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Collaborative Care:
A Model for Embedding
Counseling in Oncology
and Palliative Care





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Collaborative Care: A Model for Embedding Counseling in Oncology

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By Earon Lehning, LCSW

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FROM THE EDITOR ······

Charting Our Course: Rebranding, ACCC 50th Anniversary, and Growing Our Community

BY MARK LIU, MHA



hange is upon us in this new year at ACCC, and it brings a renewed sense of purpose and unity. In my first column of 2024, I am thrilled to share the culmination of multiple efforts in ACCC's rebranding, marking a significant

milestone in our association's history. Our new identity, the **Association of Cancer Care Centers**, reflects the entire cancer care community and underscores how the Association represents cancer centers of all shapes and sizes in our mission to serve and support all those affected by cancer. You can read more about the strategic planning and decision-making behind our name change and rebrand in the "Action" column in this *Oncology Issues*.

2024 is also the year that ACCC turns 50 years old. As we celebrate our 50th anniversary, I find myself reflecting on the journey we've taken together and the remarkable achievements we've been a part of. An interactive timeline on the ACCC 50th anniversary webpage highlights the critical role the Association has played in supporting cancer care teams and improving patient outcomes. This resource not only chronicles the pivotal moments in our organization's history but also serves as a testament to the dedication and hard work of each member of our community. From pioneering initiatives to groundbreaking research, every milestone is a testament to our collective impact in the fight against cancer. ACCC's commitment has remained steadfast throughout the years, driving us to continually evolve and innovate for the oncology community as a whole.

On the personal front, my years engaging and volunteering with ACCC have been profoundly rewarding. Whether it's through educational programs, advocacy efforts, or collaborative projects, each of us plays a vital role in shaping the future of cancer care delivery. Contributing to ACCC has given me so much perspective on how cancer care is delivered in all the different settings across the

country, an appreciation of our commonalities (and differences), and an understanding of our shared passion to provide the best care for patients and their circles of support. For me, ACCC has made an already rewarding career in oncology even more purposeful.

As ACCC celebrate its 50th anniversary, we have set an ambitious goal to reach 50,000 individual cancer care professionals at our member programs and practices, as well as our chapter members, by the end of this milestone year. Achieving this target will not only strengthen our community but also enhance our ability to advocate for policies that support cancer care teams and patients. To help us succeed in this endeavor, I encourage you to send in your staff rosters—with emails—to ACCC's membership director, Nicole Banks at nbanks@accc-cancer.org. Sharing this information allows your colleagues to benefit from critical education and resources, like Oncology Issues.

In closing, I want to express my gratitude to all of you for your unwavering support and dedication. Together, we have achieved remarkable progress, but our work is far from over. As we look to the future, let us continue to collaborate, innovate, and advocate for positive change in cancer care. Happy Anniversary ACCC. Here's to another 50 years!

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Legacy of Upskilling: Building the Future of Oncology Care

OLALEKAN AJAYI, PHARMD, MBA



s I conclude my term as ACCC president, I cannot help but reflect on the journey we've undertaken together, a journey dedicated to one crucial mission: building a future-proof

oncology workforce.

Cancer care is on the cusp of a revolution. New technologies like precision medicine, immunotherapy, and artificial intelligence are transforming how we diagnose, treat, and manage cancer. However, these advancements are only as effective as the people who wield them. That's where workforce development and upskilling come in, and that has been the cornerstone of my presidential theme.

We began with a simple yet powerful premise: the future of oncology care lies in the hands of a skilled, adaptable, and passionate workforce. We recognized the need to equip our professionals with the knowledge and tools to navigate the ever-evolving landscape of cancer research and treatment.

Our efforts have taken many forms. We launched comprehensive training programs focused on emerging technologies and evidence-based practices. We championed the development of specialized certifications to recognize and reward expertise in specific areas. We fostered collaborations with academic institutions to create seamless pathways for new talent to enter the field.

But our work was not limited to technical skills. We understood the importance of soft skills like communication, collaboration, and cultural competency. We invested in leadership training programs to empower our professionals to navigate complex situations and inspire their teams. We promoted mentorship programs to foster knowledge transfer and create a supportive network for all.

The results have been inspiring. We've seen a surge in participation in our training programs, with professionals eager to embrace new knowledge and skills. We've witnessed improved patient outcomes as our workforce adopts

cutting-edge practices. And perhaps most importantly, we've fostered a culture of continuous learning and innovation within our organization.

However, our work is far from over. The landscape of oncology care continues to evolve at a rapid pace, demanding even greater adaptability and agility from our workforce. As I pass the torch to the next president, I urge you to continue building on the foundation we've laid.

Here are some key areas for continued focus:

- Embrace personalized learning: Develop tailored training programs that cater to individual learning styles and career aspirations.
- Invest in digital learning platforms: Leverage technology to make learning accessible, engaging, and readily available.
- Promote lifelong learning: Cultivate a culture where continuous learning is valued and encouraged.
- Prioritize diversity and inclusion: Ensure that our workforce reflects the communities we serve and that everyone has equal access to opportunities for growth.
- Collaborate with industry partners: Partner with pharmaceutical companies, technology providers, and other stakeholders to develop innovative training solutions.

We are building a future of oncology care that rests in the hands of a workforce that is not just skilled, but exceptional. A workforce that is ready to tackle the challenges of tomorrow and deliver hope and healing to patients everywhere.

I am proud to have served as your president and to have played a role in shaping this legacy. Let's continue to work together, build upon our successes, and ensure that the future of oncology care is brighter than ever. Remember, the future is not something that happens to us; it's something we create. Let's create a future where every patient has access to the best possible care, delivered by the most skilled and compassionate professionals.

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Collaborative Care

A Model for Embedding Counseling in Oncology and Palliative Care





n 2018, officials at Rochester Regional Health Lipson Cancer Institute became increasingly aware that its growing program did not have enough social work resources to meet patient needs. There were only 3 social workers across the 6 clinic locations. Although medical providers were able to meet patients' physical needs, the cancer care team recognized an existing gap in addressing care for the whole person. Given the impact a cancer diagnosis has on many aspects of an individual's life, addressing these concerns became a priority. As a result, Lipson Cancer Institute began to investigate opportunities to expand social work support at the cancer program. Among the options our team explored was the existing outpatient social work program at the larger Rochester Regional Health system and, more specifically, the collaborative care program embedded in the primary care and obstetrics and gynecology (OB-GYN) clinics. Our leadership team identified that this program had the potential to be a financially sustainable solution. Building a collaborative care program in oncology would provide the financial infrastructure to allow the cancer program to expand its services and address many of the behavioral health needs of our patients.

The Need for Integrated Behavioral Health

Following a cancer diagnosis, patients are more vulnerable to mood disorders including depression, anxiety, and posttraumatic stress disorder. Additionally, patients struggle with grief on the impact that the disease has on their lives. Further, the uncertainty that accompanies a new cancer diagnosis could exacerbate underlying mental health conditions or potentially create new concerns. Research tells us that depression is one of the leading causes of disability and, in conjunction with cancer or other chronic diseases, is associated with reduced quality of life for patients as well as an increase in health care costs.¹ Among patients with cancer, clinical depression impacts around 10% of individuals and the prevalence of anxiety at a clinically significant level is around 13%.2 In addition, patients diagnosed with a rare cancer experience higher levels of anxiety when compared to patients with more common cancer diagnoses.³ Furthermore, anxiety is associated with poor adherence to cancer treatments, a decrease in the ability to complete activities of daily living, and an increase in pain and fatigue.4 These data demonstrate a clear need for behavioral health care for individuals with cancer.

For Lipson Cancer Institute providers, an embedded mental health program gives a clear, linear referral path. Providers know that once a referral is made, a social worker will reach out to the patient and talk about treatment options.

A simple solution may seem be to refer patients to an outpatient mental health provider, therapist, or support group. Unfortunately, this option is often not viable. We know that 30% to 50% of patients referred to outpatient mental health treatment never reach an intake appointment with a behavioral health provider. Barriers to engaging with behavioral health may include patient difficulties accessing the support, insurance coverage, stigma, and mental health provider shortages. Understanding this, Lipson Cancer Institute decided to establish a collaborative care program (based on the outpatient social work model discussed above) where support would be incorporated within the cancer program.

Why Collaborative Care?

Collaborative Care is a model for providing behavioral health care that was developed at the Advancing Integrated Mental Health Solutions (AIMS) Center at the University of Washington to address common mental health conditions in a medical setting. The name, Collaborative Care, is more than just a term for working together in an interdisciplinary model. This model of care embeds mental health treatment within the primary care physician's clinic and focuses on behavioral health conditions such as depression, anxiety, and post-traumatic stress disorder; collaborative care combines the knowledge and experience of several different disciplines to help individual patients move forward with their lives. It creates a team for the patient and their provider by pairing them with a therapist or social worker, oncologist, and psychiatric consultant. As Rochester Regional Health Continued on page 7



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Continued from page 5

was already successfully using Collaborative care in the primary care and OB-GYN setting, Lipson Cancer Institute was able to easily adapt this model. The model creates a bridge that addresses gaps in care for patients without the need to refer outside the cancer program.

The Model

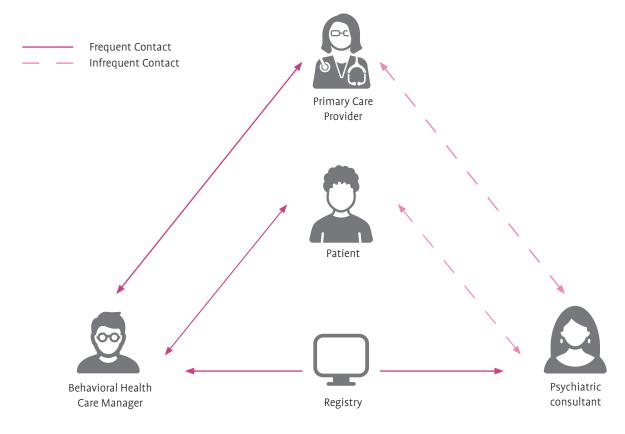
Collaborative Care includes 5 components: a patient-centered care team, population-based care, measurement-based treatment to target, evidence-based care, and accountable care. At enrollment, the care team works in partnership with the patient to develop a plan of care. Secondly, the care team tracks patients to ensure no individual falls through a gap and that treatment needs are uniquely tailored. Patient treatment and clinical outcomes are measured through validated tools such as the Patient Health Questionnaire (PHQ-9) and the General Anxiety Disorder-7 (GAD-7). Each patient is provided care through a model of treatment that is backed with researched evidence of success for their mental health diagnosis. These may include problem-solving treatment, behavioral activation, motivational interviewing, cognitive behavioral therapy, and/or medication management. Providers are accountable for their care and reimbursed on clinical outcomes not just volume of care.

The efficacy of the Collaborative Care model for behavioral health care has been established in over 90 randomized controlled trials.^{5–7} Results of a clinical trial of patients with comorbid depression and cancer showed that treatment with Collaborative Care was associated with statistically significant better depression outcomes.⁴ This study found that over 60% of people showed improvement when enrolled in the Collaborative Care model, compared with 17% of people enrolled in traditional behavioral health models.

Collaborative Care at Lipson Cancer Institute

For Lipson Cancer Institute providers, an embedded mental health program gives a clear, linear referral path. Providers know that once a referral is made, a social worker will reach out to the patient and talk about treatment options. Most patients are contacted within a few days of referral if not the same day. Our referral data shows that 8 in 10 patients who are referred to Collaborative Care are scheduling an intake appointment, and around half are choosing to enroll in the program once that intake is completed. Additionally, patients typically can schedule an intake within 1–2 weeks from their initial referral. Individuals who do not enroll may not qualify either due to a low clinical indication for behavioral health support or a need for a higher level of care than this model supports. In either

Figure 1. The Relationship Between the Patient and Their Care Team Under the Collaborative Care Model



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case, the social work team works to connect patients to services they need. Patients who may need a higher level of care include individuals who are actively suicidal or have diagnoses such as schizophrenia or bipolar disorder. In these cases, therapists provide bridge counseling to ensure patients are connected with the appropriate level of support and often meet with patients until they have completed an intake appointment with the requisite service. This support can be particularly helpful when community mental health clinics have long wait lists for intake appointments. Therapists also provide information on community resources, such as support groups, to individuals who may need additional support but do not meet clinical criteria for enrollment.

Treatment is individualized to each patient, allowing for flexibility based on each patient's situation. Once referred to the Collaborative Care program, patients can choose to enroll for talk therapy, brief check-ins, or medication management. These options are addressed over the first few intake appointments while treatment plans are being developed. Patients also have the option to receive support through a variety of modalities including in-person or virtually through telehealth and video visits. Lipson Cancer Institute patients report deep appreciation for this flexibility. At enrollment, this convenience removes the barrier of finding services and waiting for referrals while providing faster access to care. Further, the model provides continuity of care to patients while undergoing treatments. For example, patients may choose to switch an appointment from in-person to telehealth while they are recovering from surgery, chemotherapy, or other procedures. Once established in care, patients work with their therapist to create a schedule that best fits their needs.

After enrollment, all patients are reviewed by the program's psychiatric consultant. The consultant is available to anyone on the patient's care team, including oncologists, to provide recommendations regarding psychotropic medications as needed. The treatment team works to clarify goals and verify that enrolled patients are moving in the right direction. As patients reach their behavioral health goals, the therapist continues to strategize with patients to prevent a relapse in symptoms and plan for discharge from the program. Figure 1 illustrates the relationship between the patient and their care team under the Collaborative Care model.

Collaborative Care Is Fiscally Sustainable

As Lipson Cancer Institute began investigating solutions for closing the identified gap in care, our team was also looking for a financially sustainable solution. Our implementation team worked with the Rochester Regional Hospital's Outpatient Social Work Department to learn more about the Collaborative Care program that had been successfully implemented in the primary care and OB-GYN clinics. Since Collaborative Care is a billable model of service, we were able to develop a business plan that included additional staff to provide therapy services, expert training for the staff, and management support for program development. Lipson Cancer Institute administration worked closely to train a new supervisor in the Collaborative Care program, build the technical infrastructure that was needed for documentation and billing, and educate providers about this new service for patients that would be submitted to insurance under their

Since Collaborative Care is a billable model of service, we were able to develop a business plan that included additional staff to provide therapy services, expert training for the staff, and management support for program development.

credentials. The revenue stream provided by implementing this model makes the program sustainable after the initial ramp up period required to reach consistent patient volumes. Rochester Regional Hospital's Collaborative Care program has an average reimbursement rate of approximately \$111 per member per month. In addition to the direct revenue generated by the program, studies around Collaborative Care have shown positive economic outcomes regarding averted health care and productivity loss as well as reduced health care utilization. One study found that individuals participating in Collaborative Care had 114 additional depression free days compared to traditional treatment, as well as a savings of \$594 in outpatient health care costs. 11

The national recommendation from the AIMS Center is to carry a caseload of between 60 to 100 patients in a standard Collaborative Care program. Lipson Cancer Institute chose to create a program with a more therapeutic emphasis due to the nature of our population and the availability of alternative mental health supports in our community and, as such, set a caseload expectation at 70 patients. This caseload gives therapists the availability to provide specialized care to our patients with cancer while participating in weekly supervision, weekly consultation meetings, and frequent specialized training to stay abreast of both mental health training and oncology-related training.

Lessons Learned

The creation of the Collaborative Care program at Lipson Cancer Institute has addressed some of the identified needs of our program and we have learned lessons along the way. These include the following:

- It is vital to have physician supporters to champion the Collaborative Care program when starting up.
- Ongoing education for the whole treatment team is necessary when launching—both for educational purposes and for program visibility.
- Standing education about Collaborative Care for new team members plays a role in the program's ongoing success.
- Collaborative Care meets many of the needs of our patients, however, we need additional treatment options for patients who do not qualify for Collaborative Care or who have reached the maximum that insurance will allow.

Implementing a Collaborative Care program at Lipson Cancer Institute has bridged a gap in care that our team identified in 2018. We are hopeful that we will continue to innovate to address our patients' needs in the future.

Earon Lehning, LCSW, is a Collaborative Care therapist at Rochester Regional Health – Lipson Cancer Institute, Rochester, New York.

References

- 1. Moussavi S, Chatterji S, Verdes E, Tandon A, Patel V, Ustun B. Depression, chronic diseases, and decrements in health: results from the World Health Surveys. *Lancet*. 2007;370(9590):851-858. doi:10.1016/S0140-6736(07)61415-9
- 2. Sakamoto R, Koyama A. Effective therapy against severe anxiety caused by cancer: a case report and review of the literature. *Cureus*. 2020;12(6):e8414. doi:10.7759/cureus.8414
- 3. Bergerot CD, Bergerot PG, Philip EJ, et al. Assessment of distress and quality of life in rare cancers. *Psychooncology*. 2018;27(12):2740-2746. doi:10.1002/pon.4873
- 4. Sharpe M, Walker J, Holm Hansen C, et al. Integrated collaborative care for comorbid major depression in patients with cancer (SMaRT Oncology-2): a multicentre randomised controlled effectiveness trial. *Lancet*. 2014;384(9948):1099-1108. doi:10.1016/S0140-6736(14)61231-9
- 5. Fisher L, Ransom DC. Developing a strategy for managing behavioral health care within the context of primary care. *Arch Fam Med*. 1997;6(4):324-333. doi:10.1001/archfami.6.4.324

- 6. Archer J, Bower P, Gilbody S, et al. Collaborative care for depression and anxiety problems. *Cochrane Database Syst Rev.* 2012;10:CD006525. doi:10.1002/14651858.CD006525.pub2
 https://www.cochrane.org/CD006525/DEPRESSN_collaborative-care-for-people-with-depression-and-anxiety
- 7. Gilbody S, Bower P, Fletcher J, Richards D, Sutton AJ. Collaborative care for depression: a cumulative meta-analysis and review of longer-term outcomes. *Arch Intern Med.* 2006;166(21):2314-2321. doi:10.1001/archinte.166.21.2314
- 8. Panagioti M, Bower P, Kontopantelis E, et al. Association between chronic physical conditions and the effectiveness of collaborative care for depression: an individual participant data meta-analysis. *JAMA Psychiatry*. 2016;73(9):978-989. doi:10.1001/jamapsychiatry.2016.1794
- 9. Carlo AD, Drake L, Ratzliff ADH, et al. Sustaining the collaborative care model (CoCM): billing newly available CoCM CPT codes in an academic primary care system. *Psychiatr Serv.* 2020;71(9):972-974. doi:10.1176/appi.ps.201900581
- 10. Jacob V, Chattopadhyay SK, Sipe TA, et al. Economics of collaborative care for management of depressive disorders: a community guide systematic review. *Am J Prev Med.* 2012;42(5):539-549. doi:10.1016/j. amepre.2012.01.011
- 11. Katon W, Russo J, Lin EHB, et al. Cost-effectiveness of a multicondition collaborative care intervention: a randomized controlled trial. *Arch Gen Psychiatry*. 2012;69(5):506-514. doi: 0.1001/archgenpsychiatry.2011.1548

An Advanced **Practice Radiation** Therapist Role Helps This Cancer Program Reach **New Heights:** Improving Quality, Efficiency, Wellness, and **Outcomes**



he radiation therapy workforce, a cohort of highly skilled oncology personnel trained both technically and clinically, has experienced an increasingly robust role among the multidisciplinary radiation oncology team. Complex patient care needs and technological advancements have increased the radiation therapists (RTTs) scope of practice for decades. RTTs deliver daily therapeutic doses of radiation and thus provide care to patients more frequently than any other discipline within the daily operations of radiation oncology practice. These professionals are also uniquely positioned to have a significant impact on the quality of care provided.

In recent years, the Department of Radiation Oncology at the Mount Sinai Health System in New York, New York, encountered growing inefficiencies and challenges related to an increasing palliative inpatient population and complex inpatient workflows. This situation was made more complex by rising clinician burnout and the need for quality care improvements to meet the demands of value-based health care. The effort to implement new workflows for improving care and achieving cost savings resulted in a novel solution, which demanded a specific technical and clinical skill set. International

models had already demonstrated that improving the training, education, and intellectual capital of RTTs to an advanced practice level can address gaps in care and improve clinical and operational outcomes.¹ Among others, the United Kingdom and Canada have established models that increase efficiency, decrease costs, and retain skilled staff through the introduction of the role of an advanced practice radiation therapist (APRT).²-5 In this article, Mount Sinai shares its experience from initial inception to implementation of the first APRT role in the United States to provide a better model of inpatient care, elevate the role of the radiation therapist, and improve quality, efficiency, wellness, and administrative outcomes.

Current Drivers and Challenges

Modern health care delivery faces patient-related, technological, social, and financial challenges (Table 1). Perhaps the most critical of these challenges is the ever-increasing cost of health care. The Peter G. Peterson Foundation indicates that the US has the highest cost of health care in the world, climbing to nearly 20% of the gross *Continued on page 13*

Table 1. Health Care Delivery Drivers and Challenges		
DRIVERS	CHALLENGES	
Technological	 Artificial intelligence integration Fast adoption speed of new technologies (MRI Linac, proton therapy) 	
Patient Requirements	Oligometastatic state Increasing complexity and subspecialization	
Financial	Reimbursement and resource reductions Quality and efficiency in value-based care	
Social	Physician shortage and burnout COVID-19 workforce impact	

APRT, advanced practice radiation therapist.

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domestic product.⁶ Further, many manual and time-consuming health care delivery workflows are inefficient and outdated. Time is wasted on managing billing, insurance, and prior authorization processes, as well as allocating resources on inefficient processes. On the horizon, payer models will continue to change, particularly in radiation oncology, where the industry is preparing for more bundled payments and will be held accountable for reducing costs and improving efficiency with fewer resources.⁷

An APRT is a RTT who, through training and education, possesses the knowledge, elevated skills, and judgment to provide a higher level of care within the radiation oncology department—impacting quality care and physician practice.⁵

The COVID-19 pandemic has added stressors to health care delivery, particularly impacting the workforce. There are frontline health care worker shortages across the industry, and clinician—and staff—burnout is rapidly increasing.8 Currently, nursing and physician burnout rates are at 55% and nonclinical staff at 47%.9 Employee turnover in hospitals is at 20% and even higher in nursing homes. 10 Additional workforce shortages create ongoing care delivery challenges across provider specialties within oncology. Given these current obstacles, radiation oncology residency programs may struggle to fill their spots and the radiation therapy workforce already experiences a vacancy rate of 11%, as indicated for the fourth consecutive time in a national workplace survey conducted by the American Society of Radiologic Technologists. 11,12

Meanwhile, new technologies are being adopted at an increasingly rapid rate. The integration and impact of artificial intelligence (AI) in health care is mostly unknown, even as new equipment and treatment approaches, such as proton therapy or adaptive technologies, such as (magnetic resonance imaging) MRI-Linac, equip the radiation oncology industry with new tools to create improved treatment options for patients. Optimizing these new technologies requires innovative care approaches that utilize the appropriate skill set of the right individual at the right time within the multidisciplinary team.

As cancer incidence in the US continues to increase, so does the complexity of care. Under the oligometastatic state (an intermediate stage of cancer between localized and widely spread disease), patients are living longer with their disease. ¹² Approximately half of all cancer cases in the US are treated with radiation therapy. ¹³ A drive toward subspecialization affects the multidisciplinary team—not just physicians. Considering this growing demand, health systems have a responsibility to improve processes, increase efficiency, and reduce administrative waste while maintaining quality and improving the patient experience. The current state is not sustainable.

Advanced Practice Radiation Therapy

RTTs hold a distinct clinical and technical skill set that supports patients daily throughout their course of treatment. An APRT is a RTT who, through training and education, possesses the knowledge, elevated skills, and judgment to provide a higher level of care within the radiation oncology department—impacting quality care and physician practice. International literature, rooted in evidence-based practice, demonstrates that elevating the existing skill set of RTTs through education and competency to provide interventions at key points along the radiation oncology care pathway can improve access, quality, and efficiency (Table 2). ²⁻⁴ The majority of research on APRT effectiveness originates from the UK (35%), Canada (31%), and Australia (18%) (Figure 1). Many studies address the feasibility of the APRT role, and show clinical practice outcomes, task congruence with other disciplines, and role evaluation and development. International care models are often site-specific or dedicated to a patient

Table 2. International APRT Clinical and Operational Outcomes		
CLINICAL OUTCOMES	OPERATIONAL OUTCOMES	
Enhanced patient care	Enhanced capacity and improved resource utilization	
Streamlined palliative care	Improved quality	
Improved treatment outcomes	Cost-effectiveness	
Expedited and/or better access to care	Enhanced service development	
Higher patient satisfaction and/or better patient experience	Increased knowledge dissemination	

^{*} APRT, advanced practice radiation therapist.

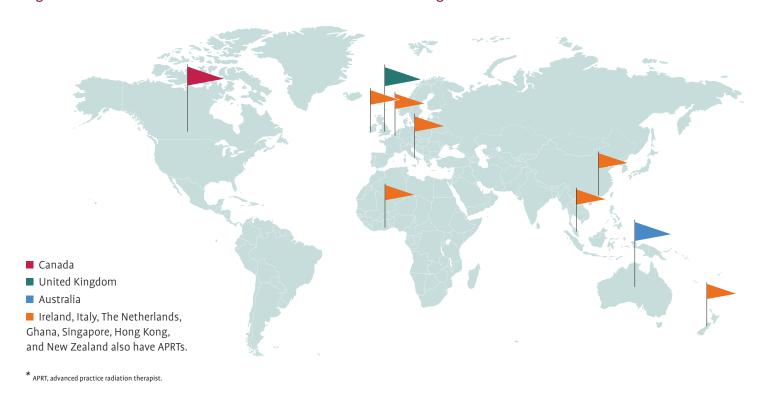


Figure 1. Global Illustration of APRT* Research and Publication Origin

population such as palliative, breast, brachytherapy, pediatrics, or head and neck^1

The European Society for Therapeutic Radiotherapy and Oncology (ESTRO) recognizes the APRT as "an advanced practitioner who works outside their standard of practice and demonstrates expert practice in a specialized area by autonomously taking on a leadership role in the development of radiotherapy services, and research associated with their specialty." Task shifting is often the mechanism to which this is done, or the rational redistribution of tasks among health care teams. Task shifting allows for service reconfiguration, enhancing physician practice, and most importantly, improving patient care within much needed patient cohorts such as the palliative inpatient population.

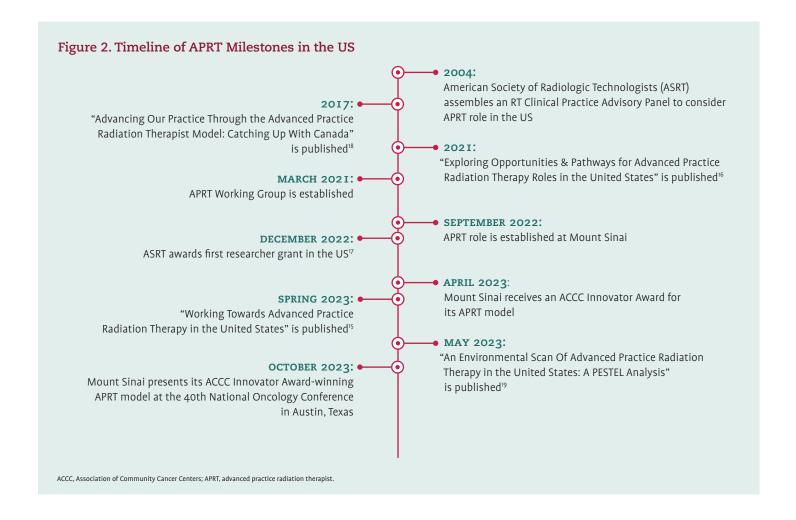
Advancing the RTT profession in the US toward advanced practice has lagged compared with international counterparts. However, clinical and educational frameworks are being developed and a growing body of literature is being established. Figure 2 illustrates a timeline of current APRT initiatives in this country.

The Advanced Practice Radiation Therapy Working Group was established in 2021 and is a grassroots group of multidisciplinary radiation oncology professionals located across the nation, interested in studying and establishing the APRT role in the US. 15 Those participating recognize the value of the APRT in enhancing the quality and advancement of clinical care. The group seeks to establish an evidence-based consensus on the APRT role definition and determine the appropriate credentialing mechanism to support the uniform

implementation of advanced practice radiation therapy with a focus on improving patient outcomes and ensuring career progression and retention for radiation therapists in the field. In 2021, the US became part of the international APRT conversation through a publication in *TipsRO*. ¹⁶ The article outlines the opportunities under the current US health system infrastructure, noting challenges and a pathway for implementation through evidence-based practice.

In 2022, the radiation therapy team at the Mount Sinai Health System was awarded a research grant from the American Society of Radiologic Technologists (ASRT) Foundation to study the implementation of the APRT model in the US for the first time which represented a hallmark of their efforts.¹⁷ In May of 2023, a collaborative publication from authors in the working group titled "An Environmental Scan of Advanced Practice Radiation Therapy in the United States: A PESTEL (Political, Economic, Sociological, Technological, Legal and Environmental) Analysis" was published in the International Journal of Radiation Oncology-Biology-Physics. The publication analyzes the current landscape under a PESTEL framework, identifying that as "patients enter different stages of their disease, the purpose of a new model is to provide individuals with the right care, at the right time, by the right team, in the right place. It is clear that the opportunity for positive change and impact on the current state of practice in radiation oncology exists."19

While work is being done in the US to solidify a national model, much can be learned from international colleagues. The most wellestablished framework was developed by the National Health Service



in the UK. The multiprofessional framework for advanced practice was developed for RTTs, diagnostic radiographers, and nurses that were practicing at a higher level. This framework includes 4 pillars for effective advanced practice: clinical practice, leadership and management, education, and research. Canadian colleagues and advisors encourage the US working group participants to study the implementation and effectiveness of advanced practice on evidence-based inquiries such as:

- Could APRTs contribute to a new model of care that could add effectiveness and efficiency to the existing model of care?
- What works well and what does not within our existing model of care and what do we propose would work better?
- Where are our pain points and where could an APRT help?
- Does the new model save the system money, improve patient experience, and enhance outcomes and/or provider experiences?

When comparing the existing RTT skill set to the APRT skill set, one can envision elevating various duties to function at a higher level. For example, education, training, and competence can provide opportunities in areas such as patient assessment, treatment planning, treatment imaging and delivery, and education, among others (Table 3).

Until recently, there has been no path in the US for RTTs to advance

clinically beyond the senior or lead RTT position. This scenario is problematic as highly skilled staff may leave the field to advance their careers. Career progression opportunities, staff retention strategies, and the need to continuously advocate for the role of the RTT against encroachment further echo the need for APRTs in the US. Therefore, establishing a clinical advancement career pathway for the RTT provides a solution to enhance care, increase staff retention, and redesign existing models of care.

The Mount Sinai Experience

Serving a high-volume, diverse patient population in New York, Mount Sinai Hospital's Department of Radiation Oncology provides inpatient radiation services to a large cohort of patients annually. The radiation oncologists are assigned to the inpatient service on a rotational basis; depending upon multiple factors, these radiation oncologists may have several inpatient consultations that can take an increasing amount of time in their practice. Frequently, oncology patients may be referred for inpatient radiation treatment without a complete understanding of treatment complexities by the referring physicians. Patients and their families often require in-depth education regarding treatment and available options. Patient length of stay is often closely examined for acute care patients, with several complex care delivery challenges in

Table 3. Examples of RTT and APRT Skills Comparison		
	RTT	APRT
Patient assessment	Monitors patients throughout treatment, recognizes patients' needs, and escalates for intervention.	Assesses patient ability to complete simulation and treatment, interviews patient for medical history, and analyzes and reports out findings to radiation oncologist to inform clinical decision-making.
Treatment planning	Checks treatment plan or calculation, compares images and makes adjustments, reviews discrepancies, and assists with action plan.	Performs calculation, reviews treatment plan with radiation oncologist to inform treatment process, reviews discrepancies and establishes action plan, contours OARs, and provides clinical mark-up.
Treatment imaging and delivery	Reviews images and makes shifts accordingly for radiation oncologist approval.	Provides initial image review and observations, performs initial isocenter placement for simulation, participates in adaptive treatment decision-making.
Education	Provides instruction to radiation therapy students and educates patients on treatment course, skin care, etc	Trains and mentors radiation therapy leadership, educates medical residents in area of expertise, conducts patient and family education.

APRT, advanced practice radiation therapist.

play, including socio-demographic issues, transportation access, and a lack of caregivers to assist the patient during their cancer care. Patients may be admitted longer than necessary due to a referral for radiation treatment. In some cases, providers may fear that if the patient is discharged, they will not return for the remainder of their required treatments, prolonging their length of stay.

Caring for patients with advanced cancer needing urgent, timesensitive radiation therapy can exacerbate the stress on the multidisciplinary team. Determining if an inpatient will benefit from radiation

Figure 3. APRT Role Development Framework

Describe the position

Identify problems it will solve

Define departmental structure

Develop strategic goals

Measure outcomes

APRT, advanced practice radiation therapist.

depends on their prognosis and on whether they complete the course of treatment.²⁰ Dependent upon the type of treatment, patients may have difficulty completing simulations and/or treatment due to appropriate workup, treatment complexity, comorbidities, pain, and other factors. Given these variables and in response to several near misses in the department, Mount Sinai Radiation Oncology recognized a need to identify a solution that would create a better model for the inpatient population that reduced the cost of care, improved the quality of care, and increased workflow efficiency for both the patients and the providers. A process mapping exercise on the existing model identified several gaps in care:

- 1. Better continuity of care at multiple stages in the inpatient process
- 2. The implementation of a new, safer inpatient workflow including daily inpatient orders from the frontline provider
- 3. Better communication and documentation between the inpatient providers and radiation oncology providers on the patient's plan of care
- 4. Quality improvement related to successful simulations and treatment courses.

In a unique position, the clinical manager and RTT in the department completed an international master's degree in advanced clinical practice, gaining the skills and knowledge of an advanced practitioner through mentorship from several radiation oncologists. With quality and clinical improvement projects in the department already underway, there was an enhanced focus on communication and a more personalized clinical approach for each patient through these efforts.

By following the UK's 4-pillar framework for advanced clinical

practice, and by leveraging the expertise of a dedicated group of multidisciplinary professionals in the department, leadership determined that an APRT position could provide an innovative solution. An APRT position description was drafted and incorporated into a comprehensive business model to navigate the justification and approval process internally. The APRT role development framework is illustrated in Figure 3. There were initially several ideas as to how to enhance the role of the RTT in the department. Ultimately the inpatient challenges presented as the greatest need and thus the APRT role would be specific to this patient population. To prevent role redundancy or encroachment issues, the position description and departmental structure were carefully designed to appropriately align with the departmental organization chart, taking into consideration the other disciplines in the department, including nursing, physics, RTTs, and medical residents. The overarching strategic goal was quality, safety, and value-based care. Finally, the group established several outcomes measures to be monitored and evaluated to improve the model. Outcomes from international literature helped define factors that influence the implementation of the role. Once in place, the clinical manager was promoted into the APRT position.

Novel Outcomes

The APRT role established at Mount Sinai addresses an existing gap in care via an elevated radiation therapy skill set, increasing continuity of care through care coordination, concise quality measurements, grant funded research, and guided enhancements.

The APRT helps patients navigate each step of the inpatient process, as illustrated in Figure 4. From consult to follow-up, the APRT's clinical practice enhanced the existing care model for inpatients through radiation therapy specific care coordination and patient education, and by addressing the psychosocial needs of the patient. The APRT completes a pain and positioning evaluation, a radiation therapy specific patient assessment tool completed on the inpatient floor. This assessment tool serves as an intervention for inpatients at a point along the care pathway that had not been previously addressed. This assessment has led to a refined process and a better experience once patients reach the radiation oncology department. Further, there are fewer hand-offs among the team, which improves patient safety and optimizes care delivery.

Mount Sinai Radiation Oncology has earned 2 grants to study the effectiveness of the APRT model. An ASRT (American Society of Radiologic Technologists) Foundation grant is investigating cost reductions and time savings through the APRT intervention. Researchers

Figure 4. Inpatient Radiation Treatment Service Workflow and the APRT's Involvement

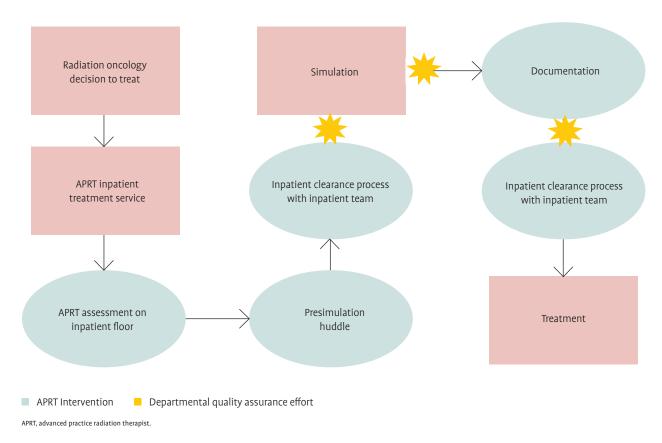


Table 4. Preliminary Outcomes Data After APRT Intervention*		
95% CI	PRE-APRT	POST-APRT
Proportion SN (scheduled but not simulated)	22.4% (16.9% - 28.6%)	17.4% (12.4% - 23.5%)
Proportion ST (simulated but not treated)	18.6% (13.6% - 24.5%)	10.8% (6.8% - 16.0%)

APRT, advanced practice radiation therapist.

hypothesize the addition of the APRT role will reduce the number of times an inpatient is scheduled and not simulated and simulated but not treated. This scenario may be due to improper workup, communication, workflow barriers, and lack of coordination between the multidisciplinary clinicians involved prior to the APRT intervention. Through an exploratory summary of preliminary results, the new model seems to be making an impact by reducing both these metrics by 5% and 7.8% respectively (Table 4). Full results will be matched using propensity score methods in the next phase of analysis. Future publications and research will be available on this topic in 2024.

The APRT role not also helps physicians manage growing patient demands, but APRTs are able to take over lower-level tasks, including task-shifting to alleviate provider burnout. For example, APRTs often visit inpatient floors and relay key information to the physician. The physician wellness impact is being evaluated through a mini-Z survey along with several embedded questions regarding work with the APRT. This work is funded through an internal Mount Sinai grant from the Icahn School of Medicine Office of Well-Being and Resilience. Physicians are asked to respond to this question: "In the [past] 6 months did you have the opportunity to work with the APRT? If yes, what went well and what did not go well?" Preliminarily results indicate that physicians returned positive responses in several key areas, including treatment, coordination, and patient care. Responses have indicated that the APRT "assisted in patient education, communication with the inpatient team, and streamlined the treatment process" and that the "[p]atient [is] more comfortable and aware of what to expect."

The value and expertise of the APRT position has led to further positional exploration beyond inpatient care coordination, including a brachytherapy role (following international groundwork already established), enhancing and managing the use of new technologies, such as adaptive radiotherapy, and high-dose treatment management and coordination.

The Path Forward

Innovation is necessary to improve care delivery in the US and decrease the rising costs. There are key drivers and associated

challenges that require individuals to think differently and devise novel solutions to common challenges. Physician burnout is growing at an increased rate, the status quo is not sustainable, and interventions are necessary to change the paradigm in modern medicine. Leadership must foster a culture of wellness by addressing staff well-being. By addressing these needs, and by creating opportunities for advancement, institutions may recruit and sustain highly skilled and talented staff. Mount Sinai Radiation Oncology leveraged the expertise of several key stakeholders and leadership to create an enhanced model of care for the inpatient radiation population. The department created a novel solution to a specific problem, allowing the radiation oncologists and RTTs to work at the top of their licenses. The new inpatient care delivery model focuses on continuity of care, safety, and departmental efficiency. Evidence-based research and experiences suggest that instituting substantial service improvements can pave the way for meaningful changes in the future of radiation therapy practice. The adoption of an APRT role depends on support from clinical management, administration, and physicians within individual departments. To ensure the APRT role is effective, managers must promote the possibility, RTTs should seek recognition and opportunities, and clinicians must become educated about its benefits. Pioneering the APRT role in the US will open new avenues for innovation and long-term value to patients and institutions. OI

References

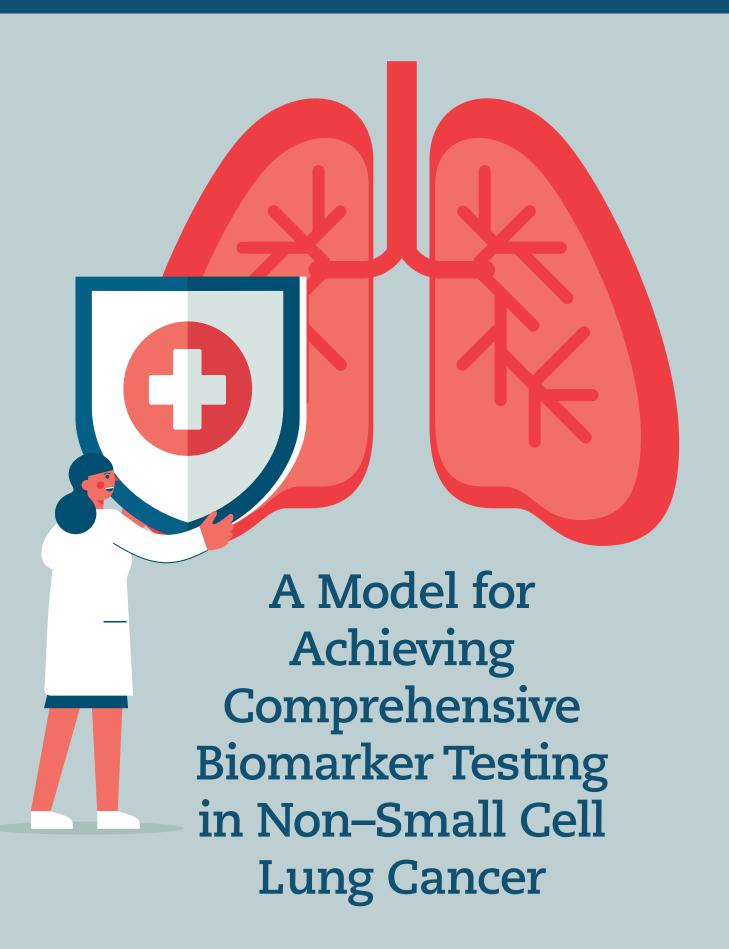
- 1. Oliveira C, Barbosa B, Couto JG, Bravo I, Khine R, McNair H. Advanced practice roles of therapeutic radiographers/radiation therapists: s systematic literature review. Radiography (Lond). 2022;28(3):605-619. doi:10.1016/j.radi.2022.04.009
- 2. Harnett N, Bak K, Zychla L, Gutierrez E, Warde P. Defining advanced practice in radiation therapy: s feasibility assessment of a new healthcare provider role in Ontario, Canada. Radiography (Lond). 2019;25(3):241-249. doi:10.1016/j.radi.2019.02.007
- 3. Harnett N, Bak K, Lockhart E, et al. The clinical specialist radiation therapist (CSRT): a case study exploring the effectiveness of a new advanced practice role in Canada. J Med Radiat Sci. 2018;65(2):86-96. doi:10.1002/jmrs.281

^{*}CIs calculated with the Clopper-Pearson method. All numbers are exploratory. Groups will need to be matched using propensity score methods in next phase of analysis

- 4. National Health Service England. Multi-Professional Framework for Advanced Clinical Practice in England. 2021. Accessed August 15, 2023. https://advanced-practice.hee.nhs.uk/multi-professional-framework-for-advanced-clinical-practice-in-england/
- 5. Duffton A, Devlin L, Tsang Y, Mast M, Leech M, ESTRO RTTC. Advanced practice: an ESTRO RTTC position paper. Tech Innov Patient Support Radiat Oncol. 2019;10:16-19. doi:10.1016/j.tipsro.2019.06.001
- 6. U.S. healthcare system ranks sixth worldwide innovative but fiscally unsustainable. Published February 3, 2022. Accessed August 16, 2023. https://www.pgpf.org/blog/2022/01/us-healthcare-system-ranks-sixth-worldwide-innovative-but-fiscally-unsustainable
- 7. Radiation oncologists urge Congress to reverse proposed CMS cuts and create more equity in access to cancer treatments. News release. American Society for Radiation Oncology. July 26, 2021. Accessed January 9, 2023. https://www.astro.org/News-and-Publications/News-and-Media-Center/News-Releases/2021/Radiation-oncologists-urge-Congress-to-reverse-pro
- 8. Shanafelt T, Ripp J, Trockel M. Understanding and addressing sources of anxiety among health care professionals during the COVID-19 pandemic. JAMA. 2020;323(21):2133. doi:10.1001/jama.2020.5893
- 9. Thompson D. Burnout levels high among U.S. health care workers. U.S. News and World Report. April 4, 2023. Accessed October 20, 2023. https://www.usnews.com/news/health-news/articles/2023-04-04/ burnout-levels-high-among-u-s-health-care-workers
- 10. Lindquist M. The real cost of turnover in healthcare. Oracle. Published March 22, 2023. Accessed October 20, 2023. https://www.oracle.com/human-capital-management/cost-employee-turnover-health care/
- 11. Ramey SJ, Ahmed AA, Jimenez B, Takita C, Yechieli R. (p101) Burnout evaluation of radiation residents nationwide: results of a survey of United States residents. Int J Radiat Oncol Biol Phys. 2017; 99(3):530-538. doi:10.1016/j.ijrobp.2017.06.014
- 12. American Society of Radiologic Technologists. Radiation Therapy Staffing and Workplace Survey: 2022. 2022. Accessed October 19, 2023. https://www.asrt.org/docs/default-source/research/staffing-surveys/radia-

tion-therapy-staffing-and-workplace-survey-2022.pdf?sfvrsn=121fbbd0_4

- 13. Surveillance, Epidemiology, and End Results Program. Cancer stat facts: common cancer sites. National Cancer Institute. Accessed October 20, 2023. https://seer.cancer.gov/statfacts/html/common.html
- 14. Reyes DK, Pienta KJ. The biology and treatment of oligometastatic cancer. Oncotarget. 2015;6(11):8491-8524. doi:10.18632/oncotarget.3455
- 15. Skubish S, Dimopoulos M, Harnett N, et al. Working towards advanced practice radiation therapy in the United States. Radiation Therapist. 2023; 32(1):43-49.
- 16. Skubish S, Starrs C, Mcdonagh D. Exploring opportunities & pathways for advanced practice radiation therapy roles in the United States. Tech Innov Patient Support Radiat Oncol. 2021;17:P59-62. doi:10.1016/j.tipsro.2021.01.005
- 17. ASRT Foundation awards \$25,000 research grant to support advance practice radiation therapists. News release. ARST Foundation. December 15, 2022. Accessed January 9, 2023. https://foundation.asrt.org/news-stories/full-story/asrt-foundation-awards-25-000-research-grant-to-support-advance-practice-radiation-therapists
- 18. Vapiwala N, Giuliani M, Harnett N. Advancing our practice through the advanced practice radiation therapist model: catching up with Canada. Int J Radiat Oncol Biol Phys. 2017;98(3):497-500. doi:10.1016/j.ijrobp.2017.02.221
- 19. McDonagh D, Tonning KL, Freeman B, et al. An environmental scan of advanced practice radiation therapy in the United States: a PESTEL analysis. Int J Radiat Oncol Biol Phys. 2023;117(1):11-21. doi:10.1016/j.tipobp.2023.05.007
- 20. Kuo J, Dariou P, Farol H, Sehgal V, Ramsinghani N. Palliative inpatient radiation therapy: the challenge of treatment non-completion. J Clin Oncol. 2018;36(34):106-106. doi:10.1200/JCO.2018.36.34 suppl.106





ung cancer accounts for almost 25% of all cancer deaths in the United States, with non–small cell lung cancer representing 85% of all lung cancer diagnoses.¹ However, the 5-year survival rate for patients with lung cancer has increased from 21% in 2014 to 25% in 2018.² While some of the improved survival rate can be attributed to a decrease in smoking rates and an uptick in preventive lung cancer screenings, the largest contributing factor is novel biomarker targeted therapies in the subset of patients with metastatic non–small cell lung cancer.

The Importance of Biomarker Testing

The National Cancer Institute outlines that biomarker testing is a way to look for genes, proteins, and other substances (called biomarker or tumor testing) that can further provide information about that patient's cancer and suggest optimal cancer treatment.³ Comprehensive biomarker testing (comprehensive genomic profiling and PD-L1 testing) is recommended by the National Comprehensive Cancer Network (NCCN) for all patients with metastatic non-small cell lung cancer. 4 It is important to delineate the different biomarker definitions and how they may affect patient treatments. Some patients may only receive biomarker testing for 1 gene, often referred to as hot spot testing. Additionally, some patients may receive what is called next-generation sequencing, where a panel of biomarkers are tested, excluding PD-L1. However, some patients receive what is called comprehensive biomarker testing, which is the tumor testing panel that includes PDL-1. For this study, Oncology Hematology Care (OHC) implemented a system to implement and improve comprehensive biomarker testing on a patient subset.

To date, there is universal agreement that not all cancers are the same and not all cancers should be treated the same. To extrapolate this further, as we continue to see the increase in the number of biomarkers, we will also continue to see the number of biomarker targeted therapies increase. Historically, biomarkers were initially only *ALK*, *ROS*, and *EGFR*, but thankfully that landscape has shifted and exponentially grown (Figure 1). It is important to note that this list may look different per location and practice due to local demographics and populations; however, the standard actionable biomarker testing list will not change. Today, 40% to 50% of patients with non–small cell lung cancer will have an actionable biomarker, and

Nearly 70% of the positive biomarkers will have an impact on a patient's first line treatment selection.

each day that number increases. Nearly 70% of the positive biomarkers will have an impact on a patient's first line of treatment selection. While lung cancer has paved the way, biomarker testing is becoming applicable to multiple other disease states as well. A comparable diagnosis state would be advanced breast cancer, where no physician would treat a patient today without ER, PR, or HER2 marker results. This shift has begun in the treatment of advanced non–small cell lung cancer as well.

Not only do targeted therapies have an impact on first-line treatment, but they are often superior to standard care and are often less toxic for patients. Prior to targeted therapies, patients diagnosed with metastatic lung cancer were thought to be untreatable. At best, patients were offered standard treatment with platinum-based therapy or perhaps best supportive care. This treatment regimen was often accompanied by a 3- to 6-month life expectancy. Thanks to comprehensive biomarker testing and targeted therapies, the prognosis for these patients is improving. As of today, there are 32 FDA-approved targeted therapy treatments for lung cancer alone. In 2020, Howlader et al wrote, "Over the past decade, the treatment paradigm for advanced [non-small cell lung cancer] has evolved dramatically. The identification of 'druggable' oncogenes (ie, EGFR and ALK) has provided new, effective treatment targets, improving survival significantly among patients harboring the corresponding driver mutation."5-7

So why, with all these facts in mind—the importance of biomarker testing and how it can lead to improved survival and patient outcomes—are we not making biomarker testing a top priority and testing every appropriate patient? Even though the NCCN⁴ recommends next-generation sequencing for biomarker testing for all patients with advanced non–small cell lung cancer, the uptake *Continued on page 23*

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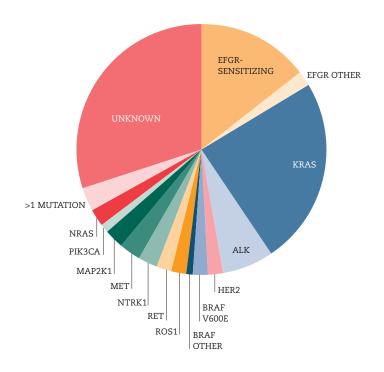
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Figure 1. Driver Mutations in Lung Adenocarcinoma



Driver mutations in	lung
adenocarcinoma	_

EGFR-sensitizing	15%
EGFR other	2%
KRAS	25%
ALK	7%
HER2	2%
BRAF V600E	2%
BRAF other	1%
ROSI	2%
RET	2%
NTRK1	0-5%
MET	3%
MAP2K1	0-5%
PIK3CA	1%
NRAS	0-5%
> 1 mutation	3%
Unknown	31%



Continued from page 21

among community and academic oncology programs is suboptimal. For patients who are diagnosed with metastatic non–small cell lung cancer, it is imperative to order and collect comprehensive biomarker testing to determine what the optimal treatment will be, as this practice has "proven to help people with lung cancer live longer with a better quality of life."

Biomarker Real-World Studies

In examining OHC's data and the impact on patient care, we knew that all patients with advanced non–small cell lung cancer should have received testing. However, we found a significant gap, and we are not alone. This problem is not unique to OHC or even community-based practices, but hospital and academic centers as well. Sadly, this problem is universal. National data have proven that we are not testing at the rates we should be. Many physicians asked will respond, "yes, of course we are testing every patient," but the data show otherwise. Despite consensus and data-driven recommendations by NCCN and other organizations, there is variable uptake in clinical practice today.⁹

When MyLung Consortium Protocol 1 results were released by The US Oncology Network,¹⁰ they provided a retrospective close-up look at current biomarker testing rates and turnaround times. This study ran from 2018 through 2020 and included the biomarkers *ALK*, *BRAF*, *EGFR*, and *ROS1* for 3474 patients.¹¹ This study was manually audited due to the difficulty of not having structured data fields. Data showed that 90% of the patients had at least 1 biomarker test; however, next-generation sequencing testing rates were poor, resulting in less than 50% having comprehensive testing. This cumulative time period did show an overall testing rate increase from 33% at the start of the study to 44% at the end of the 2-year period.

The results of MyLung Protocol 1 led to MyLung Protocol 2. This prospective, noninterventional cohort study ran from December 2020 through September 2022 and included 1000 newly diagnosed patients with early-stage or metastatic non-small cell lung cancer being treated in 12 community oncology practices that were part of The US Oncology Network.¹² OHC was one of the 12 practices involved in this study. MyLung Protocol 2 looked at ALK, BRAF, EGFR, ROS1, KRAS, MET, NTRK, RET, and PD-L1. The data collected in protocol 2 were biomarkers, timing of biomarker testing, use of single vs multigene next generation sequencing testing, clinical and socioeconomic factors, and reasons when testing was not collected. Study results found that 83% of patients had at least 1 actionable biomarker tested. Looking further into these data, 37% of the stage I to -IIIC patients and 57% of the stage IV patients had comprehensive biomarker testing completed. Digging even further into these data, OHC's testing rate during this time period was 68% internally. While OHC results were higher than the average, the OHC team was far from satisfied.

In 2024, plans are moving forward for MyLung Protocol 3. This study is being built off the foundations of MyLung Protocols 1 and 2 and will be a multi-interventional study to improve comprehensive biomarker testing and subsequent assignment of targeted therapies. Investigating interventions is where we come full circle and how work at OHC was one of the first steps in addressing these deficits.

OHC's Biomarker Study 4-Step Methodology

To address these testing gaps, OHC submitted a request for proposal with Pfizer and obtained a 1-year grant to support a quality improvement initiative. OHC's project centered around 4 primary initiatives:

- 1. Educational YouTube videos
- 2. A new standardized non-small cell lung cancer initial consult note
- 3. A new standardized non-small cell lung cancer order set
- 4. Automated data reports

OHC used plan-do-study-act (PDSA) methodology with the overall goal being to improve comprehensive biomarker testing on patients with metastatic non–small cell lung cancer over a 1-year period.

In cycle 1 of OHC's study, we created 3 two-minute educational YouTube videos that OHC physicians could watch at their convenience. The first video—perhaps the most influential—answered "the why question." This video communicated the importance of comprehensive biomarker testing and its impact on patient outcomes. Additionally, the video outlined the standardized way physicians would document non–small cell lung cancer diagnosis coding and staging. This diagnosis coding and staging would become one of the

most important key takeaways from our study. Limiting the physicians non–small cell lung cancer coding helps to create more accuracy in staging and data collection. The second video taught physicians how to document on the new standardized non–small cell lung cancer initial consult note template. The third video educated physicians on how to select and order from the new standardized non–small cell lung cancer order set in tandem with the new note template. These YouTube videos proved to be highly effective with our physicians due to their ease of use, aiding in adoption.

Cycle 2 of the quality initiative study was a newly designed Non-Small Cell Lung Cancer Initial Consult Note template in our electronic health record (EHR), McKesson's iKnowMed Generation 2 (G2).¹³ This new note contained all the primary initial consult note components but also included NCCN guidelines for non–small cell lung cancer and testing guidelines. The new non–small cell lung cancer NCCN guideline section had all the key itemized requirements that a patient may need post initial diagnosis. This section in the provider note was designed for ease of use, outlining exactly what the patient may need in an organized fashion so that physicians could simply checkmark by item. The goal of this note template was to devise a tool that was streamlined into already existing workflows. In other words, the use of this template (in partnership with the order set discussed next) eased—not increased—physician burdens when seeing a new patient with metastatic non–small cell lung cancer.

Cycle 3 of the initiative (in partnership with the new standardized note template discussed above) was the metastatic non–small cell lung cancer order set. This order set included all the essential NCCN guidelines that an advanced non-small cell patient may require, mirroring the note template. Orders included in this set included labs,

Figure 2. Oncology Hematology Care Methods: Study Design, Data Collection, and Implications

PROVIDER EDUCATION TEMPLATE CREATION ANALYTIC REPORTS Education to the providers (MDs/APPs) on the purpose of the grant, CARIS biomarker created to compile, track, and monitor the project's testing staging, and how to compliance and results use the templates SCALING PROVIDER RE-EDUCATION WEEKLY AUDITS OF ALL **PROCESS** EHR discreet fields and data **MONITORING** Continuous monitoring analytic reports make it feasible to scale internally to of data and analytic reports throughout the other diagnoses and externally remainder of the grant to other practice locations

APP, advanced practice provider: EHR, electronic health record; NSCLC, non-small cell lung cancer.

scans, biomarker testing, research consult, supportive care consult, port placement, and surgery consult. This order set helped physicians order all needed items with one simple selection. The goal of this order set was to ensure that no orders were missed on a patient and to provide ease of use for the physicians. A real-world example would be a patient being seen by the physician for their initial consult who already completed a "CT of the chest/abdomen." With one click in the EHR, the physician can remove that order. In this order set, OHC made the decision to include 1 primary next-generation sequencing vendor in the order set. Many practices support multiple vendors; however, OHC found success limiting internally to 1 primary tumor testing vendor and 1 primary liquid testing vendor. While this decision may be difficult, use of a primary vendor improved standardization and buy-in. OHC physicians became accustomed to the reporting format they were receiving back into the patient's EHR. This standardization improved physician workflow and streamlined processes.

Cycle 4 of this study, and arguably the most crucial, was the custom automated data reports and scorecards. The old saying "you can't fix what you can't measure" rang true for this study. A weekly audit report allowed us to monitor every new patient encounter, provide timely education to physicians, and adjust any workflow processes as needed. The automated reports were delivered in Excel format and included all key inclusion criteria for the study. Each week this automated Excel file was updated with all pertinent data from the EHR. Any unstructured data fields that could not be automated from within the EHR would then be manually curated on the Excel file, estimated at about 1-hour of manual work a week. For this manual process, OHC utilized a nurse to fill in any clinical data fields that were missing. It is important to note that if a practice is looking for cost savings, an administrative staff member could be trained to complete this function. These reports helped to generate weekly scorecards to track all key study outcomes. Weekly, these scorecards would compile all data fields and produce compliance percentages on staging, template utilization, order set utilization,

biomarker tests ordered, biomarker testing results received, research consults, and biomarker result documentation in structured fields.

All 4 initiatives were launched in tandem with a full practice-wide "roadshow" to all physician locations (Figure 2). This additional hands-on education and training reiterated the YouTube video trainings and allowed for in-person question and answer sessions with physicians. Physician champion buy-in was essential to this non–small cell lung cancer initiative being so impactful, however, we would argue that executive leadership and administrative buy-in is equally important. For quality improvement projects to be successful at a practice level, it takes a multitude of departments and leaders to drive success. Our physician champions initiated peer-to-peer education, which helped increase practice-wide buy-in.

Study Result and Impact

Prior to launch of OHC's quality improvement initiative, we saw a 68% comprehensive biomarker baseline testing rate through manual chart abstraction. In the 1-year grant period from September 1, 2021, through August 21, 2022, OHC saw 362 new patients with lung cancer populate on the automated custom data reports. Of that number, 316 patients ultimately met criteria for inclusion in our study for evaluation. After further examination, 111 of 316 patients (35%) had stage IV disease and met the full requirements for inclusion. Of these, 103 of 111 patients (92.7%) had comprehensive biomarker testing ordered; 8 of the 111 patients (7.3%) did not have biomarker testing ordered due to hospice enrollment, declining treatment, or opting out of testing. OHC's 4-part quality interventions helped to show significant improvement in testing from a baseline of 68% to 92.7% in a 1-year period in the advanced non-small cell lung cancer disease state (Figure 3).14 Figure 4 illustrates study data.

Post study, a full examination was conducted on OHC's actionable biomarker testing rates (Figure 5). Evaluating the actionable Continued on page 27

Figure 3. Comprehensive Biomarker Baseline Testing Rates of Patients With Advanced Non-Small Cell Lung Cancer

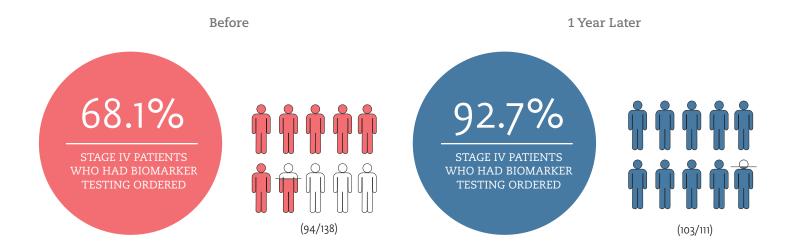
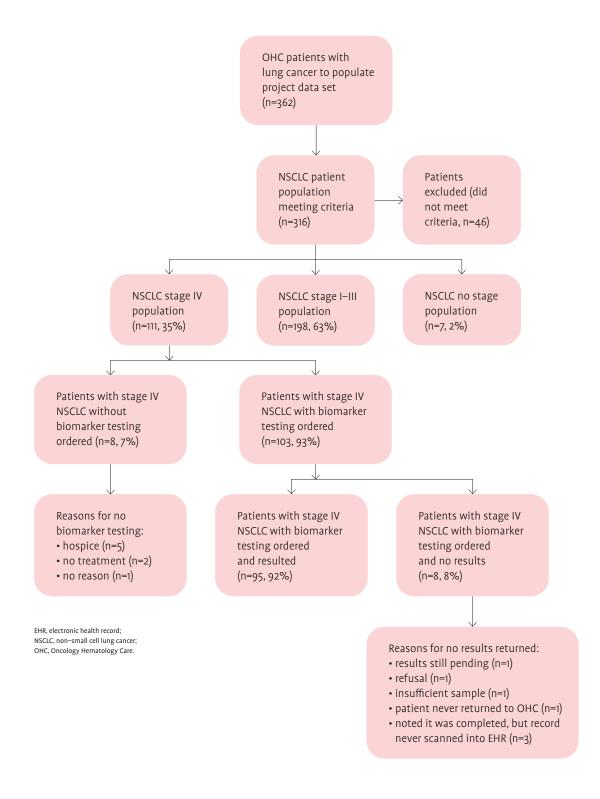


Figure 4. Study Data for Oncology Hematology Care Quality Improvement Initiative



Continued from page 25

biomarker results on the included patient population, OHC found the following positive mutations:

- PD-L1 > 1% (n=88)
- Tumor mutational burden high (n=44)
- KRAS G12C (n=12)
- EGFR exon 19, exon 20, exon 21 (n=6)
- *ALK* fusion protein (n=6)

We found no patients harboring actionable biomarkers: ROS1, BRAF, NTREK, RET, MET, or ERBB2 (HER2). This finding is not entirely surprising as our sample size is relatively small, and some of these biomarkers are considered less common.

We have also looked further into whether the actionable biomarkers found were then used to inform first-line and second-line decisionmaking. For example, if the patient had a first-line actionable biomarker, such as EGFR or ALK, were they treated with an NCCNcompliant treatment regimen? Five patients who had an actionable EGFR mutation received NCCN-compliant first-line targeted therapy, while the sixth patient was started initially on immunotherapy plus chemotherapy (chemo/IO). The 1 patient who received chemo/IO was started on treatment prior to the return of their biomarker results; after the first cycle of therapy, this patient was then switched to an NCCN-compliant treatment. This finding highlights the need to not only order comprehensive biomarker testing but also to wait for the results to return before initiating the first line of therapy, not just an OHC finding, but a national issue. All 6 of the patients who were identified as having an ALK fusion protein received an NCCNcompliant targeted therapy.

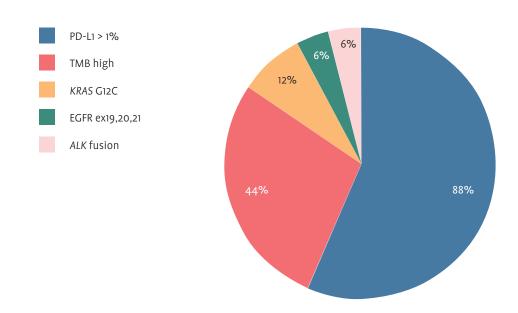
Other biomarkers only inform second-line or later therapies, such as those patients who had a KRAS G12C mutation (n=12) or ERBB2 (n=0). Several of the patients with KRAS G12C mutation either progressed through their first-line therapy or could not tolerate treatment elected best supportive care, while a few remained on their initial first line therapy. Sadly, we understand that real-world data suggests that only 60% of OHC patients will be well enough or willing to go on to second- and later-line therapies. 15 This statistic underscores the importance of obtaining comprehensive biomarker testing and ultimately ensuring that it is used to optimize first-line treatment. Anecdotally, the OHC team noticed that the provider's template notes acknowledged those mutations and suggested the possibility of such treatment in the future (upon progression). To date, only 2 patients with a KRAS G12C mutation have gone on to receive a second-line treatment, and both have received an appropriate targeted agent.

4 Key Takeaways

OHC's quality improvement initiative produced significant results, which led the team to further break down what factors led to this success in hopes that other practices could mirror our success. Post study, a full examination was conducted on OHC's actionable biomarker testing rates (Figure 5). Evaluating the actionable biomarker results on the included patient population, OHC found the following positive mutations.

Ease of use. This was crucial to the success of this project and the immediate uptick in adherence from our physicians. Finding a way to streamline this process into an already overwhelmed physician workflow was essential. Physicians are juggling countless

Figure 5. Actionable Biomarker Testing Rates



priorities throughout their workday. Finding a way for physicians to work smarter and not harder was perhaps the most important component of this new quality workflow. The initiative's ease of use improved efficiency, decreased EHR click-count fatigue, and increased overall biomarker ordering compliance. Additionally, it is important to emphasize just how simple this process truly was. Some of the best solutions do not have to be the most complex.

EHR limitations. This is very familiar to the health care industry. EHRs are not (yet) robots. To date, most EHRs are not even built with fully integrated AI (artificial intelligence) components. With the lack of AI and integration in our current state, our quality improvement initiative was built to find a way to seamlessly address these current limitations. Until our EHRs are more advanced, all health care institutions need to strive to put systems in place that health care providers can control. While EHR limitations may not be within the control of a cancer program within a hospital or large health care system, we would urge you to put in place infra-structure that helps you take ownership and move patient care forward.

Automation. Without the assistance of AI and to minimize manual processes, we created as much automation into the process as possible. Automated custom data reports help to simplify the EHR data gaps health care providers face. Although the proposed auditing process is feasible, it is not optimal and is labor intensive. Automation of this process and building automated data fields for biomarkers will be essential for widespread scaling and adoption. Additionally, future AI interfacing of biomarker results back into the EHR will elevate targeted therapy per actionable biomarker compliance. Many EHRs are currently working on this enhancement. However, it is important to call out that health care providers cannot simply build in a new enhancement tool; a new AI tool is needed to facilitate continuous quality improvement for better patient care.

Stage, stage, stage. This is a familiar phrase: garbage in, garbage out. OHC experienced an unexpected barrier: The team could not do a study on a patient population if that patient population was not in OHC data. The OHC team discovered within the EHR a high magnitude of ways to enter in a diagnosis of non-small cell lung cancer, making it nearly impossible to find all patients for inclusion in the study. To complicate matters further, many EHRs do not prompt providers to complete all staging or enter in all prognostic indicators, including biomarker results. Even if staging is entered at diagnosis, some providers do not keep patient staging updated as the disease progresses. These compounding staging problems reinforced just how big of an impact staging can have on quality studies. OHC's recommendation to all oncology programs and practices is to build out education and standardization of staging as a primary focus, especially if health care providers want to initiate quality improvement projects such as this one. Complete and accurate staging, including biomarkers, will play a pivotal role in patient targeted therapy treatment selection.

It may be important to note that no matter how easy a process is to create, health care providers will still face unanticipated problems and roadblocks. A real-world example may be team members who become primary outliers of the project initiative. Ultimately, these outliers can lead to lack of buy-in, lack of stan-

dardization, and missing biomarker orders. Having physician and executive leadership champions will be immensely helpful in this regard. OHC physician champions were able to do real-time peer-to-peer reeducation on site as issues arose. While weekly reminder emails and even making physicians re-do their note templates can be effective, physician champions are irreplaceable. As you roll out your quality improvement initiative, anticipate the unanticipated.

2 Easy Implementation Tips

Start small. Quality improvement initiatives can feel large and daunting, but they do not have to be. Consider starting conversations with your providers on the importance of biomarker testing through a textable 2-minute video. These simple education opportunities can help raise awareness and start a domino-like effect for the quality improvement initiative.

Standardization. The more your organization can standardize and streamline workflow, the more efficient the practice will be. Most cancer programs or practices have some semblance of control over the contents of their practice notes and orders. Consider adding NCCN guidelines to your physician notes and order sets. Standardizing biomarker testing into the physician's workflow will help decrease ambiguity on ordering, increase quality testing rates, simplify the process variability, and ensure consistency and productivity of physicians.

Where to Go From Here

National data suggest that nearly half the time biomarker testing is ordered and results provided, health care providers are not using the results optimally. If the collective goal is treatment optimization for patients with cancer, health care providers cannot stop at simply ordering comprehensive biomarker testing. Health care institutions and providers need to ensure we have systems in place to then order the appropriate targeted therapy per actionable biomarker. A key takeaway is to challenge each other to not only investigate cancer testing rates, but then investigate if the appropriate targeted therapy was ordered for the patient. Today, OHC is partnering with The US Oncology Network and McKesson to create and build interfaces in the EHR for next-generation sequencing vendor automation back into the patient's chart. This automated interfacing would populate discrete data fields in the patient's diagnoses to aid in staging completeness and treatment regimen selection.

This quality improvement initiative was found to be a reproducible and scalable solution for not only other malignancies but other cancer programs and practices as well. OHC was able to produce similar significant results in its metastatic breast cancer population by deploying the same PDSA methodology to genetic NCCN guideline evaluation and subsequent testing. To date, this study's methodology is currently being scaled as a best practice initiative across the country through The US Oncology Network and McKesson practices.

In tandem with being reproducible and scalable, this quality improvement initiative was found to be cost-effective. The benefit of this quality improvement project is that your cancer program or practice does not have to purchase new equipment or new technology platforms or even hire additional employees. The only potential cost is the funding for any manual auditing processes that cannot be automated by an EHR. While OHC opted to utilize a clinical employee for the manual auditing pieces needed, an administrative employee could be trained and utilized.

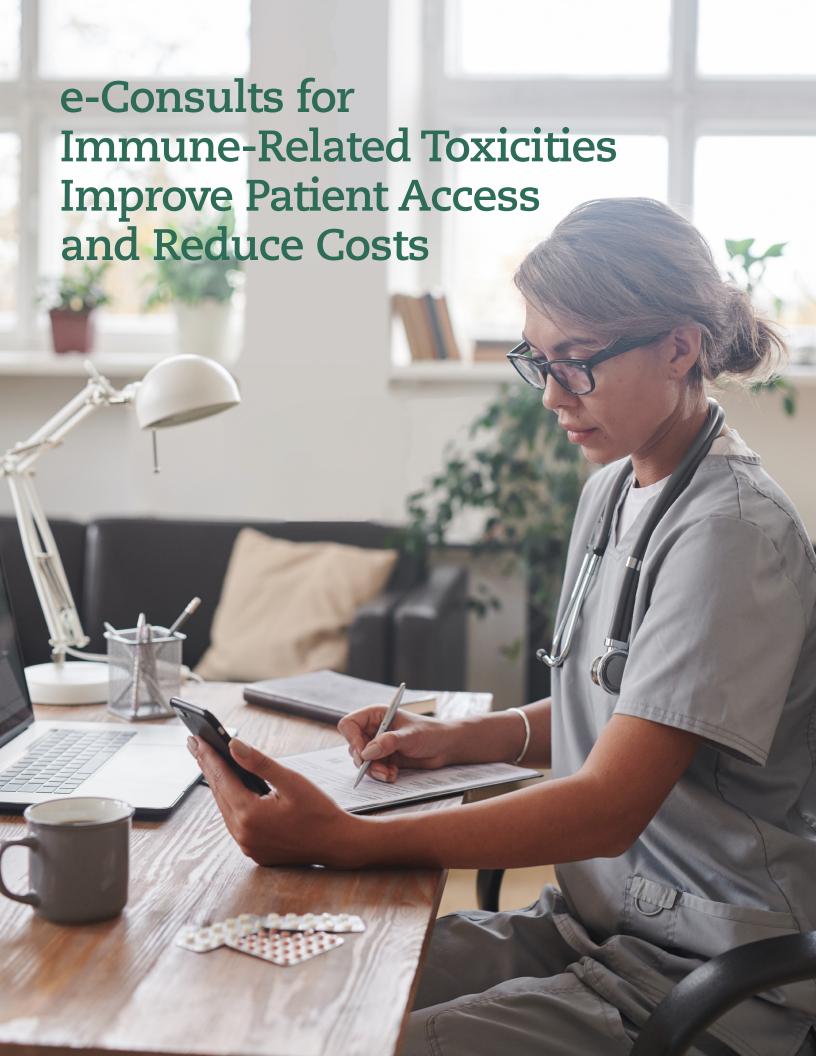
OHC's ultimate goal is for oncology programs and practices across the nation to begin using this best practice methodology to produce similar results for all patients with advanced non–small cell lung cancer. To achieve true patient-centered care and improved patient outcomes, health care providers and institutions must first achieve and maintain high comprehensive biomarker testing rates and then use those results to treat patients optimally with targeted therapy.

References

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- 1. Key statistics for lung cancer. American Cancer Society. Revised January 12, 2023. Accessed January 8, 2024. https://www.cancer.org/cancer/lung-cancer/about/key-statistics.html#:~:text5The%20American%20Cancer%20Society's%20estimates,men%20and%2061%2C360%20in%20women
- 2. American Lung Association. State of Lung Cancer Report. Lung Cancer: Key Findings. Updated November 3, 2023. Accessed January 8, 2024. https://www.lung.org/research/state-of-lung-cancer/key-findings
- 3. Biomarker testing for cancer treatment. National Cancer Institute. Updated December 14, 2021. Accessed January 8, 2024. https://www.cancer.gov/about-cancer/treatment/types/biomarker-testing-cancer-treatment#:~:text=Biomarker%20testing%20is%20a%20way,how%20certain%20cancer%20treatments%20work.
- 4. NCCN. Clinical Practice Guidelines in Oncology. Non-small cell lung cancer, version 5.2022. Accessed January 8, 2024. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
- 5. Howlader N, Forjaz G, Mooradian MJ, et al. The effect of advances in lung-cancer treatment on population mortality. *N Engl J Med*. 2020;383(7):640-649. doi:10.1056/NEJMoa1916623
- 6. Haslem DS, Van Norman SB, Fulde G, et al. A retrospective analysis of precision medicine outcomes in patients with advanced cancer reveals improved progression-free survival without increased health care costs. *J Oncol Pract.* 2017;13(2):e108-e119. doi:10.1200/JOP.2016.011486

- 7. Thompson JC, Carpenter EL, Silva BA, et al. Serial monitoring of circulating tumor DNA by next-generation gene sequencing as a biomarker of response and survival in patients with advanced NSCLC receiving pembrolizumab-based therapy. *JCO Precis Oncol.* 2021;19(5)510-524. doi: 10.1200/PO.20.00321
- 8. Lung cancer non-small cell: statistics. Cancer.Net. March 2023. Accessed January 8, 2024. https://www.cancer.net/cancer-types/lung-cancer-non-small-cell/statistics#:~:text=The%205%2Dyear%20survival%20rate%20for%20men%20is%2017%25.,and%20the%20stage%20of%20disease
- 9. Pennell NA, Arcila ME, Gandara DR, West H. Biomarker testing for patients with advanced non-small cell lung cancer: real-world issues and tough choices. *Am Soc Clin Oncol Ed Book*. 2018;39:531-542. doi:10.1200/EDBK 237863
- 10. First phase results of MYLUNG consortium provide historical view of biomarker testing patterns and identify data gaps for ongoing prospective research. The US Oncology Network. June 21, 2021. Accessed January 8, 2024. https://usoncology.com/news/first-phase-results-of-mylung-consortium-provide-historical-view-of-biomarker-testing-patterns-and-identify-data-gaps-for-ongoing-prospective-research
- 11. Evangelist M, Jotte R, Spira A, et al. D. P60.13 MYLUNG consortium: molecularly informed lung cancer treatment in a community cancer network. Pragmatic prospective RWR study. *J Thoracic Oncol.* 2021;16(10):S1170-S1171. doi.org/10.1016/j.jtho.2021.08.634
- 12. Evangelist MC, Butrynski JM, Paschold JC, et al. Contemporary biomarker testing rates in both early and advanced NSCLC: Results from the MYLUNG pragmatic study. *J Clinical Oncol*. 2023;41(16):9109-9109 doi:10.1200/JCO.2023.41.16 suppl.9109.
- 13. iKnowMed G2. Ontada. https://www.ontada.com/Providers-Solutions/iKnowMed
- 14. Waterhouse D, Ward P, Drosick DR, Davies D, Mendenhall M. Closing the testing gap: standardization of comprehensive biomarker testing for metastatic NSCLC in a large community oncology practice. *JCO Oncol Pract.* 2023;19(6):e951-e956. doi:10.1200/OP.22.00817
- 15. Bazenova L, Kish J, Cai B, Caro N, Feinberg B. Real-world observational study of current treatment patterns and outcomes in recurrent or locally advanced/metastatic non-small cell lung cancer. *Cancer Treat Res Comm*. 2022;33:100637. doi:10.1016/j.ctarc.2022.100637





challenging problem for oncology patients currently receiving immune checkpoint inhibitor therapy is immune-related adverse events (irAEs), with treatmentrelated deaths occurring in up to 2% of patients.1 While irAEs occur in various Common Terminology Criteria for Adverse Events (CTCAE) grades (1-5), they are a common reason for hospital admission noted in 8.5% of patients and can lead to treatment discontinuation in up to 87% of patients after they are admitted for a high grade toxicity.1 In recent years, Duke Cancer Institute has noted that 10% of patients receiving immune checkpoint inhibitor therapy are admitted to the hospital after less than 1 month from the initiation of therapy, and 23% of patients have been sent to the emergency department (ED), admitted to the hospital, and/or died within 6 months from therapy initiation.² In addition to the high risk of hospitalization and risk for treatment discontinuation, there is an added cost and utilization burden that falls on the health care system. For example, the estimated cost of admissions for irAEs at Massachusetts General Hospital was \$218,700 in 2011 and skyrocketed to \$1,300,000 in 2016.3 We expect that with more common use of these agents, this number will continue to escalate, underscoring the need to prioritize effective and timely irAE management so avoidable hospitalizations can be prevented.

Among irAEs, endocrine irAEs are one of the most common toxicities with resultant endocrinopathies ranging from 4% to 14.6% of cases,4 along with cutaneous, gastrointestinal, pulmonary, and musculoskeletal toxicities.5 Endocrine irAEs have been noted to contribute to 12.2% of admissions related to irAEs.⁶ For hospital admissions that are a result of an irAE, 87% of patients stop immune checkpoint inhibitor treatment. Thus, patients stop effective therapy due to irAEs. We suspect that an important reason for these hospitalizations is delayed recognition and limited access to clinicians with expertise, resulting in delayed treatment and management. Management of irAEs is contingent upon both early recognition and prompt intervention.8 The onset of irAEs can vary in presentation from an abrupt adverse event to, less commonly, one that is characterized by delayed onset and prolonged duration. Multidisciplinary teams and recommendations are critical for both evaluation and management guidance.5 Access to clinical expertise in a timely manner can be

E-communication allows for professional triage and complex care facilitation. This system reduces access time to clinic, is faster, and reduces cost for the health care system via a reduction in ED visits.

challenging in both academic and community settings due to lengthy wait times. Presently at Duke Cancer Institute, for patients with cancer, the average wait time to see an endocrine specialist is 87 days.²

One solution to this challenge is to implement expert triage from an endocrinologist who can review the case via an e-communication based platform. This platform can allow physicians to assess patients sooner and determine the need for an in-person visit. E-communication, also known as an e-consult, is an asynchronous telehealth platform that is a templated order request in an electronic health record (EHR) that allows a specialist to review a case on behalf of another provider to advise on individual patient care. E-communication allows for professional triage and complex care facilitation. This system reduces access time to clinic, is faster, and reduces cost for the health care system via a reduction in ED visits. Previous studies have demonstrated that a virtual multidisciplinary toxicity team for irAEs is easily implemented and aids in diagnosis of toxicities and recommendations for subsequent care. Herein, we describe a single-institution experience with an e-communication consult platform from oncology to endocrinology and determine its effectiveness in reducing appointment access times and hospitalizations.

Methods

Patients being treated with immune checkpoint inhibitors who received an e-consult from oncology to endocrinology from the period 5/1/2020 to 11/1/2021 were eligible for inclusion in this observational study approved by the Duke Cancer Institute Institutional Review Board (IRB). All data collection was performed with manual chart abstraction *Continued on page 33*



Empowering oncology teams to provide patient assistance through automation

- ✓ Reduce financial toxicity
- ✓ Improve patient experience
- ✓ Increase access to care
- ✓ Address cancer disparities

"Thank you so much for genuinely caring and doing everything you can to help me...this is such a relief and takes so much worry off of me!"

BREAST CANCER PATIENT

Table 1. Patient Characteristics	
TOTAL E-CONSULTS (N=102)	N (%)
Median age (IQR) (in years)	67.10 (14.86)
SEX	
Male (%)	55 (53.9)
Female (%)	47 (46.1)
RACE	
White/Caucasian (%)	87 (85.3)
Black/African American (%)	9 (8.8)
Asian (%)	0
Pacific Islander/Native Hawaiian (%)	0
Unknown (%)	3 (2.9)
Other (%)	3 (2.9)
ETHNICITY	
Hispanic (%)	3 (2.9)
Non-Hispanic (%)	98 (96.1)
Unknown (%)	1 (0.9)
MALIGNANCY	
Melanoma (%)	9 (8.8)
Non-small cell lung cancer (%)	31 (30.4)
Small cell lung cancer (%)	1 (1)
Head and neck cancer (%)	2 (2)
Bladder cancer (%)	4 (3.9)
Renal cell carcinoma (%)	17 (16.7)
Breast cancer (%)	4 (3.9)
Gastrointestinal cancer (%)	18 (17.5)
Gynecologic cancer (%)	16 (15.7)
Other (%)	5 (4.9)
E-CONSULT RELATED TO ENDOCRINE-RELATED IMMUNE TOXICITY?	
Yes	77 (75.5)
No	25 (24.5)

Continued from page 31

from Epic software and recorded in a secure REDCap database. Patient demographic data, including age at time of diagnosis, sex, race, and ethnicity were collected, in addition to pre-existing endocrine medical history, primary cancer diagnosis, and cancer stage (Table 1). Toxicity data regarding the type of immuno-oncology therapy, date of last dose received, diagnosis for which the patient is seeing endocrinology, and CTCAE toxicity grade were also collected and reviewed. During this period, 102 separate e-consults were ordered. Consult recommendations, including diagnostic tests and treatment recommendations, were individually analyzed in addition to the continuation of treatment throughout duration of the analysis period. A postimplementation provider questionnaire was also collected.

Results

A total of 102 e-consults were reviewed during the study period and demographic data among the included patients are outlined in Table 1. The most common diagnosis associated with an e-consult was related to thyroiditis, and the most common cancer diagnosis associated with the use of an e-consult was non-small cell lung cancer (NSCLC), as shown in Figure 1. Most cancers had progressed to stage IV by the time of the e-consult, and the most common immunotherapies were nivolumab and pembrolizumab, as shown in Figure 2. Of 102 e-consults reviewed, 88 provided diagnostic recommendations and 60 provided treatment recommendations at the time of consultation (Table 2). Seventy-four e-consults were followed by an in-person appointment (Table 2). Among the appointments that followed an e-consult, median time for follow-up was 38.50 days, which was reduced from 60.5 days in 2021 (Table 2).

In melanoma and lung cancer trials, high-grade endocrinopathies that required hospitalization and had life-threatening consequences or resulted in death have been reported more frequently than for

Table 2. Outcomes Following Implementation of the e-Consult Service	
MEDIAN INTERVAL BETWEEN CONSULT AND APPOINTMENT SCHEDULED IN DAYS (IQR)	37 (40.25)
VISIT PLANS FROM E-CONSULTS	
Diagnostic recommendations	88
Treatment recommendations	60
No new recommendations	4
ATTENDED FOLLOW-UP VISITS AFTER EACH E-CONSULT	
Yes	74
No	28

Figure 1. Cancer Diagnoses Associated With e-Consults

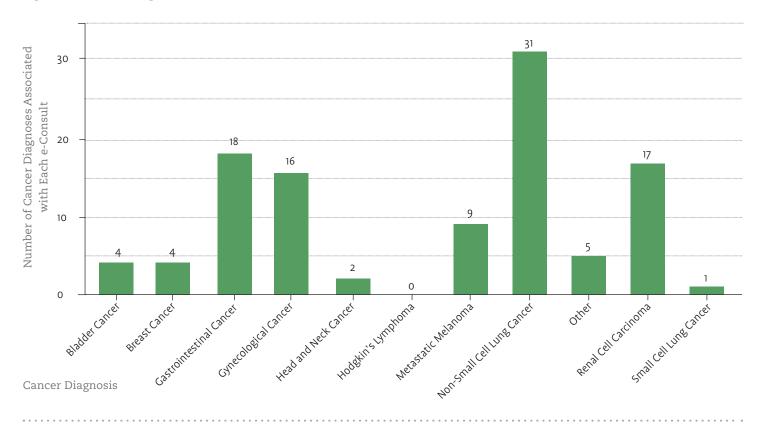
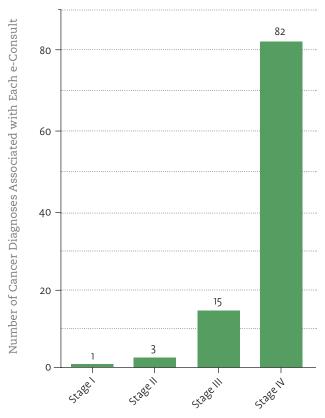


Figure 2. Stage of Cancer at the Time of e-Consult



Cancer Stage

other cancer types,9 with rates ranging from 0.3% to 1.3%.10 Among our data, most e-consults pertaining to irAEs were stratified to CTCAE grades 1 and 2 (86 out of 88 coded irAEs). Of the irAEs documented in the study, 2 (2.23%) were severe enough to warrant hospitalization for further evaluation and management. Among graded irAEs, 99% (87 of 88) received diagnostic or treatment recommendations for further management—all within 48 hours.

Thoracic oncology was the highest utilizer of this service and NSCLC was the most common cancer noted. From the provider satisfaction survey, 9/12 (75%) of providers felt the e-consult to endocrinology changed the management of their patient and 83% reported a 5/5 experience with the consult service. From the 12 providers who completed the survey, 3/12 (25%) felt the e-consult prevented a hospital or emergency department visit for their patient. We also noted that these e-consults were poorly reimbursed by all payers; average reimbursement ranged from \$15 to \$32 per consult.³

Limitations

As this is a retrospective and observational study from a single-center institution, there are limitations to our data. Due to variations in documentation by different providers, faithfully classifying and recording irAEs was challenging. For example, because the diagnosis of irAEs requires clinical suspicion, conveying and capturing symptoms from EHRs is subject to interobserver variation and bias. Future improvements include the possibility of implementing a documentation template so that details are abstracted and captured in a consistent manner.

Discussion

Immune checkpoint inhibitor therapy has transformed care for millions of patients and continues to be actively studied with regard to progression-free survival and overall survival. However, toxicities, especially severe toxicities, result in treatment holidays and treatment termination that can affect these outcomes in the long term.² Endocrine toxicities are common and often treatable with hormone replacement. The challenge, however, is to diagnose and treat adrenal insufficiency, hypothyroidism and hyperthyroidism, and new-onset type 1 diabetes when the concern is raised by oncologists and before patients progress to severe presentations like adrenal crisis, diabetic ketoacidosis, or thyroid storm. As with our institution, many organizations face access delays of weeks or months to see a specialist, and this delay can result in the progression of CTCAE from grade 2 or 3 to grade 4 or 5.

With our e-consult model we have demonstrated a care framework that improves access, mitigates gaps in specialty care, and can be scalable across other specialties that provide services to patients with cancer. We have shown a drop in appointment wait time from a median of 60.5 days to 38.5 days and a drop from 60.5 days to less than 2 days for diagnostic and treatment recommendations. We have also been successful in reducing hospitalization rates from endocrine irAEs from 11% at our institution (between 2007 and 2017) to 2.23% in e-consulted patients between 2020 and 2021. During our study, we also collected billing and reimbursement information for these e-consults and the results show an effort-reimbursement mismatch, which we anticipate will be an important factor to address before considering scalability. The demonstration of reduced health care utilization and reduced access times is ideally placed in a valuebased health care system, and we anticipate that health systems and payers will consider these important variables when considering e-consult reimbursement.

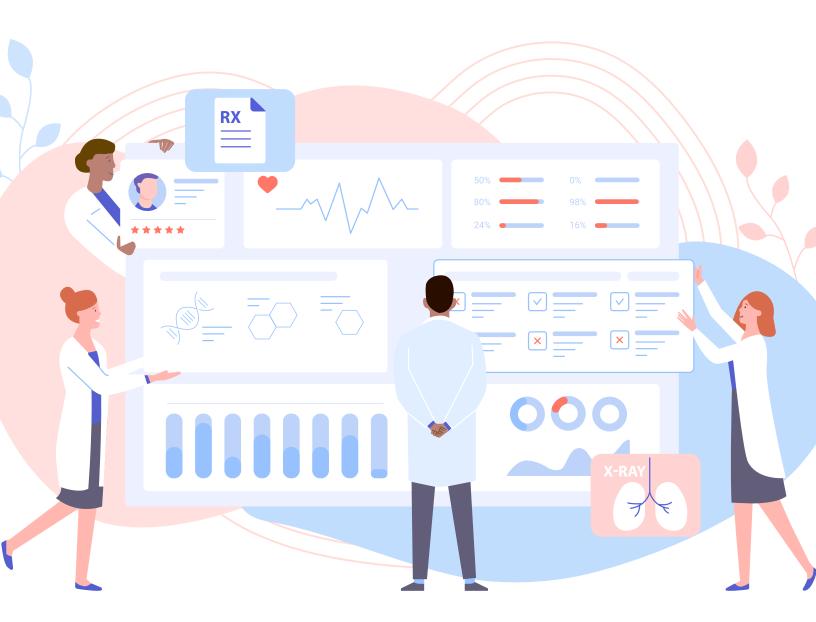
Our conclusion: a framework of e-consults revealed early signs of effectiveness in triaging consult questions and thus expediting receipt of appropriate and high-quality care while ameliorating the patient experience in a care milieu that is fraught with protracted wait times and preventable hospital admissions. To support e-consults, the effort-payment mismatch must be addressed by health systems and payers that can propel integration and scalability of these effective services across oncology and other subspecialty practices to enhance access and mitigate gaps in specialty care provided to cancer patients.

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References

- 1. Naidoo J, Zhang J, Lipson EJ, et al. A multidisciplinary toxicity team for cancer immunotherapy-related adverse events. *J Natl Compr Canc Netw.* 2019;17(6):712-720. doi:10.6004/jnccn.2018.7268
- 2. Duke University Hospital. Duke Cancer Institute Performance Services Data (2022).
- 3. Chu JN, Choi JG, Ostvar S, et al. (2018). Cost of inpatient admissions for immune-related adverse effects from immune checkpoint inhibitor therapy: a single center experience. *J Clin Oncol*. 2018;36(15):3060. doi:10.1200/JCO.2018.36.15_suppl.3060
- 4. Chiloiro S, Bianchi A, Giampietro A, Milardi D, De Marinis L, Pontecorvi A. The changing clinical spectrum of endocrine adverse events in cancer immunotherapy. *Trends Endocrinol Metab*. 2022;33(2):87-104. doi:10.1016/j.tem.2021.10.009
- 5. Puzanov I, Diab A, Abdallah K, et al. Managing toxicities associated with immune checkpoint inhibitors: consensus recommendations from the Society for Immunotherapy of Cancer (SITC) Toxicity Management Working Group. *J Immunother Cancer*. 2017;5(1):95. doi:10.1186/s40425-017-0300-z
- 6. Molina GE, Zubiri L, Cohen JV, et al. Temporal trends and outcomes among patients admitted for immune-related adverse events: a single-center retrospective cohort study from 2011 to 2018. *Oncologist*. 2021;26(6):514-522. doi:10.1002/onco.13740
- 7. Balaji A, Zhang J, Wills B, et al. Immune-related adverse events requiring hospitalization: spectrum of toxicity, treatment, and outcomes. *J Oncol Pract*. 2019;15(9):e825-e834. doi:10.1200/JOP.18.00703
- 8. Spain L, Diem S, Larkin J. Management of toxicities of immune checkpoint inhibitors. *Cancer Treat Rev.* 2016;44:51-60. doi:10.1016/j. ctrv.2016.02.001
- 9. Manne A, Mulekar MS, Escobar DE, et al. Clinical and hematological predictors of high-grade immune-related adverse events associated with immune checkpoint inhibitors. *J Clin Med Res.* 2021;13(5):268-275. doi:10.14740/jocmr4511
- 10. Wang DY, Salem JE, Cohen JV, et al. Fatal toxic effects associated with immune checkpoint inhibitors: a systematic review and meta-analysis. *JAMA Oncol.* 2018;4(12):1721-1728. doi:10.1001/jamaoncol.2018.3923

Leveraging Technology to Develop an Express Symptom Management Program and Reduce Oncology ED Visits





n the United States, of the estimated 131 million patients who visited the emergency department (ED) in 2020, only 14% were admitted into the hospital.¹ These data show that many people are presenting to the ED with health issues that likely could be addressed in a less costly care setting. In fact, it was the substantial strain placed on health care workers and organizations by unnecessary ED visits that prompted administrators at Orlando Health Cancer Institute to develop an express symptom management program in July 2021. The program was designed to effectively triage and treat cancer-related symptoms in the outpatient setting. Dana Salcedo, MSN, APRN, AGACNP-C, NP-C, an outpatient infusion and express symptom management nurse practitioner, took the clinical lead on the project. Her team had 1 goal: to capture patients and address their concerns before they needed to go to the ED.

Program Inception

Like those of most cancer programs and practices around the country, staff members at Orlando Health Cancer Institute and its outpatient services were significantly impacted by the COVID-19 pandemic. Our experienced, long-term oncology nurses were facing burnout and choosing to leave our workforce. As we struggled to replace those experienced individuals with newer and less experienced nurses entering the field, we faced greater demand and volumes across all our sites and expanded from a team of 62 physicians to 104 physicians in less than 2 years. These concurrent events had this impact:

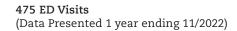
- A growing number of active oncology patients visited the ED (in some cases, multiple times)
- Patients complained about the inability to contact the cancer care provider or cancer care team during the day when they felt ill or experienced acute symptomatic concerns
- Clinical teams were overextended and unable to handle patient calls and messages about acute needs
- An OP-35 (Centers for Medicare & Medicaid Services outpatient chemotherapy measure) that was less than ideal
- Deficits in the care continuum for many patients were noted by our infusion advanced practice provider (APP) and chair placement teams.

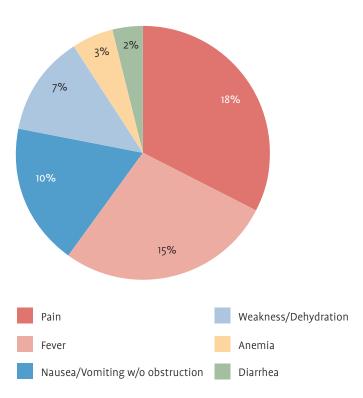
Staff at Orlando Health Cancer Institute collected data on patients who arrived at the ED by means other than ambulance and then were discharged soon after (Figure 1). Members from quality, operations,

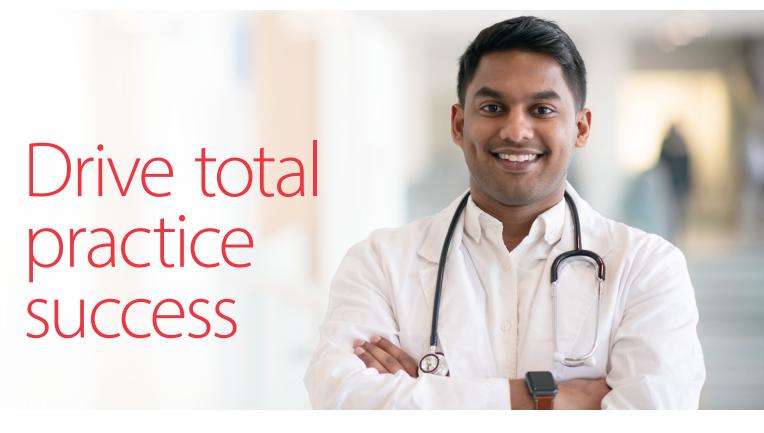
Continued on page 39

The express symptom management team was able to help patients with cancer in managing their symptoms over the phone, in person, or, when indicated, through hospital admission.

Figure 1. Reasons for ED Visits at Orlando Health Cancer Institute—January 2022 to November 2022







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Continued from page 37

and infusion teams then convened to analyze these data, finding that 55% of patients with cancer who presented to the ED could have been successfully managed in the outpatient setting.

Even with limitations to our clinic space, APP capacity, and staffing levels, we had to act. Our infusion advanced practice registered nurse (APRN) agreed to start the express symptom management program with 1 triage nurse to assist with same and next-day chair placement within our 6 infusion locations. With this new program, patients would be able to have either a virtual visit or same-day work-up and treatment within our downtown infusion center. The 2-person team managed acute adverse effects (AEs) of chemotherapy and radiation, including infectious workups, pain and supportive care, and patients at-risk for electrolyte derangement, partnering with the primary oncologist in all planning and intervention.

The team quickly worked with the marketing team to create print pieces (Figure 2) and educational in-services to target patients, RNs, patient navigators, and physicians throughout our 15 clinical outpatient locations. Within 2 weeks, rack cards were shared with the clinical teams, and refrigerator magnets were handed out to patients for ready reference. In addition, information about the new express symptom management service was added as a component of the initial infusion visit.

Even with these efforts, we did not receive the expected level of patient engagement at program launch. Traditional communication with and messaging to patients and providers clearly was not sufficient. Staff at Orlando Health Cancer Institute had to do more if patients were to be managed proactively to keep them out of the ED and avoid any associated and preventable admissions. Our goal at Orlando Health Cancer Institute is always to minimize bacterial and viral exposure of patients with cancer, especially when they are at the highest risk and immunocompromised during treatment.

Leveraging Technology

To assist in fine-tuning the express symptom management program, staff at Orlando Health Cancer Institute implemented a business intelligence dashboard to collect data on patients with cancer who presented to the ED (Figures 3 and 4). Armed with this information, the team was able to track unnecessary ED visits that could have been managed via express symptom management in real time and not while waiting for OP-35 data. The dashboard allowed for tracking and monitoring of these high-risk patients and created a measurable outcome. The express symptom management team was able to help patients with cancer in managing their symptoms over the phone, in person, or, when indicated, through hospital admission.

In 2022, the express symptom management team further advanced these services by partnering with the information technology (IT) team to create automated MyChart (Epic Systems) messages delivered before infusion (phase 1) and after infusion (phase 2). These automated messages are triggered by the electronic health record based on the scheduled chemotherapy appointment. Now patients receive reminders (Figure 5) and education (Figure 6) before infusion and, most importantly, a treatment message that includes a self-management algorithm of common AEs and management strategies after infusion (Figure 7). For issues beyond self-management, patients



The team at Orlando Health Cancer Institute poses with its 2023 ACCC Innovator Award.

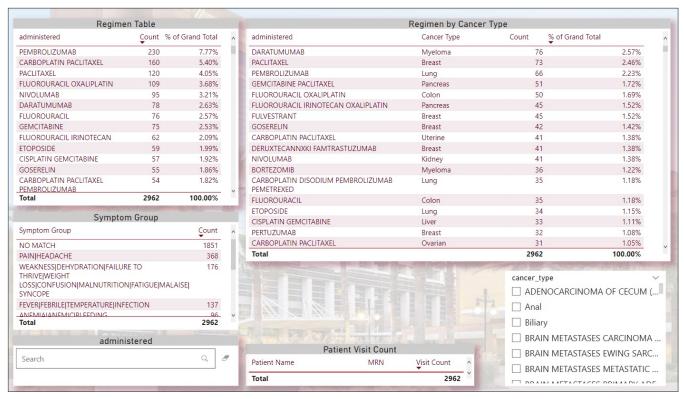
Figure 2. Marketing Piece With Referral Information



are instructed to call members of the express symptom management program for clinical evaluation.

In the summer of 2023, phase 3 of the program began by expanding the post-infusion trigger to include automated messages following every treatment. The team worried that patients would develop message fatigue and anticipated hearing patient complaints about receiving too many messages, but the opposite occurred. After phase 3, the express symptom management team saw a sudden spike in use (Figure 8) and contributed this uptick to the additional (Continued on page 41)

Figure 3. Examples of Business Intelligence Dashboard Tracking of ED and Unplanned Admissions



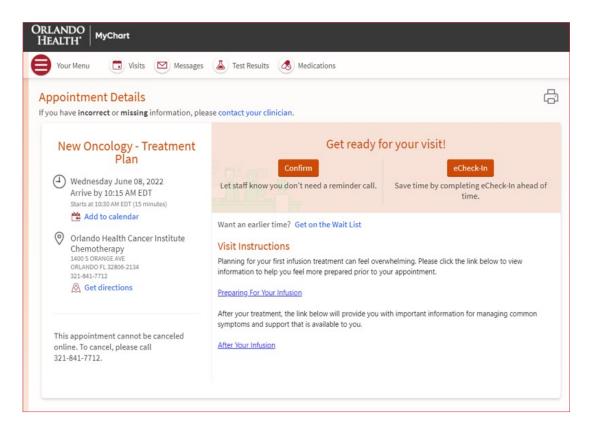
ED, emergency department; MRN, medical record number.

Figure 4. Example of Dashboard With OP-35 Data on Patients With Cancer



Chemo, chemotherapy; GI, gastrointestinal; MRN, medical record number; OP-35, Centers for Medicare & Medicaid Services outpatient chemotherapy measure.

Figure 5. Epic View of the Pre-Infusion Message in MyChart



Continued from page 39

patient messaging. Figure 9 illustrates program growth during this 3-phase process.

In addition to tracking the growth in patient calls and visits, the express symptom management team worked closely with the quality team to monitor the dashboard and proactively target disease sites and patient populations who used ED services the most. Working together, the 2 teams developed education pathways and in-service programs for health care providers and support staff. Arming clinicians and other staff members with the appropriate tools and making them comfortable with triaging and sending patients to the express symptom management team as early as possible allowed intervention before patients considered an ED visit and reduced avoidable visits. When a patient needed admission, the express symptom management team worked directly with the primary oncology team to admit patients directly to further protect them from unnecessary exposure to ED environments.

As the express symptom management team grew, so did the demands placed on the 2-person team. Administrators at Orlando Health Cancer Institute used this growth to establish a pro forma and obtain approval to add a second APRN and a part-time full-time equivalent (FTE) staff member to help cover infusion rounds and the growing patient demand for this service. This expansion allowed the APPs to spend additional educational time with patients. (Prior to this program expansion, many patients believed that their time

was rushed.) Adding additional providers had a positive impact on patients and the outpatient clinical teams who used express symptom management services.

Measuring Impact

In retrospect, administrators at Orlando Health Cancer Institute recognized that it was when the cancer program started to leverage technology on multiple fronts that the express symptom management program first started to grow. As shown in Figure 10, use was increasing slowly until phase 3, when regular MyChart patient messaging was initiated. Indeed, it seemed that patient use of express symptom management services doubled with the flip of that switch. Further, data showed that Orlando Health Cancer Institute was successfully reaching its patients and delivering interventions to keep them out of the ED and hospital.

That said, when data analyst Matt Paster started to gather ED volume and compare data sets, he was initially disappointed to see an increase in ED volume. With his understanding of express symptom management utilization and patient feedback, he performed more analyses to understand these conflicting data. He soon found that data showing an increase and then flattening of ED volume were tied to growth in overall chemotherapy volume. The data showed an almost 30% increase in ED visits; however, when the growth in chemotherapy volume and increased use of express symptom management services was factored in, ED use

Figure 6. Pre-Infusion Education Message in MyChart



Figure 7. Post-Infusion Education Message in MyChart



was actually on the decline. In other words, implementation of express symptom management services was making a considerable impact and decreasing ED visits and use (Figure 10). Extrapolation of these data showed that only about 2% of patients who had gone to the ED needed to be hospitalized; the rest just needed supportive care.

Express symptom management services have also improved and enhanced outpatient clinic flow. Providers find comfort in knowing that they have a resource available to their patients. Patients with cancer who present at Orlando Health Cancer Institute share a similar enthusiasm for the program. The patients absolutely love it—they feel like they have an extra pair of eyes to help them at a moment's notice.

The flourishing strategic partnership between the clinical oncology team and the IT team has been integral to the program's success. As in everything in the current health care environment, the appropriate use of technology is critical for moving forward. Technology allows clinical providers to maximize their time with patients, lets cancer care teams meet patients where they desire during their health care journey, and supports efforts to stabilize staffing challenges and needs. The mission of Orlando Health Cancer Institute is to provide quality of care to all patients. Members of the cancer care team receive many letters of support and thanks from patients. As a patient wrote, "...Without these 2...being there that day, I am pretty sure I would have ended up in the emergency department for dehydration.

They made the difference of going to the hospital or being able to come home that day and rest." This testimonial speaks volumes about the express symptom management program and its importance (Figure 11); it also reflects the improvements and changes made by Orlando Health Cancer Institute. Bringing patients into the infusion center to be assessed, treated, and sent home without exposing them to an unsafe ED environment or unnecessarily admitting them to the hospital is the gold standard. These types of patient feedback and recognition serve as the catalyst for plans to expand and enlarge express symptom management services into regional facilities.

Next Steps in the Journey

Growth in infusion and bone marrow transplant volumes has capped space at Orlando Health Cancer Institute. Currently, administrators are exploring expansion into additional space until its new, larger infusion center is completed in 2024 with 4 to 5 planned rooms for express symptom management. Additional hiring of express symptom management FTE staff members is being planned, which will expand this service onsite in 5 regional facilities and enable patients to stay in their community instead of traveling downtown to the larger infusion center. By end of 2024, with the new space, administrators at Orlando Health Cancer Institute plan to expand hours of operation into the evenings and weekends, as ED use spikes have been noted during those times. The express (Continued on page 45)

Figure 8. Daily Calls to Express Symptom Management Since Program Inception

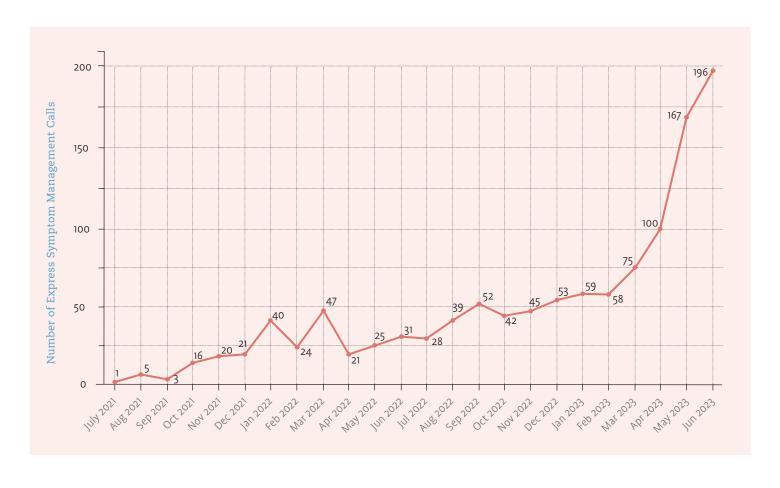


Figure 9. Express Symptom Management Implementation Timeline

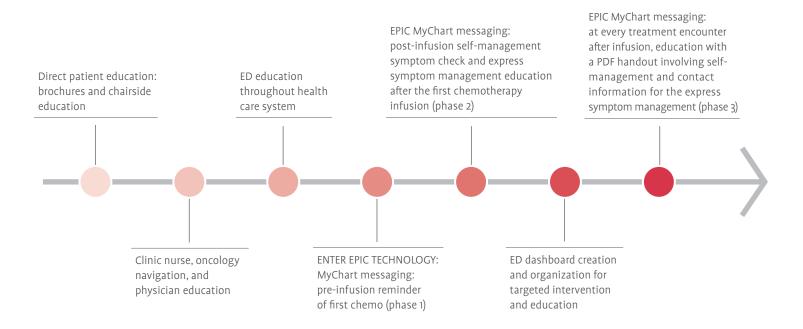


Figure 10. Express Symptom Management, ED, and Outpatient Chemotherapy Volume: A Comparison





Figure 11. Patient Testimonial

Good morning.

I called [the] Express Symptom Management [team], as I was having major diarrhea issues, and I felt very dehydrated with my chemotherapy treatments. I just did not feel good. They took the time to ask me questions to get the information needed to help me. Within an hour, these ladies wanted me to come to the cancer center to get the fluids and the testing I needed to find out why I was having such an issue. They kept me informed the entire time I was at the center that day. I was updated on everything that was going happen, and [they] made sure that I was OK. Since then, they have made sure that I have seen the correct doctors and made sure that I would be seen and [be] taken care of. They both have called me to follow up with my issue and [have] made sure I was being seen and being helped. They really cared, and that made me feel like I was important to them and not just another patient. I wanted to say that without those 2 ladies being there that day, I am pretty sure I would have ended up in the emergency department for dehydration. They made the difference of going to the hospital or being able to come home that day and rest.

Thank you for the great care.

Continued from page 42

symptom management team is excited about the considerable impact it will have with this expansion.

On the technology front, the next phase includes an AE questionnaire that will be sent through MyChart to patients for self-reporting. These will be data that Orlando Health Cancer Institute staff can use to enhance and develop new components of the express symptom management program and to design further interventions. For the first 3 phases, Orlando Health Cancer Institute members only worked within the Epic MyChart realm for automated communications. The Institute's MyChart activation rate hovered around 70%; accordingly, the team understands that delivery of this same information has been missed in 30% of patients. To reach these individuals, the express symptom management team is working closely with IT to activate texting and email communication based on individual preference to ensure that all patients receive critical information about the express symptom management service.

The advisory board suggests that these 4 tactics be used to reduce ED visits and hospitalizations:²

- 1. Implementing standardized telephone triage
- 2. Implementing flexible scheduling systems
- 3. Deploying advanced practice providers
- 4. Creating dedicated space for urgent care

With APPs already deployed in the express symptom management program and a planned expansion, growth in Orlando Health Cancer Institute's patient volume and demand led organically to a focus on triage and flexible scheduling. Currently, the Orlando Health Cancer Institute has a task force focused on cloning the triage process and skillset of its express symptom management program throughout its outpatient clinics. This training will help to minimize the time spent

within the messaging matrix and increase the number of patients directed immediately to the express symptom management team for care. Other work in progress includes establishment of clear lanes of operation and separation of infusion rounds accomplished by APPs from the express symptom management program to allow for more add-ons throughout the day—that is implementation of flexible scheduling systems. With growth in both the infusion and express symptom management programs, being intertwined with staff accomplishing infusion rounds has limited the express symptom management team's ability to have contact with patients.

The staff at Orlando Health Cancer Institute is excited about the next steps and looks forward to reporting successes and achievements at the end of 2024. Aside from best serving its patients and communities, the Express Symptom Management program will have significant impact on overall cost of care, quality outcomes, and best practice in value-based care for patients with cancer and the systems that treat them.

Alyssia Crews, MBA, AVP, is an assistant vice president; Dana Salcedo, MSN, APRN, AGACNP-C, NP-C, is an oncology nurse practitioner at the Express Symptom Management & Outpatient Infusion Clinic; and Matt Paster, MAcc, is clinical data analyst II at Orlando Health Cancer Institute in Orlando, Florida.

References

- 1. Emergency department visits. CDC; National Center for Health Statistics. Reviewed November 3, 2023. Accessed January 15, 2024. https://www.cdc.gov/nchs/fastats/emergency-department.htm
- 2. Bartz N, Fuller D, Conway L. Urgent care for cancer patients: four tactics to reduce ED visits and hospitalizations. The Advisory Board Company. 2013. Accessed January 15, 2024. https://www.advisory.com/content/dam/advisory/en/public/Advisory/Topics/Classic/urgent-care-for-cancer-patients/Urgent-Care-for-Cancer-Patients.pdf

A Model for Demonstrating Sustainable Outreach for





5. Elizabeth Healthcare, located in Northern Kentucky and Southeast Indiana, is a community-based health care system with 6 hospitals. The affiliated 800-provider group serves 400,000 patients. We recognize that prevention, early detection, the latest diagnostic work-up tools and treatments, and whole person care are essential when it comes to fighting the battle against cancer; we are committed to providing these services to our patients. With state-of-the-art facilities, advanced technologies, and compassionate care teams, we confidently ensure the best possible outcomes for our patients.

The Significance of Cancer Screening

Cancer screening plays a pivotal role in our approach to delivering comprehensive cancer care. Early detection through screening significantly improves the chances of survival and reduces the burden of cancer on individuals and communities. ^{1,2} In the United States, the President's Cancer Panel and the Cancer Moonshot initiative have placed an emphasis on increasing cancer screening uptake and closing the gaps in cancer screening, access, and follow-up care. Improving lung cancer screening rates in a manner more consistent with the trajectory patterns and penetrance of breast,

Early detection through screening significantly improves the chances of survival and reduces the burden of cancer on individuals and communities.

cervical, and colon cancer screenings is a focus of an enhanced outreach effort.³ In this article, we will present the results of our screening programs and innovative processes that have increased the uptake of these lifesaving options substantially. Our focus includes breast, colorectal, and lung cancer screenings and complementary tools. A central challenge in this process is ensuring that patients promptly follow through with their screening recommendations and orders. The effectiveness of cancer screening can be complex and resource-intensive, necessitating adherence to established protocols and demonstrating a return on investment *Continued on page 49*



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Continued from page 47

(ROI) for screening programs. Establishing ROI is critical for securing funding and support of, and long-term sustainability for, these programs that improve outreach to patients with outstanding orders.⁴

Identifying and Engaging Patients

Identifying eligible patients is crucial, and it is the first step in our screening outreach efforts. We use the latest US Preventive Services Task Force (USPSTF) criteria in leveraging our electronic health record (EHR) system Epic (Epic Systems) to achieve this goal.⁵ When a patient has not undergone appropriate cancer screening within the recommended time frame, our health maintenance section in the EHR triggers alerts for clinical associates and providers. In the case of lung cancer screening, providers receive additional prompts through a best practice alert when a patient qualifies for lung cancer screening but has not had a low-dose CT (LDCT) lung cancer screen or another qualifying chest CT within a year.

We closely monitor and maintain the uptake of cancer screening through a Qlik Sense (Qlik) dashboard, providing monthly performance reports to monitor and encourage provider compliance. Every quarter, we conduct a comprehensive review of our lung cancer screening program and rank the 192 providers and 41 primary care sites by their capture of eligible patients. Additionally,

a Provider Achievement Dashboard assists in monitoring and tracking uptake for select quality metrics including cancer screenings. These data are integrated into annual provider reviews.

Shifting Focus and Overcoming Challenges

Initially, our efforts were primarily concentrated on breast and colorectal cancer screening, as they were tied to the Healthcare Effectiveness Data and Information Set (HEDIS) measures provided by the National Committee for Quality Assurance. However, with the establishment of a robust lung cancer screening program that demonstrated notable results and successes, our attention began to shift towards supporting the uptake of lung cancer screenings. Moreover, there is an expectation that lung cancer screening will become a HEDIS measure by 2025, making it imperative to implement streamlined and effective processes in the interim.

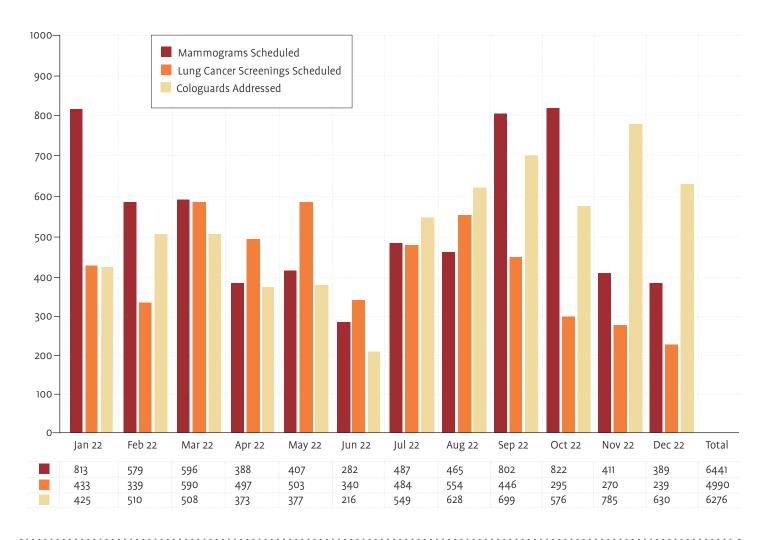
In 2018, we integrated social service workers into our practices while building the infrastructure and network to support the Comprehensive Primary Care Initiative (CPCI) of the Centers for Medicare & Medicaid Services. In the early days of the CPCI program, the social services team had the capacity to contact patients with outstanding orders. As CPCI responsibilities evolved, however, these resources became strained, leading to the decommissioning of this component of lung cancer screening program outreach. In October 2020, during the COVID-19 pandemic, our new Cancer Care Center opened, and a medical assistant was hired to support and coordinate the Integrative Medicine Program for the Cancer Care Center. Workload changes during the pandemic allowed the medical assistant to redirect time and efforts to lung cancer screening program outreach in early 2021. However, she eventually returned to her previous position and duties. Subsequently, our new Virtual Health Center Nurse Triage team assumed the outreach role in mid-2021, as the team was not yet fully used in the early phases of the program. As that program resumed, there was no available support for the outreach. Each of these short-term efforts led to substantial improvements in uptake and adherence; still, each was ultimately unsustainable for various reasons.

Demonstrating ROI: A Key to Sustainability

In 2019, we conducted an extensive and comprehensive financial analysis of our breast, colorectal, and lung cancer screening efforts. This exercise was instrumental in demonstrating positive net ROI for these programs and considering associated expenses, reimbursement, payer mix, and dowwnstream revenues. The analysis revealed net returns of \$280 per LDCT lung cancer screen, \$257 per colonoscopy, and \$126 per mammogram. This review laid the foundation for securing registered nurse (RN) resources for our Population Health Support Services team.

Our order completion outreach program, with refined workflows, commenced in August 2021 and continued throughout 2022. Presently, we employ 12 outreach specialists who contact patients with an outstanding mammogram, Cologuard (Exact Sciences), or LDCT lung cancer screening order. These outreach specialists are all licensed RNs. Data from these 2022 outreach efforts are illustrated in Figure 1.

Figure 1. Data for Outstanding Orders for Mammograms, Cologuard Testing, and Lung Cancer Screenings, 2022



Multidisciplinary collaboration among leadership from the Population Health Support Services and Quality Transformation teams, screening and thoracic oncology nurse navigators, and providers occurs every 2 weeks; it has been instrumental in the growth, improvement, and success of our programs. This level of support and contribution has been highlighted in several other outreach efforts. ⁶⁻⁹ Members of our Breast Center coordinate, track, and manage all breast cancer screening efforts; the Breast Center also benefits from this coordinated outreach and promotes lung and colorectal cancer screening.

Effective Outreach Strategies

For preventive lung cancer and breast cancer screenings, the outreach team contacts the patient by phone if an order is not followed by an appointment within 14 days. Likewise, the outreach team contacts a patient to complete a Cologuard order if no test result is available 60 days after order placement. The outreach team attempts to contact patients twice. After the first attempt, a MyChart message is sent to patients; another attempt follows after 1 week in a continued effort to schedule patients' screening. If patients are admitted to the hospital, outreach contact is delayed for 30 days. If patients remain unreachable after the first 2 outreach attempts, they return to the worklist for continued outreach attempts after 180 days. Patients who receive

active cancer treatment, long-term care, or hospice care are also excluded from outreach for 180 days.

Tracking Progress and Challenges

The historical progress of our breast, colorectal, and lung cancer screening efforts is represented in Table 1.10-12 We were on track to exceed 80% for breast cancer screening just before the COVID-19 pandemic, but the global pandemic created challenges to achieving this goal. Colorectal cancer screening rates have improved steadily, which demonstrates our persistence in driving positive outcomes despite both expanded age ranges for screening and growth in the population of eligible patients. The lung cancer screening initiative faced a significant setback in the spring of 2020, with only 13 lung cancer screenings recorded in April 2020. The year concluded with a 5.81% decline compared with 2019. Nevertheless, we have made considerable strides in improving these lung cancer screening metrics.

Through our participation in the American Cancer Society's Return to Screening Learning Collaborative project, we learned that the challenges we faced with screening rates following the pandemic were not unique to our organization. In fact, these issues were experienced at many organizations across the country.

Table 1.	St. Eliza	abeth E	Iealth	Care (Cancer
Screeni	ng Rates	s, 2018-	-2021		

YEAR	LUNG, %	BREAST, %	COLON, %ª
2018	na	68	63
2019	36.0	77.6	73
2020	29.3	72.4	74.2
2021	49.7	67.4	73.7
2022	44.1 ^b	73.3	72.8
2023, projected ^c	47.1	78.3	77.5
National ^{10–12}	6.51	66.7	68.8

CMS, Centers for Medicare & Medicaid Services; NA, not available; USPSTF, US Preventive Services Task Force.

Impact of Outreach Programs

The implementation of outreach programs to complete orders has wielded substantial influence on the uptake of each respective cancer screening program. To date, our lung cancer screening program resulted in over 37000 successfully completed lung cancer screenings since its start in 2013. In 2022, the Population Health Support Services team scheduled 4990 lung cancer screening appointments; of those, 3113 patients successfully completed screenings. Remarkably, these data account for 38% of the total 8219 lung cancer screenings completed in 2022. This achievement has contributed significantly to improving our adherence rate, which stands at 52% for 2021 and 59% for 2022.

In addition to lung cancer screenings, 7189 breast cancer screenings were scheduled by members of our program in 2022. Of those scheduled appointments, 3976 screenings were completed, which accounts for 15% of the organization's completed breast cancer screenings that were scheduled through Population Health Support Services. The impact of 12 RN outreach specialists on screening efforts for an organization with 2400 associates is outstanding. We anticipate that this outreach department will continue to grow to meet the needs of our growing patient community.

Secrets to Success

Many factors contribute to sustaining an outreach program and demonstrating the positive results and impact on patients' lives. During every outreach call, staff members attempt to close all open care gaps and provide resources and education for patients. Members of Population Health Support Services continuously stay true to the phrase "Smile and Dial." We make every outreach attempt count by

educating about the importance of preventive cancer screening and ways that it can save lives. In addition, our team collaborates with internal and external departments that include care management. For example, during outreach calls, patients may indicate that they need assistance with transportation to their scheduled appointment; we have the resources available to meet that need.

Early detection through screening significantly improves the chances of survival and reduces the burden of cancer on individuals and communities.

The Importance of Lung Cancer Screening

Lung cancer is a significant public health concern, and early detection is crucial for improving patient outcomes. Aberle et al provided a pivotal development in lung cancer screening with the landmark United States National Lung Screening Trial (NCT00047385) published in the New England Journal of Medicine in 2011; results of this study demonstrated the effectiveness of LDCT screening in reducing lung cancer mortality.13 The large-scale, multicenter study compared LDCT screening with standard chest x-rays in a high-risk population of patients who currently or formerly used tobacco products. Over 53000 participants were enrolled, making it one of the largest studies ever funded by the National Cancer Institute. The trial's findings were astounding: LDCT screening resulted in a 20% reduction in lung cancer mortality when compared with chest x-rays. This study has played a pivotal role in the field of lung cancer screening and has shaped the guidelines, policies, and strategies regarding LDCT lung cancer screening for high-risk individuals.

Although on a smaller scale, the NELSON lung cancer screening trial (NELSON Netherlands Trial Register number NL580) conducted in Belgium had a similar and profound impact in the European theater.¹⁴

Outcomes of both practice-changing studies served as catalysts for the development of associated guidelines and the integration of LDCT into lung cancer screening programs across the United States. At our healthcare system, since March 2022, we have closely followed the USPSTF 2021 guidelines for lung cancer screening, which recommend annual LDCT screening for individuals aged 50 to 80 years who have a 20 pack-year smoking history and currently smoke or quit smoking within the previous 15 years. Our screening program has been instrumental in identifying eligible patients and ensuring that they receive the recommended LDCT screening. Our program's success can be attributed to a dedicated team of nurse navigators, radiologists, thoracic surgeons, pulmonologists, and other healthcare professionals who work collaboratively to provide comprehensive care to patients at risk of lung cancer.

Overcoming Challenges in Lung Cancer Screenings

The National Lung Screening Trial and subsequent studies have highlighted the benefits of LDCT screening in reducing lung cancer

^a Rates reflect USPSTF 50- to 75-year-old patient population

^b Changed from CMS 2015 to USPSTF 2021 criteria

c Annualized from July 31, 2023

mortality, yet lung cancer screening programs continue to face many challenges. One significant challenge is identifying eligible patients and encouraging them to be screened. High-risk individuals and their providers may not be aware of their eligibility, and some may be hesitant to undergo screening due to concerns about radiation exposure or fear of a cancer diagnosis. Historically, lung cancer has had a dismal prognosis; many consider it a death sentence. This belief is difficult to combat, but the changing landscape of response to novel treatments and technologies and of improved survival have given new hope to patients with lung cancer.

Many individuals at risk for, or with a diagnosis of, lung cancer are ashamed of their tobacco dependence, or they blame themselves for developing the malignancy. No one with lung cancer deserves the disease, and certainly no one deserves to die from it. This stigma is woven deeply into the fabric of our culture, and it profoundly impedes the uptake of lung cancer screenings.

To address these challenges, our program implemented a multi-faceted approach to patient outreach and education. We use EHRs to identify eligible patients, and our nurse navigators play a vital role in educating patients about the benefits of screening and addressing their concerns. Additionally, we collaborate with primary care providers to ensure that eligible patients are referred for LDCT screening.

The implementation of lung cancer screening in our healthcare system impacted early lung cancer detection significantly. ¹⁵ Since the

inception of the program, we have screened thousands of high-risk individuals, leading to the early detection of lung cancer in many cases. We have found 1 incidence of lung cancer for every 28 unique patients screened, with over 60% of patients diagnosed with stage I disease since the inception of our program in 2013. Early detection allows for more effective treatment options, far less costly care, and improved patient outcomes. Figure 2 demonstrates that our efforts resulted in significant stage migration from 2015 to 2022–3103 diagnoses of lung cancer among 459 screened patients and 2644 individuals who were not screened. Sharing these data and successes generated within our health care system has been a huge motivator for providers, managers, associates, and administrators to support lung cancer screening.

As a testament to the impact of our lung cancer screening program, the proportion of late-stage (III/IV) lung cancer has fallen 23.1% over the 8 years between 2015 and 2022 (Figure 3). Diagnoses of early-stage lung cancer surpassed those of late-stage lung cancer in 2022. A portion of this improvement trend may also be attributed to the enhanced focus on the incidental pulmonary nodule program and implementation of supporting software for this program.

The Importance of Regular Mammograms

Breast cancer is one of the most common cancers affecting women worldwide. Mammography, a specialized x-ray of the breast, is a cornerstone of breast cancer screening programs. Early detection of

Figure 2. St. Elizabeth Healthcare Lung Cancer Screening Stage Migration, 2015-2022

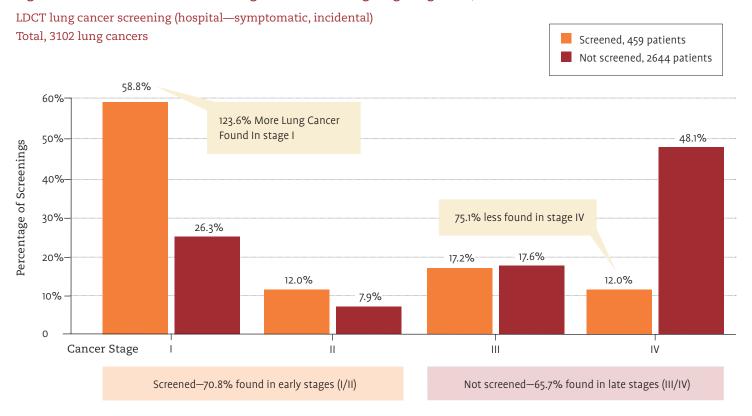
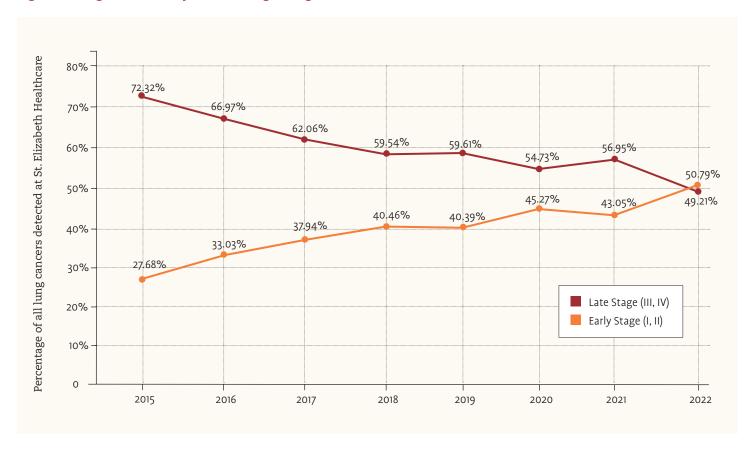


Figure 3. Diagnoses of Early vs Late-Stage Lung Cancer, 2015–2022



breast cancer through mammography can significantly improve treatment outcomes and reduce mortality rates. ¹⁶⁻¹⁸

Per USPSTF guidelines, regular mammograms are recommended for women starting at 50 years of age, although guidelines may vary based on individual risk factors and family history. ¹⁹ These screening tests play a crucial role in detecting breast cancer at an early, more treatable stage. Women who undergo routine mammograms are more likely to receive timely interventions and to experience better long-term outcomes. Staff members at our health-care system are committed to promoting regular mammography screening and ensuring that eligible women receive this important preventive service.

With our order completion process, nurse navigators contact patients who are eligible for the screening and schedule appointments as appropriate. If outreach attempts are unsuccessful, patients are contacted again until the orders expire or these individuals are successfully scheduled.

Challenges in Breast Cancer Screening

Despite the clear benefits of mammography, breast cancer screening programs face challenges like those encountered in other cancer screening efforts. These challenges may involve patient awareness, access to screening facilities, and timely follow-up for abnormal results.²⁰ To address these challenges, our breast cancer screening program employs a proactive approach to patient outreach and education. We prioritize timely follow-up for abnormal mammograms,

and a dedicated team of radiologists, nurse navigators, and oncologists work together to provide comprehensive care to patients.

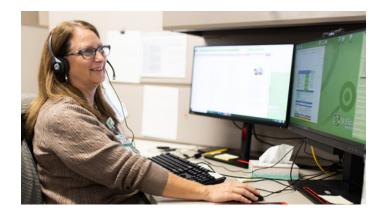
The Importance of Colorectal Cancer Screening

Colon cancer—a serious yet preventable disease—underscores the importance of regular screening. Cologuard offers a noninvasive, effective screening option that improves patient participation and early detection. ^{21,22} Cologuard detects genetic markers, DNA changes, and hemoglobin in the stool that indicate the presence of colon cancer or precancerous polyps. The test's convenience and efficacy have amplified its role in screening programs and have overcome patient hesitancy concerning more invasive procedures. The Population Health Support Services team's proactive outreach, informative initiatives, and encouraging support have inspired patients to embrace this choice.

Challenges in Colorectal Cancer Screening

Colorectal cancer screening is crucial for early detection and prevention, but it comes with its share of challenges. One significant challenge is patient compliance, since traditional methods like colonoscopy can be invasive, uncomfortable, or inconvenient and can lead some individuals to opt out of screening completely. Additionally, fear of anesthesia or lack of access to healthcare services and/or insurance coverage can limit screening opportunities for many individuals.

Cologuard has emerged as a promising option to address many of these issues. However, the test's effectiveness can vary, and false



positives or false negatives may result. Moreover, use of Cologuard may not be suitable for everyone, as it is primarily recommended for individuals at average risk.

Balancing accessibility, accuracy, and patient comfort remains an ongoing challenge in colorectal cancer screening. Cologuard offers a more patient-friendly approach, but healthcare providers must carefully consider its limitations and tailor screening recommendations to individual risk profiles to ensure effective cancer prevention and early detection.²³

Nurse navigators follow a similar process to complete orders for colorectal cancer screening. Patients are contacted 1 week after the colon cancer screening order has been placed if there is no appointment on record. If patients cannot be contacted, nurse navigators make a second attempt to contact and schedule the patient. If the second attempt is unsuccessful, patients fall back to our order completion reports in 90 days, and the process starts again.

This order completion workflow has been highly successful, since it closes many patient care gaps and serves as the patient's safety net for completing health screenings. Members of our team will tell you that patients are thankful for their care and the knowledge that a nurse is available to contact them and to assist with scheduling appointments that may have been forgotten. This collective effort has helped to establish St. Elizabeth Healthcare as one of the nation's leading users of Cologuard for colorectal cancer screening.

Conclusion

Our health care system has developed a worthwhile, profitable, and sustainable process to ensure outreach to patients with outstanding orders for breast, colorectal, and lung cancer screening. These order completion processes were designed to improve screening uptake and to provide the best care for patients. One key component of our sustainable process is the use of a dedicated outreach specialist team. These nurse navigators are trained to educate patients and the community about the importance of screening, the eligibility criteria, and the availability of screening services. They schedule patients for their appointments and connect uninsured or underinsured patients to community resources that can assist with financial support and transportation to and from screening facilities. In Kentucky, we have built relationships with multiple organizations to provide this support and to help patients complete life-saving cancer screenings. These organizations offer a combination of private, state, and federal funding.

The challenges we face in cancer screening outreach are not unique, but our commitment to addressing these challenges through innovative approaches and collaborative care has yielded substantial progress. As we continue to expand our outreach efforts and leverage technology



to identify and educate eligible patients, we are confident that we can make a meaningful impact on cancer prevention and early detection in our community.

Our processes and workflows allow us to not only identify patients in need of a screening order completion but also to track and follow up with patients until testing is completed. Our nurse navigator teams have also implemented a tightly controlled system for following up on abnormal results for mammograms, Cologuard tests, and LDCT lung cancer screenings. These outreaches are tabulated and built into a report to enable the tracking and management of these outstanding orders and subsequent results. Nurse navigators provide excellent communication and feedback to ordering providers throughout these processes. This collaborative approach ensures that patients who need further evaluation and treatment are quickly referred for surveillance imaging or to specialists, providing the most time-efficient, cost-effective, and coordinated care. Early detection of these cancers allows for easier treatment at less expense and helps us to save lives, reduce the financial burden of late-stage cancer, and ultimately deliver comprehensive cancer care to our patients.

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References

- 1. Coldman AJ, Phillips N, Wilson C, et al. Pan-Canadian study of mammography screening and mortality from breast cancer. *J Natl Cancer Inst.* 2014;106(11):261. doi:10.1093/jnci/dju261
- 2. Pasick RJ, Hiatt RA, Paskett ED. Lessons learned from community-based cancer screening intervention research. *Cancer*. 2004;101(S5):1146-1164. doi:10.1002/cncr.20508
- 3. Williams JP. President's Cancer Panel report: closing gaps in cancer screening for all Americans. National Cancer Institute. February 3, 2022. Accessed December 22, 2023. https://www.cancer.gov/news-events/cancer-currents-blog/2022/cancer-screening-presidents-cancer-panel-report
- 4. Brill JV. Screening for cancer: the economic, medical, and psychosocial issues. *Am J Manag Care*. 2020;26(suppl 14):S300-S306. doi:10.37765/ajmc.2020.88534
- 5. Baus A, Wright LE, Kennedy-Rea S, et al. Leveraging electronic health records data for enhanced colorectal cancer screening efforts. *J Appalach Health*. 2020;2(4):53-63. doi:10.13023/jah.0204.07
- 6. Dietrich AJ, Tobin JN, Robinson CM, et al. Telephone outreach to increase colon cancer screening in Medicaid managed care organizations: a randomized controlled trial. *Ann Fam Med.* 2013;11(4):335-343. doi:10.1370/afm.1469
- 7. Subramanian S, Tangka FKL, Hoover S, DeGroff A. Integrated interventions and supporting activities to increase uptake of multiple cancer screenings: conceptual framework, determinants of implementation success, measurement challenges, and research priorities. *Implement Sci Commun.* 2022;3(1):105. doi:10.1186/s43058-022-00353-8

- 8. Percac-Lima S, López L, Ashburner JM, Green AR, Atlas SJ. The longitudinal impact of patient navigation on equity in colorectal cancer screening in a large primary care network. *Cancer*. 2014;120(13):2025-2031. doi:10.1002/cncr.28682
- 9. Castañeda SF, Bharti B, Rojas M, et al. Outreach and inreach strategies for colorectal cancer screening among Latinos at a federally qualified health center: a randomized controlled trial, 2015-2018. *Am J Public Health*. 2020;110(4):587-594. doi:10.2105/AJPH.2019.305524
- 10. Fedewa SA, Bandi P, Smith RA, Silvestri GA, Jemal A. Lung cancer screening rates during the COVID-19 pandemic. *Chest.* 2022;161(2):586-589. doi:10.1016/j.chest.2021.07.030
- 11. Health, United States, 2019: With special feature on the health of young adults. Table 33. Centers for Disease Control and Prevention. Accessed October 22, 2023. https://www.cdc.gov/nchs/hus/index.htm
- 12. Colorectal cancer statistics. Health, United States, 2019. June 8, 2023. Centers for Disease Control and Prevention. Accessed October 22, 2023. https://www.cdc.gov/cancer/colorectal/statistics/index.htm
- 13. Aberle DR, Adams AM, Berg CD, et al. Reduced lung-cancer mortality with low-dose computed tomographic screening. *N Engl J Med*. 2011;365(5):395-409. doi:10.1056/NEJMoa1102873
- 14. Horeweg N, Scholten ET, de Jong PA, et al. Detection of lung cancer through low-dose CT screening (NELSON): a prespecified analysis of screening test performance and interval cancers. *Lancet Oncol*. 2014;15:1342-1350. doi:10.1016/S1470-2045(14)70387-0
- 15. Gieske MR, Kerns J, Schmitt GM, et al. Overcoming barriers to lung cancer screening using a systemwide approach with additional focus on the non-screened. J Med Screen. 2023;Online ahead of print. doi:10.1177/09691413231208160
- 16. Legler J, Meissner HI, Coyne C, Breen N, Chollette V, Rimer BK. The effectiveness of interventions to promote mammography among women with historically lower rates of screening. *Cancer Epidemiol Biomarkers Prev.* 2002;11(1):59-71.
- 17. Broeders M, Moss S, Nyström L, et al; EUROSCREEN Working Group. The impact of mammographic screening on breast cancer mortality in Europe: a review of observational studies. *J Med Screen.* 2012;19(suppl 1):14-25. breast cancer mortality in Europe: a review of observational studies. J Med Screen. 2012;19 Suppl 1:14-25. doi:10.1258/jms.2012.012078
- 18. McCarthy AM, Kim JJ, Beaber EF, et al; PROSPR consortium. Follow-up of abnormal breast and colorectal cancer screening by race/ethnicity. *Amer J Prev Med.* 2016;51(4):507-512. doi:10.1016/j. amepre.2016.03.017
- 19. Screening for breast cancer: USPSTF recommendation statement. U.S. Preventive Services Task Force. U.S. Preventive Services Task Force. January 11, 2016. Accessed October 22, 2023. https://www.uspreventiveservicestask-force.org/uspstf/recommendation/breast-cancer-screening
- 20. Mahalakshmi S, Suresh S. Barriers to cancer screening uptake in women: a qualitative study from Tamil Nadu, India. *Asian Pac J Cancer Prev.* 2020;21(4):1081-1087. doi:10.31557/APJCP.2020.21.4.1081
- 21. Imperiale TF, Ransohoff DF, Itzkowitz SH, et al. Multitarget stool DNA testing for colorectal-cancer screening. *N Engl J Med.* 2014;370(14):1287-1297. doi:10.1056/NEJMoa1311194
- 22. Ahlquist DA. Multi-target stool DNA test: a new high bar for noninvasive screening. *Dig Dis Sci.* 2015;60(3):623-633. doi: 10.1007/s10620-014-3451-5.
- 23. Cai SR, Zhang SZ, Zhu HH, Sheng S. Barriers to colorectal cancer screening: A case-control study. *World J Gastroenterol*. 2009;15(20):2531-2536. doi:10.3748/wjg.15.2531

ASSOCIATION
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Multidisciplinary Approaches to Addressing the Needs of Patients with Gynecologic Cancers: A Call-to-Action Summit

ynecologic cancer refers to any malignancy that begins in the reproductive organs.¹ There are 5 main types of gynecologic cancer including cervical, ovarian, uterine, vaginal, and vulvar. Gynecologic malignancies, while less common than other cancer types, affect 100,000 people annually in the United States.² In addition, an estimated 32,000 people died from gynecologic cancers in 2023.

Advanced stages of gynecologic cancers can lead to bowel obstructions, malnutrition, blood clots, impaired organ function, extreme fatigue, severe pain, fluid overload, and other distressing symptoms. Patients not only face disease complications, but they can also suffer from toxicities related to treatment. Invasive surgeries and procedures, radiation therapy, and systemic chemotherapy or immunotherapy can cause a variety of adverse effects. Furthermore, many patients have chronic comorbidities that may impair their overall health outcomes.

Racial disparities exist in gynecologic diseases. Rates of endometrial and cervical cancer deaths for Black patients are twice as high as their White counterparts.³ More research is needed in this area to address mortality rates.

In addition to disease- and treatment-specific complications, patients with gynecologic cancers may experience health disparities related

to socioeconomic status, educational level, ethnic background, and geographic location.³ Financial toxicity also remains a substantial concern because of the associated costs of subspecialty appointments, surgeries, hospital admissions, and systemic treatments. Until these complex barriers are addressed, disparities and compromised health outcomes will persist.

To better understand the problem and to brainstorm potential solutions, the Association of Cancer Care Centers (ACCC) held a Gynecologic Oncology Summit in Chicago, Illinois, on September 27, 2023. The half-day live summit brought together multidisciplinary experts from across the United States in the field of gynecologic cancers, along with representatives from patient advocacy organizations.

The session opened with a question posed to providers on what motivates them to improve equity and care in patients with gyne-cologic cancers. Sentiments ranged from bridging the gap, to care barriers in underserved cities, to bringing gynecologic cancer to the forefront because it is often overlooked. The general session also included a presentation by the ACCC's project advisory committee chair, Premal H. Thaker, MD, MS, professor of gynecologic oncology at the Washington University School of Medicine in St. Louis, Missouri. Dr. Thaker reviewed the current landscape in caring for patients with gynecologic cancers.

FIGURE 1. Trends in Cancer Incidence, SEER Data

Statistics in Gynecologic Cancer Care:

- 66,000 people will have been diagnosed with endometrial cancer in 2023. Trends show this continues to rise year after year.
- 19,000 people are diagnosed each year with ovarian cancer; 13,270 will die from it.
- An estimated 13,000 people in the US died in 2023 from uterine cancer.
- An estimated 4,300 people in the US died from cervical cancer in 2023.

Dr. Thaker shared a trend report from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program that reviewed data from 1975 to 2019. Trends show that uterine cancer has increased since the 1990s (Figure 1). Dr. Thaker also noted the drastic disparities by race in 5-year survival rates (Figure 2). She offered several reasons for these disparities, including biological, environmental, and access inequities for underserved populations.

Attendees then transitioned into breakout sessions and were tasked with defining challenges and opportunities in 3 key areas, including:

- Social Drivers of Health (SDOH)
- Multidisciplinary Care, Workforce, and Patient Navigation
- Community Support/Patient Advocacy

Social Drivers of Health

Challenges:

Social and environmental factors are proven to affect health outcomes.⁴ Social factors include resources needed for daily living such as food, housing, transportation, finances, and childcare, among others.

Challenges identified among the summit participants included:

- Financial toxicity related to treatments
- Distance traveled and transportation for patients
- Workforce burnout
- Establishing and maintaining care of patients
- Maintaining consistent and accurate patient education

"How do you establish and maintain care with patients who struggle with coverage and financial

toxicity?" - Summit participant

Beyond the factors already highlighted, the question arose among the group of who is responsible for tackling social drivers of health and understanding that the challenge includes setting a threshold intervention designed to reduce the burden. Health care teams may not be equipped to address some of the drivers and must rely on public or social service agencies to support the barriers identified. ACCC supports these concerns by promoting links to community resources that can help to meet ongoing needs.

Opportunities:

To improve population health, health equity needs to be prioritized and measures must be integrated to reduce disparities. Taking on social drivers of health is no small feat. The first step is to assist the patients in identifying any barriers present. This is done through screening tools, such as the Core 5 SDOH screening tool that evaluates factors such as food insecurity, housing, utilities, transportation, and safety. Only once challenges are identified can opportunities for improvement be initiated.

FIGURE 2. Survival Rates by Race, SEER Data

Summit participants identified the following opportunities to address social drivers of health:

- Advocate for comprehensive cancer care delivery within insurance provider networks
- Increase funding for health equity initiatives
- Increase access to services by advocating for telehealth payment parity
- Implement a diverse workforce and leadership
- Streamline detection of multiple cancers (MCED) and related diagnostic testing

Social media was also mentioned as an opportunity for education and dissemination of important information to leverage existing clinical services for greater awareness of inclusivity. Participants touched on opportunities to expand access to care including the National Cancer Institute's Community Oncology Research Program, which offers opportunities for patients to be involved in clinical trials and study interventions to improve care delivery.

Multidisciplinary Care, Patient Navigation, and Workforce

Challenges:

Multidisciplinary care requires different professionals from various fields to come together for the joint purpose of providing patient-centered care. This can be difficult with limited staff due to retirement, burnout, or specialty training requirements. Patient navigation, while not always available due to funding or resources, may help to reduce health disparities. B

Summit participants identified many challenges in this area, including:

- Costs associated with childcare and caregiving
- Lack of care coordination for genetic testing
- Nonstandard implementation of SDOH screening tools
- Inequitable knowledge of and/or access to community resources

"We need to make sure to say 'people,' 'individuals,' or 'persons' when talking about gynecologic cancers because, yes, [one] patient could identify as a woman but...another may not."

-Summit participant

Attendees also conveyed lack of funding for clinical trials and sufficient clinical trial enrollment of diverse patients as struggles they face in their practices. Insufficient diversity among providers is also of concern, with some breakout group members addressing the need for multidisciplinary team training around the effects of explicit and implicit bias.

Opportunities for Improvement:

This group was tasked with finding opportunities for improvement in patient care, including navigation resources and health care workforce needs.

Opportunities for improvement exist around:

- Prioritization of diversity, equity, and inclusion
- Clinical pathways and advancement in treatment options
- Increased access to genetic counseling and testing through telehealth services
- Clinical trial flexibility
- Bolstering employee recruitment and retention programs

Workforce strategies focused on diversity, equity, and inclusion, as well as increasing incentives for workforce retention. An identified goal for multidisciplinary teams is to broaden diversity into sexual and reproductive care programs, and to encompass health care providers of all racial, ethnic, and cultural backgrounds.

Clinically, institutions have an opportunity to make clinical trials more flexible; to advocate for increased access to genetic counseling and testing; and to support patient navigation, SDOH triage, caregiver education, and automation through things like wearable technologies.

Community Support/Patient Advocacy

Challenges:

Individuals who are diagnosed with gynecologic cancers require high levels of supportive care. In addition to that need, there are continuing challenges in community support and patient advocacy that were identified by summit participants.

Some of those challenges are:

- Insufficient access to care
- Bringing gynecologic malignancies to the forefront
- Lack of community awareness and education

"We have to find community resources that can help provide financial aid to patients."

-Summit participant

In addition to the challenges listed above, participants expressed concerns regarding lack of patient educational resources (after treatment), program funding, and policy implications for genetic testing and insurance coverage. Resource needs were specifically identified around sexual dysfunction, financial assistance, and navigating the search for resources. Genetic testing concerns stemmed from customized treatments that are often needed in smaller communities.

Opportunities:

Sometimes a solution is as simple as promoting services that are already available. Communities and health care institutions can benefit through partnerships that help to spread awareness of available resources. Additionally, health care institutions need to advocate for national policy change around genetic and/or genomic testing and health insurance coverage for things like care-related transportation needs. Only once these topics become part of everyday conversations will they be normalized and will change be effected.

Actions to Overcome Challenges:

- Advocate for national policy change regarding access to genetic testing and counseling
- Coordinate and support patient advocacy for health equity in gynecologic health care
- Build or strengthen patient navigation programs
- Develop integrative and palliative care delivery roadmaps
- Promote early screenings to lower risk factors

Patient advocates at the summit shared the financial impact of grants with restricted funding and limitations, both of which have a detrimental impact on patients. There is also a great need for standardization of patient navigation across centers, which will improve access to care and community awareness for unmet patient needs.

Spotlights

"The ACCC gynecological summit brought together key stakeholders such as physicians, physician extenders, social workers, geneticists, pharmacists, patient advocates, and hospital administration to discuss challenges and opportunities for improved multidisciplinary care and patient advocacy for gynecologic malignancies. Having this opportunity to brainstorm together will help all the attendees to bring back novel ideas/concepts to their institutions."

-Premal Thaker, MD, MS

University of Pittsburgh Medical Center Sexual Health Education Program

Sexual health and well-being are fundamental parts of an individual's overall health care. For oncology patients, sexual health is often impacted by surgeries, chemotherapy, radiation, and hormonal therapies, among other things. With greater advancements in therapies in recent years, patients have benefited from longer survival, but unfortunately, they experience more symptoms and adverse effects from cancer treatment.

Opening an oncology sexual health clinic at the University of Pittsburgh Medical Center (UPMC Magee Women's Gynecologic Cancer Program) has allowed for more focus on promoting overall wellness and targeting unmet needs for patients. To begin the process, a target population needs to be defined. UPMC chose to focus on patients with vulvas. They created a list of problems and diagnoses that would be treated in the clinic, and made a list of the possible tools, staff, etc. that the clinic would require. Internal resources were also identified, such as the office manager, medical director, operations, and so forth, and meetings were held to discuss needs and feasibility. It was imperative that a trusted referral network was built to ensure that the patient would receive comprehensive care.

Some possible referrals include pelvic floor physical therapists, menopause specialists, and sex therapists, among many others. The biggest recommendation for health care providers in oncology is to make sure they ask about the sexual well-being of your patients and then listen to their answers. Often oncology patients feel that if sexuality during their cancer journey was important, their providers would bring it up. Providers often refrain from discussing sexuality and intimacy to avoid embarassing the patient. However, talking about sexual health and well-being with patients is a key step in offering comprehensive, compassionate, and quality care.

Conclusion

The summit wrapped up with a call to action, where participants generated action steps for the next 2 to 5 years to establish, build, and provide solutions for providers and key stakeholders. Thirteen distinct priorities were identified that ranged from expansion of coverage to developing a national advocacy campaign to increasing visibility of existing education and creating an education library.

There were 5 key areas identified:

- Legislate to Eliminate Burdensome Prior Authorizations
 Advocate for policy change to eliminate onerous prior authorization requirements and highlight successful models where this has been implemented at the program and/or state levels and can be replicated.
- Expand Access to Reimbursement for Telemedicine and Genetic Testing

Create a national licensure system to develop joint messaging on awareness and prevention that is specific to gynecologic cancer.

 Develop a National Advocacy Campaign for Gynecologic Cancer

Develop a national awareness campaign for gynecologic cancers, similar to campaigns for breast, prostate, and other

common cancers. Additionally, an advocacy network is needed to garner more research funds and other resources for patients with gynecologic cancers.

- Legislate to Standardize Electronic Medical Records (EMR)
 Participants mentioned several high-priority items that should be built into the EMR. Among them are standardized reporting of imaging, genetics, and genomics; self-reporting of gender identity, ethnicity, and race should be considered mandatory.
- Partner with professional societies to encourage health systems to mirror the communities they serve.

Summit participants shared their thoughts regarding the need for care teams with diverse cultural backgrounds to treat gynecologic cancers. Reasons included increased innovation, decision-making, and reaching a broader patient population. They also shared ways for current providers to embrace diversity such as continually learning about unconscious bias, being an active listener, communicating with clarity, and serving as an example for peers. In addition, participants recognized a need to advocate for change regarding prior authorizations, to expand coverage of the 10 essential health benefits outlined in the Affordable Care Act, and to demonstrate the value for patient navigation through data.

The Gynecologic Oncology Summit brought together experts across many disciplines with the same goal—to face barriers and challenges head-on by calling them out, as well as to identify actionable solutions. Through the initiative, Multidisciplinary Approaches to Addressing the Needs of Patients with Gynecologic Cancers, ACCC will continue to work with partner organizations to identify, develop, and disseminate resources to support multidisciplinary care teams as they aim to provide the highest quality care for patients with gynecologic cancers.

To learn more about the ACCC's work on gynecologic cancers, please visit: accc-cancer.org/gynecologic-cancer-care.

References

- U.S. Centers for Disease Control and Prevention. June 13, 2023. Basic information about gynecologic cancers. Accessed October 30, 2023. cdc.gov/cancer/ gynecologic/basic_info/index.htm
- American Association for Cancer Research. September is Gynecologic Cancer Awareness month. September 13, 2023. Accessed October 30, 2023. aacr.org/patients-caregivers/awareness-months/ gynecologic-cancer-awareness-month/
- Collins Y, Holcomb K, Chapman-Davis E, Khabele D, Farley JH. Gynecologic cancer disparities: a report from the Health Disparities Taskforce of the Society of Gynecologic Oncology. Gynecol Oncol. 2014;133(2):353-361. doi:10.1016/j.ygyno.2013.12.039
- Hood CM, Gennuso KP, Swain GR, Catlin BB. County health rankings: relationships between determinant factors and health outcomes. Am J Prev Med. 2016;50:129-135. doi:10.1016/j.amepre.2015.08.024
- Andermann A. Taking action on the social determinants of health in clinical practice: a framework for health professionals. CMAJ. 2016;188(17-18):E474-E483. doi:10.1503/cmaj.160177
- Bechtel N, Jones A, Kue J, Ford JL. Evaluation of the core 5 social determinants of health screening tool. Public Health Nursing. 2022;39(2):438-445. doi:10.1111/phn.12983
- Taberna M, Gil Moncayo F, Jané-Salas E, et al. The multidisciplinary team (MDT) approach and quality of care. Front Oncol. 2020;10:85. doi:10.3389/ fonc.2020.00085
- Post DM, McAlearney AS, Young GS, Krok-Schoen JL, Plascak JJ, Paskett ED. Effects of patient navigation on patient satisfaction outcomes. J Cancer Educ. 2015;30(4):728-35. doi:10.1007/s13187-014-0772-1

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fast facts

Physician Survey Highlights Staffing Challenges

- Approximately 1 in 3 physicians experienced a reduction in staff in 2022 with the most shortages reported for registered nurses (90%), nursing assistants (86%), social workers (85%), physicians (84%), and licensed practice nurses (83%).
- Among those who reported staff shortages, physicians stated that the most impactful contributing factors were administrative burdens (85%), increased working hours without compensation (79%), and reduced salaries/benefits (71%).
- Almost 1/4 of physicians stated violence in the workplace as a contributing factor to staff shortages.
- 1/3 report their current practice is overextended and overworked, and nearly half of physicians report being at full capacity in their current practice.
- Approximately 1 in 5 physicians reported cutting back on their work hours.

Source. The Physicians Foundation. <u>2022 Survey of America's Physicians.</u>

Sticker Shock!

While the number of Americans with health insurance coverage has significantly increased since

the Affordable Care Act began, cost is still an obstacle for many. The annual Policygenius Health Insurance Survey of insured Americans found that:

- **45%** have avoided medical care because they knew or feared it would not be covered by their insurance (up from 41% in 2022).
- Of those who reported an annual income of \$80,000 or more, 18% would have to use mostly credit or borrow to pay their deductible, and 16% wouldn't be able to pay the deductible at all.
- Among insured Americans who have seen a mental health provider,
 42% have had their health insurance declined.



- Being able to understand what they're being billed for—29%
- Uncertainty if they can pay the bill—27%
- Not getting a bill until weeks after they received service—24%
- Uncertainty if the final bill will be consistent with the estimate of patient responsibility—20%

Source. PR Newswire. Nearly 40% of Americans Confused by Medical Bills





The State of Overall Health in America

A 2022 survey of 100 top hospital and healthcare executives found:

- 67% of survey respondents indicate they believe the health of Americans is worse now than it was before the COVID-19 pandemic.
- Staff recruitment and retention has become their top priority (71%), far ahead of growing revenue (42%), and reducing costs (38%).
- Nearly 80% indicated that workforce resilience is the greatest challenge facing their organization over the next 2 years.
- Only 26% say telehealth is among their organization's top 5 technology initiatives within the next 2 years.
- Only 4% consider their organization to be proficient or an expert at implementing remote care.

Source. Sage Growth Partners. 2022 c-Suite Report: America's Healthcare Crisis—Health Systems Prepare to be Tested Like Never Before

4 Strategies to Address **Staffing Shortages**



- Removing low-value work
- Eliminating insurance approvals
- Offering customized retention strategies
- Addressing burnout among physicians/staff.

Source. The Physicians Foundation. 2022 Survey of America's Physicians

*more online @ accc-cancer.org



Elevating Diversity in the Health Care Workforce

Last fall, Modern Healthcare's Social Determinants of Health Symposium featured several standout initiatives and programs that are addressing disparities in health care, including 2 institutions that have effected change to support a more diverse health care workforce. Founded in 1946, National Medical Fellowships works to achieve equity of opportunity in medicine and equity of access to quality health care for all groups through scholarships and support for underserved minority students in medicine and other health care professions. Meharry Medical College in Nashville, Tennessee, is one of the oldest and largest historically Black academic health science institutions in the nation dedicated to training medical professionals to aid underserved communities. Read more about their efforts in the ACCCBuzz Blog post, "Social Drivers of Health: The Role of Representation in the Healthcare Workforce."

Consensus-Based Oncology Financial **RESOURCE** Advocacy Services Guidelines

The National Institutes of Health reports that cancer survivors are 2.7 times more likely to file for bankruptcy than individuals without a cancer history and financial distress affects 22% in a nationally representative sample to 64% in a sample of of working-age survivors. ACCC's consensus-based oncology Financial Advocacy Services Guidelines are the only standardized framework exclusively for oncology financial navigators that can help programs prevent, detect, and mitigate financial hardship for their patients during cancer care.



Biomarker Testing for WEBINAR | Metastatic Colorectal Cancer

This virtual learning opportunity reviews the latest guideline recommendations regarding biomarker testing; describes when biomarker testing should be performed, including the roles of the multidisciplinary team members involved in the process; explains the need for biomarker testing to guide individualized therapy decisions; reviews targeted therapeutic options for patients; and shares a plan for testing-related discussions with patients to encourage participation in treatment planning.



CAR T-Cell Patient PODCAST Identification Framework

As the use of chimeric antigen receptor (CAR) T-cell therapy continues to expand as an effective treatment for hematologic malignancies, understanding how to identify eligible patients early and implementing of an effective framework for identification can improve care coordination and better prepare community cancer programs for widespread use of CAR T-cell therapy. In this episode, CANCER BUZZ speaks with David L. Porter, MD, director of cell therapy and transplant at Penn Medicine, about the challenges community oncologists face and the key role they can play in identifying and recommending eligible patients for CAR T-cell therapy.

ISSUES

CMS Finalizes Rule to Improve the Prior Authorization Process

BY MONIQUE J. MARINO



n January 17, 2024, more than 1 year after it was initially proposed, the Centers for Medicare & Medicaid Services (CMS) finalized the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F), establishing requirements for certain payers to streamline the prior authorization process.¹ Specifically, "the rule sets require-

ments for Medicare Advantage (MA) organizations, Medicaid and the Children's Health Insurance Program (CHIP) fee-for-service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and issuers of Qualified Health Plans (QHPs) offered on the Federally-Facilitated Exchanges (collectively 'impacted payers') to improve the electronic

exchange of health information and prior authorization processes for medical items and services." As a whole, the agency estimates these policies will improve prior authorization processes and reduce burden on patients, providers, and payers, resulting in approximately \$15 billion of estimated savings over 10 years.



Website: BeiGene.com Twitter: @BeiGeneGlobal

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Beginning primarily in 2026, impacted payers will be required to send prior authorization decisions within 72 hours for expedited (ie, urgent) requests and 7 calendar days for standard (ie, non-urgent) requests for medical items and services. For some payers, this new timeframe for standard requests cuts current decision timeframes in half.² To help facilitate resubmission of requests or appeals, the rule also requires all impacted payers to include a specific reason for denying a prior authorization request. Finally, impacted payers will be required to publicly report prior authorization metrics.²

In addition, the rule requires impacted payers to implement an electronic prior authorization application programming interface (API) to establish a more efficient electronic prior authorization process between providers and payers by automating the end-to-end prior authorization process. It is expected that this new requirement "will reduce administrative burden on the healthcare workforce, empower clinicians to spend more time providing direct care to their patients, and prevent avoidable delays in care for patients."² A fact sheet for this final rule is available on the CMS website.³

While ACCC supports these efforts, the association is concerned that this rule only applies to payers in the federal programs outlined above and does not apply to the "approximately 158 million Americans who are insured through their employment—the most common kind of coverage in the United States."

Prior authorization remains one of the most discussed barriers to timely quality cancer care delivery among health care providers.⁵ The burden placed on the multidisciplinary care team to submit authorizations, complete peer-to-peer interviews, and fight appeals is extraordinary. In a 2022 survey of American Society of Clinical Oncology (ASCO) members, nearly all participants reported that a patient they had treated had experienced harm as a result of late or denied prior authorizations, including disease progression (80%) and loss of life (36%).⁶ ASCO survey findings identified the items below as the most widely cited challenges for patients:⁶

- Treatment delays (96%)
- Delays in diagnostic imaging (94%)
- Patients being forced into using a secondchoice therapy (93%)
- Patients denied therapy (87%)
- Increased patient out-of-pocket costs (88%)

ACCC has developed tools and resources to help its provider members, including a virtual <u>Prior Authorization Clinic</u>. This educational program seeks to help providers:⁷

- Reduce the administrative burden of prior authorization processes by sharing best practices
- Address key components of prior authorization, including new technologies or areas where there are high errors in billing and coding that result in high denials
- Provide examples of standardized criteria for ordering and prescribing services that align with evidence-based guidelines
- Develop a series of case-based prior authorization scenarios that cancer programs can utilize when advocating for change, locally and nationally, at their cancer program
- Highlight successful methods to track prior authorizations and results for pertinent members of the multidisciplinary cancer care team.

As ACCC continues to advocate for long-term solutions to prior authorization challenges, including those instituted by private payers, we would love to hear from you about the impact that prior authorizations continue to have on your cancer program or practice, providers and staff, and the patients and families you treat. Contact us at rhodzic@accc-cancer.org.

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References

1. Medicare and Medicaid Programs; Patient
Protection and Affordable Care Act; Advancing
Interoperability and Improving Prior Authorization
Processes for Medicare Advantage Organizations,
Medicaid Managed Care Plans, State Medicaid
Agencies, Children's Health Insurance Program (CHIP)
Agencies and CHIP Managed Care Entities, Issuers

of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program. Centers for Medicare & Medicaid Services. Department of Health and Human Services. Accessed January 19, 2024. https://public-inspection.federalregister.gov/2024-00895.pdf

- 2. CMS finalizes rule to expand access to health information and improve the prior authorization process. Centers for Medicare & Medicaid Services. Department of Health and Human Services. Published January 17, 2024. Accessed January 19, 2024. https://www.cms.gov/newsroom/press-releases/cms-finalizes-rule-expand-access-health-information-and-improve-prior-authorization-process#:~:text=This%20final%20rule%20establishes%20 requirements,and%20reduce%20disruptions%20 for%20beneficiaries.
- 3. Fact sheet: CMS interoperability and prior authorization final rule CMS-0057-F. Centers for Medicare & Medicaid Services. Department of Health and Human Services. Published January 17, 2024. Accessed January 19, 2024. https://www.cms.gov/newsroom/fact-sheets/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f
- 4. Sausser L. Biden cracks down on prior authorization—but there are limits. The Washington Post.
 Published January 18, 2024. Accessed January 19, 2024. https://www.washingtonpost.com/politics/2024/01/18/biden-cracks-down-prior-authorization-there-are-limits/?utm_campaign=wp_the_health_202&utm_medium=email&utm_source=newsletter&wpisrc=nl_health202
- 5. Impact of prior authorizations beyond health insurer cost savings. Association of Community Cancer Centers. Accessed January 19, 2024. https://www.accc-cancer.org/docs/projects/financial-advocacy/cost-savings-infographic-prior-auth.pdf
- 6. ASCO prior authorization survey summary.
 American Society of Clinical Oncology. Published
 November 2022. Accessed January 19, 2024. https://old-prod.asco.org/sites/new-www.asco.org/files/ASCO-Prior-Auth-Survey-Summary-November-2022.
- 7. Prior authorization clinic. Association of Community Cancer Centers. Accessed January 19, 2024. https://www.accc-cancer.org/home/learn/financial-advocacy/prior-authorization-clinic

compliance -

2024 Oncology Coding Update

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

his article outlines coding changes specific to the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), Current Procedural Terminology (CPT®), and the Healthcare Common Procedure Coding System (HCPCS) for services that may be provided by or related to services by oncology specialties. Items in bold highlight changes for 2024 released by both the American Medical Association (AMA) and the Centers for Medicare & Medicaid Services (CMS).

ICD-10-CM Diagnosis Coding Updates

The following ICD-10-CM guidelines went into effect October 1, 2023, as the updates run on the fiscal year calendar. Additional updates are expected for implementation on April 1, 2024, due to the change to a biannual update to diagnosis coding.

Revised Guidelines

Many of the 2024 guideline updates focus on the need to code the diagnosis to the highest level of specificity. Language was added in several sections of the ICD-10-CM Official Guidelines for Coding and Reporting to stress this point. Notably:

Conventions for ICD-10-CM

 Documentation by clinicians other than the patient's provider. Code assignment is based on the documentation by the patient's provider (ie, physician or other qualified health care practitioner legally accountable for establishing the patient's diagnosis). There are a few exceptions when code assignment may be based on medical record documentation from clinicians who

- are not the patient's provider. In this context, "clinicians" other than the patient's provider refer to health care professionals permitted, based on regulatory or accreditation requirements or internal hospital policies, to document in a patient's official medical record.
- The term "social determinants of health" (SDOH), classified in Chapter 21, has been added to the list of items that may be documented by another provider and used to support any necessary secondary diagnosis coding.

Chapter 1: Certain Infectious and Parasitic Diseases (A00-B99), U07.1, U09.9

(Editor's Note: In 2024, copy that is struck through was replaced with the new copy in bold.)

Sepsis due to a postprocedural infection.
 For infections sepsis following a procedure postprocedural wound (surgical site) infection, use codes 781.40 T81.41 to T81.43. For infection following a procedure, use codes O86.00 to O86.03. Infection of obstetric surgical wound that identifies the site of the infection should be coded sequenced first, if known.

Chapter 2: Neoplasms (Coo-D49)

 Admission/encounter for treatment of primary site. If a patient admission/ encounter is solely chiefly for the administration of chemotherapy, immunotherapy, or external beam radiation therapy, assign code Z51.0 (encounter for antineoplastic radiation therapy), code Z51.11 (encounter for antineoplastic chemotherapy), or code Z51.12 (encounter for antineoplastic

- immunotherapy) as the first-listed or principal diagnosis. If a patient receives more than 1 of these therapies during the same admission, more than 1 of these codes may be assigned, in any sequence.
- Secondary malignant neoplasm of lymphoid tissue. When a malignant neoplasm of lymphoid tissue metastasizes beyond the lymph nodes, a code from categories C81-C85 with a final character "9" should be assigned identifying "extranodal and solid organ sites" rather than a code for the secondary neoplasm of the affected solid organ. For example, for metastasis of diffuse large B-cell lymphoma to the lung, brain, and left adrenal gland, assign code C83.39, which signifies "diffuse large B-cell lymphoma, extranodal, and solid organ sites."

Chapter 19: Injury, Poisoning, and Certain Other Consequences of External Causes (Soo-T88)

The occurrence of drug toxicity is classified in ICD-10-CM as follows:

 Underdosing: noncompliance (Z91.12-, Z91.13-, Z91.14-, and Z91.A4-) or complication of care (Y63.6-Y63.9) codes are to be used with an underdosing code to indicate intent, if known.

Chapter 21: Factors Influencing Health Status and Contact With Health Services (Z00-Z99)

Follow-up

 Follow Up Code **Z08**, encounter for follow-up examination after completed treatment for malignant neoplasm and code **Z09**, encounter for follow up examination after completed treatment for conditions other than malignant neoplasm, may be assigned following any type of completed treatment modality (including both medical and surgical treatments).

Revised ICD-10-CM Codes

These codes continue to expand to allow for specificity with diagnosis coding. Several codes were expanded from the single ICD-10-CM designation to break out into a specified diagnosis with unspecified or not otherwise specified (NOS) into a separate subcode. The following are highlights of ICD-10-CM coding changes for 2024.

Neoplasms (Coo-D49)

- New code C92: Myeloid leukemia.
 Code also, if applicable, pancytopenia (acquired) (D61.818)
- New code C94.8: Other specified leukemias.
 Code also, if applicable, eosinophilia (D72.18)

D13.9 Benign Neoplasm of Ill-Defined Sites Within the Digestive System

- Previous: Benign neoplasm of digestive system NOS, benign neoplasm of intestine NOS, and benign neoplasm of spleen
- New code D13.91: Familial adenomatous polyposis. Code also associated with conditions, such as benign neoplasm of colon (D12.6) and malignant neoplasm of colon (C18.-)
- D13.99: Benign neoplasm of ill-defined sites within the digestive system, benign neoplasm of digestive system NOS, benign neoplasm of intestine NOS, and benign neoplasm of spleen

D48.1 Neoplasm of Uncertain Behavior of Connective and Other Soft Tissue

- New code **D48.11:** Desmoid tumor
 - **D48.110:** Desmoid tumor of head and neck
 - **D48.111:** Desmoid tumor of chest wall
 - **D48.112:** Desmoid tumor, intrathoracic
 - **D48.113:** Desmoid tumor of abdominal wall
 - **D48.114:** Desmoid tumor, intraabdominal; desmoid tumor of pelvic

- cavity; desmoid tumor, peritoneal, retroperitoneal
- D48.115: Desmoid tumor of upper extremity and shoulder girdle
- D48.116: Desmoid tumor of lower extremity and pelvic girdle; desmoid tumor of buttock
- **D48.117:** Desmoid tumor of back
- **D48.118:** Desmoid tumor of other site
- D48.119: Desmoid tumor of unspecified site
- D48.19: Other specified neoplasm of uncertain behavior of connective and other soft tissue

Other Disorders of Blood and Blood-Forming Organs (D70-D77)

D57: Sickle Cell Disorders

- New code **D57.04:** Hb-SS disease with dactylitis
 - **D57.214:** Sickle-cell/Hb-C disease with dactylitis
 - **D57.414:** Sickle-cell thalassemia, unspecified, with dactylitis
 - **D57.434:** Sickle-cell thalassemia beta-zero with dactylitis
 - **D57.454:** Sickle-cell thalassemia beta-plus with dactylitis

D89: Other Disorders Involving Immune Mechanism

 New code D89.84: IgG4-related disease, Immunoglobulin G4-related disease

D61: Other Aplastic Anemias and Other Bone Marrow Failure Syndromes

 New code D61.02: Shwachman-Diamond syndrome. Code also, if applicable, associated conditions such as: acute myeloblastic leukemia (C92.0-), exocrine pancreatic insufficiency (K86.81), and myelodysplastic syndrome (D46.-). Use an additional code, if applicable, for genetic susceptibility to other malignant neoplasm (Z15.09).

Diseases of the Nervous System (Goo-G99)

G20: Parkinson's disease

New code G20.A: Parkinson disease without dyskinesia

- G20.A1: Parkinson disease without dyskinesia, without mention of fluctuation, Parkinson disease NOS, Parkinson disease without dyskinesia, without mention of OFF episodes
- G20.A2: Parkinson disease without dyskinesia, with fluctuations, Parkinson disease without dyskinesia, with OFF episodes
- G20.B: Parkinson disease with dyskinesia, excludes1: drug induced dystonia (G24.0-)
 - G20.B1: Parkinson disease with dyskinesia, without mention of fluctuations; Parkinson disease with dyskinesia, without mention of OFF episodes
 - G20.B2: Parkinson disease with dyskinesia, with fluctuations; Parkinson disease with dyskinesia, with OFF episodes
- **G20.C:** Parkinsonism, unspecified
 - Parkinsonism, NOS
 - Excludes1: Parkinson disease NOS (G20.A1)
 - Parkinson disease with dyskinesia (G20.B-)
 - Parkinson disease without dyskinesia (G20.A-)
 - Secondary Parkinsonism (G21-)
- G40: Epilepsy and recurrent seizures. New code G40.C: Lafora progressive myoclonus epilepsy, Lafora body disease, code also, associated conditions such as dementia (F02.8-)
 - **G40.Co:** Lafora progressive myoclonus epilepsy, not intractable
 - G4o.Co1: Lafora progressive myoclonus epilepsy, not intractable, with status epilepticus
 - G40.Cog: Lafora progressive myoclonus epilepsy, not intractable, without status epilepticus; Lafora progressive myoclonus epilepsy NOS
 - **G40.C1:** Lafora progressive myoclonus epilepsy, intractable
 - G4o.C11: Lafora progressive myoclonus epilepsy, intractable, with status epilepticus

 G4o.C19: Lafora progressive myoclonus epilepsy, intractable, without status epilepticus

A new section of codes was added to identify noncompliance to a patient's medication, dialysis, or other medical treatment due to caregiver noncompliance. Codes already exist to identify patient noncompliance, but previously there was no way to identify when the noncompliance was due to a caregiver. These codes would be added as informational when documented within the encounter note.

Factors Influencing Health Status and Contact With Health Services

Z91: Personal risk factors, NEC

- New code **Z91.A4:** Caregiver's other noncompliance with patient's medication regimen; caregiver's underdosing with patient's medication NOS
 - Z91.A41: Caregiver's other noncompliance with patient's medication regimen due to financial hardship
 - Z91.A48: Caregiver's other noncompliance with patient's medication regimen for other reason
- New code **Z91.A51:** Caregiver's noncompliance with patient's renal dialysis due to financial hardship
- New code **Z91.A58:** Caregiver's noncompliance with patient's renal dialysis for other reason
- New code Z91.A91: Caregiver's noncompliance with patient's other medical treatment and regimen due to financial hardship
- New code Z91.A98: Caregiver's noncompliance with patient's other medical treatment and regimen for other reason
- New code **Z91.85:** Personal history of military service, personal history of serving in the armed forces; personal history of veteran, excludes2; personal history of military deployment (**Z91.82**)
- New code **Z91.89:** Other specified personal risk factors, not elsewhere classified; increased risk for social isolation

CPT CODING UPDATES

Evaluation and Management (E/M): Revised Codes

For 2024, the office/outpatient codes were revised to remove the time range and instead list the time that must be met or exceeded. This change aligns with the other E/M codes that have been updated and only reflect time thresholds, not ranges. Additionally, the full time must be spent with the patient. There is no credit given for any time-based coding of E/M visits when spending the midpoint amount of time.

New Patient Visits

(Editor's Note: Bold copy indicates new language, or revisions, for 2024.)

- 99202: Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision-making. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.
- 99203: Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and a low level of medical decision-making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.
- 99204: Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and a moderate level of medical decision-making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.
- 99205: Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and a high level of medical decision-making. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded.

Established Patient Visits

(Editor's Note: Bold copy indicates new language, or revisions, for 2024.)

- 99212: Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision-making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.
- 99213: Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and a low level of medical decision-making.
 When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.
- 99214: Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and a moderate level of medical decision-making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.
- 99215: Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and a high level of medical decision-making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.

New Codes

- 96547: Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes (list separately in addition to code for primary procedure)
- 96548: Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; each additional 30 minutes (list separately in addition to code for primary procedure)

Revised Codes

 96446: Chemotherapy administration into the peritoneal cavity via implanted port or catheter

HCPCS CODING UPDATES

Added Codes

Three new codes are available and applicable in radiation oncology with the use of technology that provides radiation simulation and treatment with PET/CT treatment delivery linear accelerators:

- A9609: Fludeoxyglucose f18 up to 15 millicuries
- C9794: Therapeutic radiology simulationaided field setting; complex, including acquisition of PET and CT imaging data required for radiopharmaceutical-directed radiation therapy treatment planning (ie, modeling)
- C9795: Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions

Community Health Integration Services

CMS created 7 new G codes in total: 2 (G0019 and G0022) describing Community Health Integration services performed, 1 (G0136) for identification of any social determinants of health (SDOHs) that significantly limit the provider's ability to diagnose or treat the problem(s) addressed in the visit, and 4 for principal illness navigation (PIN) and principal illness navigation—peer support (PIN-PS) services codes, 2 (G0023 and G0024) specific to any provider and 2 (G0140 and G0146) specific to peer support for behavioral health. More detailed information on these new codes follows.

Goo19: Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address SDOH need(s) that are significantly limiting the ability to diagnose or treat problem(s) addressed in an initiating visit:

 Person-centered assessment, performed to better understand the individualized context of the intersection between the SDOH need(s) and the problem(s) addressed in the initiating visit.

- Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors and including unmet SDOH needs (that are not separately billed)
- Facilitating patient-driven goal-setting and establishing an action plan
- Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan
- Practitioner-, Home-, and Community-Based
 Care Coordination
 - Coordinating receipt of needed services from health care practitioners, providers, and facilities and from home- and community-based service providers, social service providers, and caregiver (if applicable).
 - Communicating with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors
 - Coordinating care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities, or other health care facilities
 - Facilitating access to community-based social services (eg, housing, utilities, transportation, food assistance) to address the SDOH need(s)
- Health education: Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s) and educating the patient on how to best participate in medical decision-making.
- Building patient self-advocacy skills so that the patient can interact with members of the health care team and related communitybased services addressing the SDOH need(s) in ways that are more likely to

- promote personalized and effective diagnosis or treatment
- Health care access/health system navigation
 - Helping the patient access health care, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them
- Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach personcentered diagnosis or treatment goals
- Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals
- Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals

G0022: Community health integration services, each additional 30 minutes per calendar month (list separately in addition to **G0019**)

Social Determinants of Health (SDOHs)

G0136: Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5-15 minutes, not more often than every 6 months

Principal Illness Navigation (PIN) Services

G0023: Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:

- Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition
 - Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors and including unmet SDOH needs (that are not separately billed)
 - Facilitating patient-driven goal setting and establishing an action plan

- Providing tailored support as needed to accomplish the practitioner's treatment plan
- Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services
- Practitioner-, Home-, and Community-Based Care Coordination
 - Coordinating receipt of needed services from health care practitioners, providers, and facilities; home- and communitybased service providers; and caregivers (if applicable)
 - Communicating with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors
 - Coordinating care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities, or other health care facilities
 - Facilitating access to community-based social services (eg, housing, utilities, transportation, food assistance) as needed to address SDOH need(s) strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors
- Health education: Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making.
- Building patient self-advocacy skills so that the patient can interact with members of the health care team and related communitybased services (as needed) in ways that are more likely to promote personalized and effective treatment of their condition
- Health care access/health system navigation
 - Helping the patient access health care, including identifying appropriate practitioners or providers for clinical care,

- and helping secure appointments with them
- Providing the patient with information/ resources to consider participation in clinical trials or clinical research, as applicable
- Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach personcentered diagnosis or treatment goals
- Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals
- Leverage knowledge of the serious, high-risk condition and/or lived experience, when applicable, to provide support, mentorship, or inspiration to meet treatment goals

G0024: Principal Illness Navigation services, additional 30 minutes per calendar month (list separately in addition to **G0023**)

Principal Illness Navigation-Peer Support (PIN-PS) Services

G0140: Principal Illness Navigation–Peer Support by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a certified peer specialist; 60 minutes per calendar month, in the following activities:

- Person-centered interview, performed to better understand the individual context of the serious, high-risk condition
 - Conducting a person-centered interview to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors and including unmet SDOH needs (that are not billed separately)
 - Facilitating patient-driven goal setting and establishing an action plan
 - Providing tailored support as needed to accomplish the person-centered goals in the practitioner's treatment plan
- Identifying or referring the patient (and caregiver or family, if applicable) to appropriate supportive services
- Practitioner-, home-, and community-based care communication

- Assisting the patient in communicating with their practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, goals, preferences, and desired outcomes, including cultural and linguistic factors.
- Facilitating access to community-based social services (eg, housing, utilities, transportation, food assistance) as needed to address SDOH need(s)
- Health education: Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s) and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making
- Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed) in ways that are more likely to promote personalized and effective treatment of their condition
- Developing and proposing strategies to help meet person-centered treatment goals and supporting the patient in using chosen strategies to reach person-centered treatment goals
- Facilitating and providing social and emotional support to help the patient cope with the condition and SDOH need(s) and adjust daily routines to better meet person-centered diagnosis and treatment goals
- Leverage knowledge of the serious, high-risk condition and/or lived experience, when applicable, to provide support, mentorship, or inspiration to meet treatment goals

G0146: Principal Illness Navigation–Peer Support, additional 30 minutes per calendar month (list separately in addition to **G0140**) **O**

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compliance

CY 2024 HOPPS Final Rule Highlights

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

n November 2, 2023, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2024 final rules for the Hospital Outpatient Prospective Payment System (HOPPS)¹ and separately released the Remedy Payment Policy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022.² The agency finalized an overall increase to the outpatient fee schedule along with some changes in payment policy that decrease the drug administration threshold and cancer hospital payment adjustment.

Payment Rates

For CY 2024, CMS used CY 2022 claims data; this is the normal process when establishing payment rates based on the most recent completed year of filing. The outpatient department increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital charges. CMS finalized a 3.1% increase to the hospital outpatient department fee schedule. The agency estimates total payments to HOPPS providers will be approximately \$88.9 billion, an increase of approximately \$6.0 billion compared with CY 2023 HOPPS payments.

Cancer Hospital Payment Adjustment

For CY 2024, CMS will continue additional payments to cancer hospitals using a payment-to-cost ratio (PCR) factor. Beginning in CY 2018, the 21st Century Cures Act required that the weighted average PCR be reduced by 1.0 percentage point. CMS finalized the target PCR of 0.88 to determine the CY 2024 cancer hospital payment adjustment to be paid at cost

report settlement, which includes the reduction of 1.0 percentage point, which 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 include payments for drugs and biologicals considered separately payable based on the assigned ambulatory payment classification or pass-through status. For CY 2024, CMS will continue this current payment policy, which has been in effect from CY 2013. Below is a summary of the items CMS finalized for CY 2024: Each year, CMS assesses payments for drugs and biologicals based on current pricing methodologies, which include payments for drugs and biologicals considered separately payable based on the assigned ambulatory payment classification or passthrough status. For CY 2024, CMS will continue this current payment policy, which has been in effect from CY 2013. Below is a summary of the items CMS finalized for CY 2024:

- CMS proposed to package drugs and biologicals estimated at a per-day administration cost less than or equal to \$140; however, in the final rule, the agency maintained the CY 2023 value of less than or equal to \$135.
- Qualifying biosimilar products (defined as a biosimilar product with an average sales price [ASP] of less than the ASP of the reference biological) for a calendar quarter during an applicable 5-year period will be paid at ASP plus 8% of the ASP for the reference biological.

- Biosimilars are excepted from the threshold packaging policy when their reference biologicals are separately paid. The agency had proposed that all biosimilars related to the reference product would be similarly packaged regardless of whether their per-day costs are above the threshold. After consideration, CMS did not finalize this proposal. Instead, these biosimilars will also be paid separately, even if their per-day cost is below the packaging threshold. The agency will continue to evaluate this issue, but it believes that this practice will help promote biosimilar use as a lower cost alternative to higher cost reference biologicals.
- To simplify the process of reporting drugs purchased under the 340B Drug Pricing Program, CMS finalized that hospitals will only use the modifier "TB" to identify drugs. In 2024, hospitals that previously reported modifier "JG" have the option to report either modifier "JG" or "TB"; effective January 1, 2025, however, the modifier "TB" must be used. Effective January 1, 2024, the description for modifier "TB" no longer includes for select entities, as all entities would report this modifier after this date. The new descriptor for modifier "TB" is now "drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities."

Remedy for the 340B-Acquired Drug Payment Policy for CY 2018–2022

After a June 15, 2022, Supreme Court ruling on the 340B Drug Pricing Program, CMS was tasked with devising a viable solution to pay

back monies to hospitals that purchased drugs under this program. After the ruling, the agency adjusted part of CY 2022 payments (from September 28, 2022, through December 31, 2022) and CY 2023 payments. In a proposal separate from the CY 2023 HOPPS proposed rule, CMS addressed the remaining payments (September 28, 2022, through December 31, 2022) in its proposal "Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022, CMS-1793-P." In the final HOPPS rule, the agency finalized what it believes is the best way to remedy these payment adjustments. Specifically, CMI will make a 1-time lump sum payment to affected 340B covered entities. To arrive at this lump sum, the agency is calculating the difference between what hospitals were paid for 340B drugs (at ASP minus 22.5%, at an adjusted wholesale acquisition cost [WAC], or at average wholesale price [AWP] amount) between January 1, 2018, and September 27, 2022, and what hospitals would have been paid at ASP plus 6%.

From January 1, 2018, through September 27, 2022, approximately 1686 hospitals were paid at the 340B payment rate of ASP minus 22.5%. CMS estimates that these hospitals are now owed approximately \$10.6 billion. The agency also estimates that these hospitals have already received \$1.6 billion in remedy payments from reprocessed claims from January 1, 2022, through September 27, 2022, reducing the overall estimated payment amount to \$9.004 billion. To determine the amount owed to each of these 1686 hospitals, CMS will calculate how much each hospital would have been paid for drugs acquired through the 340B program from January 1, 2018, through September 27, 2022, if the payment policy had been set at ASP plus 6% and minus any remedy payments already made to each hospital.

CMS will provide instructions to the Medicare administrative contractors (MACs) to remit payments to the hospitals within their jurisdiction. Each MAC will have 60 calendar days to make the lump sum payment; these payments will not include any interest to the hospital. CMS expects to begin making these

payments at the beginning of CY 2024. Any hospital that submits a request for a technical correction of the estimated lump sum payment will be paid after the request is resolved. Hospitals that do not submit a correction request will be paid first. Addendum AAA of the 2024 HOPPS final rule includes the list of hospitals and their final lump sum remedy payment as calculated by CMS.³

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

Non-drug services under HOPPS 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% was already applied for CY 2023. To determine the amount paid for non-drug services, CMS includes codes reported during the time in question and assigned to status indicator J1, J2, P, Q1, Q2, Q3, R, S, T, U, or V. CMS estimates the offset amount is \$7.8 billion, which is less than the estimated remedy amount of \$9 billion.

Beginning January 1, 2026, CMS will reduce payments for non-drug items and services to all HOPPS providers except new providers (defined as hospitals with a CMS certification number effective date of January 2, 2018, or later) by 0.5% (applied to the conversion factor) each year until the total offset amount is reached, estimated to be 16 years. CMS believes that the 0.5% reduction would be less burdensome to hospitals, especially rural entities and in situations for which other factors may impact payments over the next several years.

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References

- 1. Centers for Medicare & Medicaid Services, Department of Health and Human 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. Federal Register. November 22, 2023. Accessed January 18, 2024. https://www. federalregister.gov/documents/2023/11/22/2023-24293.medicare-program-hospital-outpatientprospective-payment-and-ambulatory-surgicalcenter-payment
- 2. Centers for Medicare & Medicaid Services,
 Department of Health and Human Services. Medicare
 program; hospital outpatient prospective payment
 system: remedy for the 340B-acquired drug payment
 policy for calendar years 2018-2022. Federal Register.
 November 8, 2023. Accessed January 18, 2024. https://
 www.federalregister.gov/documents/2023/11/08/202324407/medicare-program-hospital-outpatientprospective-payment-system-remedy-for-the-340bacquired-drug
- 3. Centers for Medicare & Medicaid Services,
 Department of Health and Human Services. Medicare
 program; hospital outpatient prospective payment
 system: remedy for the 340B-acquired drug payment
 policy for calendar years 2018-2022. Addendum AAA.
 Centers for Medicare & Medicaid Services. November
 22, 2023. Accessed January 18, 2024. https://www.cms.
 gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/
 cms-1793-f

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CY 2024 MPFS Final Rule Highlights

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

n November 2, 2023, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2024 final rules for the Medicare Physician Fee Schedule (MPFS).¹ As proposed, the agency finalized implementation of a new complexity add-on code, a new series of codes to recognize the resources provided for patients to ensure equity of and access to health care, and payment cuts across the board.

Payment Rates

The MPFS provides regulatory information and payment rates for physicians regardless of their work setting (facility and non-facility) or employer as well as office-based (non-facility) settings. Stakeholders had 60 days to submit comments to CMS on the proposed changes for CY 2024; CMS reviewed the comments and provided a rationale for its decisions.

The conversion factor (CF) is a value set that is determined each year to convert the relative value units (RVUs) of physician work, practice expenses, and malpractice expenses of each code and geographic locations of service provision into the assigned CMS payment rate; this rate is determined by building on the CF from the preceding year. As defined in previous legislation, the CF has a statutory increase of 0% through CY 2025; any adjustments are solely due to other regulatory or maintenance of the Medicare budget constraints.

For CY 2024, the CF published in Table 116 of the MPFS was incorrect. On November 2, 2023, the American Medical Association (AMA) sent out confirmation from CMS that the correct values for budget neutrality and the final CF are outlined in the paragraph preceding Table 116, but the values listed in the table itself are incorrect, stating, "CMS has confirmed to the

AMA that the 2024 Medicare conversion factor is \$32.7442, not \$32.7375 as identified in Table 116 and as previously reported. The decrease from the 2023 conversion factor is 3.37%." This results in an estimated 3.7% reduction from 2023, not 3.4% as published by CMS within their Fact Sheet for the MPFS final rule. **Table 1** shows the breakdown between facility and non-facility settings as estimated per the total allowed charges for CY 2024.

The lower CF does result in decreases for many specialties; however, additional decreases 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 adjustments to behavioral health services also factored into this 3.7% reduction.

Table 1. CY 2024 MPFS Estimated Impact on Total Allowed Charges by Setting			
SPECIALTY	TOTAL NON- FACILITY/FACILITY	ALLOWED CHARGES (MILLIONS)	COMBINED IMPACT
HEMATOLOGY/ONCOLOGY	TOTAL	\$1,595	2%
	NON-FACILITY	\$1,039	1%
	FACILITY	\$556	2%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	TOTAL	\$1,556	-2%
	NON-FACILITY	\$1,078	-2%
	FACILITY	\$478	-2%

Specific Codes and Code Set Valuations

Within the CY 2024 MPFS final rule, CMS addressed several potentially misvalued and/or value changes to new and established *Current Procedure Terminology (CPT)* codes. The agency reviewed each code or code family and whether it accepted the valuations by the Specialty Society Relative Value Scale Update Committee (RUC) and other organizations.

- Advanced care planning CPT codes 99497 and 99498. The RUC Relativity Assessment Workgroup reviewed codes 99497 and 99498 in January 2022 and determined that they should be examined due to changes in E/M services. At its April 2022 meeting, the RUC recommended no changes in physician time, work RVUs, or direct practice expense (PE) inputs for these services. For 2024, CMS finalized without refinement the RUC-recommended work RVU of 1.50 for code 99497 and of 1.40 for code 99498; the codes currently have those values.
- Hyperthermic intraperitoneal chemotherapy CPT codes **96547** and **96548**. In September 2022, 2 time-based add-on category 1 CPT codes were created: **96547** ("intraoperative hyperthermic intraperitoneal chemotherapy [HIPEC] procedure, including separate incision[s] and closure, when performed; first 60 minutes") and 96548 ("intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision[s] and closure, when performed; each additional 30 minutes"). During the January 2023 RUC meeting, the specialty societies noted that data reflected time estimates that were higher than those specified in these time-based codes. The RUC concluded that survey results for these codes were incorrect and that they 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 agreed with the RUC's recommendations; these codes will be priced individually by the different Medicare administrative contractors (MACs) until new data are available.

E/M Changes for 2024

CMS addressed 2 outstanding issues in E/M visit payment: 1) implementing separate payment for the office/outpatient evaluation E/M visit complexity add-on payment, and 2) defining split (or shared) visits, which was delayed for CY 2023.

Office/Outpatient E/M Visit Complexity Add-On

Prior to the E/M changes which began in 2021, CMS was not in agreement with the AMA. Therefore, CMS 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") was proposed as part of the CY 2021 proposed rule.

After code G2211 was established, the Consolidated Appropriations Act of 2021 put a moratorium on Medicare payment for this service by disallowing CMS from its reimbursement 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 office/outpatient E/M visits, including visit level selection based on time or MDM (medical decision-making) level. Despite revisions to the other E/M visit families in the CY 2023 final rule, CMS believed that certain types of office/ outpatient E/M visits still did not account for the complexity and resources needed to perform certain types of care.

CMS finalized a change in the status of code **G2211** to active to make it separately payable effective January 1, 2024. After many comments were received, the agency acknowledged the need to clarify when the **G2211** code can be used. Use of this add-on code is intended for services that are part of ongoing care to better account for the inherent complexity of all needed health care services and/or ongoing care related to a patient's single, serious, or

complex condition. The agency emphasized that the add-on code is not based on the characteristics of a particular patient but rather on the *relationship* between the patient and practitioner.

Providers who may best qualify to use this code are physicians who are the continuing focal point for all of a patient's health care services. These providers must not only decide upon the best course of treatment but also for every care decision; this includes best communicating with the patient during the visit to achieve the optimal health outcome and to build an effective, trusting, ongoing relationship for all primary health care needs. CMS believes that the provider has to weigh these factors even for a seemingly simple condition such as sinus congestion; this makes the physician-patient interaction inherently complex.

The ongoing care described within the code descriptor speaks to the longitudinal relationship between the provider and patient for a single, serious, or complex condition. As provided by CMS, the example of an HIV patient could easily be extrapolated to a patient with cancer who is seeing their oncologist for ongoing care. The oncologist and the primary care physician must weigh the same factors during regularly scheduled visits; the E/M becomes more complex due to the compounded building of decisions and considerations for the patient. The oncologist may not be the focal point for all services, yet cancer is a serious and/or complex condition. If the provider and patient relationship is ongoing, **G2211** could be billed along with to the E/M code for the visit.

Split (or Shared) Visits

For CY 2024, CMS again proposed to delay implementation of the updated definition for substantiative portion. However, CMS has decided to forego its previous proposed and finalized definitions and align with the AMA's CPT E/M guidelines for CY 2024. This decision was made after a review of revisions made by the AMA CPT Editorial Panel and included in the 2024 CPT manual publication—specifically, the Evaluation and Management Services

Guidelines language surrounding substantive portion for split (or shared) services.

Effective January 1, 2024, the revised definition of substantive portion of a split (or shared) visit for Medicare billing purposes means that more than half of the total time spent by the physician and nonphysician practitioner (NPP) to perform the split (or shared) visit, or a substantive part of the medical decision-making, is used to determine the appropriate code level. (Critical care visits, which only use time, are exempted from this definition.)

Telephone Evaluation and Management Services

As required by Consolidated Appropriations Act, *CPT* codes **99441–99443** for audio-only telehealth services will continue coverage and payment by CMS through December 31, 2024. *CPT* codes **98966–98968**, which describe telephone assessment and management by nonphysician health care professionals, are not considered telehealth services by CMS. However, these codes have been extended provisional status on the telehealth list, and they will be allowed through December 31, 2024.

After code **G2211** was established, the Consolidated Appropriations Act of 2021 put a moratorium on Medicare payment for this service by disallowing CMS from its reimbursement under the MPFS

Location of Practitioner Providing Telehealth Services

After feedback from a coalition of interested parties, CMS will continue to allow individual practitioners to provide telehealth services from their home without enrolling their home address through the agency. This provision was set to expire December 31, 2023; however, the coalition pointed out safety issues for providers who must disclose their home address through the enrollment process. This issue was supported by recent incidents of workplace violence identified by the coalition and the risk it may add to many health care practitioners.

CMS indicated that it will continue to allow practitioners to use their practice location address instead of their home address when providing telehealth services from their home

through December 31, 2024. The agency is also seeking information to better understand considerations involved enrolling a practitioner's home address as a practice location for Medicare telehealth services.

Place of Service for Telehealth Services

Due to the end of the public health emergency (PHE), the use of **modifier 95** along with the place of service (POS) code—as if the service had been performed in-person—is no longer accepted. Instead, providers will report **modifier 95** with 1 of 2 new POS codes specific to telehealth that identify where the patient is located, unless the physician is in the hospital setting when the visit is performed:

- **POS "02"** (Telehealth provided other than in patient's home)
- **POS "10"** (Telehealth provided in patient's home).

Beginning January 1, 2024, claims billed with **POS 02** will continue to be paid at the MPFS facility rate; claims for any services—not just mental health services—with the code **POS 10** will be paid at the MPFS nonfacility rate. CMS indicated that **POS 02** also represents services provided in an originating site such as hospitals or rural health clinics. The agency clarified that if the physician is working in the hospital and the patient is in their home for the telehealth visit, the physician will report using **modifier 95** and the POS code for the hospital.

Physician Supervision via 2-Way Audio/Video

For CY 2024, CMS extended the definition that allowed for direct supervision to be met with the use of real-time audio and video interactive telecommunications through December 31, 2024. This provision aligns with the timeframe of many of the PHE-related telehealth policies and avoids an abrupt transition to policies in place before the PHE.

Residents in Teaching Settings

For CY 2024, the teaching physician can continue to have a virtual presence in all teaching settings but only in clinical instances when the service is furnished virtually. An example of this would be a 3-way telehealth visit with all parties in separate locations. This provision permits teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service via real-time audio/video communication for all residency training locations through December 31, 2024.

New Codes for Community Health Integration, Social Determinants of Health, and Principal Illness Navigation Services

Equity and access—specifically, how social determinants of health (SDOH) impact the ability to diagnose or treat the patient—are now primary areas of focus for CMS. Accordingly, the agency 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 health care system or to removing health-related social barriers.

For 2024, CMS created 7 new G codes:

- 2 codes (G0019 and G0022) describe community health integration (CHI) services performed
- 1 code (G0136) identifies any social determinants of health that significantly limit the provider's ability to diagnose or treat the problem(s) addressed in the visit
- 4 codes for principal illness navigation (PIN) and principal illness navigation—peer support (PIN-PS) services include 2 codes (G0023 and G0024) specific to any provider and 2 codes (G0140 and G0146) specific to peer support for behavioral health.

Community health integration, principal illness navigation, and principal illness navigation—peer support can be provided under general supervision after initiating an E/M visit that addresses a serious high-risk condition, illness, and/or disease. Use of the social determinants of health code requires use of a standardized, evidence-based risk assessment tool that can be provided with in-person, audio-only, or real-time audio and video capabilities.

Dental Service Coverage for Oncology Patients

Medicare Parts A and B prohibit payment for services in connection with care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. CMS received 8 submissions to consider for CY 2024 and finalized the following related to cancer treatment services.For 2024, CMS created 7 new G codes:

The agency added these examples of services that are *not* subject to the exclusion:

- Dental or oral examination performed as part of a comprehensive workup before cancer treatment with chemotherapy, chimeric antigen receptor (CAR) T-cell therapy, and administration of high-dose bone-modifying agents (antiresorptive therapy) to treat cancer
- Medically necessary diagnostic and treatment services to eliminate an oral or dental infection before or contemporaneously with cancer treatment (eg, chemotherapy, CAR T-cell therapy, and administration of high-dose bone-modifying agents [antiresorptive therapy])
- Dental services inextricably linked to, substantially related to, and integral to the clinical success of administration of high-dose bone-modifying agents (antiresorptive therapy) in cancer treatment.

CMS also provided clarification to allow payment under Medicare Part A and Part B, for dental services required during the period after direct treatment for the head and neck cancer.

As always, the possibility of an update or correction notice from CMS regarding the MPFS final rule is a real possibility. If changes or corrections are made, impacts on payment rates—but no updates to finalized policies—are expected. Due to grassroots efforts for continued support from the US Congress to address physician payment cuts, anything is possible.

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References

1. Centers for Medicare & Medicaid Services,
Department of Health and Human Services. Medicare
and Medicaid programs: calendar year 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. Federal Register. November 16, 2023.
Accessed January 18, 2024. https://www.federalregister.gov/public-inspection/2023-24184/medicare-andmedicaid-programs-calendar-year-2024-paymentpolicies-under-the-physician-fee-schedule

Views

Improving Access to Patient Navigation for Spanish-Speaking Patients

BY JULIE MCMAHON, MPH



■he hard-won improvements in treating and detecting breast cancer at an early stage are accompanied by an unacceptable truth—not everyone has benefitted from these triumphs. Susan G. Komen's Scientific Advisory Board estimates that as many as 30% of breast cancer deaths could be avoided if everyone had access to timely, high-quality care. Although members of the Latino community represent the second fastest growing racial/ethnic group in the United States, they are less likely to have access to high-quality care, and they experience poorer health outcomes.1 Among Hispanic and Latina women in the United States, an estimated 28100 new cases of breast cancer were diagnosed and about 3100 breast cancer deaths were expected in 2021, making breast cancer the most diagnosed cancer type and the leading cause of cancer deaths for all Hispanic and Latina women during that year.2

Primary language challenges combined with lack of insurance, high cost of treatment, issues with health literacy, beliefs or fears related to culture, distrust of the health care system, and complexities with immigration status often compound to drive delays in follow-up care and cause disparate health outcomes for Spanish-speaking Latino patients.³ Additionally, when compared with White people who are not Latino, these individuals are 3 times more likely to be uninsured and less likely to have a medical home, and they tend to be diagnosed with breast cancer at later stages.⁴

The evidence confirms what we intuitively know—patients who have support in coordinating their care, communicating their preferences, understanding their diagnoses, and managing logistics through patient navigation have better

outcomes. Personalized medicine harnesses science to manage an individual's unique traits and disease, and navigation ensures that a patient's support is customized by leveraging available community resources, tools, and providers. Thus, the goal of navigation is that every patient receives the best care possible.

Improving Access

At Komen, our experiences in communities across the country have demonstrated the power of navigation and have revealed significant access issues across populations, particularly in underserved communities.

Susan G. Komen's Patient Care Center makes navigation accessible through the Komen Breast Care Helpline to anyone living in the United States and its territories with the goal of having no one face breast cancer alone.

The Patient Care Center offers information, education, emotional support and guidance, access to services, financial assistance, and additional patient support through navigation. The program's convenience and accessibility break down geographic barriers and allow people across the country to access compassionate and supportive care no matter where they live. The Patient Care Center has been successful in overcoming certain care barriers, yet data collected have highlighted opportunities to improve language accessibility. Between April 1, 2022, and March 31, 2023, 20% of the more than 37000 people served by the Patient Care Center identified themselves as having Hispanic or Latino heritage. Of patients served during that period, 7% of helpline callers and 11% of navigated patients indicated that Spanish was their preferred language.

The Case for Spanish-Speaking Support

As the navigation program grew, Komen's navigators use of translation services increased. Translation services are a helpful tool; however, they do not fully address language barriers, and they often contribute to misinformation and frustration.⁴ Navigation conducted in the patient's preferred language is associated with timely follow-up, especially among Spanish speakers with breast cancer screening abnormalities.^{5,6}

Offering education and support by Spanish-speaking navigators is preferred for a truly patient-centered approach.7 Matching a patient's needs to a culturally- or linguistically-concordant navigator builds trust with patients and supports self-advocacy during the health care journey. Adequate language services provided by Spanish-speaking navigators also help reduce and eliminate delays in care and improve health outcomes.^{3,7}

In addition to language concordance, the method of communication can improve access to navigation services. Ninety-five percent of Spanish speakers who have contacted the helpline have made phone calls rather than using email or web forms. Delivering navigation by telephone or videoconferencing allows anyone with telephone access to receive care without the cost burdens of transportation or dependent care.⁸ Further, remote support reduces distress and improves anxiety, depression, emotional distress, and fatigue.⁹

An increased workforce and streamlined method of communication could increase accessibility of navigation for Spanish speakers. However, navigation of Spanish-

speaking patients can increase a caseload considerably because of longer average call times and days enrolled for this service. Due to linguistic challenges, navigating Spanish-speaking patients often is more time intensive, as more support is needed to communicate with other agencies and apply for other programs.

Workforce and Technology to Improve Access to Spanish-Speaking Support

To ensure that Patient Care Center services are accessible to Spanish-speaking patients, our leadership identified opportunities to improve the accessibility and quality of services and to grow capacity to serve them through workforce and technology.

The Patient Care Center's bilingual staff was increased by 67% (ie, 5 additional bilingual staff members). After these bilingual navigators were added, the need for translation services decreased 50% from its peak.

Technology can be harnessed to better match Spanish-speaking patients with the support they need, including:

- Spanish options were provided in the interactive voice response system
- Automated email response were available in Spanish
- Callers' preferred language were identified, and patients were matched with Spanish-speaking staff
- Breast health information materials and communication templates were furnished when navigators addressed barriers to care.

The Steps Your Organization Can Take

Komen's Patient Care Center has improved accessibility for Spanish-speaking patients by bolstering our team of bilingual staff and leveraging technology. For other patient support programs or service lines considering the needs of non-English speaking populations, some considerations include:

 Hiring processes for a bilingual workforce must include a step for assessing the language proficiency of candidates. Komen worked with a translation services company

- to ensure the proficiency of any Spanishspeaking candidates, particularly because navigators needed to be comfortable with medical terminology.
- 2. Populations experiencing disparities are likely to present with various complex needs, and resolution of those needs may require more time than required for other patient populations. When surveying served communities, organizations and staff must be prepared for the intersectionality of community barriers and its impact on caseload. Consider staff capacity, training, and resources needed to address the complex barriers of the population served. After bilingual staffing is increased to improve capacity, those staff members also need translated resources and educational tools to accomplish their tasks.
- The availability of patient support services by phone in addition to by email increases equitable accessibility of the service, especially for an underserved population.
 Spanish-speaking individuals assisted by the Patient Care Center preferred phone calls to written communication.

Komen provides patient navigation workforce development to other organizations through Komen's <u>Patient Navigation Training Program</u>, which meets the 2024 Medicare Physician Fee Schedule training requirements for reimbursement of navigation services.¹⁰

Julie McMahon, MPH, director of patient navigation at Susan G. Komen, is responsible for the strategic direction and operational leadership of Komen's patient navigation programs, including Komen's nationwide, free navigation training program and telehealth navigation service delivery model within the Komen Patient Care Center.

References

- 1. Funk C, Lopez, H. 2. Hispanic Americans' experiences with health care. Pew Research Center. June 14, 2022. Accessed January 16, 2024. https://www.pewresearch.org/science/2022/06/14/hispanic-americans-experiences-with-health-care/
- 2. Cancer Facts & Figures 2021. American Cancer Society. 2021. Accessed January 15, 2024. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf
- 3. Simon MA, Tom LS, Nonzee NJ, et al. Evaluating a bilingual patient navigation program for uninsured women with abnormal screening tests for breast and cervical cancer: implications for future navigator research. *Am J Public Health*. 2015;105(5):e87-e94. doi: 10.2105/AJPH.2014.302341
- 4. Paz K, Massey KP. Health disparity among Latina women: comparison with non-Latina women. *Clin Med Insights Womens Health*. 2016; 9(suppl 1):71-74. doi:10.4137/CMWH.S38488
- 5. Robie L, Alexandru D, Bota D. The use of patient navigators to improve cancer care for Hispanic patients. *Clin Med Insights Oncol.* 2011;5:1-7. doi:10.4137/CMO.S6074
- 6. Charlot M, Santana MC, Chen CA, et al. Impact of patient and navigator race and language concordance on care after cancer screening abnormalities. *Cancer*. 2015;121(9):1477-1483 doi:10.1002/cncr.29221
- 7. Steinberg EM, Valenzuela-Araujo D, Zickafoose JS, Kieffer E, DeCamp LR. The "battle" of managing language barriers in health care. *Clin Pediatr (Phila)*. 2016;55(14):1318-1327. doi:10.1177/0009922816629760
- 8. Sabesan S, Simcox K, Marr I. Medical oncology clinics through videoconferencing: an acceptable telehealth model for rural patients and health workers. *Intern Med J.* 2012;42(7):780-785. doi:10.1111/j.1445-5994.2011.02537.x
- 9. Cochrane Gynaecological, Neuro-oncology, and Orphan Cancer Group; Ream E, Hughes AE, Cox A, et al. Telephone interventions for symptom management in adults with cancer. *Cochrane Database Syst Rev.* 2020;6:CD007568. doi:10.1002/14651858.
- 10. Patient navigation training program. Susan G. Komen. Accessed January 23, 2024. https://www.komen.org/about-komen/our-impact/breast-cancer/navigation-nation-training-program/

spotlight

Corewell Health-West



long the corridors of the Medical Mile in Grand Rapids, Michigan, sits Lemmen-Holton Cancer Pavilion, the main campus of Corewell Health–West. The six-story building is one of the cancer program's 6 locations across Northwest Michigan. Through its doors, patients with cancer can access the only adult blood and marrow transplant department on the west side of the state. This department has 11 infusion chairs, 4 private rooms, and is staffed by 2 physicians, 7 advanced practice providers (APPs), 6 nurse coordinators, and 6 registered nurses (RNs).

Lemmen-Holton Cancer Pavilion provides patients with surgical services, medical oncology and hematology services, an infusion clinic with 26 chairs, and laboratories for cytogenetics, flow cytometry, and molecular diagnostics. Its radiation oncology department is staffed by 10 dosimetrists, 6 physicists, 8 radiation oncologists, 15 RNs, and 37 radiation therapists. The medical oncology department is staffed by 7 oncologists, 9 APPs, 38 RNs, and 3 charge RNs. The center has 16 surgeons— 2 of whom provide gender affirmation surgery. This department's staff includes 14 RNs, 20 APPs, and 2 licensed practical nurses. "Our cancer care team largely consists of employed providers," said Anas Al-Janadi, MD, vice president, department chief, Oncology at Corewell Health-West.

The Lemmen-Holton Cancer Pavilion houses the only adult blood and marrow transplant department on the west side of the state. This department has 11 infusion chairs and 4 private rooms, and is staffed by 2 physicians, 7 APPs, 6 nurse coordinators, and 6 RNs.

Patients with cancer who present at the center have access to 6 apheresis bays, 4 linear accelerators, and a radiology department that

provides port placement, image-guided biopsies, thoracentesis, and paracentesis services. "[In this location], we get patients from as far north as the upper peninsula, and even some who will come from the south, and across state lines to receive treatment," said Katie Celentino, director of operations at Corewell Health–West.

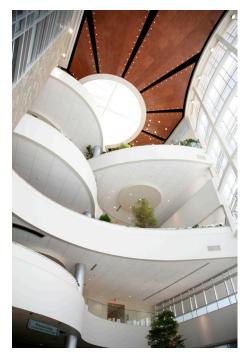
Comprehensive Cancer Care

According to Celentino, delivering care to a diverse patient population close to home is only one part of the puzzle. Ensuring the care is comprehensive is the other. "We are connected in a way that you do not always see with large systems," Celentino explained. "The

care is not going to vary or be substandard because you are in an outlier clinic or infusion facility." Consequently, each center is tailored to needs of the community in which it is located.

In Reed City, patients can find The Susan P. Wheatlake Cancer Center, equipped with a full-service pharmacy, 16 infusion chairs, and a linear accelerator. "The pharmacy just underwent a \$3 million renovation to ensure that it is meeting all the requirements for comprehensive cancer care," said Aly Dondzila, MHA, director of operations, Cancer Care at Corewell Health–West. The Gerver Cancer Center has 9 infusion chairs, while the Greenville and Ludington Cancer Centers each have 8 infusion chairs. The Pennock Cancer Center has 7









infusion chairs, and patients are provided non-oncology infusion services at Blodgett Hospital in Grand Rapids, and Zeeland Hospital in Zeeland, Michigan.

On January 16, 2024, the program opened the doors of a brand-new facility on the Ludington campus: Crane Haven Cancer Care Center.

A total of \$5.47 million was dedicated to the project, which began on November 30, 2022.

According to Barbara Schmidtman, PhD, vice president, cancer health operations, Corewell Health–West, the facility represents the program's commitment to ensuring patients receive the best care possible at state-of-the-art facilities. The Greenville facility will also undergo similar renovations later this year.

Betty Ford Breast Care Service

The 1974 breast cancer diagnosis of Elizabeth Anne Ford, the 38th First Lady of the United States, sparked the recognition of Breast Cancer Awareness Month the following year.¹ Ford, who grew up in Grand Rapids, was just 7 weeks into her role as First Lady when a routine exam revealed a lump in her chest.¹ At the time, no guidelines around breast cancer existed. Ford promptly announced that she had breast cancer and would undergo a mastectomy—a public acknowledgement that up until her announcement was unthinkable for any woman, much less the First Lady. Within a week following Ford's surgery, women across the US reported to clinics for breast exams and

newspaper articles detailed how to perform self-exams. The White House received tens of thousands of cards and letters from women offering their support and sharing how Ford's candor and confidence influenced them to get screened. The effect Ford had on the women's health in the US cannot be understated and through the Betty Ford Breast Care Service, Corewell Health–West continues her legacy. The service has 17 locations throughout West Michigan and its staff includes a radiology manager, 8 RNs, 42 mammographers, 11 ultrasound technologists, 3 mobile mammography unit drivers, and a community health program specialist who oversees grant funding. Through its mobile mammography unit, the program provides screening services to the American Indian population in Michigan.

"We have a 4-year relationship with the Inter-Tribal Council of Michigan, where we serve the American Indian women in the upper most part of northern Michigan," said Nichole Coy, director of operations, Oncology at Corewell Health-West. "This past year we were able to provide 138 mammograms to the Native American communities over a 5-day period." According to Coy, the program plans to offer these patients screening for cervical cancer in the summer of 2024. This is a necessary initiative, as American Indian and Alaskan Native women are nearly twice as likely to develop cervical cancer compared to White women.2 "Over 4 years, we have been able to improve access to an incredibly underserved and rightfully mistrustful patient population by 200%," Coy said. "That has taken a lot of meaningful conversation and intentionality to make that happen. It is something we are incredibly proud of."

From January 1, 2020, to December 31, 2022, the mobile mammography unit performed 11,466 screenings. The program's community outreach efforts also include a partnership with Grand Rapids African American Health Institute to engage Baptist Churches in conversations about cancer screening, annual melanoma screening events, the distribution of a fecal immunochemical test kit that boasts an 82% return rate, and the Irish Jig—an annual 5k run to raise awareness for all cancers with a focus on fundraising for patient assistance programs. The 40th edition of the race will happen later this year.

Support Services

Understanding the need to help patients as they navigate the cancer care continuum, the program offers a wide array of support services. "We have nutrition, salon, music therapy, massage services, and more to support patients throughout the course of their treatment and into survivorship," said Katherine Williams, supervisor for Community Programming at Corewell Health-West. The Lemmen-Holton Cancer Pavilion houses a salon that is open on Tuesdays and Thursdays, and it had 293 patient appointments in 2023. The center also hosts an expressive arts program twice a month. Patients can access individual acupuncture services at the Pavilion and Crane Haven Center and group sessions at the Susan P. Wheatlake Cancer Center.

"Under our community program, we house 3 social workers in Grand Rapids, and 3 currently support our other locations," Williams said.

"I am always eager to brag about our social work and nurse navigation team in Grand Rapids—they are disease site specialists and help navigate those patients through the continuum of their care," Celentino shared. According to Williams, a very generous philanthropic community ensures the program can deliver these services to patients at no cost.

Clinical Trials

"Clinical trials are a major component of our program," Dr. Al-Janadi said. According to Dr. Al-Janadi, the program has multiple site-specific tumor boards during the week. "There is always a clinical trial office team member present at each tumor board," he said. "This is important as each patient is screened by the clinical trial office when they are coming for a new appointment, so we are always aware of the trial pool."

The program is accredited by the American College of Surgeons in breast cancer, Commission on Cancer, Foundation for the Accreditation of Cellular Therapy, and the American College of Radiation Oncology.

According to Schmidtman, these feats demonstrate the program's commitment to excellence and collaboration as part of a larger not-for-profit health system, named Corewell Health, that provides healthcare and coverage





with a staff of more than 65000, in 21 hospitals, more than 300 outpatient locations, and several post-acute facilities.

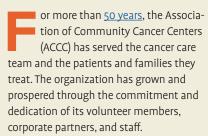
"I think our secret sauce here is truly the leadership team, as well as the people that are delivering care," she said. "Yes, we span wide and far, but our team has done an exceptional job in developing ways to care for patients in some of the most rural communities in the west side of the state that otherwise would not have access to an oncologist."

References

- Mccubin, L. Betty Ford's trailblazing legacy.
 Updated July 21, 2019. Accessed January 9, 2024. https://www.history.com/news/ betty-ford-legacy-center-cancer-womens-rights
- 2. Morgan, B. American Indians twice as likely to develop cervical cancer. Published January 21, 2020. Accessed January 9, 2024. <a href="https://www.nicoa.org/american-indians-twice-as-likely-to-develop-cervical-cancer/#:~:text=American%20Indian%20and%20Alaska%20Native%20women%20are%20nearly.stages%2C%20making%20successful%20treatment%20and%20cure%20more%20difficult.

action

ACCC Celebrates Its 50th Anniversary with a Name Change and Rebrand



For most of 2023, ACCC Board and staff undertook a strategic planning process that reflected—and celebrated—its glorious past accomplishments and looked to position the organization for continued growth and expansion to meet the changing needs of its membership. This strategic planning process included input from a broad cross section of ACCC members, key stakeholders, and professional consultants.

To reflect a changing landscape and the future direction of multidisciplinary team-based cancer care delivery, a consensus was reached to make a subtle change in the organization's name. Moving forward, ACCC will be known as the Association of Cancer Care Centers, the leading education and advocacy organization for the cancer care community. For more on this name change and rebrand, please read the "From the Editor" in this Oncology Issues.

Because words matter, below we share some of the thought processes that went into this decision.

The word "Association" reflects the gathering, inclusion, and value of everyone on the ever-expanding cancer care team. This team includes both clinical members (multi-specialty physicians, nurses, pharmacists, social

workers, etc.) and non-clinical members (COOs, CFOs, administrators, financial advocates, quality officers, etc.). It also includes those involved in discovering new treatments, clinical trial navigators, outreach specialists who spearhead cancer education and prevention efforts, those professionals in evolving treatment specialties, patients and caregivers, and everyone else looking to become part of the cancer care community.

The words "Cancer Care" have evolved during ACCC's 50-year history—from a relatively small number of anti-cancer drugs, surgical procedures, and radiation treatments to an incredible armamentarium of highly specialized personalized treatments. In addition to these scientific and medical advances, the words "Cancer Care" reflect many other critical services and patient needs, like psycho-social care, genetic counseling, and nutrition services, which allow patients and families to recognize optimal outcomes. Most importantly, the words "Cancer Care" mean care this is equitable, readily available to everyoneregardless of the community they live in.



The word "Centers" is representative of our multidisciplinary members who come from all types of cancer programs that serve the community: independent physician practices, enterprise level physician networks, small hospital cancer programs, major integrated delivery networks, academic cancer programs, and everything in between and wherever cancer care may be delivered over the next 50 years.

All those involved in this strategic planning process believe that this new name reflects the evolution and growth of our organization, aligning ACCC more closely with the diverse needs of its members and the patients they serve, and positioning ACCC for the next 50 years of growth. Over the coming weeks, you will witness updates to ACCC branding and communications as we implement this change seamlessly.

Thank you for your ongoing support, and we look forward to advancing our shared mission under our new identity as the Association of Cancer Care Centers.



ACCC Welcomes Its Newest Members



AdventHealth Parker Cancer Center

Parker, Colorado
Delegate Rep: Stacy Ban
Website: adventhealth com/

Website: <u>adventhealth.com/hospital/</u> <u>adventhealth-parker/cancer-care</u>

Baptist Health Floyd Cancer Center

New Albany, Indiana Delegate Rep: Christy Flynn

Website: <u>baptisthealth.com/blog/cancer-care/oncology-cancer-treatment-in-new-albany-in</u>

Blanchard Valley Health System-Armes Family Cancer Care Center

Findlay, Ohio

Delegate Rep: Adele Simon

Website: <u>bvhealthsystem.org/locations/</u>

locations-details?practice=30

Carle Health System

Urbana, Illinois

Delegate Rep: Anne Bowman Website: https://carle.org

Carle Cancer Institute Normal

Normal, Illinois

Delegate Rep: Joseph Prosser Website: <u>carle.org/locations/</u> carle-cancer-institute-normal

Palouse Oncology and Hematology

Moscow, Idaho

Delegate Rep: Sonya Spraul
Website: https://www.gritman.org/
services-care-areas/cancer-care/oncology

Redlands Community Hospital, Center for Cancer Care

Redlands, California Delegate Rep: Lori Arias

Website: https://www.redlandshospital.org/locations/rch-center-for-cancer-care

Titus Regional Medical Center, Cancer Care at Titus

Mt. Pleasant, Texas Delegate Rep: Laura Walsh

Website: titusregional.com/cancer

University of Maryland Cancer Network

Baltimore, Maryland Delegate Rep: Nick Jaidar

Website: https://www.umms.org/ health-services/cancer/network

University of Maryland Capital Region

Largo, Maryland

Delegate Rep: Sarah Larson Website: <u>umms.org/capital</u>

Building the Next Generation of Oncology Leaders

In his final fireside chat, 2023-2024 ACCC President Olalekan Ajayi, PharmD, MBA, chief operating officer at Highlands Oncology Group was joined by Kristen E. Wynn, program manager at Livestrong Cancer Institutes at Dell Medical School at The University of Texas at Austin, to discuss strategies for building the next generation of oncology leaders. They explored tools for developing mentorship programs for middle, high school, and college students pursuing a career in oncology as well as actionable strategies for mentoring leaders within your own cancer program or



practice. Watch this <u>video</u> to learn more about how the The University of Texas at Austin is establishing a diverse education pipeline.

ICYMI: Explore Strategies for Workforce Development

A multitude of workforce-related challenges require today's oncology programs and practices to reimagine many of their strategies, operations, and processes. To help its member programs create the positive change their clinicians, staff, and patients deserve, ACCC



has developed this <u>online curriculum</u> as part of the 2023-2024 ACCC President's Theme, (*Re*)Building the Oncology Workforce to Deliver Next Generation Care. In this free curriculum, learners explore strategies along the continuum from improving recruitment and onboarding to establishing trust and relationships with staff to implementing effective leadership development and training.

tools



Approved Drugs

- On November 15, the US Food and Drug Administration (FDA) approved Augtyro® (repotrectinib) (Bristol Myers Squibb, bms.com) for patients with locally advanced or metastatic, ROS1-positive non-small cell lung cancer (NSCLC).
- On November 8, the FDA approved **Fruzaqla**® (**fruquintinib**) (Takeda Pharmaceuticals, Inc., takeda.com) for adult patients with metastatic colorectal cancer who received prior fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; an anti-VEGF therapy; and, if the tumor is *RAS* wild-type and it is medically appropriate, an anti-EGFR therapy.
- On December 13, the FDA approved **Iwilfin®** (eflornithine) (US WorldMeds, usworldmeds. com) to reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy.
- On December 1, the FDA granted accelerated approval to Jaypirca® (pirtobrutinib) (Eli Lilly and Company, lilly.com) for adults with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least 2 prior lines of therapy that included a Bruton tyrosine kinase (BTK) inhibitor and a BCL2 inhibitor.
- On January 12, 2024, the FDA approved Keytruda® (pembrolizumab) (Merck, merck.com) given in combination with chemoradiotherapy for patients with Interna-

tional Federation of Gynecology and Obstetrics 2014 stage III-IVA cervical cancer. On November 16, the FDA approved **Keytruda in** combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced, unresectable or metastatic, HER2-negative (HER2-) gastric or gastroesophageal junction adenocarcinoma. On November 7, the FDA revised the existing indication of Keytruda in combination with trastuzumab, fluoropyrimidine, and platinum-containing chemotherapy for the first-line treatment of patients with locally advanced, unresectable or metastatic, HER2-positive gastric or gastroesophageal junction adenocarcinoma. On October 31, the FDA approved **Keytruda in combination** with gemcitabine and cisplatin for patients with locally advanced, unresectable or metastatic biliary tract cancer.

- On November 27, the FDA approved Ogsiveo®
 (nirogacestat) (SpringWorks Therapeutics, Inc., springworkstx.com) for adult patients with progressing desmoid tumors who require systemic treatment. This is the first approved treatment for desmoid tumors.
- On December 15, the FDA approved **Padcev**® (enfortumab vedotin-ejfv) (Astellas Pharma Inc., astellas.com) in combination with Keytruda (pembrolizumab) (Merck, merck.com) for patients with locally advanced or metastatic urothelial cancer.
- On November 16, the FDA approved Truqap® (capivasertib) (AstraZeneca Pharmaceuticals, astrazeneca.com) in combination with

fulvestrant for adult patients with hormone receptor-positive (HR+)/HER2–, locally advanced or metastatic breast cancer with 1 or more *PIK3CA/AKT1/PTEN*-alterations as detected by an FDA-approved test following progression on at least 1 endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

- On December 14, the FDA approved **Welireg®** (**belzutifan**) (Merck, <u>merck.com</u>) for patients with advanced renal cell carcinoma following a PD-1 or PD-L1 inhibitor and a tyrosine kinase inhibitor that targets VEGF.
- On November 16, the FDA approved **Xtandi®** (enzalutamide) (Astellas Pharma Inc., astellas.com) for patients with nonmetastatic, castration-sensitive prostate cancer with biochemical recurrence who are at high risk for metastasis.

Drugs In the News

- Oxford BioTherapeutics (oxford-biotherapeutics.com) announced that the FDA has granted fast track designation to BI 764532 for the treatment of patients with advanced or metastatic, large-cell neuro-endocrine carcinoma of the lung expressing DLL3 whose disease has progressed following at least 1 prior line of treatment including platinum-based chemotherapy.
- Bristol Myers Squibb (bms.com) announced that the FDA has accepted the supplemental biologics license application (BLA) for Breyanzi® (lisocabtagene maraleucel) to expand its current indication to include the

treatment of adult patients with relapsed or refractory CLL or SLL who received a prior BTK inhibitor and a BCL2 inhibitor.

- CG Oncology, Inc. (cgoncology.com) announced that the FDA has granted both fast track designation and breakthrough therapy designation for **cretostimogene grenadenorepvec** in patients with high-risk, Bacillus Calmette-Guérin-unresponsive, nonmuscle invasive bladder cancer with carcinoma in situ with or without Ta or T1 (papillary) tumors.
- Seagen Inc. (seagen.com) and Astellas Pharma Inc.(astellaspharma.com) announced that the FDA accepted for priority review a supplemental BLA for Padcev® (enfortumab vedotin-ejfv) in combination with Keytruda (pembrolizumab) for the treatment of adult patients with locally advanced or metastatic urothelial cancer.
- Daiichi Sankyo (daiichisankyo.com) and Merck (merck.com) announced that the FDA has accepted and granted priority review to the BLA for **patritumab deruxtecan** (HER3-DXd) for the treatment of adult patients with locally advanced or metastatic, *EGFR*-mutated NSCLC who were previously treated with 2 or more systemic therapies.
- RemeGen Co. Ltd. (remegen.com) announced that the FDA granted fast track designation to **RC88** for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, and primary peritoneal cancers.

- ProfoundBio (profoundbio.com) announced that the FDA has granted fast track designation for **rinatabart sesutecan** (Rina-S; PRO1184), a FRα-targeted antibody-drug conjugate, for the treatment of patients with FRα-expressing, high-grade, serous or endometrioid, platinum-resistant ovarian cancer.
- Janssen Pharmaceutical (jnj.com) announced the submission of a supplemental BLA to the FDA for **Rybrevant®** (amivantamab-vmjw) in combination with carboplatin and pemetrexed for the treatment of patients with locally advanced or metastatic NSCLC with *EGFR* exon 19 deletions or L858R substitution after disease progression on or after osimertinib.
- SELLAS Life Sciences Group, Inc.
 (sellaslifesciences.com) announced that the
 FDA has granted fast track designation to
 SLS009 (formerly GFH009) for the treatment
 of patients with relapsed/refractory acute
 myelocytic leukemia.
- SonALAsense (sonalasense.com) announced that the FDA has granted fast track designation to the development program of **SONALA-001** in combination with the INSIGHTEC Exablate 4000 Type-2 device for the treatment of patients with diffuse intrinsic pontine glioma.

• eFFECTOR Therapeutics, Inc. (effector.com) announced that the FDA has granted fast track designation for **zotatifin in combination** with fulvestrant and abemaciclib (ZFA triplet) as second- or third-line therapy for the treatment of adult patients with estrogen receptor-positive/HER2-, advanced or metastatic breast cancer with disease progression following endocrine therapy and treatment with a CDK4/6 inhibitor.

Devices and Assays

- Geneseeq Technology Inc. (geneseeq.com)
 announced that its multicancer early detection
 solution CanScan™ has been granted
 breakthrough device designation by the FDA.
- On November 20, the FDA approved

 FoundationOne®CDx (Foundation Medicine, foundationmedicine.com) as a companion diagnostic for Truqap™ (capivasertib) in combination with Faslodex® (fulvestrant) for the treatment of adult patients with HR+/ HER2−, locally advanced or metastatic breast cancer with 1 or more PIK3CA/AKT1/PTEN-alterations following progression on at least 1 endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy. □