overseeing its malignant hematology portfolio. Then, in 2022, M. Adham Salkeni, MD, FRCPC, was recruited as a phase 1 clinician investigator. Clinical trial accessibility has also grown to include the practice’s satellite sites with dedicated and local clinical research coordinators and an increased roster of subinvestigators. Since the inception of the research institute, Virginia Cancer Specialists, has enrolled over 3500 participants in more than 700 clinical trials, and the overarching goal remains: identifying clinical trials with promising novel agents that benefit patients in our community and continuing the mission of improving cancer care nationally.

Even with our robust program, we recognize the ample room for improvement that exists in enrolling more patients into clinical trials via the Virginia Cancer Specialists Research Institute. Although less than 5% of the adult oncology population is enrolled in clinical trials in the United States, the national oncology community aims to address health system-specific and patient-centric barriers in cancer research. Improved understanding of these factors is necessary to catalyze the development of initiatives by the Association of Community Cancer Centers (ACCC) and American Society of Clinical Oncology (ASCO), among other organizations, to help guide cancer programs and practices nationwide in breaking down these barriers to promote clinical trial accrual and increase diversity in participation that better reflects the demographics of the oncology population at large.

In 2021, The US Oncology Network announced its call for a “culture of research” grant opportunity with the goal of developing reproducible cancer research programs that promote increased accruals to clinical trials. Virginia Cancer Specialists was 1 of 4 organizations

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The goal is that the clinical trials navigator will act as the primary source of research information across the practice, including all satellite sites, and educate and act as a liaison to promote the research institute.

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BY ALEXANDER SPIRA, MD, PHD; MITUL GANDHI, MD; MARCY SULLIVAN, BSN, RN, OCN; AND CARRIE FRIEDMAN, BSN, RN, OCN
to receive the award for its proposal to create a new full-time position—the clinical trials navigator. “The clinical trials navigator has made a huge difference in accrual and patient and physician satisfaction,” Spira said. “It has provided patients with an accessible conduit to trial evaluation and entry, as well as helped providers navigate the complicated world of enrollment criteria and trial selection.”

To measure the effectiveness of the clinical trials navigator position, specific metrics will be developed (eg, overall site accrual, number of referrals to trials, and increases in enrollment by “low enroller” providers), compared to baseline numbers.

Realizing This Necessary Role
The concept of a clinical trials navigator was partly borne by reviewing the accrual patterns of the research institute. Of the approximately 35 oncologists at Virginia Cancer Specialists, historically, about one-third (11 oncologists) were participating in clinical trials. Of this subset, approximately one-third (3 oncologists) were enrolling patients into clinical trials consistently. Many of our providers and APPs, while quite interested in providing clinical trial options to patients, perceived the whole process as mystifying and complicated, despite the presence of dedicated, site-specific clinical research coordinators. The desire and willingness to refer patients to clinical trials, while evident, was clearly hindered by a lack of time and familiarity with the research institute’s protocols, as well as the logistical requirements of enrolling patients into a study. Given the demanding nature of oncology and the clinical responsibilities providers often feel, patients’ participation in clinical trials was not always at the forefront of treatment decision-making. Even with electronic aids, identifying appropriate clinical trials is a laborious endeavor for providers, who already have busy clinic schedules. Although our clinical trial coordinators are quite skilled, identification of trials and appraisal of relevant inclusion and exclusion criteria fell out of their purview and normal workflow. Moreover, these clinical trial coordinators are tasked with the day-to-day care of patients enrolled in clinical trials and lack the bandwidth to take on more responsibilities.

Spira and Gandhi say they believe that the most critical element to having a pervasive culture of cancer research at Virginia Cancer Specialists rests on the personal level. Although efforts, including provider-to-provider engagement, were conducted, these exchanges were too infrequent to catalyze substantive change in our culture. A clinical trials navigator would serve as an effective bridge to fill the knowledge gap of the research institute’s trial portfolio and coordination of patient-related logistics. More importantly, a clinical trial navigator can broaden the reach of the research institute’s leadership needs to directly engage with providers on a frequent basis to facilitate a desired change. In creating a clinical trials navigator role, we are confident that we can change the culture of research at Virginia Cancer Specialists.

Making the Business Case
It is expected that provider participation in clinical trials at Virginia Cancer Specialists will improve with this individualized support. Increased revenue from the rise in accrual will more than offset the cost of the clinical trials navigator’s salary. The navigator will also provide introductory education on clinical trials to patients and is anticipated to increase both provider and patient satisfaction scores. Although this role started as a pilot at the research institute, early validation suggests that it is a replicable model for all other sites in The US Oncology Network.

The goal is that the clinical trials navigator will act as the primary source of research information across the practice, including all satellite sites, and educate and act as a liaison to promote the research institute. This responsibility will require repetitive engagement with our providers.

The expectation is that the clinical trials navigator will enable us to increase accrual rates by approximately 10% to 20% over the next year. Additionally, we expect to decrease the number of providers who are considered to be “low enrollers” in cancer clinical trials. The responsibilities of the clinical trials navigator include as follows:

• Crafting specific and dynamic recruitment plans and identifying gaps in processes or training
• Making routine visits to all clinic locations for personalized assistance
• Assisting providers when they have questions about patient eligibility prior to consent
• Performing phone triage for referring providers and patients who are interested in a clinical trial
• Identifying, developing, and maintaining relationships with key contacts at each of the practice’s locations to facilitate timely fulfillment of accrual targets
• Attending research meetings
• Working with patients to answer their questions about clinical trial participation.

It is our expectation that the clinical trials navigator will have a significant and positive impact on clinical trial enrollment by bringing cancer research to the forefront of care for all our providers. Patient education provided by the navigator will help increase awareness of the research opportunities that exist and explain the research process and related timelines to participating patients. Regular provider engagement will not only benefit clinical trial accrual rates but also improve provider and patient satisfaction because we can offer additional treatment options. Facilitating assistance with clinical trial recruitment can also foster a more collaborative environment by giving providers greater support in navigating our research portfolio. Additionally, clinical trials will increase patient retention and network visibility.
To measure the effectiveness of the clinical trials navigator position, specific metrics will be developed (eg, overall site accrual, number of referrals to trials, and increases in enrollment by “low enroller” providers), compared to baseline numbers. Based on estimates per patient revenue, our plan is to measure the benefits of including this navigator on the team against the cost of staffing the position. Provider satisfaction will be assessed by a survey at baseline and later compared to results 1 year after full implementation. See Figure 1, above, for a detailed infographic on the implementation of the clinical trials navigator role.

Onboarding and Making the Role Her Own
As a result of receiving a US Oncology Network grant for improving the “culture of research,” Carrie Friedman, BSN, RN, OCN, was hired in March 2021 to help implement the project activities and meet predefined goals. With more than 20 years of oncology nursing experience, Friedman was new to the cancer research space but joined the team with excitement and passion to make a positive impact on increasing clinical trial accruals at Virginia Cancer Specialists. Friedman’s first task was to meet with each provider to assess their needs, challenges, and desires as they related to clinical trial accruals. Virginia Cancer Specialists providers have since embraced the clinical trials navigator role and offered consistent feedback that they do not have the time to identify available clinical trials for patients. That is where Friedman has stepped in to support providers; she identifies available clinical trials with help from Spira, Gandhi, and Salkeni, as needed, and communicates these options to all providers. Our providers are now routinely reaching out to Friedman with their referrals, and our referral numbers have steadily increased over the past year as a result (Table 1, page 8). Several of the previously identified “low enroller” providers are now consistently referring patients to clinical trials.

Friedman has also developed innovative mechanisms for providers, so they now have heightened awareness of the Virginia Cancer Specialists Research Institute portfolio. She develops and maintains active lists of available clinical trials, grouped by disease site, making it an easy to access reference for providers. Further, Friedman creates bimonthly newsletters for the practice to raise awareness of newly available clinical trials, the research institute’s successes, and general oncology research-related education, which has been well received by our care teams. Friedman meets with Spira on a weekly basis to ensure all recent patient referrals are discussed, which is crucial to providing updated information to patients as needed. Finally, Friedman attends meetings with both the phase 1 and phase 2/3 clinical trials teams to ensure they are aware of any new information relating to their roles. Figure 2, page 8, details the role Friedman has played in ensuring successful implementation of the clinical trials navigator role.

Demonstrating Return on Investment
One of the most important aspects of creating the clinical trials navigator role is being able to financially justify the position. Prior to hiring Friedman, the team estimated that 6 accruals to 10 accruals per year to Phase I clinical trials would be necessary to justify the new position. Friedman met this goal very early on and continues to meet this goal monthly and, sometimes, weekly. This financial justification excludes the benefit the clinical trials navigator has brought to both our provider and patient satisfaction scores, which is equally important to the practice. Another common issue that came up early in 1-on-1 provider meetings is the timing of when patients hear from our research team after a provider discusses clinical trial opportunities with them. Often, some time passes before the clinical research coordinators, who complete prescreening and schedule appointments, reach out to patients. In turn, patients are anxious to hear from the research team and feel that they may have been forgotten about when they do not hear from the team for some time.

(Continued on page 9)
Table 1. Total Referrals to Clinical Trials, 2021 to 2023 (YTD)

Figure 2. The Role of the Clinical Trials Navigator

WHAT WE DID...

The Virginia Cancer Specialists Research Institute is, and will continue to be, a cornerstone of the organization. The research institute houses a robust early- and late-phase program.

1. Hired the clinical trials navigator, who started at the end of March 2021.
2. Met with all physicians to discuss the role of the clinical trials navigator and determine opportunities.
3. Created disease-specific summaries of all open clinical trials.
4. Developed monthly research newsletter for all Virginia Cancer Specialists staff.
5. Created easy access to Virginia Cancer Specialists clinical trial information for internal and external patients.
6. Created a clinical trials 101 class on the Virginia Cancer Specialists website.
time. To meet this need, Friedman now calls patients during this time to educate them on the enrollment process and timing of their appointments. Often, patients are grateful to hear from Friedman and learn about the process and timing of enrolling in a clinical trial. Due to the large volume of clinical trials at Virginia Cancer Specialists Research Institute, Friedman has also taken on screening all external referrals and coordinating the care of these patients to get them a consultation. And because of the increased number of external referrals to the research institute, Virginia Cancer Specialists has hired a second position to support the clinical trials navigator, just shy of 2 years into the full implementation of the role. Table 2, above, shows the total number of combined internal and external referrals from 2021, 2022, and 2023, and Table 3, above, illustrates the differences we have seen in internal versus external referrals for 2021, 2022, and 2023.

As mentioned earlier, Friedman sent out a survey to our providers early in her role and again several months ago. Although participation hit close to 50% on the second survey, the data gleaned shows that the clinical trials navigator has made a difference in referring and enrolling patients in clinical trials. It also shows that our providers are referring patients more often today than they did in previous years (Figure 3, right, and figure 4, page 10).

**Moving Forward**
Friedman has now been in the clinical trials navigator role for almost 2 years and has defined her role successfully. She receives referrals from providers practice-wide and identifies clinical trial opportunities that are appropriate for patients. Virginia Cancer Specialists Research Institute...
Institute’s portfolio of varied clinical trials continues to grow, attracting external patients from across the region and the country. One important responsibility that Friedman has taken the lead on is navigating these external referrals. Because all referrals go through Friedman, she has valuable understanding of all the patients being evaluated for clinical trials at the research institute. This task is critical as staff at Virginia Cancer Specialists rely on Friedman to provide patient status updates.

While there have been some challenges to overcome with the implementation of the clinical trials navigator role, processes have fallen into place over time. It is difficult for Friedman to spend dedicated time at all practice locations as often as she would like because of the volume of referrals coming in; however, by having a second set of hands to help, Friedman will now be able to make those essential visits. It has also been challenging to stay current on available clinical trials, with many openings and closings occurring monthly. This is when Friedman relies on Spira and Gandhi for support. Despite settling into the role, there will continue to be challenges to overcome, and one aspect of the role Friedman appreciates the most is the genuine willingness of Virginia Cancer Specialists providers and staff to support one another to benefit patients.

Alexander Spira, MD, PhD; and Mitul Gandhi, MD, are medical oncologists; Marcy Sullivan, BSN, RN, OCN, is director of research operations; and Carrie Friedman, BSN, RN, OCN, is a clinical trials navigator at Virginia Cancer Specialists, PC, in Fairfax, Virginia. For questions email: carrie.friedman@usoncology.com.

Reference
Trending Now in Cancer Care

Part 1

- Payer-driven challenges
- Patient engagement
- New care delivery models
- Staffing models and workforce issues
n past years, the Association of Community Cancer Centers (ACCC) fielded an annual “Trending Now in Cancer Care Delivery” survey to its membership to gain insights into challenges they face and—most importantly—solutions to address those challenges. Unprecedented challenges from a global pandemic, a 3-plus years public health emergency, and feedback that members did not have the time and/or resources to take this annual survey led ACCC to look for alternative ways to collect these data. In 2020, ACCC conducted a series of focus groups to produce the 2021 Trending Now in Cancer report. In 2023, ACCC hosted a series of interactive sessions at the ACCC 49th Annual Meeting and Cancer Center Business Summit (#AMCCBS) to collect insights and solutions into 8 key areas. Below, we take a “deep dive” into 4 of these topics. Look for “Trending Now in Cancer Care Part II” in Oncology Issues Volume 38, Number 5.

Staffing Models & Workforce Challenges

With most cancer programs facing workforce shortages, improving recruitment and retention, addressing burnout, and improving morale and resiliency are top of mind for leadership at all levels.

Facilitators

- Ellen Feinstein, RD, MHA, LFACHE, Vice President, Cancer Service Line Administration, Advocate Aurora Health
- Nathalie A. Lokker, PhD, MS, then-Global Head of External Affairs, GMA, Oncology Business Unit, AstraZeneca
- Krista Nelson, MSW, LCSW, OSW-C, FAOSW, Senior Oncology Social Worker and Program Manager, Cancer Support Services & Compassion, Providence Health & Services
- Barbara Schmidtman, PhD, Vice President, Operations, Corewell Health West
- Amy Smith, BSN, RN, Cancer Center Director, Ivinson Memorial Hospital, Meredith and Jeannie Ray Cancer Center

No-Cost or Low-Cost Tips for Cancer Programs With Fewer Resources

- Begin meetings with a moment of gratitude and regularly ask staff to share their “why” for working in oncology. Remember, empathy and authenticity are necessary to engage in meaningful dialogue.
- It is well-documented in the literature that most people leave an organization because of their leadership. As a leader, create time to meet regularly with each staff member. Ask important questions, like “share 1 thing I can help you with this month” and always enquire about job satisfaction. Listen to what is said. When problems arise, do not simply fix them on the backside, but let staff know the issue that is being addressed and why.
- Regularly survey staff about what would make them feel more connected to their team members and the cancer program. Be prepared to act on what is shared; be creative in holding activities with little to no costs.
- Practice “rounding with empathy,” with staff input into the frequency of this activity. To do so, employ empathetic connection
questions, keep communication direct and transparent, offer personal recognition, and adopt a model that is driven by staff—not leadership.

- Recognition should be structured and ongoing; it can also be as simple as an extra day of PTO (paid time off) or an Employee Appreciation Day.

- It is widely accepted that today’s physicians have a very different set of needs. To understand those needs, meet regularly—and individually—with every physician and listen to what they need. Often these are simple, low-cost requests like tweaking the clinic schedule of advanced practice providers (APPs) to allow physicians to see more patients or adjusting clinic hours to make sure that physicians can leave the clinic on time to participate in activities like hospital rounding.

**Strategies for Cancer Programs With Some Level of Buy-in and Resource Allocation**

- Hire additional APPs, medical assistants (MAs), and pharmacists to help with physician shortages and/or coverage gaps. Embedded pharmacists can take over many tasks managed by physicians, including chemotherapy orders, patient education, and side effect and symptom management.

- During physician shortages, hire locum tenens to help during recruitment efforts.

- Develop a pool of floating APPs and locum tenens (retired physicians are good candidates) to travel and fill in at clinic locations so physicians can take vacation and come back to a manageable clinic schedule.

- Leverage other team members to make it easier for physicians to do their business. This could mean hiring a clinical trials coordinator to perform all the administrative paperwork; hiring a medical assistant to be physically present in the exam and responsible for scribing; and/or ensuring that nurse navigators are screening patients before they are seen by physicians to identify potential issues and challenges and, when possible, triaging them to the appropriate staff member before the physician even enters the exam room—whether that may be a nurse for additional education or a social worker for distress or a financial navigator to help with transportation challenges. This type of staffing model and proactive planning requires process mapping.

- Adopt technology like Epic’s Signal feature, a collection of data that gives insight into the daily interactions of clinicians within the electronic health record (EHR), including how much time providers spend in the EHR outside scheduled clinic hours and how that time compares to their peers. Use technology to collect data on clinician workload and how they are managing in-baskets to better inform decisions around resource allocation.

- Improve access to mental health services. Consider partnering with an organization to offer therapy sessions. Many are available 24/7 to do an emergency assessment to make sure the individual is not in danger; others will ask what staff are looking for from therapy, identify needs, and then match these needs to vetted resources.

“I don’t have trouble getting my staff engaged—but my physicians! They tell me they are burned out, but they don’t want any strategies. I’m looking for tactics that others have employed to bring physicians into these conversations and help reduce their levels of burnout.”

“We use a technology platform to help run our tumor boards. It can also be used to connect patients to appropriate clinical trials. We made a promise to our physicians that once you register for this technology, learn it, and sign in and use it, it will make your lives easier. And it did.”

“You don’t always have to buy expensive technology. Sometimes you just have to be willing to listen and solve minor problems.”

“Our health care system recognizes a duty to improve the lives of our clinicians through technology. We have tools to monitor EHR use and identify those who are at risk of spending too much time in the EHR outside of clinic hours.”
“Many of our younger physicians are coming in with 6-digit educational debt—that’s a huge stressor.”

- Subscribe to apps, such as VITAL WorkLife, so that providers can access features like concierge services to help arrange for family travel, childcare, eldercare, financial counseling, peer coaching, and more.
- Create funding streams to create percentages of time that staff can devote to programs and processes that address burnout and build resiliency so it’s not just activities that they work on in the evenings or on weekends.
- Develop a Narrative Medicine Program that allows clinicians and staff to talk about, journal, and then share their experiences. This type of program can improve connection and morale.

Models for Well-Resourced Cancer Programs

- With staffing shortages responsible for much of the burnout experienced by cancer care team members, cancer programs need to look for long-term solutions like establishing partnership opportunities with local high school and colleges in the community to educate young people about oncology and build a pipeline of future workers.
- Providence Health instituted a Department of Compassion. This 4-person team developed a “Strengthening Compassion Program” of mindfulness exercises; peer-to-peer support opportunities; intensive care unit (ICU)-therapeutic touch; “Connecting Conversations;” leader toolkits; and a 12-session compassion curriculum based on existing literature and resources, including videos, exercises, and guidebooks. Clinics closed for 1 hour during regular hours to participate and clinic staff was trained to facilitate curriculum to increase scalability. Outcomes: burnout dropped from 55% to 46%; engagement scores went up and disengagement scores went down; patient experience scores went up significantly; and productivity in the clinics that closed for an hour went up significantly compared to the clinics that did not close.
- Advocate Aurora Health developed a model for supporting comprehensive clinician well-being that included a chief wellness officer, a Well-Being council, and 3 core teams and programs: (1) culture of wellness, (2) personal resilience, and (3) efficiency of practice. Under personal resilience, core components included an Individual Well-Being Team, a spiritual health program, an employee assistance program, a healthy living program, and an integrative medicine program. Under Efficiency of Practice, a health care informatics program looked at ways to improve efficiency of EHR interactions, improve quality and efficiency of documentation, reduce time after-hours time spent working, and reduce administrative burden.
- PeaceHealth St Joseph Medical Center hired a family practitioner as a system wellness director who then designed a physician empowerment program. Physicians are invited early in their tenure to participate in this 12-week program. Physicians participate as a cohort and there is a set curriculum ranging from improving EHR efficiency and informatics to crucial conversations to effective leadership strategies. Data have shown that this program has prevented burnout.

“Our health care system developed a strategic aspiration of well-being: to embed well-being into the health system culture, so all who work here experience joy at work, feel a sense of purpose and belonging, and know that they are valued.”

Participants Share What Can ACCC Do?

- ACCC could partner with members to post online some of the resources and programs shared at this AMCCBS session so that members can read about them, hold a train the trainer session, and start implementing these solutions at their own cancer programs and practices.
- ACCC could establish a mentor program where members can connect and share resources and solutions on workforce-related issues, like burnout, recruitment, and retention.
- ACCC could develop toolkits for cancer programs and practices at 3 different levels—at a service line level, at a team level, and at an individual level—along with strategies to help members prioritize their efforts or help members be intentional about how they address workforce related challenges.
- ACCC could partner with industry to offer scholarships for its members to attend its annual conferences and other in-person learning opportunities.
“As far as next steps, data show that people leave an organization because of their leadership. So, what do our leaders need? How do we equip our leaders and get them the training they so badly need and desire? Like a mentorship program, where you have a cohort, and you meet monthly. How can ACCC facilitate a cohort of people with similar situations to connect and talk about their issues and then provide a toolkit to support this work?”

“My cancer center does not have a lot of funding to come to conferences like this...many of the people here had to go to their administration and fight for funding for this educational opportunity. And these are the people who are already engaged, so how do you reach the people who are not aware of ACCC and its resources? Are there scholarships that ACCC could offer to come to this type of conference?”

“I was hesitant to come to this workshop because I am ‘burned out’ from even talking about burnout, but I really appreciate all of the concepts that were presented—not necessarily because they were anything new, but because of the message that ‘you can do it.’ I thank you all for that ridiculous optimism because I think it is contagious. And I also just wanted to say that small community organizations really struggle. As a leader of a small organization, I don’t have a ton of time and resources...so having a repository or just an area on the website with [vetted] curriculums and resources means that I don’t have to go and make one.”

“ACCC could be a repository to gather these [workforce development and support] ideas. I am sure these ideas are somewhere online, but none of us have the time to look for them, so there is real value to be able to go to ACCC and click on burnout strategies...or maybe a mentor opportunity where we can talk to someone who has implemented a specific strategy, so it’s not just something that we are reading about, but we are connecting with real humans.”
**Patient Engagement Strategies**

*Educating and empowering patients so that they trust and feel connected to their cancer care team can improve access, health equity, and patient outcomes—particularly for at-risk and underserved communities.*

**Facilitators**
- Renea Duffin, MPA, Vice President, Cancer Support and Outreach.
- Mary Bird Perkins Cancer Center – Baton Rouge
- Lailea Noel, PhD, MSW, Assistant Professor, Steve Hicks School of Social Work, and Assistant Professor of Oncology & Health Social Work, The University of Texas Dell Medical School, LIVESTRONG Cancer Institutes
- Nicole Weis, MA, Senior Service Line Director, University of Minnesota Cancer Care

Patients enter the cancer care continuum at many points, and there are opportunities to engage patients and families right where they are at—whether that’s at a community outreach and education event, through early detection efforts, after a diagnosis, during active treatment, at the transition to survivorship, upon enrollment to hospice care or palliative care, and at the end of life. Below are tips and strategies to engage with patients and families along this continuum.

**Identification of At-Risk or Underserved Patient Populations**
- To identify at-risk or underserved patients, conduct a marketplace needs assessment. Assign each zip code a community needs index score ranging from 1.0 (low need) to 5.0 (high need). Collect social and economic data like high school graduation rates, unemployment rates, the number of adults who live in poverty, etc. Gather information on specific health behaviors, including smoking and obesity rates, alcohol consumption, and data on physical activity. Use these data to identify high-risk and high-needs zip codes where prevention outreach, screening, and education efforts should be concentrated.
- Delivering cancer care to at-risk and underserved patients requires trust. Building trust requires asking for input from the community on the best locations to conduct outreach and screening and picking dates that work best for the schedules and lifestyles of those who live in that community. Start small with 2 or 3 screenings events per year.
- Delivering cancer care to at-risk and underserved patients also requires navigation. It is not enough to simply go into these communities and screen; be prepared to help individuals reach a resolution on any abnormal finding. Instead of simply providing people with a phone number to call and schedule a follow-up appointment, navigators should educate and guide people on their journey from initial screening to diagnostic testing to treatment, if necessary. More, navigators can help address any transportation or other scheduling needs.

**The Role of the Community**
- Conduct grassroots outreach and partner with community organizations and local businesses, including barber and beauty shops,
“There is a big push for pharmaceutical companies to play a role in improving screening rates. But how do we move the needle in reducing disparities in the community setting? It’s more complex than translating a bunch of documents into different languages. Instead, we need to educate physicians and other cancer team members on how to speak to people from different cultures. But how do you start with that type of education?”

“The first thing that pharmaceutical companies need to do is to stop scaring people to death. When you see a commercial for a new drug, the side effects are longer than the actual commercial. It terrifies people. They walk away from that [commercial] thinking, ‘That drug will make me sicker than the cancer.’ Your information has to be in laymen’s terms. Language that people can understand. You have to explain the benefits of the treatment in a way that people can understand. Don’t just push your drug. Be a part of the solution to improve our prevention and screening efforts—especially in disenfranchised communities. I tell people all the time that I want to be put out of business. I want our cancer center to close because we’ve cured cancer.”

To break down transportation barriers and reach patients who cannot get to screening events, conduct a community screening event at a bus terminal or metro hub.

To engage with patients on skin cancer, identify and connect with key informants in the community. For example, a local Oncology Nursing Society chapter started a Hairstylist Melanoma Challenge to train local hairstylists to recognize potential skin cancer. After spotting a suspicious lesion, these stylists were empowered to act as “ambassadors” to encourage their client to follow up with a physician or dermatologist. The Melanoma Foundation of New England developed the “Skinny On Skin” program to offer in-person and virtual education on skin cancer to beauty industry professionals.

In patient engagement strategies, look not only to community influencers but also go directly to the individuals who live in that community. Hold focus groups and ask question like, ‘If we were to bring a mobile van to your community, where would be a safe place for you to get screened?’ and “If we were to hold a cancer screening event in your community, where is a good location—one where people will want to attend?”

When organizing a community event, use patient education tools like an inflatable colon that people can walk through. These tools make it more interesting for attendees and easier for providers to educate participants about screening procedures like colonoscopies. An inflatable colon can easily illustrate polyps and other
chronic gastric diseases, as well as malignancies and how these
growths can be removed.
• Community Cancer screening events should be supported by
robust social media campaigns that are reflective of the commu-
nities that the cancer program is trying to reach.
• The community is key to philanthropic and fundraising efforts.
One attendee shared about starting a Men’s Group that individuals
pay $1000 annually to join. “These men are engaged, and they
give [join] every year.” The Men’s Group has more than 300 men
enrolled and—based on that success—the cancer program started
a similar Women’s Group. Both groups enjoy social events with
the opportunity to hear and vote on where funds raised are spent.
“We just presented to our Women’s Group last week. And they
chose to fund a clinical pharmacist for the clinical trials team to
the tune of $400,000 over 2 years.”

“We host community events
for the 5 different cancers we screen.
We offer education on nutrition and
exercise through activities like a cooking
demonstration or a fitness demonstration.
We create a ‘festival-type’ atmosphere with
children’s activities, music, and
food. It makes it more comfortable
for people to attend, and it makes
the ‘C’ word less scary.”

“Providers do not have all
the answers. Providers are not always
experts in their communities. It’s finding
those key informants in the community
and partnering with them. It’s being part
of the community and actively engaging
with the community—not just showing
up with pamphlets. Letting people
know you are part of the community,
and you want to make a difference
in their lives.”

“If you are going to talk about health
equity, geography matters. As a health
care organization, we can have the best of
intentions, but the ‘ghosts’ of disparities,
segregation, and structural racism barriers
to care are real. We need to do the work to
get patients to trust us [providers] even
while we are branded with the names of
places where their parents or grandparents
could not receive care.”

Shared Decision-Making
• Shared decision-making is a collaborative decision about the
  treatment of care that is documented and shared with relevant stake-
  holders. While patients are stakeholders, they do not always feel
  like stakeholders. It is critical to engage patients and empower them
  with the understanding that they are important stakeholders.
• Shared decision-making means that treatment and care options
take into consideration individual values and preferences. Some-
times a patient’s preference does not look the “majority” prefer-
ence. While providers can be frustrated when patients do not
immediately “adhere” to their treatment recommendations, pro-
viders must make the effort to understand the “why” behind those
actions and when patients want—or need—providers to work
within the parameter of their preferences.
• In shared decision-making, providers share with patients the best
  available evidence for treatment options, including the risks and
  benefits, taking into consideration health literacy. When patients
  fully understand the information shared, they are empowered as
  stakeholders in their care.
• Shared decision-making requires medical trust. To build that medical
  trust, adopt these best practices: (1) ensure providers are culturally
  aware and inclusive; (2) offer education and support to inform and
  empower patients; (3) identify and make available a patient advoca-
  cate; and (4) identify and make available community resources.
• Hold cost of care discussions at initial visits so that patients
  understand if treatment needs to be delayed due to prior autho-
rization or other payer policies. These discussions should include
  all key players: the patient, their caregivers, the provider care
team, and, if available, a patient advocate. These discussions should also include patient education about when to call their care team and when to go to the emergency department (ED). More, when there is a choice about where to go for emergency care, patients need to be aware of which hospital is in network and which hospital is out-of-network. Patients need all this information to make an informed decision about their care.

**Empowered and Informed Patients**

- A multidisciplinary approach to cancer care—not just the physician or even the physician and nurse, but team members like a social worker and dietitian and, most important, patient advocate—can help empower and inform patients. This approach allows the team to effectively assess where patients are in terms of health literacy, if patients are emotionally ready to make informed decisions, and if there is anyone else who needs to be at the table, like family members.

- Education on early detection can empower patients to participate at community cancer screening events. And while statistics may inform patients, education about the importance of early detection and being there for their family empowers patients.

- Mount Sinai proactively combines its psychosocial distress screening with its social determinants of health screening to gather all key patient information in 1 location. This screening is pushed to patients through the patient portal 7 days before their second medical oncology appointment. Screenings are completed every 3 months, empowering patients, and allowing them the time and privacy to answer personal questions. Screening through the patient portal has increased the number of completed surveys. This improved engagement from patients and families has improved the cancer program’s ability to triage results. As soon as patients hit submit, information goes directly to social workers or chaplains or child life specialists, depending on specific needs. And providers are empowered to make decisions about intervention, for example, whether they meet with patients the next time they come into clinic or if it warrants an immediate phone call.

- Getting men to participate in cancer screening can present unique challenges. Men often require different strategies, including working through the women in their lives: their mothers, sisters, spouses, and significant others. Another strategy is to educate men about actions they can take that would benefit their family, for example, a healthy diet, exercise, sunscreen.

- When it comes to patients being diagnosed with cancer, especially men, providers must make sure that patients understand all their options—not just what the care team recommends, but all treatment options that are available to ensure patients make informed decisions.
The Role of Advocates and Community Health Workers

- An empowered advocate helps patients make informed decisions. Advocates understand the culture of the patient and the health care system. Among many critical tasks, advocates can assist with health literacy, benefit issues, social determinants of health, and barriers to care.
- Organizations such as Atrium Health Wake Forest Baptist and the University of Oklahoma Health use non-clinical navigators in their breast care programs as a best practice. At one program, non-clinical navigators had to be breast cancer survivors so that when patients were diagnosed and attached to a non-clinical navigator, they were essentially “hardwired” into the health care system, improving patient outcomes and patient retention.
- Cancer survivors often make highly effective advocates. Through their experience, these individuals have gained health literacy and because they have “walked the walk,” they are trustworthy to patients currently going through cancer treatment.
- Caregivers and family members of cancer survivors can also be effective advocates. Some caregivers of family members who have passed see advocacy as a way of continuing their family member’s legacy.
- Patients and families have a voice as well. Ask them what services

“Patients seem to trust different individuals within the care team at different points throughout their journey. And so, we need to eliminate that hierarchy and belief that only physicians can speak up. We need to empower everyone on the care team to speak up and say, ‘I am identifying an issue, or the patient said something to me.’ And with this new information, we may need to take a step back or circle back around with patients or caregivers or advocates to ensure that patients are comfortable with their care.”

“You have to break it down for patients. We have a lot of men at our prostate cancer screening saying, ‘OK, I’ll pee in the cup for you.’ And you have to say, ‘I’m sorry sir, that’s not how this test works.’ We have women that come to our free prostate cancer screenings. And we have to tell them that they don’t have a prostate. People don’t know their bodies. We have physicians who have actually drawn on the paper on the exam tables where the prostate is to help patients understand why that type of physical examination is the only way to get to the prostate. We have a lot of people who fail to understand the importance of a colonoscopy. I always explain to them that the day before the procedure is actually much worse than the exam—you are asleep, and you don’t feel a thing.”

“My father has advanced prostate cancer. I’m an expert in prostate and bladder cancer. I’m also his daughter. Do you think my father listens to me? No. Because he hears hormone therapy. He thinks about his mother who had hormone therapy. He thinks he is going to grow breasts because he has not had the proper education on the difference between hormone therapy when you are a menopausal woman and the type of hormone therapy you get when you are a man with prostate cancer. And for many years, he based treatment decisions on this misinformation until I called into his [virtual] appointment and insisted the doctor explain the difference. And once that education happened, my father was like, ‘Oh, that’s it?’ And filled the script. Two years of my asking him to do just that—gone. Just an example of how you break through.”

“You have to break it down for patients. We have a lot of men at our prostate cancer screening saying, ‘OK, I’ll pee in the cup for you.’ And you have to say, ‘I’m sorry sir, that’s not how this test works.’ We have women that come to our free prostate cancer screenings. And we have to tell them that they don’t have a prostate. People don’t know their bodies. We have physicians who have actually drawn on the paper on the exam tables where the prostate is to help patients understand why that type of physical examination is the only way to get to the prostate. We have a lot of people who fail to understand the importance of a colonoscopy. I always explain to them that the day before the procedure is actually much worse than the exam—you are asleep, and you don’t feel a thing.”
benefited them most and then be prepared to act on their feedback.

- Community health workers are individuals from local communities who are trained and certified to go into their communities and help health care providers build trust in that community. While not clinicians, community health workers partner with providers to educate communities about cancer, heart disease, diabetes, and other chronic health medical conditions. Community health workers can be especially useful in rural communities where providers and resources are often scarce.

“We hear over and over again from our patients that they have good resources and support while they are in the midst of their cancer treatment, but as soon as they get past that [and into survivorship], they feel like they are left on an island.”

“Cancer is so scary itself. A lot of people don’t even want to know if they have it. But if you build that trust and let them know that screening is the next step and that you [the navigator] will be stay with them until we figure out what is going on, you build that trust. They begin to recognize that you are not going to leave them.”

“In my qualitative studies, I’ve noticed that a lot of cancer survivors want to give back. Some do not want to go to support groups; these people often find their ‘support’ through giving back. If you have relationships that you’ve built with former patients and survivors—and their caregivers—that’s a great place to look for patient advocates.”

“Most of the models we’ve talked about today: navigation, patient advocates, community health workers—are not reimbursed. It’s a luxury for a community cancer program to have those services. But if your program has a development or fundraising team, these types of services sell. If you package them correctly, donors will—and want to—fund these types of services because they get at the heart of the community. Someone brought up Walmart earlier. Did you know that every local Walmart has a philanthropy arm that you can apply to for a grant? It may only be $1000 or $2000, but if you have 10 Walmarts in your area, that’s $10,000. I encourage you to work with your development and philanthropy departments—not just for events—but for grants and donors who will support these critical supportive care services.”
Strategies to Mitigate Payer-Driven Challenges

Payers continue to implement strategies, such as prior authorization, step therapy, and white- and brown-bagging, that are burdensome to providers and patients, often having a negative impact on clinical decision-making and patient outcomes.

Facilitators

• Alti Rahman, MHA, MBA, CSSBB, Practice Administrator, Oncology Consultants PA
• Susan Sabo-Wagner, MSN, RN, OCN, Executive Director of Clinical Strategy, Oncology Consultants PA
• Jorge García, PharmD, MS, MHA, MBA, FACHE, Assistant Vice President – System Oncology Pharmacy Service Line, Miami Cancer Institute, Baptist Health South Florida
• Sophia Humphreys, PharmD, MHA, BCBS, Director of System Pharmacy Formulary Management and Clinical Programs, Sutter Medical Center, Sacramento Sutter Cancer Center

Value-Based Care and Payer Contracting

• There is no one-size-fits-all value-based care model.
• Commercial payers answer and are responsible to employers. It is important to keep this mind when negotiating with commercial payers. Providers should consider if there is anything they can do or any actions they can take to better meet the needs of the employer.
• During contract negotiations, providers have the opportunity to educate payers. Educating payers about the number of new oncology drugs that are coming to market, the high price tags of these new therapies, especially with the advent of immunotherapy, and the benefits these therapies have in terms of increased life expectancy or improved quality of life is critical in provider-payer negotiations.
• Public and private payers are starting to adopt the mindset that if they are going to effectively manage high-cost specialties, like cancer, they need to think about what happens before the diagnosis. And that means primary care. So, it will be important to create payer relationships that include primary care. Cancer programs and practices with partnerships with primary care and an understanding of what happens in oncology and what happens in primary care have an advantage in payer negotiations.
• Some value-based care models use capitation as a cost-savings tool. When providers move into risk-based models, like capitation, where they are responsible for a population and receiving a fixed per capita, per person payment, other utilization management tools, like prior authorization, are effectively minimized or even removed. More advanced capitated models use stop-loss and risk stratification, which takes a population and creates different types of risks associated with different types of disease categories, age categories, etc.
• Other value-based care models are based on episodic reimbursement, paying episodes of 4 months or 6 months at a time rather than by individual codes. That is another way of shifting risk on

“Truth No. 1 is that payers don’t really understand what value in oncology means. Truth No. 2 is that payers understand cost. So how do providers bridge that together in a value-based care arrangement?”
White Bagging

- White bagging is one of the most heavily utilized cost mitigation strategies for payers. The term *white bagging* is when a payer dispenses a drug through pharmacy benefits and delivers the medication to the cancer program or practice to administer to patients. While white bagging is an effective way for payers to cut costs, the strategy has downsides for providers. For example, from an operations standpoint, it can be challenging working with external pharmacies. White bagging can create compatibility issues with IT systems, for example, if the national drug codes (NDCs) are not file, or if it’s an “infusion-able” drug and the drug is not compatible with the pump or scanning technology that the cancer program or practice uses. Most institutions have quality and safety systems in place to standardize and manage drug inventory; white bagging can circumvent or limit the quality and safety measures providers have set in place. When providers do not have supply chain records of a drug, they cannot guarantee the efficacy or safety of that the drug.

- From the patient perspective, white bagging can hinder treatment decisions. For example, payers often send drugs days in advance. Yet, when patients arrive at clinic and their most recent lab values call for a dose adjustment, providers are in the predicament of having to proceed with a dose that is suboptimal or delaying care and trying to request a different dose from the payer. White bagging often leads to other delays in care, for example, when medications are delivered after a patient’s clinic visit or delivered without clear instructions of where the medication needs to go or even if the medication needs to be refrigerated.

- Data from a 2021 Vizient survey of 260 hospitals on the overall impact of white and brown bagging found that 95% experienced operational and safety issues; 83% reported instances where the drug did not arrive in time for patient administration; 66% reported instances where the drug received was no longer correct due to an updated patient treatment course or the dose being changed; 43% received a drug that was not built into their computer system; 42% reported instances when the drug delivered was inappropriate and/or the wrong dose; and 37% reported instances when the drug delivered was damaged.

- The first protection against white bagging is an institutional-level policy that describes the boundaries in which providers are willing to accept—or not accept—white bagging that is shared with payers.

- Another option is to institute a clear bagging policy where the drug comes through the pharmacy benefit, which usually means lower reimbursement to the provider compared with the amount they receive under the medical benefit. Clear bagging is generally accepted or endorsed by providers because it negates custody concerns as the drug is controlled at all times by providers.

- In the past 2 years, there has been a lot of engagement to effect policy change on a federal level; however, progress towards addressing quality, safety, and chain of custody concerns around white bagging have been more successful at the state level. For example, Louisiana enacted a law in 2021 that allows the practice if a provider and a patient agree to it, but payers cannot unilaterally mandate white bagging. Florida has a 2-arm approach: working with state legislators and working with the Florida Board of Pharmacy. Working with the Florida Board of Pharmacy, white bagging was tied to misfills. So, if a cancer program or practice receives a drug that they did not agree to dispense, the drug is the property of the patient, but the program or practice is in custody of the drug, and the Florida Board of Pharmacy considers that a misfill. Accordingly, the specialty pharmacy that dispensed the medication is subject to Florida Board of Pharmacy disciplinary action. Florida stakeholders were purposeful not to prohibit white bagging entirely as patients who live in rural locations or those with disabilities may require a unique white bagging arrangement, but provider and patients must consent in. Support from Florida’s Board of Pharmacy gives stakeholders a much better chance to effect policy change through the legislative arm.

Prior Authorization

- While payers see prior authorization as an effective tool to control costs and to ensure providers are practicing evidence-based medicine, physicians who took a 2022 American Medical Association survey about prior authorizations found 93% report that they led to delay of care; 91% report that they led to a somewhat or significant negative outcome; 88% report that their associated burden is high or extremely high; 82% report that they led the patient to abandon treatment; and 1 in 3 (34%) report that they led to serious adverse events.

- Conducting prior authorization requests by phone is common; however, when care is denied, follow-up should be written and documented as this tends to more effective on the backend. As
opposed to a phone conversation, written follow-up captures all relevant information in one place, including documentation of medical necessity and guideline adherence.

- e-prior authorization tools can streamline workflows; however, provider data is critical. Documentation of medical necessity and adherence to guidelines is key, and cancer programs should ensure these data are verified and reviewed by providers before the prior authorization is sent out.
- Robotic process automation is another tool that can help streamline the prior authorization process. Robotic process automation is the application of technology (bots) to automate business processes that involve humans interacting with digital systems. The idea is to eliminate manual tasks that do not require higher level thinking, while simultaneously creating a scalable digital process to better submit, track, and manage prior authorizations.

“In oncology, there are new therapies in the neo-adjuvant and adjuvant space where time is of the essence. How will providers be able to manage these challenges? And how can a pharmaceutical company help?”

“Cancer progresses. When the prior authorization is sitting on somebody’s desk, cancer cells are multiplying. Delaying of treatment is a significant, negative impact for our patients.”

- Health care systems or practices with multiple clinic locations should consider a centralized prior authorization system. In this model, all prior authorizations come into a central location and then filtered to the appropriate subject matter experts.
- “Gold carding” is a more recent strategy, although adoption has been slow. The American Society of Clinical Oncology defines gold carding as “the practice where payers waive prior authorization on services and prescription drugs ordered by providers with a proven track record of prior authorization approvals.” 9 Several states are considering gold carding laws that would require health plans to waive prior authorization on services and prescription drugs ordered by providers with a proven track record of prior authorization approvals. Texas enacted a law whereby physicians who have a 90% prior authorization approval rate over a period of 6 months on certain services will be exempt from prior authorization requirements for those services.
- Patient co-pays are an important component of prior authorization. Any prior authorization process should include a step to confirm patient co-pay and deductibles. To help mitigate financial toxicity, providers should educate patients about their deductible

“As soon as the diagnosis is confirmed, the prior authorization is sent. Knowing how critical the treatment is, some pharmaceutical manufacturers provide free first dose, which helps. Patient assistance is also very important to helping reduce financial toxicity. Field reimbursement managers at the various pharmaceutical companies can be especially helpful with payer denials.”

“I’ll just add that payers have the responsibility to cover at least 1 drug per mechanism of action. And we [providers] need to hold them to it. Payers can cover more [drugs] if they want, but they cannot cover less. Providers also need to know what our patients are entitled to in terms of benefits and to effectively comanage denials down the line.”

(Continued on page 26)
“The only model that people have really used [for prior authorizations] is to throw FTEs at the problem...just hire more and more FTEs, and the more FTEs you throw at it, the more variables you introduce into the mix and the further away you move from a standardized process...I go into practices all the time and see that they can’t even pull basic reports and basic data for tracking...How much time is being spent in peer-to-peer? Benefits verification? First-level denials? First-level appeals? All those data points are critical.”

“Gold carding is kind of like finding the Willy Wonka golden ticket. We have not seen the success of it just yet...but it’s important to support those conversations that are happening.”

“As providers, we need to be very invested in talking more about gold carding, not just for the 5% of our patients but beyond.”

“Forget a systemwide prior authorization process. We have a different process for the various authorizations that need to be done within oncology. Our secretaries are doing prior auths [authorizations] for PET scans, financial navigators are doing prior auth for infusion oncolytics, and practice nurses are doing prior auths for oral drugs. Can’t we just treat cancer? Trust our clinicians to say, ‘This is the way it is based on NCCN guidelines.’ When your clinicians are doing paperwork to get paid, then they’re not taking care of patients.”

“I have found it really useful to partner with field reimbursement managers at the various pharmaceutical manufacturers. Not only do they know how to deal with prior authorizations, but they are experienced in dealing with denials. Our biggest hurdle is the payers that refuse to pay. And field reimbursement managers help us deal with this. [In one instance,] I was told that there was just a particular phrase that they [payers] were looking for, and we just had to put that in the denial paperwork.”
and their co-pay. Providers should also know if the patient can tolerate the financial burdens of their care, and if there is a patient assistance program or a co-pay card available. Resources are available to providers, including ACCC’s online prior authorization clinic\(^{10}\) and financial advocacy toolkit.\(^{11}\)

- On the policy front, in September 2022, the US House of Representatives passed the Improving Seniors’ Timely Access to Care Act.\(^ {12}\) While the legislation applied only to Medicare Advantage plans, it had key components that may be replicated in the future. One is to establish an electronic prior authorization program that meets specified standards. The second is to annually publish specified prior authorization information, including the percentage of requests approved and the average response time.

Step Therapy

- The Centers for Medicare & Medicaid Services defines step therapy as “a type of prior authorization for drugs that begins medication for a medical condition with the most preferred drug therapy and progresses to other therapies only if necessary, promoting better clinical decisions.”\(^ {13}\) This definition can frustrate the oncology community that believes most providers are already making better clinical decisions.

- Providers see step therapy (or what is often called fail first therapy) as a utilization management tool that takes clinical decision-making out of the physician and provider’s hands and putting it in the hands of people who are not necessarily specialists in the field. In cancer, if decisions are being made by someone who does not practice oncology, it may not be the best clinical decision. In the end, step therapy is typically driven by financial—not clinical—decisions.

- Step therapy creates additional barriers for patients, leading people to forgo needed medications and causing patients’ medical conditions to deteriorate; increasing the need for medical intervention in the future and, thereby, increasing health care costs; elevating frustration and incidents of depression; and increasing the risk of nonadherence and self-medication.

- Data\(^ {14-16}\) has shown that 67% of patients who have initial therapy rejected due to step therapy protocols do not receive an alternative therapy within 30 days; 38.9% of drug coverage policies apply step therapy; 20% of patients on step therapy are not getting the treatments prescribed by their providers; and only 34% of step therapy policies are consistent with corresponding clinical guidelines, with more than half of step therapy policies (55.6%) more stringent than corresponding clinical guidelines.

- To effectively advocate for step therapy reform, providers need to enter into discussions with employers, which payers must answer to. Join local and state employer coalitions and educate employers, patients, and caregivers about the negative effects of this payer strategy. Although 29 states have enacted some type of legislation aimed at step therapy reform, more advocacy is needed to enact change on the federal level. On April 13, 2023, the US House of Representatives reintroduced the Safe Step Act, a bipartisan bill to make sure patients can safely and efficiently access the best treatment available to them by improving step therapy protocols.\(^ {16}\)
NEW CARE DELIVERY MODELS

COVID-19 accelerated adoption and expansion of new care delivery models, such as virtual visits and remote patient monitoring, which often allowed providers to better meet the needs of underserved patient populations (ie, those who live in rural areas or those with transportation challenges). How does our health care system permanently adopt—and be reimbursed for—models and strategies that work?

Facilitators
- Steve Grubbs, MD, Vice President of Care Delivery, American Society of Clinical Oncology
- Mark Liu, MHA, Senior Director of Oncology Strategy, Transformation & Analytics, Oncology Service Line, Mount Sinai Health System & Tisch Cancer Institute
- Christine Meek, Service Line Business Manager, Munson Healthcare

Telehealth or Virtual Care Models
This cost-effective model for cancer care delivery is becoming increasingly accepted by providers, payers, and patients. Successful implementation requires cancer programs to understand what services can best be delivered virtually, for example, palliative care and genetic counseling, and what patients can most benefit from telehealth services, for example, those residing in rural locations or those facing transportation barriers. To gain this understanding and standardize care, cancer programs can:
- Develop criteria to identify visits and services appropriate for telehealth or virtual visits
- Create consensus-driven decision trees of oncology patients who would benefit the most from this type of care
- Establish governance oversight on telehealth and virtual visits

Community Paramedicine Model
- This model allows providers to evaluate patients while they remain in their home, addressing acute symptoms before patients are sent to the more costly ED or before they come in for an urgent visit at an outpatient cancer center. The model shares similarities with ambulatory oncology urgent care centers. Successful community paramedicine models require ongoing collaboration between paramedicine, ED, and oncology to understand the patients who can safely benefit from this care model.
- Under this model, ED physicians and paramedics become a part of or an extension to the oncology care team, working together to safely and more cost effectively treat patients in their homes.
- For cancer programs with limited space (chairs, exam rooms, or inpatient beds), this model can help to meet ever-increasing patient demand.
- Most importantly, this care delivery model can create a better overall experience and improve care coordination as most patients do not want to go to the ED or urgent care clinic. It is a value-based care model governed by 2 principles: not transporting patients to more costly care locations and keeping patients at home for more cost effective treatment.

Remote Patient Monitoring Models
- Remote patient monitoring programs can enhance and extend care delivered outside the 4 walls of the cancer program. Remote patient monitoring programs seek to decrease health care utilization, ie, reduce hospital admissions and readmissions and ED visits; improve patient-reported outcomes and symptom management; and use this technology to improve health equity and care of underserved and marginalized groups, ie, those who live in rural locations or those who face transportation barriers.
- The remote patient monitoring program at Mount Sinai Health System focused on patients who were recently discharged from the hospital. Clinicians are engaged during the hospital admission, and staff train patients and help them set up the wearable technology. For others, Mount Sinai offers this tip: consider partnering with a single vendor to supply all components for monitoring vitals, as well as technical support for providers and patients.
• All patients initiating or already undergoing systemic anticancer therapies are eligible to participate in Ochsner Health’s Chemo-therapy Care Companion. A best practice advisory automatically appears within Epic to remind physicians to enroll the patient in the program. Opening the best practice advisory activates a smart set in Epic that allows for automatic enrollment and completion of the consent process. The patient then receives an e-consent through their MyOchsner portal, including a welcome letter and barcode, with instructions to receive and set up the devices needed to participate.

• Traditionally, patients being treated with chimeric antigen receptor (CAR) T-cell therapies require a hospital admission to manage their toxicities. To avoid these hospitalizations, Vanderbilt Ingram Cancer Center developed and implemented a remote patient monitoring and telehealth model that allowed these patients to be safely treated in the outpatient clinic setting.

• Patient selection is key to implementing remote patient monitoring. Cancer programs need to identify patients with the right level of acuity or a specific patient population that they feel will benefit from this technology. Staff engagement and education is also critical to success. Clinicians and staff must buy-in to this care delivery model, including being comfortable with trusting and being able to act on these data—and patient reported outcomes—that come into the cancer program.

**Oncology Coordinator Model**

• To help move the needle in several quality initiatives, Mount Sinai Health System developed an oncology coordinator model where coordinators (non-clinical patient navigators) help patients transition between outpatient and inpatient sites of care. These oncology coordinators reduced time to treatment and improved hospital throughput. This model allowed the cancer program to think about care design in the way patients experience their care upon admission and discharge. While most cancer programs have ambulatory and inpatient teams, patients view them as one care team. Oncology coordinators can serve as a “quarterback” for both teams, improving communication and care coordination.

**Hub and Spoke Model**

• To better leverage advanced practice providers (APPs), improve APP and physician partnerships, and ease transportation challenges for rural patients, Munson Healthcare’s oncology service line implemented a “Hub and Spoke Model of Care.” Under this model, the “hub” is Cowell Family Cancer Center, located in Traverse City on the campus of the Munson Medical Center, a 400-bed tertiary care hospital that houses most of the health system’s major oncology services, including radiation oncology, medical oncology, gynecologic oncology, cardiothoracic surgery, neurosurgery, and urologic and colorectal surgery, as well as advanced diagnostic services, a compounding pharmacy, and inpatient care. The “spokes” consist of 6 community and/or critical access hospitals that offer medical oncology clinics and infusion services and 1 outpatient health center that hosts therapeutic infusion services. These regional cancer clinics provide medical oncology consultation and follow-up, chemotherapy, therapeutic infusion services, and survivorship care. An APP and nurse navigator staff all spoke clinics; a hub physician travels to spoke locations 1 to 2 times a week.

• This model allows for the delivery of care in the communities where patients live and improves standardization of care. New patients are often seen at the hub for their consult appointments, with follow-up treatment delivered at the spoke closest to home. Intake specialists at all locations check the new patient address to offer a location closer to home.

• Challenges to the hub and spoke model of care can include physician travel times, different electronic health records, inconsistent pharmacy order sets, and different Medicare carriers with different local coverage determinations for certain drugs. Specific to telehealth or virtual visits, challenges can include lack of reliable high-speed internet for rural patients and patients who may not be physically located in the state when a virtual visit is performed.

• A collaborative practice agreement with physicians and pharmacists at Munson Healthcare Cowell Cancer Center allows pharmacists to provide chemotherapy education, medication reconciliation, and adverse effect management to patients at all spoke locations. Pharmacists conduct regularly scheduled follow-up calls, and patients can contact pharmacists directly. Not only do physicians appreciate the pharmacy support, but it also frees up their time to see more patients.

• Munson’s hub and spoke physician-APP model looks to address both increased patient demand and challenges related to adequate provider staffing, retention, and compensation. Under this model, APP primary responsibilities include transition of care from primary care physicians; chemotherapy education and management; symptom management; bone marrow biopsy procedures; inpatient care management; peer-to-peer prior authorization with payers; and palliative and survivorship care.

**American Society of Clinical Oncology-Community Oncology Alliance Oncology Medical Home**

• As of July 1, this certification program is replacing ASCO’s Quality Oncology Practice Initiative (QOPI). (Note: The QOPI Certification Program will continue for several more years.) ASCO-COA OMH (Oncology Medical Home) standards have 7 domains: chemotherapy safety, patient engagement, availability and access to care, evidence-based medicine, quality improvement, equitable and team-based care, and goals of care for palliative and end of life discussions.

• The certification program was piloted by 12 volunteer programs: 3 academic-affiliated practices, a large health system, and 8 independent practices, ranging in size from 4 to 100 oncologists. Ninety-five sites of service and 492 oncologists in total participated in the pilot, which demonstrated that programs and practices of any size can meet these standards and set themselves up for success with other alternative payment models.

• Areas of focus include the delivery of patient-centered care (patient engagement, patient education, timely access to care, etc); adherence to evidence-based medicine through the use clinical pathways; utilization and cost of care; and health equity.

• For certification, cancer programs must undergo a policy review followed by an onsite survey. These surveys will be conducted
Tips to Prepare for an Alternative Payment Model

Before entering into an alternative payment model:

Know the specificity of included populations and covered services

Identify if there is a good flow of patient attribution

Make sure the episode of care you are going to be responsible for is well defined

Consider information exchange, including data and reporting responsibilities

Understand your performance measures and benchmarks

Look at risk adjustment


For cancer programs and practices new to alternative payment models or those looking to enter into an alternative payment model arrangement, ACCC suggests using its online Alternative Payment Model Implementation Checklist.

Monique J. Marino is managing editor, Oncology Issues, Rockville, Maryland.

References


Collaborative Care

A Solution for Increasing Access to Psychosocial Care in Cancer Programs and Practices
Globally, mental illnesses, such as depression, anxiety, psychosis, and substance abuse, present a significant burden of disease. Individuals with cancer, in particular, experience higher rates of depression and anxiety compared with the general population, which can have adverse impacts on cancer treatment and mortality in addition to increased risk of suicide. Recognizing the critical importance of psychosocial care, it is now widely acknowledged as an essential component of population health care in the field of oncology. Notably, psychosocial distress screening has been integrated into the accreditation standards for the American College of Surgeons Commission on Cancer. While cancer programs and practices have become increasingly effective at identifying patients who require psychosocial support, they often lack the necessary systematic infrastructure to effectively provide comprehensive treatment once it is identified.

Access to Mental Health Care Can Be Challenging
The current landscape of mental health treatment reveals significant gaps in access and availability. Only 4 in 10 patients with mental health disorders receive any form of treatment, and when they do, they typically receive treatment from their primary care provider, while a smaller proportion of patients receive care from psychiatrists. Disturbingly, the supply of psychiatrists is projected to decrease by 20% between 2017 and 2030, despite a growing demand for mental health services. This workforce shortage is compounded by the fact that many psychiatrists often do not participate in insurance plans due to low reimbursement rates. Notably, while only 3% of primary care and 8% of specialty medical care practitioners are out-of-network providers, a staggering 24% of mental health prescribers are out-of-network providers. As a result, community outpatient psychiatry clinics inundated with referrals have waitlists that can extend to more than 6 months. In cancer programs and practices, limited staff with expertise in the psychosocial care of individuals with cancer face overwhelming numbers of distressed patients. The current state of psychiatry practice is fundamentally broken and needs urgent attention to address these systemic challenges.

The Answer We Need
A solution is available. In 2017, the American Psychosocial Oncology Society (APOS) established a multidisciplinary task force to assess different models of psychosocial care that could effectively assist the large number of patients identified through distress screening programs. After careful evaluation, the task force determined that the Collaborative Care Model is the approach with the strongest evidence base that is capable of efficiently providing care for a large volume of distressed patients. The model was initially developed more than 30 years ago with the aim of enhancing access to mental health services in primary care settings. Through nearly 100 randomized controlled trials conducted across diverse medical settings, the Collaborative Care Model has consistently demonstrated its effectiveness in treating depression, anxiety, PTSD (post-traumatic stress disorder), substance abuse, and other psychosocial conditions. Further, the model has proven to enhance patient outcomes, increase satisfaction for both patients and health care providers, and contribute to cost savings with a remarkable 6:1 return on investment. Therefore, the Collaborative Care Model successfully achieves the Triple Aim of health care reform by improving patient experiences, enhancing population health, and reducing health care expenses.

The traditional referral-based model still predominates in most cancer programs and practices today. However, as evidence for the Collaborative Care Model in oncology continues to emerge and more cancer programs and practices embrace its implementation, some of the barriers, such as limited awareness outside primary care and psychiatry and perceived complexity in adaptation, are expected to diminish.
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<td>Sharpe et al (2014)39</td>
<td>3 cancer centers and associated clinics, Scotland</td>
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<td>Collaborative Care Model delivered by a nurse under supervision of a psychiatrist in coordination with patient’s primary care physician</td>
<td>Collaborative Care Model more effective at reducing depression severity, as well as anxiety, role functioning, quality of life, and perceived quality of care</td>
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*Adapted from Breitbart et al. Psycho-Oncology, 4th ed; 2021.*
What is Collaborative Care?

The term “collaborative care” likely evokes visions of psychiatrists sharing offices and clinical notes with oncology providers to foster increased collaboration. While co-location can promote a sense of camaraderie, it is not the defining aspect of the Collaborative Care Model, nor is it sufficient for achieving coordinated care. Rather, the model is a population-based delivery model that emphasizes a coordinated and integrated approach to patient care. Figure 1, below, illustrates a comparison of how patients and providers interact in a usual or traditional care model and in the Collaborative Care Model.

In a traditional referral-based or co-located consultation model, patients often receive treatment from multiple providers who work independently, resulting in fragmented and disconnected care. Individuals with mental health needs may be referred to psychiatry services and placed on lengthy waiting lists that fail to prioritize patient acuity and clinical needs. Additionally, there may be limited feedback if the patient fails to follow up or show improvement. In contrast, the Collaborative Care Model employs a team-based approach, involving health care professionals, such as oncology providers, psychiatrists, and care managers, who collaborate to provide efficient and comprehensive care. Effective communication, shared decision-making, measurement-based stepped care, and ongoing collaboration are key features of this model. Patients are assessed and managed based on their acuity and clinical needs, while those who do not show improvement or fail to follow up receive appropriate attention and tracking, which may include referral to psychiatry or psychology.

Key components that distinguish collaborative care typically include:\(^1\)

- **Care manager.** Typically a social worker, the care manager supports medical providers in addressing the mental health needs of their patients while working closely with a consulting psychiatrist. Care managers play a crucial role in providing psychoeducation, delivering evidence-based brief behavioral health interventions, and facilitating effective communication among team members and patients, which may include communicating psychiatric medication recommendations and monitoring adherence.

- **Population-based care.** The collaborative care team assumes responsibility for the well-being and health outcomes of a defined group of patients. This approach involves using a registry to track and monitor the progress of these patients, ensuring comprehensive and targeted care.

- **Measurement-based care.** Collaborative care employs measurement-based care, where validated patient-reported outcome measures are used to guide shared clinical decision-making. By collecting and analyzing data, this approach ensures that timely

Figure 1. Comparison of Traditional Care vs Collaborative Care Model\(^a\)
treatment-to-target is delivered, based on the individual patient’s needs and progress.

- **Regular case reviews.** Regular (eg, weekly) meetings between the care manager and consulting psychiatrist are held to review patients’ treatment plans and monitor their progress, focusing attention on patients with high distress or who are not responding to treatment. During these meetings, the psychiatrist provides treatment recommendations, including whether to adjust the treatment. If necessary, referrals to psychiatry or other specialists can be made.

In 2023, the American Society of Clinical Oncology updated its guidelines for managing anxiety and depression in patients with cancer, and it now recommends the implementation of a stepped care approach. The Collaborative Care Model incorporates the stepped care model to effectively address the varying levels of patient needs and optimize resource utilization. Considering the limited availability of psychiatrists both nationally and in cancer programs and practices, the stepped care approach allows for the effective extension of these resources and enhanced accessibility for the population in need. Figure 2, below, illustrates how the Collaborative Care Model makes use of the stepped care approach, enabling a flexible and personalized treatment approach that aligns with each patient’s specific needs. By initiating with less intensive interventions and escalating the level of care as necessary, while also stepping down when appropriate improvements are observed, this model maximizes resource efficiency, optimizes patient outcomes, and enhances the overall delivery of health care services.

To illustrate how collaborative care with a stepped care approach is implemented, let’s consider an example. A patient may enter the Collaborative Care Model through referral by oncology providers or a distress screening. A care manager with mental health expertise, most commonly a clinical social worker, conducts a comprehensive evaluation that includes standardized validated instruments, such as the Patient Health Questionnaire-9 (PHQ-9) and General Anxiety Disorder-7 (GAD-7). Based on the patient’s presentation, the care manager may set goals together with the patient and initiate brief evidence-based behavioral interventions, such as cognitive-behavioral therapy, behavioral activation, or motivational interviewing. During weekly case review meetings, the care manager discusses the patient with a consulting psychiatrist (in person or remotely). If the patient is experiencing major depression, for example, the psychiatrist may suggest additional behavioral strategies and make a recommendation that is communicated by the care manager for the oncology team to prescribe a first-line antidepressant medication, such as a selective serotonin reuptake inhibitor. The care manager continues to provide

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**Figure 2. Stepped Care Model**

- **Severe or treatment-related mental illness.** Referral to psychiatry and/or psychology consultation.
- **Moderate mental illness.** Oncology care team providers are supported by collaborative care team, backed up by case reviews with psychiatrist, with systematic treatment to target.
- **Mild mental illness.** Oncology care team provides first-line treatment interventions; supported by evidence-based behavioral health interventions from care managers.
- **At-risk groups.** Provide resources and early intervention with evidence-based behavioral health interventions from care managers.
- **Whole population.** Distress screening.

*Adapted from A stepped care approach to mental health. Murray Primary Health Network; 2023.*

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behavioral treatment and to systematically monitor treatment response with the standardized validated instruments. Patients who do not receive timely adjustments in the treatment plan, with potential referral to the psychiatrist and other support services, if needed. This approach optimizes resource utilization, allowing psychiatrists to focus on complex cases while providing consultation for others. By employing a population health approach that includes screening, tracking, stepped care, and treatment to target, the Collaborative Care Model enhances overall health outcomes, reduces access barriers, and promotes equitable health care delivery for a broader population.

**Implementation Examples**

To provide an overview of how the Collaborative Care Model has been implemented in real-world settings, let’s look at cancer programs that have adapted this approach either partially or fully. By examining these models, we can gain insights into the practical aspects and unique features of the model’s implementation. This will shed light on the diverse ways in which institutions have tailored their approaches to suit their specific patient populations, health care systems, and organizational structures.

**Fred Hutchinson Cancer Center (Fred Hutch), Seattle**

More than a decade ago, Fred Hutch was the first cancer program to transition mental health services to the Collaborative Care Model. Psychiatry and clinical oncology social work joined together to create an integrated psychosocial oncology program that incorporated the fundamental principles of the model:

- Patients are screened and followed with the PHQ-9 and GAD-7 (and other validated instruments, as appropriate for an individual patient).
- Oncology social workers function as the care managers, conducting assessments, delivering behavioral interventions, monitoring clinical progress, and collaborating with the oncology team and consulting psychiatrists, as well as psychologists, advanced practice providers, and patient navigators on the psychosocial team.
- The consulting psychiatrists provide treatment recommendations and individual consults when needed.

This model has expanded to include a dual diagnosis clinic and community-based satellites, including rural sites with the addition of telehealth.

**Dana-Farber Cancer Institute, Boston**

This cancer program consists of 2 main campuses and 6 community-based satellite sites in Massachusetts and New Hampshire. To address the challenges of staffing the community-based satellite sites with psychiatrists, the implementation of the Collaborative Care Model used the existing workforce, incorporating a consulting psychiatrist from the main campus and care managers (social workers) from the satellite sites as integral members of the Collaborative Care Model team. To further optimize limited resources at the satellite locations, the model is expanded to include a consulting psychologist, as well as a palliative care physician from the main campus who partners with a palliative care nurse practitioner or physician assistant from the satellite site to address pain and the management of complex symptoms. This model was feasible because these supportive services are all part of the Department of Psychosocial Oncology and Palliative Care at Dana-Farber. The multidisciplinary approach enhances the capacity to provide comprehensive psychosocial and palliative care, leveraging the expertise of different professionals across campuses and satellite sites to better meet the needs of patients throughout the network.

**Looking Forward**

In March 2023, the Association of Community Cancer Centers (ACCC)—with its partners, the Association of Oncology Social Work and APOS, and with support from BeiGene—held a multistakeholder summit meeting, “A Call to Action: Delivery of Psychosocial Care in Oncology.” The meeting’s primary objective was to bring together key leaders from advocacy organizations, academic medical centers, and community cancer programs to establish priorities and develop strategies aimed at overcoming barriers to access and delivering psychosocial care in oncology. Among the top priorities identified during this meeting was the promotion of the Collaborative Care Model. Recognizing this model as the solution to many barriers of patients accessing psychosocial care, ACCC and its leadership are committed to developing resources on how this model can be implemented in the community cancer setting.

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Machine Learning and Predictive Analytics Solution Transforms Infusion Center Operations
In 2022, the Association of Community Cancer Centers (ACCC) teamed up with LeanTaaS—a technology-driven health care innovator—to better understand the state of cancer program and practice operations from the perspectives of nursing directors and operational leaders. ACCC intended to use this survey to understand the current infusion center operations landscape and analyze how artificial and business intelligence, among other technologies, can help improve efficiencies for patients and staff.

Respondents to the survey encompassed community-based and academic cancer programs, as well as private oncology practices. Further, the majority of survey respondents report managing an infusion center ranging from 10 chairs to 30 chairs total. Survey findings show that cancer programs and practices across the United States face 3 major challenges in efficiently operating their infusion center(s):

1. Resource constraints
2. Staffing shortages and burnout
3. Limited access to data in the electronic health record (EHR).

The first 2 challenges listed above may not come as a surprise for many in health care, as the COVID-19 pandemic and its impacts exacerbated already felt workforce-related challenges, heightening people’s burnout and desire to leave the health care field altogether. Additionally, lower-resourced cancer programs and practices may be limited in their ability to add new technologies and staff to enhance their operations, including having staff dedicated to the EHR and understanding the full scope of its functionality.

Fifty percent of survey respondents report finding it “somewhat difficult” or “extremely difficult” to access the EHR data they need, while another 50% currently track their operational performance manually in spreadsheets. These data illustrate a need to improve EHR utilization across the board to ensure staff can access and leverage data to improve capacity for care, as well as the patient and provider experience. Further, manual tracking of any kind can be tedious, inefficient, and prone to human error. So, how can cancer programs and practices, including smaller and/or lower-resourced organizations, improve the efficiency and data utilization of their infusion center(s)?

iQueue calculates all the patient wait times and provides an overview of how many patients should be there at a certain time. That makes it easier for the schedulers...

I can compare patient wait times in the different pods—the lobby wait time to the chair, and the wait time to their first drug administration.

iQueue for Infusion Centers
LeanTaaS developed the iQueue for Infusion Centers solution to help cancer programs and practices improve their infusion efficiency, with technology that can be customized via templates to best meet staff and patients’ needs. The solution uses artificial intelligence and predictive analytics to assist infusion center staff and schedulers in level-loading their daily schedules and provides data to help flag issues that can be targeted for quality improvement efforts. According to the company, iQueue for Infusion Centers has helped those who use the technology increase revenue and lower patient wait times.

To better understand how ACCC members can leverage iQueue for Infusion Centers to improve their cancer program or practices’ bottom line, employee satisfaction, and the patient experience, Oncology Issues (OI) spoke with 2 member programs who have been using this technology for more than a year now and are seeing positive results.

The University of Alabama at Birmingham
The O’Neal Comprehensive Cancer Center at the University of Alabama at Birmingham is the only National Cancer Institute (NCI)-designated comprehensive cancer center in the state. Located
in the heart of Birmingham, Alabama, the cancer program offers a full suite of cancer care services, from medical, radiation, and surgical oncology to infusions (both oncology and non-oncology), research, and supportive cancer services.

In 2019, the team at the University of Alabama at Birmingham transitioned their scheduling and insurance authorizations to be done through a central team. The team then complementarily implemented iQueue for Infusion Centers to further enhance the scheduling team’s ability to schedule infusion center appointments, while keeping patients from waiting too long for their treatment, and the infusion nursing staff’s ability to balance out their workload each day. Oncology Issues spoke with Molly Webb, MSHQS, BSN, RN, OCN, nurse manager for infusion services, and Alicia Griffith, director of ambulatory access, at the O’Neal Comprehensive Cancer Center at the University of Alabama at Birmingham, to learn more about the implementation of iQueue for Infusion Centers and how it has made a positive impact on the cancer program.

OI. What challenges were you faced with at your infusion center prior to implementing technology as a solution?

WEBB. One of our big challenges was the expansion of our infusion center from 24 chairs to 84 chairs at the end of 2019. We also combined our interdisciplinary, hematology, and oncology spaces into one, and it is very hard to coordinate that many patients in a day. Everyone ends up running into each other. Infusion is unique in the fact that it is not a 30-minute spot every time, similar to a clinic visit. That is something we really needed this iQueue technology for—to make these appointments make sense. On a larger scale, overbooking was always an issue. We could schedule a few 2-hour appointments, but, if we had four 8-hour appointments hanging out there, they were bound to clash at some point. So, it’s just hard to tell without technology.

GRIFFITH. It is difficult to know what slots are available when you’re not in the clinic, looking at chairs as a queue continues to grow in the waiting room. A challenge on our end was being able to know that a patient is a 4-hour spot and ensure that overbooking does not happen. If overbooking does occur, it really can build that queue in the waiting room and have a negative impact on the patient experience.

OI. Why did you feel technology was the right tool to solve these challenges?

WEBB. Based on the algorithms these companies run, their programs can do the work for you on such a large scale. A technology like
iQueue can take it [the data] all in, comprehend it, and display it for us to see—vs us trying to think it through. We are doing a lot of counting and asking questions like, “How many patients do we think are going to be here at this time? Is it viable to book a patient in a specific time slot?” It was really appealing to use to use the algorithms and equations technology provides, given the scale and complexity of our scheduling process.

**GRIFFITH.** It is like going from using a paper map or an atlas to using a Garmin, electronic navigation system. The atlas will get the job done, but are you going to be as efficient as you want to be? A Garmin or any kind of navigation system can tell you the shortcuts and help you navigate that journey in a more efficient manner.

**OI.** What other technologies did you consider before choosing LeanTaaS’ iQueue for Infusion Centers?

**WEBB.** Other options were considered, but the only valued option for an infusion center as large as ours was the iQueue platform.

There are so many complexities with all the moving parts within an infusion center that I do not think our human brains could put together all those puzzle pieces without the assistance of technology to pair with the human experience.

**OI.** Can you discuss the iQueue platform and any specific features that appeal to your team?

**WEBB.** There are so many cool features. We divided our schedules into 4 different templates each day because there are so many chairs. Our schedulers do not schedule through iQueue, we use a different system (IDX Scheduling) because that is what we started with. Of our 4 different templates, 3 of them are about the same size. It is a lot easier now because they [schedulers] can look at the infusion center pods and say, “Pod A has 70 patients, pod B has 60 patients, and pod C has 55 patients.” At a quick glance they can look at everything together.

iQueue calculates all the patient wait times and provides an overview of how many patients should be there at a certain time. That makes it easier for the schedulers. I personally use iQueue for wait times. I can compare patient wait times in the different pods—the lobby wait time to the chair, and the wait time to their first drug administration. I pull the statistics every month from all the pods, and they are all compared to each other. Each pod has a different group of nurses and medical assistants, so it’s like a unit. With these data, we can compare wait times for each pod and each team, so it creates a little bit of healthy competition. And we have seen a big improvement on our wait times as a result.

It also helps me calculate our utilization rate for chairs when we are doing our financial reporting. It is significantly easier to be able to pull the data from iQueue, instead of calculating by hand because I am no mathematician. I cannot say enough good things about iQueue—it is a wonderful tool for me.

**GRIFFITH.** I agree with everything Molly said from a scheduling perspective. It is really our road map to what we do every day.

**OI.** What specific outcomes did you expect when implementing this technology solution?

**WEBB.** At the end of May 2022, we extended our clinic hours. We went from operating from 7:00 AM to 5:30 PM to 7:00 AM to 7:30 PM. iQueue helped us come to that decision by allowing us to efficiently observe our chair utilization rates. We were able to add patients to our templates each day.

It also helped us visualize those peak hours, which are the busiest times in the day. We were able to see when too many patients were here at one time. We were seeing that between the hours of 10:00 AM and 2:00 PM we were slammed—no patients were moving. We adjusted our templates for that and took some appointments slots away at this period, while adding appointments toward the end of the day to even it out. Then the patients were not having to wait as long. We also tried to schedule fewer patients during lunch hours (that is 12:00 PM to 2:00 PM), so the nurses could take a meal break.

**OI.** From idea inception to launch, how long did it take your cancer program to access and implement the iQueue platform and when did you start to achieve anticipated financial, operational, or clinical benefits?

**WEBB.** It took 6 months, primarily because we had to have our access team trained with this program, and it is just a new element to add in your workflow. We were all new to the technology. Tracking our wait time was something that we have talked about for a little while, and we started that in April 2022. Our informatics department had to develop a system to track that data. It took about 5 months.

**GRIFFITH.** The centralized scheduling piece moved over to Access Center Scheduling in March 2021. At that time, the utilization of iQueue was not where it needed to be. Since that time, the scheduling teams are now utilizing iQueue to its full benefits. That was another piece as well—the utilization.

**OI.** What were the positive impacts this technology had on patients and your staff—from schedulers, infusion nurses, administrators, and others like pharmacy and labs?

**WEBB.** For our pharmacists and nurses, the even distribution of patients means that they are not getting huge waves of patients or tons of medication orders activated at the same time. It has helped their workflow, and that is best for patient safety. Spreading out
To echo what I shared previously, it is just the visibility to be scheduling for our partners in the clinic and really have a bird’s eye view into the clinic as it relates to scheduling. The visibility iQueue brings helps us and enhances the patient experience. If we are not overbooking and we are spreading those appointments out based on being able to see the full picture, then we will have happy patients, who do not have to wait an extra amount of time in the waiting room.

If a cancer program or practice is considering using an AI-based technology solution to improve their infusion center operations, what is one insight or piece of advice you would offer them?

I would encourage them to think about what works best for their clinic. If they have any issues or roadblocks right now, then giving staff the time to think is important in a 12-hour day.

For administration, our template utilization is great. The schedulers have done an awesome job, and that just shows us that this technology investment is worth it. It is easy to aggregate the data and use it in any way we need to use it.

I also touched upon this earlier, but the best feature of iQueue is tracking patient wait times. I can pull up any date range, and I can look at our wait times. I can look at the volume of patients that were completed. I can see how many appointments per nurse there were and compare my three main pods to each other. I can make sure everyone is on the same page with their workflow—that has been very important for me. The chair utilization rates have been a game changer for me because they are ridiculously hard to calculate by hand.

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**Executive Summary**

Executive Summary is a view in iQueue designed to help managers easily deliver executives the data they need to make strategic, proactive decisions and quickly spot operational issues that need attention.

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Figure 2. Executive Summary

<table>
<thead>
<tr>
<th>Metric</th>
<th>Goal</th>
<th>Average</th>
<th>Trend</th>
<th>Count</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed Volumes</td>
<td>9,920</td>
<td>12,000</td>
<td>3%</td>
<td>2,080</td>
<td>3%</td>
</tr>
<tr>
<td>Infusion Wait Times (mins)</td>
<td>33</td>
<td>30</td>
<td>1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appointments Per Nurse</td>
<td>9</td>
<td>10</td>
<td>3%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Cost**

- Days Past Close: 6/24 (2%)
- Chair Turns: 3.4/3.6 (2%)

**Growth**

- Template Utilization: 57% (>AVERAGE, 90%)
- Completed Volumes: 9,920 (TOTAL, 12,000, 3%)

**Quality**

- Template Compliance: 87% (AVERAGE, 85%)
- NS/Cx: 6% (TOTAL, 5%, 1%)
- New Patients: 5125 (TOTAL, 5000, 2%)

**Service**

- Infusion Wait Time (mins): 33 (AVERAGE, 28)
- Drug Wait Time (mins): 48/47/1% (AVERAGE, GOAL, 1%)

**Staff**

- Appts Per Nurse: 9/10 (AVERAGE, GOAL, 3%)
- Acuity Per Nurse (daily pts): 16/15 (AVERAGE, GOAL, 1%)

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**Webb.** I would encourage them to think about what works best for their clinic. If they have any issues or roadblocks right now, then they
can look at root causes, and use iQueue to try and overcome those challenges—that is what we did. We were looking to see at what time every patient was here at the same time and figuring out how we were going to move our appointments around to try and fix those bottlenecks. I think it’s best for a larger infusion center. It is a game changer to be able to have 70 infusions of all different durations scheduled in 1 day and take 1 look at a graph to know what your day looks like. It is incredibly helpful. I would say, really think about what works best for your clinic and your goals. There are a lot of things to think about, but it is also “learn as you go” sometimes.

**Monument Health Cancer Care Institute**

The only large cancer program in a 350-mile radius in Rapid City, South Dakota, Monument Health Cancer Care Institute offers medical, radiation, and gynecological oncology to the patients who present for treatment. Within medical oncology, the health system provides patients their anti-cancer infusion treatments in a single infusion center. The health system implemented the iQueue for Infusion Centers platform in 2020. Although it uses Epic as its EHR provider, Monument Health staff can make infusion scheduling changes in Epic that are then integrated simultaneously in iQueue.

To learn more about the Monument Health team’s experience with this new technology, *Oncology Issues* spoke with Kristi Gylten, MBA, director cancer care institute; Michelle Boelter, RN, nursing director; Nancy Sanders, clinical operations supervisor; and Jan Lowe, PharmD, BCOP, oncology pharmacist; Jill Rasmussen, patient access supervisor; and Dani Collins, RN, OCN, charge nurse.

**OI.** What challenges were you faced with at your infusion center prior to implementing technology as a solution?

**BOELTER.** Prior to the use of iQueue, the infusion center was subjective on our chair utilization. We needed objective data like how we’re scheduling or how we’re turning over chair time. iQueue gives you a nice platform that you can slice and dice your data, and you can look at where your opportunities are as far as scheduling. We are still looking at that.

**GYLTEN.** We did not have the data and metrics an infusion center needs and wants to have to evaluate what our opportunities were, such as workflows, inefficiencies, and wait times, to name a few. We did not quite know where to prioritize our time and our efforts with making root causes, and use iQueue to try and overcome those challenges—that is what we did. We were looking to see at what time every patient was here at the same time and figuring out how we were going to move our appointments around to try and fix those bottlenecks. I think it’s best for a larger infusion center. It is a game changer to be able to have 70 infusions of all different durations scheduled in 1 day and take 1 look at a graph to know what your day looks like. It is incredibly helpful. I would say, really think about what works best for your clinic and your goals. There are a lot of things to think about, but it is also “learn as you go” sometimes.

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**Figure 3. Chair Utilization**

![Chair Utilization Chart](image)

The chair utilization chart is a forward-looking visualization of how your chairs will be utilized over the day based on your scheduled appointments, and how that relates to your scheduling template.
improvements and to help prepare for the future. Without that technology [iQueue], we were relying on the subjective, our feelings, vs the data.

LOWE. We had a lot of patients who needed chemotherapy, but our chairs were just full. We wanted to ensure we were optimizing chair time. iQueue helped us level out our chair time so we reduced empty time and maximized time to treat as many patients as possible.

OIE. Why did you feel technology was the right tool to solve these challenges?

GYLTEN. It takes the subjective nature out of the formula. With artificial intelligence, it gives our team the factual data, identifies better opportunities to improve and in a way that a human brain probably cannot. There are so many complexities with all the moving parts within an infusion center that I do not think our human brains could put together all those puzzle pieces without the assistance of technology to pair with the human experience.

SANDERS. It also helped us identify which patients were actually linked to a provider appointment same-day vs just a lab and infusion. These are important data, too.

GYLTEN. Our infusion center is not a standalone. It’s driven by our providers’ schedule as well. So having to coordinate between a clinic schedule and infusion center is another element of complexity, where, I think, some of those independent infusion centers that are standalone do not face those same challenges. This technology removes and helps with some of that complexity.

With the help of LeanTaaS, completed patient hours went up, so we can handle more volume or more hours both in the infusion and fast-track center.

OIE. What other technologies did you consider before choosing LeanTaaS’ iQueue for Infusion Centers?

SANDERS. I think Epic had a snap board, but we just did not understand how that could work for us. We talked about it with our Epic team, but I think it was not something we could implement at that time. The reporting capabilities from LeanTaaS are very important. There are so many data points that it’s able to pull what we cannot. We don’t have the true picture of what is happening in our infusion center until we have the reports from LeanTaaS, and their team is available to us anytime we want to go into the portal.

OIE. Can you discuss the iQueue platform and any specifics that appeal to your team?

GYLTEN. Back in 2020, we knew that we were going to be expanding our clinic, and we wanted to have a good picture of what our current state was, as it pertained to infusion chair utilization. And then use that data to help us build for the future. We also wanted to make sure—in the current state and before expanding—that we had efficiencies in place and the appropriate human capital and chairs to handle the volume for today and the future. We also knew that we had limitations to how much we could expand. This played a role in confirming what we thought we would need to build for the future—efficiencies in our workflows and efficiencies gained with the right number of staff to manage our infusion center. This all helped us in the planning process.

COLLINS. It’s also helped us with knowing where we can put people in, where we’re full, and where we’re not. We can see that information easily, so that helped with add-ons.

OIE. What specific outcomes did you expect when implementing this technology solution?

LOWE. Initially, when we were looking at our use of chair time, we had some patient dissatisfaction with wait times between doctors’ and chemotherapy appointments. It just always felt like we were behind, and patients were not satisfied. I think implementing iQueue and then the queuing portion, where we could have a timestamp on what really is going on, took the subjective portion out and made it more objective. What we learned is that we are really good at getting patients in chemotherapy at their appointment time. Also, we just wanted to have some real numbers for patient satisfaction purposes.

GYLTEN. We implemented iQueue in 2020, and then LeanTaaS came back in 2021 to do a review of how we were using the platform. Initially, patient wait times were a concern. Post implementation, the wait times did go down. The average time nurses and patients were waiting for the chemotherapy to be made was another metric we thought we had an opportunity to improve. This metric improved as well.

RASMUSSEN. It [iQueue for Infusion Centers] gave the schedulers a better idea as to what was scheduled, where before they were counting and not working off a template. But we also had to figure out the template that worked best for our infusion center. Like Nancy said, it gives us the data and the numbers that we need. In our fast-track area, we are able to handle more patients. With the help of LeanTaaS, completed patient hours went up, so we can handle more volume or more hours both in the infusion and fast-track center.

GYLTEN. As Jill mentioned, iQueue assists us in making better scheduling decisions. The dashboard and tools are used by schedulers and nursing staff to help them make better decisions. Or for those challenging decisions, they can look at the dashboard together in real time to make better decisions on behalf of our patients and caregivers.

OIE. From idea inception to launch, how long did it take your program to access and implement the iQueue platform and when did you start to achieve anticipated financial, operational, or clinical benefits?
LOWE. We met weekly to review the data that was available with just a small amount of time since implementation, but it was several months before we could draw any conclusions from the initial data. It was 3 to 6 months before we met with LeanTaaS to review the results of our changes. We had frequent meetings back and forth and tweaked things, and worked on it. But finally, I think it was several months before we had enough data to potentially draw conclusions.

GYLTEN. Start with the basics. Then consider the additional features and enhancements as you get more comfortable with the platform. It took us at least a year before we could introduce the next phase or next step, so it’s a continual work in progress.

BOELTER. We continue to meet with the LeanTaaS team on a regular basis and look at our data, looking at how we are performing. They will give us some suggestions or changes that have come along with Epic and their processes. LeanTaaS will also give us some suggestions on how to work with that and what our opportunities are. So, when we meet with them, they go through our dashboard with us, and they may say, “It looks like you’re still bottlenecking at this time, and maybe this is the opportunity to fix that.” It’s a continual improvement process.

OI. What were the positive impacts this technology had on patients and your staff—from schedulers, infusion nurses, administrators, and others like pharmacy and labs?

Figure 4. Volumes and Utilization

Easy to understand retrospective dashboards help staff review past performance, and provide insights into cycle times, volumes and utilization, wait times, and add-on patterns.
I remember being overwhelmed at the beginning and thinking, “How are we going to implement this?” It just seemed like a lot of work, but it was worth it. And having accurate input regarding initial, current processes is important. Trust the process and technology, even though it may seem like it’s not going to work when the technology first goes live. It is worth it; stay with it.

Maddelynne Parker and Chidi Ike are associate editors of Oncology Issues in Rockville, Maryland.

References
Therapeutic Art:

Transforming Self-Awareness for Those Impacted by Cancer
Receiving a cancer diagnosis is an emotionally driven, life-changing event for individuals and their loved ones. According to Mazzocco et al, anxiety, fear, and worry impact patients’ decision-making in a complex process.1 Once anticancer treatment begins, anxiety, depression, and unmet needs are associated with decreased physical and emotional health.2 Further, long-term effects, such as cognitive changes, fatigue, and sleep disturbances, linger into and throughout survivors’ life after treatment.3 Many studies report seeing anxiety and depressive disorders among those who are being treated for cancer, while patients’ relationships may also be negatively impacted.3

To address patients’ emotions and adverse effects induced by cancer, many people seek creative outlets like art. Art therapy and therapeutic art are distinct concepts (Figure 1, page 51). The American Art Therapy Association defines art therapy as an “integrative mental health intervention involving creative processes, [the] application of psychological theories, and human experiences within a psychotherapeutic relationship.”4 Facilitated by art therapists, art therapy improves individuals’ quality of life and decreases their anxiety and depression.5,6 The difference between art therapy and therapeutic art is demonstrated in Figure 1.

Therapeutic art is a long-standing practice of creating items in the absence of psychotherapy.7 Participants use creative techniques to become self-aware. Led by facilitators, individuals who participate in therapeutic art are invited to create and experience transformation, as sessions encourage attendees to reflect on the process of creation and sharing.8 Additional benefits include social interaction with other participants and feelings of catharsis.9

Sites and Insights, a Colorado-based, nonprofit organization founded by Vicki Mackie in 2015, offers therapeutic art sessions through patient-centered support for individuals who have been impacted by cancer. Newly diagnosed individuals, long-time survivors, and caregivers may participate free of charge. Complementary art supplies are provided.

Created to support self-discovered needs, this organization initially offered 6-week sessions. As demand increased in 2016, sessions were reduced to 4-week sessions to accommodate more participants and offer the workshops across the Colorado front range. Spanish-speaking sessions were subsequently introduced. In 2018, online sessions were introduced for home-bound individuals and caregivers who could not leave their loved ones. Online sessions have continued during the COVID-19 pandemic, and participants have joined these sessions from as far away as California and New York.

The goal of the workshops (offered over 4 or 6 consecutive weeks) is to provide people impacted by cancer with avenues to express their anxieties, fears, and grief. Multiple innovative methods, including art, color, mindfulness, sensory integration, and complementary therapies are used (see Figure 2, page 52). Commonly used art mediums include watercolors, photography, mixed media, acrylic paints on canvas,

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IN BRIEF

Community-based therapeutic art workshops provide people who have been impacted by cancer with avenues to express their anxieties, fears, and grief. As with any program, it is important to collect and analyze feedback from participants. Accordingly, this observational, community-based study was conducted to understand participants’ in-person and online therapeutic workshop experiences. Study outcomes were participant satisfaction and perception. Overall, 97.8% (89 participants out of 91 total participants) of those in-person and 100% (34 participants out of 34 total participants) of those online found the workshops to be “extremely” or “moderately” helpful vs only “somewhat” or “not” helpful at all. These data support the hypothesis that in-person and virtual community-based therapeutic art workshops have positive psychosocial associations related to one’s emotions, coping strategies, creativity, quality of life, and stress levels. Specifically, community-based therapeutic art workshops address quality of life issues for survivors of cancer who may have unmet emotional mental health needs decades after their diagnosis.
and guided masks. Further, workshops offer mindfulness techniques, such as breathing and meditation, and complementary therapies such as laughing yoga, music therapy, aromatherapy, and chromotherapy. Colors are used to help others express concepts that may be difficult to verbalize and/or write. Colors may also reveal emotions that are submersed in lost or sensitive memories. Concepts, such as psychoneuroimmunology and the effects of emotions on the immune system, are also introduced to workshop participants. Sites and Insights uses evidence-based methods and teaching strategies to help participants discover, explore, share, and reframe their negative emotions into positive emotions (eg, seeking empathy rather than sympathy). The curriculum is then adapted based on participants’ suggestions and feedback. The content used in these workshops is illustrated in Figure 2.

**Measuring Impact**

An observational community-based study was conducted to better understand Sites and Insights’ workshop experiences among participants who attended in person or online. Study outcomes were participant satisfaction and perception.

As of December 2021, more than 400 individuals participated in live and virtual therapeutic art sessions with Sites and Insights. Preassessments, postassessments, and evaluations were collected from all participants to measure the impact of this programming for people who have been impacted by cancer.

In conjunction with workshop supplies, participants received a preassessment survey that asked about their personal feelings of anxiety, fear, happiness, hope, joy, loneliness, peace, and stress within the previous 30 days. Participants were also asked to rate their feelings on a scale of 1 (“none of the time”) to 5 (“all of the time”). This survey further asked about participants’ coping tools, such as breathing, creative projects, exercise, meditation, and yoga.

Participants then received a postassessment survey after completing the 4- or 6-week workshop sessions, asking them to rate the same feelings as the preassessment in relation to how well the workshop impacted these feelings on a scale of 1 (“no benefit”) to 4 (“extremely beneficial”). Written comments and suggestions were also collected using the assessment.

**Data Collection and Analysis**

The descriptive summaries present the mean (standard deviation) and median (Q1, Q3), with the online vs in-person and pre- vs posttherapy questionnaires being summarized separately. Any responses of “not applicable” to survey questions are considered as missing data. Mean values with a 95% confidence interval (CI) are also visualized as bar graphs, where bounds are truncated to the possible range of responses (eg, a max score of 5 for the presurvey questionnaire and 4 for the posttherapy questionnaire). All analyses and figures were completed in R v4.1.0 (Vienna, Austria).

**Calculated Results**

At the time the data were analyzed, a total of 95 participants completed the in-person workshop and provided feedback. An additional 34 total participants participated in the online version of the workshop and provided feedback. In-person workshop participants (N = 95) reported using mediation (35.8%), yoga (23.2%), breathing (47.4%), exercise (54.7%), and creative projects (37.9%) as coping tools within the previous 30 days. For the online workshops, participants (N = 34) reported using mediation (33.3%), yoga (9.1%), breathing (42.4%), exercise (30.3%), and creative projects (45.5%) in the previous 30 days. The median [25th percentile, 75th percentile] number of coping (Continued on page 53)
THERAPEUTIC ART: Provides a creative process in helping participants improve mental health and wellness.

NEUROSCIENCE AND EMOTIONS: The interplay of emotions and cognition. How stress, anxiety, and other kinds of emotions can profoundly influence key elements of cognition, including selective attention, working memory, and cognitive control.

GUIDED IMAGERY: A technique in which a person focuses on positive images in his or her mind. It can help reach a relaxed, focused state and help reduce stress and give a sense of well-being.

PSYCHONEUROIMMUNOLOGY: The study of the effect and interactions of the mind, neural, and endocrine function on health and resistance to disease and immune system.

AROMATHERAPY: A type of complementary and alternative medicine that uses plant oils that give off strong pleasant aromas (smells) to promote relaxation, a sense of well-being, and healing.

5 SENSES INTEGRATION: Combining all 5 senses for the purpose of touching the subconscious mind, which activates the participants senses and arouses creativity.

LAUGHING YOGA AND PLAY: Enhances brain structure and function. Promotes executive functioning; the process of learning that helps us focus while ignoring distractions. Reduces and manages toxic stress while building resilience. Decreases symptoms of depression and anxiety.

HEART MATH: A technology that is an innovative approach to improving emotional well-being.

ELECTROMAGNETIC ENERGY AND EMOTIONS: Thoughts and feelings are an electromagnetic force inside all of us. Thoughts are the electric part of our internal electromagnetic force. Feelings and emotions are the magnetic part.

MINDFUL TECHNIQUES: A type of meditation in which you focus on being intensely aware of what you are sensing and feeling in the moment, without interpretation or judgement. Practicing mindfulness involves breathing methods, guided imagery, and other practices to relax the body and mind and help reduce stress.

NEUROGRAPHICS: A creative process that uses a drawing technique linking the conscience with the subconscious. Said to be a way that leads to transformation.

COLOR EXPRESSION: A way to use color to express emotions through intuitive-ness without judgement or preconception.

EXPRESSIVE WRITING: Shown to impact a wide range of health outcomes, such as stress, mood, immune system response, and outcome from cancer treatment.

MUSIC STIMULATION: Enhances intelligence, improves mental health, self-esteem, confidence, and quality of life. Used to relax, boost and lift mood, and improve concentration. Used to aid in insomnia, helping to encourage and induce a deeper sleep.

DANCE AND MOVEMENT: Broad range of health benefits clinically effective at improving body image, self-esteem, focus, attention, communication skills and self-awareness. Reduces stress, fear, and anxieties, and lessens feelings of isolation, body tensions, chronic pain, and depression.

SINGING: Lowers stress, boosts immunity and lung function, enhances memory, improves mental health, and helps cope with physical and emotional pain.
tools those surveyed used was 2 [1,3] and 1 [1,3] for in-person and online participants, respectively.

Overall, 97.8% (n = 89) of in-person and 100% (N = 34) of online participants found the workshop to be “extremely” or “moderately” helpful vs “only somewhat” or “not” helpful. The same proportions of participants also reported the workshop as “extremely” or “moderately” enjoyable. Within the in-person workshop participant population, 44% reported no background in art prior to participating in the workshop, with 48% reporting some and 8% reporting extensive backgrounds in art. Similar art-related backgrounds were reported among online participants; 44% had no, 53% had some, and 3% had extensive backgrounds in art. Even though nearly half of participants had no background in art, nearly all felt the workshops were helpful and enjoyable.

Figure 3 (below) presents the pre- and post-workshop average scores with a truncated 95% confidence interval for both in-person and online workshops; larger values represent a greater frequency in experiencing the feelings discussed in the preworkshop survey (1 “not

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Figure 3. Bar Plots of Average (95% CI) Pre- and Post-Workshop, Self-Reported Scores by In-Person and Online Workshop Participants

In-Person Preworkshop: Mean Scores with 95% CI

In-Person Postworkshop: Mean Scores with 95% CI

Online Preworkshop: Mean Scores with 95% CI

Online Postworkshop: Mean Scores with 95% CI
at all,” 2 “somewhat,” 3 “sometimes,” 4 “a lot,” and 5 “all the
time”) or in finding the workshop helpful in achieving the given
feeling or coping strategies in the post-workshop survey (1 “did not
help at all,” 2 “helped somewhat,” 3 “helped moderately,” and 4
“extremely helpful”). In general, average preworkshop survey scores
for both in-person and online participants were around 3 (sometimes)
across all emotions, with 95% CIs covering much of the range in
responses. This suggests that most participants “sometimes” felt each
emotion that was addressed, but there was also large variability across
participants given the wide CI. After completing the workshop,
however, most participants felt that the experience was helpful for
them in feeling positive emotions or developing coping mechanisms
for negative emotions. Further, average scores ranged from 3.3 to 4,
with tighter 95% CIs. This indicates that, on average, participants
found the workshop to be extremely helpful, and there was less
variability in their responses.

Table 1 (below) summarizes the postworkshop surveys, organized
by in-person and online experiences. The median score across all
questions was the maximum possible score, showing that partici-
pants found the workshop to be “extremely” helpful and that it
provided several tools to help. Further, the 25th percentile for each
question is either the maximum score of 4 or a response of 3, for
self-perceived moderate benefit or helpfulness of the workshop.
Overall, these high scores show that participants had a positive
experience while in the workshops.

Participants further shared gratitude and praise for the workshops
in their anecdotal feedback. Notable feedback included being chal-
gened to creatively and safely express and release feelings, feeling
supported to grow, gaining new and hopeful perspectives, looking
forward to additional sessions, and achieving a sense of peace.
Participants also expressed feelings of joy, as well as feelings of
belonging and connection with others they may never have met and
who were also impacted by serious medical conditions like cancer.

What Do These Data Really Show?
The above data show an overwhelming positive proof of concept.
Community-based, therapeutic art workshops were successfully
conducted with positive results. In-person and online participants
found these workshops overwhelmingly positive, and more than
90% found them to be helpful. Furthermore, the online
workshops facilitated cross-country participation during the
COVID-19 pandemic.

Study Limitations
There are several limitations regarding the data collection and mea-
surement for these community-based workshops. No formal statistical
planning occurred prior to beginning the workshops. The ranges for
the pre- and postworkshop surveys were different (0 to 5 for the
preworkshop survey and 0 to 4 for the postworkshop survey). There
were also subtle differences with the wording used in each survey. In

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>IN-PERSON WORKSHOP</th>
<th>ONLINE WORKSHOP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>MEAN (SD)</td>
</tr>
<tr>
<td>Did you find the workshop helpful?</td>
<td>91</td>
<td>3.89 (0.38)</td>
</tr>
<tr>
<td>Do you feel the workshop gave you a new tool to use in different areas of your life?</td>
<td>91</td>
<td>3.75 (0.49)</td>
</tr>
<tr>
<td>Do you feel the workshop gave you new insight to your emotions and/or feelings?</td>
<td>91</td>
<td>3.84 (0.45)</td>
</tr>
<tr>
<td>Do you feel the workshop helped you cope with what you are presently experiencing?</td>
<td>90</td>
<td>3.79 (0.46)</td>
</tr>
<tr>
<td>Do you feel the workshop helped with the quality of your life?</td>
<td>91</td>
<td>3.53 (0.69)</td>
</tr>
<tr>
<td>Do you feel the workshop helped you discover more of your creativity?</td>
<td>91</td>
<td>3.85 (0.42)</td>
</tr>
<tr>
<td>Did the workshop help with your stress?</td>
<td>90</td>
<td>3.51 (0.60)</td>
</tr>
<tr>
<td>Did the workshop help with your anxiety?</td>
<td>90</td>
<td>3.52 (0.66)</td>
</tr>
<tr>
<td>Overall, did you enjoy the workshop?</td>
<td>90</td>
<td>3.93 (0.29)</td>
</tr>
</tbody>
</table>
the future, modifications should be made to support more rigorous comparisons. Additionally, the pre- and postworkshop survey scores were quite similar.

Conclusions
In-person and virtual community-based, therapeutic art workshops have positive psychosocial associations with people who have been impacted by cancer. Such community-based workshops acknowledge emotions like anxiety and sadness and help address the psychosocial needs for those who have been diagnosed with cancer and their loved ones. These workshops address quality of life issues for chronic cancer survivors, who may continue to have emotional and mental health needs decades after their diagnosis.

Community-based, therapeutic art workshops also provide an opportunity for people affected by cancer to feel heard, known, and respected outside the cancer program or practice, clinic, or hospital. Virtual therapeutic art workshops reach many more people, who may not otherwise be able to participate (ie, those who are immunocompromised, homebound, and living in rural areas). Ultimately, workshops that seek to address unmet needs and foster peer-to-peer support should be further explored and shared.

Acknowledgements
The authors would like to express gratitude to the participants who engaged in therapeutic art through this method and the volunteers who led the workshop sessions.

References

Acknowledgements
The authors would like to express gratitude to the participants who engaged in therapeutic art through this method and the volunteers who led the workshop sessions.

Vicki Mackie is director and founder of Sites and Insights in Centennial, Colorado; this is a volunteer (unpaid) position. Xinyi Yang, MSPH, is research assistant at University of Colorado Anschutz Medical Campus and Alex Kaizer, PhD, is assistant professor at the University of Colorado School of Public Health, Department of Biostatistics and Informatics, in Aurora, Colorado. Carlin Callaway, DNP, RN, ACNP-BC, ACNS-BC, AOCNP, is an advanced practice provider in the Medical Oncology Survivorship Clinic at the University of Colorado Hospital, UCHealth-Oncology Services in Aurora, Colorado. For more information about Sites and Insights visit, www.sitesandinsights.org and/or email: vicki@sitesandinsights.org.
A Comprehensive Cancer Risk Management Clinic for Families With Hereditary Cancer Syndromes

Outcomes After 6 Years
Hereditary cancer predisposition syndromes are common health conditions. An estimated 1 person in every 400 individuals has a pathogenic variant (or “mutation”) in BRCA1 or BRCA2, and 1 person in every 280 individuals has a pathogenic variant in MLH1, MSH2, MSH6, or PMS2. The prevalence of these conditions is even higher for those with a diagnosis of breast, ovarian, colon, or uterine cancer. In addition, there are multiple other genes linked to hereditary risks for cancer. The prevalence of pathogenic variants in moderate penetrance genes may be even higher than the prevalence of pathogenic variants in high penetrance genes, collectively making these conditions common.

Genetic testing for hereditary cancer syndromes increased in popularity following several events in the early 2010’s, such as the Association for Molecular Pathology v Myriad Genetics US Supreme Court decision, Actress Angelina Jolie’s op-ed in the New York Times, increasing availability of next-generation sequencing testing and multigene panels, and decreasing testing-related costs. As a result, more individuals are being identified as having a hereditary cancer syndrome and requiring long-term, multiorgan risk management.

Due to increasing demands for genetic counseling, many disclosures of one’s testing result occur via a 1-time telephone call or post-test visit, whereas a positive genetic testing result affects patients’ decision-making over the lifetime. In addition, our understanding of cancer risks and optimal management changes over time. Without having a provider dedicated to the management of one’s hereditary cancer syndrome, patients may not be informed of updated management recommendations. Long-term management of hereditary cancer syndromes often falls to patients’ primary care provider or the physician who referred them to genetic counseling. Primary care providers have demonstrated a knowledge gap about the management of BRCA1 and BRCA2 and report feeling uncomfortable with cancer risk management due to the rapidly changing landscape of genetics. Patients also report that they receive differing...
or incorrect medical management recommendations from their non-genetics providers.18,19

The Hereditary Cancer Prevention and Management Center

With the above challenges in mind, the Aurora Health Care Department of Genomic Medicine developed the hereditary cancer center, which is formally known at the Hereditary Cancer Prevention and Management Center. Aurora Health Care is part of Advocate Aurora Health, an integrated health care system in northern Illinois and eastern Wisconsin. It employs 11 genetic counselors to staff multiple subspecialty clinics. Aurora Health Care sees more than 7500 new patients with cancer each year, and its genetic counselors identify as many as 200 individuals per year as having a hereditary cancer syndrome. Prior to the development of the hereditary cancer center, patients were referred to genetic counseling for comprehensive pretest counseling. In addition to disclosing their testing results, the genetic counselor would provide patients with published medical management guidelines if they tested positive for a hereditary cancer syndrome. These recommendations were routed to the referring provider to manage the patient’s cancer risk(s). This model is like those reported in Hooker et al13 and Puski et al17 Genetic counselors also recommended testing for patients’ relatives at the time of results disclosure. Relatives of a proband (ie, a person serving as the starting point for the genetic study of a family) seen at Aurora Health Care would obtain a separate referral to genetic counseling from their provider. If positive, the relative would then receive long-term management from their referring provider. This pathway can result in inconsistent recommendations for cancer risk management among patients and their relatives.

The Hereditary Cancer Prevention and Management Center is a multidisciplinary clinic with the mission to “address the prevention and cancer risk management of patients and their at-risk relatives with hereditary cancer conditions by providing continuity and coordination of care.” Similar clinics have been created around the world with reported positive patient outcomes.20-25 The following is a summary of the hereditary cancer center’s development, clinic workflows, patient volumes and demographics after 6 years, and specific patient outcomes.

Clinic Development and Workflow

Prior to the inception of the program, the medical oncologist and cancer nurse coordinator of the hereditary cancer center attended City of Hope’s Intensivist Course in Genomic Cancer Risk Assessment to ensure the base knowledge necessary for managing complex hereditary cancer syndromes. The oncologist and nurse coordinator then worked with genetic counselors to:

- Create an Epic order for referrals and schedules for the clinic
- Identify workspaces
- Outline a workflow
- Define documentation requirements and ownership
- Develop a case conference format
- Research video conference resources for remote participants (ie, referring providers, genetic counselors)

As the caseload grew, the team identified opportunities to better serve patients with hereditary cancers. For example, the hereditary cancer center partnered with radiology to establish a whole-body MRI protocol (eg, for patients with Li-Fraumeni syndrome, hereditary paraganglioma, and pheochromocytoma syndrome, among others) and a dedicated MRI screening of the pancreas. The team also partnered with gastroenterology to identify physicians skilled in advanced endoscopic techniques and interested in hereditary cancer screening. The clinic was originally held twice per month at a tertiary facility in Milwaukee, Wisconsin. Since then, the clinic has expanded to a weekly occurrence, with the addition of a monthly clinic in Green Bay, Wisconsin.

At clinic appointments, patients learn about their hereditary cancer syndrome and participate in shared decision-making regarding their cancer risk management. The hereditary cancer center team stays current on evolving management guidelines and supervises longitudinal management.

The hereditary cancer center is formatted as a multidisciplinary clinic. The first hour is dedicated to a team review of the cases being seen that day. Initial consultations are scheduled as a 90-minute appointment per new family unit. The proband is the focus of the visit, and time is initially spent updating their medical, surgical, and family history. The medical oncologist and genetic counselor provide education regarding the identified variant and appropriate screening or risk-reducing measures. Case identification and subsequent genetic testing for family members is then offered. Identified screening tests and referrals for risk-reducing surgery are managed by this team. Healthy lifestyle modifications are also reviewed and encouraged. A physical exam may be done based on patients’ germline variant and age. Once patients are established in the clinic, follow-up appointments are typically 30-minutes every 6 months to 12 months to review screening tests, perform a physical exam, and update their personal and family history. Figure 1, page 41, illustrates the clinic workflow.

Most patients seen in the clinic are referred by the genetic counselor at the time of results disclosure. The hereditary cancer center team works extensively to present information about the center to multiple internal referral sources, as well as to other health care organizations. This practice has resulted in referrals from Advocate Aurora Health medical oncologists and primary care providers, as well as from external genetic counselors.

Study Demographics

From May 2015 to December 2021, 889 individuals established their care in the hereditary cancer center; 716 were assigned female at birth, and 173 were assigned male at birth. The average age at presentation to the clinic was 48.9 years (range, 4 years to 84 years).

The primary indication for referral is the identification of a genetic variant associated with elevated cancer risk. In total, 731 patients
had a positive genetic test result or a clinical diagnosis of a hereditary cancer syndrome. Further, 39 of the 731 patients had pathogenic variants in 2 or more genes (not including autosomal recessive conditions). Patients with 51 unique gene indications were seen (see Figure 2, page 59). Other indications for referral include a family history of a pathogenic variant, provocative family history with no pathogenic variant identified, pancreas cancer screening, and other/miscellaneous conditions.

Of the 889 patients who established care with the hereditary cancer center, 648 individuals were the first person in their family referred to the clinic (proband). A small proportion of the 241 non-probands already knew of their positive genetic test result when they presented to clinic, while most attended their relative’s appointment and established care with the clinic to be tested for the familial variant. Approximately half of all non-probands (n = 133) had a positive genetic test result; 94 individuals had a negative genetic test or only variant(s) of uncertain significance reported, while 10 individuals were not tested for various reasons and genetic testing was not recommended for 4 individuals.

Of the 731 patients with a positive genetic test result, 365 had a prior diagnosis of cancer or neoplasm when they established their care with the clinic. The predominant cancer type was breast cancer. Another 23 patients had features of their condition (eg, polyposis in a patient with an APC pathogenic variant, pancreatitis in a patient with a PRSS1 pathogenic variant) without a diagnosis of cancer. Previvors—those at higher risk of cancer—accounted for 343 patients with a positive genetic test result.

Patients with a positive genetic test result underwent 233 risk-reducing surgeries (either risk-reducing in an unaffected patient or risk-reducing combined with anticancer treatment) prior to being seen in the clinic. Another 62 risk-reducing surgeries occurred within a year of a patient establishing their care with the hereditary cancer center, and 13 risk-reducing surgeries occurred more than a year after the patient established their care.

There are several reasons why patients may not have pursued risk-reducing surgery. Sixty-six surgeries are not currently recommended due to the young age of a patient. Another 81 surgeries were recommended but are not currently desired by the patient. Finally, 424 patients have not had any risk-reducing surgery because it is not recommended for their hereditary condition.
Outcomes
The hereditary cancer center has been open for 6 years and has documented 33 outcomes for 30 patients in that time. These outcomes can be sorted into 4 categories.

One patient with a biallelic disease diagnosis. This patient presented to genetic counseling due to her family history of cancer. Multi-gene panel testing was performed, and a pathogenic variant in PMS2 was found. Genetic testing was recommended for her husband to determine his risk for constitutional mismatch repair deficiency syndrome since the couple was of reproductive age and had young children. A multigene panel for the husband also revealed a pathogenic variant in PMS2. The couple elected to have their 3 living children and an ongoing pregnancy tested for constitutional mismatch repair deficiency syndrome. One of the children was found to have both PMS2 pathogenic variants. Their child has since established care with pediatric providers for cancer screening.

Four patients with variants of uncertain significance were reclassified. Four patients had variants of uncertain significance identified, which were suspected to be pathogenic. The hereditary cancer center coordinated additional work-up of these variants, which resulted in the reclassification of the variants. This allowed for more accurate cancer risk assessment and identification of at-risk relatives.

One patient was referred for genetic counseling due to his personal history of colon polyps and family history of cancer. The patient also had a distant history of a single neurofibroma. An 81-gene panel revealed a variant of uncertain significance in NF1. He was later diagnosed with Stage IIA colon cancer and multifocal carcinoid tumors. A physical exam in the hereditary cancer center revealed 12 cafe au lait macules, with 9 measuring greater than 15 mm. The clinic recommended a referral to dermatology for multiple cutaneous nodules, 1 of which was a neurofibroma. This gave the patient a clinical diagnosis of neurofibromatosis type 1, and the lab used this information to upgrade the NF1 variant to being likely pathogenic.

Another patient was referred to genetic counseling for a personal history of colon polyps. Genetic testing revealed a pathogenic variant in MUTYH and variant of uncertain significance in MUTYH. The phase of these variants could not be determined. The clinic then recommended genetic testing for the patient’s mother, who was found to have the pathogenic variant. Since the variants were found to be in trans, the lab reclassified the uncertain variant as being likely pathogenic.

A third patient was found to have an amplification of exon 3 of

Figure 2. Gene Indications Seen at the Hereditary Cancer Center

* Indicates an individual with a clinical diagnosis. Indicates an individual with CHEK2 I157T in trans. ~Indicates three variants found to be not constitutional by skin punch biopsy. *Indicates an individual with three MUTYH variants.
the SDHB gene. The lab could not determine if the extra copies of exon 3 were in tandem and thus disrupting the gene sequence, or if they were located elsewhere in the genome. The report listed the variant as uncertain significance. The hereditary cancer center coordinated an additional blood sample from the patient and sent it for a gene-centric array comparative genomic hybridization. The amplified material was found in tandem, and the variant was classified as being likely pathogenic.

Most recently, a 25-year-old woman presented to the clinic due to the family history of polyposis in her father. She had a history of normal colonoscopies and previous, negative APC gene analysis. The hereditary cancer center coordinated genetic testing for her father, who was found to have a variant of uncertain significance in APC, c.531+3A>T (intrinsic), which can have an effect on splicing. Follow-up testing with RNA analysis was coordinated, and the variant was classified as being likely pathogenic. The female patient is now considered a true negative and can follow general population colon cancer screening guidelines.

The clinic removed or clarified a diagnosis (n = 7). Seven patients had a diagnosis of a hereditary cancer syndrome that was removed or clarified by the hereditary cancer center. Three patients tested positive for pathogenic or likely pathogenic variants in TP53. The variants were reported as mosaic in 2 patients. Although the variant was reported as heterozygous in the third patient, his personal and family history did not meet modified Chompret criteria, and clonal hematopoiesis of indeterminate potential was suspected. These 3 patients initially elected to do cascade testing for their close relatives, which returned negative. Skin punch biopsies were obtained, and genetic testing was performed on cultured fibroblasts. All 3 patients tested negative for the TP53 variants on cultured fibroblasts, making a diagnosis of Li-Fraumeni syndrome unlikely.

Two patients were seen for genetic counseling in 2012 and 2013 for uterine cancer and a family history of cancer. Microsatellite instability testing by immunohistochemical staining on their tumors was abnormal. However, germline testing showed no pathogenic variants. Due to the patients’ personal and family cancer history and abnormal tumor test, they were told to consider following Lynch syndrome screening guidelines. Paired tumor and germline molecular testing were performed in 2017 for 1 patient and in 2021 for the other patient. Again, no germline variants were identified. Although somatic testing did not identify 2 acquired pathogenic variants, the hereditary cancer center informed the patients that a diagnosis of Lynch syndrome was unlikely.

Another patient was referred to the clinic for genetic counseling due to a family history of ovarian cancer. Genetic testing showed 3 pathogenic or likely pathogenic variants in MUTYH. The phase of these variants could not be determined. Family members were either unwilling to be tested, unavailable for testing, or uninformative. The patient completed a baseline colonoscopy, as recommended by the clinic, and had 28 tubulovillous and tubular adenomas. This clarified a diagnosis of MUTYH-associated polyposis.

Finally, a patient that was referred to the hereditary cancer center had patient-initiated research and genetic testing results that were positive for a germline variant in the 3’ UTR of KRAS, which is reported to be associated with breast, ovarian, and lung cancers. Based on her family history of cancer, clinical hereditary cancer testing was recommended to the patient. This testing returned negative for any pathogenic variants, and the patient was informed that she does not have a hereditary cancer syndrome.

Patients diagnosed with cancer (n = 21). An often-stated goal of the clinic is to minimize the impact of cancer on patients and their families through prevention and early detection. Since risk-reducing surgeries are not possible for all cancer types or not recommended for certain gene mutations, diagnoses of cancer are inevitable in this high-risk population. Nineteen patients were diagnosed with 21 cancers or benign tumors through screening recommended by the hereditary cancer center. The majority (n = 12) were diagnosed with cancer at Stage I, while no cancers were diagnosed at Stage III or IV. The cancer or tumor types and stages can be seen in Figure 3 (above).

Discussion
As genetic testing for hereditary cancer becomes standard of care for more indications, an increasing number of individuals are being
identified with hereditary cancer syndromes that require long-term cancer risk management.11 Genetic counselors and other genetics providers often are not involved in the long-term care of these patients after coordinating testing and disclosing results.17 Management usually falls to the patients referring and/or primary care provider, who may not have a good understanding of hereditary cancer syndromes or the time to consistently seek updates to cancer risk management guidelines.4,19 To better address the needs of patients with hereditary cancer syndromes, Aurora Health Care developed the hereditary cancer center.

At clinic appointments, patients learn about their hereditary cancer syndrome and participate in shared decision-making regarding their cancer risk management. The hereditary cancer center team stays current on evolving management guidelines and supervises longitudinal management. Patients are referred to appropriate specialists (eg, gynecology-oncology, gastroenterology), and education and recommendations are shared with all providers involved in a patient’s care. Finally, the clinic encourages cascade genetic testing and welcomes family members to attend the proband’s appointment(s) to learn about the hereditary cancer syndrome and get testing if desired.

The hereditary cancer center’s approach to hereditary cancer risk management has demonstrated several positive patient outcomes during a 6-year period. Diagnosing a biallelic disorder in the child of a patient, removing or clarifying a diagnosis of a hereditary cancer syndrome, or getting a variant of uncertain significance reclassified as pathogenic or likely pathogenic significantly changes the medical management for associated patients and/or their families. In some cases, patients are actually determined to not require high-risk cancer screening.

The most common outcome from the clinic was diagnosing a neoplasm related to an individual’s hereditary cancer syndrome. Nineteen patients were diagnosed with 21 cancers through recommended cancer screening since 2015. While a diagnosis of cancer can feel inevitable in this high-risk patient population, it is reassuring that no cancers were diagnosed later than stage II for patients being seen by the hereditary cancer center. In fact, most cancers diagnosed by the clinic were found in stage I. This demonstrates that adherence with recommended screening, with the help and guidance of a knowledgeable care team, leads to better health outcomes for patients when diagnosed with a cancer.

Future Directions
Patients established with the Aurora Health Care Hereditary Cancer Prevention and Management Center are offered the opportunity to participate in research for which they may be eligible. The clinic team has already enrolled patients in several studies and continues to identify studies for which their patients may be eligible.

The hereditary cancer center hopes to expand geographically. Advocate Health Care in Illinois established 2 hereditary cancer centers in 2018 and 2020. This expansion will not only allow the clinic to serve more patients, but it will also allow for more robust data collection on patient outcomes and preferences.

Conclusions
The identification of a hereditary cancer syndrome provides an opportunity for cancer risk management. However, patients with hereditary cancer syndromes may not undergo optimal risk assessment, screening, and risk-reducing management with a nongenetics provider. The hereditary cancer center is an effective model to care for patients with hereditary cancer syndromes. The positive patient outcomes from this clinic demonstrate the benefits of this model.20

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Disclosure of interest
The authors report no competing interests to declare.

References
Supportive Oncology in Lung Cancer

Program Development for Patients and Care Partners
As the second most common cancer and most frequent cause of cancer-related death, lung cancer is a health care challenge. Advances in treatment have led to only modest improvements in overall survival. For those with advanced disease, symptom management is essential. Patients with lung cancer experience a higher symptom burden than other patients with cancers; these include dyspnea (difficulty and labored breathing), fatigue, impaired function, negative impacts on quality of life, and pain. The array of these symptoms and needs underscore the vital role of supportive care to improve patient quality of life regardless of prognosis.

Patients’ unmet needs are greatest in those who are younger, have advanced disease, and have a lower quality of life. Care partners’ unmet needs include anxiety about the patient, disease-related information, and personal emotional support. Both groups share common needs, including increased information, health care professional interactions and services, and strategies for daily living. Resources and customized support services should address these unmet needs. Tailored interventions must span lung cancer pathology, disease stage, and treatment types. Several initiatives have aimed to reduce patient pain and care partner anxiety, modify risk factors for pulmonary complications, and improve patient well-being. Consistently, these individual interventions enhance health outcomes.

Across studies, educational programs have been designed and aligned with the patient population. Educational programs reduced length of inpatient stay and postoperative complications and lowered patient anxiety and pain scores. In coping skills training and group education programs, patients show improved depression, quality of life, and self-efficacy, while care partners show lower anxiety and better self-efficacy. The literature includes face-to-face education; web-based or telephonic programs; and programs provided through single session, multiple sessions over several weeks, disseminated and printed educational materials, or focus groups to garner information locally on how best to meet patients’ needs. To understand the comprehensive local needs of patients with lung cancer and their care partners, we studied a regional, multisite cancer program—Atrium Health, Levine Cancer Institute in Charlotte, North Carolina.

**Patients and Methods**
A dedicated project team and qualitative needs assessment informed the development of a supportive care program for patients and their care partners. The project team and program development were supported by local stakeholders, including the Levine Cancer Institute’s thoracic oncology section chief, Department of Supportive Oncology, and cancer committee executive leadership, as well as community and philanthropic partners (Figure 1, page 65).

**IN BRIEF**
This study provides a standardized methodology for supportive oncology patient and care partner program development that cancer programs and practices can tailor to guide future projects that serve other tumor site populations, including those with regional diversities and multiple locations. This study and its preliminary findings were accepted as an abstract by the American Society of Clinical Oncology for the association’s 2022 annual meeting in Chicago, Illinois, and the proceedings are available online.

**During lung resection, educational programs reduced length of inpatient stay and postoperative complications and lowered patient anxiety and pain scores.**
In coping skills training and group education programs, patients show improved depression, quality of life, and self-efficacy, while care partners show lower anxiety and better self-efficacy.
The needs assessment was created in 2015 and was fielded within thoracic medical oncology at Levine Cancer Institute. The medical oncologists who focus on lung cancer provide care across more than 25 locations within the Atrium Health system and are supported by multidisciplinary teams. Within the health system, there are about 1000 new lung cancer diagnoses per year, mostly non-small cell lung cancer and about one-third are metastatic at diagnosis. The patient population for this study included 50% female, 18% Black, and 10% never smokers. The institutional review board at the cancer institute approved this study as a quality improvement project. Two qualitative methods were employed: (1) focus groups and (2) self-administered paper surveys. The focus groups shaped the surveys’ design, and the data were analyzed to identify group overlaps.26

Focus group participants included health care professionals, a local lung cancer support group leader, patients, and care partners (n = 19), who were recruited based on purposeful sampling to garner critical viewpoints across groups.27 Three, 90-minute focus groups were facilitated with a script based on prior patient, care partner,4,11-13,28 and support program development research.15-19,29 The project team reviewed and commented on the script prior to implementation to ensure it used common language. Focus group meetings took place virtually and were recorded (video and audio) and transcribed by Microsoft Teams—a digital communication and collaboration software tool with the capability of hosting group video calls and virtual meetings.30 Focus group data were de-identified and analyzed thematically,31 related to unmet needs, as well as format and content preferences. Thematic analysis required reading the transcribed data several times to identify patterns. These patterns were then coded into themes and codes, and further analysis was conducted to specify relationships across these themes.32

The self-administered paper surveys were based on qualitative, lung cancer, unmet needs research, support program research,16-21,24,25,33 and our focus group analysis. Prior to finalization, the surveys were optimized for patient literacy. Patients and their care partners completed these surveys in the clinic waiting room. Participants (n = 44) were unique individuals from the focus groups. Survey data were managed using REDCap electronic data capture tools hosted at Atrium Health Wake Forest Baptist in Charlotte, North Carolina.34,35 REDCap is a secure, web-based software platform designed to support data capture for research studies that has: (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for data integration and interoperability with external sources. Survey data were extracted using REDCap report functions for descriptive analysis.36

**Results**

Table 1, page 66, provides an overview of participants. Among the participants, 14 are female and 5 are male. Not all survey items were answered by all respondents. Available survey respondent demographics are in Table 2 (page 67); respondents (N = 39) are female
(61%) and male (29%). Analysis of the focus groups identified 4 themes and 3 unique codes within each theme to provide analytic depth. Themes appear in order of frequency (n) of unique comments across these data (Table 3, page 67), including the following:

- Unmet needs (n = 25), with the unique codes of care of the care partner, loneliness, and onboarding burden
- Program structure (n = 24), with the unique codes of innovation, variability, and virtual
- Barriers to care (n = 20), with the unique codes of knowledge gaps, psychosocial barriers, and transportation
- Program content (n = 18), with the unique codes of content and services, educational, and financial

These codes were compared with survey data for overlap and were vital for informing the supportive care program. Representative quotes from participants are found in Table 4, page 68.

**Unmet Needs**

Care of the care partner involves assistance for those who support patients with cancer. A participating care partner shared that supporting her loved one was an experience that made her feel like she had posttraumatic stress disorder. The second code, loneliness, encompasses focus group reflections on being alone in one’s cancer experience, summarized as, “You finally meet with your oncologist…then you go back out to the real world, and you’re the only one there.”

Finally, onboarding burden reflects the toll that a day of diagnosis-, treatment-, and financial-related discussions has on patients and their care partners. One patient shared the need to “shorten the onboarding experience” to alleviate the overwhelming quality of their first day in the clinic.

**Program Structure**

Innovation includes ideas on how to best serve the local lung cancer population. This includes services like “the caregiver gets a 20-minute visit to the…respite room.” Variability speaks to a program with various service platforms and media for content dissemination. This was supported by a participating patient navigator, who said, “I think we definitely would need to have multiple modes of media.” Virtual encapsulated concerns regarding the need to maintain a virtual presence, which was shared by a participating nurse manager, stating that “We’ve…learned a really useful lesson through [the COVID-19 pandemic].”

**Barriers to Care**

All participants spoke of knowledge gaps as barriers to acquiring information about their diagnosis, treatment, and finances. A participating nurse shared that she has “patients come in that…want every single resource that we have.” Transportation was also recognized as a barrier to attending treatment visits or symptom management services. A participating patient, who relies on her care partner for...
Table 2. Thoracic Oncology Self-administered Paper Surveys Respondent Demographics

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>RESPONSE FREQUENCIES (N, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (n = 39)</td>
<td>Female (24, 61%); Male (15, 39%)</td>
</tr>
<tr>
<td>Age groups (n = 40)</td>
<td>40-49 years (2, 5%); 50-59 years (6, 15%); 60-69 years (13, 33%); 70-79 years (19, 47%)</td>
</tr>
<tr>
<td>Hispanic, Latino, or Spanish (n = 40)</td>
<td>Yes (1, 2%); No (39, 98%)</td>
</tr>
<tr>
<td>Race (n = 39)</td>
<td>White or Caucasian (26, 67%); Black or African American (13, 33%)</td>
</tr>
<tr>
<td>Community (n = 32)</td>
<td>Rural (9, 28%); Urban (10, 31%); Suburban (13, 41%)</td>
</tr>
<tr>
<td>Medical insurance (n = 39)</td>
<td>Yes (38, 97%); No (1, 3%)</td>
</tr>
<tr>
<td>Care partner employed (n = 19)</td>
<td>Yes (5, 26%); No (14, 74%)</td>
</tr>
<tr>
<td>Highest education level (n = 37)</td>
<td>Less than high school diploma (7, 19%); High school diploma (8, 22%); Some college, no degree (10, 27%); Associate degree (5, 14%); Bachelor’s degree (5, 13%); Master’s degree (2, 5%)</td>
</tr>
</tbody>
</table>

Table 3. Comparisons Across Focus Group and Self-administered Paper Survey Data

<table>
<thead>
<tr>
<th>THEME (FREQUENCY = N)</th>
<th>FOCUS GROUP CODE*</th>
<th>SURVEY RESPONSES (N, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unmet needs (n = 25)</td>
<td>Care for the care partner</td>
<td>Neutral (6, 38%); Agree (3, 36%); N/A</td>
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<tr>
<td></td>
<td>Loneliness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Onboarding burden</td>
<td></td>
</tr>
<tr>
<td>Program structure (n = 24)</td>
<td>Innovation</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Variability</td>
<td>Print (9, 75%) &amp; Digital (5, 42%)</td>
</tr>
<tr>
<td></td>
<td>Virtual</td>
<td>Prefer (6, 38%)</td>
</tr>
<tr>
<td>Barriers to care (n = 20)</td>
<td>Knowledge gaps</td>
<td>Disagree (23, 68%); Agree (34, 59%); Agree (33, 67%)</td>
</tr>
<tr>
<td></td>
<td>Psychosocial</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Transportation</td>
<td></td>
</tr>
<tr>
<td>Program content (n = 18)</td>
<td>Content and services</td>
<td>Agree (23, 61%); Agree (18, 90%); Agree (34, 56%)</td>
</tr>
<tr>
<td></td>
<td>Educational</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Financial</td>
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</tbody>
</table>

*Codes capture patterns within a theme.

transportation, shared that “it [is] just hard...there’s days that he doesn’t drive, and there’s days that he does.” Psychosocial-related concerns include patients’ fears and worries that are barriers to care.

Program Content

The content and services code describes the activities that combine the required content into service offerings. For example, a participating nurse manager shared that “integrative [oncology] provides awesome support for [fatigue] and…couple that [with] physical therapy.” Educational barriers were described by a participating patient as wanting “to know more about...[what] they were looking at...the genetic stuff.” While financial concerns are described as “really hard, especially if someone [doesn’t] qualify for charity,” by a participating leader from a local lung cancer support group, “they [patients] also are broke.”

Analysis of focus group and survey data revealed strong overlap between participants’ responses in knowledge gaps, psychosocial barriers, content and services, financial and educational content, variability, and virtual. Most focus group and survey participants agreed on knowledge gaps and psychosocial-related concerns as being barriers to relief of their unmet needs. The majority across both groups agreed with content and services and the importance of educational and financial issues. Modes of variability were specified with printed and patient-portal digital materials, with a moderate preference for virtual meetings among participants. Discordance across both data sets was found for loneliness and transportation, while care for the care partner, onboarding burden, and innovation were neutral or irrelevant.

(Continued on page 69)
**Table 4. Representative Quotes for Each Theme/Code From Focus Group Data**

<table>
<thead>
<tr>
<th>NEEDS</th>
<th>Quote</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care for the care partner</td>
<td>“When you’ve been swimming in those waters…I really felt like I had PTSD.” (Care partner 1*)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>“They must be their own advocates, and that, I guess, that’s not really fair.” (Nutritionist 2)</td>
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<tr>
<td>Loneliness</td>
<td>“…finally meet with your oncologist…you go back out to the real world…you’re the only one there.” (Patient 1*)</td>
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<td></td>
<td>“It’s almost like a sense of relief for them that…they found their people.” (Local lung cancer support group leader)</td>
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<tr>
<td>Onboarding burden</td>
<td>“We give a lot of information at consult…so overwhelming.” (Patient navigator 1)</td>
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<tr>
<td></td>
<td>“Shortening the onboarding experience.” (Patient 1)</td>
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<thead>
<tr>
<th>PROGRAM STRUCTURE</th>
<th>Quote</th>
<th>Source</th>
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<tbody>
<tr>
<td>Innovation</td>
<td>“You could do more…caregiver gets a 20-minute visit to the...respite room they have now.” (Occupational therapist 1)</td>
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<td></td>
<td>“…someone can, you know, get transportation for a chemo[therapy] treatment or something like that.” (Care partner 1)</td>
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<tr>
<td>Variability</td>
<td>“I think we definitely would need to have multiple modes of media, you know, for different people...” (Patient navigator 1)</td>
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<td></td>
<td>“Like maybe an orientation…introduce the mentorship platform [and] some partner groups.” (Local lung cancer support group leader)</td>
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<tr>
<td>Virtual</td>
<td>“I’ll still keep some things virtual ‘cause we’ve learned a really useful lesson through [COVID-19]...” (Nurse manager 1)</td>
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<tr>
<td></td>
<td>“Virtual. I will say that.” (Patient 1)</td>
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<tr>
<th>BARRIERS</th>
<th>Quote</th>
<th>Source</th>
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<tbody>
<tr>
<td>Knowledge gaps</td>
<td>“I have patients [wanting] every resource...others that just finished chemotherapy but [are] now interested in this thing.” (Nurse 1)</td>
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<tr>
<td></td>
<td>“[Patients with] lung cancer...[are] different; some that ‘wanna know everything...and some do not.” (Patient 1)</td>
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<tr>
<td>Psychosocial</td>
<td>“There’s a pool of [patients with] lung cancer...who are afraid to leave the house.” (Patient 1)</td>
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<td></td>
<td>“It’s really hard to get people to find the energy or motivation to come to stuff.” (Nutritionist 1)</td>
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<tr>
<td>Transportation</td>
<td>“Patients say they don’t want to ask for one more ride...they’re not gonna come in.” (Occupation therapist 1)</td>
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<td></td>
<td>“It [is] just hard for [the care partner]...there’s days that he doesn’t drive and [days] that he does.” (Patient 3)</td>
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<tr>
<th>PROGRAM CONTENT</th>
<th>Quote</th>
<th>Source</th>
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<tbody>
<tr>
<td>Content and services</td>
<td>“Fatigue is going to be prevalent...integrative [services] provides support and couple that [with] physical therapy.” (Nurse manager 1)</td>
<td></td>
</tr>
<tr>
<td>Financial</td>
<td>“Unfortunately, lung cancer doesn’t mean cancer...someone [doesn’t] qualify for charity, but they also are broke.” (Local lung cancer support group leader)</td>
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<tr>
<td></td>
<td>“People are making decisions and leaving money on the table.” (Patient 1)</td>
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<tr>
<td>Educational</td>
<td>“API or BRAC, you know, give me a good word for that all the genetic stuff.” (Patient 2)</td>
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<td></td>
<td>“Patients that are years into treatment...I don’t know if it’ll ever get through.” (Patient navigator 1)</td>
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Program Development

Following the needs assessment, subject matter experts with interest and the capacity to participate in the working group began a project feasibility phase. This entailed identifying relevant and existing service lines, which comprise individual or group activity programs that support end users’ goals. At the time of review, there were no active care partner support services offered by thoracic or supportive oncology at Levine Cancer Institute. Next, in the feasibility phase, programs that required engagement outside of the cancer institute’s Department of Supportive Oncology were considered. These external programs include the departments and/or clinical sections that coordinate thematic activities and ongoing evaluation of outcomes, as well as objectives and goals that align with the needs of patients and their care partners.

This feasibility phase recognized gaps that needed to be resolved by creating new or reviving older services and programs. Table 5, below, outlines the relationships between qualitative themes and codes and the associated services or programs that emerged from these findings. For example, the barriers to care theme and related knowledge gaps code were associated with treatment advances delivered through Facebook Live, tobacco cessation through supportive oncology services, and other relevant specialty clinics. The final supportive care program included services like cancer rehabilitation, financial counseling, genetics counseling, nurse navigation, oncology nutrition, and tobacco cessation, as well as programs like integrative oncology, a patient resource center, palliative medicine, psycho-oncology, senior oncology, and survivorship clinics.

Before the services and programs with new content launched, a series of mechanisms were established to support promotion and dissemination. A one-page paper flyer was created that included health-literate descriptions of specialty clinics and a quick response (QR) code—an innovative use of a digital barcode that can be easily scanned with a cell phone and that assists in information accessibility. A QR code responds to the need for virtual program access and the variable need for a “digital” program structure (Table 5). Users can access specific content from our Supportive Care Lung Cancer Program online and trusted community resources about loneliness using QR technology. Specialty clinics include integrative oncology, a lymphedema clinic, neuropsychology, palliative medicine, psycho-oncology, and senior oncology. The QR code technology enhanced awareness for our new programs and services.

Educational videos were posted online within a dedicated playlist on the Levine Cancer Institute supportive oncology YouTube channel. Videos are always accessible and address the variability and virtual codes identified in this study. Our videos also address the barriers to care that were identified in the knowledge gaps code. One innovative use of YouTube was the creation of the Kazoo Blews program. In these videos, a Levine Cancer Institute music therapist introduces the pursed lip breathing technique for better inhaling and exhaling using a kazoo. This multi-video playlist shares why and how one should use and clean the kazoo and provides the opportunity to play alongside Levine Cancer Institute’s music therapist from the comfort of their home. Kazoos are now available in the thoracic oncology clinic, along with the QR code for access to the playlist.

As patients and care partners live across rural and urban settings, Facebook Live allows subject matter outreach to patients and care

<table>
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<tr>
<th>THEME</th>
<th>FOCUS GROUP CODE*</th>
<th>PROGRAMS OR SERVICES</th>
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<tbody>
<tr>
<td>Unmet needs</td>
<td>Care for the care partner</td>
<td>Transferring loved one from and in and out of a car/chair (YouTube videos)</td>
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<tr>
<td></td>
<td>Loneliness</td>
<td>Community resources</td>
</tr>
<tr>
<td></td>
<td>Onboarding burden</td>
<td>One-page paper flyer with program contact and referral information, navigating health care (Facebook Live)</td>
</tr>
<tr>
<td>Program structure</td>
<td>Innovation</td>
<td>Quick response (QR) code to access lung specific programming</td>
</tr>
<tr>
<td></td>
<td>Variability</td>
<td>YouTube videos, 1-pager with program specifics</td>
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<tr>
<td></td>
<td>Virtual</td>
<td>Facebook Live events</td>
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<tr>
<td>Barriers to care</td>
<td>Knowledge gaps</td>
<td>Treatment advances (Facebook Live), tobacco cessation (LCI DSO services), specialty clinics</td>
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<tr>
<td></td>
<td>Psychosocial barriers</td>
<td>Lower anxiety (Facebook Live)</td>
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<td></td>
<td>Transportation</td>
<td>Resource center, navigation, and social work</td>
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<tr>
<td>Program content</td>
<td>Content and services</td>
<td>Specialty clinics, how to beat fatigue, pain management, and sleep</td>
</tr>
<tr>
<td></td>
<td>Educational</td>
<td>Financial counseling (LCI DSO services)</td>
</tr>
<tr>
<td></td>
<td>Financial</td>
<td>Genetics counseling (LCI DSO services), navigating health care (Facebook Live)</td>
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LCI DSO, Levine Cancer Institute Department of Supportive Oncology
*Codes capture patterns within a theme.
partners with transportation barriers (Table 3). Topics delivered by subject experts include exercise during treatment, fatigue tips, and how to lower anxiety and pain. This platform provides education about lung cancer treatment advances and health care navigation. This content addressed multiple codes identified in this study, including psychosocial, knowledge gaps, educational, and virtual. Patients and care partners can engage with our subject matter experts virtually in a well-known and easily accessible platform free of charge.

Further, the project team will oversee the new supportive care program and monitor the unmet needs and barriers of patients with lung cancer and their care partners. This includes trends in information accessed by patients and their care partners, as well as referrals from the thoracic oncology clinic to the Department of Supportive Oncology. The team will continue to assess face-to-face and online class attendance, as well as these services and programs.

A commitment to using common language across materials was an important step that strengthened participant engagement.

Discussion
In this study, we conducted 3 focus groups and administered paper-based surveys to identify unmet needs and barriers to care for patients with lung cancer and their care partners. Based on these data, we developed a supportive care program at Levine Cancer Institute to address identified issues. Focus group analysis identified 4 themes, and each theme was analyzed further into 3 unique codes. Among survey responses, strong overlap existed in 6 areas:

- Knowledge gaps
- Psychosocial barriers
- Content and services
- Educational and financial content
- Variability
- Virtual

Participating patient, care partner, and health care professional voices provided rich perspectives to develop a robust supportive care program. Overall, the needs assessment followed steps that articulated the study’s purpose, identified participants to provide insights into local needs, established the study’s resource needs, and determined how to implement findings and improvements. Throughout this process, we reflected on the strengths and weaknesses of this project.

Several aspects of this study worked well with our supportive care program development. A strength of this project was the enthusiastic project team, working across departments, and patient group that supported the study’s methods. For example, the project included an engaged physician leader who supported health care professional participation and that subject matter experts be ready to establish specialized program content. A commitment to using common language across materials was an important step that strengthened participant engagement. Outside thoracic medical oncology at Levine Cancer Institute, several individuals provided vital patient-facing material, and local community and philanthropic partners helped bring these materials to our target population. To our knowledge, this is the first report on QR code usage in supportive oncology, which is an innovation in this patient population.

The complementary needs assessment methods provided in-depth, local knowledge to support unmet needs and address barriers to care. The discordance between focus group and survey data might appear problematic, however, this became a strength. For example, focus group data were highly significant and articulate about the theme of caring for the care partner. However, survey data suggested no significance. The importance of the focus group data necessitated educational programming content. This decision is also supported by previous research findings that recommend health care partners receive resources, information, and support to maintain good health and sustain their role in the patients’ cancer journey.56-60 Levine Cancer Institute’s supportive oncology YouTube channel provides this content, for example, how caregivers can safely and efficiently transfer a patient in and out of the car or a chair.

Alongside the strengths of this project, we also recognize weaknesses. The project team did not take the time to capture baseline data before program implementation, which would be helpful to assess program outcomes. Additionally, only 1 researcher collected and analyzed data, which limits the rigor associated with intercoder reliability. However, our study was not intended to produce generalizable data. We did not focus on cancer- or population-specific demographics as end points; study findings may not adequately represent the care continuum or subsets of lung cancer.

Lung cancer is both common and lethal; yet organized support trails other more common and less-stigmatized malignancies. The creation of a resource platform addresses unmet and evolving needs, while minimizing barriers to accessing care.

Still, the study provides a standardized methodology for supportive oncology patient and care partner program development that cancer programs and practices can tailor to guide future projects that serve other tumor site populations, including those with regional diversities and multiple locations. ☑

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the Hemby Family Endowed Chair in Supportive Oncology and serves as the chair of the Department of Supportive Oncology at Atrium Health, Levine Cancer Institute in Charlotte, North Carolina.

References

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Evolving Biomarkers: Strategies for Keeping Up with Precision Medicine

A cancer program’s ability to pivot and adapt is increasingly important in the ever-changing precision medicine landscape each year. As new and emerging biomarkers are introduced, oncology programs must launch new protocols and additional processes, and increase staff. In rural and underserved areas, the challenges are even more pronounced. Here, implementation of new molecular therapies and immune-directed biomarkers presents complex hurdles, including financial and operational limitations. A lack of access to experts and multidisciplinary teams for collaboration and oversight is an additional problem, as are lengthy turnaround times for biomarker test results.

In 2020, the Association of Community Cancer Centers (ACCC) conducted a survey to gauge the readiness of cancer programs to establish and provide biomarker testing. Findings revealed that respondents from more than 50% of programs believed that their processes and procedures for established and emerging biomarkers needed improvement. Study results have also shown that more than 70% of patients treated at community cancer programs do not receive guideline-concordant biomarker testing. Also, study results have shown striking disparities in the utilization of molecularly targeted treatments among patients from racial and ethnic minorities. For example, compared with White patients, African American patients with non–small cell lung cancer were less likely to be treated with EGFR-targeted therapies. 1

Further, research and development for new biomarker-driven therapies and immune checkpoint inhibitors for patients with advanced or metastatic non–small cell lung cancer are progressing rapidly. This underscores the critical need for increased comprehensive biomarker testing for mutations in certain genes (eg, KRAS, EGFR, ALK, ROS1, BRAF, RET, MET, NTRK) at community cancer programs, which can mean the opportunity for advanced treatments via new targeted therapy drugs. 2

In December 2022, the US FDA granted accelerated approval for new therapies for adult patients with KRAS G12C–mutated non–small cell lung cancer. 3 Because KRAS mutations are found in about 20% to 30% of non–small cell lung cancer cases 4 and 13% of patients with nonsquamous non–small cell lung cancer have an actionable KRAS G12C mutation, 5,6 the capacity of a cancer program to test for the KRAS G12C mutation is important and relevant.

This rapidly evolving landscape has created a formidable gap for community cancer programs, particularly those located in rural and underserved areas, that seek to incorporate newly actionable biomarkers into clinical practice. To address these disparities, ACCC, with its partners the Association for Molecular Pathology and LUNGevity, and with support by Amgen, launched an education program called “Evolving Biomarkers in Non–Small Cell Lung Cancer.” It examines these challenges and develops strategies to improve the capability of community cancer programs to quickly incorporate and adapt to new testing innovations. The program builds upon the important work ACCC and its partners conducted in 2022 to develop the “Biomarker Testing Implementation Roadmap for Advanced NSCLC,” an innovative learning tool designed to help multidisciplinary cancer care teams implement, expand, and sustain biomarker testing.

In this article, ACCC shares a closer look at how 6 community cancer programs worked to assess and
improve their biomarker testing programs, which can serve as a guide for any other cancer program seeking to improve its ability to provide comprehensive biomarker testing for less-common driver mutations and to act swiftly as new treatments become available.

Virtual Workshops: Expert Insights

To understand the complexities that community cancer programs face when establishing or expanding comprehensive biomarker testing services, ACCC designed a series of virtual workshops led by experts to discuss common challenges and to pinpoint strategies to improve testing processes for evolving biomarkers.

Collaborating with 6 cancer programs across the country from January to March 2022 and October to December 2022, the workshops brought together multidisciplinary providers and expert faculty to discuss common challenges and to establish strategies to improve testing processes for evolving biomarkers.

Participating cancer programs were CaroMont Hematology and Oncology in Gastonia, North Carolina; Englewood Health in Englewood, New Jersey; Fairfield Medical Center’s Cancer Care and Infusion Center in Lancaster, Ohio; Glens Falls Hospital’s C.R. Wood Cancer Center in Glens Falls, New York; Ochsner Medical Center’s St. Tammany Cancer Center in Covington, Louisiana; and Thompson Cancer Survival Center, part of the Covenant Health System, in Knoxville, Tennessee.

Workshops were led by expert faculty: Adam Fox, MD, pulmonologist, Medical University of South Carolina, Charleston; Pablo Gutman, MD, MBA, chairman of the pathology department and medical director, Holy Cross Hospital Cancer Institute, Silver Spring, Maryland; Dana Herndon, RN, MSN, ONN-CG, CPHQ, thoracic oncology nurse navigator, Cone Health Cancer Center, Greensboro, North Carolina; Alexander Spira, MD, PhD, FACP, Virginia Cancer Specialists Research Institute, Fairfax; and Yifan Tu, MD, Mercy Hospital South, David Sindelar Cancer Center, St. Louis, Missouri.

Organizational Pre-Assessment

Prior to the workshops, participants were provided with an opportunity to complete an organizational pre-assessment to measure their cancer program’s readiness and capacity to conduct testing, and to evaluate current organizational practices related to testing. Participants included administrators, oncologists, advanced practice providers, nurse navigators, nurses, pathologists, and other multidisciplinary staff.

Notwithstanding the diversity of participating programs, outcomes from the pre-assessment showed that all 6 sites shared common strengths, including:

- Commitment to comprehensive biomarker testing
- Organizational culture oriented toward precision medicine
- Established relationships with external laboratories to execute biomarker testing
- Regular use of practice guidelines (eg, those of the National Comprehensive Cancer Network and College of American Pathologists)
- Utilization of biomarker test results as part of shared decision-making with patients

While all programs faced challenges related to the lack of a standing, multidisciplinary team to regularly review advanced non-small cell lung cancer biomarker testing procedures, as well as to the lack of biomarker testing integration with electronic health record systems, programs were in varied states of readiness regarding the following areas:

- Availability/use of established reflex protocols
- Appropriate technical expertise to implement comprehensive biomarker testing
- Appropriate financial resources to conduct biomarker testing on site
- Availability of patient navigators to educate and support patients and caregivers regarding biomarker testing and to mitigate distress while waiting for results
- Availability of staff to navigate reimbursement for biomarker testing
Workshops: Lessons Learned

During the workshops, participants had the opportunity to discuss current challenges and gain expert insights on how to overcome clinical and operational hurdles. Groups also focused on identifying opportunities for improvement and determining whether those opportunities could be addressed within the next 3 months (ie, high and low feasibility) as well as anticipated level of impact (ie, high and low) for patients with advanced non-small cell lung cancer.

Common themes discussed across workshops included:

- Clinical guidelines
- Protocols and challenges related to obtaining adequate tissue for testing
- Patient navigation
- Creation of biomarker testing workflows
- Utilization of ACCC’s “Biomarker Testing Implementation Roadmap for Advanced NSCLC”

High–feasibility/high–impact opportunities for improvement identified during workshops included:

- Reviewing current workflows related to tissue collection to ensure that adequate tissue is obtained
- Reviewing turnaround times from tissue collection to send-out for testing
- Determining roles and responsibilities for test ordering and results tracking
- Reviewing processes related to reimbursement and prior authorization requirements
- Leveraging navigators to improve communication and alleviate patient distress around biomarker testing process
- Incorporating liquid biopsy to help inform decision-making while waiting for tissue results

From Opportunities to Action

After the virtual workshops, each program set out to develop an action plan for a process improvement that could be implemented over a 3-month period. Programs were asked to identify goals, activities, measures of success, deadlines, and the resources and responsible parties needed to support each activity. Following a 3-month period, ACCC revisited these programs through guided interviews to gauge progress and successes.

The action plan goals identified by individual programs included:

- Develop a process for blood draw for liquid molecular testing for patients with suspected locally advanced or metastatic lung cancer
- Develop and implement the “Future State Workflow Process” for obtaining biomarker testing for patients with non-small cell lung cancer
- Implement new lung biopsy processing protocol (ie, split tissue between 2 cassettes for immunohistochemistry/diagnosis and molecular studies)
- Review non-small cell lung cancer biomarker testing processes and procedures, and convene a multidisciplinary group to begin developing a new comprehensive biomarker testing workflow
- Develop new process for tissue collection and slide preparation to improve completion rates for comprehensive biomarker testing
- Review current non-small cell lung cancer biomarker testing practices and develop a workflow plan for implementation across all practices with consensus from other disciplines

While progress on these goals varied across programs, participants reported successes in gaining buy-in and commitment from interdisciplinary staff and leadership to support these goals. Participants also reported overwhelming satisfaction with the expert insights and key takeaways from the workshop series (more than 75% satisfaction across reported gains, confidence, attitudes, and intent to change practices related to comprehensive
Incorporating liquid biopsy to help inform decision making identified during workshops included:

- Leverage navigators to improve communication and results tracking.
- Review current workflows related to tissue collection and results tracking.
- Review current non-small cell lung cancer biomarker testing processes and procedures, and convene a multidisciplinary team to improve biomarker testing processes by showcasing strategies to obtain sufficient tissue for testing, create efficient workflows, improve communication, and assess program readiness. It is led by workshop experts Dr Fox and Dr Gutman and an expert team from Fairfield Medical Center in Lancaster, Ohio: Chad Stoltz, MBA-HM, BSN, director of Cancer Services, Pharmacy, Imaging, Palliative Care, and Research; Celeste Schmelzer, MSN, RN, clinical research coordinator; and Roopa Srikantiah-Saha, MD, oncologist.

Webinar: Practical Insights

Expanding on the success of the virtual workshop series, in April 2023 ACCC developed an on-demand webinar, “Practical Insights on How to Improve Comprehensive Biomarker Testing in Advanced Non–Small Cell Lung Cancer.” The webinar highlights how community cancer centers can improve biomarker testing processes by showcasing strategies to obtain sufficient tissue for testing, create efficient workflows, improve communication, and assess program readiness. It is led by workshop experts Dr Fox and Dr Gutman and an expert team from Fairfield Medical Center in Lancaster, Ohio: Chad Stoltz, MBA-HM, BSN, director of Cancer Services, Pharmacy, Imaging, Palliative Care, and Research; Celeste Schmelzer, MSN, RN, clinical research coordinator; and Roopa Srikantiah-Saha, MD, oncologist.

Supplemental Resources for Biomarker Testing Implementation

The “Evolving Biomarkers in Non–Small Cell Lung Cancer” education program joins a suite of powerful resources curated by ACCC to aid multidisciplinary cancer care teams in their journey to implement, expand, and sustain patient biomarker testing. The “Biomarker Testing Implementation Roadmap for Advanced NSCLC” is an online learning tool that provides step-by-step guidance across 4 areas: laying the groundwork for biomarker testing, training and preparing care teams to offer testing, implementing the program, and evaluating progress.

In addition to the Roadmap, ACCC has curated a comprehensive resource library with helpful tools, solutions, and guidance on key topics related to implementation of biomarker testing. These resources include articles and toolkits regarding program evaluation, process improvement strategies, testing guidelines, biomarker basics, patient navigation, reimbursement, and more.

REFERENCES

NTRK Gene Fusions

As advances in biomarker testing reveal more about the drivers that cause cancers, identifying and integrating guideline-concordant testing for rare cancer types, such as neurotrophic tyrosine receptor kinase (NTRK) gene fusion–positive cancers, is becoming increasingly necessary. NTRK gene fusions can result in activation of tropomyosin receptor kinases (TRK) proteins that act as oncogenic drivers.1 In 2018, larotrectinib was the first drug approved by the United States Food and Drug Administration (FDA) for the treatment of adult and pediatric patients with solid tumors with NTRK gene fusions.2 In 2019, the FDA approved entrectinib for the treatment of NTRK-positive solid tumors.3 The efficacy data for both agents came from several clinical trials that included patients with various types of advanced solid tumors, including salivary gland tumors, soft tissue sarcoma, non–small cell lung cancer (NSCLC), mammary analogue secretory carcinoma, breast, thyroid, and colorectal cancer. Despite the availability of these TRK inhibitors for “tissue agnostic” indications, the identification of NTRK gene fusions remains challenging in community cancer settings.

In 2022, the Association of Community Cancer Centers (ACCC) launched an education project, Emerging Biomarkers: Innovative Therapies for Rare Disease – A Spotlight on NTRK Gene Fusion Testing, in partnership with NTRKers, a non-profit patient support organization, and with support by Bayer, to explore ways to address barriers to optimal care for patients with TRK fusion-positive cancers. In this article, ACCC shares a look at the current NTRK testing landscape and identifies effective ways to optimize comprehensive biomarker testing in practice.

NTRK Testing Landscape

Many commercially available multigene panels using next-generation sequencing (NGS) include methods to detect fusions in the NTRK1, NTRK2, and NTRK3 genes. NGS tests may interrogate DNA, RNA, or both.4 Other methods used to detect NTRK fusions include immunohistochemistry (IHC), fluorescence in situ hybridization (FISH), and reverse transcriptase–polymerase chain reaction (RT-PCR).5

The 2022 American Society of Clinical Oncology (ASCO) Provisional Clinical Opinion on somatic genomic testing recommends the use of multigene panel–based assays if more than one biomarker-linked therapy is approved for a particular type of cancer, and makes the following recommendations:

- “Site-agnostic approvals for any cancer with a high tumor mutation burden, mismatch repair deficiency, or [NTRK] fusions provide a rationale for genomic testing for all solid tumors. Multigene testing may also assist in treatment selection by identifying additional targets when there are few or no genotype-based therapy approvals for the patient’s disease.”
- “NTRK fusion testing should be performed in patients with metastatic or advanced solid tumors who may be candidates for TRK-inhibitor therapy, considering the prevalence of NTRK fusions in individual tumor types.”

The European Society for Medical Oncology (ESMO) consensus recommendations for NTRK testing include the following:

- In tumors where NTRK fusions are relatively common, FISH, RT-PCR or RNA-based sequencing panels can be used as part of the initial regimen of biomarker testing.
- In tumors where NTRK fusions are uncommon, pursue either frontline NGS (preferentially RNA-based NGS) or screening by IHC followed by RNA sequencing of positive cases.
Yet, despite multiple guideline recommendations for NTRK testing in patients with advanced solid tumors, sometimes tissue samples are not adequate, or pathologists may not know which testing method will yield the best results.8

Because there are clear pros and cons to different testing approaches, from IHC-based screening to the use of hybrid DNA/RNA NGS panels, molecular pathologists should be involved in shaping institutional biomarker testing policies and protocols.9 Molecular pathologists can also help clinicians interpret test results if an NTRK genomic alteration is noted on a test report. While NTRK gene fusions are actionable using FDA-approved therapies, other detectable genomic alterations (e.g., single nucleotide mutations or amplifications) may not be actionable.8

In October and November 2022, ACCC held a series of focus groups with multidisciplinary care team members from cancer programs nationwide to explore current practices in biomarker testing (including NTRK gene fusion testing), barriers to testing, and awareness and common misconceptions related to NTRK testing. During these discussions, ACCC members emphasized the importance of building strong communication channels between oncologists and pathologists to determine the optimal testing approach based on factors such as tumor type, in-house testing capabilities, tissue quantity, and turnaround time for results. Focus groups also formulated a series of suggested workflows and recommendations to optimize guideline-concordant testing, which are highlighted in this article (view the full report here).

### Liquid Biopsy

The use of liquid biopsy (circulating tumor DNA [ctDNA]; cell-free DNA [cfDNA]) is rapidly expanding and is ordered when biopsy tissue quantity is not sufficient (QNS) for testing or when patients are unable to tolerate a biopsy.9 Although liquid biopsy results can be helpful when they are positive, they may have up to a 30 percent false-negative rate in advanced lung cancer.10

Research has shown that liquid biopsy can be used to detect NTRK gene fusions in patients with multiple types of advanced solid tumors.11 In a recent study, NTRK fusions detected by liquid biopsy were confirmed in tissue tests in 88 percent of patients with various advanced solid tumors.12 Liquid biopsy may also be used to detect resistance mutations and identify patients who may be eligible for clinical trials investigating next-generation TRK inhibitors.10

Therefore, understanding the nuances between testing types and when to utilize the various approaches becomes critically important. One focus group participant, Mary Walters, PharmD, BCOP, clinical pharmacist and co-director of the Oncology Precision Medicine Program at Aurora Health Care in Milwaukee, Wisconsin, described their solution—a robust precision medicine program in place to support oncologists. “We help curate when orders are made for our NGS panels, if they have a specific disease state or if they are at a specific place within their cancer treatment, and help them [oncologists] determine which panel may be appropriate for that patient based on their characteristics, whether or not they want to do a tissue-based specimen, or whether it should be liquid-based testing- we help them make that decision.”

### Optimizing Biomarker Testing Policies and Procedures

As cancer programs review their current biomarker testing practices, they may benefit by exploring ways to optimize processes to ensure that every eligible patient is considered for comprehensive biomarker testing. ACCC focus groups suggest the following recommendations:

- **Develop NGS testing policies and procedures:** Implement a workflow that ensures that patients with advanced or metastatic solid tumors have NGS testing performed on their tumors. This will enable timely and equitable testing and increase the likelihood of finding NTRK gene fusions.

- **Incorporate liquid biopsy for appropriate patients:** Aim to establish consensus around when and how liquid biopsy should be used in patients with advanced
solid tumors. Remind oncologists that the ASCO Provisional Clinical Opinion states the following about liquid biopsy:6

- “cfDNA testing has the additional advantage of capturing tumor heterogeneity because of pooling in the blood of DNA from throughout the tumor or from multiple tumors.”
- “Fusion testing may be more limited in common cfDNA tests used currently.”

- **Leverage technology to track the status of send-out tests:** If most biomarker tests are sent out to reference labs, create electronic orders that allow clinicians to track the status of these tests. Establish direct access to reference lab portals. This will reduce the potential for duplicate orders and provide an easier way to measure turnaround time for results.

- **Clearly label somatic vs. germline test reports:** As somatic and germline tests may both use NGS platforms, this may cause confusion when test reports are reviewed. Find ways to clearly label reports as somatic vs. germline. The Consistent Testing Terminology Working Group recommends that clinicians use the following terms:13

  - “Biomarker testing” to discuss tests that identify characteristics, targetable findings, or other test results originating from malignant tissue or blood
  - “Genetic testing for an inherited mutation” and “genetic testing for inherited cancer risk” for tests to identify germline mutations

- **Address disparities in biomarker testing:** Certain patients with cancer may be at risk for experiencing testing disparities. Studies have shown lower rates of NGS testing in Black and Hispanic patients compared with White patients.14 Reflex testing protocols may be the most effective way to improve testing equity and to ensure that every eligible patient is tested, regardless of race, ethnicity, or socioeconomic factors.

These recommendations have proven successful at several cancer programs, including Aurora Health Care. “We have a standardized reflex testing algorithm. So, for certain disease states that have a high prevalence of targetable alterations, like non-small cell lung cancers and colorectal cancers, our pathologists are authorized to order reflex testing for in-house NGS panels, which includes 50 genes, including common NTRK fusion variants as well,” explained Walters. At their center, a multidisciplinary committee that includes pharmacy, precision medicine experts, medical oncologists, pathologists, oncology leadership, and others meet monthly to review updates, new targeted therapies, and new recommendations to update these reflex testing standards.

Another interesting workaround for community hospitals that do not have an in-house molecular pathologist but could benefit from molecular pathology expertise when diagnosing and ordering biomarker testing is pathology services collaboration. Michelle Shiller, DO, AP/CP, MGP, medical director of Genomic and Molecular Pathology Services and cancer liaison physician at Baylor Sammons Cancer Center in Dallas, Texas, shared how they created a dedicated email group with a team of molecular pathology experts (including physicians who are certified molecular pathologists as well as PhD-level molecular biologists, bio geneticists, cytogenetic specialists) to support providers from community hospitals, who can access guidance from this expert network. As Shiller explained, “Between this number of people [molecular pathologists], there is someone watching it [the email] at almost any given moment. So, the community pathologist can email the group with a question, and an expert will answer, usually within 15 minutes or less.”

**Opportunities for Future Development**

Although interest and utilization of comprehensive biomarker testing for rare cancers continues to increase, there are important opportunities for improvement that both community and academic cancer programs have identified. One such area relates to shared decision-making with patients. Many patients may not understand the importance of biomarker testing, especially if they hear similar terms such as “genomic or genetic testing.” Oth-
er patients may be reluctant to undergo testing because of privacy concerns or they may believe the results will worry their family members. Furthermore, in some instances—when test ordering is reflexive or at centers without a precision medicine navigator—tests are ordered without having a dedicated patient conversation.

Many focus group participants agreed on the need for improvement, including Shiller, who shared these insights. “From a germline perspective, patients may be referred to genetic counseling, but they rarely know why they are referred and so they are unlikely to follow up with an appointment. For somatic testing, because it happens reflexively, providers may not think about explaining it [somatic testing] to the patient, so that the patient can understand why testing may be an important thing to consider. And therefore, I think that’s why patients may say they don’t want to be tested. But I think if they understood that this kind of testing informs therapy that’s much more tolerable, they might be more open-minded toward it. So, I think there is a very long runway of improvement, both in the somatic and germline space, with respect to communication about the need for testing and/or meaning of testing.”

Clearly explaining how test results may guide treatment decisions that potentially provide better outcomes and clarifying the difference between biomarker testing vs. genetic testing for an inherited mutation can enhance patient communication and improve shared decision-making. Cancer clinicians should also be prepared to discuss the potential costs associated with biomarker testing. While state policy initiatives are underway to ensure coverage of NGS testing by commercial insurers, currently certain insurance companies may not cover NGS testing. Thus, cancer programs should have financial advocates in place who can work with patients and help them apply for patient assistance programs.

Focus group participants also identified a need to address disparities in access to testing for underserved populations. With multiple layers of barriers, such as geographic location, transportation, insurance coverage, and high out-of-pocket costs, ensuring access to comprehensive biomarker testing for underserved populations is a growing concern.

Although most cancer programs recognize that there are disparities, many institutions are simply trying to get an idea of the scope and size of the problem. By examining testing rates across different patient populations and leveraging data from electronic health records (EHR) systems and external testing vendors, they hope to get a clearer picture to develop tools to combat these disparities. In the meantime, providing guideline-concordant broad biomarker testing for every patient who requires it, while working with navigators to identify opportunities for financial and other means of support, is the best route.

Carla Strom, MLA, and Director of Operations in the Office of Cancer Health Equity at Atrium Health Wake Forest Baptist in Winston-Salem, N.C. adds this: “You do have to be able to recognize concerns, but not let them [social determinants] keep you from offering and talking about things like biomarker testing or clinical trials.”

**Final Thoughts**

Because NTRK fusions are relatively uncommon, it remains imperative to perform broad biomarker testing that includes both DNA and RNA testing in patients with advanced solid tumors. The use of a multigene NGS panel may represent the optimal balance across effectiveness, efficiency, and cost for most patients with solid tumors. Optimal communication is necessary to coordinate timely testing on tissue, plasma, or both.

Dr Joseph Kim is President of Xaf Solutions and is a consultant specializing in education and quality improvement projects for cancer programs. He is also a Fellow of the American College of Healthcare Executives (FACHE) and holds degrees from MIT, UAMS, UMass Amherst, and St. Joseph’s University.

For more information and resources, visit the ACCC program webpage
REFERENCES


fast facts

Tips to Help You Lead with Empathy

• **Dig deep to identify what is driving your team members anxiety.** Is it challenges with remote work or a return to the office? Is it related to their family or home life? Are they facing financial stressors from inflation and rising grocery and housing costs? Understanding the root of anxiety helps leaders determine if and how they can help alleviate any of those concerns.

• **Be honest and transparent about work-related concerns.** Leaders can alleviate some stress by offering flexibility, shortening meetings, and offering activities that promote self-care and connection.

• **Prioritize mental health.** Beyond employee-assistance programs, other solutions could be to bring in health professionals to focus on mental wellness, or to help team members improve empathy and connection; invite therapists to offer initial counseling sessions for free or at a reduced price; and/or reimburse a percentage of out-of-pocket mental health costs.

• **Normalize wellness journeys.** Demonstrate your commitment to mental healthcare, learn to recognize signs of team members in crisis, and model behavior that helps team members manage their own anxiety.


10 Ted Lasso Lessons for Leaders

Lesson 1. Lead with empathy
Lesson 2. Being vulnerable doesn’t make you weak
Lesson 3. Optimism is infectious
Lesson 4. Doing the right thing is never the wrong thing
Lesson 5. Optimists take more chances
Lesson 6. Embrace change
Lesson 7. Empowerment breeds confidence
Lesson 8. Humor cuts through tension
Lesson 9. Nobody is bigger than the team
Lesson 10. Stay teachable


Three Pillars of Psychological Safety

1. **Prevent harm.** Staff feel secure in the knowledge that they are protected from physical, emotional, and psychological harm.

2. **Promote health.** The organization actively builds an environment where staff feel physically, emotionally, and psychologically healthy.

3. **Resolve incidents and concerns.** When incidents occur or staff raise concerns, the organization takes steps to resolve the issue and takes responsibility.

For every $1 invested in employee mental health, employers see a $4 return on investment.


3 Strategies for Eliminating Recruitment Bias

1. Blind resume screening. Remove the names, addresses, names of educational institutions, graduation dates, and affiliated organizations. Remember: information gathered from social media, like a LinkedIn photo, can play a role in bias.

2. Broaden your talent pool. Use social media, online job boards, and professional networks, including organizations like the National Association of Black Oncologists and the Society for Women in Radiation Oncology.

3. Build diverse interview panels. Include individuals from different departments, levels of seniority, generations, and backgrounds to bring a range of perspectives to the interview process.


Critical Conversations: Navigating Drug Shortages and Empowering Oncology Pharmacists

This virtual round table of experienced pharmacists explores the management of drug shortages and offers valuable perspectives on the specific challenges associated with the current shortage of cisplatin and carboplatin. Through interactive discussions and real-world scenarios, participants will enhance their knowledge, hear ideas, and develop actionable plans to tackle drug shortages effectively. youtube.be/tPHFiJIooDQ

Express Symptom Management Prevents Unnecessary Oncology ED Visits

Read how this 2023 ACCC Innovator Award winning cancer program used a business intelligence dashboard to collect data on the patients with cancer who were presenting to the ED. Armed with this data, the cancer care team now monitors high-risk patients, tracks unnecessary ED visits, and measures outcomes. accc-cancer.org/express-symptom-management. Then attend the ACCC 40th National Oncology Conference, Oct. 4-6, in Austin to hear more about their challenges and successes.

A New Registry Study for a Rare Form of Breast Cancer

Working under the hypothesis that a subset of patients who are treated with a combination of systemic therapy, surgery, and radiation or ablation of metastatic sites will have long-term distant metastasis free and overall survival, this multi-cohort, prospective, nationwide registry study will enroll newly diagnosed oligometastatic HER2+ breast cancer patients. accc-cancer.org/podcast-ep-116.

Integrating Oral Oncolytics into Chronic Lymphocytic Leukemia Practice

This ACCC Effective Practice Guide highlights case studies profiling effective integration practices to facilitate caregiver education, improve medication adherence, and mitigate the financial burden experienced by patients with chronic lymphocytic leukemia. accc-cancer.org/cll-effective-practice-guide.

Trans-Inclusive Cancer Care: An Important Part of Health Equity

Released in recognition of National Pride Month, this blog shares what it takes for cancer programs and practices to provide trans-inclusive care, including links to resources like a list of questions that all patients should ask their health care providers prior to receiving any cancer screening, a database that helps people locate an LGBTQ+-friendly provider in their area, and LGBTQ+ cancer peer support groups. accc-cancer.org/trans-inclusive-cancer-care.
As ACCC’s new Director, Cancer Care Delivery and Health Policy, I look forward to communicating with the Association’s interdisciplinary membership about important issues. In addition to the four priorities ACCC has previously announced as a focus for 2023, I will delve into additional policy areas impacting patients with cancer, such as ensuring ongoing access to care through telehealth, increasing access to and diversity in clinical trials, and advancing value in the provision of (and payment for) oncology care. Together with ACCC’s blog, ACCCBuzz, I will also use this bi-monthly column to highlight urgent issues that arise for ACCC members and patients with cancer, such as the current shortage of anti-cancer medicines highlighted in the Association’s June 15 statement.1

ACCC advances its priorities in several ways, including letters of support for specific pieces of legislation that our members can personalize and send to their elected officials using the ACCC Legislative Action Center. ACCC also works with a range of coalitions to voice support for (or concern about) proposed legislation, regulations, or policies. Given the multidisciplinary nature of the membership, ACCC often partners with organizations that represent clinician groups, such as physicians, nurses, and pharmacists, among others.

For example, in March, ACCC joined a broad coalition of patients, advocacy organizations, cancer centers, and healthcare professionals to sign a letter in support of The Reducing Hereditary Cancer Act.2 ACCC policy priorities also align with an American Medical Association-led effort that developed guiding principles related to the use of prior authorizations and utilization management.3 “This group strongly urges health plans, benefit managers, and any other party conducting utilization management (“utilization review entities”), as well as accreditation organizations, to apply the following principles to utilization management programs for both medical and pharmacy benefits.” Not only does this effort align nicely with the Association’s focus to preserve provider and patient choice and to reduce delays in care due to utilization management, it complements tools and resources ACCC has developed as part of its Prior Authorization Clinic.4

And now I would like to take the opportunity to share a little bit about myself. Trained as an attorney, I have worked on health care legislation, regulations, and policy for more than 25 years in the U.S. and internationally. My experience spans the public, non-profit, and private sectors and has afforded me the opportunity to advise senior government officials, corporate executives, and policy experts on a range of issues affecting access to health care coverage and services. My work has focused on the development, implementation, and analysis of comprehensive and incremental health coverage and systems reforms.

My family’s history with cancer has also fueled my passion for ACCC’s mission and work. While my father’s prostate cancer was diagnosed early and treated effectively, my mother had a different experience. Her ovarian cancer was diagnosed at a later stage and, after more than 5 years of varied and difficult treatments, she succumbed to the disease in her sixties. I was fortunate to be able to help my mother navigate aspects of her treatment journey, and I look forward to my personal and professional experiences informing my work with ACCC, its diverse membership, and its broad advocacy and policy agenda.5

References
Understanding Medicare Payment Adjustments to Avoid Overinflated ROIs

TERI BEDARD, BA, RT(R)T, CPC

Success in health care, particularly oncology, is often measured in patient outcomes. To achieve those outcomes, oncology programs and practices must be able to invest in the latest technology and drug therapies, so it is important to understand the true return on investment (ROI) on these purchases. Developing an accurate ROI is complicated. Administrators must understand the Medicare payment systems, the Medicare Physician Fee Schedule (MPFS)¹ and the Hospital Outpatient Prospective Payment System (OPPS),² and the various applicable Medicare payment adjustments that can dramatically change the final payment rate.

Regardless of whether your cancer program is office- or outpatient hospital-based, there may be several reasons you may not be paid for all services provided to patients and/or paid at the “finalized” Medicare rate. Some of the more common payment adjustments may be due to annual or quarterly procedure code valuation updates, sequestration, packaging and bundling, multiple procedure reductions, and/or comprehensive ambulatory payment classifications (C-APCs).

Annual Procedure Code Updates
Valuations for procedure codes paid under MPFS and OPPS are updated quarterly when new Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) codes are released. Other adjustments could be due to legislative action, or most often final rule policy updates.

Services provided by physicians and physician practices in a facility (hospital or ambulatory surgical center) and nonfacility (office-based/freestanding) setting are paid under MPFS. Rates are calculated using a complex equation based on assigned values known as relative value units for physician work, practice expense, and malpractice. These values, adjustments based on cost of living within geographic locations, and, finally, a conversion factor are all used to calculate a recognized dollar amount that results in a final assigned payment.

Services provided by the hospital in the facility setting are paid for under OPPS. Services reimbursed under OPPS are assigned an Ambulatory Payment Classification (APC) with multiple CPT or HCPCS codes receiving the same APC designation. Services considered similar from both a clinical and resource aspect may be placed in a single APC. All procedure codes within a single APC are paid the exact same amount by Medicare. These Medicare finalized rates for the start of each year are released at the time of final rule, typically on or by November 1 of each calendar year. Over the past several years, due to various Congressional interventions, the finalized rates have been subsequently adjusted from the rates finalized by CMS. It is vital that administrators update their fee schedules, chargemasters, and ROI models with the most recent and accurate Medicare rates to ensure they are establishing an accurate baseline.

Sequestration
Outside of a temporary hold placed during the COVID-19 public health emergency (PHE), a 2% reduction “sequestration” has applied to all Medicare Fee-for-Service (FFS) payments since April 1, 2013, as required by The Budget Control Act of 2011.¹ The sequestration is only applied to the Medicare portion of payment, 80% of the assigned rate, at the individual code level. The other 20%, which is the responsibility of the patient or their secondary insurance, is not adjusted.

During the PHE, sequestration was suspended due to various mandates. The Coronavirus Aid, Relief, and Economic Security (CARES) Act¹ suspended sequestration reductions to all FFS claims from May 1 to December 31, 2020. The Consolidated Appropriations Act, 2021,¹ extended the suspension of sequestration until March 31, 2021. The Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes,¹ extended the suspension until December 31, 2021. Finally, The Protecting Medicare and American Farmers From Sequester Cuts Act¹ suspended sequestration through March 31, 2022, implemented a sequestration of 1 percent from April 1 to June 30, 2022, and resumed the 2% sequestration effective July 1, 2022. Sequestration is scheduled to continue through fiscal year 2023.¹

Packaged Services
The terms “packaged” and “bundled” are often used interchangeably by health care providers, but there are very important differences. Understanding these differences can help providers avoid incorrect coding practices and even potential revenue loss for the health care organization.

Packaging is a reimbursement term that relates only to outpatient hospital services. It refers to the practice of making a single payment that includes payment for a significant procedure, as well as the “minor, ancillary services” generally associated with the procedure. Even though CMS may not provide separate payment, the codes for packaged...
services should still be reported on the claim unless contraindicated by authoritative coding guidance or National Correct Coding Initiative (NCCI) edits.

CMS addresses drug administration codes specifically within Chapter 4 of its *Medicare Claims Processing Manual*: “Hospitals should report all HCPCS codes that describe the drug administration services provided, regardless of whether or not those services are separately paid, or their payment is packaged.” It is especially important hospitals continue to charge for packaged services so CMS can collect accurate cost data for individual procedures. Also, not all payers follow Medicare payment policies, and some may provide payment in situations where CMS does not.

There are a few different scenarios when packaging of services impacts oncology. For example, radiation oncology hospital outpatient departments have not been paid for image-guided radiotherapy (IGRT) since 2008. Hospitals have continued to report IGRT, and other imaging during the course of treatment, even though CMS has not made separate payments as they consider the services to be part of other, more primary services. Similarly, the use of contrast with setup simulations is not separately reimbursed.

One note, CMS establishes a drug packaging threshold each year. Drugs and biologicals estimated at a per day administration cost less than or equal to the finalized amount, for 2023, drugs with payments of $135 and less are not paid separately. Any diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies or devices when used in a surgical procedure are also not paid separately when their estimated per day cost is greater than the set threshold. Although there may be instances when conditionally packaged services are paid when they are the only service for an encounter, when combined with other services, these services are not paid separately.

**C-APCs and Bundled Services**

Under OPPS, CMS also created C-APCs, which have created a hierarchy of services common to single day surgical procedures. The primary code of the single-day surgical procedure is assigned a status indicator “J1,” which means it is the highest valued code. When any other services are performed, which are considered ancillary to the primary service and assigned a status indicator of anything except “F,” “G,” “H,” “L,” and “U,” the services are not paid separately, but considered packaged into the primary service.

If 2 services both designated as J1 are performed as part of the same encounter, they may qualify for a complexity adjustment, where the lesser valued code is included in the higher J1 code and not paid separately. For example, when CPT 38220 for bone marrow aspiration and 38221 for bone marrow biopsy are reported on the same claim, a complexity adjustment is made, and they are paid the same as the combination code 38222 for bone marrow biopsy and aspiration.

For radiation oncology, in gynecological brachytherapy when needles and HDR tandem and ovoid applicator are placed in the OR, needle placement (reported with CPT 55920) and tandem and ovoid applicator placement (reported with CPT 57155) have a complexity adjustment into the next APC. However, when hydrogel is placed and billed with CPT 55874, and fiducial markers are placed and reported with CPT 55876, the marker placement code is not separately reimbursed. It is considered ancillary to the hydrogel placement and part of the primary designated procedure.

Bundling refers to the application of coding rules to ensure the procedure codes submitted on the claim accurately reflect the services provided. CMS utilizes the Medicare National Correct Coding Initiative, which provides an overall set of guidelines that define how multiple procedure codes will be reimbursed if submitted for the same patient on the same date of service. Other payers may employ the same NCCI edits or develop separate payer-specific bundling guidelines. Providers who have a signed participation agreement or contract with an insurer have generally agreed to accept their payer-specific bundling edits, which may be different from those applied by Medicare.

Bundling edits apply across all practice settings. CMS has repeatedly stated that bundled services should not be billed to Medicare; the physician, practice, or facility should apply all bundling edits prior to issuing a claim. According to Coding Clinic for HCPCS, “procedures should be reported with the most comprehensive CPT code that describes the services performed.” For example, within radiation oncology, all simulations with IMRT planning are commonly bundled. Regardless of the medical necessity and documentation, the work by the physician, physician office, and hospital for the simulation process is not reported on the claim with IMRT. In medical oncology, infusions and injections include items that are considered integral and bundled into the administration, such as:

- IV start or access to indwelling catheter, IV, or port
- Local anesthesia
- Standard supplies (tubing, syringes, etc)
- Flush at initiation and/or conclusion of infusion
- Monitoring for adverse reactions

Although Medicare’s nonpayment for services due to packaging and bundling cannot be avoided, there may be scenarios where “hurry up and treat” is not in the best interest of the patient or practice. However, CMS has repeatedly said that unbundling of services (to split them out over different days and maximize reimbursement) is not appropriate, as well as use of modifiers for the sole purpose of increasing payment rates.

**Multiple Procedure Reduction**

Under the MPFS, when multiple procedures are provided during the same single encounter, CMS will typically not reimburse at 100% of the assigned rate for all the services provided because the agency believes there is duplicity in the utilization of the overhead (eg, supplies, equipment, and staffing). Instead, CMS will apply a multiple procedure reduction. The reduction may apply to designated surgical and diagnostic imaging. The procedure with the
highest assigned value is paid at 100%, each subsequent service is paid at a reduced rate, such as 50% or 25% of the assigned rate.

To determine if a procedure or imaging service is subject to a multiple procedure reduction under MPFS, within the quarterly RVU file, CMS will identify under the column titled “Mult Proc” the assigned designation. Procedure codes assigned 1, 2, or 4 would most likely apply to oncology and are subject to reductions. For example, bone marrow biopsy and aspiration codes, intramuscular chemotherapy therapy codes, placement of brachytherapy applicators, and hydrogel are all assigned a designation of 2. When performed with other designated multiple procedures, the highest code in the group is paid 100% of the assigned rate and the others are paid at 50%.

Even if your program or practice treats very few Medicare beneficiaries, an understanding of Medicare payment systems is important because many private payers use Medicare rates as a baseline for their contracts.

Remember: An accurate ROI is only as good as the data put in. Overvaluing or forgetting some of the factors impacting Medicare’s assigned payment can skew the ROI. In the end, if the calculated return on investment and reimbursement outlook seems too good to be true, it probably is.

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References


The concept of patient navigation in health care owes its origin to Harold P. Freeman, MD. Born and raised in the District of Columbia, Dr. Freeman received his doctor of medicine from Howard University College of Medicine, where he completed his residency in general surgery at Freedmen’s Hospital (now Howard University Hospital). In 1990, following an observation on the number of Black women who received a diagnosis of terminal breast cancer at Harlem Hospital Center, New York, New York, and in combination with findings from the American Cancer Society on the effects poverty has on the treatment of cancer and other chronic diseases, Freeman launched the first ever patient navigation program. Dr. Freeman credits this innovation to his background and is one in a long line of Black scholars that Howard University has produced. Carla D. Williams, PhD, is another.

Dr. Williams is an associate professor of medicine and public and health at Howard University and serves as the interim director of the Howard University Cancer Center. Founded in 1932, the cancer center is 1 of 5 cancer programs in DC. It is adjacent to Howard University’s main campus and is dedicated to delivering equitable and comprehensive cancer care to patients in in DC, Maryland, and northern Virginia. Like many cancer programs within academic health systems, all Howard University Cancer Center’s clinicians have a faculty appointment in the medical school. Dr. Williams said she believes this facilitates the education of health care professionals to deliver next generation cancer care through the lens of equity and diversity.

“Our history and founding have always been centered around health equity,” said Dr. Williams. “I think when you look at the people who have trained here, they carry that zeitgeist—that spirit to wherever they go.” It is this spirit that inspired Dr. Freeman’s innovation, and Dr. Williams said that is what makes Howard University Cancer Center unique. “Howard [University] is known as the capstone, as the mecca, so we have an obligation to train our physicians to transform how care is delivered,” she said. “All of our graduates, who are now practicing throughout the country, carry that vision, and I am here to try and continue that legacy.”

Building Community Partnerships in Cancer Screening

Understanding the challenges underrepresented communities have in accessing health care, the cancer center created several robust screening programs—each of which Dr. Williams describes as a “true partnership,” with community-based organizations. “Those partners are the ones navigating patients to us, and we have found that tailored navigation makes a big difference in whether patients show up for care,” she said. “When our partners navigate their clients, patients are more likely to show up.”

The Rosemary Williams Mammody Program was developed as a high-risk breast cancer screening program that targets women who are uninsured, underinsured, or not able to easily access routine care. The program has since expanded to include all women in the area. Men Take Ten, which launched more than 15 years ago as a prostate screening program, has now grown into a general men’s health program at Howard University Hospital.

“For some Black men, we know that there are various barriers to accessing primary care, so we have been able to integrate diabetes, blood pressure, and oral cancer screening into the program,” Dr. Williams said. “These are all designed to get people into care.”

Delivering Comprehensive Cancer Care

Patients are primarily referred to the cancer center through 1 of the 3 primary care clinics at Howard University Hospital. The cancer center is part of a group practice called the Howard University Faculty Practice Plan.

“We have all specialties represented here, and I believe this is beneficial to patients with cancer who present at the center, as they have access to multidisciplinary expertise,” Dr. Williams said. For outpatient oncology services, patients must visit the Ambulatory Care Center—a physician center where the cancer clinics are open Monday through Thursday.

For the infusion suite, patients must visit the main cancer center—a 6-story standalone facility that offers infusion services on the first floor. The infusion suite has 10 chairs and is staffed by 5 nurses, 1 certified nurse assistant, and 1 medical secretary. Patients also have access to Howard University hospital pharmacy, which is staffed by 15 pharmacists and 20 pharmacy technicians. The cancer center employs 2 full-time equivalent (FTE) and 1 part-time medical oncologists, who also oversee all hematology cases. Further, the cancer center has 3 surgical oncologists, 2 breast surgeons, and 2 specialized colorectal surgeons. Patients can also access radiation oncology services here, as the cancer center offers intensity-modulated radiotherapy, stereotactic body radiotherapy, external beam radiation, and radium Ra 223 dichloride injections. The radiation oncology clinic is
staffed by 1 FTE and 1 part-time physician, 1 part-time dosimetrist, 1 FTE physicist, and 1 FTE registered nurse.

“We currently maintain 4 multidisciplinary tumor boards,” Dr. Williams said. “Patients are prospectively seen in these tumor boards, where we have all the specialties represented. That is where we can identify other challenges that patients may face.”

According to Dr. Williams, 10% to 15% of patients in DC choose to receive their cancer care at Howard University Cancer Center. A fair number of those patients come from Ward 7, on the east side of DC an area that Dr. Williams says has historically lacked cancer care services. “At different points in time, we have operated a satellite clinic in Ward 7, but unfortunately that has not been sustained without interruption,” Dr. Williams said. “Our challenge is [that] we don’t have a lot of medical providers, so it is hard to keep a satellite clinic running efficiently and effectively.” However, through a strategic partnership with Unity Health Care East of the River Health Center, the cancer center has maintained 1 satellite location where patients can access breast imaging services closer to home.

Supportive Care
In early 2020, during the COVID-19 pandemic and when groceries and household items were in short supply, the cancer center opened a pantry. “It was developed so [that] our patients did not have to fight crowded stores to get simple household supplies like toilet paper,” Dr. Williams said. “Some our patients experience some level of food insecurity, so it also serves that purpose. Now, patients with cancer can access healthy meal ingredients through this pantry.

The cancer center offers transportation services, as well as gas cards. “[The District of Columbia] has medical transportation services that patients can access, so we make sure they are signed up for that,” Dr. Williams said. “Many of our patients have financial barriers that are challenging, and we are just finding small ways to overcome those barriers.”

According to Dr. Williams, two-thirds of the patients with cancer that present to the cancer center are publicly insured, either through Medicaid or Medicare. Dr. Williams wagers that the cancer center has had to deal with issues of inequities and reimbursement of services from certain payers, years before the groundswell of health equity initiatives permeated the oncology space. “We want to make sure that there is equitable access to good quality care despite insurance type and other kinds of disparities of health,” Dr. Williams said. “This is something that we have always done and, sometimes, we don’t think of it as a separate diversity and inclusion goal—it is really how we operate.”

In the 1970s, Howard University Cancer Center was one of the first National Cancer Institute–designated cancer centers. “It was a joint designation with Georgetown Community Hospital, Georgetown Cancer Center, and it represents what I [am] most proud of with our center,” Dr. Williams said. “We have endured. We have endured periods of known inequities long before there were mandates to address them. We were seeing patients who could not be seen anywhere else.”

Reference

Approved Drugs

• On May 19, the US Food and Drug Administration (FDA) granted accelerated approval to Epkinly® (epcoritamab-bysp) (Genmab, genmab.com) for relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy.

• On May 31, 2023, the FDA approved Lynparza® (olaparib) (AstraZeneca, astrazeneca.com) in combination with abiraterone and prednisone (or prednisolone) for adult patients with deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer, as determined by an FDA-approved companion diagnostic test.

• On April 17, the FDA approved Omisirge® (omidubicel-only) (Gamida Cell, gamida-cell.com) for use in adult and pediatric patients with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning.

• On April 19, 2023, the FDA approved Polivy® (polatuzumab vedotin-piiq) (Genentech, gene.com) in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone for adult patients who have previously untreated DLBCL, not otherwise specified, or high-grade B-cell lymphoma and who have an International Prognostic Index score of 2 or greater.

Drugs In the News

• Bristol Myers Squibb (bms.com) and 2seventy bio (2seventybio.com) announced that the FDA accepted a supplemental biologics license application (BLA) for Abecma® (idecabtagene vicleucel) for the treatment of adult patients with relapsed and refractory multiple myeloma who have received an immunomodulatory agent, proteasome inhibitor, and anti-CD38 monoclonal antibody.

• Agenus (agenusbio.com) announced that the FDA granted fast track designation to the AGEN2034 (balstilimab) and AGEN1181 (botensilimab) combination.

• Takeda (takeda.com) and Hutchmed (hutch-med.com) announced that the FDA accepted a new drug application (NDA) for fruquintinib for the treatment of adult patients with previously treated metastatic colorectal cancer.

• Janssen (janssen.com) announced that it submitted a supplemental BLA to the FDA for Carvykti® (ciltaclabtagene autoleucel) for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy, including a proteasome inhibitor, immunomodulatory agent, and are refractory to lenalidomide.

• Accord BioPharma (accordbiopharma.com) announced that the FDA accepted the BLA for HLX02—a proposed biosimilar to Herceptin® (trastuzumab) (Genentech, gene.com)—for the adjuvant treatment of HER2-overexpressing and overexpressing metastatic breast cancer, as well as HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

• GSK (gsk.com) announced that the FDA accepted a supplemental BLA for Jemperli® (dostarlimab) in combination with chemotherapy for the treatment of adult patients with mismatch repair deficient, primary advanced, or recurrent endometrial cancer.

• Merck (merck.com) announced that the FDA accepted for review a supplemental BLA for Keytruda® (pembrolizumab) in combination with standard-of-care chemotherapy (gemcitabine and cisplatin) for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer.

• Iovance Biotherapeutics (iovance.com) announced that the FDA accepted a BLA for lifileucel for the treatment of patients with advanced melanoma.

• Taiho Oncology (taihooncology.com) announced that the FDA accepted for priority review the supplemental NDA for Lonsurf® (trifluridine and tipiracil) as a monotherapy or in combination with bevacizumab for the treatment of adult patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
Devices and Assays in the News

- On May 4, the FDA approved the FoundationOne® Liquid CDx (Foundation Medicine, foundationmedicine.com) as a companion diagnostic for Exkivity® (mobocertinib) (Takeda, takedaoncology.com), which is approved for the treatment of adult patients with locally advanced or metastatic NSCLC with epidermal growth factor receptor exon 20 insertion mutations, as detected by an FDA-approved test, and whose disease has progressed on or after platinum-based chemotherapy.

- On June 9, the FDA also approved the FoundationOne Liquid CDx as a companion diagnostic for Braftovi® (encorafenib) (Pfizer, Pfizer.com) in combination with cetuximab, which is approved for adult patients with previously treated metastatic colorectal cancer harboring a BRAF V600E alteration.

- Lumicell, Inc. (lumicell.com) announced that the FDA has accepted and granted priority review to the NDA for Lumisight™ (an optical imaging agent). The company also announced that the FDA accepted a premarket approval application for the Lumicell™ direct visualization system.

- Lantheus Holdings (lantheus.com) announced that the FDA granted fast track designation to 177Lu-PNT2002 for the treatment of metastatic castration resistant prostate cancer.

- Daiichi Sankyo (daiichisankyo.com) announced that the FDA extended the review period for the NDA of quizartinib in combination with standard cytarabine and anthracycline induction, standard cytarabine consolidation chemotherapy, and as continuation monotherapy following consolidation for the treatment of adult patients with newly diagnosed acute myeloid leukemia that is FLT3-ITD positive.

- Bristol Myers Squibb (bms.com) announced that the FDA accepted the supplemental BLA for Reblozyl® (luspatercept-aamt) to expand its current indication to include treatment of anemia without previous use of erythropoiesis-stimulating agents (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes who may require red blood cell transfusions.

- Bristol Myers Squibb (bms.com) announced that the FDA accepted the NDA for repotrectinib for the treatment of patients with ROS1-positive locally advanced or metastatic non-small cell lung cancer (NSCLC).

- Galera Therapeutics (galeratx.com) announced that the FDA granted orphan drug designation to rucosopasem manganese for the treatment of pancreatic cancer.
Recent years have seen alarming shortages of several anti-cancer drugs that serve as mainstays of treatment. Currently, the Association of Community Cancer Centers (ACCC) is highly concerned about the ongoing shortages of platinum-based chemotherapy agents (e.g., cisplatin and carboplatin), two medications that (individually or in combination) treat and cure a wide range of cancers, including but not limited to gastric, pancreatic, colorectal, esophageal, cervical, and ovarian. These shortages are occurring across treatment settings and geographies, including community cancer centers, hospital-based programs, and private practices. The widespread and critical nature of the shortage has already forced clinicians to choose between and among patients eligible for curative and supportive therapies. Hence, the quality of care for patients with cancer and their very lives are at stake.

“An ACCC member program recently shared how drug shortages were essentially forcing oncologists to ‘prioritize’ patients receiving curative treatment over those receiving palliative care,” said ACCC Chief Medical Officer and Deputy Executive Director, Leigh Boehmer, PharmD, BCOP. “That is not a decision any cancer care provider wants to—or should need to—make.”

Platinum drug shortages were first reported to the U.S. Food and Drug Administration (FDA) on February 10, 2023. In a recent survey by the National Comprehensive Cancer Network (NCCN), released on June 7, 93% of NCCN centers surveyed reported a shortage of carboplatin and 70% reported a shortage of cisplatin. These types of shortages are demonstrative of broader challenges with prescription drug manufacturing integrity in the U.S., stemming from production delays, unavailability of raw ingredients, and/or quality deficiencies, among other factors.

ACCC is pleased that the FDA has worked with Qilu Pharmaceutical Co. Ltd. (Qilu) and its distributor Apotex Corp. to allow for the temporary importation of cisplatin during the shortage. Only Qilu and Apotex Corp. are allowed to import or distribute Qilu’s cisplatin injection in the U.S. Qilu issued a “Dear Healthcare Professional” letter that highlights some labeling changes and clarifies certain safety questions that may arise from the importation and distribution of its product in the U.S.2

ACCC stands behind its members as they work with stakeholders across the health care system, including federal and state governments, the pharmaceutical industry, payers, cancer care team members, and patients and caregivers, to find solutions to the current shortages. The Association also supports its members’ efforts to develop longer term solutions to avoid recurrences of these and other anti-cancer drug shortages. Such life-threatening challenges to the provision of high-quality cancer care simply must not continue. ACCC is committed to partnering with our members and other organizations to aggregate experiences, resources, education, and advocacy efforts to help the cancer care community respond to this urgent challenge in the service of its patients.

ACCC and its managed oncology state society chapters are encouraging members to report any drug shortages to the FDA. The more reports the agency receives, the better understanding it will have of where these shortages are occurring. Shortage notifications and updates may be reported to the FDA at drugshortages@fda.hhs.gov.

References
In June, ACCC partnered with the Hematology/Oncology Pharmacy Association and the Association of VA Hematology/Oncology to host a virtual round table to provide a unique opportunity for oncology pharmacists, healthcare professionals, and stakeholders to explore the management of drug shortages and gain valuable perspectives on the specific challenges associated with the current shortage of cisplatin and carboplatin. As the demand for effective oncology treatments continues to rise, drug shortages have become a significant concern that poses numerous challenges to healthcare providers and patients alike. Oncology pharmacists play a crucial role in addressing these shortages and ensuring optimal patient care through their expertise in drug management, therapeutic alternatives, and communication with healthcare teams. This round table webinar brought together experienced oncology pharmacists to share their insights, experiences, and practical strategies to tackle drug shortages effectively, with a particular focus on the management of cisplatin and carboplatin shortages. Watch this roundtable online at: youtube.com/watch?v=tPH5jl0oDQ.

Virtual Oncology Reimbursement Meeting: Value Based Care Best Practice to Support High-Quality Care Delivery

An expert panel discusses what cancer programs and practices need to do to effectively prepare and implement an alternative payment model. Learn best practices when developing and implementing an alternative payment model, including how you can maintain person-centered care in practice and protect your bottom line with such arrangements. ICYMI: Watch today at: courses.accc-cancer.org/products/virtual-2023-orm-value-based-care-best-practices-to-support-high-quality-care-delivery.
We all know that the globe is warming. Twenty years ago, few people believed it was real; 10 years ago, some people believed it was real but not as a result of human activity; and now, many people believe that either it is real but will not affect them for a long time (so why suffer the pain and expense of changing our lifestyle now?) or that it is real and will be catastrophic, yet nothing can be done.

I am a medical oncologist, and, until recently, found myself in the latter category. Actually, that is not quite true. I was in the “I’m-too-busy-to-do-something-about-it-maybe-someone-else-will” category. And then, the trees around our cabin in the mountains in southwest Colorado started dying due to infection by spruce beetles, as the trees became increasingly stressed by drought and heat. It was also around the same time that forest fires started emerging as billion-dollar events in the West, including in Colorado, and it occurred to me that my grandchildren might never see these magnificent forests. These events made it clear to me on a personal level that climate change is happening now.

To be transparent, I have since retired and thus no longer have the “I’m-too-busy-to-do-something-about-it” excuse. However, it has become clear to me that the “maybe-someone-else-will” excuse is no longer a viable option. Climate change is affecting us today, and the impacts are largely irreversible; they will only increase in the future depending on the actions we take now.

Climate change is typically seen through an environmental, political, or socioeconomic lens. Yet it should also be seen as a catastrophic health threat. Climate change will have major impacts on children; pregnant women and their unborn babies; older adults; low-income and disadvantaged people in our society; low- and middle-socioeconomic countries, among others. It will change our way of life, including our ability to care for patients with cancer. A warming climate will impact patients with cancer in many ways, including increases in:

- Vector-borne diseases
- Diseases due to poor water quality
- Asthma and allergies
- Dehydration and renal impairment
- Food insecurity
- Mental stress
- Cardiovascular and pulmonary morbidity and mortality

Perhaps 2 of the biggest areas we will see these impacts in the US are in air pollution and access to care (see Figure 1, page 95).

Pollution

Air pollution and climate change are 2 sides of the same coin; they are both largely due to the burning of fossil fuels. The Institute for Health Metrics and Evaluations’ “Global Burden of Disease Study 2017” calls it out as the second most common cause of lung cancer, after smoking. Epidemiological studies have reported between a 13% to 14% increase in the risk for lung cancer mortality per each 10 mg/m³ increase in fine particulate matter (PM2.5) concentrations. In patients who have never smoked, each 10 mg/m³ increase in PM2.5 concentrations is associated with a 15% to 27% increase in lung cancer mortality.

Access to Care

As the planet warms, we are seeing more extreme weather events—hurricanes, sea rise, droughts, floods, and wildfires. A meta-analysis of the effects of natural disasters on cancer care found significant impacts, including damage to infrastructure and workforce management; loss of medical records and tissue samples; the need for evacuation of patients and staff; disruption to communication services and supply chains; and a lack of medications. Perhaps, most importantly, interruptions in a patient’s anticancer treatment can worsen their prognosis and survival.

Taking Action

What can we (oncology health care professionals, health systems, and organizations) do? After all, we are busy, and climate change’s direct impact on providers and patients seems both abstract and decades away. We could embrace the status quo argument that the “climate scientists and politicians will take care of it.” After all, we are physicians, nurses, and other health care professionals—we take care of patients with cancer, not polar bears. But it is precisely because we care about our patients and ourselves that we need to get involved in the climate change movement. In addition to educating our patients and the public (physicians are rated among the most trusted health care professionals) and changing our individual lifestyle practices—all of which are important—we can advocate for the environment with our legislators and policymakers. We can also look in the mirror and act.

The US health care sector is estimated to contribute about 8% of all pollution in the country, including acid rain (12%), greenhouse gas emissions (10%), smog formation (10%), air pollutants (9%), stratospheric ozone depletion (1%), and carcinogenic and non-carcinogenic air toxins (1% to 2%). The country’s health care emissions account for...
27% of the total global health care footprint and is the highest in the world.\textsuperscript{14} It also contributes an estimated 23 million to 44 million tons of municipal solid waste.\textsuperscript{15}

We need to dramatically reduce the carbon footprint of the US health care sector. Eighty percent of health care’s carbon emissions come from the production, transportation, utilization, and disposal of goods and services, such as pharmaceuticals and other chemicals, food and agricultural products, medical devices, and hospital equipment and instruments.\textsuperscript{16} Although it is difficult to estimate how much our specialty’s contribution is, compared to this larger problem, given the magnitude of oncology’s impact on most health care organizations through the use of chemotherapy, radiation therapy, surgical oncology, and diagnostic services, it is likely to be a significant amount.\textsuperscript{17} Climate scientists have summarized key actions to lower emissions, including:\textsuperscript{18,19}

- Powering health care with clean and renewable energy
- Investing in zero emissions buildings and infrastructure
- Transitioning to zero emissions
- Offering sustainable travel and transport options
- Providing health and sustainable food options
- Incentivizing and producing low-carbon pharmaceuticals
- Embracing sustainable health care management

These actions will require organizational change. Health care systems, hospitals, clinics, and practices are starting to recognize the profound and growing threat to public health that is posed by climate change. In October 2020, the UK’s National Health Service became the world’s first nationwide health system to commit to reaching carbon net zero.\textsuperscript{20} In the US, the Department of Health and Human Services created its Office of Climate Change and Health Equity and promoted the voluntary Health Sector Climate Pledge, asking health care organizations to reduce their greenhouse gas emissions.\textsuperscript{21} As of April 2023, 116 health care organizations have signed on to the pledge.\textsuperscript{22} The US Department of Veterans Affairs also released its Climate Action Plan in August 2021, with targeted energy efficiency and renewable energy goals.\textsuperscript{23} Additionally, in March 2023, the Joint Commission requested feedback from the public on a draft accreditation standard to facilitate health care decarbonization. The 4 action points are:\textsuperscript{24}
Unfortunately, the commission has since decided to make its decarbonization standard voluntary, giving “extra credit” to those who meet these goals. This change was due to negative feedback from senior administrators, who were concerned about the logistics and financial challenges of the targets.

These initiatives require buy-in from our health care system, hospital, clinic, and practice leaders. We need to help find cost-neutral and/or cost-saving solutions. Resources are available to help health care organizations track greenhouse gas emissions and set reduction goals.

Many of us recognize that the effects of climate change will be catastrophic, especially upon our daily lives and ability to care for our patients. However, we often cite a range of personal, professional, and societal barriers that impede us from changing our actions, with the lack of time being the most important one.

Regardless, the climate crisis is unfolding rapidly, and we need to act now. We need you—as individual health care professionals and/or administrators—to recognize that while systemic factors that impact health care may be harder to see and require systemic solutions, they are nonetheless real. We need to advocate with our leaders, organizations, and stakeholders to mobilize toward education, research, and action in this critical space.

As oncologists who care deeply about our patients, it is our responsibility to do whatever we can to prevent cancer and reduce its complications. We all took oaths to “first, do no harm.” To have it within our power to prevent harm to future patients and not speak out—or not act—is a violation of that pledge.

Joan H. Schiller, MD, is a board member of the Lung Cancer Research Foundation and the former (retired) deputy director of clinical investigation at Inova Schar Cancer Institute in Fairfax, Virginia.

References