ONCOLOGY ISSUES

Developing a Disease-Site Specific Oncology Patient Navigation Program

ACCC
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Developing a Disease-Site Specific Oncology Patient Navigation Program

In 2020, this community-based cancer program started laying the foundation for a disease-site specific oncology patient navigation program that would grow exponentially over the next 2 years. In addition to a rapidly growing patient caseload, nurse navigator responsibilities grew extensively, largely due to increasing physician and system support of the program and role. To date, this 3-person oncology nurse navigator team has received over 2100 referrals from more than 259 providers.

By Stephanie Bonfilio

DEPARTMENTS

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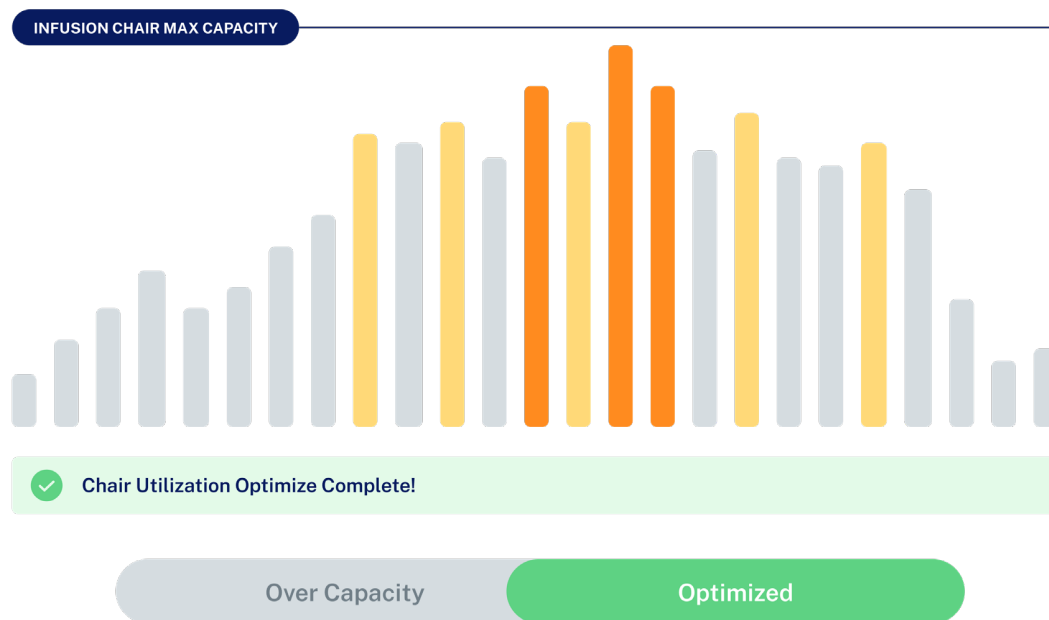
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Health is Wealth

BY MARK LIU, MHA

This summer has flown by, and I cannot believe it is winding down! I hope everyone was able to take some time for themselves to spend with friends and family or at least enjoy some scheduled rest and relaxation. Time does fly and we often are so quick to step up and offer to help that it can be easy to forget about self-care. For me, I took a week off to relax and disconnect by the beach and set some fitness goals to work towards this Fall. Between getting COVID-19 (the second time) and some other health challenges, it was a good reminder of the saying, "Health is wealth." These experiences drove home the importance of taking time for myself—both scheduled time and unexpected time to rest and recover.

Self-care is a term we hear more often now in the workplace and most leaders encourage this behavior, but it's also a concept that looks different for everyone. Self-care does not always have to be a big splurge or a massage (although there's nothing wrong with that type of activity). Self-care can be a group effort or even a team-based event at the workplace. For example, a colleague of mine makes a wellness Bingo card for different activities, such as carving out time to take a 15-minute walk to break up the workday, taking a moment to share appreciation for a colleague, or drinking 3 liters of water a day. I encourage you all to think about and take inventory of what has brought you joy and healthy habits, how often you do those activities, and if that is the right frequency for you.

And ACCC has resources to help. In her blog, Healthcare Leadership Strategies: Taking Time Off for Yourself, ACCCBuzz contributor Barbara Schmidtman, PhD, shares a bit about her recent self-reflection, which led to the realization that she was on a path leading to burnout, and the steps she took to course correct.

For those looking for a deeper dive and resources to support an entire team, this 2020 *Oncology Issues* article, Caring for the Caregiver, is a model for developing a self-care and resiliency program for oncology professionals. Among the "pearls of wisdom," this ACCC member shares to help others develop a similar program: 1) collaboration between spiritual services, psychosocial staff, and clinical staff is vital; 2) it is important to offer a wide range of activities from in-person events to digital communication, like apps; and 3) self-care education should be optional for staff; some will need these resources, others may already have robust support systems in place.

Finally, while the word "culture" has become a bit of a buzz word for organizations, we all know that the culture of our workplace has a huge influence on how we feel when we are there. Healthy and supportive work cultures tend to lead to workers who *feel* healthier and supported. In this 2022 *Oncology Issues* article, Cancer Centers of Colorado at SCL Health St. Mary's Medical Center shared how it transformed the workplace culture by implementing a Daily Improvement Program. Nothing that I could say would be more powerful than the author's words, "The positive impact the Daily Improvement Program had on the culture of the cancer center is in some ways immeasurable. For the many staff who experienced the cultural transformation firsthand, the impact reverberates throughout the entire building." **OI**
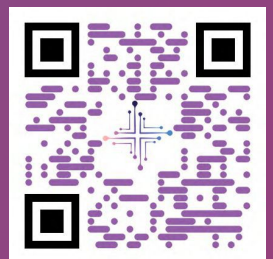
The Need for an Equitable Cancer Care Delivery System

BY OLALEKAN AJAYI, PHARMD, MBA

Despite scientific and medical advances, the incidence and mortality rates of cancer remain disproportionately high among certain populations. Geographic location now plays a significant role in predicting cancer mortality due to several factors, including socioeconomic status, race and ethnicity, and access to care.

People with lower socioeconomic status are more likely to be diagnosed with cancer and to die from the disease; they are more likely to live in areas with poor air quality, to have unhealthy diets, and to have less access to preventive care. These people are also more likely to delay seeking care, which can lead to later-stage diagnosis and poorer outcomes.

A study by the American Cancer Society found that people with low socioeconomic status were more likely to be diagnosed with breast cancer at a later stage than people with high socioeconomic status.[1] They were also more likely to die from breast cancer, even after adjusting for other factors such as age, race, and stage at diagnosis.[1] People of color are also more likely to be diagnosed with cancer at a later stage when the disease is more difficult to treat.

Another study by the National Cancer Institute found that Black Americans were more likely to be diagnosed with prostate cancer at a later stage than other men.[2] Black Americans were also more likely to die from prostate cancer, even after adjusting for factors such as age, stage at diagnosis, and treatment.[2]

Inequity in cancer care is a major public health problem that cannot be ignored. This inequity reveals a gaping hole in our healthcare delivery system; one that was only exacerbated by the COVID-19 pandemic. More patients seeking cancer care today are more likely to present with advanced disease due to gaps in screening during the pandemic, adding more pressure to an already strained cancer delivery system.

Fixing this inequity may not be that far out of our reach. However, a fair dose of determination and alignment among all stakeholders in the cancer care delivery system is necessary to implement solutions like those below:

- Expand access to health insurance and improve access to preventable care. This solution will allow patients to seek care earlier and providers to detect and treat cancers before they become more advanced.
- Leverage technology to improve access to care. Technology is an essential tool to help reduce barriers to cancer care for people living in underserved areas. Embracing and investing in the right technology will help providers identify our most vulnerable patients and intervene before it is too late.
- Improve diversity in the healthcare workforce. A more diverse workforce leads to inclusion of ideas that can help us expand how we deliver care. A more diverse workforce also provides the opportunity to build trust with patients in underserved areas.
- Fund research to understand the root causes of cancer care disparities. These data will allow us to develop effective interventions that improve cancer care equity and help us engineer best practices into our processes.

Making cancer care more equitable is a complex challenge, but one worth fighting for. We all have a responsibility and a role to play to ensure all patients access to the care they need. ACCC's long-time motto, "Together We Are Stronger" holds true in this scenario. Only by working together can we protect our most vulnerable patients. **OI**

References

1. Giaquinto AN, Sung H, Miller KD, et al. Breast cancer statistics, 2022. *CA Cancer J Clin*. 2022;72(6):524-541. doi: 10.3322/caac.21754

2. Lillard JW, Jr, Moses KA, Mahal BA, George DJ. Racial disparities in black men with prostate cancer: a literature review. *Cancer*. 2022;128:3787-3795. doi: 10.1002/cncr.34433

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Developing a Disease-Site Specific Oncology Patient Navigation Program

BY STEPHANIE BONFILIO, MSN,
RN, OCN, ONN-CG

The National Cancer Institute (NCI) estimated that in 2020, approximately 1,806,590 new cases of cancer would be diagnosed in the United States and 606,520 people would die from the disease, with the most common types of cancer being breast, lung and bronchus, prostate, and colorectal.[1] Based on 2015-2017 data, NCI estimated that almost 40% of men and women will be diagnosed with cancer in their lifetimes.[1] Estimated national expenditures for cancer care in the US in 2018 were $150.8 billion, with costs likely to increase as the population ages, more people are diagnosed with cancer, and new, potentially more expensive, treatments become the standard of care.[1]

Based on these data, St. Elizabeth Healthcare in Edgewood, Kentucky, took a firm stance on improving outcomes for patients with cancer. In April 2020, amidst a looming global pandemic with unanticipated downstream financial health care consequences, a disease-site specific oncology patient navigation program started to take shape. Based on the recognition that patients diagnosed with cancer need support, resources, and treatment, this community-based cancer program started laying the foundation for an oncology navigation program that would grow exponentially over the next 2 years.

St Elizabeth Cancer Center At-a-Glance

The cancer program at St. Elizabeth Healthcare is a hub and spoke model, comprised of the main cancer center in Edgewood, Kentucky, 2 additional sites in Northern Kentucky (Grant County and Fort Thomas), and 1 location in Southern Indiana (Dearborn County). In October 2020, a new 250,000-square-foot cancer center opened in Edgewood. This spacious building includes a plethora of resources for patients, caregivers, and staff, including an integrative oncology space with a demonstration kitchen, art therapy room, music therapy and group rooms, massage, acupuncture, on-site counseling services through Cancer Family Care, support groups with on-site assistance from Cancer Support Community, and many other services. Shortly after the building opened, Douglas Flora, MD, LSSBB, executive medical director, Oncology Services, shared, "The oncology nurse navigators are the glue that holds this building together." These high expectations helped to catapult the oncology patient navigation program forward.

The Oncology Patient Navigation Program

Although oncology nurse navigators had previously existed at St. Elizabeth Cancer Care, the role was unclear to both patients and staff. Many of the nurse navigators felt as though they were the "junk drawer" of oncology—if an issue could not be "fixed," it was sent to the navigator. The oncology nurse navigators were not disease-site specific, but instead associated with providers, most of whom treated all types of cancer, as well as benign hematologic diagnoses. There was no specialization and oncology nurse navigators did not spend enough time on direct patient care. Specifically, St. Elizabeth senior leadership recognized these areas of improvement:

- Job descriptions for oncology nurse navigators lacked utilization of core competencies and national guidelines.
- Oncology nurse navigator orientation needed to be structured, clearly tailored to the unique aspects of the role.
- Oncology nurse navigators performed many clerical functions; they were not working to the top of their license.
- There were no metrics to report on navigation impact or caseloads.

- Providers and staff needed additional education on the role and responsibilities of the oncology nurse navigator.
- Process mapping was needed to identify key points of contact between oncology nurse navigators and patients.

Accordingly, senior leadership looked to create an oncology navigation program tailored to the needs of the patients, improving the patient experience and patient outcomes, while also demonstrating sustainability through a proven return on investment.

As a first step, multiple role delineation meetings were held to determine what oncology nurses in the various clinics and roles were currently doing and what these nurses wanted to do. These meetings also helped to begin process mapping, with everyone collaborating to understand current patient pathways and brainstorm ways to make these pathways more efficient. In addition to these meetings, the oncology navigation manager met regularly with a cancer survivor and active member of the Cancer Patient Family Advisory Committee to discuss program planning through the lens of a patient and their family.

The team understood the importance of establishing a physician champion, someone who would help drive necessary practice change that would inherently come with the inception of this new program. With Kentucky's high lung cancer incidence and mortality rates, St. Elizabeth Healthcare had already developed a robust lung cancer screening program, so the team quickly determined to first roll out thoracic oncology navigation. Based on this decision, the team selected the thoracic surgeon who was most heavily involved in the lung cancer screening program, including the nodule review board, as the physician champion. This physician participated in multiple meetings to explore and identify resources needed from a provider's perspective. Soon after, a medical oncologist specializing in lung cancer joined the St. Elizabeth Cancer Care team and became an important partner with the navigation program, offering additional physician perspective.

In October 2020, shortly before the new cancer center opened its doors, the oncology navigation program officially launched with

> Although many of these platforms offered desirable capabilities, the team always came back to putting patients first by allowing oncology nurse navigators to spend more time with patients and less time documenting.

2 full time thoracic oncology nurse navigators and these short-term program goals:

1. Utilize technology as a means of oncology nurse navigator documentation and communication with other members of the care team and patients.
2. Develop care coordination processes for patients in collaboration with other departments and disciplines, especially during transitions from one treatment modality to the next, from active treatment to maintenance, and into surveillance and survivorship.
3. Establish 2 to 3 navigation metrics to:
   - Develop discrete data fields to measure
   - Determine baseline measurements
   - Implement strategies to improve metrics

Goal 1. Technology: Innovation Without Expense

Funds were budgeted to support the oncology navigation program's technology needs, including navigation specific software for documentation and metrics tracking. During the planning phase in early 2020, multiple software companies were vetted to determine how to track and measure navigation specific metrics. Although many of these platforms offered desirable capabilities, the team always came back to putting patients first by allowing oncology nurse navigators to spend more time with patients and less time documenting. This required the team to reduce the amount of duplication within the oncology nurse navigators' documentation. Equally as important was the ability for all members of the care team to have a simple way to view what oncology nurse navigators had done at any given time—barriers assessed, interventions initiated, what members of the multidisciplinary care team were involved, etc. The team decided that the electronic health record (EHR) would be the most efficient way to keep everyone on the care team informed.

After a thorough exploration phase and multiple conversations with the in-house information systems (IS) team, it was decided that the needs of the oncology patient navigation program could be met through building navigation specific discrete documentation fields within the existing EHR. It is extremely important for any new program to establish a relationship with the IS team and, ideally, partner with someone from that team to help with ongoing needs and changes. The oncology nurse navigators continue to meet regularly with IS to touch base on how processes are working, update flowsheets, and brainstorm ways to document more efficiently. Over the

years, through this partnership, the oncology navigation program has been able to:

- Measure and fine-tune multiple navigation metrics
- Maintain adequate counts of caseload per navigator and per disease-site
- Improve documentation efficiency to maximize oncology nurse navigator time spent directly with patients

The oncology navigation program uses navigation episodes that allow all members of the navigation team to share tasks, as necessary. These episodes follow the patient throughout their trajectory of care. The team uses a standardized flowsheet with discrete data fields to mark patients as active versus inactive, track diagnosis and treatment start dates, and track assessment of barriers to care and interventions initiated. The navigation team also tracks time spent navigating each patient, both per encounter and a cumulative count of total minutes. This metric allows the navigation manager to track how much time the team spends doing different types of tasks. Because of these discrete data fields, the team was able to create an oncology navigation dashboard populated with relevant reports that can be refreshed throughout the workday, outlining the exact tasks each oncology nurse navigator has to follow-up on, and providing a visual of various metrics at a glance.

> Putting these barriers aside, after 6 months of thoracic oncology nurse navigation, the time from diagnosis to treatment for lung cancer patients in the navigation program was 24 days compared to 2020 registry data of 31 days.

Goal 2. Care Coordination: Moving Away From "The Way We've Always Done It"

Adding another person dedicated to assisting patients and their families throughout the care continuum sounded like it would be simple. Yet securing people as resources can be challenging and embedding these individuals into already established processes and clinics proved to be a more daunting task. "This is the way we have always done it" was being played on repeat. Change is hard, and it was clear that implementing the oncology navigation program would be no different. It was important for the navigation leadership team to utilize the background of tenured oncology nurses in program implementation, as their experience was of great value. To leverage this expertise, the team held regularly scheduled focus groups to introduce the oncology navigation program, discuss goals, and work as a team to outline current processes while proposing ways to make improvements.

St. Elizabeth Cancer Care is fortunate to have many resources for patients, including financial counselors, disease-site specific social workers, dietitians, and many others. Creating a collaborative environment with these support services was essential, and these care team members were also included in the focus groups during the planning phase.

As mentioned previously, provider buy-in was integral. The physician champion identified early on was instrumental in initial planning, participating in the interviews for the first oncology nurse navigators. As the role of the oncology nurse navigator became more clear, multiple physicians became champions for the navigators and the program.

Finally, it was important to incorporate national standards and guidelines, including the Oncology Nursing Society (ONS) Core Competencies for Oncology Nurse Navigators[2] and information around building a navigation program from the Academy of Oncology Nurse and Patient Navigators (AONN+). These resources were folded into the structured orientation and job descriptions developed for oncology nurse navigators.

Goal 3. Metrics: The Measurement of Success

In a 2018 article discussing standardized oncology navigation metrics, the authors discuss the timeline of navigation coming to the forefront of cancer care.[3] Not all cancer centers implemented navigation programs at the same time. Further, "navigation programs are diverse, and the lack of standardized metrics to evaluate the impact of navigation on patient quality outcomes has made it difficult to measure programmatic success."[3] In its 2013 publication, *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*, the Institute of Medicine wrote that "cancer treatment in the United States lacks in consistent quality and is neither patient-centric nor well-coordinated."[4] At that time, many cancer centers were still trying to determine how they would tackle this opportunity for improvement.

At St. Elizabeth, the team carefully planned how to measure successful implementation and growth of the oncology navigation program over time. Understanding it would be too large a task to track all

35 AONN+ standardized metrics, the team decided to initially track 2 metrics:

1. Time from diagnosis to treatment (measured by the number days from the day pathology signs off on biopsy result to the start of treatment: surgery, radiation, and/or chemotherapy treatment).
2. Emergency department (ED) utilization (measured by the number of navigated patient visits to the ED per month).

The measurement of time from diagnosis to treatment was easy to obtain for navigated patients because the team built discrete fields into their EHR documentation to mark the date the pathology was signed off (date of diagnosis) and the date the patient started treatment, including surgery, radiation, or systemic treatment (chemotherapy, immunotherapy, etc.). The challenge came when trying to compare these new data for navigated patients to previous data for non-navigated patients, as the system did not have discrete fields outside of the navigators' flowsheets to capture the same measurement points. The team used historical data from the Cancer Registry; however, the measurement of the "date of diagnosis" is not as well-defined within this data set. Putting these barriers aside, after 6 months of thoracic oncology nurse navigation, the time from diagnosis to treatment for lung cancer patients in the navigation program was 24 days compared to 2020 registry data of 31 days.

Measurement of ED utilization proved difficult, and the team was not able to track this metric during initial implementation of oncology navigation services. Patient admissions and ED utilization continue to be metrics the team tracks without extensive manual chart diving. This improvement opportunity is explored later in the article.

As the thoracic oncology nurse navigation program began, the technology created prior to go-live assisted the team in tracking additional metrics not initially planned for, including the number of referrals to the oncology navigation program over time. During the first 6 months of the program, growth was rapid. In the first 3 months, there was an average of 33 referrals per month, which increased to an average of 59 referrals per month in the following 3 months. Early tracking of these metrics helped make the business case for both additional oncology nurse navigators and expansion to other disease sites.

Sustainability

While research suggested the necessity of implementing navigation programs for cancer centers and oncology practices, would the model be sustainable?[5] At many facilities, navigation programs were non-revenue generating services, and this was also the case at St. Elizabeth. How then, during a global pandemic and an economic downturn that significantly impacted health care and overall hospital staffing, could this type of program be maintained?

This question spoke to the necessity of using metrics to show the value of the oncology navigation program on patient experience, patient outcomes, and return on investment. In her book, *Oncology Nurse Navigation: Transitioning into the Field*, Lillie Shockney, MAS, writes that "in today's health care landscape, it is essential for

Figure 1. Active Patients Per Month, Per Oncology Nurse Navigator (Average)
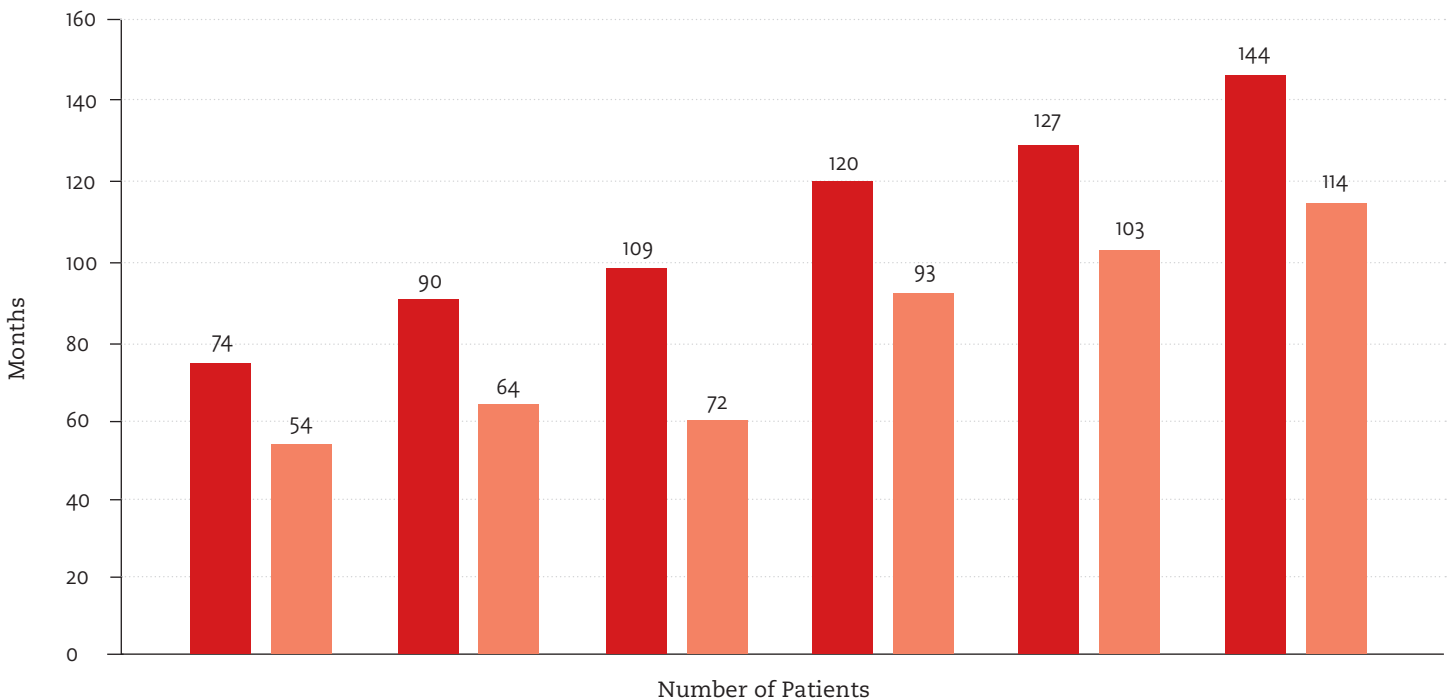
cancer programs to harmonize their performance initiatives or create 'metric synergy.'"[6] Often, the goals of the oncology navigation program directly support the goals of the cancer center, as well as national oncology guidelines and standards related to CoC accreditation and payment models that support patient experience, patient outcomes, and return on investment.[6] It was important to track what the team was doing—not only growth in real time, but also projecting future growth. To do so, several key questions needed to be answered:

- How can technology be used to track caseloads per disease site and per oncology nurse navigator?
- What additional metrics should be monitored to explain to senior leadership the benefit of navigation to the key areas of patient experience, patient outcomes, and return on investment?
- How does the patient navigation program continue to improve internally, not just compared to "pre-navigation" data, but comparing month to month against its own data?

Navigation Caseloads

In the literature, it is difficult to find an answer to the question: How many patients should 1 oncology nurse navigator manage and/or follow? This uncertainty is partially due to many factors, including that fact that not all navigation programs are created equal and that only some are disease-site specific, where each navigator is assigned

a specific patient population based on diagnosis. Additionally, some programs only navigate patients during their initial diagnosis and work-up while others follow the patient through the entire continuum of care, from diagnosis through survivorship or end-of-life. There is no "right way" to establish a patient navigation program, but this variation certainly makes it difficult to establish standardized patient-to-navigator ratios.[3]

Finally, not all patients are created equal. This statement may seem obvious, but it is more complicated the deeper one digs. For instance, there is a large difference in the basic care coordination needs of a patient with lung cancer versus a patient with tonsil cancer. Furthermore, a patient with stage I lung cancer likely has very different clinical needs than a patient with stage IV lung cancer. Clearly, diagnosis and staging create a large difference in the time and effort required of the navigator to properly manage patients' care. Also, patient A with stage I lung cancer may have a great support system, no issues with transportation, no financial struggles related to their health care, and not facing other issues such as food insecurity; patient A may only need the navigator to do initial education, reeducation, and verification of ongoing monitoring and surveillance. Meanwhile, patient B with stage I lung cancer is homeless, does not have reliable transportation or a reliable method of communication with the care team, does not have social support, and is worried about their ability to pay for treatment. Patient B has a much higher acuity, although patient B has the same diagnosis and stage as patient A.

Figure 2. Referrals to Oncology Nurse Navigation
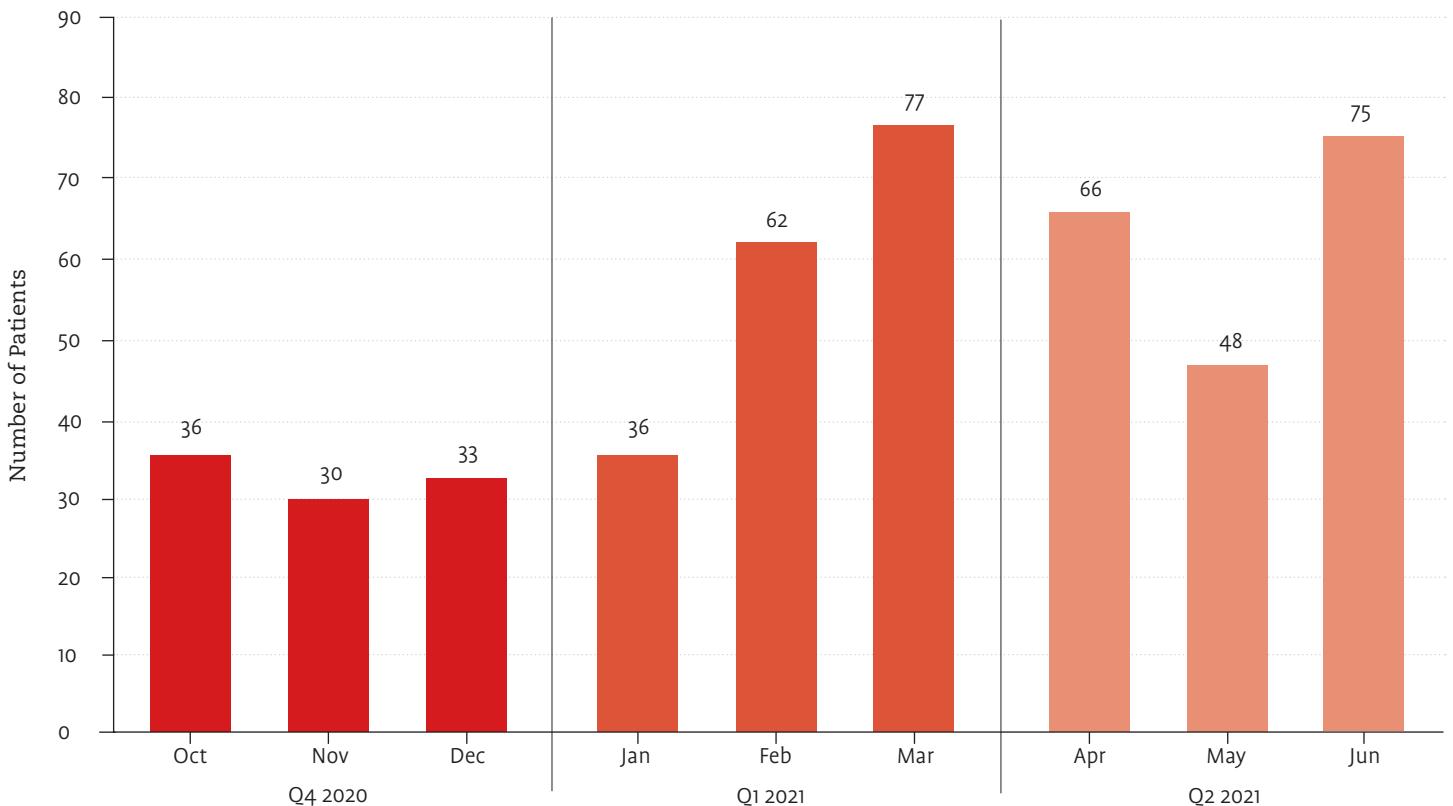
Figure 3. Thoracic Navigation Program: Average Active Patients per Month
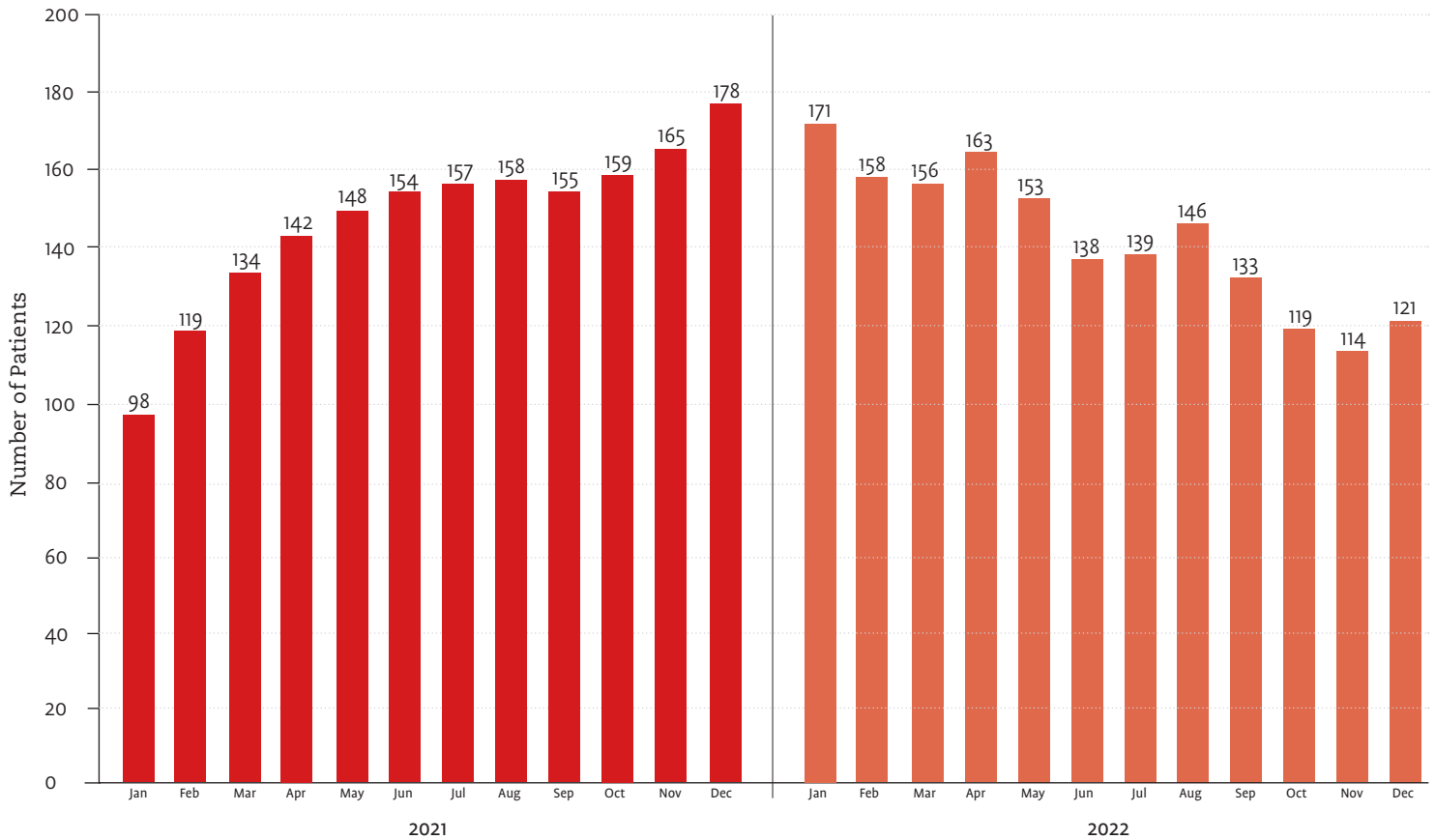
Thus, many factors play a part in determining what constitutes a reasonable caseload for each navigator.

To meet this challenge and establish program goals, the navigation team at St. Elizabeth started to measure active patients, per oncology nurse navigator and per disease site. These data allowed the team to determine where inefficiencies were hindering growth and patient load and when additional staff would be needed to sustain growth.

To differentiate active patients from inactive patients, a timeline must be determined for key patient touch points, structured for the overall program but customizable based on each disease site and specific patient needs. In this care trajectory, the appropriate timeframe for "closing" a patient was established. At St. Elizabeth, the oncology patient navigation program was built with patients at the forefront of every decision. It was common during program planning to ask the question, "What is best for the patient?" The team holds tight to this mantra today and because of this, "closing" a patient or "discharging" patients from the oncology navigation program seemed harsh and unattached. Instead, the team determined that using the terms "active" and "inactive" allowed oncology nurse navigators to focus on patients with more timely needs; typically, those in their diagnostic phase, those being worked up for staging and treatment planning, and those on active treatment. The team maintained an understanding that inactive patients still had the oncology nurse navigator available if they needed assistance at any point down the

road. When patients are determined to be inactive, navigators notify patients that they are available but will not be actively checking on medical charts or providing follow-up calls or visits. This communication puts some responsibility on the patient and family to reach out when a need arises, and some responsibility on providers and clinics to notify oncology nurse navigators about changes in the patient's plan of care.

Once this timeline was established, beginning in January 2021, the team tracked and reported the average number of active patients during their weekly huddles. These data gave a real time view of how many patients received regular follow-ups, support, and care coordination. The average number of active patients for each oncology nurse navigator for the first 6 months of 2021 is illustrated in Figure 1.

In February of 2021, just 4 months after program initiation, navigation services were extended to patients with gastrointestinal (GI) cancers. The oncology navigation program was seeing a positive growth in metrics and a positive impact on patient experience. A poor patient experience was reported to a provider who supported the navigation program extensively, and the patient was immediately sent to navigation for service recovery. Based in part on the exceptional care the oncology nurse navigators provided to this patient and his family, referrals of GI patients to oncology navigation continued to grow exponentially over the following months (Figure 2).

Growth Over Time

Throughout 2021, the thoracic caseload continued to grow rapidly, and the responsibilities of the nurse navigators grew extensively, largely due to increasing physician and system support of the program and role. At the start of 2021, the team consisted of 1 GI oncology nurse navigator and 1 thoracic oncology nurse navigator. Due to a steadily increasing number of thoracic patients, an additional full-time (FTE) nurse navigator was hired to share this caseload, growing the team to 3 nurse navigators (2 thoracic and 1 GI).

With the ability to share the caseload, the thoracic nurse navigators were able to dive deeper into overall lung program growth. They worked closely with a medical oncologist specializing in lung cancer to develop clinical pathways for patients with lung cancer. These pathways followed National Comprehensive Cancer Network guidelines to ensure patients were receiving the right care at the right time from the right provider, including appropriate imaging to complete work-up and staging.

The oncology nurse navigators are active members on the disease management teams. These teams are made up of disease-site-specific stakeholders so, for example, the thoracic team is comprised of pulmonologists, medical oncologists, radiation oncologists, thoracic surgeons, and various support staff, including oncology dietitians, oncology social workers, palliative care, integrative oncology, and the oncology nurse navigator(s) who manage those patients. The thoracic

oncology nurse navigators who created these pathways (with provider assistance) had them approved by the thoracic disease management team, giving the oncology nurse navigators the autonomy to help patients receive the care they needed, and most notably, be completely staged prior to their medical oncology consult. This includes having tissue sent for molecular testing, when appropriate. This process saved the patients time, travel, and money by avoiding unnecessary visits and decreasing their time from diagnosis to treatment by approximately 30%. The thoracic oncology nurse navigators had the honor of sharing their work improving patient outcomes at the 2022 AONN+ Annual Conference, where their poster presentation won an award for best in category. Since then, these data have been shared at multiple conferences and symposiums to highlight the work that the oncology nurse navigation team focuses on to improve patient care.

In addition, the thoracic oncology nurse navigator team wanted to improve its outreach efforts. In December 2021, in collaboration with the lung cancer screening navigators, they started to receive referrals for patients who were identified by the lung nodule review board as likely to have lung cancer. This process allows the oncology nurse navigators to be introduced to and develop a relationship with patients well before a diagnosis. It also gives patients a resource to help them coordinate the care needed to complete a diagnostic work-up. Lastly, it offers an extra layer of emotional support for patients, whether they need assistance with smoking cessation,

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Figure 4. GI Navigation: Average Active Patients per Month
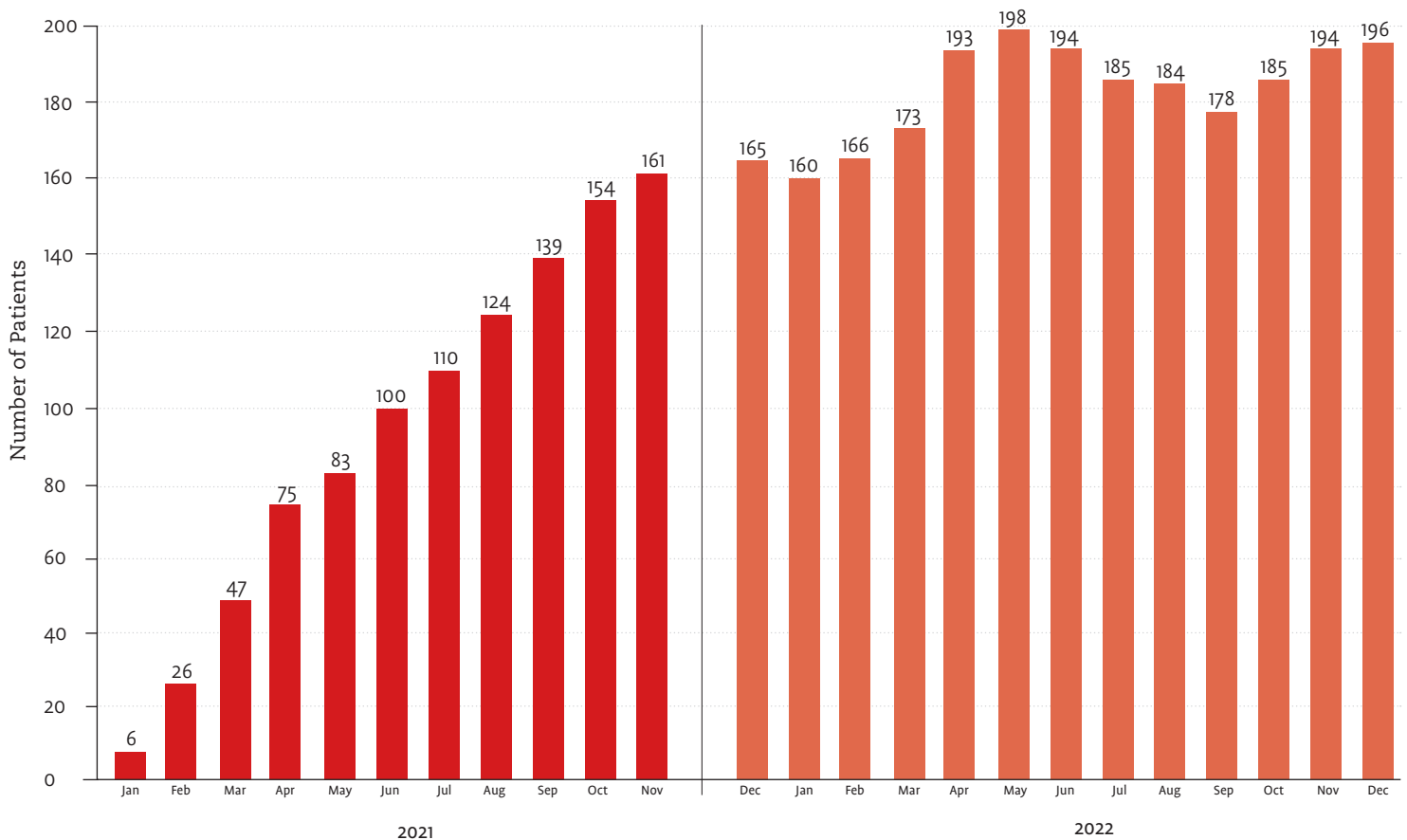
oncology nurse navigator joined the team, taking over the esophageal cancer patients from the GI oncology nurse navigator. Growth of the GI oncology nurse navigation program is illustrated in Figure 4. Later that same year, in June, head and neck cancer navigation was rolled out (Figure 5). Lastly, in November 2022, genitourinary (GU) navigation was rolled out, utilizing current staff but reallocating resources due to efficiencies created by the oncology nurse navigation team—both in system processes, as well documentation and time spent on nonpatient facing tasks. Specifically, the thoracic oncology nurse navigators streamlined processes so that the caseload became manageable for 1 oncology nurse navigator, allowing the second thoracic oncology nurse navigator to build out the additional disease site. The roll out structure followed the other disease sites, starting with a meeting of key stakeholders and an assessment of patient needs; in the first 2 months following roll out, the GU oncology nurse navigator received 40 patient referrals. Figure 6 depicts overall program growth, with time stamps of key points during 2021 and 2022.

Other Duties as Assigned

As processes continue to be fine-tuned and the oncology nurse navigation team continues to build on the foundation, many additional functions have been established. A common statement on many job descriptions, the "other duties as assigned" category, also holds true for the oncology nurse navigators. That said, the navigation leadership team at St. Elizabeth is diligent to make sure that these "other" duties are meaningful to patient care, in some way impacting patient experience, patient outcomes, and the program's return on investment, while allowing the oncology nurse navigators to function at the top of their licenses in a way that is engaging and provides them with autonomy and job satisfaction. Early in the planning process, the

coping, or general understanding of the care plan.

Growth of the thoracic oncology nurse navigation program over time is illustrated in Figure 3. Note: the decrease in patients with thoracic oncology is largely due to the navigation team making patients inactive sooner based on better follow-up processes, as well as the large number of patients who are active without a diagnosis, as these are measured separately as of February 2022.

The thoracic and GI oncology nurse navigation programs continued to grow throughout 2021 and 2022, creating a need for additional support while building availability to begin navigating an additional disease site. In February 2022, a new FTE

Figure 5. Head and Neck Cancer Navigation: Average Active Patients per Month
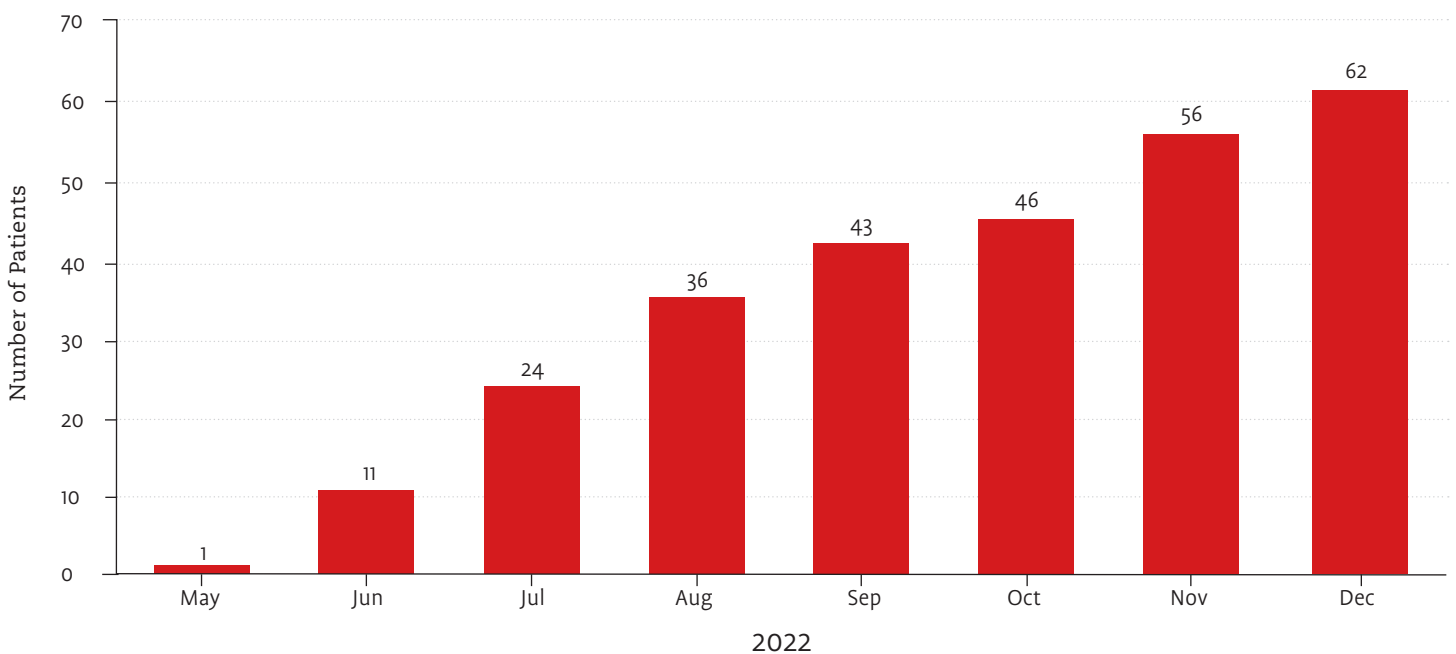
Figure 6. Active Patients Per Month, All Disease Sites

Legend: ■ 2021 ■ 2022

Y-axis: Number of Patients (0 to 500)

Monthly data (2021 / 2022):
- Jan: 104 / 375
- Feb: 145 / 374
- Mar: 185 / 381
- Apr: 217 / 414
- May: 234 / 399
- Jun: 262 / 404
- Jul: 282 / 403
- Aug: 302 / 432
- Sep: 314 / 421
- Oct: 334 / 417
- Nov: 348 / 452
- Dec: 370 / 470

Annotations:
- Thoracic navigation only
- GI navigation launched
- Hired Additional ONN (Total = 4)
- Hired Additional ONN (Total = 8)
- Head/Neck Navigation Launched
- GU Navigation Launched
- Started getting LNRB "high" patients

leadership understood and supported the importance of structuring the oncology nurse navigator role in a way that allowed these nurses to work to the top of their license, removing tasks that were clerical in nature, such as scheduling appointments and completing Family and Medical Leave Act paperwork, while retaining other non–patient-facing tasks that directly impact patient care and require clinical expertise to optimize efficiency and functionality.

One such task is management of disease-site specific tumor boards. A large quality improvement (QI) project aimed at restructuring, standardizing, and optimizing tumor boards kicked off at St. Elizabeth in 2021. Part of this QI project focused on creating a leadership team for each disease-site specific tumor board, composed of an RN and an MD who would co-lead the discussion for their respective disease-sites. The disease-site specific oncology nurse navigators run their respective tumor boards, managing patient lists, documenting discussions, following up on and—most importantly—participating in conversations as an integral member of the care team. This oncology nurse navigator responsibility has made tumor board discussions much more structured, meaningful,

and geared toward improving patient care.

To continue these QI efforts, the oncology nurse navigators created disease-site specific collaboratives supported by the disease-site specific multidisciplinary teams but facilitated by the oncology nurse navigators and consisting of frontline care team members directly involved in patient care. Participants include nurses and medical assistants from the oncology clinics and referring provider offices, infusion nurses, schedulers, financial counselors and prior authorization specialists, as well as staff from imaging, research, genetics, and more. The goal of these collaboratives is to fix patient-related process problems reported by frontline team members who interact with patients daily. The team at St. Elizabeth recognizes that frontline staff are the best ones to identify and establish solutions to everyday problems that patients face, including long wait times, bottlenecks in the system, poor care coordination, and more. In short, these collaboratives offer a forum for identification and problem-solving.

Long-Term Goals and Opportunities

Oncology nurse navigation program leadership continually looks for ways to grow and improve. Patient referrals to the oncology nurse navigation team continue to increase, with November 2022 being the highest month to date: 140 referrals.

While the oncology nurse navigation team has received over 2100 referrals from more than 259 providers, the team continues to look for ways to improve by streamlining the referral process. For example, although referrals can be made directly through the EHR, the team continues to receive referrals by email, through Teams messages, or in person. This inefficiency creates additional work on the oncology nurse navigators and increases the risk of patients being missed. In addition, the oncology nurse navigation team would like to increase the number of referrals received at diagnosis or sooner, as a large portion of referrals are being received from medical, surgical, and radiation oncologists after patients have already been through some tests and procedures. Often, patients receive their original diagnosis from a specialist, such as pulmonology, gastroenterology, ear-nose-throat, etc, and a referral from these providers as soon as the patient is aware of a diagnosis would be ideal, allowing the oncology nurse navigators to get involved earlier in the care continuum, improving care coordination, providing earlier emotional support for patients, and ideally decreasing the time from diagnosis to treatment initiation.

Another QI opportunity stems from the initial goal of measuring navigated patients' admissions and ED visits, as mentioned previously. The oncology nurse navigation team developed a process to follow-up closely with patients after an admission or ED visit. After collaboration with a multidisciplinary team, the oncology nurse navigators also developed and are in the process of implementing an oncology admission risk score calculator within the EHR to tailor treatment and care to patients based on their risk of being admitted or visiting the ED.

The oncology nurse navigation team continues to work on ways to fine-tune appropriate caseloads and/or patient-to-navigator ratios. As stated previously, this process is highly correlated to patient acuity and the number of patients who are actively followed. Although a productivity score is combined with average case numbers to gain insight into the current team members ability to add or not add cases, using a tested acuity tool will help establish standards and allow us to continue to add staff and disease sites.[6]

Looking to the Future

St. Elizabeth's oncology nurse navigation team continues to look for ways to improve the care of patients with cancer. As its mission states, St. Elizabeth strives to lead Northern Kentucky to become one of the healthiest communities in America. Patients with cancer require a great deal of support. The oncology nurse navigation team likes to call themselves "friends in the business," meaning that they are the patients' people—the ones to call when a patient is unsure where to go or what to do. With patients at the forefront of their plans, the oncology nurse navigation team strives to align the structure described in this article with data and metrics to support program growth to a place where every patient with cancer is offered an oncology nurse navigator to guide them along their cancer journey. It is said frequently that no one walks this path alone, and at St. Elizabeth Cancer Care, the oncology nurse navigators ensure this statement is true. OI

Stephanie Bonfilio, MSN, RN, OCN, ONN-CG, is oncology navigation manager at St. Elizabeth Cancer Care in Edgewood, Kentucky.

References

1. National Cancer Institute. Cancer statistics. Updated September 25, 2020. Accessed July 27, 2023. https://www.cancer.gov/about-cancer/understanding/statistics

2. *Oncology Nurse Navigator Core Competencies*. Oncology Nursing Society. 2013. Accessed July 28, 2023. https://www.ons.org/sites/default/files/ONNCompetencies_rev.pdf

3. Johnston DS, Sein E, Strusowski T. Standardized evidence-based oncology navigation metrics for all models: A powerful tool in assessing the value and impact of navigation programs. *J Oncol Nav Surv*. 2017;7(5):220-237. Accessed July 28, 2023. https://www.jons-online.com/issues/2017/may-2017-vol-9-no-5/1623-value-impact-of-navigation-programs

4. Committee on Improving the Quality of Cancer Care: Addressing the Challenges of an Aging Population; Board on Health Care Services; Institute of Medicine. *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*. Levit L, Balogh E, Nass S, Ganz PA, eds. National Academies Press; 2013. Accessed July 28, 2023. https://www.ncbi.nlm.nih.gov/books/NBK202148/

5. Garfield KM, Franklin EF, Battaglia TA, et al. Evaluating the sustainability of patient navigation programs in oncology by length of existence, funding, and payment model participation. *Cancer*. 2022;128(suppl 13):2578-2589. doi:10.1002/cncr.33932

6. Shockney LD. *Oncology Nurse Navigation: Transitioning Into the Field*. Jones & Bartlett Learning, 2021. https://www.jblearning.com/catalog/productdetails/9781284198607

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Trending Now in Cancer Care

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Part 2

Precision medicine

Research and clinical trials

BY MONIQUE J. MARINO
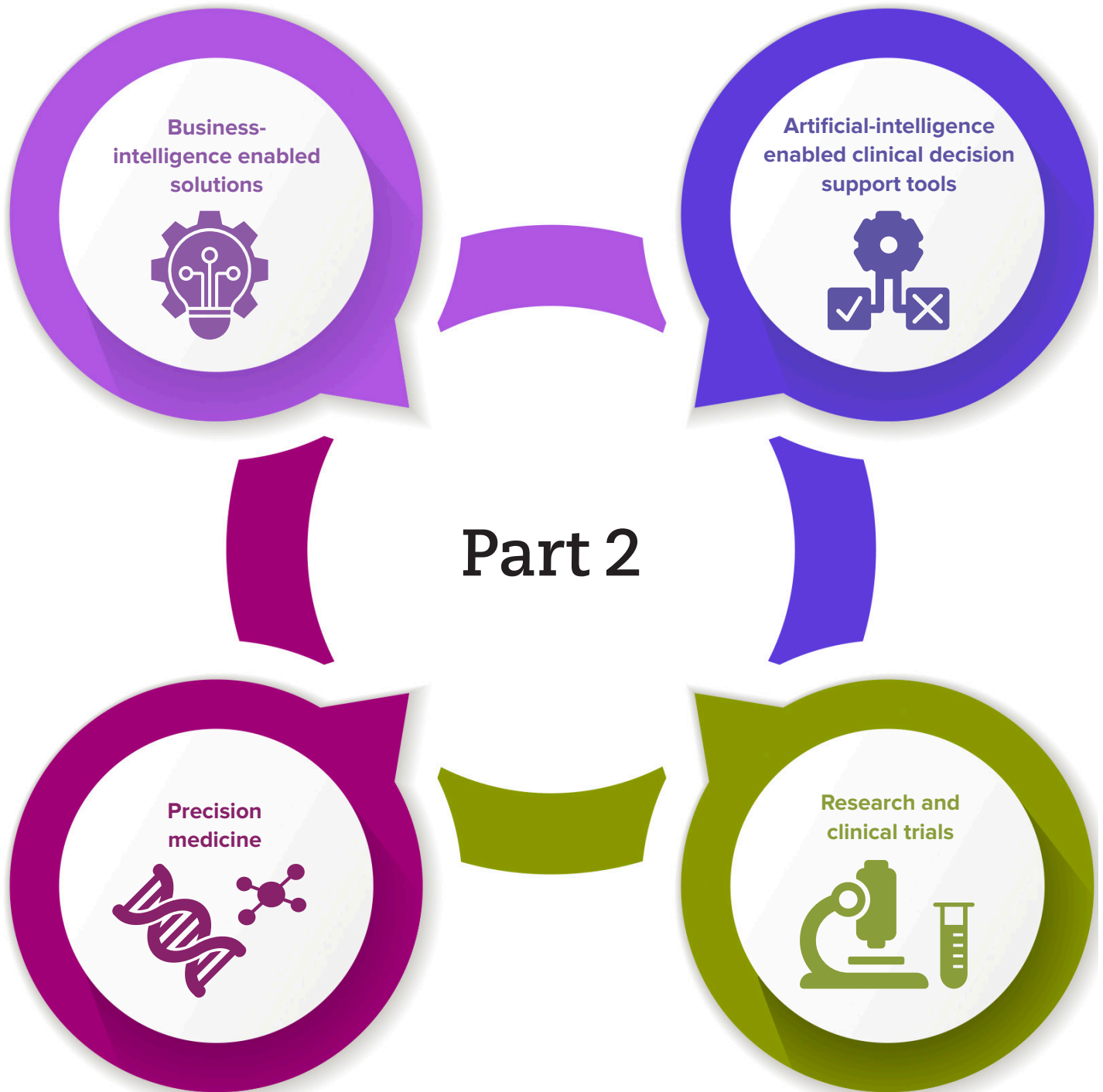
I n past years, the Association of Community Cancer Centers (ACCC) fielded an annual "Trending Now in Cancer Care Delivery" survey to its membership to gain insights into challenges they face and, most importantly, solutions to address those challenges. Unprecedented challenges from a global pandemic, a 3+ year 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 the 8 key areas. Below, we take a "deep dive" into 4 of these topics. Look for "Trending Now in Cancer Care Part I" in the *Oncology Issues* volume 38, number 4.[1]

Business Intelligence–Enabled Solutions

Business intelligence (BI) tools and technology are helping today's cancer programs and practices to streamline clinic workflow and processes, improve business and financial operations, and mitigate workforce shortages by automating manual processes.

Facilitators
- Amy Ellis, Chief Operating Officer, Northwest Medical Specialties, PLLC
- Douglas Flora, MD, LSSBB; Executive Medical Director, Oncology Services, St Elizabeth Healthcare
- Jeff Hunnicutt, Chief Executive Officer, Highlands Oncology Group
- Ashley Joseph, Vice President, Client Services–Infusion, LeanTaaS
- Matthew Manning, MD, FASTRO; Chief, Department of Oncology, Cone Health Cancer Center

Challenges Facing Oncology
- How do we contain costs? Health care costs are on the rise, and oncology is one of the most expensive cost centers. These costs contribute to poor patient experiences, with an increasing number of patients with cancer having to file for bankruptcy due to treatment-related costs.
- How do we integrate technology into disease management?
- How do we access real-world data in real time and then apply it to practice?
- How do we ensure data privacy and security?
- How do we integrate new BI platforms with existing systems (eg, electronic health records [EHRs], electronic patient-reported outcomes [ePROs]) and processes (eg, triage, bundled payments).

- What are the ethical and regulatory concerns, and how do we address these concerns around big data and use of BI technology?

Information Overload
Today's busy providers are faced with so much data that they often do not know what to do with it. Some providers share that it may be asking too much for them to keep up with the barrage of data information coming at them. Yet most providers realize that we need to move away from intuition and that we must use these data for drug development, health equity, and improved cancer care delivery.

Defining Business Intelligence
BI is a term used to describe a set of techniques, processes, and technologies used to gather, analyze, and visualize data to make better, informed business decisions. BI can be used to:
- Streamline operations and processes, identify inefficiencies and redundancies, and then develop process-related improvements and efficiencies.
- Identify operational patterns and trends (eg, issues with scheduling and patient throughput and/or reimbursement challenges related to specific services or payers).
- Improve patient outcomes by providing clinicians with real-time access to patient data, allowing them to make data-driven decisions about care and treatment.

> "Health care is late to the game compared to many other industries that are using and leveraging business intelligence and artificial intelligence technology to improve efficiency."

- Identify trends and pattens in patient populations. By analyzing large amounts of patient data (eg, demographic information, social drivers of health, treatment history, and outcomes), providers can gain a better understanding of patient populations they treat.

Rapid Uptake of BI Technology

Use of BI-technology is accelerating rapidly in the field of oncology, helping providers to manage their time and tasks and preventing problems before they occur. Yet many providers are not using this technology as efficiently as possible, and providers know that they can make better use of these technology platforms. Advantages to BI-enabled technology include:

- Automation of tasks that are time-consuming and repetitive, freeing up providers to spend more time doing direct patient care
- Increased efficiency in scheduling appointments
- Improved communication between healthcare providers
- Enhanced patient engagement
- Optimized resource utilization
- Streamlined diagnostic process
- Personalized treatment plans
- Reduction in treatment-related adverse events.

BI-Solutions in Practice

Real-Time Tracking Systems. To streamline its operations, St. Elizabeth Cancer Center in Edgewood, Kentucky, implemented a [real-time tracking system](#) of patients and equipment to identify both areas for improvement and inefficiencies. On arrival, patients receive a clipped badge that tracks their location so that providers can see in real time how patients are progressing through their center. This BI-enabled technology can be used to:

- Set a tolerance threshold for how much time patients should be allowed to wait, and to monitor patient alone time.
- Generate reports on the time from patient entry into the institution to examination by a provider, as well as capture patient-provider interactions.
- Identify bottlenecks, similar to the mechanism of an air traffic control system.
- Track behaviors or tasks in which providers are slow to improve processes or reallocate staff, if necessary.

Care Management. Northwest Medical Specialties, PLLC, in Washington State adopted the [Canopy Intelligent Care Platform](#) (Canopy Oncology) to help optimize staffing resources by reducing workflow redundancies and improving communications. This BI-enabled platform offers an easy-to-navigate ticketing (task) dashboard to help staff prioritize tasks and communicate with other team members about outstanding tasks and areas in which they may need support. For example, the analytics dashboard captures data that include the median time to pick up of tickets by staff and the median time for staff to close a ticket (address the issue or task). These data can be used to support decisions to reallocate tasks and/or staff as necessary. This BI-enabled technology platform allows these data to be integrated into the practice's EHR.

Infusion Center Optimization. Many infusion centers face challenges related to patient wait times and capacity management (eg, midday peaks, staffing and allocation of infusion nurses). Whereas some cancer programs have developed in-house solutions to improve infusion center operations, several BI-enabled platforms are available commercially. One such platform, [iQueue for Infusion Centers](#) (LeanTaaS), uses business and artificial intelligence (AI) technology to run thousands of simulations to identify scheduling templates that will work best for specific infusion centers. This type of predictive scheduling supports resources and staff allocation decisions.[2] In her presentation, facilitator Ashley Joseph shared that the nearly 500 infusion centers that have adopted this technology report these data:

- 15% average increase in patients served
- 30% wait time reduction at peak times
- 25% average increase in provider satisfaction
- 50% average decrease in staff overtime.

Revenue Cycle Management. As staff at infusion centers seek technological solutions to optimize operations, those at cancer programs are developing home grown solutions and/or leveraging commercially developed BI platforms to perform revenue cycle tasks best suited to automation, freeing business and revenue staff to tackle issues that require human intelligence and intervention. BI technology can help cancer programs streamline revenue cycle management, achieve better understanding about payer policies and insurance claims data, and collect metrics on key performance indicators of cancer program business health.[3]

Data Collection, Analysis, and Reporting. Highlands Oncology Group in Arkansas is looking to normalize data in practice operations and analysis; this requires building algorithms to take individual data

reports and/or datasets and submitting them into 1 application to provide a single report with all data points brought together. This multisite practice is using the Microsoft BI platform to generate this report, with all data using the same terminology and then using these normalized datasets to review and analyze practice trends (eg, payments).

Use of Chatbots. Providers should look for opportunities to use this technology to execute repetitive and time-consuming administrative tasks, like writing recommendation letters for staff and supporting charting efforts.

Radiation-Oncology Specific Considerations
Automation. The potential exists for technology to inform and execute treatment plans with minimum human intervention and its attendant errors. Radiation oncology is a field with many processes and tasks that could benefit from automation; these include treatment planning, contouring, image registration, treatment field transfer from the treatment planning system to the treatment delivery system, radiation delivery recording and verification, data aggregation for analysis of radiation treatment, and quality assurance checks.

Revenue and Financial Implications. Cone Health of North Carolina used a BI platform to develop a digital preauthorization checklist for radiation oncology and financial navigation staff to track prior authorizations. The health system also uses BI-enabled technology to analyze reimbursement data and look for billing errors, allowing staff to adjust as needed.
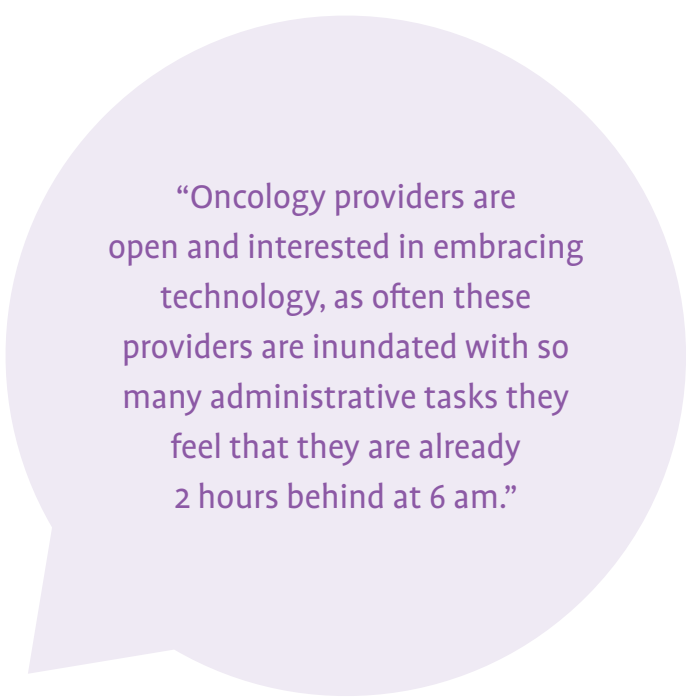
Performance. BI-enabled technology supported the build of an in-house performance dashboard that Cone Health uses to track trends across the Radiation Oncology Department and to collect and analyze performance metrics data. For example, staff members collect metrics on linear accelerator on time status and time to treatment and analyze data to see which tasks are taking more time and where efficiencies can be realized.

Small Group Discussion
After the series of facilitated presentations and discussions, meeting participants split up for small group discussions. Below are the reports from these discussions.

Group 1. Discussion revolved around using BI technology to drive efficiency.
"There's room for efficiency improvement across all settings—community and academic. Keeping the end user experience in mind is the common theme we discussed. What does the end user experience look like? And how can we make change easy for clinicians, as well? Take a location tracking system, how much is that [technology solution] taking providers out of the clinical workflow to implement? [We also talked about] the importance of ePROs going forward and what that's going to look like as time goes on. How do we action these insights? How do we analyze these datasets and create the right efficiencies?"

> "Oncology providers are open and interested in embracing technology, as often these providers are inundated with so many administrative tasks they feel that they are already 2 hours behind at 6 am."

Group 2. Discussion revolved around using BI technology to improve the patient and provider experience.
"Our group talked about Midmark's real-time location system and its impact on patient experience, because we're decreasing wait times. We talked about its impact on staff satisfaction, because now our nurses and team members essentially know where our patients are at all times. We talked about how this BI technology solution could work in tandem with a solution like iQueue, because we're maximizing providers' schedules. And if providers are taking longer to see patients, these technologies allow us to modify patient and provider schedules to be more efficient. The downstream impacts are improved staff, clinician, and patient satisfaction."

"That discussion led into a conversation about physician burnout, which we are seeing across the board, and the importance of quality of life when managing physicians. [We talked about] the importance of culture and how the right culture can help manage physician burnout and attract physicians to your organization—all very helpful in a competitive market."

"Then our discussion turned into a conversation about the importance of patient navigation…how new solutions like Jasper (Jasper Health) [a digital guiding and navigation experience that improves the lives of individuals affected by cancer and their caregivers] take many patient navigation components and turn them into a technology solution, allowing patients to watch video programs and such, to help support our patient navigators and improve the patient experience."

Group 3. Discussion revolved around barriers to using technology, the relationship between technology and people, its impact on revenue, and more.

"There are definitely barriers to implementing [bi-enabled technology] in terms of cost versus return on investment. How do you decide what technology solution(s) to adopt? How do you decide when to invest in a technology solution versus hiring another FTE [full-time equivalent]? [The group believed] that technology does provide some sustainability in terms of workforce shortages and reducing burden on existing staff. Potentially, technology can help do more work with fewer team members. We talked about automation in general and got into the automation driver discussion and ethics: what happens to your labor force as you begin to replace their responsibilities?"

"[Our group] talked about how BI and AI must train on existing historic data, which may not predict the future. How does infusion software account for how things are changing? For example, what happens when a medicine that was once an 8-hour infusion is now just an injection?"

"We talked about how BI allows the analysis of broad swaths of information. On any given day, you can see how busy the infusion clinic is, whether the staffing level is appropriate, and patient wait times. [With BI technology], some inefficiencies pop up, like patients sitting in infusions chairs while waiting for preauthorizations. We view these tech solutions as tools or helpers, but not problem solvers. You still need humans to implement solutions and solve problems."

"We also discussed the revenue cycle. Using BI [technology], you can look at your patient population in terms of, 'What's our payer mix of Medicare, private, self-pay?' [You can] then use predictive analysis to see how your revenue is going to look based on who's in your clinic that day. You can also use BI to analyze your data by clinic or by provider, allowing you to drill down on outliers and discover issues like high overtime utilization."

"Finally, we talked about the 99% of the time patients are not in your clinic. One percent of their life, they're sitting right in front of you; the other 99% they're not. BI-enabled registries can track when patients miss appointments and notify providers to keep patients from falling through the cracks. The technology then becomes a health equity tool. ePROs [are], too, as the technology facilitates check-ins with patients when they're not physically in the clinic."

Group 4. Discussion revolved around data, how to acquire data, and what to do with the data once you have it.

"In health care, in general, we tend to see screenings taking place in departments. And then departments try to figure out where that data and information go. What we need to do is develop a model where the screening is completed by the same individuals, at established times, and who are then responsible for filtering these data to the appropriate departments."

Group 5. Discussion revolved around post-COVID-19 trends like urgent and 24/7 care.

"We talked about trends [that] we're seeing post-COVID, which took us to the topic of urgent care and using BI-enabled technology to try to get ahead of things so that there's better predictability of who's going to come into [the] clinic. We spent time talking about cancer being a 24/7 medical condition, with infusion centers, most clinics, and many supportive care services offered only Monday through Friday."

Artificial Intelligence-Enabled Clinical Decision Support Tools

Artificial intelligence tools and technology are helping today's providers work faster and smarter with consensus-driven clinical pathways and processes to measure and report adherence to evidence-based guidelines and algorithms that help proactively identify at-risk patients and guide follow up and early interventions.

Facilitators

- Olalekan Ajayi, PharmD, MBA; Chief Operating Officer, Highlands Oncology Group
- Douglas Flora, MD, LSSBB; Executive Medical Director, Oncology Services, St Elizabeth Healthcare
- James Hamrick, MD, MPH; Vice President, Clinical Oncology, Flatiron Health
- Rebecca Maniago, PharmD, BCOP; Associate Director, Clinical Oncology, Flatiron Health
- Matthew Manning, MD, FASTRO; Chief, Department of Oncology, Cone Health Cancer Center

Defining AI

AI is the development of computer systems that can perform tasks that typically require human intelligence; these include recognizing patterns, making decisions, and solving problems.[4] AI has the potential to revolutionize the health care industry by enabling us to diagnose diseases and develop personalized treatments faster and more accurately than ever before. Today, AI platforms are helping providers quickly and accurately diagnose cancers and develop customized treatment plans based on the unique characteristics of each patient's disease. The technology has the potential to significantly improve patient outcomes and increase the speed and accuracy of diagnosis. AI platforms also are being used to analyze vast amounts of medical data and identify new treatment strategies based on the analysis of large clinical datasets. The technology has the potential to significantly advance our understanding of cancer and accelerate the development of new and effective treatments. AI is also expected to help cancer programs and practice:[5]

- Generate revenue
- Be more competitive
- Improve workflows and processes
- Recruit talent.

> "Artificial intelligence has infiltrated our lives whether we're aware of it or not. And if you're not aware of this technology, you are already behind."

Robotic Process Automation and Our Workforce

Cancer care and cancer treatment are complex; today's providers must digest enormous amounts of information to deliver care that is tailored to the individual (ie, precision medicine). Combined with increases in administrative burdens related to patient documentation, data collection, prior authorization requests, and more, these factors are all contributing to rising levels of burnout among clinical and non-clinical providers. In turn, this burnout is exacerbating health care workforce shortages across disciplines and specialties. So, how can AI help? Providers can train AI to take over and complete tasks; *robotic process automation* is a term for technology that automates

manual, repetitive tasks through the use of software robots. Not only will robotic process automation alleviate burnout and help ensure providers are working at the top of their license, but it can increase the accuracy of tasks, reduce costs, and streamline processes. Successfully robotic process automation follows these 4 steps:

1. *Define the process* (identifying the process that can be automated and the desired outcome).
2. *Design the automation* (creating a plan for how the automation will be implemented).
3. *Test the automation* (running tests to ensure the automation is working correctly).
4. *Deploy the automation* (putting the automation into production and monitoring its performance).

Today's oncology programs and practices are using robotic process automation to do patient registration, complete prior authorizations, streamline workflows, code and bill for services, and accomplish claims adjudication.

AI and Health Equity

Half of physicians (51%) believe that they have little to no time/ability to effectively address their patients' social drivers of health.[6] Most physicians want greater time and ability to address these (87%) but believe that addressing social drivers of health contribute to burnout (83%). And that's where AI can help.[6] Prescriptive analytics platforms can collect large amounts of data on social drivers of health and combine AI algorithms with machine learning techniques to identify at-risk patients (ie, those with a higher chance of experiencing poor outcomes).[7]

So how does this technology work? First, patients are identified as part of a population of interest (eg, Black women with metastatic breast cancer). Prescriptive intelligence then collects and/or purchases historical, nonclinical data and imports patients' current clinical data into the provider's EHR.[8]

Jvion offers a commercially available prescriptive analytics platform

> "The oncology program of the future may have an AI assistant for every practicing physician to support operations and allow physicians to spend more with patients."

> "Artificial intelligence is only as good as the models we use to train this technology; that makes our data so important!"

that generates patient-specific, dynamic, and actionable insights that help inform appropriate resource usage and initiation of downstream workflows. At Northwest Medical Specialties, PLLC, a patient care coordinator team tracked these insights, reviewed flagged patients, EHRs, and risk factors, and recommended interventions for medium- to high-risk patients.[7]

Another commercially available platform is AdaptX, a cloud-based platform that collects patient data that providers can monitor, evaluate, and use to improve the quality, equity, and efficiency of patient care. At *Modern Healthcare's* virtual Social Determinants of Health Symposium—held on August 11, 2022—Daniel Low, MD, chief medical officer at AdaptX, explained that this technology adds an equity layer to health care by using AI to scan an organization's EHR for racial, language, and gender disparities either throughout the care continuum or among patient outcomes.[9] Crunching vast amounts of data, this system accomplishes in a few minutes a feat that would take a team of analysts years to do.[9]

In 2021, the National Cancer Institute's (NCI) Small Business Innovation Research Program solicited proposals for the development of oncology-specific software to address social determinants of health in oncology practices.[10] Last year, ACCC reported on works in progress from 3 recipients of this NCI funding:[11]

- Pistevo Decision. This integrated, multilevel, decision support platform will include a patient-facing application (app) to empower patients to answer social determinants of health screening questions when it is comfortable and convenient for them. In developing the platform, the company is engaging with stakeholders from the oncology community (eg, Johns Hopkins Medicine oncologists, patient advocates, community-based social services, staff at Johns Hopkins Bloomberg School of Public Health).
- Pieces Technology. This company is partnering with NCI Community Oncology Research Program members to develop a workflow and tools to identify patients with social determinants

of health needs. The company's platform, Pieces Connect, brings together patient assessment and integration of positive screening data, closed-loop referrals, and access to pertinent community-based organizations.

- XanthosHealth. The ConnectedNest platform is an EHR-enabled mobile health technology developed in partnership with researchers from the University of Minnesota to safely and securely collect data on patients' social risk factors (eg, housing, transportation, financial, social support).

AI and Clinical Decision Support Solutions

Clinical decision support solutions augment complex decision-making for clinicians. There are 2 basic types: knowledge-based and non-knowledge-based. Knowledge-based clinical decision support tools use AI to develop rules (also called *if-then statements*), retrieve data, and produce an action or output. Non-knowledge-based clinical decision support tools use AI, machine learning, and/or statistical pattern recognition to better inform clinical treatment decisions. AI-enabled clinical decision support tools help providers in many areas:

- *Patient safety* is supported with tasks like automated quality assurance in radiation oncology, gravimetric verification of dose using robotic pharmacy technology, and identification and elimination of drug-drug interactions. (Note: Use of AI in this area can result in providers experiencing alert fatigue.)
- *Clinical management* is supported with tasks like adherence to clinical guidelines that improve quality and standardize care, follow-up and treatment reminders, and chatbot follow-up visits. (Note: Use of AI in this area can result in a negative impact on user skill as users come to trust and rely on

> *"Clinical decision support tools are really point-of-care support, helping to get the right information to the right person at the right time."*

the system.)

- *Cost containment* is supported with help in reducing test and order duplication and suggesting more cost-effective medications and/or treatment options (eg, a biosimilar strategy).
- *Administrative functions* are supported with tasks like diagnostic code selection, automated documentation, and note auto-fill capabilities.
- *Diagnostics support* is supported by provision of suggested diagnosis based on patient data and imaging, laboratory results, and pathology reports.
- *Patient decision support* is assisted by analysis of and reporting on data from individual health records. (Note: This support may require technological proficiency on the part of the patient.)
- *Improved documentation* is supported with aggregation of large amounts of data across multiple sources. (Note: Use of AI can lead to note bloat and/or propagation of erroneous data.)
- *Workflow improvements*.

Cancer programs can develop and implement their own clinical decision support solutions (homegrown solutions) or adopt one of many commercially available clinical decision support solutions. For example, Flatiron Assist™ is an oncology-specific, evidence-based clinical decision support tool. This customizable tool is embedded in the EHR and provides:

- *Decision support*, entailing standardized clinical pathways, real-time updates incorporating National Comprehensive Cancer Network (NCCN) Guidelines and other recent evidence, and the ability to track regimen usage.
- *Research support*, involving the ability to match clinical trials based on specific patient factors and to collect data on eligibility criteria, study protocol, and research team contact information.
- *Administrative support*, entailing data collection for prescribing patterns and maintenance of key prior authorization data within the EHR.
- *Opportunities to collaborate with payers*.

Small Group Discussion

After the series of facilitated presentations and discussions, meeting participants split up for small group discussions. Below are the reports from these discussions.

Group 1. Discussion revolved around EHRs and how AI can improve data collection, reporting, and sharing.

"Overall, EHRs are finally achieving their goals in being usable and adding value. But the biggest challenge is interoperability, and a main barrier here is lack of standards when it comes to terminology and data, especially when it comes to genomic data. Our group talked about how, as genomics become more and more important, AI could be a helpful tool in interpreting and standardizing that data for better data sharing. AI is a promising investment to support the patient experience when they're not in the 4 walls of your clinic—in other words, using AI to help manage care and track patients in the home setting. This

technology is helping to improve treatment adherence and the overall patient care experience."

"We also talked about how AI requires money on hand. And so many cancer programs and practices are struggling financially after a 3+year global pandemic. Many are only now getting back up to speed when it comes to funding innovations."

"In oncology, we see AI less of a game changer and more of a game accelerator, because we have to be careful and methodical in this space. One area that we see AI as having a really big impact is overhauling the revenue cycle and reducing the staff required to maintain billing operations. A big place for improvement is in prior authorizations, where our group thought AI can help providers eliminate delays and challenges."

Group 2. Discussion revolved around using AI to improve revenue cycle management.

"Our group also talked about using AI and bots to look at revenue cycle processes. At my cancer program, our patient population is very heavily managed-care patients; [only] 20% [of our patients have] traditional Medicare. Most of our patients require prior authorization, so that is one of the key areas that we are looking at. Our EHR is lacking in a lot of the functionality that we need, so we constantly struggle with adding applications to help. Many applications do not currently have interfaces that work with our EHR."

"We had a lot of conversations around interactions with pharma and how that has changed. How pharma has helped providers over time. We've seen that change since managed-care plans now have preferred drugs that they want providers to utilize."

"We had discussion around patient portals and the utilization of those platforms—for example, whether the platform is inside or outside of the EHR, and what the patient experience looks like. We see automation and AI as the next big investments for oncology."

> "AI will not replace health care providers. Instead, this technology can support providers and help bring back the humanity in medicine."

Group 3. Discussion revolved around current use of AI technology at participant's cancer programs and the need for continued investment and evaluation of its impact on patient care.

- Midmark's real-time location system
- AI-supported mammogram screening
- AI-supported digital pathology
- AI-supported analysis of urine specimens
- AI-supported prior authorization workflows aimed at reducing the number of denials
- AI-supported scheduling in the infusion center
- Curation of regimen libraries like OncoEMR (Flatiron), which has over 3000 regimens spanning more than 90 diseases

Research and Clinical Trials

Across many fronts, the oncology community is working to make research more equitable, enrolling diverse patient populations into clinical trials, making this type of care standard in all communities, and spurring adoption of new models (eg, decentralized and virtual clinical trials).

"The community belongs in oncology research, and oncology research belongs in the community."

Facilitators
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The Importance of Clinical Trial Participation in Cancer Research

Data from a seminal 2016 study by Unger et al strongly suggested that a "clinical trial system that enrolls patients at a higher rate produces treatment advances at a faster rate and corresponding improvements in cancer population outcomes."[12] The authors wrote, "Viewed in this light, the issue of clinical trial enrollment is foundational, lying at the heart of the cancer clinical trial endeavor."[12] Even with this knowledge, the data show that clinical trial accrual remains a challenge for cancer programs and practices:[13]

- Overall, approximately 6% of adults with cancer enroll in treatment trials; enrollment in nontreatment trials is higher (biorepository, 13.4%; registry, 8.1%; prevention, 6.4%).
- Accrual rates at National Cancer Institute- (NCI-) Designated Cancer Centers average 18.9%.
- When asked, 70% of Americans expressed interest in clinical trial participation, and more than 50% of patients said that they would participate in a clinical trial if offered the opportunity.
- Investigators in 24% of cancer clinical trials fail to accrue over 50% of goal.

Bottom line: lack of clinical trial availability in the community and lower participation in clinical trials is slowing our progress in alleviating the burden of cancer.

Increasing Racial and Ethnic Diversity in Cancer Clinical Trials

In 2020, ACCC and the American Society of Clinical Oncology (ASCO) entered into a partnership (the ASCO-ACCC Joint Initiative) to increase racial and ethnic diversity in US cancer clinical trials, with a specific focus on Black and Latino/Latina patients. The 2 organizations convened an expert, blue-ribbon panel, which included representatives from the FDA, the NCI, academic institutions, community cancer programs, and, most importantly, patients and patient advocates. Within 2 years, the 2 organizations published the ASCO-ACCC research statement, "Increasing Racial and Ethnic Diversity in Cancer Clinical Trials: An American Society of Clinical Oncology and Association of Community Cancer Centers Joint Research Statement," which outlined 6 recommendations to increase diversity in research participation:[15]

1. *Improve access*—every person with cancer should have the opportunity to participate in clinical trials, as an integral component of high-quality cancer care.
2. *Equity-focused design*—trials should be designed with a focus on reducing barriers and enhancing equity, diversity, and inclusion (EDI) and work with sites to conduct clinical trials in ways that increase participation of underrepresented populations.
3. *Partnerships*—clinical trial sponsors, researchers, and sites should form long-standing partnerships with patients, patient advocacy groups, and community leaders and groups.

Barriers to Clinical Trial Accrual[14]

Health System Barriers	Organizational Barriers	Payer Barriers	Provider Barriers	Patient Barriers
eg, escalating costs	eg, overly-burdensome institutional review boards	eg, prohibitive reimbursement policies	eg, physicians reluctant to enroll patients due to logistical and practical concerns	eg, practical concerns like lack of transportation or childcare services

4. *Education and training*—those designing or conducting trials should complete recurring education, training, and evaluation to demonstrate and maintain cross cultural competencies, mitigation of bias, effective communication, and a commitment to achieving equity, diversity, and inclusion in clinical trials.
5. *Invest in equity, diversity, and inclusion*—research stakeholders should invest in programs and policies that increase equity, diversity, and inclusion in clinical trials and in the research workforce.
6. *Sharing data and strategies*—research stakeholders should collect and publish aggregate data on racial and ethnic diversity of trial participants when reporting the results of trials, programs, and interventions used to increase equity, diversity, and inclusion.

The ASCO-ACCC Joint Initiative released resources to help research sites increase the racial and ethnic equity, diversity, and inclusion in cancer clinical trials. The Just ASK™ Training Program and Site Self-Assessment are available free of charge and represent a full and complementary set of resources that can help research sites address barriers to participation in cancer clinical trials among racial and ethnic populations that have been historically underrepresented.

- The ASCO-ACCC Equity, Diversity, and Inclusion Research Site Self-Assessment helps research sites identify systemic areas that are known to affect the diversity of clinical trials and provides site-specific recommendations to modify rules and procedures.
- The Just ASK™ Training Program identifies opportunities for change at the individual level and provides real-world examples to enhance understanding of participants.
- The Just ASK™ Training Facilitation Guide helps providers continue the conversation around implicit biases after the initial training.

Cancer Research Workforce

In addition to the physicians and advanced practice providers (APPs) who act as principal and subinvestigators, research teams include administrators, coordinators (research nurses, research associates), regulatory experts, data managers, community health educators, and patient advocates. These teams face great challenges, including the *great resignation* of the health care workforce that partially was a response to the more than 3 years of the COVID-19 pandemic and an aging health care workforce.[16] While some cancer programs have successfully brought retired, experienced research professionals back to work, this solution is short-term. The oncology community needs to identify long-term solutions and that means bringing younger people into the field of clinical research. Many research coordinators are not planning on that position as a career; they may have a bachelor's degree, and they eventually may enter other professional schools, like medical school. The oncology community needs to figure out how to better sustain the cancer research workforce, and that means building out career ladders and opportunities for advancement for all members of the research team.

Meanwhile, to improve clinical trial accrual, the cancer research workforce needs to take certain steps:

- *Work together to improve the conduct of clinical trials.* Leaders need to lead, be inclusive, and recognize everyone's value in the process.
- *Recognize that principal investigators do not always have to be physicians.* Principal investigators can be APPs, including pharmacists, depending on the clinical trial.
- *Ensure that clinical research is accessible, affordable, and equitable for patients and sites.*
- *Help to design more pragmatic and efficient clinical trials that are better integrated into routine clinical care.*

"Administrators are so key to research. If your cancer program administration is not involved in research or doesn't believe in it, then your research program is simply not going to work."

- *Work with industry and trial sponsors to simplify, streamline, and standardize protocol requirements and research operations.*
- *Recruit, retain, and support a well-trained clinical research workforce.* These efforts may include salary reviews and salary increases.
- *Promote appropriate oversight and review of clinical research conduct and results.*
- *Work with the state's licensing body to ensure APPs can participate in clinical trial research.* Coordinating with legal, regulatory, and IRB bodies paves the way for APPs to act as principal investigators.

> "The data start with the investigator. If investigators don't provide good clinical trial conduct and document appropriately, then it's a real headache for our research coordinators and data managers."

> "I want to underscore the importance of community health educators in helping to inform and educate the community about clinical trials."

between research and clinic teams, and specific and targeted training and education on clinical research for APPs in the clinic.
- Hiring a clinical research APP with the expectation that this APP would be the provider for patients on clinical trials. The APP would build a portfolio of clinical trials, becoming the provider who best understands these trials and ways to best screen for these trials in the clinic.
- Partnering APPs who work in the clinic and who are already well-trained in the diseases, symptoms, and assessments with physicians to provide training that would allow APPs to assume care of patients enrolled to a specific clinical trial.

The Role of APPs in Clinical Trials

There is a movement to increase use of APPs in clinical research—not only as principal investigators of clinical trial conduct but also as leaders of other types of trials outside of treatment trials (eg, supportive care trials, cancer care delivery trials, and registry trials). Many times, APPs are the providers who spend the most time with patients; they know the specific needs of each patient and are experts in identifying those most suited to participate in clinical trials.[17] The time required to introduce and educate patients about a clinical trial is a recognized barrier to accrual. With their deep understanding of cancer, cancer treatment, and symptom management, APPs are uniquely trained and positioned to facilitate these discussions with patients.[18] As noted by Ulrich et al, APP "knowledge and expertise can lead to a more thorough discussion augmenting specific trial information provided by other members of the research team."[19] To achieve a model in which APPs are active in conducting trials, it is very important to have a physician champion.[17]

During open discussion, 1 participant shared that her cancer program found APPs working in the clinic—and not in the research department—to be a barrier to increasing use of APPs in clinical research. Conference participants shared several solutions to this challenge, including:
- Creating a culture shift that promotes clinical research as a component of the care provided in clinic, better integration

> We've had research coordinators bring a feasibility study into a meeting and share feedback of issues they have identified. If physicians don't listen to this feedback and push the study through, it is the research staff who is then tasked with working out these issues. To avoid situations like this, we need to value everyone's input."

The Role of the Oncology Nurse Navigator

To increase clinical trial accrual, Virginia Cancer Specialists, PC (a large, multidisciplinary, community-based oncology practice in Northern Virginia) created the role of a clinical trials navigator to fill knowledge gaps of the practice's trial portfolio, provide introductory education on clinical trials to patients, and coordinate patient-related logistics.[20] Today, the clinical trials navigator is the primary source of research information across the practice, including all satellite sites. Clinical trials navigator responsibilities include:[20]

- 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.

Two years after implementation of this new role, the clinicals trials navigator receives referrals from providers practice-wide and identifies all clinical trial opportunities appropriate for patients. More, the practice continues to grow a portfolio of varied clinical trials, attracting external patients from across the region and the country.

Industry's Role in Clinical Research

During open discussion, an industry participant asked, "From the provider perspective, how would you define a good trial sponsor? In other words, do you have specific advice for helping industry become better partners on clinical trials?"

A provider offered 3 recommendations:

1. First, industry should look at underserved communities and figure out how to bring trials to the people who live in those communities. Industry should "make it their mission to look at a map of the United States and say, 'There are no clinical trials for people who live in this part of the United States.' Find out who those people are, and bring the clinical trials to them. And you will be rewarded with unique perspectives."
2. Second, industry should invite more people to the table when designing clinical trials to gain insight into patients' and providers' barriers to participation. What support(s) do patients need? Are there patient and provider concerns? What patient and provider education is needed? "It doesn't work all that well to design the whole package and then say, 'Now, let us tell you about this clinical trial and see if you can do it.' You will have a much better product when you have providers involved from the beginning."
3. Lastly, industry should report back to communities about the benefit of their clinical trial participation. "It builds a learning community. It builds a trust community. It spreads the word. It's helpful to go back to people and just say, 'Thank you.'"

"We see the problems facing our population health counterparts at community health centers. They build navigator teams, but they keep losing team members because of a lack of career pathways for these professionals. And when these individuals go out the door, they take with them all the knowledge they have acquired about the patients in their community. So, how do we keep our research coordinators and research navigators engaged in the work, engaged in the clinical research process?"

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"That is true for clinical research coordinators and data coordinators as well. Unless you have a robust research program where there is a tiered staffing structure or a way for these professionals to move into a career ladder, retention is difficult. It was mentioned earlier that many people use research coordination as a steppingstone to something else, but not everybody [does]. And for those that don't, there really isn't a great career trajectory."

Another provider participant suggested that when industry takes a clinical trial to an academic institution (many of which have community networks), the sponsor shares its expectation that the academic institution extend the clinical trial to its community network. "I hear from colleagues in my network that these clinical trials are too specific or too complicated or that patients need to come to an academic center to participate. I don't think that's true. And we need partners who are advocating for those community cancer programs that are capable of participating. [For industry] to put that kind of pressure on when you are engaging with academic institutions for your studies will really help." Pharma has to be a bridge and help community research programs build the infrastruc-

ture required to participate in clinical trials and fund those infrastructure improvements.

One provider participant asked industry to think about the patient populations that each clinical trial serves and then design that trial for cohorts mapped to that population. Not only would that improve equity, diversity, and inclusion in cancer research, it also requires industry to go into the community to accrue patients who are not coming to the academic medical center.

Several providers brought up the costs related to clinical trial participation. Industry funding needs to support the total cost of the clinical trial. If participation in a clinical trial is likely to have negative financial impact on the cancer program's bottom line, organizations are likely to say, "No," to participation.

> "I would ask that industry think about this: we have all these drugs that are [FDA] approved, but my Pacific Islander patient population reacts very differently to these drugs and their toxicities—and that's the same with older adults. So, consider sponsoring some of your phase 4 trials with these patient populations in mind; you would then be able to collect better data for drugs already approved."

Small Group Discussion
After the series of facilitated presentations and discussions, meeting participants split up for small group discussions. Below are the reports from these discussions.

Group 1. Discussion revolved around funding and clinical trial budgets.
"When negotiating clinical trial budgets, there is usually a line item for coordinator time and effort—in addition to PI [principal investigator] time and effort, we should negotiate more money for clinical trials with higher acuity (for example, lymphoma and leukemia patients who require more time and effort). More care coordination and management. So negotiating with industry and other entities so the budget reflects the cohort of patients being managed, (their acuity level), and the provider work required. This additional money

> "Depending on the clinical trial, the amount of funding we receive from the sponsors for the trial work is significant. Some of these unique patient populations require a [provider] workload that is not easily recognized—whether it's the care coordination or the level of community resources needed [for patients to participate]. So, I would say appropriate funding of clinical trials is an imperative for sponsors."

might allow cancer programs to fund an additional FTE [full-time equivalent] to support existing research staff."

"We've been asked to help find more money for physicians [to participate in clinical research]. We first ask, 'How are you using your research staff to support your physicians? Have you developed patient education on research and clinical trials to save physician time on patient education?'"

"We talked about budgeting for a clinical trials navigator. And maybe it's not just for 1 trial. Maybe you are accruing to 5 different industry trials, and each 1 has a percentage of an FTE budgeted for a clinical trials navigator."

"Our patient population is underserved, so I know that for many of these patients, clinical trial participation will require resources for transportation and childcare. And I put those costs into my research

> "More and more of my clinical trials include a thank-you card and how to get more information from the trial sponsor when the trial is complete. I've seen a big switch in how industry is approaching their provider relationships, and I've appreciated that change."

budget. IRBs allow that kind of support now. It is not enticement; it is taking care of the patient's financial reality, thereby improving patient access to clinical trials."

Group 2. Discussion revolved around institutional support and physician champions.

"There's only so much that pharma can do [around reimbursement]. [Successful research programs] have the right institutional structure. If you are going to adopt the hub-and-spoke research model, it needs to be leadership supported throughout the health care system and each institution.

"One thing we've found when we work with our hospital and physician groups to increase their clinical trial enrollment is physicians who say, 'It takes too much time for us to do that.' The real gamechanger is a physician champion who can get the rest of the physicians to come along."

Group 3. Discussion revolved around implicit bias and improving health equity.

"Our group identified 1 concrete action we could start with, and that was exploring implicit bias training for PIs and research staff—working to overcome our own biases on who is a clinical trial patient. Starting with ourselves and then spoke-wheeling implicit bias education and training out to our colleagues."

"How many practices or programs actually understand the patient population they currently serve? How many know the racial and ethnic makeup of the patients they are enrolling to clinical trials? I am going to be honest. My program didn't know how to do that [collect that type of patient information] until we took the research site assessment tool. So, we've only been collecting these data for between 9 to 12 months. But you don't know if you are actually improving diversity in clinical trials until you measure your efforts. We are novices at this type of exercise."

"Some research programs have navigators for specific disease sites or for specific ethnic or racial groups. That's an opportunity and a responsibility for our institutions—to bring in these types of community navigators to provide training and deployment. It not only enriches our workforce; it enriches the individual, their family, and the community they live in. These navigators take the health information, what they've learned about cancer, and the opportunity to participate in clinical trials back to the community. We need to bring those people into our cancer programs and make them part of our team. Train them up. And let them improve the health of our communities."

Group 4. Discussion revolved around innovative ways to improve clinical trial accrual.

"We talked about using a hub-and-spoke model to enroll more diverse patient populations in clinical trials. We agreed that there are likely deserts in this country where clinical trials aren't even available, where patients need to go outside their communities and possibly even to another state to participate. Smaller community sites within a geographic area could partner together in a model where 1 site offers breast trials, another site offers prostate trials, and a third site offers lung trials. These smaller cancer programs could come together and build a collective portfolio instead of 1 site trying to open a clinical trial for every disease site. Absent of an academic center in that same geographic area, these sites essentially create their own research network."

"We also talked about networking and mentorship opportunities between academia and community. Where the clinical trial process might get started at the academic institution and then transitioned back to a community program. We discussed decentralized trials where large research sites push out clinical trials throughout an entire network—not just 1 or 2 academic institutions. And centralized IRB is critically important to help smaller research programs get through all the regulatory requirements, or what I like to call the muckety-muck. Educational materials should be updated and culturally appropriate for all patients. Translated consent forms. That seems like it should be simple, but it's not. I have to go to my IRB, then a translator, and then back to the IRB to get it certified. It's a lot of time. Industry could help by developing a library of consent forms that are readily available—a tremendous time savings."

"We discussed how AI could solve the patient-matching portion of the clinical research challenge. AI technology for not just the pre-screening but also the final screening of patients. There is a huge unmet need there in clinical trial matching. A tool to empower patients to participate in that process."

"While COVID-19 blew telehealth wide open, we have since retreated from this care delivery model. For example, the ability to cross state barriers and other exemptions have expired. But there are clinical trial-related tasks and/or procedures that community providers could complete so patients would not have to drive or travel to the academic center. Could some of the procedures be done closer to where patients live? We just need networking between the academic and community centers to identify opportunities."

"Finally, we talked about doing a better job of getting information on clinical trials out to the communities, whether that's through local events, churches, health fairs, or high schools, colleges, and trade schools. In essence, piggybacking on networks that already exist in the community and getting this information to someone who knows someone with cancer who would benefit from a clinical trial."

Closing Remarks

At the conclusion of these reports, 1 of the facilitators closed the deep dive by paraphrasing these words from Margaret Mead, "Never doubt the ability of a small group of committed citizens to change the world." He followed that with his own affirmation, "We are committed. We can do this. Go home and change the world."

Precision Medicine

New roles, like precision medicine stewards and navigators, are rapidly spurring adoption of precision medicine, bringing this care into all communities so that all patient populations may benefit.

Facilitators
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- Leigha Senter, MS, CGC; Licensed Genetic Counselor and Professor, Internal Medicine, Arthur G. James Cancer Hospital and Richard J. Solove Research Institute at The Ohio State University
- Emily Z. Touloukian, DO; Medical Oncologist and Hematologist and President, Coastal Cancer Center

Defining Precision Medicine
In the context of this discussion, facilitators defined precision medicine as treatments administered following the identification of a targetable alteration in the tumor or patient.

Why is Precision Medicine So Important?
Facilitators set this stage with this statement: "Targeted therapies improve survival and are often less toxic, resulting in a better quality of life for patients." For example, historically, patients with metastatic non-small cell lung cancer (NSCLC) have had poor overall survival with standard chemotherapy, with an overall survival of around 1 year. After the introduction of targeted therapies, overall survival more than tripled for a subset of these patients with NSCLC who had *EGFR* mutations and who were treated with tyrosine kinase inhibitors (TKIs).[21] Another example of successful targeted therapy includes PARP inhibitors for patients with prostate cancer that has advanced and patients with breast cancer with a *BRCA1* or *BRCA2* mutation. These and many other data highlight the critical importance of precision medicine. Personalized medicine for nearly all tumor types has become standard of care for patients with cancer; indications are expanding and entering earlier lines of therapy. Yet less than 50% of eligible patients receiving next-generation sequencing (NGS).[22] How can providers ensure patients receive testing to determine eligibility for these targeted treatments?

Operationalizing Precision Medicine
Busy providers are inundated with a wide choice of molecular tests and testing facilities. Some providers are contracted and must use a laboratory of choice. Even if the choice is up to the provider, there can be disagreement across providers on what tests and laboratories to use. How do providers make informed decisions?

Sometimes the answer is easy—for example, when there is a compendium test that the FDA has assigned to the approval of a certain drug, essentially tying that drug to a specific laboratory test. Providers who want to use that drug with a patient will then use that test to inform them if the drug is going to work for their patient. Unfortunately, that is not the case with most targeted therapies.

Instead, providers must understand the large group of actionable mutations—*PIK3CA*, *EGFR*, *BRAF*, and *NTRK*, among countless others—for which a drug has been developed and has become commercially available for targeted therapy and then decide what patients and where to test for these mutations. Providers must also understand the sample they need to send for molecular testing (eg, tissue, blood, saliva). Once providers identify the test they want to order and the laboratory they want to use, they must still navigate a complex order process that includes:
- An understanding of how and where to order the test (eg, is there a portal that providers must join by providing a National Provider Identifier number and other credentials, or, if the test is ordered by paper, how do providers track if the order was received?)
- Complex requisition forms.
- Specimen acquisition. Providers see many patients for second opinions, which means that patient specimens are often at another location, perhaps even outside of the provider's health care system; this adds even more complexity to molecular testing.
- Patient consent. Not only are these tests gathering genetic information that could have huge treatment implications, but there are also Health Insurance Portability and Accountability Act requirements and the need for cost discussions in case the test is not covered by the patient's health care plan.
- Payer coverage and/or financial assistance options.
- Physician signature process.

This complex decision-making process is 1 factor behind the slow uptake of molecular testing.

Front End Barriers and Best Practices

Identifying the *right* patient for the *right* test is still the biggest barrier for providers. With our competitive testing market, understanding the benefits and limitations of similar tests is cumbersome for providers. Currently, that decision is 100% a physician's function. Until EHRs can automate candidacy notification for specific molecular tests, oncologists and hematologists are making those decisions when they see patients in the clinic. But should oncologists make those decisions, or should molecular testing be a function of pathologists, who have much more expertise in handling this information? And should individual providers order molecular testing, or should the testing decisions be made by committee? Should next-generation sequencing (NGS) be ordered for every tumor at identified times so that oncologists seeing patients in clinic always have access to the most comprehensive information when choosing treatment? And how do providers improve testing? Is it up to the individual learner (provider) to keep up-to-date with patient populations who would benefit from certain tests, or is a more comprehensive approach needed in which decisions are made by consensus at molecular tumor boards or through national guidelines?

Another barrier is a lack of a navigation process. Successful precision medicine programs navigate patients through the testing process, which includes patient consent, patient (and physician) signatures, and cost discussions.

Best practice for molecular testing includes:
- Preparing order requisitions, including a way to ensure orders are filled out completely and accurately (correct test, correct specimen) to avoid treatment delays.
- Monitoring the molecular testing process to ensure the form was received, the laboratory is requesting a specimen from the correct pathology department, and the pathology department has packed and sent the specimen.
- Tracking. Did the specimen get to the laboratory? Where is the laboratory with processing? What is the estimated time of arrival on the results? Are there quality control issues that require new and/or additional specimens. Are there add-on orders?
- Retrieval of test results (ie, portal vs email vs fax).

Advocate Aurora Health employs an full-time equivalent (FTE) to act as a single point of contact (POC) for all precision medicine efforts. This nonclinical staff member supervises the entire molecular testing process from start to finish. All molecular testing requests are channeled through the POC, who has expertise with requisition forms and information requirements. In addition, this single POC:
- Has established personal contacts with all testing laboratories.
- Ensures that all patients fill out financial aid applications.
- Follows up on all testing, including retrieving specimens (blood, saliva kits) from pathology, the laboratory, or the patients' home; confirming that specimens have arrived at the testing laboratory; procuring updates on test progress and retrieving test result(s) from the laboratory; sharing test results with the ordering physician; and then scanning test results into the EHR.

Once test results are entered into the EHR, physicians interpret the results and report back to patients.
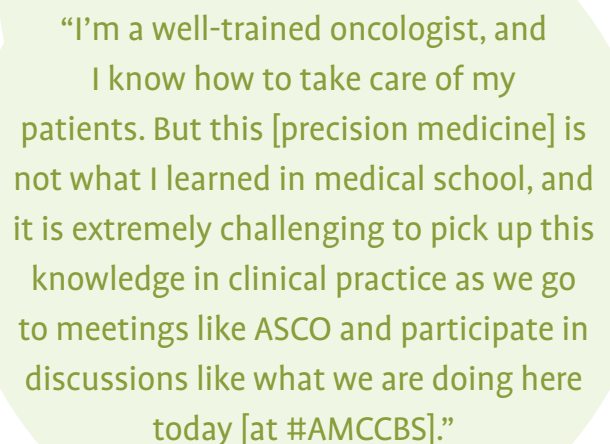
Back End Challenges and Quality Assurance Opportunities

Once molecular testing is complete, one of the common challenges is that most EHRs do not store the results in discrete fields—at least not yet. Molecular testing results usually come back to the provider as a PDF, which is then scanned into the EHR. Often, the molecular testing results are labeled differently, making it difficult for providers to find them in the EHR.

Once the molecular testing results are located and interpreted, providers must then answer the question, "How do these test results apply to patient care?" Testing results need to support appropriate therapeutic decision-making. Based on these molecular testing results, is the patient appropriate for a clinical trial?

In addition, testing results are automatically released to patients. This is a good practice in some ways, yet without upfront discussion about the molecular testing, patients get their results, call the provider, and ask questions, often with concerns about hereditary issues that may or may not be relevant. Molecular testing reports are generally not written in patient-friendly language.

Another challenge is interpretation and reporting differences between testing laboratories; these differences can lead to seemingly discrepant results. This variation impacts the ability and capacity to build clinical decision-support tools (eg, best practice alerts). If testing laboratories do not report results in the same way (eg, staff at 1 laboratory label

"I'm a well-trained oncologist, and I know how to take care of my patients. But this [precision medicine] is not what I learned in medical school, and it is extremely challenging to pick up this knowledge in clinical practice as we go to meetings like ASCO and participate in discussions like what we are doing here today [at #AMCCBS]."

a result "pathogenic," but those of another laboratory do not), essentially AI tools are rendered somewhat useless due to lack of a naming convention.

Variant reclassification, while often clinically relevant, can also be a burden on clinical staff. In addition, infrastructure is needed to re-evaluate all evidence available about the pathogenicity of a genetic variant while considering any new evidence made available since the previous interpretation.

The potential for incidental germline findings is another challenge. What happens when the molecular test is performed in a patient for 1 purpose, but the test identifies an unexpected abnormality that is not related to the initial reason for doing the test? These findings can be surprising to both patients and providers.

Developing quality assurance opportunities to meet the above challenges is key. These opportunities include:

- Developing a standardized process to ensure molecular testing is being conducted equitably (ie, molecular testing is performed in all patients deemed appropriate).
- Setting up a standardized documentation process for molecular testing and its results.
- Implementing standardized labeling of molecular testing results in the EHR.
- Establishing laboratory and system partnerships for reporting and flagging patients for whom action is needed.
- Collaborating with tumor registry and practice analytic teams to streamline the molecular testing process.

Large Group Discussion

After the series of facilitated presentations, participants took part in open discussion and a question-and-answer session on what is happening in practice, challenges and barriers, and ideas and solutions to

"Most molecular tests that are ordered give providers more information than they need at that particular moment. There's always a little nervousness around, 'I am going to find out all of these other things that I wasn't looking for.'"

"I am a research nurse. Some clinical trials will only accept certain NGS results as part of the documentation of getting patients enrolled. So, 1 study will take this molecular testing result, and another study will require a different molecular test. And then trying to get back in touch with providers can be challenging. But physicians are the only ones who can make these decisions, and so everything just keep getting delayed."

meet those barriers. This discussion has been captured below.

The Cost of Providing Personalized Care

One participant asked how Aurora Health's single point of contact salary is funded and whether there is some way of getting reimbursed for these services. After learning that the physician practice absorbs the cost of this FTE position, the participant expressed concerns about this model's replicability, since many cancer programs and practices are not in the position to fund this type of FTE.

Financial navigation was suggested as the best model to look to when implementing a single POC to help providers navigate molecular testing. Financial navigation is another service that is not yet reimbursed by payers, but data have shown that FTE financial navigators pay for their salaries through cost-savings (eg, reduced denials and uncompensated care) and the downstream revenue they bring to the cancer program. Advocate Health expects to realize similar benefits from the work done by the molecular testing POC (eg, saving providers from ordering the wrong tests or having results sent to the wrong laboratory). With the many potential pitfalls in the testing process, elimination of these problems and the streamlined process and workflow developed by the POC ultimately are expected to save the health care system time and money.

"This might sound a little cheesy, but the reason I come to work is to give the best possible care to my patients. And that's where precision medicine really comes into play: the right patient at the right time with the right test is what all providers strive for. That 1 FTE is a worthwhile investment to achieve that goal."

There was consensus that much of health care is uncompensated time, but that it is the cost of providing care. There was recognition that payers are looking at chronic care management codes, principle illness navigation services, and other ways to reimburse for some of the uncompensated care provided. But, as a participant pointed out,

"The work must be credentialed. And not everyone doing this work has a credential behind their name.

"Time is money. As a participant shared, "Time is a significant barrier to molecular testing and retesting. Sometimes a patient can't wait 5 to 6 weeks for results. We've tried to work with our health care system to block biopsy time for cancer patients so that I can order a biopsy, and it's done within a week. And they did that for a time, and then it stopped, because the health care system doesn't bring in revenue on open biopsy slots."

Guidelines and Standardization of Care

With the rapidly evolving field of precision medicine, use of guidelines and institutional pathways help ensure providers stay up-to-date with the latest medical and scientific advances.

At Advocate Health, providers were able to rally around standardization of oncology care through adoption of Via Oncology pathways (now ClinicalPath). These types of pathways and resources, like the National Comprehensive Cancer Network (NCCN) Guidelines and the ASCO Clinical Practice Guidelines, help cancer care teams make decisions at the bedside that are driven and supported by precision medicine and, often, AI. These decision support tools enable physicians to have the knowledge at their fingertips to develop life-changing, targeted, and personalized treatment plans.

As a participant shared, "And while some believe that [standardization] is rubber stamping cancer care, having been in oncology now for more than 20 years, I see the benefits. Humans are creatures of habit; many physicians are going to do what they did last week, because it worked. There are patients who receive substandard care, because not all physicians are going to national meetings and [are] able to keep up with the latest, cutting-edge treatments."

The Importance of Reflex Testing

Reflex testing requires a pathologist to arrange for testing of the specimen at the time of diagnosis. There was discussion about the importance of reflex testing and ways that providers can best use this testing. Communication and a unified EHR is key.

"How can we reflex test in lung cancer? It's easy with breast cancer and initial diagnosis. Everyone gets ER (estrogen receptor), PR (progesterone receptor), and HER2 testing—no matter what. But with lung cancer, pathologists don't know staging when the biopsy is in front of them. So, pathologists don't know if they need to [perform a] reflex test. We need to figure out those issues and [ways] to put processes in place and establish pathways so that we can communicate that information forward. It's likely a little simpler if you work in a large health care system where everyone is on the same EHR. I am in a community practice; my pathologist, my radiation oncologist, and my pulmonologist are all in different practices. That's 4 different EHRs and 4 different practices trying to communicate about 1 patient. We need automation, leveraging AI to standardize processes so that information is not lost from 1 care setting to the next, and providers can act."

Another participant noted that the molecular landscape of tumors is not static. If a patient was biopsied at diagnosis and then went through 2 or 3 lines of treatment, providers should retest—especially when it comes to lung cancer—so the reflex testing process itself becomes more complex.

Payer Roadblocks

Many participants wanted to discuss the elephant in the room—payers—and the roadblocks payers have put in place that have slowed the uptake of precision medicine.

"Why aren't we talking about the role of the payer? Blue Cross [and] Blue Shield of Louisiana is my largest payer, and it labeled NGS testing as experimental, which means that all testing requests require prior authorization. We are seeing delays of 5 to 15 business days, in general. And if you have a patient with an aggressive form of cancer, there is an impetus to get them started on any kind of treatment. The worst care scenario is when NGS testing comes back, and providers realize the patient was put on a treatment with no benefit. These are the struggles we deal with daily. We've tried to bring Blue Cross to the table with Caris [Life Sciences] and Tempus. Our payers say the panel is too large and costs too much money. And Blue Cross is unbending. So, while the technology is amazing, we are facing a lot of real-world challenges just trying to get the best treatments to our patients."

Another participant agreed, "These are artificial challenges we create for ourselves. We're not struggling because the technology isn't there. The technology is there. The patients are there. The tumor specimens are there. It's all this other stuff [like reimbursement] that creates these barriers and pitfalls. I am grateful for your comment that payers play 1 of the biggest roles in erecting barriers to care."

Industry participants agreed. "I worked at Foundation Medicine for many years. And payers told us there was no reason to run a panel testing 324 genes, let's say, for lung cancer when there are only 36 genes that will have a targeted therapy. We went back and forth for months—even years—with payers to cover a test, sometimes even after the patient passed. This was an experience I lived day in and day out. I hear the challenges that you are all sharing, and I agree [that] payers are 1 of the biggest barriers to getting this technology into the hands of every patient who would benefit."

EHR Integration

There was consensus among providers that the process of filling out testing forms needs to be streamlined and—even better—standardized. One participant succinctly summed up the issue, "What I'm hearing from everyone is that you are all using your EHR, so the ability to order tests directly through the EHR has got to be a key component. The idea of going to a separate portal or, worse, having to fill out a paper form is absurd. Why not just click a button in the EHR to order the test—regardless of the test or testing lab? And that EHR integration needs to be done first and foremost with Epic (since it's the largest) and then with Cerner, Flatiron, and the other community-based platforms. EHR integration alone would save providers so much time."

Providers in the audience agreed and expanded on the role EHRs could play in improving molecular testing. "The other component to that is providers need to know when to order a test. It shouldn't necessarily be a physician deciding that they are going to order a test. It should be the EHR that tells the physician a test should be ordered. There should be a dropdown in the EHR to inform providers, 'The patient is now at stage 4. NCCN guidelines call for molecular testing.

These are the commercially available tests.' And then we need to go 1 step further and get that testing data back into the EHR, with alerts and notifications when there is actionable data. I believe that it all goes back to the EHR."

One participant shared that he was part of his organization's genomic integration team and that it takes senior leadership buy-in to support the infrastructure to build this type of technology. "Some [testing] companies have made it a lot easier than others. It does take some effort on the part of your IT [information technology] team to get this technology operationalized, but, once it happens, it's like a whole new world."

Several testing vendors shared that they have decision support tools within their platforms to assist providers in picking the appropriate tests; many said they offer precertification assistance to providers, as well.

One provider countered with this statement: "The pushback I would give is that this information is lab specific. So that's only helpful if you do what my institution is doing—essentially marrying ourselves to 1 lab. And that is not the typical experience at most cancer programs or practices. Most use multiple testing labs, and that means multiple processes. Multiple contacts. Knowledge of which vendors offer which services. And so, while I appreciate your efforts, I believe that providers need to be involved at the front end when processes are developed instead of at the back end, having to now deal with different information from different testing laboratories. There should be a streamlined process for providers. That is why meetings like this [#AMCCBS] is so important. To bring stakeholders together to develop solutions that benefit all providers and all patients. We need to learn what tools are out there, how they are currently being—or, in some cases, not being—used, and how can we overcome those barriers."

A participant who worked in hospital data integrations brought up the concept of single source of truth (ie, data that everyone agrees is the real, trusted number). "I think it's remarkable that your organization chose to partner with 1 testing vendor. The problem we run into working with multiple testing vendors, and I will use the example of a patient with non-small cell lung cancer. If a patient is EGFR-positive with [an EGFR] T790M mutation, Tempus has a different test than Foundation Medicine. And what you lose is a single source of truth. When I speak to CIOs [chief information officers] about true integration, I tell them that without a single source of truth, you can't really have a tumor-informed assay, especially in the monitoring space. So that's what we're looking to solve. But a lot of institutions don't want to choose only 1 vendor, because they feel liable and that they are not giving freedom of choice to their oncologists."

Most participants agreed that the EHRs themselves can act as barriers to molecular testing. Most EHR platforms were not built to integrate with third-party systems; they were built as vertical siloes. Clinical pathways face similar challenges. "It's very hard to get data out [of an EHR] and even harder to write data in. EHR vendors need to agree on standards if they are going to offer interoperability with molecular testing vendors. We want to be able to build reflex testing into clinical decision support so that EHRs can trigger appropriate test(s). Otherwise, providers are up against limited IT resources. Hospital IT resources can't keep up with building different decision support rules for which reflex tests to order based on the latest medical

and scientific advances."

A participant who does EHR integration at Foundation Medicine agreed that 1 of the most common reasons for institutional pushback is the amount of IT resource burden on cancer programs. "Our EHR integration is not an upgrade; nothing needs to be done in Epic. There is a small amount of IT testing that we need to be able to do. It's about 10 hours of work over a 2-week period to set up online ordering and delivery of tests. But it's still a request that goes into a queue with all the other requests that require IT time and resources. And we've heard that's burdensome. The testing facilities are trying to make that process as streamlined and easy as possible for providers. I can only speak for Foundation Medicine, but we provide this service at no cost to providers. We don't charge anything for our labor and the software we use to get this process up and running on your EHR."

One participant recognized the efforts of the various testing vendors but noted, "The higher ups still have to give approval that these testing platforms can integrate with the EHR. Most importantly, contracts need to delineate who owns what patient data and where. There is so much pressure on the C-suite right now around issues like protection of patient data and effective use of IT resources. To be honest, I am not sure if molecular testing is their number 1 concern."

Another participant zeroed in on the price of integration. "It's the cost. Our cancer program offers something like 700 tests. And what they [vendors] want to charge us to be able to interface with all those tests and all those labs is cost prohibitive. A lot of times the barrier to providing the best possible care to our patients with cancer comes down to cost. That's the pink elephant in the room."

One participant suggested that the solution may require regulatory intervention. "We all want to cure cancer. And the technology and the targeted therapies are putting us ever closer to that goal. But how do you translate these advances to a provider in the room with the patient? That is really where the rubber meets the road. If we had a federally-regulated EHR and a unified health care system where everyone was using the same EHR so they truly talked to one another, I would not reorder a CT scan that was done just 2 weeks prior by another health care system. In my opinion, about a good third of our health care dollars is in waste and inefficiencies like duplicative ordering of tests and scans. We need bigger solutions as a country."

Diversifying the Testing Pool and Clinical Trials
One participant pointed out that—for better or worse—genomic data are about 80% from White male or female patients. The participant asked how oncology could help diversify genomic data, helping to ensure all patients access to this technology.

"Part of the answer is to make sure that we are testing diverse patient populations now so that these data then become part of our greater knowledge. There is justified mistrust about the large genomic testing endeavors we've conducted over the years. Even with all the back-pedaling [that] we are doing to try and catch up with these data, it remains a huge, huge, issue for oncology."

One participant from a laboratory testing facility talked briefly about challenges to kicking off a large study of approximately 100000 patients. "We recognize that we need to provide diversity in the population we are screening. We've engaged with large institutions, both integrated health systems and academic networks. One of the chal-

> "Every time I hear a provider gets an NGS test result back—whether it's from Foundation Medicine, or Tempus, or Caris—and has to scan it into the EHR, it makes my skin crawl. And someone earlier talked about faxing in a lab request? That's just crazy with the technology that is available today."

lenges we are facing is that some of our partners are not really set up to recruit diverse populations. These institutions have set ways and patterns for patient recruitment to clinical trials. It has to be a true collaboration between the academic institutions, the communities where these diverse patients live, and industry if we are truly going to increase accrual of diverse patient populations to clinical trials. We can set those goals and expectations for our own studies, but if our partners are not set up to deliver those patient populations—which we've been told takes a lot of effort—and we are not working towards the same goals, it will be challenging for all of us."

Clinical Trials and Molecular Testing

A participant asked how others are layering in clinical trials with molecular testing. "How are you differentiating from the alphabet soup you receive on the genomic report to know that a specific marker has opened up an opportunity for the patient to enroll to a clinical trial?"

Another provider offered these insights. "That is the bane of my existence. I spend literally hours in meetings trying to automate that process. We lose at least 50% of our patients who are eligible for clinical trials, because the physicians either don't think of the clinical trial when they saw the patient in front of them, they didn't think the patient would be eligible, or that they didn't even know that the trial exists and was available to them. When it comes to precision medicine, it is even harder. I have been a big fan of basket trials [ie, when a single investigational drug or drug combination is studied across multiple cancer populations], which have really brought the whole concept of precision medicine to the forefront. These trials have allowed us to group patient populations with specific alterations together, treat them with a specific regimen, and see if it makes a difference. And now we know what works and what doesn't work for a tumor. But we have had the hardest time matching patients with a genetic or a genomic alteration to a basket clinical trial, because physicians don't think of

agnostic therapeutics [ie, a drug treatment used to treat any kind of cancer, regardless of where in the body it started or the type of tissue from which it developed] when they see a patient with breast, lung, or colon cancer in front of them. And because I am a physician, I am advocating for taking the physician out of this process. Historically, we are trained differently. We have a one-on-one mentality. Every patient is a different scenario. It's very difficult for us to think in broader terms. We need automated mechanisms to quickly see information on appropriate molecular tests and appropriate clinical trials. If we can figure it out for standard of care, we can certainly figure it out for clinical trials."

"Our institution has clinical pathways. When I put a new patient into our EHR, I give them a diagnosis. I stage the diagnosis. Then I click on a treatment plan, and it is linked to our clinical pathway. With the information that I have fed into the EHR, it will then channel me to first-line choice of therapy. If our institution has a clinical trial that aligns with this treatment option, it will be my first choice. That has been my work over the last year: to create that intersection in the EHR so that our clinical trials are fed into our clinical pathway, and I can easily see that there is an appropriate clinical trial for a specific patient. So, that's probably as good as it gets."

But even that solution has its drawbacks.

"Here's the problem. I have 20 minutes with the patient. So when do you think I do this? When the patient is long at home. It's 6:30 [pm]. I've seen all my patients, and now, I am finally able to get to my charts. I am going into the EHR and giving this patient a diagnosis. I'm developing a treatment plan. I'm contacting my whole team and saying we need a precertification and that I am bringing this patient back next week for a treatment plan. And now the EHR is telling me there's an available clinical trial."

"My administrators are saying, 'I don't understand why this process does not work for you?' And I tell them that it is not my workflow. I am not in the room with the patient when I am staging and developing a treatment plan. I am not on the EHR when the patient is in the room. So, do I really pick up the phone at 6:30 and say, 'I know what we talked about at 3:30, but now I have revised my opinion, and there might be a clinical trial option'? The devil is in the details. You can have all this wonderful technology and processes, but if the physician cannot use them, what is the actual benefit?"

"Here's what I want. I want to walk in at 8:30. I want to look at my clinic schedule. And I want my clinical nurse and research nurse to tell me that your 3:30 patient is a candidate for this clinical trial. And your 4:20 patient has shown disease progression on the CT scan; we don't have a clinical trial, but you should do genomic testing, because they may be a candidate for a new targeted therapy that was approved last week. I want to enable my clinical nurses and my research team to be my back filler so that I can be the doctor I want to be."

In response, a participant shared that whereas the process at her cancer program does not capture the patient in the above scenario (ie, an individual seen earlier in clinic), "We have weekly huddles with all physicians about their new patients who are going to be seen in clinic that week. We also have a multidisciplinary clinic every week where we look at each patient and decide whether they are a fit for a clinical trial. And sometimes I see the patient a day before or only an hour before the physician, but we are trying to be proactive in our

processes."

Yet it is not the new patients who are getting lost in the process. "My biggest issue is not the new patient; I have 60 minutes I can spend with a new patient. My issue is the patient who is on fourth-line treatment. I know this patient well. I know their daughter. I know the name of their dog. Now their disease is progressing, and I only have 20 minutes [with an established patient] to think about a clinical trial. Those are the patients we are losing, because they are not discussed in multidisciplinary conferences. They are silent in our systems. No pathologist saw that latest CT scan to tell me that I should order a certain molecular test. This is the problem we need to figure out. How do we best treat patients along the continuum of care? Genomic testing is fluid, and clinicians need to be able to adapt to that fluidity."

A participant from the community oncology setting shared that they conduct weekly screening of all patients for clinical trial eligibility. They also prescreen patients 24 hours before they come to clinic to make sure nothing was missed. This cancer program uses a clinical trials software scrubber that integrates with its EHR and alerts physicians prior to the visit that the patient is eligible for a clinical trial(s). The research team educates clinicians regularly about open clinical trials, embedding research staff at each clinic location to talk to and receive consent from patients while they are in clinic. "We focus our efforts around next-generation sequencing and immunotherapy, especially for patients who are on Medicare (dis)Advantage plans, because those payers are not interested in paying for that technology, and clinical trials are a wonderful way to get those patient access to cutting-edge therapies. Is it a lot of work? You bet. The people we employ to scrub our patients [ie, ensure that insurance claims for a patient are without mistakes that would lead to coverage denial]—

"I see 20 patients in clinic daily. I have 20 minutes with a patient to tell them, 'You have stage 4 disease, and you are going to die from this. I am going to fight to make you live as long as you can with this disease. We are going to transform this disease into a chronic illness. These are your treatment options. What's it going to be?' And now I'm going to introduce a clinical trial? The reality is that would make me late for my next 6 patients."

that's uncompensated work. But it is what we must do to provide the best clinical care to our patients."

One participant asked what was required on the front end to get patient data into the EHR so that it is able to be scrubbed. "One of the challenges we have when we try and pull reports out of the EHR is that every physician puts their staging in the EHR differently. Have you had to standardize physician practices? Or is that something your research team is helping with?"

The community provider responded, "Our physicians are busy providing care, so the clinical research staff cleans up the data on the back end. They put data where it should go [in the EHR] so that it is more identifiable and easier to locate. I'm not going to put that burden on the physicians; that won't go over well."

This solution is not without its drawbacks, with 1 participant sharing an inability to use scrubbing software due to red tape. "Ultimately, these solutions also need to work from an IT perspective, from a HIPAA perspective, and from a leadership perspective. Personally, I think these scrubbing technologies are fabulous. They are plug and play IT platforms that log into your EHR and quickly analyze your patient data—by physician, by day, by whatever parameters you establish—to assess eligibility for clinical trials. Fabulous. The latest reason my organization has given for saying, 'No,' is because it does not want the scrubbing platform to be oncology specific. Our organization does research in neurosciences and cardiology, etc. And if we spend that kind of money, our organization wants a platform that will look at all clinical trials."

Provider Education

One participant commented that more and more drugs are being used in the adjuvant and neoadjuvant setting, making screening even more important in both the oncology world and the community health care setting, which will require education and connection with providers in primary care, internal medicine, general practice, and medical specialties.

A provider in the room agreed. "Cancer screening does originate outside of oncology most of the time. My program brings in our primary care colleagues and educates them about NGS testing—why it is so important for patients to get this type of testing. This type of clinician-to-clinician education is especially critical, because screening rates have not yet bounced back to pre-COVID-19 rates."

Another provider pointed out that the education gap in precision medicine shares similarities with the challenge faced 10 years ago when immunotherapy was new. Smiliar to the strategy ACCC championed for the successful adoption of immunotherapy, this provider advocated for the need to bring together multidisciplinary teams to educate patients about th e importance of molecular and genomic testing. "And my question to you all today is this: what role does the patient play? When oncology was overwhelmed by having to educate primary care and urgent care about the mechanisms of immunotherapy, we empowered our patients with tools like the ACCC immunotherapy wallet card to help with this education. Wouldn't it be great if a patient came to us and said, 'I have lung cancer, and you should be testing me for EGFR'? Any thoughts on that?"

The discussion then turned to new technology like multi-cancer early detection. "About 70% of cancer incidences have no routine

screening today. If, and when, screenings like multi-cancer early detection become [a] standard of care, clinicians may find those incidences of cancer that we are not even looking for today." This type of screening may help identify certain types of colon, breast, prostate, ovarian, and cervical cancers much earlier in the disease trajectory when they are easier to treat.

Patient Education

A participant wanted to know how providers are handling patient education about molecular and genomic testing. "A lot of people are afraid to get this type of testing. Patients want to know what is being done with that information. Coming from the pharma side, I see the benefit: we find another marker, and we can ultimately match a drug that can help. But many patients have different biases, and we need to get education out."

There was consensus about the importance of patient education, particularly for underserved patients and individuals other than White patients. One provider shared that it was rare for her to see a patient who does not want to have molecular testing done on their tumor. "Knowledge is power, and patients recognize that. I get much more pushback when we're talking about germline testing and genetic predispositions—not always how it will affect the patient who already has cancer but how it may impact the daughter who is sitting next to them in the clinic."

And germline testing comes with its own barriers. "Patients should not be punished for being diagnosed with cancer. But if you look at payer policies, all of them say that a patient can't get germline testing unless they've first had some kind of genetic counseling."

Most agreed that patients are more accepting of genetic and genomic testing now than they were 5, or even 10, years ago. "I have seen an evolution. It used to be that patients were worried about losing their insurance after germline testing. Now legislation protects against loss of coverage—although life insurance and long-term care disability are not protected. People are still worried about [with whom] providers will share this information…Patients are worried about the government, their health insurance company, and even their employers having access to this information. These concerns are not to be taken lightly."

Discussion around patient education included shared language and a 2016 [white paper](#) on consistent language around molecular and biomarker testing from the LUNGevity Foundation. Words matter. "Is it a biomarker? Is it a mutation? Is it a variant?…The genomics field has moved away from some of the terms. For example, we're not supposed to say mutation anymore, but we've come to understand [that is the term] patients want us to use. They understand and accept the term mutation. Shouldn't we ask patients first about the language they prefer?" There was consensus that shared language helps and allows everyone—patients, caregivers, and providers—to understand molecular testing and ways that it may impact treatment decisions. Tools like ACCC's [biomarker lexicon](#) can help guide these discussions.

One participant shared that he works for [CancerPath](#), a new start-up aimed at educating patients about biomarker testing so that they can talk to their physicians about getting tested. "We're trying to address 2 concerns. The first is to stop people turning to unreliable sources on the internet to get their health information. And the second is to ensure that patients receive the testing that can inform—and hopefully improve—their treatment decisions. We have the patient empowerment and education piece down. What we're trying to figure out is how not to antagonize physicians. How can we work with physicians and not seem like adversaries?"

A provider in the audience admitted that a culture shift may be needed on both ends. "Physicians and patients must understand and accept that physicians don't know everything."

Many providers in the room agreed with that statement. "I am just the doctor. And this is just another patient in my day. But to the patient, this is their life. We [physicians] need to recognize that patients are fighting for every week, every month, every year. We [physicians] need to humble ourselves and remember that we are here to serve the patient." Another participant shared, "For an oncologist who treats every kind of cancer, it has become nearly impossible to stay current with every single practice-changing publication. But there is nobody more motivated to learn about their disease than the person who is affected by it. As much as I am a very compassionate oncologist, I am not personally affected by the disease in the same way my patients are. I want to empower that motivation. Give my patients a playbook. There are many 1- to 2-physician practices that are drowning—financially and from patient volume—and 1 way we can help these physicians is by empowering patients with knowledge and education."

A participant asked the physicians in the room how they react when a patient comes in asking for a specific test or even a specific therapy.

"It's a 2-edged sword. Because sometimes what the patient wants is completely ill-advised. But I am a huge proponent of education, education, education. I would much rather have that problem and discuss with a patient why that test or that therapy is not appropriate for them than miss a conversation with a patient that prompts me to look or think about treatment differently."

And what about when patients agree to molecular testing and do not see a benefit? "We have a trial right now looking at how providing a patient education video about tumor genomic testing at the time of ordering translates to patient outcomes. Our prior data suggest that there is a drop off in trust in their provider if patients have genomic testing, and it does not result in a therapeutic change. This knowledge is important, because it can help improve patient education and patient-provider communication."

One provider stated that she has experienced exactly this scenario. "I go into a room, and I'm introducing the concept of molecular testing of the tumor. I'm excited about investigating their tumor tissue, because I could find something truly life changing. The reality is that this patient is in their fourth-line therapy, and now I have to throw out the big net of NGS testing. But first I must explain that big net to the patient. And then at their next visit, I tell them that I have found nothing. That really weighs on the patient-provider relationship. The patient asks, with all of the technology they see on TV and this talk about personalized medicine, why I don't have something to offer them?"

Other providers shared similar experiences. "I've stopped testing everybody, because I was so dismayed by the lack of results that were actionable, by the promise that I come to the bedside with and, ultimately, just disappoint my patient."

One provider started framing patient discussions differently. She tells patients that whereas targeted therapies are becoming more common, and cancer treatments are becoming more individualized, only a very small number of patients have these mutations. "My patients hear [that] from the get-go and are not automatically thinking they will have 1 of these actionable mutations. I tell my patients that if they have 1 of these mutations, there are really good treatments out there, and that's why I am testing. It's important to frame the discussion, but it takes longer than 20 minutes. While patients will hear what they want to when they're in the room, patient education is so important."

Even with this low incidence, many in the room expressed support of broad testing for all patients with cancer. "Payers ask, 'Do you really need a 360-panel test?' And the answer is, 'Yes, we do if you want to ensure [that] patients with low incidence mutations get the best possible care.' Ultimately, we need to get to the understanding that every patient should have the broadest test possible. But someone still must pay for that kind of testing. And so, like we've shared previously, cost is a huge barrier."

Yet the promise of molecular testing is clear. "We have enough targeted drugs that are tumor agnostic that we should push forward with making sure that genomic testing is offered to every cancer patient," noted a participant. "The collective knowledge that comes from that testing is infinite." ◙

References

1. Marino MJ. Trending now in cancer care part I. *Oncol Issues*. 2023;38(4):11-30. doi:10.3928/25731777-20230710-04

2. Parker M, Ike C. Machine learning and predictive analytics solution transforms infusion center operations. *Oncol Issues*. 2023; 38(4):39-47. doi:10.3928/25731777-20230710-06

3. Patton A. Data analytics + business intelligence = operations insights. *Oncol Issues*. 2022; 37(4):36-41. doi:10.1080/10463356.2022.2083816

4. Artificial intelligence. Britannica. Updated February 10, 2023. Accessed March 2, 2023. https://www.britannica.com/technology/artificial-intelligence

5. The AI effect: how artificial intelligence is making health care more human. MIT Technology Review, GE Healthcare. Accessed March 2, 2023. https://www.technologyreview.com/hub/ai-effect/

6. Addressing health worker burnout: the U.S. Surgeon General's advisory on building a thriving health workforce. US Department of Health and Human Services. 2022. Accessed September 6, 2023. https://www.hhs.gov/sites/default/files/health-worker-wellbeing-advisory.pdf

7. Blau S. Technology solutions in practice. *Oncol Issues*. 2022;37(4):2. doi:10.1080/10463356.2022.2090191

8. Optimizing cancer care delivery in 2022: part 2. Association of Community Cancer Centers. May 3, 2022. Accessed August 9, 2023. https://www.accc-cancer.org/acccbuzz/blog-post-template/accc-buzz/2022/05/03/optimizing-cancer-care-delivery-in-2022-part-2

9. Technological strategies to improve health equity. Association of Community Cancer Centers. September 27, 2022. Accessed August 9, 2023. https://www.accc-cancer.org/acccbuzz/blog-post-template/accc-buzz/2022/09/27/technological-strategies-to-improve-health-equity

10. US Department of Health and Human Services. Program Solicitation PHS 2021-1. Small Business Innovation Research Program. October 26, 2020. Accessed August 9, 2023. https://sbir.cancer.gov/small-business-funding/contracts/past/program-solicitation-public-health-service-2021.pdf

11. Digital solutions connect resources to patients at the right time. Association of Community Cancer Centers blog. September 15, 2022. Accessed August 9, 2023. https://www.accc-cancer.org/acccbuzz/blog-post-template/accc-buzz/2022/09/15/digital-solutions-connect-resources-to-patients-at-the-right-time

12. Unger JM, Cook E, Tai E, Bleyer A. The role of clinical trial participation in cancer research: barriers, evidence, and strategies. Am Soc Clin Oncol Educ Book. 2016;35:185-198. doi:10.1200/EDBK_156686

13. Unger JM, Fleury M. Nationally representative estimates of the participation of cancer patients in clinical research studies according to the commission on cancer. *J Clin Oncol*. 2021;39(suppl 28):74. doi:10.1200/JCO.2020.39.28_suppl.74

14. Winn RJ. Obstacles to the accrual of patients to clinical trials in the community setting. *Semin Oncol*. 1994;21(4; suppl 7):112-117.

15. Oyer RA, Hurley P, Boehmer J, et al. Increasing racial and ethnic diversity in cancer clinical trials: an American Society of Clinical Oncology and Association of Community Cancer Centers joint research statement. *J Clin Oncol*. 2022;40(19):2163-2171. doi:10.1200/JCO.22.00754

16. Linzer M, Griffiths EP, Feldman, MD. Responding to the great resignation: detoxify and rebuild the culture. *J Gen Intern Med*. 2022;37(16):4276-4277. doi:10.1007/s11606-022-07703-1

17. Gabriel B. Paving the way for APPs in clinical research. *Oncol Issues*. 2020;35(6):14-21. Association of Community Cancer Centers. Accessed September 6, 2023. https://www.accc-cancer.org/docs/documents/oncology-issues/articles/2020/nd20/nd20-paving-the-way-for-apps-in-clinical-research.pdf

18. Braun-Inglis C, Boehmer LM, Zitella LJ, et al. Role of oncology advanced practitioners to enhance clinical research. *J Adv Pract Oncol*. 2022;13(2):107-119. doi:10.6004/jadpro.2022.13.2.2

19. Ulrich CM, Zhou Q, Ratcliffe SJ, Ye L, Grady C, Watkins-Bruner D. Nurse practitioners' attitudes about cancer clinical trials and willingness to recommend research participation. *Contemp Clin Trials*. 2012:33(1):76-84. doi:10.1016/j.cct.2011.09.005

20. Spira A, Gandhi M, Sullivan M, Friedman C. Increasing clinical trial accrual through the implementation of a clinical trials navigator. *Oncol Issues*. 2023;38(4):5-10. doi:10.3928/25731777-20230710-03

21. Thai AA, Solomon BJ, Sequist LV, Gainor JF, Heist RS. Lung cancer. *Lancet*. 2021;398(10299):535-554. doi:10.1016/S0140-6736(21)00312-3

22. Robert NJ, Espirito JL, Chen L, et al. Biomarker testing and tissue journey among patients with metastatic non-small cell lung cancer receiving first-line therapy in The US Oncology Network. *Lung Cancer*. 2022;166:197-204. doi:10.1016/j.lungcan.2022.03.004

Development of a
Cancer Center Support Group
Training Program

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The psychosocial impact of cancer and its treatment is well documented in the literature. The offering and availability of support groups within a cancer program can help improve psychosocial outcomes (eg, well-being and coping) for patients with cancer and their family members. Support groups provide a multi-faceted framework within which there is realistic acknowledgement of the biopsychosocial effects of illness, with substantial improvements posited to patients' quality of life.[1,2] Such support groups include trained facilitators to foster a compassionate environment through facilitation of supportive discussions and equip the group members with appropriate cancer-related education. The mutual sharing that occurs within this peer support culture can enhance feelings of empowerment by reducing feelings of alienation and helplessness.[2] By extension, holding the space for others' lived experiences can allow patients increased acceptance of their own existential ambivalence, rather than avoiding, denying, or framing their situation differently than it is. Collectively, this multidetermined approach to psychosocial treatment can help patients develop a more motivated, participatory, and proactive attitude toward their illness and, simultaneously, feel supported throughout their cancer experience.[1]

Despite strong evidence of the benefits that support groups hold for patients with cancer and their family members, several barriers can prevent cancer programs from implementing these groups. Barriers can include:

- A lack of organization or structure in developing a support group
- Lack of training for those interested in support group facilitation
- Uncertainty about how to begin development of a support group
- Time commitment and the resources to effectively market and/or advertise these groups.

This article describes the project our cancer center undertook to address these barriers, increase the number of support groups offered, and improve patient accessibility to support groups.

> In January 2021, the proposal was accepted by our Cancer Committee. A multidisciplinary workgroup was then established to begin the process of developing a cancer center support group training program to increase accessibility and offerings.

In the Beginning

Due to the COVID-19 pandemic, all support groups within our cancer center (Siteman Cancer Center in St Louis, Missouri) were paused beginning in March 2020. Prior to the pandemic, our cancer center hosted 5 support groups; most groups were cancer-specific, including breast cancer, head and neck cancers, gynecological cancers, prostate cancer, and a group for children whose parent and/or caregiver has cancer. Due to the limited support group options, oftentimes patients were referred to other community-based organizations for support groups. In addition, although some support groups had been in place for 18 years with good attendance, there was little oversight, standards, consistency, training, or administrative support for groups or group facilitators. The cancer center recognized 3 distinct problems with its support groups:

1. Lack of standardized support group facilitator training and standards
2. Limited support group offerings
3. No centralized tracking system for patient attendance, interest in support groups, or staff hours.

Also in 2020, new cancer survivorship guidelines were established with publication of the American College of Surgeons' Optimal

> While therapy groups and support groups both offer a supportive environment to improve coping skills, the goal of group therapy is treatment of mental health conditions and/or facilitation of behavior change, while the goal of support groups is to share personal experiences and build support networks.

Resources for Cancer Care,[3] guidelines which were then incorporated into Commission on Cancer (CoC) accreditation requirements. In response, our cancer center shifted focus from survivorship care plans to development of survivorship programs and services.

CoC Standard 4.8 requires survivorship programs to select 3 services to focus on annually, support groups being 1 of the 13 options. Additionally, CoC Standard 7.4 requires cancer centers' cancer committees to establish a program goal each year. In response to these standards, our cancer center's survivorship program proposed a detailed SMART (specific, measurable, achievable, relevant, and time-bound) goal to develop a standardized support group training program. This goal served as a way to meet standard requirements of CoC accreditation, as well as address the unique identified needs of our cancer center. The primary goals of this project were 3-fold:

1. Development and implementation of a support group facilitation training manual and training competencies
2. Development of policies and procedures for cancer center support groups
3. Establishment of a support group tracking process and database.

In January 2021, the proposal was accepted by our Cancer Committee. A multidisciplinary workgroup was then established to begin the process of developing a cancer center support group training program to increase accessibility and offerings.

Our Workgroup and Process

In 2020, survivorship and psychology program managers partnered to create a multidisciplinary workgroup consisting of 3 clinical psychologists, a social worker, a registered nurse, and a graduate student, all of whom had expertise in oncology. The workgroup's 1-hour meetings were extensively collaborative and occurred biweekly for 11 months. By early 2021, the workgroup developed a robust draft of the support group facilitator training manual.

The project was then expanded to create a support group facilitator training program, including a supplemental support group facilitator tool kit (described in more detail later) for individuals interested in facilitator training and eventual facilitation of support groups at our cancer center. These resources would help support group facilitators as they developed and implemented new support

groups and provide much-needed tools and standardization for support groups already in existence.

Early workgroup meetings focused on defining the key terminology of support groups. First and foremost, the workgroup sought to create a definition of support groups, differentiating these groups from therapy groups based on functional differences. Within our cancer center, the Psychology Service provides both individual and group therapy; thus, the workgroup sought to establish a clear delineation between these groups and support groups. Ultimately, the workgroup defined support groups as meetings of members who are experiencing a similar disease or condition and who have a desire for further support from and connection to those who understand their difficulties. Furthermore, support groups, led by trained staff, provide a safe, inclusive environment where participants can receive emotional support, education, and information. Support groups are not intended to provide mental health services, nor are they meant to be solely social.

In contrast, the workgroup defined group therapy as psychotherapy facilitated in a group setting and led by a mental health clinician with the goal of creating psychological change through evidence-based interventions. While therapy groups and support groups both offer a supportive environment to improve coping skills, the goal of group therapy is treatment of mental health conditions and/or facilitation of behavior change, while the goal of support groups is to share personal experiences and build support networks. Group structure often differs as well, with therapy groups generally requiring more commitment from members to attend the group for a prescribed time span or frequency.

Next, the workgroup defined facilitator criteria and the overall structure of support groups. Facilitators must be cancer center staff and have a co-facilitator who is either another cancer center staff member or a volunteer. Facilitators are required to complete the online training, including the posttest, prior to starting a support group at our cancer center. In addition, each facilitator is asked to commit to 1 year of facilitation, maintain a list of participants, and track attendance. Support groups require open registration, allowing participants to join and participate as often as they wish, and support group facilitators determine support group length (eg, 1 hour or 90 minutes) and frequency of meeting (eg, weekly or monthly).

The workgroup then defined the main components of the support group facilitator training project, dividing them into 3 distinct phases:

1. Development of a facilitator training manual and toolkit (the contents of which are described later in this article)
2. Creation of an online training module
3. Integration of the module into our health care system's learning management system (LMS).

Phase 1. Support Group Facilitator Training Manual and Tool Kit

The first phase consisted of identifying topics and concepts to be included in the support group facilitator training manual. The workgroup reviewed literature and online documents to guide these decisions. Various members of the workgroup held virtual benchmarking meetings with similar academic institutions to discuss online training structures, peer-led groups, and facilitator roles and administrative support.

Additionally, the workgroup reviewed an external tool kit that contained information regarding co-facilitator training and skills. The workgroup added specific facilitator skills on which to focus, including communication skills, managing disruptions, and emergency procedures.

Once the workgroup identified key topics for the support group facilitator training manual, each member was assigned to write a section of the manual, which was then reviewed and edited by the workgroup in its biweekly meetings. After editing by the workgroup, the document was sent to the cancer center's marketing and creative services team to convert into a manual with the cancer center's branding and images that reflect the diversity of our cancer center patient population. Multiple revisions were made in collaboration between the workgroup and marketing and creative services.

During this first phase, the workgroup also identified tool kit content, which was pulled from the support group facilitator training manual. Throughout the project, the workgroup made additions to this tool kit. The tool kit supplements training with quick start materials and resources to support group facilitation.

Phase 2. Develop Online Facilitator Training Module Virtual Presentation

Next, the workgroup created an online facilitator training module, which consists of the support group facilitator training manual, a virtual presentation, and a posttest. The online training module complements the support group facilitator training manual and ensures all facilitators receive standardized training in specific areas, including cancer center ground rules, managing conflict and difficult behaviors, and addressing emergency procedures.

Created as a supplement to the support group facilitator training, the virtual presentation module provides visual and audio instruction of the material. The workgroup selected specific topics from the support group facilitator training manual to highlight during the virtual presentation module, and workgroup members divided presentation script writing into sections and completed them independently. Review of material and edits were done collaboratively in biweekly workgroup meetings. The presentation was created in PowerPoint and recorded with scripted audio so that all individuals receiving the support group facilitator training would obtain standardized instruction. Prior to recording, the media services department provided recommendations on the recording process as well as a microphone to record audio of the presentation. Presentation components were also sent to marketing and creative services for review; they made no changes.

The workgroup developed a posttest to be completed after the virtual presentation to reinforce the primary concepts of the training and correct any misunderstandings of the content.

Phase 3. Learn at Work Course

Once the online training materials were completed, the course was submitted to our Information Technology Office of Change Management for learning and development specialists to build the course. (Initially, the survivorship program manager was going to build the class; however, the workgroup determined that process to be cost and time prohibitive.) Our LMS is an online software application used for

> ...the online module covers topics such as training objectives, facilitator and co-facilitator skills, roles and expectations, meeting logistics, and what to do in case of emergency. Communication skills, ground rules, and common challenges and issues are also presented.

training and tracking of educational content. The LMS is an established training platform that is currently used to track yearly competencies for all staff. The decision was made to house this course in our LMS so that training could be completed on demand and without requiring a trainer (additional staff) in real time. Using the LMS also allowed for tracking of completion of and scores on the posttest.

To reinforce learning and to be consistent with our institution's training platform and strategies, the workgroup also created support group training videos. These support group scenario videos were scripted by the workgroup. Scenarios included examples of challenges and skills from the support group facilitator training manual and online training module. Local professional actors volunteered to participate in filming. An unexpected surge in COVID-19 infections delayed production of the training scenarios by 3 months. The final component of the online training, 6 videos, were taped on a Saturday over 2 hours.

Tools Developed

The workgroup created 8 tools to assist in the training and ongoing support of group facilitators.

Support Group Facilitator Training Manual

This comprehensive 20-page guide includes detailed information on meeting preparation, how to open and close a meeting, facilitator roles, facilitator skills, co-facilitation, confidentiality, bereavement issues, safety issues, patient resources, and considerations for virtual groups. This manual is intended to be used first as a training tool and then as a reference and guide for all support group facilitators throughout the course of their support group facilitation.

Support Group Facilitator Quick Start Guide

As a supplement to the support group facilitator training manual, a 1-page "quick start" guide (Figure 1) provides "how-to's" for facilitators to use during meetings. The supplement also includes helpful emergency numbers and contact information for nonemergency support.

Online Facilitator Training Module

The online facilitator training module (see Figure 2) for training module objectives) is a PowerPoint that consists of 18 slides supporting the main points of the manual as a visual aid to be used in

Figure 1. Quick Start Guide

BEFORE THE MEETING	AFTER THE MEETING
• Review resources, including facilitator training manual	• Provide a 5-minute notice that the meeting is wrapping up to allow for final remarks
• Review potential topics	• Ask for future topic ideas
• Contact guest speaker(s)	• Remind participants of the next meeting
• Ensure you are comfortable with Zoom or other virtual meeting applications	• Encourage attendees to invite others
• Prepare yourself mentally and emotionally	• Thank everyone for attending
• Relax: Take 3 deep breaths, meditate, listen to music	• Encourage feedback by using the chat feature or Post-It notes
	• Review notes and reflect on how the meeting went
DURING THE MEETING	**HELPFUL NUMBERS**
• Open on time	• 24-Hour Suicide Crisis Hotline: (phone number)
• Greet attendees or use a virtual waiting room to admit them and encourage them to turn on their cameras	• To Report Elder Abuse and/or Neglect: — Illnois: (phone number) — Missouri: (phone number)
• Make introductions (self, guest speaker, participants)	• To Report Child Abuse and/or Neglect: — Illnois: (phone number) — Missouri: (phone number)
• Establish or review ground rules: confidentiality, courtesy and respect, listen to others and avoid interrupting and side conversations, share appropriately, and do not diagnose or recommend treatment	• Behavioral Health Response — Missouri only: (phone number)
• Take notes	• Nonemergency Support: — Siteman Psychology Service: (phone number)
• Guide the discussion using techniques learned in training	

conjunction with the support group facilitator training manual. Like the manual, the online module covers topics such as training objectives, facilitator and co-facilitator skills, roles and expectations, meeting logistics, and what to do in case of emergency. Communication skills, ground rules, and common challenges and issues are also presented. The slides are accompanied by scripted voiceover with open captioning and used in an online training format for group facilitators. The online module is intended to reinforce learning from the manual.

Support Group Facilitator Training Module Scenario Videos

Six 1- to 2-minute videos feature mock support group meetings. These videos feature actors portraying support group attendees and facilitators in different scenarios that could be expected to occur during support group meetings. In each scene, actors then illustrate learned skills, including setting boundaries, problem-solving, effective listening, and possible solutions for each scenario.

Support Group Facilitator Training Posttest

At completion of the online facilitator training module and scenario videos, a posttest is given to assess participant understanding. The test is comprised of 16 multiple-choice questions. A score of 80% is required for an individual to progress to the point of facilitating a support group. If participants do not pass, they are allowed to retake the test until they receive a passing score.

Figure 2. Training Objectives

By the end of this training, you will be able to identify:

- The difference between a support group and a therapy group

- The benefits of a support group

- The purpose of ground rules

- Facilitator skills, including de-escalation, communication, and problem solving

- How to prepare for a meeting

- Health boundary setting in a group

- Advantages of co-facilitation

- How to handle a crisis situation

- Ways to keep a virtual (Zoom) meeting safe and secure.

Zoom Resource Guide

As an adjunct to the support group facilitator training manual, a 1-page (front and back) guide to Zoom resources is provided to help with the facilitation of virtual support groups. This resource guide provides detailed instructions on how to use Zoom, considerations for facilitating a virtual support group, and how to assist group members in using the platform.

General Guidelines

In alignment with our cancer center operations, the workgroup created this document to describe standard policy and procedures for support groups.

Supporting Documents

Additional tool kit contents include a speaker request letter, a tool to track group attendance, a template for creating a support group flyer, and a list of potential group topics to help facilitators organize and plan the support group.

Discussion

Support groups provide a pathway for cancer centers to offer interactions between patients with cancer and their families that can help decrease isolation, fear, and anxiety while increasing connections with others who are facing like circumstances.[4] Based on this and other evidence in the literature, we expect that support groups help improve care.

While we recognize support groups offer several benefits, we also recognize and encountered barriers that may hinder effective development and implementation. Accordingly, this project sought to address the barriers cancer centers can experience in the creation of support groups for patients with cancer and their loved ones. By providing structure and guidance, our aim was 3-fold:

1. To increase the number of support groups our cancer center offered
2. To provide an easy to use, standardized system to train facilitators
3. Ultimately, to improve psychosocial outcomes for those impacted by cancer.

Additionally, a standardized support group program can provide training and standard of care in the facilitation of cancer center support groups. It is our hope that this project can help other organizations develop and implement a similar training program at their institutions.

Lessons Learned

While establishing a dedicated multidisciplinary workgroup was essential to the completion of this project, including a more diverse group of stakeholders, such as oncologists, patients, and preexisting support group facilitators, could have been beneficial.

We also realized the need to include administrative team members during various stages of the project. It may be worthwhile to consider other teams like IT and marketing and creative services earlier in the planning process for future projects. We experienced unexpected delays when consulting with departments and teams outside of the workgroup. For example, the cancer center's marketing and creative services team was consulted throughout the project for branding, mock-ups, and filming; it would have been beneficial to include this team at the beginning of the project to better understand their processes and timelines and their impact on completion time frames.

We recognized that there is great benefit to having project management knowledge and skills (eg, navigating scope, timelines, and risk management) for a project of this size and with multiple stakeholders. None of our workgroup members had prior experience as a trained project manager. Furthermore, while the scope of the project was expanded from creating a facilitator training manual to developing a complete training program, our workgroup felt the final product was worth the additional time spent.

Although the COVID-19 pandemic occurred at the launch of this project, it did not prevent the workgroup from moving forward. It did, however, contribute to a change in scope due to a lack of in-person meetings. Initially, the project was to create a manual to be used for face-to-face training led by a cancer center staff member. An unexpected result of the pandemic was the rapid adoption of virtual meetings and trainings. This created an opportunity for the workgroup to rethink the training format. In addition to the manual, an entire training program was developed, which ultimately resulted in a more seamless method to train and track facilitators. This development also eliminated the need for current staff to devote time to conduct training. We anticipate that this model will improve

> Support groups provide a pathway for cancer centers to offer interactions between patients with cancer and their families that can help decrease isolation, fear, and anxiety while increasing connections with others who are facing like circumstances.[4]

ease of adoption across the 6 satellite locations operated by our cancer center.

Throughout our project, communication was key. Over the course of the project, several workgroup members managed documents simultaneously. Early adoption of a shared communication tool allowed multiple individuals to make edits to documents and ensured that all members had accurate real-time access to tool kit components. The use of cloud-based document sharing had a positive impact on workgroup efficiency, communication, and overall productivity.

Next Steps

This project was initiated with the objective of increasing the number of support groups at the cancer center, therefore meeting more patients' needs. With the new training program in place, we have identified next steps to ensure we have met our initial goals and continue to expand.

First, communication and dissemination of the new program is critical. Sharing information about the program with the many oncology practices within our cancer center will increase awareness of both program resources and the need for facilitators. Regular communication will increase use of the facilitator training and ultimately result in the development of the correct number and type of support groups to fit the needs of our patients. Once this communication becomes a part of our culture, expanding support group training for other disciplines and departments could potentially benefit a much larger group of patients.

Next, a needs assessment project may further help in understanding the particular areas in which support groups may be most beneficial. This may include assessing patient interest based on cancer type, sequelae, and other topics of importance relating to cancer care. Additionally, a needs assessment can be used to gather logistical information, such as best time, location, and the frequency at which patients prefer to participate. Provider needs assessment may be used to explore interest in facilitating a support group. We will also monitor the number of support groups, with the expectation that this number increases in the first year.

Finally, a formal process for receiving and evaluating facilitator trainees' feedback is needed. This evaluation will allow for the use of data to identify any challenges and inform decisions regarding facilitator needs. It will also allow for feedback regarding needed training program enhancements. ◼

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References

1. Cipolletta S, Simonato C, Faccio E. The effectiveness of psychoeducational support groups for women with breast cancer and their caregivers: a mixed methods study. *Front Psychol*. 2019;10:288. doi:10.3389/fpsyg.2019.00288.

2. Gottlieb BH, Wachala ED. Cancer support groups: a critical review of empirical studies. *Psychooncol*. 2007;16(5):379-400. doi:10.1002/pon.1078

3. American College of Surgeons. Optimal resources for cancer care: 2020 standards. Updated June 2023. Accessed July 26, 2023. https://accreditation.facs.org/accreditationdocuments/CoC/Standards/Optimal_Resources_for_Cancer_Care_Feb_2023.pdf

4. Montazeri A, Jarvandi S, Haghighat S. Anxiety and depression in breast cancer patients before and after participation in a cancer support group. *Patient Educ Couns*. 2001;45(3):195-198. doi:10.1016/s0738-3991(01)00121-5

Pancreatic Cancer and Community Engagement

A Scoping Review of the Literature

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Pancreatic cancer is a burdensome disease with high morbidity and mortality. In 2023, 64,050 individuals are projected to be diagnosed with pancreatic cancer, and 50,550 people will die from the disease.[1] Clinicians must be able to address the clinical, supportive, and palliative needs of patients with pancreatic cancer. It is important that patients with pancreatic cancer are engaged in their care and that their voices are heard as they go through the management for their disease.[2] Engaging patients and community members in cancer research brings personal experiences and preferences to the attention of researchers who can then be more responsive to the needs of patients with pancreatic cancer.[3] To do so, researchers must employ community engagement, defined as the "process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of these people."[4,5]

Community engagement allows for patient participation in medical care and higher levels of trust between health care workers, researchers, and the communities they serve.[6] Community engagement has been found to help mitigate asymmetry (a lack of equality or equivalence) between patient and researchers.[6] The community engagement approach has been found to help foster people-powered, bidirectional, mutually beneficial efforts that inherently offset power differentials.[7] By bridging this gap, community-engaged research and interventions in clinical settings can encourage trusting relationships and lead to better health outcomes.[8] Furthermore, by showing genuine interest in what is important to patients as people rather than research subjects, these approaches can help overcome mistrust in the medical community and contribute to larger community health efforts.[9]

In the cancer setting, community engagement has been used to improve the quality of life in those with disease, reduce disparities in cancer incidence and outcomes, and allow patients to have their voices heard. Community-engaged programs have improved health-related quality of life and emotional-wellbeing of patients with cancer.[10] Engaging stakeholders in the development of community-engaged studies has helped guide research priorities,[11] establish research methods,[12] and improve the uptake of research findings.[13] Community engagement has been suggested as a way of reducing cancer disparities and was successfully implemented to increase the participation of

> **Inform is the lowest level of the spectrum and is defined as providing the public with balanced and objective information to assist them in understanding the problem, alternatives, opportunities and/or solution.**

minority patients in clinical trials.[14] Culturally sensitive partnerships between academic and community organizations have improved screening among individuals at risk for breast cancer.[15] For these reasons and many others, engaging patients with cancer in research efforts will make research more meaningful and responsive to the communities we hope to serve.

Despite the clear benefits of engaging patients with cancer in community-engaged research, there is a gap in knowledge particularly for patients with pancreatic cancer.[2,16] This scoping review aims to explore the community-engaged research that has been carried out in the setting of pancreatic cancer.

Methods
This scoping review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Extension for Scoping Reviews (PRISMA-ScR).[17] The use of scoping review methodology allowed us flexibility to include a variety of publications including commentaries and research studies.

Eligibility Criteria
We included articles that involved patients with pancreatic cancer and used or identified community engagement strategies in their research approach. We defined community-engaged research based on the definition, "a process of inclusive participation that supports mutual respect of values, strategies, and actions for the authentic partnership of people affiliated with or self-identified by geographic proximity, special interest, or similar situations to address issues

affecting the well-being of the community or focus."[10] There was no requirement regarding the type of study design for inclusion in this review.

Information Sources and Literature Search
We developed the search strategy in conjunction with a research librarian. We searched OVID Medline, Scopus, and Web of Science Core Collection using combinations of the following terms to identify relevant studies: pancreas*, neoplas*, tumor, cancer*, oncolog* metastas*, carcinoma*, adenocarcinoma*, communit*, consumer*, public*, engag*, based*, participat*, involve*, outreatch*, CENR*, CER*. There was no exclusion based on publication date. Only articles written in English were included due to the researchers' abilities. The search was conducted on September 7, 2022.

Selection of Sources of Evidence
Titles and abstracts were screened by 4 investigators; papers with majority agreement were read in full by 4 investigators. A senior author was available for disagreements. The research team used the internet platform "rayyan.ai/reviews" to screen and categorize the abstracts. This platform allows the categorization of each researcher to be blinded to the others.[18]

Data Extraction
The following information was extracted from the sources: Author(s), Title, Type of Paper, Year of Publication, Objective, and Main Findings. Each investigator independently reviewed the included papers to determine the level of community engagement. The spectrum of community engagement used was developed by Wieland et al in accordance with the International Association for Public Participation's Spectrum of Public Participation.[19] This strategy is consistent with that used by Wieland and colleagues. The research team met to discuss this categorization. Evidence that supported the level of community engagement assigned to each source was noted. Disagreements were resolved by discussion of the evidence, ultimately allowing for consensus to be reached by the entire team. Again, a senior author was available for disagreements.

Synthesis of Results
Common themes among sources were identified as the team met to discuss the included papers and perform data extraction. Subsequently, sources were summarized and grouped by theme as well as their level of community engagement.

Search Results
The search resulted in 1237 articles after removal of duplicates. Screening of abstracts excluded 1201 articles; 36 articles were read in full. Full-text screening excluded 21 additional articles. The remaining 15 articles met inclusion criteria. Our literature search and selection process are outlined in Figure 1.

Characteristics of Studies
Most of the papers in this study were descriptive studies using either survey (n = 2) or qualitative methods (n = 9). Two (n = 2)

> The authors found that trusting relationships between providers and patients is key to screening for pancreatic cancer.

studies used social media to study phenomena related to pancreatic cancer. Papers can also be characterized by subject matter. Two (n = 2) papers were commentaries on increasing participation in tissue biobanks using community-engaged methods. Seven (n = 7) of the included studies focused on shared decision-making between patients with pancreatic cancer and their providers. Two (n = 2) papers looked at patient preferences and perceptions of screening tests for pancreatic cancer. One (n = 1) study ascertained the research priorities of those individuals diagnosed with pancreatic cancer.

To understand the depth of community engagement published in the literature, each included article was given a ranking on the International Association for Public Participation's (IAP2) spectrum of public participation. This method of classifying research based on the spectrum of public participation is in line with previous scoping reviews on community engagement.[19] The spectrum, along with definitions, can be found in Figure 2. Each of the papers included in our review is categorized based on which of the 5 community engagement levels they exemplify and displayed in Table 1.

Level 1. Inform
Inform is the lowest level of the spectrum and is defined as providing the public with balanced and objective information to assist them in understanding the problem, alternatives, opportunities and/or solution. Five papers fell into this category. One paper in this category evaluated discussions around pancreatic cancer on Twitter to identify topics important to patients with pancreatic cancer and also health care providers.[20] Similarly, blogs and online cafes were studied to understand the relationship between the public's feelings about pancreatic cancer and the factors impacting those emotions.[21] One commentary paper explored the experience and research potential of the Pancreatic Cancer Action Network (PanCAN) registry, an online registry developed by researchers that patients with pancreatic cancer can participate in if they wish to share their health data.[16] Another group of researchers used surveys to determine whether the amount of information given about a screening test for pancreatic cancer reduces the acceptance of that test.[22] Finally, the inform group included a commentary on how to enhance Black patients participation in biobanking. This commentary included a call to action for stakeholders to build collaborative partnerships with faith and civic leaders in the community to solve the problem of Black patients being underrepresented in pancreatic cancer research.[23]

Figure 1. Literature Search and Selection Process

Identification

Records identified from:
Ovid MEDLINE (n = 410), Scopus
(n = 898), Web of Science (n = 570).

Total (N = 1878)

Records removed before screening:

Duplicate records removed

(n = 641)

Records after duplicates removed:

(n = 1237)

Screening

Abstracts screened:

(n = 1237)

Reports excluded: (n = 1201)

(Did not meet inclusion criteria,
abstract not available)

Full-text articles assessed
for eligibility:

(n = 36)

Reports excluded: (n = 21)

(Did not meet inclusion criteria,
full text unavailable)

Included

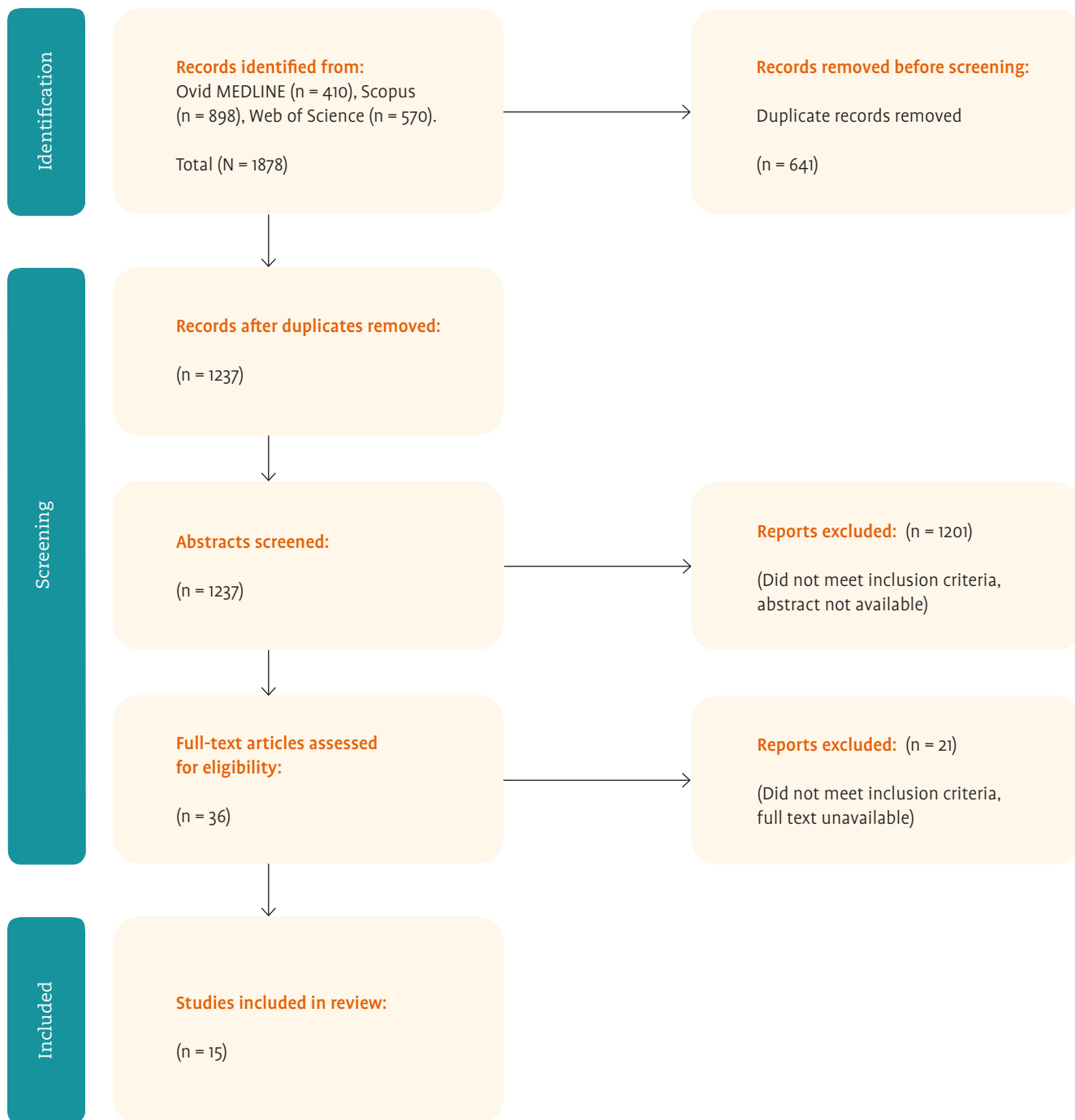Studies included in review:

(n = 15)

Figure 2. IAP2 Spectrum of Community Engagement[2]

This tool was designed to assist with the selection of the level of participation that defines the public's role in any public participation process. The spectrum is used internationally, and it is found in public participation plans around the world.

INCREASING IMPACT ON THE DECISION →

	INFORM	CONSULT	INVOLVE	COLLABORATE	EMPOWER
Public participation goal	To provide the public with balances and objective information to assist them in understanding the problem, alternatives, opportunities, and/or solutions.	To obtain public feedback on analysis, alternatives, and/or decisions. We will keep you informed, listen to, and acknowledge concerns and aspirations, and provide feedback on how.	To work directly with the public throughout the process to ensure that public concerns and aspirations are consistently understood and considered.	To partner with the public in each aspect of the decision, including the development of alternatives and the identification of the preferred solution.	To place final decision-making in the hands of the public.
Promise to the Public	We will keep you informed.	Public input influenced the decision.	We will work with you to ensure your concerns and aspirations are directly reflected in the alternatives developed and provide feedback on how public input influenced the decision.	We will look to you for advice and innovation in formulating solutions and incorporate your advice and recommendations into the decisions to the maximum extent possible.	We will implement what you decide.

IAP2=International Association for Public Participation. Figure used with permission from ©International Association for Public Participation.

(*Continued from page 53*)

Level 2. Consult

Consult is the next level of public participation and is defined as obtaining public feedback on analysis, alternatives, and/or decisions. Two papers fell into this category. The first was a survey-based study to assess patient experiences and preferences around a fast-track discharge program after surgery for pancreatic cancer.[24] The authors noted that almost half of the patients perceived they had not been involved enough in their care or discharge planning. The second study in this category was an article written to study and address disparities in pancreatic cancer research, specifically the challenge of recruiting minority individuals to participate in biobanks.[25] The authors indicated they worked with the Pancreatic Cancer Action Network to involve pancreatic cancer survivors and advocates on their community advisory board.

Level 3. Involve

Involve is the next level of public participation. It is defined as working directly with the public throughout the process to ensure

that public concerns and aspirations are consistently understood and considered. Six papers fell into this category. All 6 were qualitative studies with a common theme of identifying needs and examining perspectives of patients with pancreatic cancer. Three studies focused on shared decision-making. In the first study, older patients with pancreatic cancer were interviewed about their preferences around shared decision-making and communication.[26] Patients preferred decision-making to be divided into more sessions to build trust in their relationship with the oncologist. The authors suggest these findings should be implemented to improve the training of providers. A similar study used qualitative methods to explore patients with pancreatic cancer preferences on shared decision-making and treatment.[27] Patients were found to rely more on physician guidance initially whereas in the latter stages of disease, patients wanted to have more control over their health decisions. The third study on shared decision-making sought to identify barriers faced by patients with pancreatic cancer.[28] Patients often felt pressured into choosing surgery, confused when clinical opinions differed, and hopeless about the likelihood of survival.

Table 1. Studies Exhibiting Community Engagement Principles and Their Objectives

AUTHOR (YEAR)	TITLE	TYPE OF PAPER	OBJECTIVE	LEVEL OF COMMUNITY ENGAGEMENT
Behar-Horenstein et al (2020)23	Enhancing African American Participation in Biospecimens: A Case in Point for Pancreatic Cancer	Commentary	Survey biobanks and identify disparities in pancreatic biospecimens, provide explanations for disparities, and suggest ways to increase African American participation in organ and biospecimen donation.	Inform
Domenighetti et al (2000)22	Does Provision of an Evidence-Based Information Change Public Willingness to Accept Screening Tests?	Randomized, survey-based study	Investigate the willingness of the general population to undergo a screening test for pancreatic cancer based on the quality and the extent of the information provided.	Inform
Grewal et al (2022)20	Twitter Conversations About Pancreatic Cancer by Health Care Providers and the General Public: Thematic Analysis	Thematic analysis	Evaluate the content of discussions around pancreatic cancer on Twitter and identify subtopics of greatest interest to health care providers and the general public.	Inform
Gupta et al (2021)16	Leveraging Patient Reported Outcomes (PROs) in Patients with Pancreatic Cancer: The Pancreatic Cancer Action Network (PanCAN) Online Patient Registry Experience	Retrospective study	Describe the creation, user experience, and research potential of the PanCAN Registry.	Inform
Park et al (2020)21	Understanding the Public's Emotions about Cancer: Analysis of Social Media Data	Retrospective study	Explore the relationship between the public's emotions about pancreatic cancer and factors affecting emotions using social media.	Inform
Larnebratt et al (2018)24	Information is the Key to Successful Participation for Patients Receiving Surgery for Upper Gastrointestinal Cancer	Cohort study	Identify and explore patient participation among patients who had surgery for liver, bile duct, or pancreatic cancer and followed a fast-track program.	Consult
Permuth et al (2021)25	The Florida Pancreas Collaborative Next-Generation Biobank: Infrastructure to Reduce Disparities and Improve Survival for a Diverse Cohort of Patients with Pancreatic Cancer	Commentary	Study and address pancreatic cancer disparities by building a robust biobank containing viable tissues, biofluids, images, and data with a racially/ethnically diverse cohort of Floridians with pancreatic cancer.	Consult
Geessink et al (2016)26	Key Elements of Optimal Treatment Decision-Making for Surgeons and Older Patients with Colorectal or Pancreatic Cancer: A Qualitative Study	Qualitative cohort study	Identify key elements of optimal treatment decision-making for surgeons and older patients with colorectal or pancreatic cancer.	Involve

(Table continued on next page)

Table 1. (*Continued*) Studies Exhibiting Community Engagement Principles and Their Objectives				
AUTHOR (YEAR)	TITLE	TYPE OF PAPER	OBJECTIVE	LEVEL OF COMMUNITY ENGAGEMENT
Guo et al (2021)30	Compounded Trauma: A Qualitative Study of the Challenges for Refugees Living with Advanced Cancer	Qualitative cohort study	Identify the needs and experiences of adult refugees in Jordan with advanced cancer and informal caregivers.	Involve
Lewis et al (2009)29	Pancreatic Cancer Surveillance Among High-Risk Populations: Knowledge and Intent	Qualitative cohort study	Understand perceptions and intent to screen for pancreatic cancer among those with an increased risk due to a hereditary cancer predisposition syndrome or family history.	Involve
Ibrahim et al (2018)31	'I want to know why and need to be involved in my own care…' A Qualitative Interview Study With Liver, Bile Duct or Pancreatic Cancer Patients About Their Experiences with Involvement in Care	Qualitative cohort study	Explore experiences of involvement among patients who had surgery for upper abdominal tumors and were cared for according to a fast-track care program.	Involve
Schildmann et al (2013)27	'One also needs a bit of trust in the doctor …' A Qualitative Interview Study With Pancreatic Cancer Patients About Their Perceptions and Views on Information and Treatment Decision-Making	Qualitative cohort study	Reconstruct perception of patients with pancreatic cancer regarding the disclosure of diagnosis and treatment decision-making, and explore patients' preferences regarding information and treatment decisions and the reasons for their preferences.	Involve
Ziebland et al (2015)28	Barriers to Shared Decisions in the Most Serious of Cancers: A Qualitative Study of Patients With Pancreatic Cancer Treated in the UK	Qualitative cohort study	Explore patients with pancreatic cancer perceptions of barriers to shared-decision making in a condition in which shared decision making might be difficult.	Involve
Sato et al (2022)32	Assessing the Need for a Question Prompt List That Encourages End-of-Life Discussions Between Patients With Advanced Cancer and Their Physicians: A Focus Group Interview Study	Qualitative cohort study	Assess the need for a question prompt list that encourages end-of-life discussions between patients with advanced cancer and their physicians.	Collaborate
Saunders et al (2009)33	As the Bell Tolls: A Foundation Study on Pancreatic Cancer Consumer's Research Priorities	Qualitative	Explore the views of people affected by pancreatic cancer about research priorities	Collaborate

PanCAN=Pancreatic Cancer Action Network.

The other three studies in the involved category also used qualitative methods to involve patients with pancreatic cancer in their research. In the first study, patients at high risk of pancreatic cancer were interviewed about their willingness to undergo cancer screening.[29] The authors found that trusting relationships between providers and patients is key to screening for pancreatic cancer. It was suggested that the patient's primary care physicians, along with the oncologist, were involved in this decision. Another study identified the needs and experiences of refugees in Jordan with advanced cancer, such as pancreatic cancer.[30] Patients were interviewed to explore the impact of compounded trauma and give a voice to the participants. In the last article in the involve category, patients who went through a fast-track discharge program after surgery for pancreatic cancer were interviewed regarding their experience in hopes of improving the program for patients.[31]

Level 4. Collaborate

Collaborate is the next level of public participation. It is defined as partnering with the public in each aspect of the decision, including developing alternatives and identifying the preferred solution. Two (n = 2) papers fell into this category. Again, both used qualitative methods. The first study was a focus group to assess the need for a question prompt list to guide end-of-life discussions between patients with pancreatic cancer and their providers.[32] The patients in the study developed the questions on their own in accordance with their thoughts and values. The authors stated these questions would be used to develop the question prompt list. Lastly, people affected by pancreatic cancer, including patients, caretakers, and advocates were interviewed to ascertain the most important research priorities.[33] The authors investigated the issues that patients with pancreatic cancer and caretakers face to guide how the scientific community may best serve them.

Level 5. Empower

Empower is the highest level of public participation. Empower means placing the final decision-making in the hands of the public. None of the papers in this study reached the empower level of community engagement.

Discussion

Our scoping review demonstrates that community engagement strategies have been used in the setting of pancreatic cancer to some extent. However, we did not find evidence of "deep" community engagement that ultimately leaves decisions in the hands of the research participants. Such a finding provides the opportunity for future research using multiple study designs, including randomized control trials. Community engagement is especially relevant among vulnerable groups that are often not consulted for input, such as individuals with pancreatic cancer who have been diagnosed with a frightening disease with a very low survival rate.[34] There is room for deeper, more meaningful community engagement in the setting of pancreatic cancer to allow for the patient's voice to be at the forefront of research studies.[2]

One common theme revealed in this scoping review was the abundance of "community-based" work without actual evidence of

> **Historically, research has collected information from communities while rarely giving back to the people we learn from, and often taken without the cultural context from which these communities exist.**

"community engagement," as defined in this study and by the Spectrum of Public Participation. In medical literature, there is an abundance of information stemming from work done in the community. Still, these studies often lack aspects of the bidirectional, collaborative nature of community-engaged work where the research teams take direction and learn from the community being studied. Several studies assessed during the initial stage of this scoping review highlighted work done within a community hospital setting but with little other involvement of patients. For example, 2 papers provided a thorough retrospective study of postoperative outcomes after surgical resection of pancreatic cancer in community-based academic hospitals.[35,36] Although such studies can provide researchers with valuable clinical information (ie, length of hospital stay, operative blood loss, and potential intraoperative or postoperative complications like an anastomotic leak), they do not consider the experiences and values of patients regarding their operative course. One could argue that this information can eventually inform the patient community, but additional steps must be taken to involve the community being studied for this to be considered true community engagement. Our findings echo those of other systematic reviews on similar topics that have found few studies achieve high levels of community engagement.[34]

Similarly, several retrospective studies identified the characteristics of patients with pancreatic cancer without actively engaging with them or learning from their lived experiences.[37] Retrospective chart reviews that examine trends in cancer treatment and barriers to care can also provide valuable information to inform providers and contribute to public health efforts. However, these studies do not contain individual perspectives from community members. Further steps should be taken to involve and empower communities of patients with cancer to make a sustainable impact on the community in the future. For example, researchers could share their findings with patients with pancreatic cancer to learn about their reactions and opinions. This action would allow patients to be involved in the research and foster bidirectional learning experiences. Taking a more community-engaged approach could provide researchers with the information needed to meet the needs of the community rather than examining it from afar.

The framework of community-engaged research developed by the International Association for Public Participation's Spectrum of Public Participation places the ultimate community influence at the "empower" level. Just because the community can make the final decision does not necessarily equate to a standard of community engagement. As Graeme Stuart wrote in a blog post, "a decision

could be made by the community through a process that requires little interaction or engagement (eg, a referendum)."[38] An additional limitation of this discussion on the empower level is the effect of improper implementation of an empower-based research study. This can potentially leave communities stranded if they do not have the resources or capacity to support the project or understand the decision. The empower level must still be created using the 7 core principles of community engagement to truly be community centered.[5] However, the focus of our discussion will focus on opportunities to engage the community more meaningfully, allowing researchers to advocate for the community's specific needs, and promote community-engaged research studies in the realm of pancreatic cancer research.

Even though our review did not demonstrate evidence of any published studies incorporating the "empower" standard of community engagement, a few research articles we sorted within the "collaborate" level describe the outcomes of instances when the public helped guide research questions for funding priority.[32,33] These studies elaborate on the collaborative nature of qualitative research and use of focus groups in multiple stages of the program, allowing the community to have a say in the research that goes on within the context of their environment. Creating community-engaged research allows the focus to transition to a bi-directionality approach and gain insight into a particular cultural context. Historically, research has collected information from communities while rarely giving back to the people we learn from, and often taken without the cultural context from which these communities exist. Research on the higher end of the public participation spectrum has the power to uncover results that are more meaningful within both the scientific and public contexts while also having the potential to diversify participants by increasing trust between these communities.

The "empower" level of community engagement can be viewed similarly to civic government elections. In this analogy, voters are the community members who can decide for themselves whom to vote for and ultimately become the elected official. The candidates running for the position in question aim to build trust with the community they wish to serve. This trust is commonly accomplished by going into the community, building relationships with trusted members, and advocating for the needs of specific groups of people. This example of democracy describes enlisting power to the people to elect someone who can listen and respond to the needs and desires of their community. This process can also be demonstrated within research, the standard that the empower level aims to utilize. For example, Saunders et al. involved the pancreatic cancer community by exploring the research priorities of those affected by the disease.[33] If the authors had shown that these research priorities were funded and pursued as a direct result of their engagement process, that would constitute "empower" level of community engagement.

There are many challenges to engaging community members in pancreatic cancer research. Researchers must forge and maintain meaningful relationships with members of the community. Such an endeavor can be both logistically and practically challenging. Additionally, studies have found that high-quality community engagement sometimes requires adaptations to research protocols making them less rigorous.[39] Another study found that lack of funds and power struggles between stakeholders were the main barriers to community engagement.[40] Patients with pancreatic cancer may want to participate in research but are limited by their physical or mental health. It is essential that researchers work to overcome the barriers to community engagement to empower the groups they set out to study. Engaging the community in research will ensure equitable and meaningful improvements to health and quality of life among patients with pancreatic cancer. ◼

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References

1. Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer statistics, 2022. *CA Cancer J Clin*. 2022;72(1):7-33. doi:10.3322/caac.21708

2. Nipp RD. Palliative and supportive care for individuals with pancreatic adenocarcinoma. *Hematol Oncol Clin North Am*. 2022;36(5):1053-1061. doi:10.1016/j.hoc.2022.07.009

3. Leader AE, Aplin AE. From the community to the bench and back again: the value of patient and community engagement in cancer research. *Cancer Discov*. 2021;11(9):2135-2138. doi:10.1158/2159-8290.CD-21-0693

4. McCloskey DJ, Akintobi TH, Bonham A, Cook J, Coyne-Beasley T. *Principles of Community Engagement*. 2nd ed. National Institutes of Health; 2011.

5. Israel BA, Coombe CM, Cheezum RR, et al. Community-based participatory research: a capacity-building approach for policy advocacy aimed at eliminating health disparities. *Am J Public Health*. 2010;100(11):2094-2102. doi:10.2105/AJPH.2009.170506

6. Holzer JK, Ellis L, Merritt MW. Why we need community engagement in medical research. *J Investig Med*. 2014;62(6):851-855. doi:10.1097/JIM.0000000000000097

7. Rodríguez L, Banks T, Barrett N, Espinoza M, Tierney WM. A medical school's community engagement approach to improve population health. *J Community Health*. 2021;46(2):420-427. doi:10.1007/s10900-021-00972-7

8. Attree P, French B, Milton B, Povall S, Whitehead M, Popay J. The experience of community engagement for individuals: a rapid review of evidence. *Health Soc Care Community*. 2011;19(3):250-260. doi:10.1111/j.1365-2524.2010.00976.x

9. De Weger E, Van Vooren N, Luijkx KG, Baan CA, Drewes HW. Achieving successful community engagement: a rapid realist review. *BMC Health Serv Res*. 2018;18(1):285. doi:10.1186/s12913-018-3090-1

10. Mina DS, Au D, Brunet J, et al. Effects of the community-based Wellspring cancer exercise program on functional and psychosocial outcomes in cancer survivors. *Current Oncol*. 2017;24(5):284-294. doi:10.3747/co.23.3585

11. Esmail LC, Roth J, Rangarao S, et al. Getting our priorities straight: a novel framework for stakeholder-informed prioritization of cancer genomics research. *Genet Med*. 2013;15(2):115-122. doi:10.1038/gim.2012.103

12. Enzinger AC, Wind JK, Frank E, et al. A stakeholder-driven approach to improve the informed consent process for palliative chemotherapy. *Patient Educ Couns*. 2017;100(8):1527-1536. doi:10.1016/j.pec.2017.03.024

13. Concannon TW, Meissner P, Grunbaum JA, et al. A new taxonomy for stakeholder engagement in patient-centered outcomes research. *J Gen Intern Med*. 2012;27(8):985-991. doi:10.1007/s11606-012-2037-1

14. Wieland ML, Doubeni CA, Sia IG. Community engagement with vulnerable populations. *Mayo Clin Proc*. 2020;95(9S):S60-S62. doi:10.1016/j.mayocp.2020.05.041

15. Kamaraju S, DeNomie M, Visotcky A, et al. Increasing mammography uptake through academic-community partnerships targeting immigrant and refugee communities in Milwaukee. *WMJ*. 2018;117(2):55-61.

16. Gupta A, Khalid O, Moravek C, et al. Leveraging patient-reported outcomes (PROs) in patients with pancreatic cancer: The Pancreatic Cancer Action Network (PanCAN) online patient registry experience. *Cancer Med*. 2021;10(20):7152-7161. doi:10.1002/cam4.4257

17. Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*. 2021;372:n71. doi:10.1136/bmj.n71

18. Ouzzani M, Hammady H, Fedorowicz Z, Elmagarmid A. Rayyan—a web and mobile app for systematic reviews. *Syst Rev*. 2016;5(1):210. doi:10.1186/s13643-016-0384-4

19. Wieland ML, Njeru JW, Alahdab F, Doubeni CA, Sia IG. Community-engaged approaches for minority recruitment into clinical research: a scoping review of the literature. *Mayo Clin Proc*. 2021;96(3):733-743. doi:10.1016/j.mayocp.2020.03.028

20. Grewal US, Gupta A, Doggett J, Lou E, et al. Twitter conversations about pancreatic cancer by health care providers and the general public: thematic analysis. *JMIR Cancer*. 2022;8(1):e31388. doi:10.2196/31388

21. Park SK, Park HA, Lee J. Understanding the public's emotions about cancer: analysis of social media data. *Int J Environ Res Public Health*. 2020;17(19):7160. doi:10.3390/ijerph17197160

22. Domenighetti G, Grilli R, Maggi JR. Does provision of an evidence-based information change public willingness to accept screening tests? *Health Expect*. 2000;3(2):145-150. doi:10.1046/j.1369-6513.2000.00081.x

23. Behar-Horenstein L, Warren RC, Setiawan VW, Perkins C, Schmittgen TD. Enhancing African American participation in biospecimens: a case in point for pancreatic cancer. *Cancer Health Disparities*. 2020;29(12):PO-236. doi:10.1158/1538-7755.DISP20-PO-236

24. Larnebratt A, Fomichov V, Bjornsson B, Sandstrom P, Lindhoff Larsson A, Drott J. Information is the key to successful participation for patients receiving surgery for upper gastrointestinal cancer. *Eur J Cancer Care (Engl)*. 2019;28(2):e12959. doi:10.1111/ecc.12959

25. Permuth JB, Dezsi KB, Vyas S, et al; The Florida Pancreas Collaborative. The Florida Pancreas Collaborative next-generation biobank: state-wide infrastructure to reduce disparities and improve survival for a racially and ethnically diverse cohort of patients with pancreatic cancer. *Cancers (Basel)*. 2021;13(4):809. doi:10.3390/cancers13040809

26. Geessink NH, Ofstad EH, Olde Rikkert MGM, van Goor H, Kasper J, Schoon Y. Shared decision-making in older patients with colorectal or pancreatic cancer: Determinants of patients' and observers' perceptions. *Patient Educ Couns*. 2018;101(10):1767-1774. doi:10.1016/j.pec.2018.06.005

27. Schildmann J, Ritter P, Salloch S, Uhl W, Vollmann J. 'One also needs a bit of trust in the doctor ... ': a qualitative interview study with pancreatic cancer patients about their perceptions and views on information and treatment decision-making. *Ann Oncol*. 2013;24(9):2444-2449. doi:10.1093/annonc/mdt193

28. Ziebland S, Chapple A, Evans J. Barriers to shared decisions in the most serious of cancers: a qualitative study of patients with pancreatic cancer treated in the UK. *Health Expect*. 2015;18(6):3302-3312. doi:10.1111/hex.12319

29. Lewis ZK, Frost CJ, Venne VL. Pancreatic cancer surveillance among high-risk populations: knowledge and intent. *J Genet Couns*. 2009;18(3):229-238. doi:10.1007/s10897-008-9205-9

30. Guo P, Alajarmeh S, Alarja G, et al. Compounded trauma: A qualitative study of the challenges for refugees living with advanced cancer. *Palliative Med*. 2021;35(5):916-926. doi:10.1177/02692163211000236

31. Ibrahim F, Sandstrom P, Bjornsson B, Larsson AL, Drott J. "I want to know why and need to be involved in my own care...": a qualitative interview study with liver, bile duct or pancreatic cancer patients about their experiences with involvement in care. *Support Care Cancer*. 2019;27(7):2561-2567. doi:10.1007/s00520-018-4548-8

32. Sato A, Fujimori M, Shirai Y, et al. Assessing the need for a question prompt list that encourages end-of-life discussions between patients with advanced cancer and their physicians: a focus group interview study. *Palliat Support Care*. 2022;20(4):564-569. doi:10.1017/S1478951521001796

33. Saunders C, Gooden H, Robotin M, Mumford J. As the bell tolls: a foundation study on pancreatic cancer consumer's research priorities. *BMC Res Notes*. 2009;2:179. doi:10.1186/1756-0500-2-179

34. Cyril S, Smith BJ, Possamai-Inesedy A, Renzaho AMN. Exploring the role of community engagement in improving the health of disadvantaged populations: a systematic review. *Global Health Action*. 2015;8(1):29842. doi:10.3402/gha.v8.29842

35. Bashir MU, Kandilis A, Jackson NM, Parikh JA, Jacobs MJ. Distal pancreatectomy outcomes: perspectives from a community-based teaching institution. *Ann Hepatobiliary Pancreat Surg*. 2020;24(2):156-161. doi:10.14701/ahbps.2020.24.2.156

36. Metreveli RE, Sahm K, Abdel-Misih R, Petrelli NJ. Major pancreatic resections for suspected cancer in a community-based teaching hospital: lessons learned. *J Surg Oncol*. 2007;95(3):201-206. doi:10.1002/jso.20662

37. Walker BB, Schuurman N, Wen CK, Shakeel S, Schneider L, Finley C. Cancer resection rates, socioeconomic deprivation, and geographical access to surgery among urban, suburban, and rural populations across Canada. *PLoS ONE*. 2020;15(10):e0240444. doi:10.1371/journal.pone.0240444

38. Stuart G. What is the spectrum of public participation? *Sustaining Community*. Published February 14, 2017. Accessed July 19. 2023. https://sustainingcommunity.wordpress.com/2017/02/14/spectrum-of-public-participation

39. Jensen PS, Hoagwood K, Trickett EJ. Ivory towers or earthen trenches? Community collaborations to foster real-world research. *App Dev Science*. 1999;3(4):206-212.

40. Swainston K, Summerbell C. The effectiveness of community engagement approaches and methods for health promotion interventions. National Institute for Health and Clinical Excellence; 2008.

Human-Centered Design

A Possible Solution to Rural Clinical Trial Enrollment

BY WADE T. SWENSON, MD, MPH, MBA;
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Rural cancer patients face barriers to care, including clinical trial enrollment.[1] An understanding of strategies to increase patient enrollment in clinical trials is limited.[2] Incorporating a human-centered design approach to trial development may address the recruitment barriers faced by patients and providers.

Human-centered design is a creative problem-solving method that is increasingly used in health care settings.[3] It is a philosophy based on the discipline of design thinking that addresses issues by putting the end-user experience at the forefront. By keeping the end user in mind, products and services that ignore the needs and context of the users are avoided. The design process begins with an understanding of the affected individuals and develops a product or service centered on their experience. Human-centered design is a collaborative process well suited for complex systems like health care delivery. Human-centered design principles include cyclical rounds of ideation, prototyping, and testing.

Clinical trials are critical to the field of oncology and have enabled revolutionary developments. Over the last few decades, clinical trial design has become increasingly complex, with more narrowly defined patient subpopulations and increased requirements for patient-reported outcome measures, visits, and procedures.[4] The increasing complexity of clinical trials creates undue burdens on participants.

> A human-centered approach to designing clinical trials that considers the preferences and experiences of rural cancer patients and providers could increase the number of patients enrolling in trials and help close the health equity gap in rural areas.

Patients and providers are the end users of clinical trials. The increasing complexity of clinical trial enrollment and the increased burden on patients and providers is a barrier to care. We must reexamine our clinical trial infrastructure and consider the patient and provider experience in trial development.

Rural cancer patients face many barriers to care, including limited access to oncology providers, long travel times, and low clinical trial enrollment.[5] A SWOG study revealed that when rural and urban patients have equal access to trials, they experience similar outcomes.[6] Despite established rural clinical trial programs, patients are commonly either ineligible by study criteria or the schedule or travel requirements are too onerous. Rural patients require high-value clinical trials. A human-centered design approach may change the nature of the clinical trials offered and improve trial enrollment among rural patients.

In my rural oncology practice in central Minnesota, clinical trial access was provided to patients through collaborations with larger regional health systems over 2 decades. A team of dedicated clinical trial nurses screened all patients for clinical trial eligibility. The institutional goal was to achieve 1% to 3% clinical trial enrollment; the goal was never reached. Logistical challenges, such as accessing dry ice for laboratory specimen shipment, prevented clinical trial enrollment. Hundreds of patients were screened and found ineligible for trial enrollment. Despite a significant organizational effort to support a clinical trial infrastructure, patients were not adequately enrolled in clinical trials.

Table 1. High-Value Characteristics of Rural-Focused Clinical Trials*
• Minimal disruption to personal and family life
• Emphasis on advanced-stage diseases
• Access to promising pharmaceuticals in development
• Ability to conduct laboratory and imaging testing locally
• Open-label study design

*As shared by patients treated at Dr. Swenson's practice.

Over the years, several themes emerged in discussions with my rural cancer patients regarding their interest in clinical trials (Table 1). Rural cancer patients find value in protocols that provide minimal disruption to personal and family life. They value access to promising pharmaceuticals that are otherwise unavailable. They prioritize clinical trials that are focused on advanced-stage diseases. They tend to decline to participate in protocols that require travel for laboratory studies and imaging. They embrace open-label study designs and are often leery of placebo-controlled trials. They are willing to participate in observational trials and are not opposed to telehealth follow-up visits.

A human-centered approach to designing clinical trials that considers the preferences and experiences of rural cancer patients and providers could increase the number of patients enrolling in trials and help close the health equity gap in rural areas. ◨

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References

1. Virani S, Burke L, Remick SC, Abraham J. Barriers to recruitment of rural patients in cancer clinical trials. *J Oncol Pract*. 2011;7(3):172-177. doi:10.1200/JOP.2010.000158

2. Treweek S, Pitkethly M, Cook J, et al. Strategies to improve recruitment to randomised trials. *Cochrane Database Syst Rev*. 2018;2(2):MR000013. doi:10.1002/14651858.MR000013.pub6

3. Altman M, Huang TTK, Breland JY. Design thinking in health care. *Prev Chronic Dis*. 2018;15:E117. doi:10.5888/pcd15.180128

4. Getz KA, Campo RA. Trial watch: trends in clinical trial design complexity. *Nat Rev Drug Discov*. 2017;16(5):307. doi:10.1038/nrd.2017.65

5. Levit LA, Byatt L, Lyss AP, et al. Closing the rural cancer care gap: three institutional approaches. *JCO Oncol Pract*. 2020;16(7):422-430. doi:10.1200/OP.20.00174

6. Unger JM, Moseley A, Symington B, Chavez-MacGregor M, Ramsey SD, Hershman DL. Geographic distribution and survival outcomes for rural patients with cancer treated in clinical trials. *JAMA Netw Open*. 2018;1(4):e181235. doi:10.1001/jamanetworkopen.2018.1235

Introduction

Small cell lung cancer (SCLC) is considered an aggressive form of lung cancer with poor prognosis. It is characterized by rapid and uncontrolled growth of cells in the lungs.[1] Small cell lung cancer has a doubling time as short as 30 days and is notable for rapid metastases to lymph nodes and other organs.[2] Approximately 1 in 4 lung malignancies are small cell lung cancer.[2]

Tobacco use is the primary risk factor for small cell lung cancer.[1] Individuals who smoke have a risk of developing lung cancer that is 10 to 17 times higher than nonsmokers.[2] Increased risk is attributed to the number of cigarettes smoked per day and the number of years smoked. In addition, symptoms vary from person to person, with most individuals presenting with respiratory symptoms (eg, cough, dyspnea) at diagnosis.[3]

Staging is used to define patients with disease limited to thorax only, referred to as limited-stage disease, and small cell lung cancer that has metastasized, referred to as extensive stage disease.[3] Limited-stage small cell lung cancer is considered curable in approximately 25% of individuals, while extensive stage is considered difficult to treat.[1] Recurrent disease refers to disease that has returned after treatment. Standard treatment varies by stage, options are outlined in **Table 1.**[4]

Although progress has been slow over the past few decades in new treatments for small cell lung cancer, recently there are multiple clinical trials underway examining targeted therapies to treat the disease.[1] The results of which are likely to change the way small cell lung cancer is treated.

Lessons Learned From Phase I

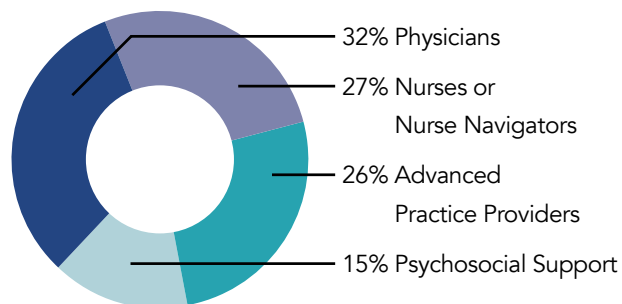### Provider and Patient Surveys

In 2022, the Association of Community Cancer Centers (ACCC) deployed surveys to providers and patients to uncover barriers in obtaining optimal care for patients with small cell lung cancer. The intention was to gain a better understanding of the factors that delay diagnosis and treatment, as well as lead to poor symptom management among patients.[5]

Table 1. Standard Treatment Options for Patients With Small Cell Lung Cancer[4]

Stage	Standard treatment options
Limited-stage disease	• Chemotherapy and radiation therapy • Combination chemotherapy alone • Surgery followed by chemotherapy or chemoradiation therapy • Prophylactic cranial irradiation • Clinical trial
Extensive-stage disease	• Immune checkpoint modulation and combination chemotherapy • Combination chemotherapy • Radiation therapy • Thoracic radiation therapy for patients who respond to chemotherapy • Prophylactic cranial irradiation • Clinical trial
Recurrent disease	• Chemotherapy • Immune checkpoint modulation • Clinical trial • Palliative therapy

The provider survey had 100 provider responses. Break out by provider type is shown in **Figure 1.** [5]

- 32% Physicians
- 27% Nurses or Nurse Navigators
- 26% Advanced Practice Providers
- 15% Psychosocial Support

Physicians, advanced practice providers, and nurses or nurse navigators were equally split among working environments. Thirty-four percent (34%) work in community cancer program and 34% work in private practice.[5] By comparison, 47% of psychosocial support providers noted working in a private or physician practice.

The patient survey had 51 respondents.[5] Median patient age was 40 years, and 59% had limited-stage small cell lung cancer. Forty-five percent (45%) of patients held private insurance, 33% were Medicare beneficiaries, 8% had Medicaid, and 2% were under- or uninsured. Racial and ethnic breakup for patients

showed 69% were White, 10% were Black, and 6% were one of the following Asian/Asian American, Hispanic/Latinx, American Indian/Alaska Native, or Native Hawaiian/Pacific Islander.

Diagnosis and Management of Small Cell Lung Cancer
Small cell lung cancer, known for its rapid growth and spread to other parts of the body, is important to detect as early as possible. Additionally, clinical presentation can be consistent with pulmonary inflammatory or infectious conditions, leading to delays in appropriate management.[6] ACCC's patient survey, showed patients saw an average of 3 doctors for their symptoms prior to receiving a diagnosis of small cell lung cancer.

The top 3 contributors to a delay in small cell lung cancer by providers is outlined in **Figure 2**. They included biopsy confirmation or pathology results, patient access to care, and scheduling delays such as availability of office appointments.[5]

Quality of life was examined in the provider survey. A good quality of life is defined as the ability to continue daily living or desired activities, achieve goals, and interact with family and friends. Providers reported quality of life as an important factor in making treatment decisions, see **Figure 3.**[5]

Figure 2. Provider-Reported Reasons Contributing to Delays in Small Cell Lung Cancer Diagnosis

	Physician (n=32)	APP (n=26)
Delay in biopsy confirmation or pathology results	59%	77%
Patient delays in accessing care	59%	62%
Scheduling delays (office appt. unavailable in a timely manner)	44%	54%
Referral patterns from PCP or pulmonologist	31%	42%
Limited access to specialists/ tumor board	25%	19%
Other	0%	0%

How significant is patient quality of life when making treatment recommendations?

■ Physician (n=32)　■ APP (n=26)　■ Nurse (n=27)　■ PSS (n=15)

Is the most important factor
- 22%
- 27%
- 30%
- 27%

It depends on the patient's staging and goals of care (curative vs. palliative)
- 41%
- 46%
- 26%
- 40%

It depends on the patient's stated preference(s) and goals
- 34%
- 27%
- 44%
- 33%

Is not a primary consideration
- 3%
- 0%
- 0%
- 0%
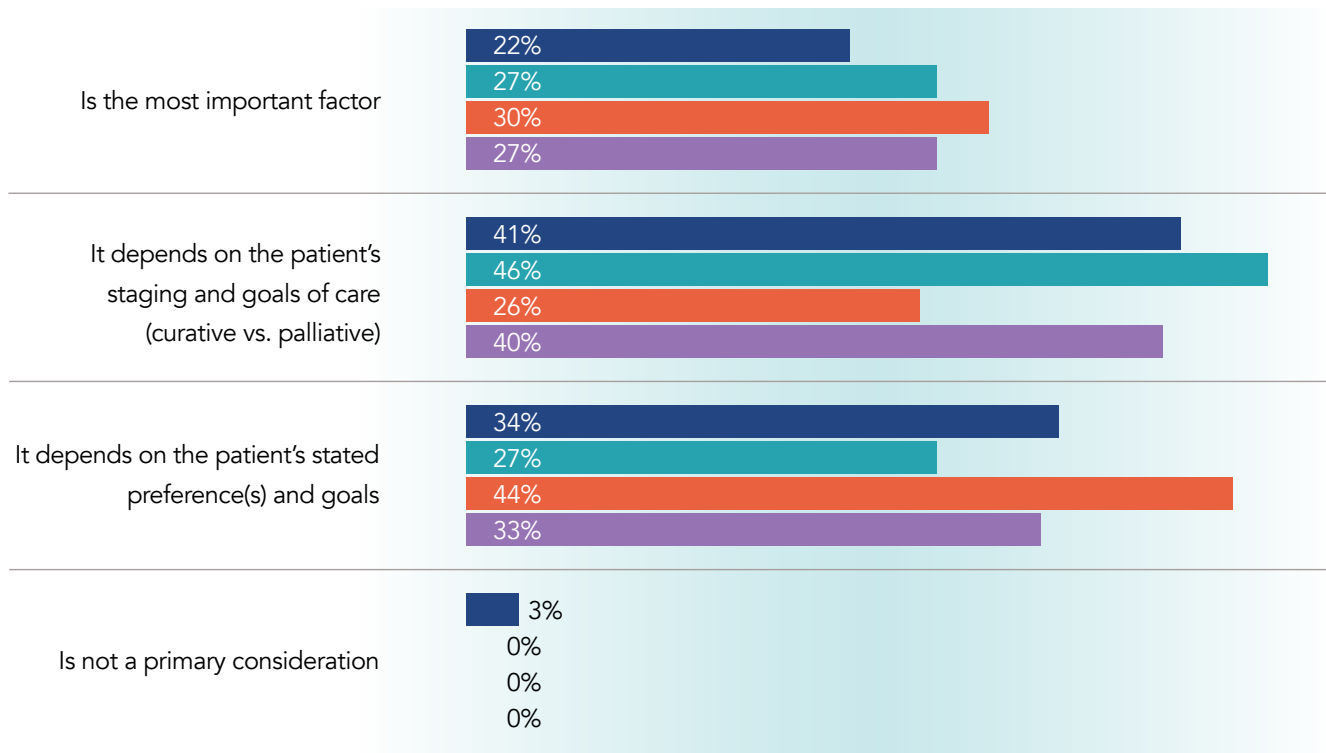
Most providers reported the importance of quality of life in treatment planning was dependent on disease staging, and type of treatment (ie, curative vs palliative).[5]

The patient survey found that patients reported that their quality of life could be improved with support of the following challenges during treatment: management of their pain or any other unwanted symptoms, addressing their psychological well-being, help with logistical aspects of care (eg, financial barriers and living situations), and addressing spiritual or existential suffering.[5]

This disease has a considerable burden on patients, with significant impact on quality of life. Patients with small cell lung cancer often present with symptoms indicating widespread metastatic disease (eg, weight loss, bone pain, and neurologic compromise). Increasing symptom burden has a negative impact on patients' quality of life. ACCC's patient survey identified the most bothersome symptoms of small cell lung cancer, see **Figure 4.**[5]
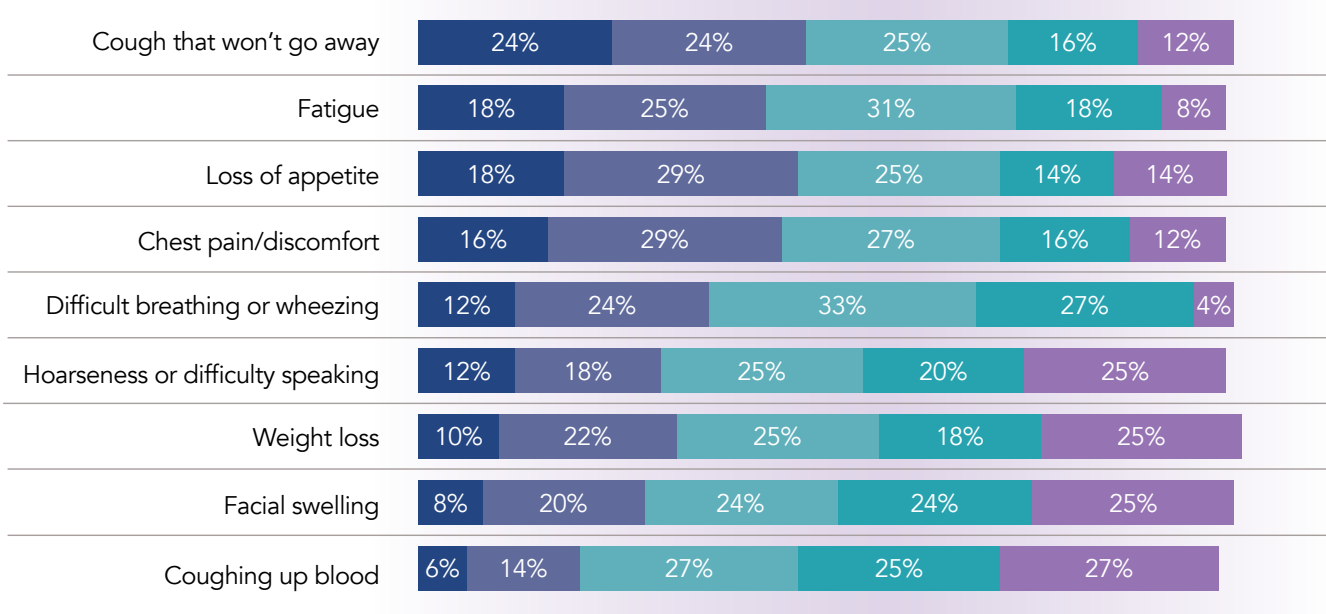
Treatment Patterns and Referrals

The provider survey examined treatment patterns and clinical trial referrals. Most physicians (51%) and advanced practice providers (67%) said they were highly likely to refer patients to a clinical trial, based on availability.[5] However, it was noted that first-line treatment would be used first. Barriers to clinical trial participation were also identified as lack of trial availability, lack of transportation or other logistical barriers, patient preference, narrow inclusion criteria, and need for more immediate treatment.

For treatment of patients with extensive-stage small cell lung cancer, providers noted that 80% of patients receive a platinum doublet plus atezolizumab or durvalumab as first-line therapy.[5] For the 18% of patients who receive chemotherapy only as first-line treatment, providers noted, autoimmune disorders, prior allergies, and cost concerns were reasons for doing so. Providers also noted that 4% of patients with extensive-stage small cell lung cancer did not receive first-line treatment due to fac-

How often are each of the following potential symptoms of SCLC bothersome to you?

■ Multiple times per day ■ Daily ■ Weekly ■ Present, but bothers me less than once per week ■ Not present

	Multiple times per day	Daily	Weekly	Present, but bothers me less than once per week	Not present
Cough that won't go away	24%	24%	25%	16%	12%
Fatigue	18%	25%	31%	18%	8%
Loss of appetite	18%	29%	25%	14%	14%
Chest pain/discomfort	16%	29%	27%	16%	12%
Difficult breathing or wheezing	12%	24%	33%	27%	4%
Hoarseness or difficulty speaking	12%	18%	25%	20%	25%
Weight loss	10%	22%	25%	18%	25%
Facial swelling	8%	20%	24%	24%	25%
Coughing up blood	6%	14%	27%	25%	27%

Other symptoms related to SCLC

Sleep issues/tired/weakness **8%** | Back/spine pain/localized pain **6%** | Trouble eating/weight loss **6%** | Fever 3% | Blood issues/bleeding **3%** | Inflammation/swelling **3%**

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tors such as poor performance status, multiple comorbidities, and patients' decision to choose palliative care.

An examination of second-line treatment found 13% of physicians, and 20% of advanced practice providers reported that less than or equal to 50% of their patients with extensive-stage small cell lung cancer initiated second-line treatment at disease progression.[5] The physician survey found many factors at play when considering whether to recommend platinum-based rechallenge when choosing subsequent systemic therapy for patients with small cell lung cancer. These include degree and duration of first response, patient performance status and organ function, as well as number of comorbidities. Barriers to second-line treatment were identified as patient fitness, management of treatment-related adverse events, and the presence of multiple comorbidities.

Support Services

The physician survey found that education and information shared with patients, including an explanation of the diagnosis, answering questions, providing educational handouts and trusted internet resources, and providing referrals to supportive care services, was most often done by advanced practice providers, nurses, and psychosocial support providers.[5]

In addition, physicians reported patient referrals to palliative or supportive care occurred at various stages during treatment. This includes after failure of multiple lines of therapy, upon first recurrence or refractory disease, at diagnosis, or when symptoms become difficult to manage or are uncontrolled. Comparatively, advanced practice providers noted referring patients to supportive services when symptoms became difficult to manage or after multiple lines of therapy.
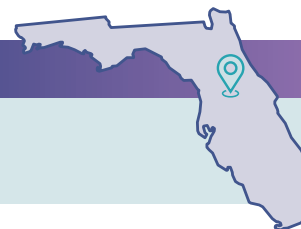
In addition to the patient and providers surveys, ACCC examined best practices in treatment of small cell lung cancer. The following cancer programs highlight best practices in specific areas of cancer care.

AdventHealth Cancer Institute Waterman

LOCATION: Tavares, Florida

EFFECTIVE PRACTICE: Patient Navigation and Community Partnerships

AdventHealth Cancer Institute Waterman (Advent Waterman) established a lung nodule clinic to further streamline the diagnosis of lung cancer after a positive screen and reduce delays in the assessment of incidental nodules. As a result, the lung navigator's role expanded to support the lung nodule clinic and connection to the cancer treatment team.

Next Steps: AdventHealth Waterman has a strong, skilled multidisciplinary team committed to caring for patients impacted by small cell lung cancer. Moving forward, the team at AdventHealth aims to grow the lung cancer screening program and lung nodule clinic and expand community partnerships to support patients across the lung cancer continuum.

"Navigation is key. Capturing patients up front, helping them figure out their next step is critical. Then getting patients to the right specialist at the right time whether through the lung nodule clinic or connecting them to our multidisciplinary cancer care team—navigation is the glue that holds the process together. Plus, the clinical outcomes that can be addressed are substantial."

— **Leslie K. Maxwell, MBA,**
   Director,
   AdventHealth Cancer Institute Waterman

Corewell Health

LOCATION: : Taylor, Michigan

EFFECTIVE PRACTICE: Timely Diagnosis to Treatment Initiation

Corewell Health's lung clinic includes a multidisciplinary provider team comprised of pulmonologists, interventional pulmonologists, nurses, a nurse coordinator, a clinical nurse manager, lung cancer nurse navigators, a cardiothoracic surgeon, oncologists, radiation oncologists, and many more providers and staff who play a critical role in ensuring quality, patient-centered care. The lung clinic has a strong referral network, and typically receives 25 to 50 referrals a week for diagnostic workup. The team works together to triage patients and get them in as quickly as possible.

Next Steps: Building on the strong foundation, Corewell Health is investing in additional diagnostic tools and research to improve outcomes of patients impacted by lung cancer. The team hopes the innovative work they are doing in Michigan will be able to be replicated across the country for all patients.

"Start simple. What is it that you are intending to do? Are you intending to optimize your diagnostics? Are you attempting to accelerate recovery? Are you attempting to improve your therapeutics? Or something else? Then decide how do you get your toe in the water, and then you must crawl before you walk, and you must walk before you sprint. But collective intelligence is going to be the key for success."

— **Gustavo Cumbo-Nacheli, MD, FCCP, DAABIP**
   Interventional pulmonologist,
   Corewell Health

Levine Cancer Institute

LOCATION: : Charlotte, North Carolina

EFFECTIVE PRACTICE: Comprehensive Support Program

The Levine Cancer Institute's Cancer Committee identified an opportunity to improve support for patients who receive a diagnosis of lung cancer. Levine sees a wide range of people impacted by lung cancer. Each year, the Health System diagnoses 900 new cases of lung cancer, with approximately 150 cases representing small cell lung cancer. The cancer committee coalesced around a lung cancer support program. A thoracic medical oncologist championed the initiative and assembled a passionate and committed multidisciplinary team including a physical and occupational therapist, music therapist, psychologist, patient resource manager, nurse navigators, nutritionist, social worker, research scientist, and program coordinators.

Next Steps: Levine Cancer Institute now has a solid foundation in place to provide ongoing support to people impacted by lung cancer. There remains a commitment from the multidisciplinary team to continue to innovate and build out additional services to meet patients' needs.

> "In my experience, people living with lung cancer commonly feel their needs are not recognized. I am proud of the fact we started a support program for patients with lung cancer to show we do care, and we can offer tailored services based on the patient's type of lung cancer."
> — **Michele Szafranski, MS, RD, CSO, LDN**
> Clinical nutrition manager,
> *Levine Cancer Institute*

White Plains Hospital Cancer Program

LOCATION: : White Plains, New York

EFFECTIVE PRACTICE: Whole-Person Care

All patients receiving lung cancer care at White Plains Hospital Cancer Program are presented at the multidisciplinary thoracic tumor board, which meets 2 to 3 times a month. Patients are also quickly connected to a medical oncologist and the multidisciplinary team works to meet patients' needs beyond the disease itself across the care continuum. The White Plains team knows any cancer diagnosis and its treatment can significantly impact patients' quality of life. Therefore, the team has taken a whole-person approach to the structure of the infusion center. The infusion center is nursing led; nurse practitioners round regularly and follow their patients to ensure continuity of care and early intervention.

Next Steps: The team remains committed to their approach, while also identifying new opportunities, such as expanding its partnership with the American Lung Association, piloting a new palliative care model, and offering increased transportation services to reduce barriers to care.

> "Our infusion center is not just a place for the delivery of treatment. It is an opportunity for us to try and make our patients' day a little easier by providing whole-person care during that time."
> — **Victoria Assumma, LCSW-R, ACSW, OSW-C**
> Oncology social worker,
> *White Plains Hospital Cancer Program*

David M. Waterhouse, MD, MPH, Oncologist

LOCATION: : Cincinnati, Ohio
EFFECTIVE PRACTICE: Clinical Trials

David M. Waterhouse, MD, MPH, a medical oncologist, has been leading the charge in lung cancer clinical trials for decades. While clinical trials for small cell lung cancer have not moved forward in the same way as trials in other disease areas, Waterhouse offers systems-level solutions to change how trials are conducted and leverage underutilized resources:

- Design trials that are patient centric. For small cell lung cancer, change enrollment criteria and allow patients to be enrolled even after the first dose of chemotherapy, eliminate central lab and radiology reviews, and be more pragmatic about what data is necessary to collect.

- Use lessons learned from the COVID-19 pandemic such as electronic consent, remote monitoring, delivery of treatment to home, home nurse visits, and telemedicine encounters.

- Centralize trial coordination, investigator support, consent, and other necessary research operations while decentralizing the delivery of the treatment.

- Build hybrid partnerships between academic and community programs.

- Reimburse for providers' time spent on a trial whether through a Medicare designation or J-code.

Waterhouse also stresses the importance of mentorship to foster and support researchers in building clinical trial capacity.

"Eighty-five percent of cancer care is delivered in the community. The question we should be asking is— how can we develop trials that are community-centered? Trials need to reflect the world we see, not the world we can treat."
— **David M. Waterhouse, MD, MPH**

Clinical and Nonclinical Challenges in Treatment

Clinical Challenges

Clinical challenges affecting care for patients with small cell lung cancer are numerous. Patients often have significant comorbidities such as chronic obstructive pulmonary disease, cardiovascular disease, or diabetes. These preexisting comorbidities complicate a patient's ability to tolerate treatment, and may shorten their overall survival.[8] Additionally, because of the rapid growth of small cell lung cancer, it presents as a centrally located mass that can obstruct major airways and lead to rapid clinical decline.

There are also concerns with small cell lung cancer treatments. Platinum-doublet chemotherapy, although highly effective in the initial treatment of small cell lung cancer, also has the potential to be very toxic to patients. This with poor performance status at baseline. Key findings from the ACCC survey found treatment-related adverse events were the greatest deterrent to receiving the best possible small cell lung cancer care among patients.

In addition to side effects attributable to traditional chemotherapy, providers need to be cautious of immune-related adverse events (irAEs). The most frequently reported irAEs are hypothyroidism, hyperthyroidism, rash, and colitis.[9] However, any organ system can be subject to autoimmune damage from immunotherapy use. To facilitate appropriate clinical management of irAEs, cancer providers should equip patients with immunotherapy "wallet cards" that can be presented to non-oncology providers with clear contact information for the oncology team.[10] Additionally, patients should be instructed to inform their routine nononcology providers (ie, primary care provider, pulmonologist) if they are receiving immunotherapy.

Nonclinical Challenges

In addition to clinical challenges, health care providers and patients face nonclinical challenges in the management of small cell lung cancer. Nonclinical challenges include financial barriers, psychosocial issues, inadequate support systems, among others. The ACCC survey showed little consensus among physician providers in identifying the most significant barriers to providing optimal care to patients with small cell lung cancer.[5] Top nonclinical barriers were identified as inadequate support systems, cost of care, and lack of transportation. Other hurdles were identified as poor health literacy, difficulty comprehending diagnosis, lack of access to treatment, family care considerations, and difficulty communicating with the health care team.

Financial barriers are often among the top challenges encountered by cancer patients. With the recent addition of immunotherapy to the treatment of small cell lung cancer, there is also a new layer of financial burden. Specifically, because immunotherapies can be given as maintenance therapy until disease progression or unacceptable toxicity. In the ACCC survey, physicians, more than any other provider, found treatment cost and location (ie, at home vs in clinic) to be less significant to patients in their treatment choice compared to other factors, such as overall survival or adverse events from treatment.[5]

Nurses, however, consistently perceived treatment cost, treatment location, and number of office/lab visits for ongoing treatment monitoring, to have more impact on a patients' treatment choice. In the ACCC patient survey, approximately one-third reported out-of-pocket costs or surprise bills were considered an extreme problem.[5] Financial counselors or navigators can be a great resource to guide patients through the financial difficulties of treatment by overseeing insurance authorizations and providing co-pay assistance.[11]

Other nonclinical challenges include stigmatization, psychological well-being, equitable care, and health literacy levels. Study results show that lung cancer stigma can result in deterred screening, delayed diagnosis, and severe psychosocial distress.[12] Along with potential stigmatization, psychological well-being and spiritual/existential suffering are also pervasive among patients with small cell lung cancer. The ACCC patient survey found 20% reported spiritual/existential suffering as a substantial hardship, and 35% reported that support for psychological well-being was the most important aspect in assisting with treatment challenges.[5]

In addition, the patient survey found 30% indicated difficulties understanding medical language which significantly hindered optimal care.[5] Discussions about diagnosis and treatment should always be conducted at a health literacy level appropriate to the patient to foster productive conversations and shared decision-making. Similarly, to better understand disparities, health care team members should complete a cultural competency training to recognize their own implicit biases in communicating with patients.

Multidisciplinary Care

Due to the rapid growth of small cell lung cancer, prompt diagnosis and treatment are vital and depend on the collaboration of various providers. Management of patients with small cell lung cancer is not possible without a dedicated multidisciplinary team consisting of medical oncologists, radiation oncologists, pulmonologists, primary care providers, pathologists, thoracic surgeons, nurses, advanced practice providers, pharmacists, palliative care providers, social workers, financial navigators, among others.[13] Primary care providers and pulmonologists must be able to recognize symptoms associated with small cell lung cancer and to refer patients efficiently to medical oncologists and/or thoracic surgeons. Treatment decisions are best discussed in a multidisciplinary tumor board with input from different specialties.

Patients with small cell lung cancer are often hospitalized due to the acuity of their symptoms, which means that coordination of care between inpatient and outpatient teams is critical. To assist with treating symptoms, primary oncologists should refer patients to palliative care teams, radiation oncologists, and interventional pulmonology teams for consideration of palliative procedures and interventions. Ancillary team members, such as social workers and financial navigators, can support patients in managing nonclinical barriers to care.

Conclusion

In a post–COVID-19 era, cancer programs have seen a significant decrease in lung cancer screening, diagnosis, and treatment.[14] This is particularly impactful for those with small cell lung cancer due to the aggressive nature of the disease. To address the specific needs of these patients, ACCC engaged in a multiphased educational initiative to address the challenges and burdens faced by patients with small cell lung cancer in community oncology programs and practices.

The first phase of this project focused on survey data collection and identifying barriers and gaps in care. To accomplish this, ACCC deployed surveys to providers and patients to uncover barriers in obtaining optimal care for patients with small cell lung cancer. After successful completion of the surveys, quality-of-life challenges experienced by patients with small cell lung cancer were examined. ACCC collected best practices on comprehensive care for small cell lung care to share with member cancer centers. The results of both are shared in this article among other published resources.

ACCC is dedicated to ensuring cancer programs have the knowledge and shared best practices to support all patients on their cancer journeys.

REFERENCES

1. Small cell lung cancer. National Organization for Rare Disorders. Updated January 12, 2023. Accessed June 1, 2023. https://rarediseases.org/rare-diseases/small-cell-lung-cancer/

2. Types of lung cancer. National Cancer Institute. SEER Training Modules. Accessed June 2, 2023. www.training.seer.cancer.gov/lung

3. Rudin CM, Brambilla E, Faivre-Finn C, Sage J. Small-cell lung cancer. Nat Rev Dis Primers. 2021;7(1):3. doi:10.1038/s41572-020-00235-0

4. National Cancer Institute. Small cell lung cancer treatment (PDQ)–health professional version. Updated March 2023. Accessed June 5, 2023. www.cancer.gov/types/lung/hp/small-cell-lung-treatment-pdq

5. Association of Community Cancer Centers. Examining patient-centered small cell lung cancer care: patient and provider perspectives. Oncology Issues. 2023;38(2):63-73. www.journals.healio.com/doi/10.3928/25731777-20230309-1

6. Henry DH, Viswanathan HN, Elkin EP, Traina S, Wade S, Cella D. Symptoms and treatment burden associated with cancer treatment: results from a cross-sectional national survey in the U.S. Support Care Cancer. 2008;16(7):791-801. doi:10.1007/s00520-007-0380-2

7. Lung cancer survival rates. American Cancer Society. Revised March 1, 2023. Accessed June 27, 2023. www.cancer.org/cancer/types/lung-cancer/detection-diagnosis-staging/survival-rates.html

8. Islam KM, Jiang X, Anggondowati T, Lin G, Ganti AK. Comorbidity and survival in lung cancer patients. Cancer Epidemiol Biomarkers Prev. 2015;24(7):1079-1085. doi:10.1158/1055-9965.EPI-15-0036

9. Fu Y, Zheng Y, Wang PP, Ding ZY. Toxicities of immunotherapy for small cell lung cancer. Front Oncol. 2021;11:603658. doi:10.3389/fonc.2021.603658

10. Association of Community Cancer Centers. IO wallet card. Updated July 23, 2020. Accessed March 28, 2023. www.accc-cancer.org/home/learn/resource-detail/publication-io-wallet-card

11. Yezefski T, Steelquist J, Watabayashi K, Sherman D, Shankaran V. Impact of trained oncology financial navigators on patient out-of-pocket spending. Am J Manag Care. 2018;24(suppl 5):S74-S79.

12. Ostroff JS, Riley KE, Shen MJ, Atkinson TM, Williamson TJ, Hamann HA. Lung cancer stigma and depression: validation of the Lung Cancer Stigma Inventory. Psychooncology. 2019;28(5):1011-1017. doi:10.1002/pon.5033

13. Glatzer M, Rittmeyer A, Müller J, et al. Treatment of limited disease small cell lung cancer: the multidisciplinary team. Eur Respir J. 2017;50:1700422. doi:10.1183/13993003.00422-2017

14. Van Haren RM, Delman AM, Turner KM, et al. Impact of the COVID-19 pandemic on lung cancer screening program and subsequent lung cancer. J Am Coll Surg. 2021;232(4):600-605. doi:10.1016/j.jamcollsurg.2020.12.002

ACCC
Association of Community Cancer Centers

fast facts

ACCC member responses to 5 survey questions required when registering for the July 10, 2023, ACCC President Fireside Chat: Strategies to Address Burnout Among Your Workforce.

When you feel overwhelmed at work, what causes these feelings?

Most Common Answers/Themes (n=87)

- **42%**—Workload
- **21%**—Competing priorities
- **17%**—Leadership and/or organizational challenges
- **14%**—Lack of resources
- **14%**—Staffing challenges
- Other responses included: lack of support, low morale, stress, patient concerns, and financial challenges.
- 1 individual shared simply, "Saying 'yes' too much."

What motivates you at work?

Most Common Answers/Themes (n=92)

- **29%**—Patients
- **29%**—Other staff and/or colleagues
- **12%**—Making a difference and/or making an impact
- **11%**—Positive outcomes and/or advancements
- **9%**—Helping others
- **8%**—Professional growth
- Other responses included: being part of a solution, overcoming challenges, caring for others, and saving lives.
- 1 individual shared, "Post-COVID, that is still up for discussion."

What strategies do you use to help relieve stress?

Most Common Answers/Themes (n=88)

- **40%**—Physical activity
- **23%**—Take a break and/or disengage from work
- **18%**—Meditation or deep breathing
- **17%**—Self-care and/or mindfulness activities
- **13%**—Organize tasks, set priorities and deadlines, and/or problem-solving
- **13%**—Talk to trusted others
- **11%**—Hobbies
- Other responses included: spend time with family and/or friends; focus on the positives; look for opportunities to laugh and/or have fun; spirituality and/or religion; and sleep.
- 1 individual suggested, "Avoiding confrontation and talking with a therapist."

What can your leader do to best support you at work? (n=92)

- **25%**—Offer support
- **19%**—Listen
- **8%**—Positive encouragement and/or affirmations
- **8%**—Help with financial and/or personal growth
- **8%**—Support and help to achieve a positive work-life balance
- **7%**—Provide clear direction(s)
- **7%**—Remove silos and barriers
- **Other responses** included: regular check-ins; ask what is needed; flexibility; trust; support collaboration; ensure accountability; employ creative problem-solving; and use effective communication.
- **2 individuals** focused on workload, "Don't ask more of physicians without taking things off of their plate." and "Hire more staff and not worry as much about the budget."

Why do you love taking care of patients? (n=89)

Most Common Answers/Themes

- **20%**—To help patients and/or because of a need or desire to help
- **19%**—To make a positive impact and/or make a difference
- **17%**—Brings purpose and/or meaning; the work is rewarding
- **13%**—To build relationships
- **8%**—Because it is my passion and/or life work
- **7%**—To reduce burdens for others
- **Other responses** included: it brings an appreciation of life and/or a new perspective on life; it instills admiration of patients' courage; to improve the patients' quality of life; and to improve overall health and wellness.
- **1 individual** said, "I love being a part of their journey through cancer care and being someone they remember."

⤷ more online @ accc-cancer.org

WEBINAR | **Proactive Interventions for the Prior Authorization Process**

For providers, the necessity of seeking permission to give patients the best possible care, the paperwork to fight payment denials, and the time necessary to educate medical reviewers on why certain therapies are needed are overly burdensome. Learn how to navigate these challenges by watching this 6-part series of on-demand webinars.

BLOG | **Psychosocial Care in Oncology: Advocating for Policy Changes that Improve the Culture of Care**

This blog touches on why it is important that cancer programs and practices advocate for policies that drive patient access to psychosocial care, including continued access and increases for mental health coverage and reimbursement and access to mental health services delivered via telehealth.

PODCAST | **Combatting Caregiver Isolation Through Awareness and Education**

Isolation is a common concern among caregivers. Studies show that the lack of social interaction and stimulation from individuals other than their care recipient, especially when cognitive impairment is present, can be an undeniable trigger for loneliness. Addressing isolation is critical and any way that caregivers can connect with peers, professional support, and friend and colleague support networks is a priority. Hear strategies for combatting the feeling of isolation among caregivers

PUBLICATION | **A Financial Advocate's Guide to Biomarker Testing**

While biomarker testing allows providers to assess targeted therapy as a treatment option for patients with cancer, prior authorization is often required to order these valuable tests. Additionally, patients may face steep out-of-pocket costs related to this type of testing. Learn more about how to improve access to biomarker testing for patients with cancer.

RESOURCE | **Strategies to Improve Regional Access to Chronic Lymphocytic Leukemia Care**

Learn how 3 cancer programs are using community outreach and other support strategies to improve care for patients diagnosed with chronic lymphocytic leukemia who are in underserved populations. In this spotlight series, ACCC examines state and regional disparities and each cancer program's unique approach to overcome barriers and provide equitable care for those with this disease.

Chemotherapy Drug Shortages Result in Access Challenges and Difficult Choices

BY NICOLE TAPAY, JD

Over the past 6 months, shortages of several anti-cancer drugs have jeopardized the quality of cancer care and placed the lives of some patients with cancer at risk. These shortages are occurring across treatment settings and geographies, including community cancer centers, hospital-based cancer programs, and private physician practices. In some cases, clinicians are being forced to choose who gets treatment between and among patients eligible for curative versus palliative intent. In addition to the alarming effects on patient treatment, these shortages pose risks to cancer research in the near and longer term.

Patients with cancer and oncology programs have been facing scarce supplies of a number of key chemotherapy agents, and there has been a particularly dire shortage of platinum-based chemotherapy agents (eg, cisplatin and carboplatin).[1] These two medications (individually or in combination) treat a wide range of cancers, including but not limited to gastric, pancreatic, colorectal, esophageal, cervical, and ovarian. Platinum drug shortages were first reported to the U.S. Food and Drug Administration (FDA) on February 10, 2023.[2] In a 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.[3]

In certain cases, cancer programs and the clinicians who work there have been faced with the prospect of only being able to treat some of their patients. This past summer, "[A]n ACCC member program 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."

Fortunately, some providers have been able to alleviate the shortages by coordinating within their own networks,[1] or with other practices or hospitals. Some have also benefited from strong drug procurement management by their pharmacy teams. Furthermore, alternative treatment options are available for some but not all anti-cancer therapies on shortage.[1] In some cases, providers have adjusted the dosing or intervals of the drugs.[4] Finally, certain oncology professional societies have issued recommendations regarding how to conserve and allocate the limited supplies.[2]

Cancer research and clinical trials are also affected by the shortages. Depleted supplies and uncertainty about the availability of certain drugs in the future affect researchers' ability to enroll patients in certain clinical trials. The National Cancer Institute (NCI) has reported that at least 174 of its 608 trials may be affected by the drug shortages.[5]

These shortages reflect broader challenges with prescription drug manufacturing integrity in the US, stemming from production delays, unavailability of raw ingredients, and/or quality deficiencies, among other factors. In the late spring, the FDA 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 US. 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.[6]

While this step by the FDA provided some near-term relief, additional changes will be needed to address the systemic issues that have led to these and other drug shortages. For example, some clinicians are calling for legislation to incentivize more domestic manufacturing of generic drugs.[1] It is critical that policymakers, patients, providers, and other experts continue to work on long-term solutions to the drug shortages challenge. To this end, ACCC is working key stakeholders to help educate providers and patients on the issue, share best practices, and help develop policy solutions that recognize the many complex factors that have contributed to the current situation. ◻

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References

1. Sava J. Oncologists call for legislative action to address US drug shortages. Targeted Oncology. Published August 30, 2023. Accessed August 31, 2023. https://www.targetedonc.com/view/oncologists-call-for-legislative-action-to-address-us-drug-shortages. Citing U.S. Food and Drug Administration. Current and resolved drug shortages and discontinuations reported to the FDA. Accessed August 28, 2023. https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm and Advisory Board. 'People will die from this: 4 cancer drugs in short supply. Published March 21, 2023. Accessed August 29, 2023. https://bit.ly/44jdwE9

2. Society of Gynecologic Oncology. SGO statement: carboplatin and cisplatin shortages. Published April 21, 2023. Accessed August 31, 2023. https://www.sgo.org/news/drugshortage

3. National Comprehensive Cancer Network Best Practices Committee. Carboplatin and cisplatin shortage survey results. Published June 7, 2023. Accessed August 31, 2023. https://www.nccn.org/docs/default-source/oncology-policy-program/nccn-drug-shortage-survey.pdf?sfvrsn=dece5503_7

4. Sharfstein J. How drug shortages are affecting cancer treatments. Published July 118, 2023. Accessed August 31, 2023. https://publichealth.jhu.edu/2023/drug-shortages-are-affecting-cancer-treatments

5. Christensen J. Drug shortages' effects on cancer research may be felt for years to come. Published July 20, 2023. Accessed August 31, 2023. https://www.cnn.com/2023/07/20/health/drug-shortage-cancer-research/index.html

6.   Qilu Pharmaceutical Co., Ltd. Dear Healthcare Professional Letter, "Subject: Temporary Importation of CISplatin Injection with non-U.S. Labeling to Address Drug Shortage." Published May 24, 2023. Accessed September 1, 2023. https://dailymed.nlm.nih.gov/dailymed/lookupcfm?setid=be185d9c-d82f442b-81db-348e3715e7a4&version=2#!

compliance

Highlights of the CY 2024 MPFS and HOPPS Proposed Rules

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

On July 13, 2023, the Centers for Medicare & Medicaid Services (CMS) released its proposed rules for calendar year (CY) 2023 the Medicare Physician Fee Schedule[1] (MPFS) and Hospital Outpatient Prospective Payment System[2] (HOPPS). Once again, a main highlight of the proposed MPFS is a reduction in the conversion factor, resulting in payment reductions. For HOPPS, the main new issue is a proposed increase in payments for CY 2024, which may be offset by the 340B Drug Discount Program payback adjustment.[3]

MEDICARE PHYSICIAN FEE SCHEDULE

Payment Rates
The MPFS provides the regulatory information and payment rates for physicians—no matter what setting they work in (facility and non-facility) or who employs them—and office-based (non-facility) settings. Stakeholders had until 5:00 PM on September 11 (60 days) to submit comments to CMS on the proposed changes for CY 2024.

A value established each calendar year by building on the conversion factor (CF) from the preceding year, the CF converts the relative value units (RVUs) of physician work, the practice expense (PE) and malpractice expense of each code, and their geographic locations into the assigned CMS payment rate. As defined in previous legislation, the CF has a statutory increase of 0 percent through CY 2025; any adjustments are solely due to other regulatory actions or maintenance of the Medicare budget constraints.

For CY 2024, CMS was required, per the Consolidated Appropriations Act of 2023[4], to reduce the CY 2023 CF ($33.8872) by 2.5 percent first before determining the base value to begin the 2024 calculations. The decrease was a result of the one-time only increase legislated for the CY 2023 CF; the CF base for 2024 was $33.0607. CMS is proposing a decrease of 2.17 percent for budget neutrality, due to proposed 2024 total payments over the budget limitations, but this decrease is "softened" by the 1.25 percent increase required by the same act. Considering these factors, CMS proposes a CF of $32.7476, an estimated 3.34 percent decrease from 2023. Below is the impact on facility and non-facility settings as estimated per the total allowed charges for CY 2024.

- Hematology/Oncology Combined Impact: Total: 2%, Non-facility: 1%, and Facility: 2%
- Radiation Oncology and Radiation Therapy Centers Combined Impact: Total: -2%, Non-facility: -2%, and Facility: -2%

The reduction of the CF does result in decreases for many specialties and their estimated impacts; however, additional decreases are proposed to RVUs due to misvalued codes, the inclusion of the office/outpatient evaluation and management (E/M) complexity add-on code, year 3 phase-in of clinical labor updates, and proposed adjustments to behavioral health services.

Specific Codes and Code Set Valuations
Within the CY 2024 proposed rule, CMS addressed multiple misvalued and/or proposed value changes to specific series of new and established CPT® codes. The agency explains the rationale for the proposed changes are based on values recommended by AMA Specialty Society Relative Value Scale Update Committee (RUC) and other organizations which CMS uses for assistance in setting appropriate values for codes.

Changes to Advanced Care Planning CPT Codes 99497 and 99498
The RUC's Relativity Assessment Workgroup (RAW) reviewed codes **99497** and **99498** in January 2022, and determined these codes should be examined due to the changes in the E/M services. At its April 2022 meeting, the RUC recommended no changes in physician time, work RVUs, or direct PE inputs for these services. For 2024, CMS is proposing the RUC-recommended work RVU of 1.50 for code **99497** and 1.40 for code **99498**, which are the current values for these codes; and the RUC-recommended direct PE inputs without refinement.

Hyperthermic Intraperitoneal Chemotherapy (HIPEC) CPT Codes
In September 2022, 2 time-based add-on Category I CPT codes were created:

- **9X034** (Intraoperative hyperthermic intra-peritoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes)
- **9X035** (Intraoperative hyperthermic intra-peritoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; each additional 30 minutes).

During the January 2023 RUC meeting, specialty societies noted that the data reflected time estimates that were higher than the time

specified in these time-based codes. The RUC concluded the survey results for these codes were incorrect, and therefore should be resurveyed for 2025. Based on this, the RUC recommended contractor pricing and referral to the CPT Editorial Panel for revision. For CY 2024, CMS is proposing the RUC-recommended contractor pricing for codes **9X034** and **9X035**.

E/M Visits

In the MPFS proposed rule for CY 2024, CMS is addressing 2 outstanding E/M visit payment issues: implementing separate payment for the E/M visit complexity add-on payment and the definition of split (or shared visits) which was delayed for CY 2023.

E/M Visit Complexity Add-On

Prior to the E/M changes that began in 2021, CMS was not in agreement with AMA, so the agency created an add-on code to recognize complex care provided to Medicare beneficiaries not represented in the updated values. The add-on code, **G2211**: (Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. [add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established]), was proposed as part of the CY 2021 proposed rule.

After code **G2211** was established, the Consolidated Appropriations Act of 20215 put a moratorium on Medicare payment for this service by disallowing CMS from reimbursing it under the MPFS before January 1, 2024. For CY 2023, the rest of the E/M visit code families (except critical care services) were revised to match the general framework of the E/M visits, including visit level selection based on time or medical decision-making (MDM) level. Despite revisions to the Other E/M visit families in the CY 2023 final rule, CMS believed certain types of E/M visits still did not account for the complexity and resources needed to perform certain types of care.

CMS is proposing to change the code status indicator of **G2211** from "B" (bundled) to "A" (active), effective January 1, 2024. Based on feedback received, CMS is also proposing policy revisions relating to HCPCS code **G2211**, including it would not be payable when the E/M visit code is reported with payment **modifier 25** due to performance with a minor procedure. The components of the minor procedure, along with the E/M, would negate the opportunity to bill for the added complexity.

Split (or Shared) Visits

For CY 2024, CMS is proposing to again delay the implementation of its definition of "substantiative portion" as more than half of the total provider time through at least December 31, 2024. In addition, CMS is proposing to maintain the current definition of the substantiative portion that allows for use of either 1 of the 3 key components (history, exam, or MDM); or more than half the total time spent to determine the billing practitioner. The delay will also allow stakeholders more time to consider the proposals and provide feedback for future rulemaking.

Telephone E/M Services

In previous rulemaking and in response to the COVID-19 public health emergency (PHE), CMS recognized and finalized separate payment for E/M services furnished via telephone, CPT codes **99441–99443** and **98966–98968**. Codes **99441–99443** are telehealth services and will continue coverage and payment by CMS through December 31, 2024. Codes **98966–98968**, which describe telephone assessment and management by non-physician healthcare professionals, are not considered telehealth services by CMS. For CY 2024, CMS is proposing to continue payment for **CPT codes 98966–98968**, extending the telehealth-related flexibilities provided to other audio-only services covered in the Consolidated Appropriations Act of 2023.[1]

Complex Drug Administration Payments

CMS has received several comments concerning payments for nonchemotherapeutic complex drug administrations. Specifically, these payments are not in alignment with or inadequate considering the resources and costs to provide the infusion services. Stakeholders have stated these infusion services are like complex chemotherapy and other highly complex biological agent administration ("chemotherapy administration") services billed with CPT codes **96401–96549**, rather than the therapeutic, prophylactic, and diagnostic injections and infusion services CPT codes **96360–96379**.

For CY 2024, CMS is seeking comments regarding Part B drug payment policies to promote consistency in payment and patient access. CMS is gathering resources relevant to help the agency determine the appropriate coding and payments for complex nonchemo-therapeutic drug administrations. CMS is also seeking comments on whether the agency should revise policy guidelines to better reflect how specific infusion services are furnished and should be billed.

Physician Supervision Via Two-way Audio/Video

For CY 2024, CMS is proposing to extend the definition that allowance for direct supervision to be met with the use of real-time audio and video interactive telecommunications through December 31, 2024. This extension would align with the timeframe of many PHE-related telehealth policies and avoid an abrupt transition to pre-PHE policies. CMS is also seeking comments on whether the definition of direct supervision to permit virtual presence should be extended beyond December 31, 2024.

Residents in Teaching Settings

For CY 2024, CMS is proposing to allow the teaching physician to have a virtual presence in all teaching settings, but only in clinical instances when the service is furnished virtually (3-way telehealth visit, with all parties in separate locations). The proposal would permit teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service through real-time audio/video communication for all residency training locations through December 31, 2024.

New Codes for CHI, SDOH, and PIN Services

A primary focus for CMS now is related to equity in and access to care and how social determinants of health (SDOH) impact the ability to diagnose or treat the patient. As part of this focus, CMS is trying to determine how to improve payment accuracy for additional time and resources dedicated to helping patients with serious illnesses as they navigate the healthcare system or remove health-related social barriers.

CMS is proposing to create two new G codes describing Community Health Integration (CHI) services performed by certified or trained auxiliary personnel, such as a community health worker (CHW), incident to the physician services, but under general supervision. The proposal would include CHI services furnished monthly, as medically necessary, once a CHI initiating E/M visit is provided. The practitioner would need to identify the social determinants of health (SDOHs) that significantly limit their ability to diagnose or treat the problem(s) addressed in the visit.

For CY 2024, CMS is proposing a single G code to identify and value the work involved in administering a SDOH risk assessment as part of a comprehensive social history in relation to an E/M visit; this code would be furnished on the same date as the E/M. CMS is also proposing 2 principal illness navigation (PIN) services codes that would be provided under general supervision, following an initiating E/M visit addressing a serious high-risk condition/illness/disease.

HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

Payment Rates

The Outpatient Department (OPD) increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital charges. CMS proposed a 2.8 percent increase to the OPD fee schedule.
The agency estimates total payments to HOPPS providers will be approximately $88.6 billion, an increase of approximately $6.0 billion compared to CY 2023 HOPPS payments.

In July of 2023, CMS published a proposed rule referred to as the "remedy proposed rule", to address the reduced 340B Drug Discount Program payment amounts for CYs 2018 through 2022 while complying with budget neutrality. The remedy proposed rule does not offer any changes to CMS' proposed CY 2024 HOPPS drug payment policy or conversion factor but does propose changes to the calculations of the HOPPS conversion factor beginning in CY 2025. For CY 2024 CMS proposes to continue to pay the default rate, which is generally ASP+6 percent, for 340B acquired drugs and biologicals.

Cancer Hospital Payment Adjustment

CMS proposed to continue for CY 2024 the additional payments to cancer hospitals using a payment-to-cost ratio (PCR) factor. Beginning in CY 2018, the 21st Century Cures Act required the weighted average PCR be reduced by 1.0 percentage point. CMS proposed a target PCR of 0.88 to determine the CY 2024 cancer hospital payment adjustment to be paid at cost report settlement, which includes the 1.0 percent reduction; this is a decrease from recent year adjustment factors.

Payments of Drugs, Biologicals (Including Biosimilar Products), and Radiopharmaceuticals

Each year CMS assesses payments for drugs and biologicals based on current pricing methodologies, which includes payments for drugs and biologicals considered separately payable based on the assigned APC or pass-through status. For CY 2024, CMS proposed to continue the current payment policy in effect since CY 2013. Additionally, CMS indicated it does not believe the agency must continue to propose the longstanding payment policies year-after-year. Instead, only if there is a change to a policy regarding payment for drugs, biologicals (including biosimilars), and radiopharmaceuticals will the proposed policy be outlined.

The few items in which CMS is proposing new policy or payment incudes:

- CMS proposed to package drugs and biologicals estimated at a per day administration cost less than or equal to **$140**; in CY 2023 this amount was set at less than or equal to $135.
- Proposal to except biosimilars from the threshold packaging policy when their reference biologicals are separately paid. If a reference product's per-day cost falls below the threshold packaging policy, CMS has proposed that all the biosimilars related to the reference product would be similarly packaged regardless of whether their per-day costs are above the threshold.
- Proposal to simplify the process of reporting drugs purchased under the 340B Drug Discount Program by using only the **"TB" modifier** to identify drugs. Hospitals would report the **"TB" modifier** effective January 1, 2025, even if the hospital previously reported the **"JG" modifier**. In addition, the **"TB" modifier** descriptor: (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities) would be changed effective January 1, 2024, to no longer include "...for select entities" as all entities would report this modifier after this date.

Proposal to Remedy Payment Adjustment for 340B-Acquired Drugs from CY 2018 Through September 27 of CY 2022

Due to a Supreme Court ruling on the 340B Drug Discount Program, on July 7, 2023, CMS uploaded a revised payment file for HOPPS drugs to be paid at ASP+6 percent from September 28, 2022, through December 31, 2022. For CY 2023, CMS reduced the HOPPS conversion factor by 3.09 percent for budget neutrality, due to the adjustment from ASP-22.5 percent to ASP+6 percent for qualifying drug payments. The agency still needed to address and propose a plan for paying back monies from January 1, 2018, through September 27, 2022. CMS addresses this in a separate proposal from the CY 2023 HOPPS proposal; Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-

Acquired Drug Payment Policy for Calendar Years 2018-2022, CMS-1793-P.[3] In its proposal, CMS considered the following ways to remedy the needed payment adjustments.

1. Make additional payments to affected 340B covered entity hospitals for 340B-acquired drugs from CY 2018 through September 27 of CY 2022 without proposing an adjustment to maintain budget neutrality.
2. Full claims reprocessing from January 1, 2018, through September 27, 2022.
3. Aggregate hospital payments from January 1, 2018, through September 27, 2022.

CMS believes the best way to remedy the payment adjustments is to make a one-time lump sum payment to affected 340B covered entities, by calculating the difference between what they were paid for 340B drugs (ASP-22.5 percent or an adjusted wholesale acquisition cost [WAC] or average wholesale price [AWP] amount) between January 1, 2018, through September 27, 2022, and that amount that would have been paid if ASP+6 percent were applied. CMS believes this method will be easier than reprocessing clams and the burden that would create.

Approximately 1,649 340B covered entity hospitals were paid at the 340B payment rate (ASP-22.5 percent) January 1, 2018, through September 27, 2022. CMS estimates these hospitals were paid approximately $10.5 billion less than if the reduction had not been in place. These figures are expected to be updated in the final HOPPS rule as the agency continues to receive updated claims data for CY 2022, which would be claims submitted by September 27, 2023.

CMS estimates 340B providers have already received $1.5 billion in remedy payments from reprocessed claims from January 1, 2022, through September 27, 2022, reducing the overall estimated payment amount to $9.0 billion. CMS then calculated the estimated aggregate payments for 340B drugs assigned **status indicator (SI) "K"** (non-pass-through drugs and non-implantable biologicals, including therapeutic radiopharmaceuticals) and billed with **modifier "JG"** (drug or biological acquired with 340B Program

discount, reported for informational purposes), and their difference between the payment policy rates (ASP+6 percent vs. ASP-22.5 percent, or the corresponding WAC or AWP). CMS invited comments on its methodology.

To determine the amount owed to each hospital, CMS proposes to calculate how much each hospital would have been paid if the policy was ASP+6 percent, January 1, 2018, through September 27, 2022, for drugs acquired through 340B Program, minus any remedy payments already made to each respective hospital. For example, if a hospital was estimated to have been paid $10 million for 340B drugs, and with the reduced payment policy the hospital was paid $7.31 million for the 340B drugs, the difference is $2.69 million and that difference would be the lump sum payback amount.

CMS will provide instructions to the Medicare Administrative Contractors (MACs) to remit payments to the hospitals within their jurisdiction. Each MAC would have 60 calendar days to make these payments. CMS specifically asked for comments on the payback timeline.

To address beneficiary cost-sharing, CMS estimates $1.8 billion is the amount paid by beneficiaries as part of their cost sharing (co-payment) to the covered hospitals; estimated from the $9 billion total owed to 340B covered hospitals. CMS proposes 340B covered entities may not bill beneficiaries for coinsurance on remedy payments, regardless of any adjustment.

Non-drug services under HOPPS were increased from January 1, 2018, through December 31, 2022. CMS must calculate these increases to offset the remedy payments made and maintain budget neutrality. A reduction of 3.09 percent was already applied for CY 2023. To determine the amount paid for the non-drug services, CMS includes codes reported during the time in question and assigned **SI (status indicators)** of **J1, J2, P, Q1, Q2, Q3, R, S, T, U, and V**. CMS estimates the offset amount is $7.8 billion; this amount is less than the estimated remedy amount.

CMS proposes to adjust payments for services to all providers made between 2018

and 2022. This calculated impact is solely related to the 340B Program adjustment made to hospital payment policy. Beginning with CY 2025, CMS proposes to reduce all payments for non-drug items and services by 0.5 percent (applied to the conversion factor) each year until the total offset amount is reached, estimated to be 16 years. By delaying implementation by 1 year, this allows the agency to finalize the methodology, calculate and publish rates in the CY 2025 proposed rule, and allow stakeholders time to review and comment. CMS believes the 0.5 percent reduction would be less burdensome to hospitals, especially rural entities, especially when there may be other factors impacting payments over the next several years. CMS sought comments on the proposed annual percentage reduction to the conversion factor and whether a different timeline could be used to offset budget neutrality.

CMS is proposing to exclude new hospitals enrolled in Medicare after January 1, 2018, so that they are not subject to the prospective rate reduction, which is predominantly designed to offset those non-drug item and service payments made during CY 2018 through CY 2022. These hospitals would be paid with a conversion factor if no remedy payment were needed and identified per their CMS certification number (CCN) effective date. CMS has provided a list of these entities, approximately 300, in Addendum BBB of the proposed rule.

The final MPFS and HOPPS rules are expected on or before November 1, 2023. This is when providers will find out if the various payment policies and regulatory updates were finalized as proposed or something different. As for the 340B Drug Discount Program, it is likely the final rule will be released prior to the end of 2023. ◼

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References

1. Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. CMS-1784-P. Published Accessed August 30, 2023. https://public-inspection.federalregister.gov/2023-14624.pdf

2. Centers for Medicare & Medicaid Services. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction. Published July 31, 2023. Accessed August 30, 2023. https://www.federalregister.gov/documents/2023/07/31/2023-14768/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment

3. Hospital Outpatient Prospective Payment Remedy for the 340B-Acquired Drug Payment Policy- Notice of Proposed Rulemaking with Comment Period. Regulation No. CMS-1793-P. Accessed August 30, 2023. https://www.cms.gov/medicare/medicare-fee-service-payment/hospitaloutpatientpps/hospital-outpatient-regulations-and/cms-1793-p

4. Consolidated Appropriations Act of 2023, HR 2617, Pub L No. 117-328. Accessed August 30, 2023. https://www.congress.gov/bill/117th-congress/house-bill/2617/text

5. Consolidated Appropriations Act of 2021, HR 133, Pub L No. 116-260. Accessed August 30, 2023.https://www.congress.gov/bill/116th-congress/house-bill/133/text

views

10 Tips for Using RECIST 1.1 in the Community Setting

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As clinical trials coordinators in a large community-based hospital system in North Carolina, we use Response Evaluation Criteria in Solid Tumors (RECIST 1.1)[1] guidelines for evaluation of the disease state of oncology patients on clinical trials. In this article, we offer 10 tips for coordinating RECIST 1.1 at a community hospital. The information shared here is a culmination of our experience with RECIST tracking and the tool we utilize to accomplish this task. We offer this guidance to other community research programs to set them up for success, with the understanding that every research site is different and that some of the information may not apply to your specific situation.

Tip 1. Use the Same Reading Radiologist or a Core Group of Radiologists

FirstHealth of the Carolinas has approximately 20 reading radiologists. It's optimal to have dedicated staff or at least a core group of radiologists to read for consistency. Depending on your resources, this may not be possible.

Tip 2. Screening Scan: Standard of Care vs Study Specific

Always refer to the protocol; any notes and/or trainings, such as Site Initiation Training; presentations for study-specific guidelines regarding the allowed timing for standard of care imaging that may have already been performed; and whether standard of care scans are acceptable to use for the baseline screening requirement. If the scan was standard of care, the radiologist should read the scan to obtain measurements on all identified lesions. Remember to save

correspondence regarding the identified lesions as source documents.

Tip 3. Know Your Protocol

Refer to the protocol to determine how lesions will be identified and followed. While many protocols use RECIST 1.1, immunotherapy-based clinical trials sometimes use Immune Related Response Criteria (irRECIST),[2] which takes into account the additional time often needed to demonstrate response using immunotherapy treatments. There are a few differences between the 2 methods, so be sure to know which criteria the protocol uses.

Tip 4. Identify Baseline Lesions

Review lesions with the treating physician and include the lesions on a tracking tool for comparison at subsequent time points. If the treating physician is unsure of what lesions should be followed, consider asking the principal investigator for assistance. Try to use the same terminology as the imaging report to describe the lesions on the tracking tool. Remember: measurable, reproducible, and representative of overall disease burden. Refer to protocol-specific guidelines regarding use of lesions noted with prior radiation, in a surgical field, or areas that have been biopsied, as these lesions may be required to be classified as nontarget lesions.

Tip 5. Communicate Lesion (Target and Nontarget) Information to the Radiologist Ahead of Time

Take time to understand your facility and workflow. Identify a contact in the imaging department to facilitate your requests. When communicating regarding follow-up scans,

include target lesion information in the order and send an email prior to the scan to your contact in the imaging department. Include the location and image slice from previous scans, if known. Request lesions to be measured in 2 dimensions.

Tip 6. Consider Scan Timing

Understand what works best for the patient within protocol parameters. If the patient is not a "morning person," ensure that their appointments are scheduled for the afternoon to promote compliance. Scans should occur before provider visits to allow ample time to analyze and review the results. Consider obtaining scans a few days prior to avoid having to do them the day of the provider visit and/or day 1 of the treatment cycle. In some cases, getting scans after the start of a cycle may be preferred to allow for time to evaluate RECIST response. Remember, scans typically follow set schedules regardless of treatment delay.

Tip 7. Be Proactive

Check for scan results and review the results with the treating physician. This physician may or may not be the principal investigator, and this individual may not be as familiar or

comfortable with the review process. Ideally, RECIST-trained radiologists document the bidimensional measurements, including slice numbers of all target lesions and the presence or absence of nontarget lesions directly within the imaging report. Ask for clarifications or addendums from the radiologist, if necessary. If the treating physician has additional questions, contact the radiologist for clarification. We have found Epic Secure Chat to work well.

Tip 8. Patient Notification

EHR (electronic health record) patient portals release results when completed. Consequently, patients may see their results before the physician or the clinical trials coordinator. When this occurs, patients might call and want to know what the results mean. Understanding this, prepare patients and alleviate fears ahead of time. Have a conversation with patients, assure them that their care team will review the scans, and advise patients that if there is any cause for concern, someone will reach out to them.

Tip 9. Use a Tracking Tool

Make sure the tracking tool lists the protocol information. We use an Excel file that completes the basic RECIST calculation. However, understanding the calculation is critical. Overall response: percent of change is equal to the (current sum of diameters minus baseline sum of diameters) divided by baseline sum of diameters multiplied by 100. Using this formula, a negative number is a decrease and a positive number is an increase in size. Do not forget to include the nadir. If your patient is having a positive response to treatment, the nadir will likely change after each scan. Remember to change the denominator. Also remember that

progressive disease is based on a 20% increase from the nadir and at least a 5-mm increase in sum of the diameters. The tracking tool should be reviewed for accuracy and signed off by the treating physician at each assessment for demonstration of continued physician oversight.

Tip 10. Know Your Resources

These resources include the study protocol; reference articles[1,3,4]; your team members, physicians, and principal investigators; and ancillary staff in other departments. We are all in this together. Ask questions; it's how we learn. ◙

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References

1. Eisenhauer EA, Therasse P, Bogaerts J, et al. New response evaluation criteria in solid tumours: revised RECIST guideline (version 1.1) *Eur J Cancer*. 2009:45(2)228-247. doi:10.1016/j.ejca.2008.10.026

2. Somarouthu B, Lee SI, Urban T, Sadow CA, Harris GJ, Kambadakone A. Immune-related tumour response assessment criteria: a comprehensive review. *Br J Radiol*. 2018;91(1084):20170457. doi:10.1259/bjr.20170457

3. Schwartz LH, Litière S, de Vries E, et al. RECIST 1.1-update and clarification: from the RECIST committee. *Eur J Cancer*. 2016;62:132-137. doi:10.1016/j.ejca.2016.03.081

4. RECIST 1.1 Criteria Toolkit: a resource for success in clinical trials with solid tumor evaluation requirements. NRG Oncology. Published February 8, 2022. Accessed July 25, 2023. https://www.nrgoncology.org/Home/News/Post recist-11-criteria-toolkit-a-resource-for-success-in-clinical-trials-with-solid-tumor-evaluation-requirements

spotlight

Kelsey-Seybold Clinic Cancer Center, Houston, Texas

Mavis Parrott Kelsey, MD, was born in Deport, Texas, on October 7, 1912, to John Roger and Bonita Kelsey. He was named after his mother's friend, Mavis Graham, who saved Bonita's life while they were college roommates. When Bonita's mother learned what had happened, she suggested Bonita's firstborn child be named Mavis, and so it was. In a remarkable stroke of faith, Dr. Kelsey would grow up to become one of the most influential physicians of his generation and be responsible for saving countless lives. He would live to be 101 years of age, having spent the better part of a century revolutionizing health care delivery in the Houston area. His legacy lives on through the Kelsey-Seybold Clinic, which he founded in 1949.

A Legacy Built on Accessibility

Although the Kelsey-Seybold Clinic offered infusion therapy for years, the incorporation of their cancer service line did not happen until April 2015. Once established, the Kelsey-Seybold Clinic Cancer Center operated with a clear objective in mind: increasing access for patients with cancer in the greater Houston region. The primary vehicle for achieving that goal has been the strategic establishment of sites across their catchment area. "We established our main campus location with a vision to bring as many cancer specialties and services to our patients as possible, including surgeons specializing in cancer treatment as well," said Bobby Lester, senior director for Cancer Services at Kelsey-Seybold Clinic. "The goal is that 90% of

Houstonians will live within 15 minutes of our smaller clinics, and within 30 minutes of a campus."

The cancer program currently has 2 main campuses at which patients with cancer have access to oncology/hematology and radiation oncology services, as well as infusion services and a full-service pharmacy. The cancer program has 3 more smaller clinics that only offer oncology/hematology services, however, according to Lester, these sites will become hubs within the next year. "Our Fort Bend, Bay Area, and Memorial Village locations, are all undergoing large expansions," he explained. Lester credits this growth to Kelsey-Seybold Clinic Cancer Center's drive to deliver value-based care to patients close to home. "Throughout this development process, we have been working to match our offerings to the needs of residents," he said. "For our cancer services team, we are acutely aware of how difficult it can be for a patient with cancer to receive care close to their home or place of work."

The person-centered ethos the cancer program prides itself on also dictates how quickly patients are seen. According to Lester, the patients with cancer who present at the center come almost exclusively through referrals from other Kelsey-Seybold Clinic specialties. "Specialties will make an internal referral that will be managed by our nurse navigation team who then intake the patient and schedule them accordingly with our providers," Lester said. "We focus on getting patients seen as quickly as possible, with most patients being able to be seen by a physician within a week."

Delivering Comprehensive Cancer Care

The cancer program has maintained OOPI certification with a plan in the pipeline to obtain APEx accreditation. At each campus location, oncology/hematology and infusion services are in adjacent spaces while radiation oncology is located on a separate floor directly below. Infusion suites have private bays with between 18 chairs to 29 chairs. Suites are staffed by 19 registered nurses, 2 charge nurses, and 8 medical assistants. There is also a dedicated sterile compounding pharmacy, which is staffed by 11 pharmacists and 12 pharmacy technicians. According to Lester, 1 pharmacist is embedded in each infusion suite to provide patient education. Radiation oncology is staffed by 3 radiation oncologists who service both campus locations, 3 registered nurses, 2 medical assistants, 11 radiation therapists, 4 dosimetrists, and 4 physicists. While oncology /hematology includes 22 registered nurses, 3 charge nurses, 14 medical assistants, 2 oral chemotherapy registered nurses, and 11 medical doctors.

The cancer program offers a range of treatment options including external beam radiation only using photons or electrons with a range of different modalities: 3D, IMRT/VMAT, SBRT, and SRS/SRT. In addition, patients have access to surface-guided radiation therapy (SGRT), deep inspiration breath hold (DIBH), atypical partial breast irradiation (APBI), and image-guided radiation therapy (IGRT). Understanding the need to support patients as they access the cancer care continuum, the cancer program has an embedded nutritionist, and 3 social workers to service their primary locations. "We have our social workers physically at each of our locations along with the option of meeting with patients virtually," Lester said. "With our nutritionist, we currently have one that supports the cancer program, and she rotates between our 2 largest clinics with the ability to meet with patients virtually as well." The cancer program also provides patients with a prescription delivery service, as well as a transportation service.

Clinical Trials

Clinical trials are an important part of the cancer program's mission, and patients can access trials through the Kelsey Research Foundation— the Kelsey-Seybold Clinic's non-profit affiliate established in 1956. "All patients are screened for eligibility in currently available clinical trials by the Kelsey Research Foundation team members," Lester said. The Kelsey Research Foundation staff attend weekly interdisciplinary team meetings at the cancer program. As patient cases are discussed, members of the research team consider if a clinical trial would be an appropriate option for that patient, which allows for immediate discussion with the presiding physician.

The current portfolio of trials includes diagnostic studies aimed at improving early detection of cancer, therapeutic trials testing groundbreaking treatment and adjuvant therapies, and lifestyle interventions that improve recovery and reduce the risk of recurrence after successful treatment. Further, the Kelsey Research Foundation is engaged in strategic partnerships with other cancer programs to develop algorithms coupled with advanced imaging to identify and monitor those at higher risk of developing certain cancers usually diagnosed at later stages and with high mortality rates. The foundation remains committed to ensuring that clinical trials are representative of the diversity of the communities the patients they hope to treat reside within. Lester takes pride in this and other accomplishments the cancer program has managed to accomplish in a relatively brief period of time.

"I would say that we are most proud of the embodiment of our organization's strong values that have placed us a leading health care organization within the Houston market," Lester said. "These values include continuous improvement in high quality care and high patient experience, all while having strong employee engagement." Lester asserts that through the rapid growth the cancer program has maintained the same passion for delivering comprehensive and equitable cancer care. "Our model is geared toward having an engaged staff to provide high quality care, and because of our focus on access and efficiency, I think we show that we have personalized relationships and care with our patients," Lester said. That model continues to build on the legacy of a man named after his mother's hero. OI

tools

Approved Drugs

● On August 11, the US Food and Drug Administration (FDA) approved the fixed dose combination of **Akeega™ (niraparib and abiraterone acetate)** (Janssen, janssen.com), **in combination with prednisone**, for adult patients with deleterious or suspected deleterious BRCA-mutated castration-resistant prostate cancer, as determined by an FDA-approved test.

● On June 15, the FDA granted accelerated approval to **Columvi® glofitamab-gxbm** (Genentech, Inc., gene.com) for relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified or large B-cell lymphoma arising from follicular lymphoma, after 2 or more lines of systemic therapy.

● On August 14, the FDA granted accelerated approval to **Elrexfio® (elranatamab-bcmm)** (Pfizer, Inc., pfizer.com) for adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

● On August 9, the FDA approved **Gavreto® (pralsetinib)** (Genentech, gene.com) for adult patients with metastatic rearranged during transfection fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

● On August 14, the FDA approved **Hepzato® (melphalan)** (Delcath Systems, Inc., delcath.com) as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extra-hepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation.

● On July 31, the FDA approved **Jemperli® (dostarlimab-gxly)** (GSK, gsk.com) **in combination with carboplatin and paclitaxel** followed by single-agent **dostarlimab-gxly** for primary advanced or recurrent endometrial cancer that is mismatch repair deficient, as determined by an FDA-approved test, or microsatellite instability-high.

● On August 2, the FDA approved **Lonsurf® (trifluridine and tipiracil)** (Taiho Oncology, Inc., taihooncology.com) **in combination with bevacizumab**, for metastatic colorectal cancer previously treated with fluoro-pyrimidine, oxaliplatin and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.

● On June 20, the FDA approved **Talzenna® (talazoparib)** (Pfizer, Inc., pfizer.com) **in combination with enzalutamide** for homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer.

● On August 9, the FDA granted accelerated approval to **Talvey® (talquetamab-tgvs)** (Janssen, janssen.com), for adults with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

● On July 20, the FDA approved **Vanflyta® (quizartinib)** (Daiichi Sankyo, Inc., daiichisankyo.com) with standard **cytarabine and anthracycline induction and cytarabine consolidation**, and as mainte-nance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia that is FLT3 internal tandem duplication-positive, as detected by an FDA-approved test.

Drugs In the News

● BeiGene (beigene.com), announced the FDA has granted a supplemental new drug application (NDA) for **Brukinsa® (zanubrutinib) in combination with obinutuzumab** for the treatment of adult patients with relapsed or refractory follicular lymphoma after at least 2 prior lines of therapy.

● Actuate Therapeutics, Inc. (actuate-therapeutics.com) announced that the FDA has granted orphan drug designation for **elraglusib** for treatment of patients with pancreatic cancer.

● Geron Corporation (geron.com) announced the submission of an NDA to the FDA for **imetelstat** for the treatment of transfusion-dependent anemia in adult patients.

- GSK (gsk.com) announced that the FDA has extended the review period of the NDA for **momelotinib** by 3 months to provide time to review recently submitted data. The extended action date is 16 September 2023.

- Ipsen (Ipsen.com) announced that the FDA has accepted its supplemental NDA for **Onivyde® (irinotecan liposome injection)** plus 5 **fluorouracil/leucovorin and oxaliplatin** as a potential first-line treatment for metastatic pancreatic ductal adenocarcinoma.

- Kazia Therapeutics Limited (kaziatherapeutics.com) announced the FDA granted fast track designation to **paxalisib** for the treatment of solid tumor brain metastases harboring PI3K pathway mutations in combination with radiation therapy.

- Genprex, Inc. (genprex.com) announced that the FDA has granted fast track designation to **Reqorsa®** immunogene therapy, in combination with Genentech's (gene.com) **Tecentriq®** in patients with extensive-stage small cell lung cancer who did not develop tumor progression after receiving Tecentriq and chemotherapy as initial standard treatment.

- Elevar Therapeutics (elevartherapeutics.com) announced that the FDA accepted an NDA for **rivoceranib in combination with camrelizumab** as a first-line treatment option for unresectable hepatocellular carcinoma.

- Servier (Servier.com) announced the FDA has accepted a supplemental NDA and granted priority review for **Tibsovo® (ivosidenib tablets)** in the treatment of patients with isocitrate dehydrogenase 1 (IDH1)-mutated relapsed or refractory myelodysplastic syndromes.

- Merus N.V. (www.merus.nl) announced that the FDA has granted breakthrough therapy designation for **zenocutuzumab** for the treatment of patients with advanced unresectable or metastatic NRG1 fusion (NRG1+) pancreatic cancer following progression with prior systemic therapy or who have no satisfactory alternative treatment options.

- Astellas Pharma Inc. (astellas.com) announced that the FDA has accepted and granted priority review for the company's biologics license application (BLA) for **zolbetuximab**, for first-line treatment of patients with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma whose tumors are Claudin 18.2-positive.

Approved Diagnostic Tests and Assays

- On August 14, the FDA approved **FoundationOne®CDx** (Foundation Medicine, foundationmedicine.com) to be used as a companion diagnostic for **Akeega™** (niraparib and abiraterone acetate) (Janssen, janssen.com), which was approved by the FDA for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated castration-resistant prostate cancer. **OI**