ONCOLOGY ISSUES

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Improving the Care of Patients Newly Diagnosed With Breast Cancer

ACCC ASSOCIATION OF CANCER CARE CENTERS™ | 50 Years STRONG

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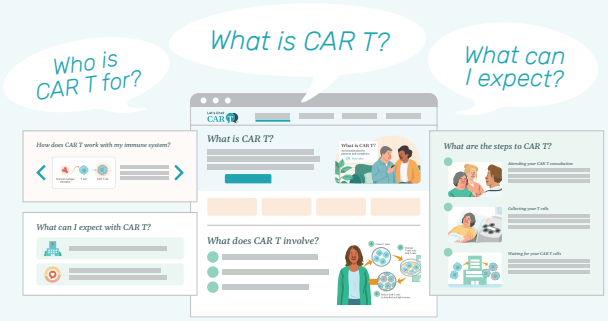

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ONCOLOGY ISSUES

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FROM THE EDITOR

Cultivating Strong Teams in Oncology Care

BY MARK LIU, MHA

In the dynamic environment of oncology care, the strength of our teams is paramount. As clinicians, researchers, administrators, and advocates, our ability to collaborate effectively directly impacts the quality of care we provide to patients and the advancement of cancer treatment as a field. I particularly enjoyed Dr. Katherine Meese's recent presentation at the ACCC 50th Annual Meeting & Cancer Center Business Summit (#AMCCBS), which offered invaluable insights into leading healthy teams.

A crucial aspect highlighted was the establishment of standards of behavior. Clear expectations regarding respect, communication, and accountability lay the foundation for a culture of mutual respect and trust. Understanding and appreciating the differences among team members further enriches collaboration, fostering an environment where diverse perspectives are not just tolerated but celebrated. Central to cohesive teamwork is the alignment of individuals with the organization's mission, vision, and shared goals. When everyone is working towards a common purpose, synergy flourishes, driving innovation and progress. However, this unity should not come at the expense of tolerating subpar performance. Dr. Meese cautioned against allowing workarounds for low performers, as it undermines team morale and effectiveness.

Encouraging collaborations across departments and disciplines not only creates efficiencies in problem-solving but also fosters a sense of interconnectedness and collective achievement. Equally important is ensuring that every voice within the team has the opportunity to be heard. Actively soliciting and incorporating diverse perspectives not only leads to better decision-making but also cultivates an inclusive culture where every member feels valued and empowered.

Lastly, Dr. Meese reminded me of the importance of having fun in the workplace. While the nature of our work in oncology is serious and demanding, finding moments of levity and camaraderie can strengthen bonds and alleviate stress. Importantly, these opportunities do not always have to happen outside of work; simple gestures like celebrating achievements or organizing team-building activities during work hours can have a profound impact on team morale.

It is clear that building and maintaining healthy teams in oncology care requires deliberate effort and commitment from all stakeholders. By prioritizing people, embracing diversity, aligning with shared goals, fostering collaborations, and infusing joy into our work, we not only enhance the well-being of our teams but also elevate the quality of care we provide to our patients.

Dr. Meese's presentation was a special collaboration between ACCC and the American College of Healthcare Executives (ACHE). Given the considerable overlap in membership between both organizations, I would love to hear your thoughts on this collaboration and any ideas for future opportunities. I certainly welcomed the opportunity to earn CE credits!

Here's to cultivating resilient, compassionate, and effective teams that continue to drive progress in the fight against cancer. To read highlights from #AMCCBS, turn to "Action" (page 75) in this issue. And for more valuable in-person learning opportunities and to hear presentations from the 2024 ACCC Innovator Winners, be sure to join me October 9-11 in Minneapolis, Minnesota. OI

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Reimagining Community Engagement and Equity in Cancer

BY NADINE J. BARRETT, PHD, MA, MS, FACCC

In 2020, this country was ravaged by COVID-19 bringing to light what we already knew existed—social and health inequities including a lack of access to clinical research. Eventually, we were able to develop vaccines to address the disease. Yet acceptance and trust in these vaccines lagged, and only after we engaged with our communities could we achieve widespread vaccination.

At the same time, we experienced political unrest and high-profile instances of ongoing social injustice with the murders of Ahmaud Arbery, Breonna Taylor, and George Floyd.

We cannot change the past, but we can change the future. When I reflect on how ACCC as an organization can effect positive change, I know that **community engagement** and **equity** will be key.

Let's start with how we talk about historically marginalized populations. We need to think about the issue in a way that does not speak to a deficit but, instead, comes from a place of strength. What are the strengths of our community, and how do we as an institution build on those strengths in partnership with our community?

My colleague and friend, Robert Winn, MD, shared this gem in a speech delivered at the ACCC 50th Annual Meeting & Cancer Center Business Summit. "[Health care organizations have] been asking the wrong question about doing something different [with historically marginalized populations]. The question isn't 'How do we get trust?' but, instead, 'How do we become more institutionally trustworthy?'"

At this same meeting, I was privileged to facilitate a session that truly brought home the importance of community engagement. Two ACCC member programs shared how they partner with their communities and patients in meaningful ways to understand what quality health care looks like—not the cancer care team working the issue alone behind its building, but leaving the cancer center, going out into the community, and using what is learned to inform and drive their efforts. That is the very definition of community engagement.

Equity. It's a word we hear daily. But advancement of health equity requires more than talk. Many organizations issued statements against social injustice and pledged to make changes. "We're going to bring an end to systemic racism!" And these organizations created new positions and hired chief diversity officers in an almost knee-jerk reaction to a structural inequity that has existed for a very long time. Fast forward to today—and few of those efforts are still in place. Instead, we found that in times of adversity, these diversity roles are some of the first to go.[1]

ACCC took a different approach. Instead of hiring a diversity officer, ACCC committed to integrating equity in everything it did, so equity became a part of the Association's DNA.

In 2020, Randall Oyer, MD, used his ACCC President's Theme to focus on equitable access to clinical trials. In her ACCC President's Theme, Krista Nelson, MSW, LCSW, OSW-C, FAOSW, identified "health equity and social justice as critical drivers of quality cancer care" and noted that "practice-based solutions were needed to reduce barriers and improve health outcomes." ACCC Immediate Past President Olalekan Ajayi, PharmD, MBA, championed efforts to develop education and resources to diversify the health care workforce so members of the multidisciplinary cancer care team reflect the communities they serve.

That's how an organization integrates and embeds health equity into every aspect of the organization's programs and activities.

In this, my first column, I am privileged to share the 2024-2025 ACCC President's Theme—*Reimagining Community Engagement and Equity in Cancer.*

ACCC is a community of individuals who can work together to create the change that we want to see. Person-centered care requires a multidisciplinary team. It also requires our organizations to reach into our communities and actively engage with and learn from the people we serve, anchoring equity at the center of our work. OI

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- Addressing the Unmet Need of Sexual Health in Oncology Patients
- Exploring Montefiore Health System's Community Health Worker Institute Model
- Pipeline Partners: Developing Training and Recruitment Programs for the Oncology Workforce
- Participation in Fall Risk Self-Assessment by Hospitalized Oncology Patients
- Integration and Outcomes of Universal Multigene Panel Testing for Patients Newly Diagnosed With Breast Cancer
- AI in Healthcare - The Effect on Current and Future Care

Improving the Care of Patients Newly Diagnosed With Breast Cancer

BY BETH FISHER, MED, MBA; HUNTER HAYES, MBA;
KIM STANBERY, DNP, RN, OCN, NEA-BC;
AND KELLEY D. SIMPSON, MBA

Prior to 2020, patients newly diagnosed with breast cancer at Atrium Health Wake Forest Baptist Comprehensive Cancer Center experienced a highly variable delay before they could consult with a breast cancer provider. New patients had to wait 4 business days to meet with Radiation Oncology, 13 business days to consult with Medical Oncology, and 6 business days to meet with Surgical Oncology. Scheduling was decentralized across the treatment teams, and multiple visits rarely could be coordinated for the same day and within the same location.

Addressing this issue required a coordinated, multidisciplinary approach that involved engaging the cancer center leadership across the 3 treatment teams, administrators, physicians, advanced practice providers (APPs), patient navigators, genetic counselors, scheduling staff, imaging and laboratory technicians, and pathologists. The primary goals of the initiative were to transform the patient experience and improve timeliness of care for every newly diagnosed patient (Figure 1).

Process

A *Plan-Do-Study-Act* framework was used with extensive process mapping, stakeholder interviews, review of best practices, and design sessions.

During the *plan* phase, all patient points of entry—including electronic referrals, faxes, and phone numbers—were identified and mapped. The breast clinical performance group, a multidisciplinary team made up of clinical and administrative breast cancer experts, collaborated with a steering committee to develop and adopt a provisional review process for patients newly diagnosed with breast cancer. With stage, type of cancer, and tumor characteristics as determining factors, an oncology nurse navigator now conducts this patient review and determines which providers from particular disciplines should consult with patients during their first appointment.

The introduction of an oncology nurse navigator–led provisional review process with coordinated physician schedules improved timeliness to care and patient satisfaction among individuals newly diagnosed with breast cancer.

The *do* phase begins when a patient receives a pathologically confirmed cancer diagnosis. Within 1 business day of receiving a referral for a new patient, an oncology nurse navigator performs a provisional review and schedules the patient for an appointment with the Breast Cancer Multidisciplinary Clinic within 1 week (Figure 2).

(*Continued on page 9*)

Figure 1. Patient Desires, Dissatisfiers, and Identified Solutions

	DESIRES	DISSATISFIERS	IDENTIFIED SOLUTIONS
Patient	• Speaking to an oncology professional as quickly as possible about their diagnosis • Trusting their care team throughout their journey • Receiving help with insurance issues • Accessing the latest treatment options • Accessing care close to home	• Having difficulty receiving help on the first call • Having their first appointment rescheduled • Needing to return to the facility multiple times to meet with all their providers and having multiple co-pays • Being given inaccurate expectations about members of their care team.	• Offering a patient-centric access platform to easily schedule appointments, partner with the patient, and access necessary oncology services • Being introduced to a multidisciplinary care team early • Being assessed quickly, including for participation in clinical trials

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- **20% of rural residents live >60 miles from a medical oncologist**, creating a barrier to treatment[1]
- **Self-care for cancer patients proves difficult**, particularly within safety-net environments, due to reduced health literacy and various other barriers[2]

Equitable Care

- Black women are **41% more likely to die** of breast cancer than white women[3]
- Only about **5% to 15% of US clinical trial participants are Black or Latino**, yet non-white people are predicted to make up the majority of the US population by the year 2045[4-7]

Precision Medicine

- **1 in 3** patients with advanced non–small cell lung cancer **did not receive next-generation sequencing (NGS) testing**[8]
- White patients with NSCLC **received timely NGS testing at higher rates** (~8%) compared to Black or Latinx patients[9,10]

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Within the Breast Cancer Multidisciplinary Clinic, the patient is scheduled to see providers from up to 3 specialty disciplines on the same day. A review of provider schedules and new-patient volumes led to the decision to stand up Breast Cancer Multidisciplinary Clinics 3 days per week. The first phase of interventions created the opportunity for a new patient to see all providers in all 3 disciplines on the same day, but appointment locations were scattered across the cancer center, and a separate registration process was required for each clinic appointment (Figure 3).

After 3 months, during the *study* phase, the data for time to appointment were reviewed and an improvement was noted; however, multiple appointment check-ins and check-outs on different floors of the cancer center increased wait times and led to patient dissatisfaction. In the next phase, *act*, the Breast Cancer Multidisciplinary Clinic schedule was changed to address this issue—all patients remained on the same floor and stayed in 1 room as physicians rotated through for consultations. This change offered the added benefits of keeping physicians in the same location during the Breast Cancer Multidisciplinary Clinic and allowing for real-time collaboration and treatment planning (Figure 4).

Results

The baseline period for this initiative includes the months before the COVID-19 pandemic began and the early months following its outbreak. During the third quarter of 2019, the Breast Cancer Program logged 242 new-patient visits; the new-patient lag time (ie, time from making an appointment to completing the consultation) averaged approximately 12 business days (ie, 2.5 weeks). At the height of the COVID-19 pandemic in 2020, there were as few as 163 new-patient visits per quarter; the average new-patient lag time was 7 to 10 business days—both patient volume and new-patient lag days decreased during that time. In February 2021, with a return to a quarterly volume of 252 new-patient visits, the first Breast Cancer Multidisciplinary Clinic workflows were deployed, and new-patient lag days were drastically reduced to 4.5 business days.

In May 2021, the enhanced second iteration of the Breast Cancer Multidisciplinary Clinic workflows were deployed. Quarterly volumes steadily held above 289 new-patient visits with a peak of 368 new-patient visits in the third quarter of 2021; further, new-patient lag days remained steady between 4 to 6 business days. As a result of

(*Continued on page 11*)

Figure 2. Provisional Review Conducted by Oncology Nurse Navigator

DISEASES STAGE/FEATURE	MEDICAL ONCOLOGY	SURGICAL ONCOLOGY	RADIATION ONCOLOGY
Eligible for neoadjuvant therapy			
Lymph node-positive	●	●	●
Lymph node-negative, tumor > 2 cm	●	●	
HER2-positive breast cancer	●	●	
Triple-negative breast cancer tumor ≥ 1 cm	●	●	
Likely to need trimodality care up front			
Inflammatory breast disease	●	●	●
Early-stage disease/High-risk lesions			
DCIS/LCIS/Atypia		●	
Hormone receptor-positive breast cancer, tumor ≤ 2 cm		●	
Triple-negative breast cancer ≤ 1 cm	●	●	
Advanced stage			
Stage IV/Metastatic breast cancer	●		
Stage IV/Metastatic breast cancer with pain	●		●

DCIS, ductal carcinoma in situ; LCIS, lobular carcinoma in situ.

Figure 3. Breast Cancer Multidisciplinary Clinic Appointments: PDSA Cycle 1

PDSA CYCLE 1	MEDICAL ONCOLOGY		SURGICAL ONCOLOGY	RADIATION ONCOLOGY	GENETICS
	DOCTOR 1	DOCTOR 2	DOCTOR 3	GENERAL RADIATION ONCOLOGY	GENERAL GENETICS
8:00-8:30 AM	Established patient		New/MDC patient		
8:30-9:00 AM	Established patient	Treatment visit	New/MDC patient		
9:00-9:30 AM	Established patient	Treatment visit	New/MDC patient		
9:30-10:00 AM	Established patient	Treatment visit	New/MDC patient		
10:00-10:30 AM	MDC patient	MDC patient	New/MDC patient		
10:30-11:00 AM			Established patient		
11:00-11:30 AM	MDC patient	MDC patient	Established patient	MDC patient	
11:30-12:00 PM			Established patient	MDC patient	
12:30-1:00 PM	Admin	Admin	Admin		
1:00-1:30 PM	Established patient	Treatment visit			
1:30-2:00 PM	Established patient	Treatment visit			
2:00-2:30 PM	Established patient	Treatment visit			
2:30-3:00 PM	Established patient	Established patient			
3:00-3:30 PM	Established patient	Established patient			MDC patient (phone)
3:30-4:00 PM	New patient	Established patient			MDC patient (phone)
4:00-4:30 PM		Established patient			MDC patient (phone)

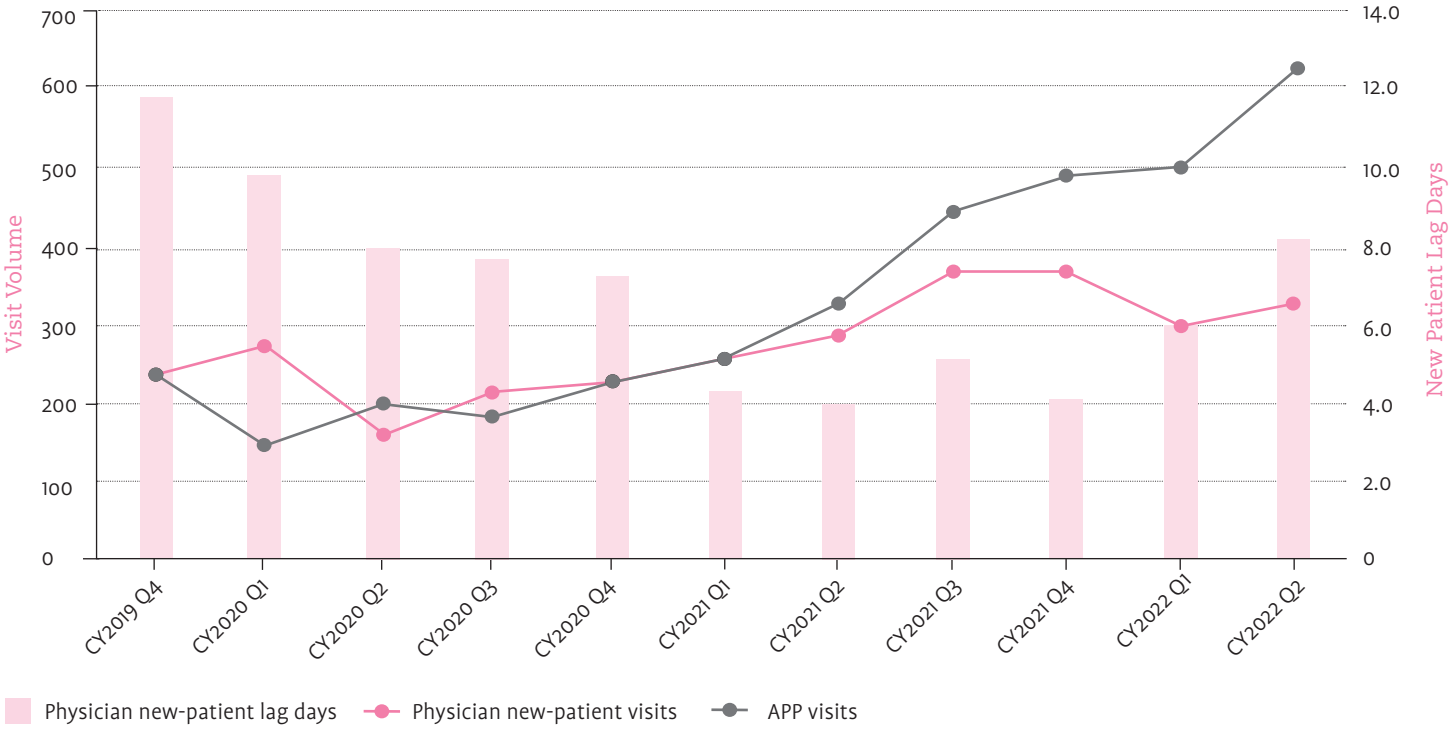
Admin; administration; MDC, multidisciplinary care; PDSA, plan-do-study-act.

Figure 4. Breast Cancer Multidisciplinary Clinic Appointments: PDSA Cycle 2

PDSA CYCLE 2	PATIENT 1/ROOM 1	PATIENT 2/ROOM 2	PATIENT 3/ROOM 3
12:30-12:50 PM	Arrive*	Arrive*	Arrive*
1:00 PM	Medical Oncology	Radiation Oncology	Surgical Oncology
1:30 PM		Surgical Oncology	Genetics
2:00 PM	Surgical Oncology	Medical Oncology	
2:30 PM	Genetics		Radiation Oncology
3:00 PM		Support Services^	Medical Oncology
3:30 PM	Radiation Oncology	Genetics	
4:00 PM	Support Services^		Support Services^
4:30 PM	Support Services^	Support Services^	Support Services^

PDSA, plan-do-study-act.
* Patient arrival times will be staggered to allow time for check-in.
^Support services could include: navigation, laboratory testing, plastic surgery, nutrition, social work, and clinical trials.

Figure 5. Breast Cancer Multidisciplinary Clinic Appointment Statistics



APP, advanced practice provider; CY, calendar year; Q, quarter.

(*Continued from page 9*)
the new Breast Cancer Multidisciplinary Clinic workflows, APP visit volumes also steadily rose over time. Before the COVID-19 pandemic, APPs had 243 independent patient visits in the fourth quarter of 2019. During the height of the pandemic in 2020, APPs had an average of 195 independent patient visits each quarter. As the first Breast Cancer Multidisciplinary Clinic stood up in February 2021, APPs saw their highest quarterly volume of 250 independent visits; volumes steadily grew quarter over quarter to a peak of 630 independent visits in the second quarter of 2022 (Figure 5).

In addition to positively impacting timeliness to care and patient experience (patient retention rate during the first 9 months, 95%), the market share for breast cancer also improved. From 2017 to 2019, new breast cancer market share within the primary service area grew from 37.8% to 43.4%. During 2020, the breast cancer market share fell to 35.7% within the primary service area. With the deployment of the new Breast Cancer Multidisciplinary Clinic, market share in the primary service area jumped to an all-time high of 46.7% during this 5-year period.

Conclusions

The introduction of an oncology nurse navigator–led provisional review process with coordinated physician schedules improved timeliness to care and patient satisfaction among individuals newly diagnosed with breast cancer. Locating physicians into 1 clinic space for initial consults increased synchronous physician communication and improved patient and care-team satisfaction and APP use.

Sustainability of this multidisciplinary clinic model depends upon collaborative physician and APP coverage across the 3 major cancer treatment modalities. Physicians are required to have dedicated new-patient half-day sessions while empowering the APPs to independently see returning patients. Additionally, the coverage model must accommodate provider vacations, speaking engagements, holidays, and continuing education events. This coverage can be difficult to maintain every week without fail. Thus, flexibility of consultation timelines is crucial. For example, when schedules vary, the ability of patients to consult with 1 specialist and then meet with physicians from other specialties at a later time should be explored. Based on diagnoses, the provisional review guideline could be used to schedule patients with a provider in 1 discipline or with staff in all 3 disciplines to maximize multidisciplinary clinic slots. In conclusion, the role of an oncology nurse navigator is vital for making a clinical judgement about appropriate specialties and establishing a patient relationship with the institution to drive patient retention.

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Integrating Discrete Genomic Data with an EHR Improves Patient Care, Provider Satisfaction, and Program Metrics

BY KAREN HUELSMAN, MS, LGC; LEAH VASILIADIS, MHI; ADAM LIETTE; KAREN WERNKE; ANDREW PARCHMAN, MD; JAMES MAHER, MD, PHD; AND COURTNEY RICE, MS, LGC

As the use of genomic tumor profiling to guide personalized therapy increases, the volume of clinical data applied to complex clinical decision-making also increases.[1] The adoption of broad clinical tumor profiling presents many challenges for medical oncologists and a need to present actionable genomic data efficiently to assist with therapy decisions.[2] With the rapid growth of genomically targeted agents, some have advocated for universal tumor profiling.[3] Broader biomarker testing with more than 600 data points requires technical solutions in the electronic health record (EHR) to streamline clinical workflow.

Clinicians have faced several barriers to adopting genomic-driven care for patients with cancer, including as follows:

- Use of third-party portals outside of the EHR working environment to place orders
- Unreliable and inconsistent workflows
- Potential for inequitable distribution of tumor profiling
- Difficulty accessing genomic data in real time during clinical encounters
- Time-consuming processes to measure testing utilization and outcomes.

Although the implementation of discrete data fields in the EHR is a crucial step in overcoming some of these challenges, EHR integration requires time and resources to complete and maintain. Health systems must consider the return on investment for EHR integration, including software updates and staffing. By integrating ordering and resulting of genomic testing into the EHR, the time savings may offset some of these expenses. Data from a University of Pennsylvania study demonstrated that ordering and resulting for genetic tests after an EHR integration saved approximately 10 minutes per test order.[4] Compounded annually by the number of tests ordered and resulted, this can lead to compounded savings in personnel time. This article describes additional benefits of having an integrated EHR.

TriHealth at a Glance

TriHealth is a community-based teaching hospital with multiple locations across various specialties in Cincinnati, Ohio. TriHealth has 4 acute-care hospitals, 1 short-stay hospital, and 800 adult beds. TriHealth includes 140 locations across the greater Cincinnati region and 1600 medical staff with more than 12,000 team members. The Precision Medicine Institute, led by a dyad medical oncologist and genetic counselor director, includes 14 genetic counselors with several unique roles such as precision oncology lead and precision medicine test coordinator. Precision Oncology also is led by a dyad medical oncologist and genetic counselor. The precision medicine team supports the TriHealth Cancer & Blood Institute, which includes 20 medical hematologist oncologists, 4 gynecology oncologists, 3 surgical oncologists, 3 breast surgeons, 5 radiation oncologists, and 16 advanced practitioners (clinical nurse practitioners and physician assistants). In 2019, the Precision Medicine Institute received internal grant funding from 2 local foundations (bi3 and Good Samaritan Foundation) to support a system-wide precision medicine program to incorporate genetic information into standard of care.

> TriHealth's information services and precision medicine teams have collaboratively built innovative clinical decision support and leveraged discrete genomic elements to design, build, and customize multiple tools.

EHR Integration

TriHealth adopted Epic as its electronic health record in 2010. Most molecular testing is sent to outside labs, and there is very limited in-house biomarker testing. TriHealth's laboratory does not use the Epic Beaker module to integrate results. TriHealth was an early Epic EHR integration partner in precision oncology, with its first complete integration in 2020. TriHealth and its first partner lab completed point-to-point HL7 bidirectional integration of results and orders in 4 months on December 15, 2020. A conversion of historical data dating back to February 2019 was completed in June 2021.

The TriHealth team that worked on this project included 2 Epic

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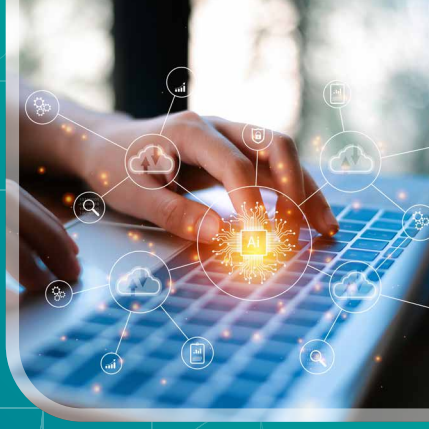

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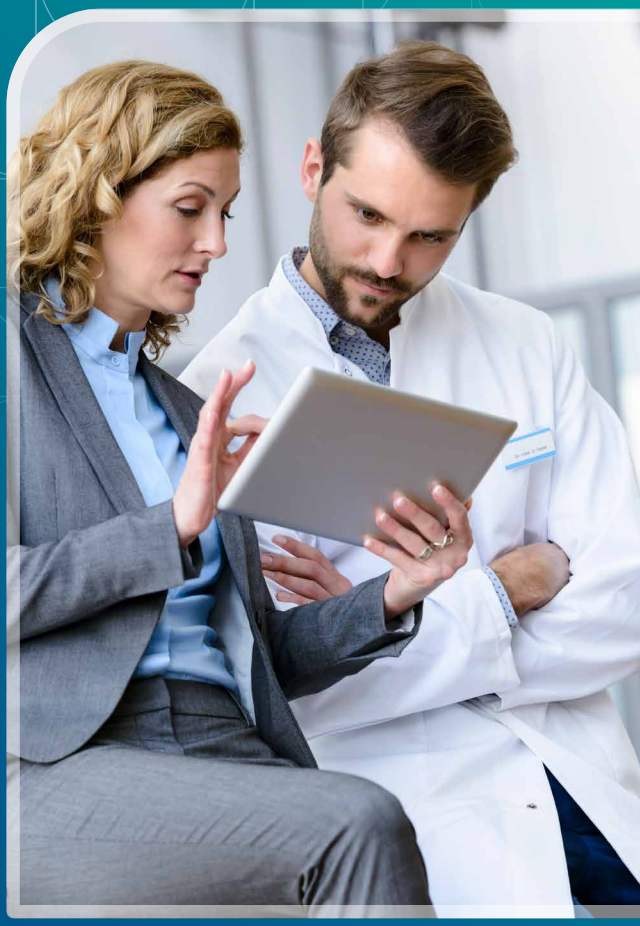

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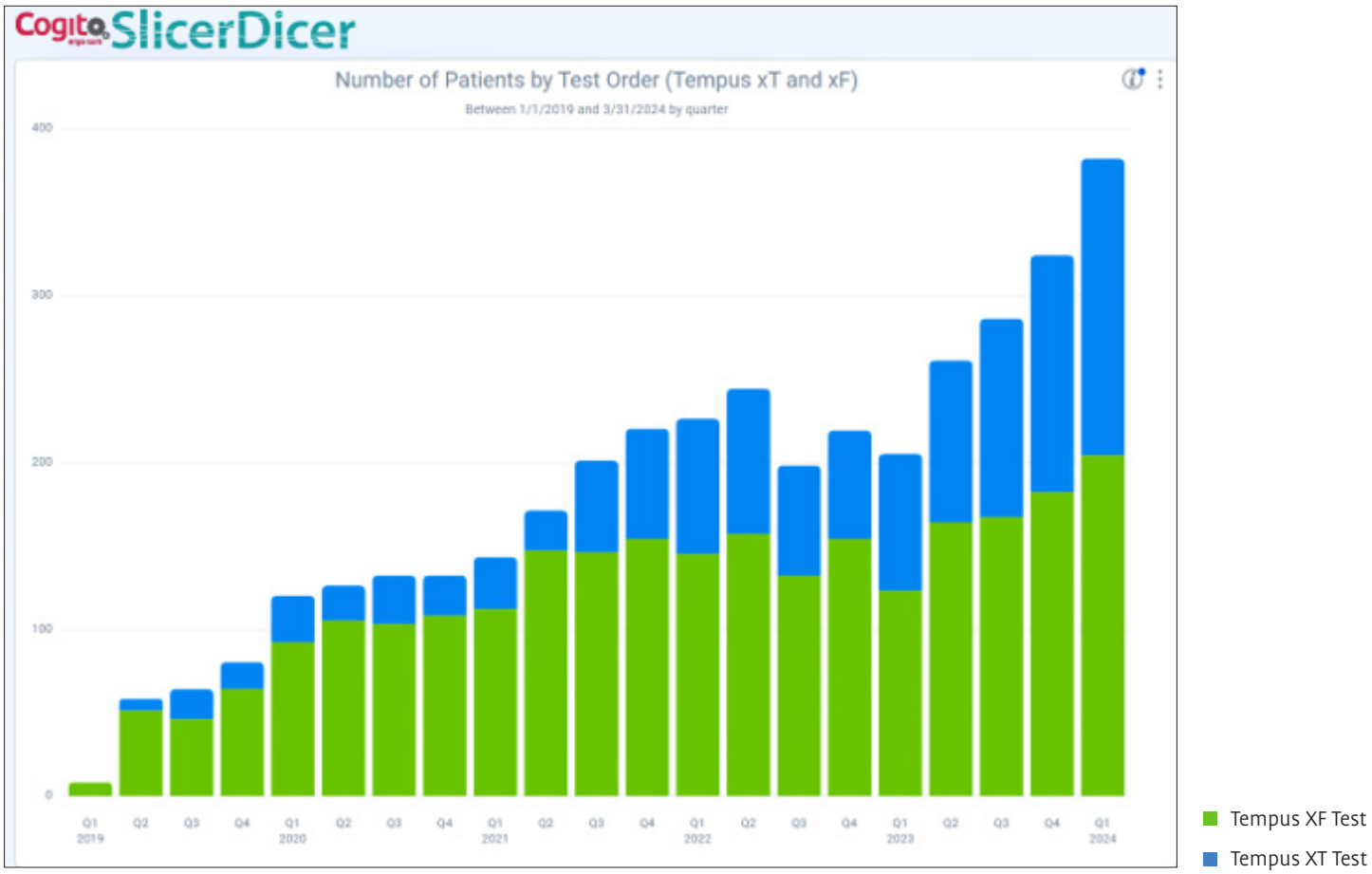
Figure 1. Growth of Genomic Tumor Profile Testing Post EHR Integration



(*Continued from page 13*)
engineers, an Epic Bridges data integration engineer, a data analytics engineer, a project coordinator, and 2 genetic counselor champions. This was TriHealth's first genomic lab EHR integration; the team concurrently implemented the Epic Genomics Module. Since the initial integration, significant improvements have been accomplished in the speed of deployment, and several clinical and reporting applications have been developed. The TriHealth team has completed 6 additional HL7 integrations and 1 Aura integration with germline laboratories and continued to customize existing integrations to optimize the user experience. Subsequent integrations require only 1 Epic engineer.

At the time of this submission, TriHealth had 7 additional lab integrations in varying pipeline stages. Clinician uptake and benefits post integration have not been well-characterized in the literature. In this article, TriHealth demonstrates the benefits of integrated ordering and discrete results as they impact the clinical workforce and other departments across the health system.

Key Developments and Innovations

Since TriHealth's first somatic tumor profile integration using the Epic Genomics Module, there have been key developments and innovations in TriHealth's use of the Epic EHR, including as follows:

- Understanding best practices for efficient and seamless deployment of orderables
- Customizing the Epic ordering interface for ease and efficiency of use
- Adopting new test components as testing expands to include new types of results (examples include pharmacogenomics genes *DPYD* and *UGT1A1* for patients on relevant therapies) and how this expansion supports efficient adoption of new tests by oncologists
- Leveraging new discrete data for clinical care and decision-making; reliable genomic data in the EHR is used in clinic and clinician EHR tools to improve documentation accuracy and efficiency
- Automating referral for incidental germline patients to genetic counseling creates efficient and easier decision-making for oncologists

- Applying discrete results to track and report measurable precision oncology outcomes has increased self-service reporting efficiency for cancer program administrators
- Using discrete data to identify patients who may benefit from a newly approved therapy or meet inclusion and exclusion criteria for clinical trials.

Best Practices and Measurable Outcomes With EHR Integration

TriHealth's information services and precision medicine teams have collaboratively built innovative clinical decision support and leveraged discrete genomic elements to design, build, and customize multiple tools. These include best practice alerts, as well as sophisticated

Figure 2a. Multiple Genomic Tests in 1 Epic View of Variant Results Report

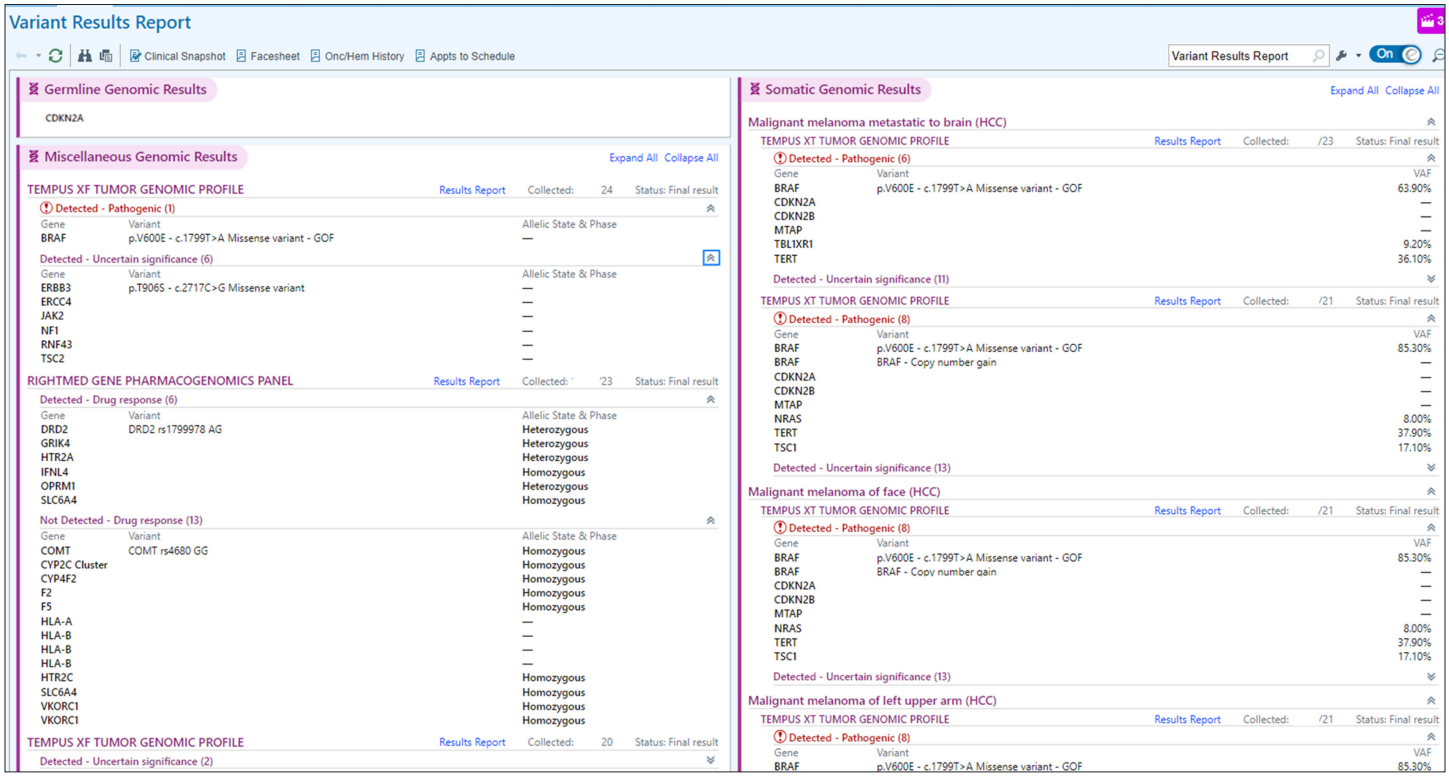
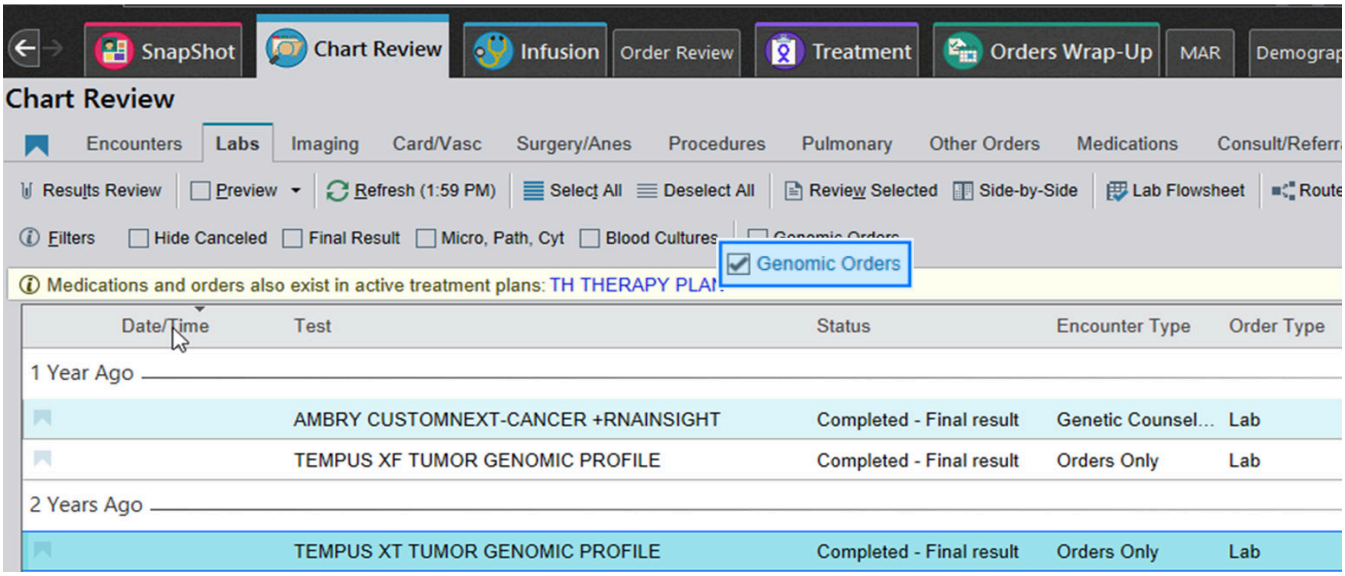


Figure 2b. Genomic Orders Filter Showing All Tests in 1 View



clinical trial matching algorithms. TriHealth has demonstrated how genomic integration (ie, having all integrated genomics in 1 location, the EHR) led to streamlined workflow, reduction in time to access results, and efficiency in clinical decisions. EHR integration has empowered this community cancer program to become an informatics leader. The benefits of discrete variants, genomic smart phrases (Epic's note-writing tools), the use of the EHR to identify patients with specific biomarkers, and the ability to consider patients for research are described below. Specifically, an integrated EHR helped TriHealth achieve innovations and customizations in 11 key areas.

Testing Volume Increases

Precision oncology tumor genomic testing through the EHR order interface correlates with increased testing volume. After its December 15 EHR integration go-live date, tumor profile tests at TriHealth increased by 46% from 2020 to 2021 and by 20% from 2021 to 2022. Although volume data are not complete for 2023, TriHealth did add 12 new precision oncology tests in FY2023 (Figure 1).

Orders and Results Time Savings

EHR integration correlates with a reduction in time to enter orders and find results in the Epic EHR. Based on the University of Pennsylvania study, which found 10 minutes saved on average per test post integration, and the volume of testing,[4] TriHealth calculated the hours saved in the first year. Somatic tumor profile testing at 1000 tests/year equated to 167 FTE hours/year. Germline testing at 1500 tests per year equated to 250 FTE hours/year. Taking into consideration the 3 completed integrations and 7 integrations in the pipeline, the time savings for 10 integrated labs compounded annually can be used to make the case for investment in EHR integration and return on investment. Bottom line: Spending less time on routine ordering and resulting allows clinicians to spend more time patient bedside.

Reliable Location of Results

Integrated resulting allows for the structured report (in PDF format) to easily be found in the patient's chart (lab tab) upon completion. A genomic order filter in Epic will efficiently pull up all genomic tests (eg, somatic, germline, pharmacogenomic). Integrated resulting eliminates the need for staff to scan reports to the media tab (a part of the Epic EHR) and confusing or inconsistent file names. When integrated with multiple labs, the genomic variant page in the Epic Genomics Module allows clinicians to visualize results from multiple sources on a single variant page (Figures 2a and 2b). Updates and customizations occur post integration and require dedicated time from the Information Systems team after the system goes live. Examples include new testing components added by the laboratory (eg, homologous recombination deficiency, *DPYD* pharmacogenomic, tumor of origin).

Smart Phrases for Clinical Documentation

Discrete variants in the EHR allow deployment of customized smart phrases (note-writing tools that are a feature of the Epic EHR) to document genomic results in the clinic note. The ability to place genomic results efficiently and intentionally in the Epic workflow—without the need for an outside portal—reduces documentation time and errors. Reliable results allow clinicians to confidently review results with patients at the point of care during encounters. Figures 3a–3d illustrate customized smart phrases; examples include PD-L1, full tumor profile results from solid tumor biopsy and liquid biopsy tests simultaneously, and relevant biomarker-driven therapy.

Systemwide Visibility of Orders and Results

Order and result information in the Epic EHR is accessible to all clinicians systemwide, including pathologists and radiologists. In the past, with individual portal access, only the ordering clinician

(*Continued on page 19*)

Figure 3a. Use of Epic Smart Phrases in Clinic Note to Document Genomic Results

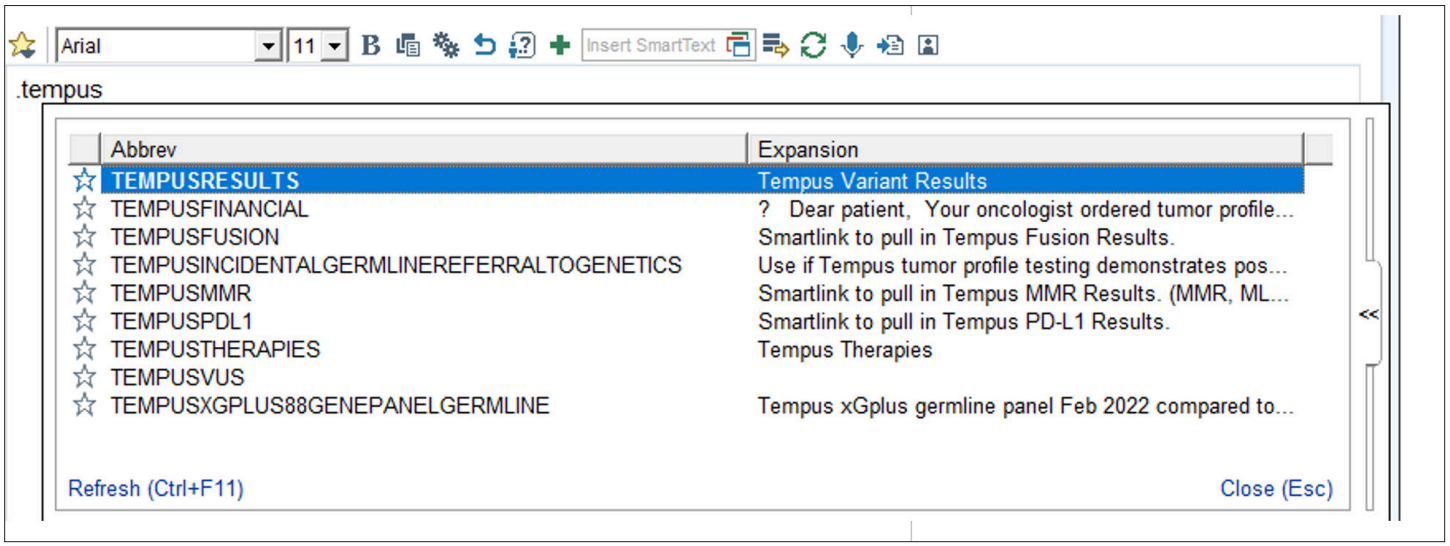


Figure 3b. Use of Epic Smart Phrases in Clinic Note to Document Genomic Results

Test Info:
Tempus xT Tumor Genomic Profile (600+ somatic panel & paired germline)
Result Date:
Specimen Source:
Pathology Case #:TriHealth Laboratories - Cincinnati - Pathology
SN21-6737

Tempus xF Tumor Genomic Profile
Result Date:
Specimen Source: Peripheral Blood
Pathology Case #:

Genomic Variants
Somatic (Potentially Actionable and Biologically Relevant):
There are no somatic variants associated with this patient.

xF Liquid Biopsy (Pathogenic/Likely Pathogenic):
PIK3CA p.M1043I - c.3129G>A Missense variant (exon 20) - GOF 0.001

CDKN2A p.D74N - c.220G>A Missense variant - LOF 0.009

Germline (Pathogenic/Likely Pathogenic):
No pathogenic variants were found in the limited set of genes that are reported.

Other Tempus results:
Lab Results

Component	Value	Date/Time
MSI	Not detected	

Tempus Therapies:
Therapy 1

Component	Value	Date
Gene	PIK3CA	
Agent	Alpelisib	
Association	response	
Evidence Status	Clinical research	
Evidence Type	therapeutic	
FDA Approved	Yes	
On Label	No	

Figure 3c. Use of Epic Smart Phrases in Clinic Note to Document Genomic Results

PD-L1 Results:

Tumor Proportion Score

Date	Value	Ref Range	Status
	20	%	

Combined Positive Score

Date	Value	Ref Range	Status
	20		

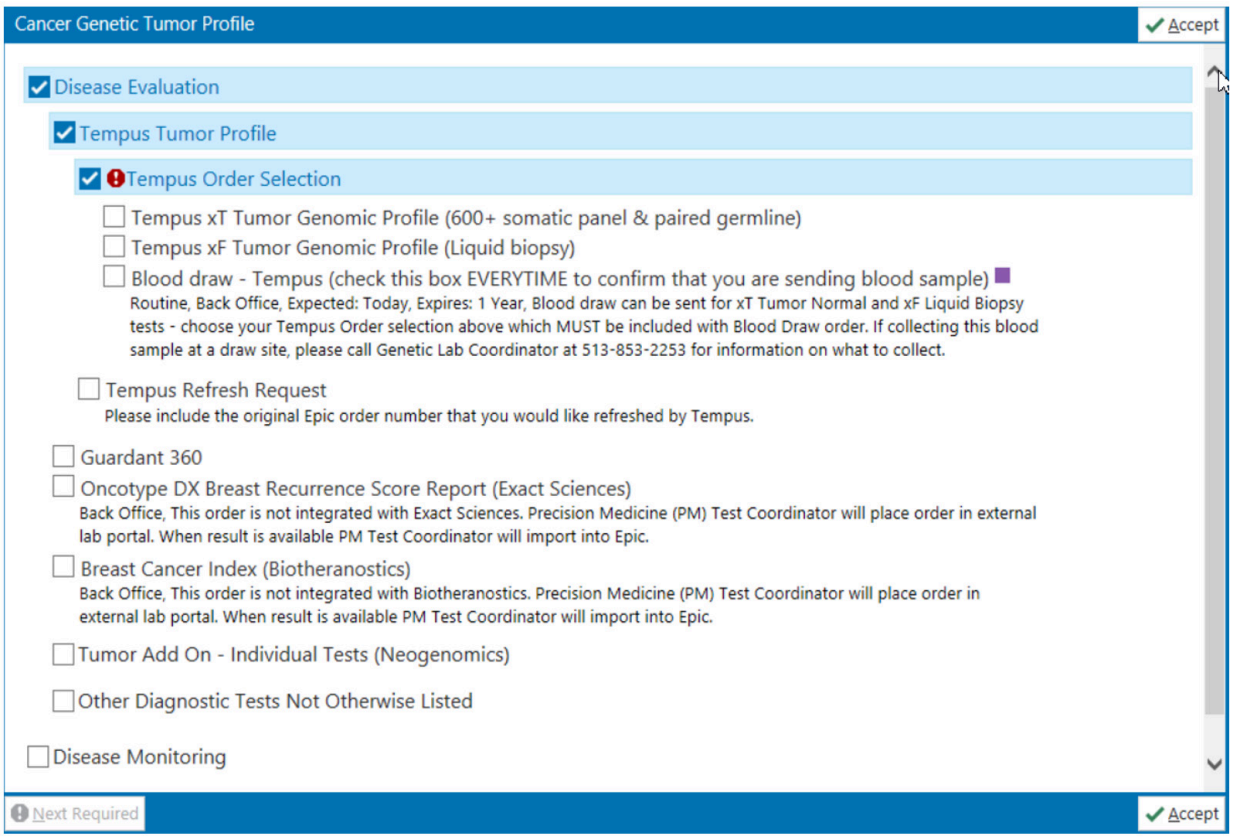
Figure 3d. Use of Epic Smart Phrases in Clinic Note to Document Genomic Results

Tempus Therapies:

Therapy 1

Component	Value	Date
Gene	PIK3CA	
Agent	Alpelisib	
Association	response	
Evidence Status	Clinical research	
Evidence Type	therapeutic	
FDA Approved	Yes	
On Label	No	
Tissue	Solid Tumors	
Variant	p.M1043I	
Pubmed ID	29401002	
Pubmed URL	https://www.ncbi.nlm.nih.gov/pubmed/29401002	

Figure 4. Universal Tumor Profile Genomic Order Page



(*Continued from page 17*)

had access to orders and results, or other clinicians needed to rely on results in the scanned media tab. The ability to review orders facilitates multidisciplinary teamwork. For example, pharmacists now have access to tumor profile results needed for prior authorization for personalized therapies. Interventional radiologists and pulmonologists need access to ensure adequate biopsy tissue for next generation sequencing (NGS), and pathologists need access to ensure tumor content for testing. Broader awareness of tissue that is intended for tumor profiling has contributed to reduced instances of quality and/or quantity not sufficient (QNS) and

turnaround time (TAT) while eliminating access barriers. From 2019 to 2022, the TriHealth QNS rate decreased from 25% to 10%; TAT decreased from 27 days to 9 days.

Consistent Workflow for Integrated and Nonintegrated Tests

TriHealth created a single universal starting place in Epic (eg, "tumor profile") for all genomic tumor profiling orders. The initial order starts with the options "disease evaluation," "disease monitoring," and "cancer screening." Disease evaluation includes all solid tissue and liquid biopsy tests that identify biomarkers for therapy and clinical trials. Disease monitoring includes circulating tumor DNA (ctDNA) or liquid biopsy testing that monitors for effects of therapy, signs of residual disease, recurrence, or resistance. Cancer screening includes blood-based multicancer early detection (MCED), which was included because it relies on ctDNA in the blood. The universal order includes integrated and nonintegrated labs because TriHealth uses a "shell" order for nonintegrated tests. In those cases, the precision medicine test coordinator uses information provided by the ordering clinician in an Epic shell order to transcribe the order into the outside lab portal. For the clinician, the process is seamless, and when tests are eventually built as an integrated test there is minimal change to workflow for the ordering provider. This allows the Epic team to build new integrations while maintaining a consistent workflow for clinicians. Figure 4 illustrates the universal tumor profile genomic order page with decision-tree logic and tests at various stages in the integration pipeline.

Support of Social Determinants of Health Measures

Since discrete data from somatic tumor profile or germline testing can be combined with other patient data in Epic and connected based on medical record number, reporting measurable outcomes related to social determinants of health is possible using SlicerDicer, a feature of the Epic EHR. The precision oncology lead and other administrators can harness discrete genomic results in a self-service manner, increasing efficiency in reporting. Since discrete variants from integrated testing labs feed reports in real time, reporting updates are also available in

Figure 5a. Epic Self-Service Reporting Workbench to Identify Patients With New Incidental Germline Mutation

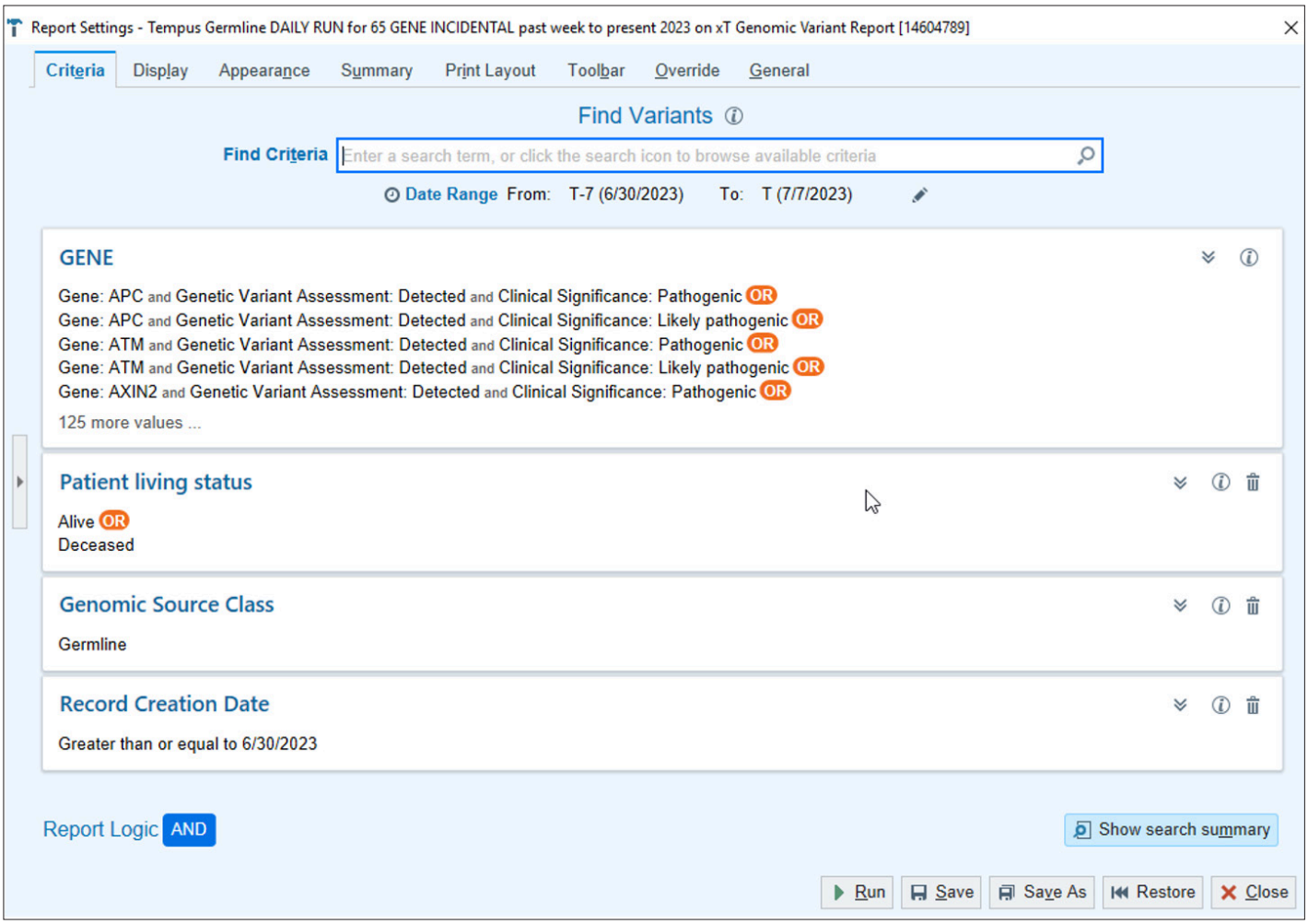


Figure 5b. Output From Reporting Workbench for Daily Identification of New Incidental Germline Mutation (Deidentified)

Variant Name	REF1114 Date	Gene	Significance	Assessment	MRN	Patient	Ordering Provider	Display Name
c.		CDH1	Likely pathogenic	Detected			Kuritzky, Benjamin	Tempus xT Tumor Genomic Profile (600+ somatic panel & paired germline)
p. variant	2/13/2024	MSH2	Pathogenic	Detected			Draper, David James	Tempus xT Tumor Genomic Profile
p. variant	2/10/2024	MSH6	Likely pathogenic	Detected			Budde, Leanne S.	Tempus xT Tumor Genomic Profile
p.	5/22/2023	PMS2	Pathogenic	Detected			Maher, James F	Tempus xT Tumor Genomic Profile
p. LOF	1/26/2024	ATM	Likely pathogenic	Detected			Parchman, Andrew J	Tempus xT Tumor Genomic Profile
p. c. . frameshift_variant	2/13/2024	CDH1	Likely pathogenic	Detected			Crane, Edward J	Tempus xT Tumor Genomic Profile
p. LOF	10/31/2023	CDKN2A	Pathogenic	Detected			Kuritzky, Benjamin	Tempus xT Tumor Genomic Profile
p. LOF	1/22/2024	APC	Pathogenic	Detected			Shatavi, Seerin Viviane	Tempus xT Tumor Genomic Profile

real time. Once the cohort of patients with tumor profile testing is defined in Epic SlicerDicer, patient lists are easily exported and analyzed. In July 2023, the TriHealth precision oncology team demonstrated that tumor profiling for disease evaluation performed between January 1, 2021, and June 30, 2023, had no statistically significant differences when analyzed by social determinants of health (race and zip code of residence).

Building of Reporting Dashboards

Continuous updating of discrete data allows real time dashboards to be built for reporting to cancer program leadership. TriHealth uses several reporting dashboards in Tableau that are fed by Epic-integrated discrete data. These include standard reports used for cancer program quality measures. Examples include dashboards that show use of tumor profile volume by test, orders for germline and pharmacogenomic tests, and clinician ordering patterns. Epic also offers reporting workbench dashboards.

Identification of Patient Cohorts by Specific Genetic Result or Specimen Source

Epic's discrete variant data allows identification of patients with prior genomic profile results that can be matched with updated therapy or new clinical trials. Partnering with a tumor profile lab, TriHealth is piloting a concept to update reports with new FDA-approved therapies based on original tumor mutations. For example, when the FDA approved therapy for patients with non–small cell lung cancer with somatic KRAS G12C mutation, the precision oncology lead was able to run a report to identify patients in Epic who met the criteria and alert their clinicians to the possibility of an update in therapy. This reporting capability is used repeatedly when new markers are identified. Other examples include identifying postmenopausal patients with metastatic breast cancer with ESR1 somatic mutations for new therapy or finding patients with ovarian cancer with specific biomarkers for a new research study.

Identification of Patients With New Incidental Germline Mutations

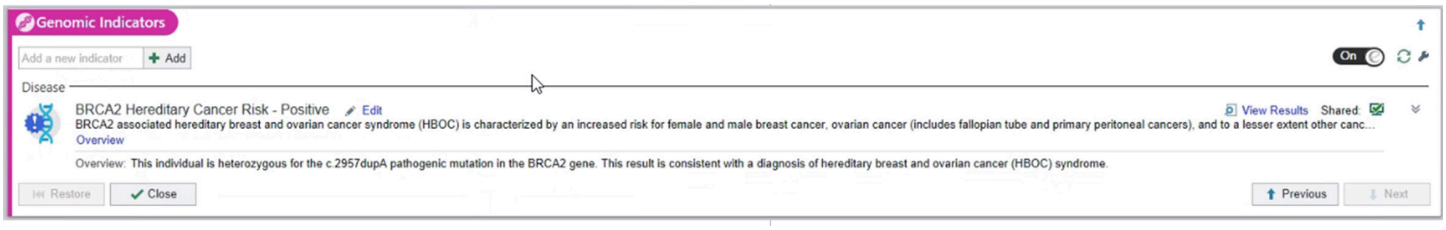
TriHealth's precision oncology program has a goal to ensure that patients with an incidental germline mutation on tumor profiling are referred to genetic counseling for confirmatory testing so they can be offered family cascade testing. Previously, the precision oncology lead reviewed every tumor profile report to identify these patients, and the volume of testing eventually outpaced the ability to review. With lab integration and genomics module implementation, TriHealth now runs a daily report in Epic to identify new incidental germline patients. This automated process requires approximately 2 minutes, consistently and efficiently identifying patients with new pathogenic or likely pathogenic germline mutations among the 65 genes reported by the tumor profile lab. Figure 5a shows the build in the Epic reporting workbench, and Figure 5b shows an example of report output with patient identifiers removed.

Epic Decision Support Tools

Implementation of the Epic Genomics Module and discrete genomic variants in the EHR delivers new opportunities for clinical decision

(*Continued on page 23*)

Figure 6a. BRCA2 Genomic Indicator and Best Practice Advisories for Referral to Gynecology Oncology and Genetic Counseling



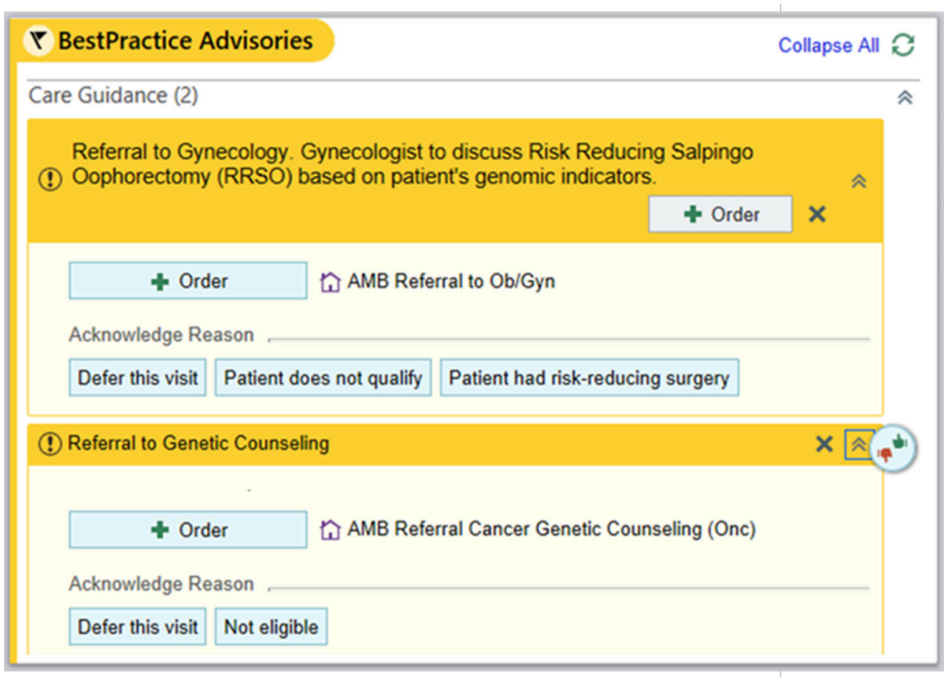
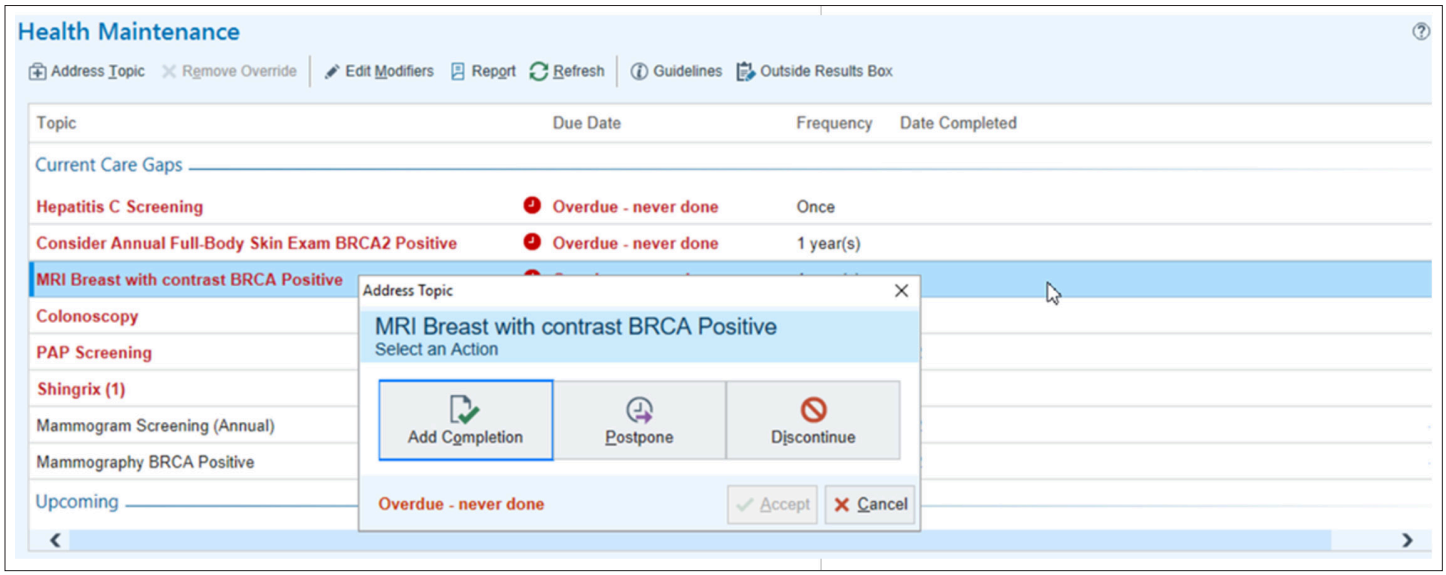


Figure 6b. Care Gap Logic for Newly Identified BRCA Germline Mutation Carrier to Include Breast MRI



(*Continued from page 21*)
support. Discrete variants can automatically trigger genomic indicators, patient-level alerts indicating genetic factors that should be considered during patient care. In the current Epic environment, new potential incidental germline mutations will not fire a genomic indicator, but a pathogenic variant on confirmatory germline test will fire for any genes with built genomic indicators. A genomic indicator will fire downstream best practice alerts and care gaps in the Epic EHR. This includes indicators created for 26 cancer genes and rule-based triggers that incorporate patient sex, age, family history, and completed procedures. The TriHealth team built best practice alerts to address care gaps for actionable germline mutations with National Comprehensive Cancer Network guidelines. Care gap logic is used to trigger clinical follow-up items for patients with specific indicators. An example is a referral for breast MRI in a patient with a newly identified germline BRCA2 mutation. Best practice alerts are also employed to drive clinical workflows and guide patient care. In addition, the team created patient-facing content in MyChart that provides additional information and resources about positive germline results. An example is "referral to genetic counselor" for confirmatory germline testing when incidental germline result occurs. Figures 6a and 6b include visualizations of active best practice advisories and care gap logic in the TriHealth Epic EHR. The precision medicine team continues to build reporting tools that measure uptake of genetic counseling referrals, breast MRI, and downstream revenue.

Communication with Patients

Due to these genomic module and lab integrations, patients can see their reports, come to visits prepared, and receive fact sheets about their germline results. This feature in the Epic MyChart is called "My Genomic Profile." Based on the 21st Century Cares Act,[5] discrete integrated genomic results are shared with patients immediately. TriHealth embraced the concept that genetic information should be shared immediately with patients like other medical information. It has not proven to be harmful to patients or resulted in extra messages to the clinical team.

Lessons Learned

TriHealth has completed 6 point-to-point HL7 integrations. Many additional labs are in the pipeline for integration because of the tremendous value this offers clinicians, patients, and the health system. These are at various stages of build with a mix of HL7 and Aura. Through this work, the TriHealth team has become skilled in EHR integration. This experience allows the TriHealth team to carefully vet new partners in an environment where some third-party laboratories are more ready than others for EHR integration. Epic Aura integrations can be deployed with less effort than HL7 integrations, which require more time and experience. Although TriHealth is fortunate to have seasoned and committed integration champions, limited Information System resources can still present barriers.

When planning for initial EHR integration, include engineers with experience and strong backgrounds in lab, orders, ambulatory, and HL7 integrations. Collaboration and resource alignment between the clinical and technical teams early and often are crucial. TriHealth recommends the inclusion of genetic counselors from initial build to postintegration customizations, given their expertise in genetics and genomics. TriHealth elected to concurrently implement the Epic Genomics Module in parallel with the first lab integration. Although the functions of the Epic Genomics Module exist without lab integration, TriHealth found that having a lab integration at the module go live allowed the team to fully benefit from genomic indicators that can drive clinical decision support.

The Epic Genomics Module features automated genomic indicators, best practice advisories, and health maintenance logic to help providers use actionable genetic information for patients at point of care. Genomic indicators are a key driver of the value of the Epic Genomics Module. Genetic results are now housed in a standardized location that is easy to find and connected to actions in the EHR. With discrete results in the Epic Genomics Module, TriHealth achieved the goal of integrated genomic results as part of standard patient care and clinical workflow. EHR integration of discrete genomic variant results can accelerate the application of personalized medicine and supports workflows using genetic and/or genomic information in routine patient care.

Consideration of the end user, clinician interface, and patient experience is important in the initial integration planning. Once live, TriHealth found it necessary to have an efficient method of providing clinician and patient feedback to the technical team. This allowed the teams to quickly incorporate feedback into real time workflow optimizations, a huge clinician satisfier. It is important to balance the benefits of presenting a clinical decision support alert to providers with the potential disruption to workflow and the extra time needed to read and select the decisions. For this reason, clinical decision support alerts are only presented if there is strong evidence for the recommendation and the alert changes a care recommendation, for example, the need to order an additional image or lab test. We do not use alerts with "softer" recommendations such as "monitor for" or "may consider." More research is needed to understand the needs of patients when reviewing discrete genomic results in MyChart. TriHealth has found that patients who review their genomic results prior to their next clinical encounter can consider questions ahead of the visit. However, these issues need to be assessed for a range of educational levels and those with fewer resources.

Reporting and measurable outcomes are made possible by discrete variants in the EHR, and Epic's reporting tool (SlicerDicer) is a valuable self-service analytic tool. Analysis supported by discrete variants allows the health system to understand its patient population in new ways. For example, uptake and outcomes data allow TriHealth to understand areas in our program with inconsistent performance (or outcomes) and then focus quality improvement efforts in these areas. This ensures that all patients benefit from a highly reliable process. Measurable outcomes allow TriHealth to identify patients who are overdue for procedures and consider targeted interventions. In addition, reporting in the EHR advances health equity in genomic testing and the ongoing evolution of reporting capabilities.

Previously, clinicians and administrative leaders relied solely on business intelligence teams for reports. Demand for reports was high, which meant there was a lag in receiving those reports. TriHealth decided to identify key clinical champions to learn how to to run reporting in SlicerDicer, a tool that allows clinical users to run many reports on their own (referred to as "self-service reports).

Nearly 3 years after the first EHR integration, the TriHealth team has found more downstream benefits of EHR integration than initially realized, including new partner opportunities due to the active integrations in place, identification of patient cohorts by biomarker with inclusion and exclusion criteria, increased matching to oncology research and trials, discovery of new ways to use self-service reporting tools, and partnerships that have developed secondary to EHR integration. OI

Karen Huelsman, MS, LGC, is precision oncology lead at TriHealth. Leah Vasiliadis, MHI, was a lead Epic engineer at TriHealth. Adam Liette is the director of information technology clinical applications for TriHealth Information Systems. Karen Wernke is a genetic counselor III with the TriHealth Precision Medicine Institute. Andrew Parchman, MD, is a medical oncologist with TriHealth Cancer & Blood Institute. James Maher, MD, PhD, is a medical oncologist, medical director of the Precision Medicine Institute, and system chief for oncology at TriHealth. Courtney Rice, MS, LGC, is a genetic counselor and director of precision medicine at TriHealth.

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Disclosures

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Author's Note

The images in this article contain fictitious demonstration data. No real personal identifiers (eg, patient name, provider, date of birth, ID, date of service, transaction date) are used in these images.

AI-Driven Patient Charting for Rapid, Efficient, Effective Cohort Sizing and Patient Inclusion

Bryan Allinson, director of partnerships at Deep 6 AI

Dan Fort, PhD, MPH, biomedical research informatics leader and associate professor for the Ochsner Center for Outcomes Research

Oncology clinical trials have led to the development of new therapies and treatments that help patients with cancer to live longer, healthier lives. As a result, the volume of clinical trials is expanding dramatically. According to the Association of Clinical Research Professionals, over the past 20 years, the number of investigational treatments targeting cancer has nearly quadrupled from 421 to 1489.[1] Further, there are over 11930 active oncology interventional clinical trials underway including 5500 with a biopharmaceutical company as a sponsor.

Due to an increasing number of eligibility criteria, laboratory tests, and complicated trial designs, oncology clinical trials are becoming more complex. Additionally, screening and treatment durations are much longer in phase 2 and 3 oncology clinical trials compared to other drug trials. Oncology clinical trials generate a much higher volume of data, particularly in terms of phase 2 protocols, compared to other drug trials. Compared to trials involving other drugs, phase 2 and 3 trials of oncologic agents have more protocol deviations and generate more substantial protocol amendments.[1] As a result, clinical research teams are stretched thin, and trial durations for oncology drugs are 30% to 40% longer than needed for other drug trials.[1]

For the biopharmaceutical company sponsoring the development of an oncology drug for approval, multiple factors contribute to increased volume and complexity of trials. First, a complete molecular profile is now often necessary to understand the underlying cancer biology.[2] This includes immune, DNA and RNA, proteomic, and/or other biomarker screening. Second, therapy should be matched to the biology of the tumor, including combinations of drugs to target the multiple drivers that are present in most metastatic cancers. Third, trials are designed to accelerate drug development and regulatory approval while lessening adverse effects. Fourth, innovative trial designs—including platform studies and umbrella, basket, multi-arm, and adaptive trials—have the common goal of using novel methods and master protocols to answer many questions simultaneously in a single trial.[3] These decisions are designed to enhance outcomes for the corporate sponsor but often lead to increased complexity for the oncology research site.

To meet the increasing demand of numerous and more complicated oncology clinical trials, physician investigators and research teams at the study site increasingly are using electronic systems to support the conduct of clinical research. Critical questions for research staff to answer involve where and how much to invest organizational resources to support eligibility screening by clinical research teams for higher volumes and increased complexity of studies. If too little is invested in patient screening, then too many ineligible patients are enrolled, and research teams waste precious time with screen failures. If too much time is invested in screening patients, then the cost of running the trial can drain precious resources from the cancer center.

To address these issues, Ochsner Health in New Orleans, Louisiana, is employing a new type of artificial intelligence (AI) and natural language processing to enhance its ability to screen patients for studies and reduce the personnel cost of screening.

In 2020, Ochsner Health formed a partnership with Deep 6 AI, an artificial intelligence and natural language processing software company that focuses on AI-supported charting solutions that include sizing and characterization of cohorts, recommending cohorts for specific patients, and developing business intelligence tools.

(Continued on page 28)

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In this article, Bryan Allinson, director of partnerships at Deep 6 AI in Pasadena, California, interviews Dan Fort, PhD, MPH, a biomedical research informatics leader and associate professor for the Ochsner Center for Outcomes Research, part of Ochsner Health, about challenges related to oncology clinical trials. Before joining Deep 6 AI, Allinson served as senior director for AdventHealth, in Orlando, Florida, where he led oncology clinical research operations. Previously, Allinson served as executive director for the University of Texas, leading statewide clinical and translational research partnerships, and as a director at Geisinger Health System, focused on data, device, and biopharmaceutical innovation.

In his role at Ochsner Health, Dr Fort facilitates oncology physicians and investigators with access to research resources, including biostatistics and data analytics, collection, and extraction. He uses Epic (Epic Systems), Ochsner Health's electronic health record (EHR) system, to precisely size potential cohorts for research studies, especially when these studies have numerous and complex inclusion and exclusion criteria. Dr Fort has 55 articles that have been published in such journals as *The New England Journal of Medicine*; *The American Journal of the Medical Sciences*; *American Journal of Transplantation*; *Applied Clinical Informatics Journal*; *Cancer Immunology, Immunotherapy*; *Cancers*; *Clinical Imaging*; *Frontiers in Oncology*; *Journal of the American Informatics Association*; and *Value in Health*.

Allinson. Can you tell us about the role of artificial intelligence in the development of new cancer therapeutics?

Dr Fort. Obviously, AI applications are rapidly evolving, and [they] have already proved instrumental in [the] targeted development of novel therapeutics and parsing the complex interactions of the relationships between germline and tumor genetics. But in my world, the number 1 impact of AI in clinical trials has been the ability to automatically parse and evaluate evidence in unstructured text. Subtle diagnoses, [those] of exclusion, suspicions, and differential diagnoses—particularly when monitoring patients for either first line treatment failure or recurrence—can frequently only be detected in text. Additionally, the results of certain classes of procedures, namely radiology and pathology, exist only as notes and are often the earliest sign of a patient reaching qualification for targeted oncology trials. Application of AI to these inclusion and exclusion criteria has saved countless hours of manual chart review.

Allinson. How can AI tools be applied to EHRs to precisely characterize a cancer cohort based on the inclusion and exclusion criteria?

Dr. Fort. Recruiting eligible participants for clinical trials is a significant bottleneck in the development of new medical interventions. Hospitals and practices often struggle to efficiently identify suitable candidates within their patient populations. This challenge can lead to delays in trial initiation, increased costs, and, sometimes, the inability to conduct a trial due to inadequate participant recruitment.

Identifying the right patients for a particular trial requires a comprehensive understanding of complex eligibility criteria, frequently requiring expert research personnel to accomplish. These criteria can involve factors such as medical history, age, gender, previous treatments, and specific health conditions all outside the targeted characteristics of the cancer itself. Manual screening of patient records to match these criteria is laborious, time-consuming, and prone to human error.

At Ochsner Health, my teams support clinical research operations primarily by assessing feasibility even before we make the decision to open a [clinical] trial. We start by evaluating historic availability of patients in the system as a whole, then the recruiting hospital location, the recruiting specialty department, and finally the recruiting specialty department with a scheduled appointment in the next 2 weeks. If recruitment can be met based on scheduled appointments, then our research coordinators merely need to meet the patients in the waiting room. Part of the feasibility assessment is not simply a number but a strategy to meet that number. One crucial additional insight is to assess feasibility using the same tools we would use for real patient identification. Often, it does not matter how many qualifying patients we *have*, but how many we can actually *find*. Once a trial is activated, the same queries and reports we used for the feasibility assessment turn into a feed of potential patients for prospective screening, evaluation, and, hopefully, trial recruitment.

AI and natural language processing provide us with an opportunity to read unstructured data with the same understanding and context as a trained researcher.

I should also mention that the traditional way researchers find patients for clinical trials is by either searching structured data ([eg], diagnosis codes, dates) or doing keyword searches. Then staff manually review the patients' chart files to make sure they match all of the trial's inclusion and exclusion criteria. Often, these searches are performed by other departments ([eg], the IT [information technology] team) and can take weeks or months to receive. These types of searches generate large lists that research teams must review and validate to find the small number of patients they can enroll. This tedious and time-consuming process is one of the key contributors to study recruitment delays.

One reason for this scattershot approach is because study eligibility criteria [do] not correspond to available information in the EHR, called *structured data*. In other words, structured data are what can be presented and evident as a data point of the EHR.

The biggest issue with cohort sizing is that structured EHR data only represent a small portion (10%) of all the available data in health care. The remaining information is in the form of unstructured data, such as free-form clinical notes, imaging, biopsies, [laboratory] results, pathology reports, or patient-reported outcomes. The challenge here is that unstructured data are largely inaccessible to research teams without writing complicated and time-consuming record queries. Harnessing the value of unstructured data sources

to match eligibility criteria lies in their diversity and disparate locations and the ability to parse and understand free form text as well as changes in systems and data standards over time. Until recently, there have been many attempts to overcome these roadblocks with little success.

However, AI and natural language processing provide us with an opportunity to read unstructured data with the same understanding and context as a trained researcher.

Allinson. Can you describe some tangible benefits of using AI-assisting charting to access unstructured data?

Dr. Fort. The use of AI and natural language processing results in a dramatic increase in precision ([ie], reducing the number of patients identified as eligible for the study and finding patients who are not possible to find with structured data alone). This reduces the amount of effort required while simultaneously increasing the number of patients identified. And for phase 1 trials for which our targeted enrollment may be as low as a single patient, the ability to rapidly eliminate patients who do not qualify—even if it turns out we have no patients for the trial—is still a win.

For example, for a single lung cancer study using AI to match patients, 1 patient was matched, and that same patient was approved for enrollment. If the research team had used traditional manual screening methods, maybe 292 patients would have been matched, but still only the same 1 patient approved.

Leveraging AI-assisted charting optimizes resource allocation by focusing efforts on patients likely to meet the trial criteria and reducing reliance on human chart reviewers, saving both time and resources.

In another example for gynecologic cancer, AI matched 64 patients, and 62 were approved. If the operations teams had used manual screening,…834 patients would have been matched to the study criteria, and only 40 would have been approved. This example shows both a reduction in false positives from 794 to 2 and a reduction in false negatives from 22 to zero.

Expanding further, cancer treatment is moving toward more targeted therapies. Researchers are identifying cancer molecular pathways and targets, and it's becoming possible to treat the target tumor regardless of the organ of origin. More targeted therapies may change, which may benefit patients and treatment of cancers… since a given treatment may only impact very specific biomarkers and genetic profiles.

Platform-type studies aiming to open and close cohorts quickly based on surrogate end points can help explore these targeted therapies more efficiently. These study designs often include multiple substudies examining the investigational treatment's effect on different populations and targets. Such study designs challenge sponsors, contract research organizations, and research sites to manage incoming data and make and disseminate decisions. It can be a challenge for the institutional review board as well—balancing the need for a complete and timely review. All of this work takes time and drains resources. So, it is critically important to select only the best trials for which the site can actually enroll.

To expand on this, there are 4 ways to leverage AI for accessing unstructured data. First, this technology can be used to confidently size the cohort. Protocol eligibility criteria are often complex and specific, especially in oncology studies. Clinical research teams need to demonstrate to the sponsor that they precisely understand how many patients they have in their system who are eligible for a study. The study may have dozens of individual inclusion and exclusion criteria, and it is nearly impossible for a human being to evaluate all of those variables from disparate data sources simultaneously. With AI, complex and numerous data can be processed simultaneously with minimal human effort.

Second, AI can help confirm potential participants. Clinical research teams use chart reviews to meticulously evaluate patient records against these criteria, ensuring that only suitable candidates are considered for enrollment. Staff carefully examine patients' medical records to determine whether they meet the eligibility criteria of the study. AI can create a virtual chart to compare eligibility criteria as independent variables and specific patient data as the dependent variables. Through the visual display, clinical research teams can confirm eligibility in a matter of seconds.

Third, this technology can screen and enroll participants. Based on the AI-assisted virtual chart review, research teams can identify patients who meet the initial eligibility criteria and flag them for further evaluation. These candidates are then formally screened for study enrollment. Because the AI has already confirmed patient eligibility, the result is a highly precise cohort with a low false-positive rate in a short amount of time with only minimal burden on research teams. By contrast, without AI-assisted virtual charting, the result is a low-precision cohort with a high false-positive rate, high operational burden, and longer time spent.

And lastly, AI can help maximize enrollment by identifying remote and unknown patients. AI-assisted virtual charting can find patients who are in the organization's system but have not yet visited the physician's clinic. Since the AI is searching the organization's entire EHR, these patients are positively confirmed for eligibility. Research teams can then reach out to their providers to see if they are interested in study participation.

Allinson. Can you describe the advantages of using AI-assisted patient charting for eligibility criteria?

Dr. Fort. There are 4 main advantages of using AI here. The first is efficiency and accuracy. AI-assisted charting enables clinical research teams, including study coordinators, to efficiently screen many patient records. What takes a person 1 hour to do, AI can do in seconds. Also, AI gives better results, ensuring a thorough evaluation for trial eligibility with enhanced accuracy.

The second is streamlined patient recruitment with high precision. AI can review an unlimited number of eligibility criteria simultaneously to avoid limitations of human screening, resulting in dramatically fewer false positives.

The third is the ability to recall a patient from anywhere in the system and at any time. AI can quickly identify suitable candidates through guided chart reviews. AI evaluates candidates currently on the schedule to be seen at the site location, candidates on the schedule at clinics elsewhere in the organization (even geographically distant locations), and candidates not on the schedule. Without AI, clinical research teams are only drawing from candidates on the schedule.

The fourth is cost savings. Leveraging AI-assisted charting optimizes resource allocation by focusing efforts on patients likely to meet the trial criteria and reducing reliance on human chart reviewers, saving both time and resources.

Allinson. Your research focus is informatics. How does AI relate to informatics for oncology teams?

Dr. Fort. The traditional funder of research informatics is the National Library of Medicine. In the same way that library science is a set of skills to rapidly identify appropriate sources of information, informatics can be understood as a set of skills to rapidly identify and use appropriate analytic methods. AI is not a single technique but an umbrella term that describes techniques starting somewhere on the fuzzy boundary between multivariate regression and machine learning, stretching through neural-network and deep-learning models and the current frontier of large language models. For oncology teams or any clinical research team, for that matter, AI can seem intimidating, because the term obscures what is actually being used and proposed. Having a partner to explain what and why a technique is used and how it can be evaluated can make all the difference.

Allinson. ACCC's membership includes medical oncology, radiation oncology, pathology, laboratory medicine, radiology, palliative care, pharmacy, hospice, primary care, administrators, genomics vendors, and others. Each of these stakeholders provides input into oncology clinical trials of new therapies. Can you discuss AI from their perspective?

Dr. Fort. It's common to have different specialists or health care professionals as part of the cancer care treatment team. So a multidisciplinary approach to clinical trials is just a natural extension of this.

By way of background, having different professionals and disciplines work together is an approach that is used in many hospitals and clinics before, during, and after cancer treatment. Some have had specialized additional training that focused on a specific type(s) of cancer treatment, a particular area of the human body, comorbid health problems, and overall coordination of care factoring in all those variables. Clinical trials are increasingly being looked at as a care option, and they are also known as *research as care*. So identifying a team or teams of diverse health professionals to support clinical trials is completely consistent with this approach.

Allinson. When selecting an AI partner, what criteria do you look for?

Dr. Fort. First, we look at the AI performance. We look at how good the technology is, how fast it can deliver results for our team, and key performance indicators such as false positives and false negatives. Second, we look at the network. We wanted to pick a partner that had significant experience, especially in oncology studies. Finally, not everyone is experienced in AI software, especially in our research teams. So we need to ensure that any partner has a strong operational customer success team. The people making the decisions on which partner to pursue are almost never the day-to-day users, so access to responsive trainers for new users has been crucial to our success. OI

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The Impact of the *Living Well After Cancer* Program on Multiple Indicators of Wellness and Quality of Life

A Community-Based Feasibility Study

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In Brief

Many cancer survivors experience lingering physiological and psychological symptoms post treatment. Unfortunately, hospitals and cancer programs and practices often lack the resources necessary to properly address these conditions. The *Living Well After Cancer* program is a community-based wellness program that offers survivors of all types of cancer a chance to address these symptoms outside of the clinical setting. In this study, we evaluated the effect of this program on various factors of wellness and quality of life, including self-confidence, mood and emotions, social roles and activities, and support. Participation in the *Living Well After Cancer* program was associated with a significant improvement in many wellness and quality of life indicators, supporting the feasibility and efficacy of this program.

As a result of improved early detection, screening, and treatment, the number of cancer survivors continues to grow in the United States—with the population expected to reach more than 20 million by 2026.[1] With the growing population of cancer survivors, there is an urgent need for public health initiatives to address and improve the quality of life (QOL) of these individuals following treatment. Considering this, the promotion of physical activity should be an important component of cancer care, from diagnosis to survivorship. In fact, growing evidence suggests that increased physical activity is associated with a decrease in mortality risk among cancer survivors.[2]

A meta-analysis of 44 studies—including participants with different cancer types—asserted that cancer survivors who were randomly assigned to an exercise intervention had a significant reduction in cancer-related fatigue levels.[3] Additionally, physical activity following a breast cancer diagnosis is associated with up to a 24% lower risk of recurrence, 41% lower risk of breast cancer mortality, and a 48% lower risk of all-cause mortality.[4-7] A cross-sectional study from Singapore also demonstrated the importance of regular physical activity in decreasing the risk of cancer recurrence; all-cause mortality; and breast, colon, and prostate cancer-specific mortalities among cancer survivors.[8]

The positive benefits of physical activity on general health are well documented in literature. Research strongly suggests that physical activity improves cardiovascular fitness, strength, body composition, fatigue, anxiety, depression, self-esteem, physical function, bone health, and QOL.[9] However, the benefits of physical activity extend beyond psychosocial wellness, as it is also closely associated with an improved QOL.[10]

Nonadherence to the physical activity guidelines among cancer survivors can be attributed to several factors, including lack of time, increased fatigue, treatment-related adverse effects, and lack of awareness regarding exercise recommendations and benefits.[8]

The literature suggests that exercise may reduce the physical and psychological impact of cancer survivorship, improve QOL, prevent recurrence, and improve overall survival.[11] However, meeting the recommended frequency and duration of physical activity appears to be a challenge for cancer survivors. For cancer survivors between the ages of 18 and 64, the American College of Sports Medicine recommends at least 150 minutes per week of moderate-intensity aerobic physical activity or 75 minutes per week of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity aerobic physical activity.[9] Despite these recommendations, many cancer survivors do not meet these guidelines.[9]

Nonadherence to the physical activity guidelines among cancer survivors can be attributed to several factors, including lack of time,

increased fatigue, treatment-related adverse effects, and lack of awareness regarding exercise recommendations and benefits.[8] The need for increased physical activity in cancer survivors is and will continue to be an important public health issue, especially as survivorship rates increase. Thus, the following feasibility study aims to address this public health issue by assessing the impact that a moderate physical activity intervention has on the QOL of cancer survivors. This paper will examine the impact of the *Living Well After Cancer* program on the following multiple indicators of wellness:

- Self-confidence
- Feelings and mood
- Social roles and activity
- Support of cancer survivor participants.

Methods

The pilot study utilized a quasi-experimental design to evaluate the viability of conducting pre- and post-intervention testing on participants in the *Living Well After Cancer* program. Participants were required to complete a validated questionnaire that inquired about their demographics and assessed various aspects of physical, mental, and social well-being. The protocol and informed consent were approved by the City of Hope's institutional review board and Claremont Graduate University's, and all methods were performed in adherence to the relevant guidelines and regulations governing research involving human subjects. The end points were assessed at baseline and after completing the program (at week 13).

Participants and Recruitment

The study included individuals who have survived cancer (regardless of the type or stage at diagnosis) and were registered in The Claremont Club's *Living Well After Cancer* program. Recruitment took place during the orientation sessions of 4 cohorts that commenced in September 2017, February 2018, September 2018, and February 2019. All participants provided written consent after receiving comprehensive information about the study.

Outcome Measures

To assess the impact of the *Living Well After Cancer* program on multiple indicators of wellness, researchers utilized the Patient Reported Outcomes Measurement Information System (PROMIS). PROMIS evaluates physical, mental, and social health in various health conditions across these domains: depression, anxiety, fatigue, sleep disturbance, pain interference, and ability to participate in social roles and activities.[12]

At baseline and post intervention, participants filled out short forms to assess the effect of the program on their QOL through the PROMIS domains. These forms included: Anxiety (4 items), Depression (4 items), Fatigue (6 items), Pain Interference (6 items), Physical Function (4 items), Sleep Disturbance (4 items), Ability to Participate in Social Roles and Activities (4 items), Satisfaction with Participation Social Roles (4 items), Self-Confidence in Managing Daily Activities (4 items), Self-Confidence in Managing Emotions (4 items), Self-Confidence in Managing Symptoms (4 items), Companionship (4 items), Emotional Support (4 items), Cognitive Abilities (4 items), and Cognitive Function (4 items).

These PROMIS measures are standardized to a T-score metric (M = 50; SD = 10). Higher T-scores represent an increase in the construct the item is measuring. Therefore, a decrease in T-score after the intervention would indicate a worsening of certain constructs measured, including pain interference, fatigue, sleep disturbance, depression, and anxiety. However, an increase in T-score after the intervention would indicate an improvement of other constructs, including physical functioning and the ability to participate in social roles and activities. PROMIS measures were scored using the Assessment Center Scoring Service.

Program Description

The *Living Well After Cancer* program in Claremont, California, is a community-based initiative that provides cancer survivors with resources to manage and mitigate long-term symptoms. Founded in 2005, the program has served over 1340 individuals, with each individual program spanning a period of 13 weeks. This includes exercise classes at the Claremont Club offered twice a week. Additionally, participants are provided with social support through gendered cohorts which encourages healthy lifestyle modification such as increased physical activity, improved nutrition, and regular follow-up visits.[13]

So far, the success of the program has been evident among participants, with a significant decrease in several metabolic measures and an increase in physical fitness.[14] This study aimed to assess the effects of the *Living Well After Cancer* program on various indicators of wellness, such as self-confidence, emotions, social roles and activities, and support for participants.

Statistical Analyses

Statistical analyses were conducted using R version 3.6. Normality probability plots and the Shapiro-Wilk statistic were used to determine normality. Appropriate nonparametric statistics were applied. Normally distributed pre- and post-outcome measures were tested using a paired T-test with a significance level of $\alpha = 0.05$. Nonparametric data were analyzed using Wilcoxon signed-rank tests. Pairwise deletion was used to address missing data.

Results

During each orientation session, researchers provided a concise overview of the study and notified the attendees that only 20 individuals would be selected for enrollment. Out of the total 88 participants who provided written informed consent, 78 attended the baseline testing (88%) and 64 individuals attended the post-program testing session (72%).

Table 1 displays the baseline characteristics of the 78 study participants who were enrolled at baseline and completed the baseline QOL questionnaire. On average, participants were 58 years of age or older with a primary diagnosis of breast cancer (n = 49, 64.47%). There were 64 (82.05%) females and 14 (17.95%) males. Most of the participants were non-Hispanic/Latino (n = 58, 74.35%). The majority of participants attained vocational training, some college education, a 2-year associate in arts degree (n = 29, 37.18%), or a graduate/professional degree (n = 26, 33.33%). Over two-thirds (n = 53, 67.95%) of the participants

Table 1. Baseline Characteristics of Study Participants

VARIABLE	MEAN	SD
AGE	58*	10.82
VARIABLE	**SIZE (n)**	**PERCENT (%)**
SEX		
Female	64	82.05
Male	14	17.95
ETHNICITY		
Hispanic/Latino	16	20.51
Not Hispanic/Latino	58	74.36
I'd rather not say	4	5.13
Not reported	0	0
EDUCATION		
High school or less	5	6.41
Vocational, some college, or 2-year associate in arts degree	29	37.18
4-year college	14	17.9
Graduate/professional school	26	33.33
Not reported	4	5.12
MARITAL STATUS		
Never married	8	10.26
Married, in a civil union, domestic partnership, or living as married	53	67.95
Divorced/separated	12	15.38
Widowed	5	6.41
Not reported	0	0
PRIMARY CANCER DIAGNOSIS		
Breast	49	64.47
Others	27	35.53
Not reported	2	2.56

*Calculated for the 78 participants who returned the demographic baseline questionnaire.

were married, in a civil union, domestic partnership, or living as married.

Table 2 presents the impact of the *Living Well After Cancer* program on the well-being and QOL of participants by comparing their baseline and post-intervention scores across different dimensions. The results showed significant improvements in anxiety and fatigue, with mean differences of 2.64 (P = .011) and 3.02 (P = 0.005), respectively. Pain interference and physical functioning also significantly improved post intervention, with mean differences of 2.42 (P = 0.025) and 2.13 (P = 0.001), respectively. Sleep disturbance and social satisfaction also demonstrated significant progress after the program, with mean differences of 3.41 (P = 0.001) and 1.81 (P = 0.024), correspondingly. Furthermore, compared to baseline, self-confidence in managing daily activities, self-confidence in managing emotions, and emotional support showed significant improvements, with P values of 0.004, 0.001, and 0.038, respectively. The mean differences across these dimensions ranged from 2.79 to 3.35, demonstrating significant improvements post intervention.

Cognitive abilities and cognitive concerns also displayed significant improvement post intervention, with mean differences of 2.37 (P = 0.008) and 2.38 (P = 0.001), respectively.

However, the results reflected nonsignificant improvements in

Table 2. Changes in Participants Quality-of-life Dimensions Before and After the *Living Well After Cancer* Program

QUALITY OF LIFE DIMENSION	n	BASELINE MEAN (SD)	FOLLOW UP MEAN (SD)	MEAN DIFFERENCE	P-VALUE
Fatigue	64	51.16 (10.65)	48.13 (9.07)	3.02	.005
Anxiety	64	55.14 (9.41)	52.50 (7.73)	2.64	.011
Cognitive ability	64	47.93 (9.43)	50.30 (9.57)	2.37	.008
Cognitive concerns	64	34.55 (8.16)	32.17 (7.87)	2.38	.001
Companionship	63	53.07 (8.99)	53.86 (8.28)	0.79	.294
Depression	64	49.17 (8.60)	48.83 (7.86)	0.34	.682
Emotional support	64	53.38 (8.90)	54.99 (8.43)	1.62	.038
Pain Interference	64	51.39 (9.34)	48.97 (7.72)	2.42	.025
Physical functioning	64	46.29 (7.54)	48.41 (7.45)	2.13	.001
Self-efficacy in managing daily activities	64	49.03 (7.35)	51.82 (7.20)	2.79	.004
Self-efficacy in managing emotions	64	47.76 (7.24)	51.11 (8.37)	3.35	.001
Self-efficacy in managing symptoms	63	50.21 (8.83)	51.87 (7.86)	1.67	.090
Sleep disruption	64	51.05 (7.72)	47.65 (7.60)	3.41	.001
Social participation	63	49.53 (8.55)	50.93 (8.40)	1.40	.060
Social satisfaction	63	50.66 (6.49)	52.47 (6.69)	1.81	.024

depression (P=0.682), companionship (P=0.294), self-efficacy in managing symptoms (P=0.090), and social participation (P=0.060) post intervention.

Discussion

This pilot study examined the impact of a community-based exercise program on multiple indicators of wellness, including self-confidence, feelings and moods, social roles and activity, and support in a population of cancer survivors. These psychosocial parameters were assessed before and after participation in the program. Results of this study indicated statistically significant improvement in anxiety, fatigue, pain interference, physical functioning, sleep disturbance, social satisfaction, cognitive abilities, cognitive concerns, self-confidence in managing daily activities, self-confidence in managing emotions, and emotional support following participation in the *Living Well After Cancer* program. While not statistically significant, this study also found slight changes in depression, companionship, social participation, and self-efficacy in managing symptoms.

The results of this study are largely consistent with findings in previous literature regarding physical activity and cancer survivors. Alfano et al investigated physical activity and health-related quality of life (HRQOL) in a cohort of breast cancer survivors and found that increased physical activity after cancer was significantly related to lower fatigue and pain and better physical functioning.[15] Likewise, a more recent study that similarly examined the association between physical activity and HRQOL in breast cancer survivors demonstrated that breast cancer survivors who practice more physical activity were more likely to have low scores for fatigue and pain and higher scores of sexual functioning.[16] Future research is needed to further explore the relationship between physical activity and indicators of QOL in cancer survivors.

Perhaps the most studied dimension of QOL in cancer survivors is fatigue. This pilot study found a significant reduction in fatigue levels from pre- to post-intervention. The reduction in fatigue found through this study is consistent with the literature on exercise interventions and fatigue.[17-19] A meta-analysis by Meneses-Echávez et al reported that supervised aerobic exercises are effective in reducing cancer-related fatigue in breast cancer survivors.[17] A review of 59 trials by Mishra et al found that exercise interventions resulted in a decrease in fatigue from baseline to follow-up.[18] Thus, the results of our study are consistent with the literature in terms of physical activity being associated with reduced levels of fatigue.

Psychological function and anxiety are important dimensions of QOL that have been extensively studied in cancer survivors. Stout et al conducted a systematic review of 51 studies that investigated the effect of exercise interventions on these outcomes. The review demonstrated that exercise interventions significantly improved psychological function and anxiety in cancer survivors.[20] While the specific magnitude of the effect and the types of exercise that were effective varied across studies, these results are consistent with our study's finding that exercise is associated with reduced anxiety levels in cancer survivors.

Furthermore, pain interference and physical function are important dimensions of QOL that have been shown to significantly improve

following physical activity interventions. While more research is needed to confirm the impact of physical activity on pain interference, Ferioli et al investigated the effects of exercise on pain among cancer survivors and found a positive effect in most patients undergoing or having finished treatment.[21] This aligns with our study's findings, but more research is necessary to further establish the relationship. However, the impact of exercise on physical function among patients with cancer has been well studied by the same scholars, who reviewed the literature on the influence of physical activity on various aspects of physical function, such as bone and muscle loss, weight imbalance, cachexia, and peripheral neuropathy, and demonstrated a consistent body of evidence supporting that exercise has a crucial impact on physical function.[21]

Our analysis also found a significant reduction in sleep disruption, which is consistent with previous research. For example, a randomized controlled trial by Rogers et al reported a significant improvement in global sleep quality, as measured by the Pittsburgh Sleep Quality Index, for participants who received an aerobic physical activity intervention.[22] However, in contrast, Sprod et al did not find a statistically significant improvement in sleep quality for participants in the exercise group post intervention.[23] One potential mechanism that may explain how exercise impacts sleep is by regulating proinflammatory cytokines.[24] This regulation, in turn, can influence neural processes in the brain and is thought to improve sleep. When combined, these findings suggest that the improvements in sleep quality seen in this study may be attributed to the exercise intervention.

A promising aspect of the current study is the observed improvements in psychosocial dimensions of QOL. Post-intervention results showed significant improvements in satisfaction with participation in social roles, self-confidence in managing daily activities, self-confidence in managing emotions, and emotional support. Improvements in companionship and self-efficacy in managing symptoms were not statistically significant. Despite limited studies exploring these dimensions of QOL, Musanti, Chao, and Collins found improvements in social role satisfaction among cancer survivor participants in a community exercise program.[19] Furthermore, Luoma et al found that among breast cancer survivors, peer support from those participating in group exercise interventions helped participants to improve psychological support and gain a sense of normality.[25] Additionally, the researchers asserted that participants may gain a sense of mastery over their disease through simply participating in the intervention and meeting other breast cancer survivors.[25] These findings reinforce the enhanced psychosocial aspects identified in our study, which contribute to an enhanced quality of life for cancer survivors.

Regarding research into the influence of physical activity on the cognitive abilities of cancer survivors, research conducted by Hartman and colleagues suggests that physical activity may also be effective for some domains of cognitive functioning.[26,27] These findings are consistent with those of our intervention study, which found a significant improvement in cognitive abilities compared to baseline. Additionally, another randomized controlled trial found that a 12-week physical activity intervention significantly improved processing speeds among breast cancer survivors, providing further support to our findings.[28] However, researchers have indicated that more studies are needed, specifically among cancer survivors in general, to reach a deeper understanding of the relationship between physical activity and improved cognitive functioning.[26,27]

Limitations

Considering that our study is indeed a pilot intervention, we would be remiss to not acknowledge the limitations of our findings. First, our study consisted of a single group where all participants received the intervention. Thus, it is not possible to tell if improvements in QOL were due to participation in the intervention or the natural course of cancer survivorship. Second, due to the quasi-experimental design of the study and the cross-sectional nature of the data, causal inferences cannot be made from the observed associations. However, as reviewed in the literature above, previous experimental studies and meta-analyses have found evidence suggesting that physical activity can lead to improvements in QOL. Third, only univariate associations were assessed in this study because it was not powered for multivariate analysis; therefore, we were unable to control for potential covariates and confounders.

Conclusion and Implications

The *Living Well After Cancer* program is a community initiative designed to evaluate whether integrating physical activity can enhance well-being, social roles and activities, mood and emotions, self-confidence, and support among cancer survivors. Results from this pilot study support that participation in our exercise intervention led to significant improvements in various indicators of QOL, including anxiety, fatigue, pain interference, physical functioning, sleep disturbance, satisfaction with participation in social roles, self-confidence in managing daily activities, self-confidence in managing emotions, emotional support, cognitive abilities, and cognitive concerns. These results suggest promising directions for research into the QOL of cancer survivors and can provide valuable insights for developing future community programs aimed at enhancing their overall well-being and QOL.

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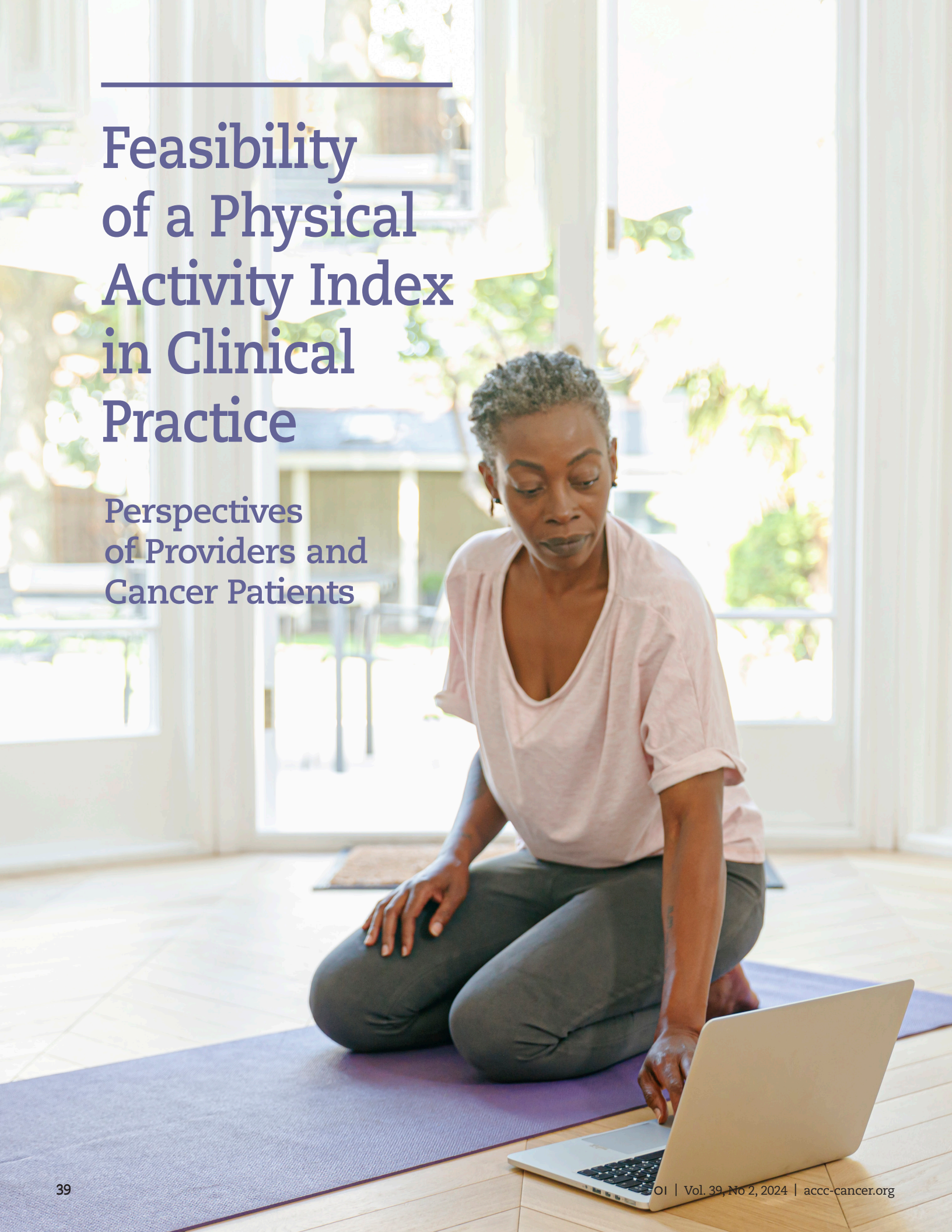
Feasibility of a Physical Activity Index in Clinical Practice

Perspectives of Providers and Cancer Patients



BY BRIANNA N LEITZELAR, PHD; FRANK PERNA, EDD, PHD;
AND SHIRLEY M. BLUETHMANN, PHD, MPH

In Brief

Physical activity is a common clinical recommendation for cancer survivors, yet the use of clinical tools to counsel patients is understudied. We developed an integrated Physical Activity Index to assist with this task. The purpose of this project was to conduct interviews to assess the feasibility and clinical utility of the Physical Activity Index from both provider and patient perspectives. Our findings indicate that a Physical Activity Index may be a useful tool to facilitate productive patient-provider communication about physical activity goals.

Physical activity is a well-established clinical recommendation for older adults,[1] and it has specific benefits for cancer survivors (adults with cancer history). This finding was reaffirmed by the American Cancer Society in 2022.[2] For decades, physical activity has shown benefits for recovery from a variety of health conditions including cancer. Considering the global incidence and growing prevalence of cancer propelled in part by the aging of the population,[3] there is interest in physical activity for cancer prevention and control. However, the ability to assess and monitor physical activity over time in clinical settings has not been fully explored.[4]

Clinicians play an important role in supporting positive behavioral changes,[5] although there are several barriers to conducting physical activity counseling in clinical practice. Provider barriers to physical activity counseling include insufficient time, uncertainty of what to recommend, and the perception that activity counseling is too complicated or outside their skillset.[6] New tools that facilitate the implementation of physical activity counseling in clinical practice are needed for clinical staff, including physicians and nurses.[7]

Previously, we developed an integrated Physical Activity Index screener to briefly assess physical activity in concert with relevant assessment of related behaviors, including sedentary behavior and physical performance metrics. These studies provided evidence on the efficacy of a multicomponent physical activity assessment strategy (ie, the Physical Activity Index) in estimating key health outcomes with both the general population and cancer survivors.[8,9] However, these studies did not assess clinical utility from such stakeholders as clinicians and patients. The purpose of this project was to conduct interviews to assess the perceptions and clinical utility of the Physical Activity Index from provider and survivor perspectives.

For decades, physical activity has shown benefits for recovery from a variety of health conditions including cancer...Clinicians play an important role in supporting positive behavioral changes...

Materials and Methods

This qualitative study used cognitive interviewing[10] and a structured interview guide. Research was carried out by a team at the National Cancer Institute and supported by Westat, a research consulting firm with experience conducting interviews. Fidelity to the interview procedure was maintained through an interviewer training session and direct observation for approximately one third of interviews (6 patients). Study procedures were consistent with National Institutes of Health Institutional Review Board (IRB) policies for quality improvement and were also approved by the Westat IRB. Weststat conducted the interviews in February 2016 in Rockville, Maryland.

We purposively sampled 18 participants from the Washington, DC, area (9 providers and 9 posttreatment cancer survivors) for one-on-one, in-person interviews. Providers were selected from primary care or oncology practices. Eligible providers reported seeing cancer survivors regularly (ie, ≥ 10% of their practice). Eligible survivors completed treatment (eg, surgery, radiation, chemotherapy) within the last 5 years; these individuals were racially diverse. All participants provided verbal consent to participate.

All interviewers were female. They presented participants with the Physical Activity Index brief screener and report card. The Physical Activity Index screener assesses minutes per day of moderate- and vigorous-intensity physical activity, hours per day of sedentary behavior

(ie, screen time), and days per week of strength training activities using validated questions. The Physical Activity Index screener is then scored as a personalized report card based on Physical Activity Index screener responses. The purpose of the Physical Activity Index report card is to help providers and patients understand how to interpret results generated through the Physical Activity Index screener and to counsel patients on their specific physical activity needs. Physical Activity Index report cards also include links to cancer-specific physical activity guidelines.[2] A mock-up example of the Physical Activity Index report card was used for this study. Mock ups also included examples of talking points to facilitate provider-patient conversations about results of the Physical Activity Index report card. Participants were asked about the usefulness of this tool.

Cognitive interviews took place to assess comprehension of the Physical Activity Index screener, and structured qualitative interviews were completed to evaluate perceptions and perceived clinical utility of both the screener and the report card. During cognitive interviews, cancer survivors completed the Physical Activity Index screener while thinking aloud in the presence of an interviewer.[10] Interviewers then conducted retrospective probing to address questions from the cancer survivor about completion of the Physical Activity Index screener, hesitation in responding, or changes in responses. Qualitative questions assessed perceptions of the Physical Activity Index screener and report card. Questions gauged initial reactions to the Physical Activity Index screener and report card, preferences for format of completion (paper vs electronic), clinical utility of the Physical Activity Index tool, and barriers and facilitators to using the Physical Activity Index in clinical practice.

An interview guide strengthened consistency in data collection. Interviews were audio recorded and transcribed verbatim. Cognitive interviews were analyzed using a segmented coding strategy; qualitative data were analyzed using a similar structured coding format corresponding with the interview guide. Coding and thematic analysis was supported by direct comments and quotes.

Table 1. Participant Characteristics

CLINICAL PROVIDERS (PHYSICIANS, NURSE PRACTITIONERS, NURSES)				
ID	GENDER	AGE, YEARS	CLINICIAN TYPE	POST-TREATMENT CANCER SURVIVORS, %
C1	Male	55	Oncologist	20%
C2	Femaie	49	Oncology nurse	40%–50%
C3	Femaie	50	Primary care physician	10%
C4	Femaie	58	Nurse/Nurse practitioner	10%
C5	Femaie	59	Nurse/Nurse practitioner	10%
C6	Male	65	Primary care physician	10%
C7	Femaie	46	Oncology nurse	50%
C8	Male	47	Oncologist	30%
C9	Male	62	Oncologist	25%

CANCER SURVIVORS							
ID	GENDER	AGE, YEARS	TUMOR SITE	EDUCATION	RACE	TIME SINCE CANCER DIAGNOSIS, YEARS	TIME SINCE TREATMENT COMPLETION
S1	Female	70	Breast	College	White	4	4 years
S2	Male	65	Prostate	Graduate school	White	4	3 years
S3	Male	76	Prostate	High school	Black	3	2 years
S4	Male	79	Prostate	College	White	6	5 years
S5	Female	79	Breast	Graduate school	Black	9	3 years
S6	Male	72	Prostate	Graduate school	White	7	7 years
S7	Female	65	Breast	High school	White	10	10 years
S8	Female	61	Breast	High school	Black	5	3 years
S9	Female	55	Breast	High school	Black	5	7 months

Results

Five oncology providers (3 physicians and 2 nurses) and 4 primary care providers (2 physicians and 2 nurse practitioners/nurses) were interviewed. On average, survivors were 4 years post–cancer treatment (mean age, 69 years) (Table 1).

Cognitive and Qualitative Interviews

Survivors reported that the Physical Activity Index was easy to understand and complete; however, there was confusion about how to report physical activity intensity. Survivors recommended using relatable examples like walking the dog, gardening, or heavy chores to help elucidate these differences. Additional clarification between occupational and leisure-time physical activity was also needed. Survivors misunderstood the screen time question, which was also intended to include time sitting by a computer or other screen; some only reported time spent watching television. Strength training frequency was well understood, but few survivors engaged in strength training activities.

Perceptions of the Physical Activity Index

Most providers were receptive to the Physical Activity Index as a screener; however, they identified a need to differentiate between moderate- and vigorous-intensity physical activity as well as occupational versus leisure-time physical activity. Providers recommended simplifying and

Table 2. Exemplar Quotes From Participants

	PARTICIPANT GROUP	EXEMPLAR QUOTES
Perceptions of the Physical Activity Index	Clinical providers	"It's very simple and very user-friendly. It's not complicated. I think even a patient [who] is not educated should be able to fill it out…This is not complicated. It is user-friendly and gives you a lot of information." [C9] "It's really good and thorough, but there are too many words for the patients. We give lots of things to fill out, different surveys for depression, sleeping habits, and we've noticed that the less words, the better." [C3]
	Cancer survivors	"I like the way it's laid out. You have your different points. You've got your different goals that you can work toward. That's what I like about it. It's like a report card." [S3] "People are intimidated by paperwork. If it's smaller, you become more intimidated. I would make [the font size] as big as possible." [S2]
Clinical utility of the Physical Activity Index	Clinical providers	"I think it will be an excellent tool to have in your practice. At least you know how much the patient is doing at home. If they come and [the score is] low, you know you're not doing much exercise at home. That would encourage them to do more, because there's a result. There's an outcome of what their status is." [C7] "[The output is] a little bit [useful], but not greatly, because it takes effort to go through it. Looking at this, to me, this is not intuitive…Then on the part of the patient, [it] probably [would be[handed to me [as the patient asks], 'OK, so what do you think, Doc?' Then we [would ask ourselves], 'I'm going to spend the time analyzing it for them?'" [C1]
	Cancer survivors	"It really gives me…good input to what I am doing okay and what I am not doing and [gives] me guidelines on how to help myself to change my routine or change the habits I have." [S7] "I just know that this is not something that's going to happen, because these doctors…don't spend that much time with you, and they're not going to do this. There are no nursing assistants who aren't harried and rushed to death. I just don't think it's very realistic…My experience has not been spending any appreciable amount of time with a medical doctor. I think they will entertain your questions, if they're not too long or too complicated." [S5]

shortening wording to facilitate comprehension. Overall, providers liked the report-card style output to monitor and counsel patients on lifestyle changes (Table 2) and provided some suggestions for changing the configuration of the report card. Provider preferences for Physical Activity Index format (paper vs electronic) were mixed.

Cancer survivors were also receptive to the Physical Activity Index. Survivors held positive perceptions of the Physical Activity Index report card and liked that it would be tailored specifically to them. Survivors indicated that the report card was visually pleasing and informative, although some thought there was too much text. Most survivors indicated that they prefer to complete the Physical Activity Index on paper.

Clinical Utility of the Physical Activity Index

All providers indicated that they assess physical activity in their patients but do not use a standardized tool. A standardized tool was viewed as potentially helpful, with 1 participant (C6) stating, "It will be more objective. I can see the progress and measure something in the beginning and see how it progresses or regresses." Providers indicated it would be feasible for their patients to complete the Physical Activity Index screener in the waiting room before their appointment. Providers indicated the Physical Activity Index report card would be useful (Table 2), although some reported limited time as a concern. Patient motivation to engage in physical activity was seen as an important factor to consider. The ability to link Physical Activity Index responses to clinical records was suggested to facilitate Physical Activity Index use in practice.

Cancer survivors reported that their providers frequently recommended exercise. However, these survivors wanted additional advice on how to exercise safely with chronic health conditions. Although survivors held positive perceptions of the Physical Activity Index, they expressed concern that it would not be reasonable to expect to do this during a clinic visit. One patient (S5) stated, "I would say that most of the physicians, and especially if they're good ones...don't have the time. To me, it would just be very unrealistic for my doctor to do." Most cancer survivors believed that the Physical Activity Index report card would motivate their behavior, especially if they clinicians offered extra support. Survivors indicated that it would be most useful to track their behavior with the Physical Activity Index over time and to implement results to discuss specific strategies with their clinicians.

Discussion and Conclusion

The Physical Activity Index could be feasible in clinical practice for providers and cancer survivors, especially if results could be integrated in electronic health records. All participants liked the Physical Activity Index and provided helpful suggestions to clarify instructions for its use. Provider education resources on patient counseling would facilitate use of the Physical Activity Index in primary care and oncology programs. Cancer survivors may specifically benefit from physical activity, but they could need additional support from providers to adapt physical activity goals based on individual health concerns.

This brief study was meant to affirm the need for a clinical tool that would support productive patient-provider communication about physical activity and behavioral goals. We believe that there was sufficient interest and consensus in the benefit of such a tool to continue the development of this approach.

The study's main strength was the direct input of clinical stakeholders. These include different types of providers (physicians and nurses) with whom, and settings (oncology and primary care) in which, cancer survivors would be likely to receive physical activity counseling. Additionally, our patient participants were all older adults (mean age, 69 years) who were similar to members of the general population of cancer survivors. We also intentionally included breast and prostate cancer survivors and racially diverse participants to ensure that we had a range of perspectives on the clinical utility of materials from the patient perspective.

However, there were study limitations. We used a convenience sample to identify participants, which does not support representativeness of the population. Additional work on how to reach survivors in nonurban areas would be valuable given the evolution of the US population. OI

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A Treatment-at-Home Pilot

Barriers to Home Cancer Care

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In Brief

During the COVID-19 public health emergency, patients with cancer faced significant challenges presenting for their in-clinic visits. In-home administration of intramuscular and subcutaneous therapies provided an opportunity to deliver antineoplastic therapy while lowering infection risk. This quality improvement study of adult patients with neuroendocrine and breast cancers at Memorial Sloan Kettering Cancer Center was conducted from February 16, 2022, to October 14, 2022, and involved nurses delivering outpatient pharmacy-dispensed in-home intramuscular or subcutaneous treatments. The study concluded that while home administration of antineoplastic therapies was safe and patient-centric, administrative barriers—primarily pharmacy benefit denial—prevented the study from achieving its primary end point. As cancer care evolves, there should be a focus on regulatory changes that minimize financial and time toxicity and allow for patient convenience.

At the start of the COVID-19 pandemic, patients with cancer were particularly vulnerable to COVID-19, as evidenced by their high rates of hospitalization and death.[1] Cancer programs and practices that administered antineoplastic therapies in the home were embraced and accelerated to lower risk and offset health care demands. The Centers for Medicare & Medicaid Services (CMS) released provisions that enabled providers to deliver care in the safest, most appropriate setting, allowing in-home pilots;[2] in-home delivery of antineoplastic therapy was considered safe and patient satisfaction was high.[3] Many pilots occurred at large health systems that already had in-home nursing or infusion service lines.[3,4] The feasibility, safety, and patient satisfaction for institutions implementing these programs without preexisting home services was unknown.

Patients with breast and neuroendocrine malignancies receiving subcutaneous or intramuscular therapies are an ideal population to test in-home care delivery, as therapies are administered repeatedly over extended periods, patients are generally well, and therapies have favorable safety profiles. Therefore, we hypothesized that this patient cohort could benefit from an in-home care delivery program.

Method

This feasibility study received a waiver of review and informed consent from the Memorial Sloan Kettering Cancer Center (Memorial Sloan Kettering) institutional review board because it was a quality improvement study. This study is reported following the Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) reporting guideline.

> Insurance approval was the main barrier to in-home visits for 57% of visits where the patient had agreed to participate.

Program Description

The vision of the program was to test the safety and satisfaction of using Memorial Sloan Kettering expert oncology nursing care in the home to reduce travel for our vulnerable patients during the COVID-19 pandemic. A multistakeholder team comprised of nurses, physicians, pharmacists, informaticians, and administrators was convened to develop the program, including a workflow (Figure 1) and a security screening form (Figure 2). Permission was sought and received from the New York State Department of Health during the public health emergency to provide this service as a hospital under its existing license.

Pharmacy

Prescriptions were filled by Memorial Sloan Kettering retail pharmacy. External pharmacies were beyond the scope of this pilot.

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Figure 1. Treatment-at-Home Workflow

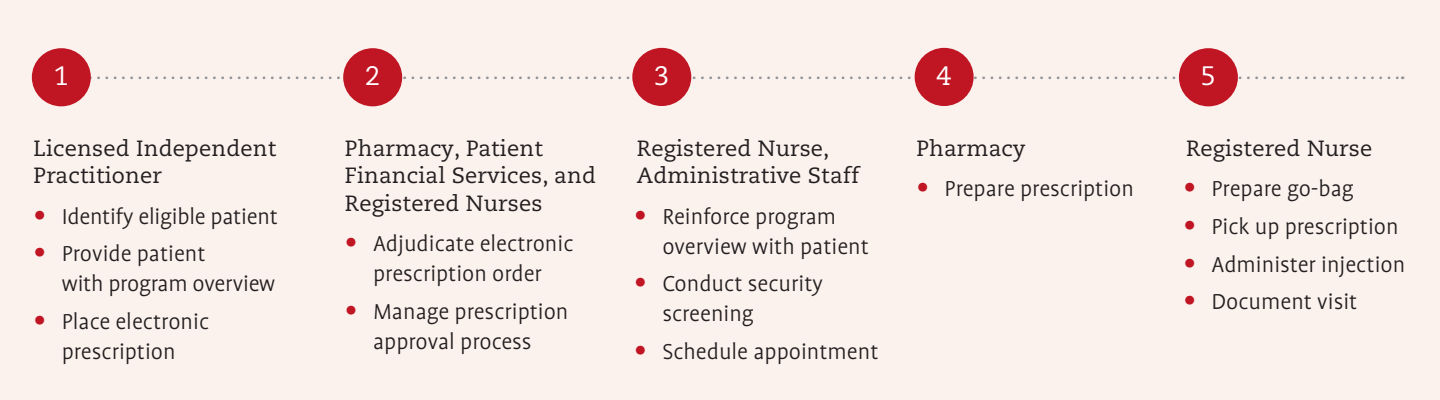

Figure 2. Security Screening Form

Patient name:
MRN:
Date of visit:
Reason for visit:

HIGH RISK	YES	NO	DON'T KNOW	
1. Is there a potential for violence or aggression in the home (ie, active order of protection, police called to the home, domestic violence, sexual abuse, violence and/or aggression with service providers, etc)?				• If Yes, consult with a manager to develop a safety plan (ie, buddy system, police escort, etc). • If Don't Know, carry a cell phone, consult with staff who know the family, or consult with a manager. • Reminder: complete the Sign-In/Sign-Out Sheet before conducting the visit.
2. Is there a history of weapon-related incidents?				
MODERATE RISK	**YES**	**NO**	**DON'T KNOW**	
3. Has the client or client's family been verbally abusive to service providers?				• If Yes to more than one of the questions in this category, consult with a manager to discuss safety precautions. • If there are false allegations from this client about service providers, consult with a manager to discuss safety precautions. • If there are dangerous animals on the property, request an office visit with the client (if possible) or request that the client restrain the animal. If the client refuses to restrain the animal, leave the home. • If Don't Know, carry a cell phone, consult with staff who know the family, or consult with a manager. • Reminder: complete the Sign-in/Sign-Out Sheet before conducting the visit.
4. Are there any illnesses/conditions that might affect client's behavior (eg, dementia, psychosis, brain trauma, etc)?				
5. Is there a history of drug or alcohol abuse in the home?				
6. Have there been false allegations from this client about service providers?				
7. Is the cell phone service inadequate?				
8. Is the home located in an area that one might consider dangerous?				
9. Are there dangerous animals on the property?				
LOW RISK	**YES**	**NO**	**DON'T KNOW**	
10. Is the home in an area that is physically isolated from other homes?				• If Yes, take the necessary safety precautions before conducting the visit. • Reminder: complete the Sign-In/Sign-Out Sheet before conducting the visit.
11. Are there any factors affecting access to the home (eg, lighting, broken stairs, parking, etc)?				

(*Continued from page 46*)

Patient Cohort

Adults with breast and neuroendocrine tumors receiving octreotide, lanreotide, denosumab, fulvestrant, or leuprolide acetate living within 30 minutes of the Memorial Sloan Kettering Manhattan campus were included. We chose a 30-minute radius because Memorial Sloan Kettering registered nurses (RNs) who were deployed also had on-site responsibilities.

Care Delivery

Patients seek care at National Cancer Institute (NCI)-designated comprehensive cancer centers for the clinical expertise and experience of the multidisciplinary team. We maintained that expertise in the home by employing Memorial Sloan Kettering nurses (n = 9). An evidence-based nursing standard of care was developed to support in-home nursing practice; it provided guidelines for nursing assessment, interventions, education, environmental safety, and documentation (Figure 3). We measured the amount of time the RN spent providing care, including travel, and administered an environmental and physical safety survey after each visit.

Feasibility

The study was conducted from February 16, 2022, to October 14, 2022, with a goal of converting 40 in-clinic administrations to home administrations. This threshold was determined by the multistakeholder group to represent the minimum number of visits to have an adequate understanding of home administration before making a consideration of scale.

Safety

Safety was evaluated by both patient- and provider-reported adverse events following at-home administration.

Patient Satisfaction

Patients were surveyed via telephone or electronic form after each home visit using a 5-point Likert scale to gauge patient experience. The survey was developed in collaboration with the Patient and Caregiver Engagement department, who have expertise in health literacy and question design. A net promoter score was calculated based on responses to the statement, "I would recommend receiving treatment at home to other patients like me." The percentage of respondents who disagreed or strongly disagreed (detractors) with this statement was subtracted from those who agreed or strongly agreed (promoters). The net promoter score has been used by a variety of companies and organizations both inside and outside of health care to assess customer satisfaction.[5,6] Based on other health care delivery studies, our goal net promoter score was 0.7. We also estimated time and cost savings to patients.

Results

Feasibility

Fifty-four eligible visits for 32 patients were identified (Table 1). For most visits, patients and providers were agreeable to home treatment (56% [30/54]). Thirty-eight percent of patients declined to participate. Reasons patients declined are included in Table 2; the primary reason was that patients preferred to be on-site for their treatment (36% [4/11]). Representative patient quotes are below:

- "I like crossing town on the bus and visiting [the] clinic. I am 86 years old, and it gives me an excuse to get out of my house. Also, I haven't vacuumed, and my house is dirty, so I was embarrassed."
- "I was used to going to get the injections. I like that it's on his calendar and [I] walk down for the day—it's programmed. If they were to come to the house, it might be interruptive, and they are coming into 'my personal space' where the medical treatment wasn't part of it."
- "I thought about it and just thought my care and injections should be in the clinic and not in my personal space in the home."

One hundred percent of post-home-visit respondents would recommend the program to others and agreed that it made the most of their time.

Insurance approval was the main barrier to in-home visits for 57% of visits where the patient had agreed to participate. For all orders, take-home prescriptions were initially rejected by patient's pharmacy benefits, mainly due to plan-exclusion of the drug on their formulary; most required an appeal with a letter of medical necessity. Six patients in 11 visits had their take-home prescriptions covered after subsequent prior authorization was reviewed: 5 patients on octreotide and 1 patient on denosumab. For 2 visits, prescriptions were subsequently covered after prior authorization but did not meet our inclusion criteria due to a mandate of a specific external specialty pharmacy process.

Safety

All patients on this pilot were stratified to the low-risk category during the home safety screening. No adverse events were reported by patients or nurses for any completed visit.

Patient Satisfaction

One hundred percent of post-home-visit respondents (n = 11 responses) would recommend the program to others and agreed that it made the most of their time (Figure 4).

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Figure 3. Nursing Standard of Care Document

	ASSESSMENT	NURSING INTERVENTION	PATIENT & CAREGIVER EDUCATION	ENVIRONMENTAL SAFETY	DOCUMENTATION
	Reviews patient history including allergies, contact precautions, and active orders for care in the home. Assesses last received dose of the medication to ensure timing is appropriate for dose administration. Assesses whether there have been any changes in the patient's wellness or new problems since last being seen by a clinician.	Calls patient to review patient and caregiver education, home preparation, and conduct security screening. Conducts security screening survey. "As part of the eligibility criteria and Memorial Sloan Kettering security recommendations, we will ask a few screening questions about the safety in your home." Sends completed security screening survey to security for review (24 hours before appointment). Charges batteries for laptop, MiFi, and cell phone.	Educates patient on: • Need for a private space for medication administration. • Need for a clean surface space for medication preparation (table, counter, etc). • Securing all pets prior to arrival of RN. • Time window to expect RN arrival. • Need to report if anyone in the home becomes ill. • Medications ordered for home administration and anticipated adverse effects.	Verifies with patient that no one in the home has an active communicable disease (eg, flu, COVID-19). Informs patient there are 2 Memorial Sloan Kettering employees coming to the visit. Requests area to set up (not in kitchen) and access to faucet for hand washing. Requests that pet(s) be secured.	Telephone/electronic communication note. Include the security screening survey responses in the note.
	Assesses that no changes have been made to the patient's active orders prior to departing for the patient's home. Verifies content of Tx@Home Go-Bag includes: • Cell phone • Gloves • Yellow gown • Alcohol swabs • Wipes • Chucks pads (waterproof disposable underpads) • Sharps container • Resealable (eg, vial) • Primapore (wound) dressing • Gauze • Booties • Laptop • MiFi	Obtains the Tx@Home Go-Bag from the NL office on site. Obtains drug(s) from the retail pharmacy (M-F 9:00 to 5:45) in an insulated bag with ice pack. Provides handoff to coverage for ongoing clinical responsibilities during home visit. Documents time leaving Memorial Sloan Kettering.	Ask administration to print: • Downtime form with patient's name and address. • Home medication list. • Patient education material: - Preventing Falls Care Plan. - Patient Education: What you can do to avoid falling. - Patient Education: How to choose safe shoes to prevent falling.	Reviews patient history including allergies, contact precautions, and active orders for care in the home. Assesses last received dose of the medication to ensure timing is appropriate for dose administration. Assesses whether there have been any changes in the patient's wellness or new problems since last being seen by a clinician.	

(*Table continued on next page*)

Figure 3. Nursing Standard of Care Document (continued)

	ASSESSMENT	NURSING INTERVENTION	PATIENT & CAREGIVER EDUCATION	ENVIRONMENTAL SAFETY	DOCUMENTATION
Upon Arrival to the Home	Completes patient identification following Memorial Sloan Kettering policy. Completes a rapid visual assessment of the environment for any safety concerns such as: • Loose rugs • Small furniture • Clutter • Electrical cords • Poor lighting	Verifies the strength of hotspot connectivity and connects Memorial Sloan Kettering laptop. Removes medication from the insulated bag to come to room temperature while doing patient assessment.	Reinforces education that was provided in advance via phone. Educates patient and caregiver on the anticipated plan of care for the visit.	Ensures patient has secured all pets before entering the home.	
Care Delivery in the Home Setting	Completes a nursing assessment note. Assesses if there have been any changes in the patient's wellness or new problems since the patient was last seen by a clinician. Assesses the patient's understanding of plan of care and medication(s) to be administered. Conducts medication reconciliation.	If unable to successfully connect to Memorial Sloan Kettering hotspot, follows downtime procedures. Completes medication preparation and administration following standard Memorial Sloan Kettering policy. Escalates unexpected assessment findings to ordering licensed independent provider prior to medication administration.	Educates patients on medications ordered for the day and provides the patient with an opportunity to ask questions. Reinforces adverse effects related to the drug(s). Provides patient education materials on falls prevention: • Falls • Safety	Prepares the environment for medication administration by wiping down the table and/or surface with a PDI wipe before medication preparation. Secures sharps after medication administration in sharps container. Places vial in Ziploc bag to return to Memorial Sloan Kettering. Disposes of all non-sharps garbage before departure.	Nursing Encounter, Outpatient: Medical Oncology Patient Education Documentation Form System: Safety Learning Needs
Visit completion	Assesses patient tolerability of medication administration prior to leaving the home.	If downtime procedures were followed in the home, documents it in the medical record upon return to Memorial Sloan Kettering. If full, disposes of sharps container with Memorial Sloan Kettering facilities department and obtains a new one for the Tx@ Home Go-Bag. Restocks Tx@Home Go-Bag supplies and returns the bag. Emails NL/scheduler to document the time spent for the visit away from Memorial Sloan Kettering.	Educates patient on how and when to contact the office for any new symptoms or adverse effects. Informs patient that they may receive a satisfaction survey on the experience via their Memorial Sloan Kettering patient portal.	Laptops will be changed out by IT every 2 weeks to ensure current updates are installed.	

Table 1. Eligible Patient Visits Converted to Treatment-at-Home*

	Total Visits Eligible	Licensed Independent Practitioner Agreed	Patient Agreed	Insurance Approved	Visits Completed
TOTAL	Visits: 54 Patients: 32	Visits: 51 Patients: 26	Visits: 30 Patients: 15	Visits: 13 Patients: 6	Visits: 11 Patients: 6

*2 insurance-approved visits were not completed, 1 because the patient had COVID-19 and 1 because the patient was not home when the nurse arrived.

Table 2. Reasons That Patients Declined Home Administration

REASON	PATIENTS
Didn't want anyone to go to their home	1
Has other onsite appointments	1
Preferred to be on site	4
Declined without providing a reason	5

(*Continued from page 48*)

Patient Time and Cost Savings

The median self-reported patient commute to Memorial Sloan Kettering was 65 minutes (range: 45 to 85 minutes), and median wait time for intramuscular and subcutaneous therapies was 33 minutes from check-in to receipt of treatment. Injections in the home took a median of 15 minutes of patient time, decreasing total patient time by 83 minutes. The median transportation cost saved per patient was $5.50.

Copays

Memorial Sloan Kettering absorbed copay costs during the pilot to reduce barriers to care during the public health emergency, with a median copay of $30 (range: $3.00 to $2,277.28).

RN Time

RNs required a median of 120 minutes to provide a home administration; most of this was travel time (Table 3).

Discussion

The recent National Cancer Plan highlights challenges to ensuring high-quality cancer care delivery, including high treatment cost and socioeconomic and cultural barriers that prevent timely access to care. Additionally, the plan calls for research in cancer care delivery innovation to overcome these barriers.[7] One large study of cancer treatment in the home reached its feasibility end points, but studies where barriers prevented successful implementation must also be reported.[3]

Our feasibility study failed to meet its end point of converting 40 visits from in-clinic to at-home administration. For over half of eligible visits, the pharmacy benefit would not cover a take-home prescription or in-home administration. For in-home care programs to succeed, these administrative burdens must be lifted. Regulators should also consider how to foster continued experimentation to support the challenges identified by the National Cancer Plan.

Utilizing existing nurses for the pilot was difficult. Travel for in-home care required a median of 2 hours, which was unsustainable at scale. We are evaluating in-home self-administration of subcutaneous and intramuscular antineoplastics to potentially lower cost and ease personnel, administrative, and licensing barriers. However, not all patients can self-administer, and some drugs have safety concerns; alternative approaches to allow injections at home that can be administered by clinicians or caregivers must be considered.

Limitations

There are several study limitations, including its size and conduct at a single institution. Though we evaluated subcutaneous and

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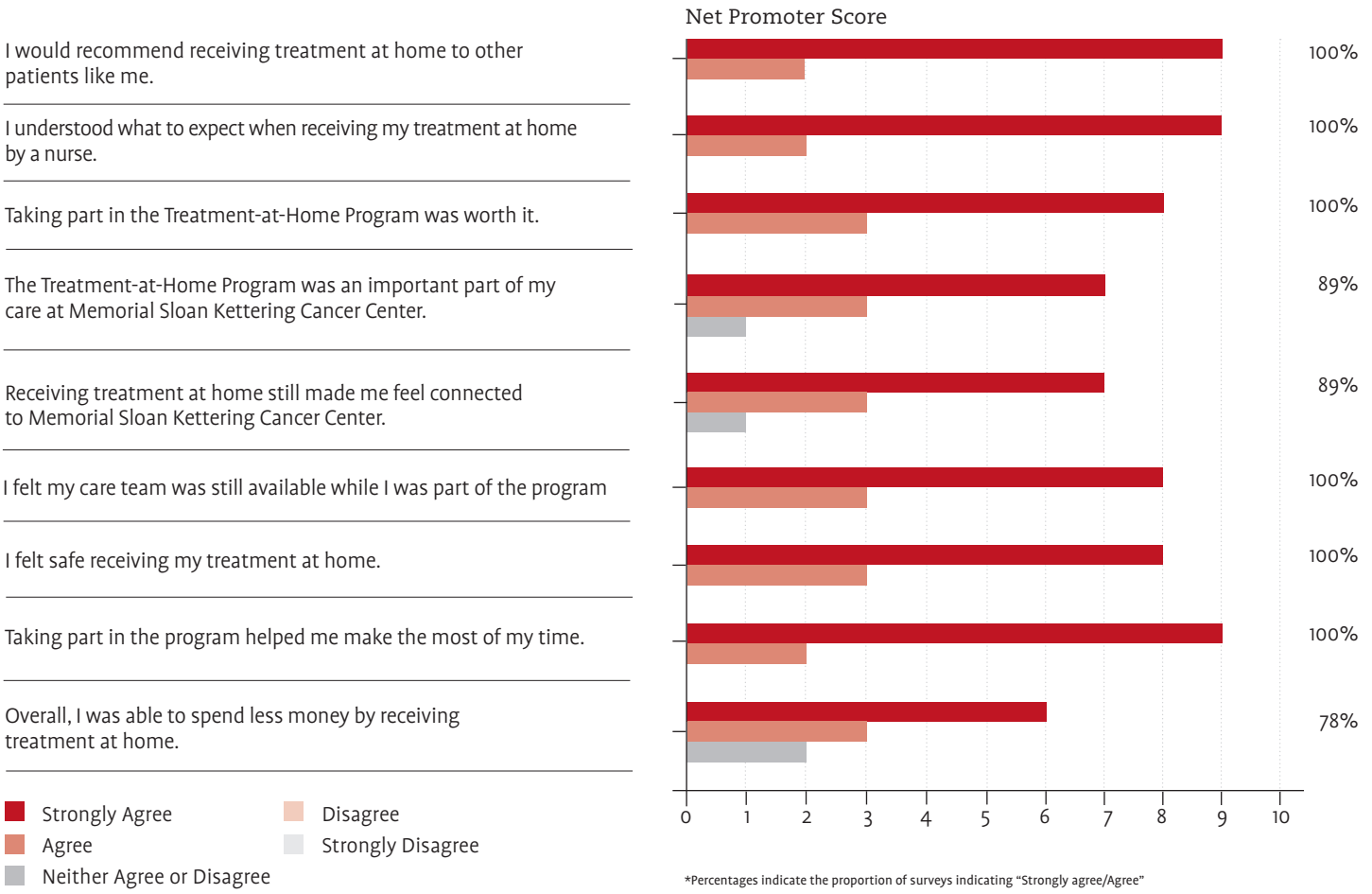
Figure 4. Patient Satisfaction With At-Home Treatment (n = 11 responses)*



*Percentages indicate the proportion of surveys indicating "Strongly agree/Agree"

Table 3. Nursing Time Spent During Home Visit

#	Patient	Date of Visit	Time Spent Outside of Cancer Center	Time Spent in Patients' Home
1	Patient #1	04/08/2022	1:15	0:30
2	Patient #2	06/23/2022	2:00	0:15
		07/21/2022	1:45	0:15
		09/12/2022	2:00	0:15
3	Patient #3	04/29/2022	2:00	0:25
		07/11/2022	2:00	0:15
		08/10/2022	2:00	0:15
		09/07/202	2:30	0:15
4	Patient #4	10/14/2022	2:00	0:25 (translation services)
5	Patient #5	10/14/2022	2:30	0:15
6	Patient #6	9/19/2022	2:00	0:15
		Total Hours	**19:00**	**3:20**

(*Continued from page 51*)
intramuscular antineoplastics, other agents might have more favorable pharmacy benefit approval processes. The patient's insurance status should be an important future consideration. Out-of-pocket costs vary greatly by primary payer, secondary insurance status and coverage, retail pharmacy coverage, and whether deductibles or out-of-pocket caps have been met. We observed wide variability in copayments. In addition, though ideal from a clinical safety profile, many eligible patients (38%) chose not to participate. Interestingly, as reflected in the patient testimonials, our urban location might have precluded some patients from participating given the small size of many New York City apartments, where personal space is prized. A larger catchment area where patients faced more time constraints and financial toxicity to a face-to-face encounter may have benefited the pilot.

Conclusion

As oncologic therapeutics evolve from intravenous to oral and subcutaneous formulations (eg, immunotherapies) the need for untethered oncology care will broaden.[8] Patients prefer subcutaneous therapies, and these formulations reduce resource utilization and improve tolerability and health-related quality-of-life outcomes. We found high patient satisfaction with home administration, but regulatory barriers impaired our ability to realize these benefits and deliver on the goals of the National Cancer Plan.

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INSTITUTE FOR COMPREHENSIVE CANCER CARE SERVICES

The Centers for Medicare & Medicaid Services Will Pay for Patient Navigation—Now What?

INSTITUTE FOR COMPREHENSIVE CANCER CARE SERVICES

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The Centers for Medicare & Medicaid Services Will Pay for Patient Navigation—Now What?

In Brief

Following decades of research demonstrating the efficacy of patient navigation on clinical and patient-reported outcomes, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that pays for patient navigation and navigation-related services effective January 1, 2024. This article reviews the new codes to reimburse for principal illness navigation (PIN) services, social determinants of health (SDOH) assessment, community health integration, and PIN-Peer Support (PIN-PS). A description of the codes, how to use them, who can perform services, and next steps for the field are reviewed.

The evidence is overwhelming that patient navigation improves access to care and health outcomes for patients with cancer. Following decades of research demonstrating the efficacy of patient navigation on clinical and patient-reported outcomes,[1-4] on November 2, 2023, CMS issued a final rule announcing a change to Medicare payments effective January 1, 2024.[5] Published on November 16, 2023, the calendar year (CY) 2024 payment policies under the Medicare Physician Fee Schedule (MPFS)[5] allow for payment for PIN services under Medicare Part B that were provided by auxiliary health care staff working under a qualifying billing practitioner to help those affected by cancer and other serious illnesses.

Under the new rule, health care support staff, such as community health workers, patient navigators, and peer navigators, can now be reimbursed for their time supporting patients with "serious, high-risk disease"[5] that is expected to last at least 3 months and require ongoing monitoring of a treatment plan. Examples of qualifying conditions include but are not limited to cancer, congestive heart failure, dementia, HIV/AIDS, severe mental illness, and substance use disorder.

What Are the New Billable Services?

CMS created new codes to reimburse for support services to assist patients with health-related social barriers that interfere with treatment adherence for cancer and other serious illnesses. The rule includes several types of reimbursement under the supervision of a qualifying billing practitioner. These include:

- SDOH risk assessment
- Community health integration (CHI) service coordination responsive to SDOH assessment
- PIN services to help patients complete a treatment plan for a serious condition expected to last at least 3 months
- PIN-PS that aligns with rigorous training, primarily for behavioral health support, such as peer-led mental health and substance use programs under the Substance Abuse and Mental Health Services Administration.[6,7]

Services that are necessary to help improve adherence to treatment plans that are typically provided by oncology patient navigators and community health workers are now reimbursable as PIN services. The rule provides a number of examples of qualifying activities, including provision and facilitation of: [5,8]

- Person-centered assessments, which involve assessing how SDOH might affect a person's health care adherence and outcomes
- Patient-driven goals of care
- Care planning
- Care coordination
- Communication, including in-system navigation and coordination of community-based care
- Health education
- Coaching and mentoring to support patient self-advocacy
- Collection of health outcomes data.

Who Can Provide Services?

CMS uses various codes for billing, including *Current Procedural Terminology (CPT)* codes for medical procedures and services and G codes for functional limitation reporting. The new G codes for PIN may be used by anyone performing these services, provided they are appropriately trained. However, CMS does not endorse any specific organization, certification process, or credential, deferring to state-based credentialing requirements where they exist.[5]

The rule defines patient navigation, "[i]n the context of healthcare," as "individualized help to the patient (and caregiver, if applicable) to identify appropriate practitioners and providers for care needs and support, and access necessary care timely…and includes identifying or referring to appropriate supportive services."[5, p. 361] While advance care planning, chronic care management, behavioral health, psychiatric care, transitional care, and home health and hospice supervision were already reimbursable services, the new codes effective January 1, 2024, are specifically for patient navigation services not previously covered.

These codes can be used by any staff performing eligible services (SDOH assessment, CHI, PIN, PIN-PS), including nurses or social workers as well as oncology patient navigators who are based in clinic or in community settings, community health workers, and other auxiliary personnel.[5-8] The codes do not specify any particular role or profession. Recognizing that social needs have a major influence on access to and completion of cancer care, the new rule provides 2 new G codes for CHI services that can be performed by appropriately trained personnel, including community health workers and navigators, to assess and address patient SDOH affecting a practitioner's ability to diagnose or treat a major illness. An initial CHI assessment by the billing practitioner (**G0023**) is required before nonclinical auxiliary staff performing follow-up CHI services can use code **G0024** as "incident to" billing under the practitioner who performed the initial assessment.[5]

How Do I Bill for Navigation Services?

To bill for PIN services, the person being navigated must have a health condition that the practitioner expects to require management for at least 3 months. PIN services can be performed by a patient navigator, community health worker, or other auxiliary staff member working on a health care team or under an agreement with a health care practice if there is a supervising practitioner. Besides physicians, clinicians that qualify as supervising practitioners vary based on state scope of practice laws for advanced practice registered nurses (APRNs) and physician assistants (PAs).[9,10] In addition to PIN services, codes for CHI services, PIN-PS, and SDOH assessment are also new (Table 1).

Documentation for CHI, PIN, and SDOH risk assessment must include time spent providing services, documentation of patient consent (which can be verbal), description of services performed, and inclusion of associated *International Classification of Diseases, 10th Revision (ICD-10) codes; ICD-10, Clinical Modification Z codes* (ie, reasons for encounters); and G codes. The initiating visit can be an office visit or an annual wellness visit.[5]

Importantly, patient consent is required for CHI and PIN services, as there is cost-sharing associated with all Medicare billing. Standard cost-sharing for Medicare is 20% after the deductible has been met. Medicare Advantage beneficiaries are responsible for coinsurance after the deductible has been met. Consent may be obtained by auxiliary personnel, including a navigator, nurse, or social worker. Only 1 practitioner a month may bill. If this provider changes, another consent must occur.[5]

CMS requires institutions to document credentialing first based on existing individual state requirements. CMS also requires documentation of sufficient knowledge for practice, which state requirements would not necessarily demonstrate.

It is important to note that these new CPT codes do *not* replace *CPT* codes for chronic care management (**99437, 99439, 99490, 99491**), complex chronic care management (**99487, 99489**), and principal care management (**99424-99427**).[5-11] These codes also do not replace health behavior assessment and intervention services that can be provided by clinical social workers and other trained mental health professionals (**96156, 96158, 96159, 96164, 96159, 06167, 96168**).

In addition to the new CHI, PIN, PIN-PS, and SDOH codes, the 2024 MPFS rule also includes *CPT* codes for group behavior training (96202, 96203), caregiver training to facilitate in-home and community-based supports (97550, 97551), and group caregiver training (975552).[5] In addition, while G0511 previously could be used for general care management from federally qualified health centers, remote patient monitoring is also acceptable as of January 1, 2024.[12]

Finally, the 2024 MPFS rule delayed any permanent decision about virtual supervision (telehealth) established under the Consolidated Appropriations Act of 2023, extending approval for telehealth services through December 31, 2024.[13]

How Much is Reimbursement?

CY 2024 rates for select codes are included in Table 1. The American Society of Clinical Oncology (ASCO) also publishes a reimbursement breakdown by for various services.[12] Given that these rates will change each CY, we refer readers to the ASCO annual updates for guidance on future reimbursement rates.[11]

Navigator Credentialing

Credentialing can be confusing. Regardless of the auxiliary health personnel title or professional role, CMS requires institutions to document credentialing first based on existing individual state requirements.[14,15]

For example, New Mexico has existing state requirements for community health worker training and practice with oversight from the New Mexico Department of Health, Office of Community Health Workers.[16,17] Community health worker certification costs about $100 and requires either: 1) completion of a specific training provided by the New Mexico Department of Health or from an approved Department of Health training partner along with field experience, or 2) 2000 hours of experience in the last 2 years plus 2 letters of reference. Although CMS does not require field experience, the State

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TABLE 1. PATIENT NAVIGATION-RELATED G CODES AND 2024 MEDICARE RATES FOR SELECT SERVICES

Code	How to Use	2024 Rate[12]	Minimum Time to Bill	Training Required
G0136	Risk assessment is based on a practitioner's reason to believe there are unmet SDOH needs; it is not intended for routine screening for patients at every visit or for every patient. It typically is not administered in advance of the visit. If conducted during an annual wellness visit, cost-sharing does not apply. If conducted at a visit for any other reason, cost-sharing applies. CMS does not require a particular tool but cites the CMS Accountable Health Communities Tool and Protocol for Responding to and Assessing Patients' Assets, Risks and Experiences (PRAPARE) as appropriate tools. This code is permanently added to telehealth visits as well.	$18.67	5-15 minutes not more than every 6 months per practitioner per beneficiary	State-based requirements OR documentation of key competency domains
G0019	CHI staff make an initial visit with assessment by a clinical health worker under the direction of a billing practitioner to document and address SDOH needs that significantly limit the ability to complete diagnosis or treatment of the chronic health condition. Examples of CHI services include person-centered care planning, health system navigation, referral and coordination to community-based resources, care coordination, and patient self-advocacy promotion.	$78.92	60 minutes (once monthly)	State-based requirements OR documentation of key competency domains
G0022	CHI staff address SDOH needs that are significantly limiting the ability to complete diagnosis or treatment of the chronic health condition after an initial assessment under supervision of a billing practitioner.	$49.45	Additional 30-minute increments (unlimited)	State-based requirements OR documentation of key competency domains
G0023	Initial person-centered assessment for PIN services; staff should assess SDOH, facilitate patient-driven goal setting, and establish an action plan for tailored support. Such support can include coordination of community-based services and care transitions, health education, patient self-advocacy skill coaching, active navigation of the health care system, facilitation of behavior change, provision of social and emotional support, mentorship, and inspiration to help patients meet treatment goals.	$78.92	First 60 minutes per calendar month (once monthly)	State-based requirements OR documentation of key competency domains
G0024	PIN services after the initial assessment is billed using G0023. Note that "incident to" billing can used for services provided by navigators working within the cancer care setting and for navigation conducted external to the cancer care setting with appropriate agreements with trained staff at community-based organizations. Clear integration of community-based services with the supervising practitioner are required for billing.	$49.45	Additional 30-minute increments per calendar month (unlimited)	State-based requirements OR documentation of key competency domains
G0140	PIN services by peers are intended for mental and substance abuse support based on training from SAMHSA.	$78.92	First 60 minutes per calendar month (once monthly)	SAMHSA standards[6]
G0146	PIN services by peers are intended for mental and substance abuse support based on training from SAMHSA.	$49.45	Additional 30-minute increments per calendar month (unlimited)	SAMHSA standards[6]

CHI, community health integration; CMS, Centers for Medicare & Medicaid Services; PIN, principal illness navigation; SAMHSA, Substance Abuse and Mental Health Services Administration; SDOH, social determinants of health.

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of New Mexico Community Health Worker Certification does require field experience within the structure of approved training programs. University- and community college-based, approved trainings have required practicums or clinical agency components.[16,17]

It is unclear whether navigators seeking to be newly credentialed in New Mexico would need field hours in addition to training if that training is obtained outside of the approved list of New Mexico Department of Health, Office of Community Health Workers, programs. Certification regulations for community health workers imply that navigators seeking to be credentialed in New Mexico must look to satisfy the state's requirement and have some field-based experience.[17,18] While a patient navigator completing the community health worker certification in New Mexico would be satisfying the minimum requirement credentialing, CMS also requires documentation of sufficient knowledge for practice, which state requirements would not necessarily demonstrate.[18,19]

Effective, consistent navigation services elevate the reputation of a cancer program or practice and can potentially save institutions money. Navigation is optimal when its delivery is cost-effective, time-efficient, and compassionate.

In another example from the state of California, Medi-Cal covers community health worker services to help control and prevent chronic, infectious, mental health, perinatal, sexual, reproductive, and other conditions with a written recommendation from a supervising practitioner.[20] California requires community health workers to share lived experience with the population being served and complete an approved curriculum that comes with a certificate of completion. Community health workers may practice for a maximum of 18 months under a supervising practitioner without a certificate of training if the community health worker can demonstrate appropriate skills and document 2000 hours of work, including paid or volunteer roles, within the previous 3 years. All community health workers must complete 6 hours of continued education training annually.[20] Unlike many other states, California also specifies that "health navigators, health coaches, community outreach workers, recovery specialists, and family support workers" fall under the same credentialing requirements as do community health workers.[21]

In states that do not specifically include "navigators" within the definition of community health workers for payment credentialing, it is currently unclear whether navigators with a more focused scope of practice are required to fulfill state-specific community health worker requirements.[22] We do know, however, that obtaining community health worker credentialing based on state requirements and documenting training in appropriate competencies for the oncology navigator role should be sufficient. Specific competencies that must be met include "patient and family communication, interpersonal and relationship-building, patient and family capacity building, service coordination and systems navigation, patient advocacy, facilitation, individual and community assessment, professionalism and ethical conduct, and the development of an appropriate knowledge base, including specific certification or training on the serious, high-risk condition/illness/disease addressed in the initiating visit."[5, p. 389] Cancer programs and practices can comply with the rule by documenting that navigators have successfully completed training that meets these competencies (Table 2).

The GW Oncology Patient Navigation Training: The Fundamentals (Principal Investigator: Pratt-Chapman) was created and maintained with support from the Centers for Disease Control and Prevention (CDC) (cooperative agreements #NU38DP004972, #5NU58DP006461, and #NU58DP007539 and has been available since 2015 at bit.ly/PNTraining. Other excellent state-based or national trainings—with or without a fee—also meet CMS training requirements.[21] Additionally, the Gallaudet University Center for Deaf Health Equity has a patient navigation curriculum for speakers of American Sign Language adapted from the GW Cancer Center Oncology Patient Navigator Training: The Fundamentals. This curriculum is currently in use for a clinical trial, but it is not yet publicly accessible.

Training to Provide Affirming Care to Priority Populations

CMS acknowledges that navigation is most effective when focused on populations that have the greatest need for support. In addition to navigation basics, CMS requires that navigators have content-specific knowledge relevant to the type of navigation services they will perform. In the ACCURE Trial,[23] for example, navigators also had critical racial health equity training. Myriad of health equity resources are available, including from the CDC's funded National Networks.[24] In addition to having a strong foundation of cancer patient navigation knowledge, a deep understanding of the community being served is critical to effectively navigating patients and families. See Table 3 for training resources on priority populations.

Training is not the only way to demonstrate appropriate expertise for a navigator's knowledge for practice. In 2008, the National Consortium of Breast Centers began providing certification for certain types of breast cancer navigation. In 2020, the Academy of Oncology Nurse & Patient Navigators (AONN+) inaugurated the Oncology Patient Navigator-Certified Generalist (OPN-CG) credential. Both credentials are helpful to document appropriate knowledge for practice in serving a specific patient population. Supplemental knowledge resources specific to cancer basics are offered from the National Cancer Institute (cancer.gov), the American Society of Clinical Oncology (cancer.net), and the American Cancer Society (cancer.org). For licensed clinical professionals, the authors anticipate that social work licensure and nurse licensure should be sufficient documentation of training given the heightened rigor of these credentials. We will collectively benefit from lessons learned and shared across navigating roles as institutions begin to pilot and roll out billing for PIN services.

Beyond Training: Navigator Professional Development, Program Implementation, and Evaluation

Training is the start, not the end, of strong navigation. Expertise in navigation requires ongoing personal and professional development from navigators eager to learn and seek out reliable information such as core competencies for community health workers[25] and oncology patient navigators,[18] as well as the Oncology Navigation Standards of Professional Practice.[19] Navigators should understand

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TABLE 2. TRAININGS OR CREDENTIALS THAT MEET CMS REQUIREMENTS FOR REIMBURSEMENT OF SERVICES

Training	Scope	Costs	How to Access	Considerations
Academy of Oncology Nurse and Patient Navigators (AONN+) – OPN-CG certification	National certification that requires successful completion of an examination and a number of years of experience.	$150	Online at aonnffl.org/renew	Currently on hold, but still valid to document appropriate training for those with the credential. Requires renewal after 3 years
American Cancer Society Leadership in Oncology Navigation (LION)	National training and certification.	$495	Online at cancer.org/health-care-professionals/resources-for-professionals/patient-navigator-training.html	Cost associated. Requires renewal every 3 years. Approximately 10 hours.
GW Cancer Center Oncology Patient Navigator Training: The Fundamentals	National training for those supporting patients of all cancer types. Certificate provided. Prepares learners for AONN+ OPN-CG certification.	Free	Online at bit.ly/PNTraining	Funded by the Centers for Disease Control and Prevention, this training aims to level set navigator knowledge. Institutions should provide supplemental context-specific and cancer-specific training tailored to the specific duties of the navigator following this foundational training. 10 hours of core requirements plus supplemental reading (estimated 17 hours total).
Patient Navigation and Community Health Worker Training	A full curriculum for patient navigators, care coordinators, and community health workers.	Varies	Sign up at Patientnavigatortraining.org (course is hybrid: in-person and online)	Requests for financial aid considered on a case-by-case basis. May not cover all required competencies for CMS billing with level 1 training only. Hours vary based on level and degree of tailoring.
Susan G. Komen Patient Navigation Training Program	National training for those affected by all cancers with additional breast cancer focused content.	Free	Online at komen.org/about-komen/our-impact/breast-cancer/navigation-nation-training-program	Originally adapted from GW Cancer Center Oncology Patient Navigator Training: The Fundamentals with additional unique content developed by Komen. Features virtual ongoing educational events and peer networking. 10 hours of core requirements plus special topics.

CMS, Centers for Medicare & Medicaid Services; GW, George Washington; OPN-CG, oncology patient navigator–certified generalist.

TABLE 3. TRAINING FOR SPECIFIC PATIENT POPULATIONS

Focused Content	Resources	Type of Resource	Scope	Additional Information
State-based requirements	ASTHO overview of state requirements	Online brief	Review of state requirements for community health worker credentialing as of June 2022.	Accessible at astho.org/topic/brief/state-approaches-to-community-health-worker-certification
Breast cancer patients	National Consortium of Breast Centers	Certification	Credential to affirm core knowledge for breast cancer for navigation.	Cost associated. Accessible at navigatorcertifications.org
	Susan G. Komen	Online training	Training aligned with CMS requirements plus additional breast cancer-specific lessons.	Free, self-paced, online. Accessible at komen.org/about-komen/our-impact/breast-cancer/navigation-nation-training -program
Black, Latino, LGBTQI people	GW Cancer Center Together, Equitable, Accessible, Meaningful (TEAM) Training	Online training	Training to assist health care teams in identifying and implementing changes to advance health equity in Black, Latino, Latina, Latinx, and LGBTQI populations.	Free, self-paced, online Accessible at bit.ly/GWCCTEAMtraining
People who use American Sign Language (eg, those who are deaf, deaf-blind, or hard of hearing)	Gallaudet University Center for Deaf Health Equity	Online training	Training specifically focused on health disparities of people who are deaf, deaf-blind, or hard of hearing.	In development; will be made available for continuing education.
Elderly persons from 13 diverse ethnic backgrounds	Stanford Internet-Based Successful Aging (iSAGE)	Online training	Training to improve quality of life and care for older persons of diverse backgrounds.	Free, but limited capacity. Includes community of practice with secure interaction forum and dialogue. Accessible at geriatrics.stanford.edu/about.html
LGBTQI persons	National LGBT Cancer Network Welcoming Spaces Training	Online training	Training to elevate cultural humility to serve LGBTQI populations.	Free, self-paced, online. Accessible at cancer-network.org/welcoming-spaces
Native American and Alaska Native persons	Native American Cancer Research Corporation	Virtual and in-person training	Education to address cultural and political issues that impact navigation across the cancer continuum for Indigenous populations.	Cost associated. Competency-based modules; include personal skills assessment. Ranges from 80-200 hours based on number of modules and tailoring. Accessible at natamcancer.org/Patient-Navigator-Training

ASTHO, Association of State and Territorial Health Officials; CMS, Centers for Medicare & Medicaid Services; GW, George Washington; LGBTQI, lesbian, gay, bisexual, transgender, queer/questioning (one's sexual or gender identity), and intersex.

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the complexities of the health sequelae and social conditions faced by their patients. Effective navigators have strong relationship- and team-building skills, assess community resources to ensure responsiveness and credibility of services, and consistently deliver navigation services to build trust with patients, caregivers, and clinicians. Effective, consistent navigation services elevate the reputation of a cancer program or practice and can potentially save institutions money. Navigation is optimal when its delivery is cost-effective, time-efficient, and compassionate. Professional development, continuing education, and mentorship are critical to supporting the health and growth of the patient navigation workforce. Finally, the scope of navigator practice should be appropriate to licensure, training, and experience.[25-27]

Successful navigation programs require strategic integration of key stakeholders and information technology (IT) support. Focused implementation of risk-stratified patient navigation responsive to specific patient populations and care contexts—as well as IT support to chart, track, and evaluate navigation—is key for optimal program impact.[28-32] Successful planning before implementation includes these 4 key steps:

- Convening IT and administrative leaders to build new G codes into the electronic health record (EHR)
- Tracking navigation activities either within or outside of the EHR
- Optimizing patient demographic data to stratify outcomes
- Piloting the billing of new codes prior to full implementation.

Early engagement of key stakeholders will improve the incorporation of patient navigation data, streamlining workflows and enhancing reporting capabilities. Recommended key stakeholders to engage include billing specialists, the compliance team, data analysts, and informatics specialists. A practical guide published by the Association of Community Cancer Centers (ACCC) that was cited by CMS in the 2024 MPFS rule provides guidance on refining the focus, models, and workflows of a navigation program.[30]

A critical part of patient navigation implementation is outcomes tracking. In the ACCURE Trial, which eliminated health outcome disparities between White and Black patients with breast and lung cancer, the navigation intervention was matched with rapid data reporting through clinical quality dashboards that allowed practitioners to see disparities in real time.[24] The GW Patient Navigation Barriers and Outcomes Tool (PN-BOT) is a free resource for case management and data tracking.[27] While this tool is limited to 1 user and is not integrated into EHRs, the software can be adapted to customize an EHR, and EHR vendors may have examples of templates that have worked to document navigation in various settings. Investments in commercial software and/or tailored EHR fields that support case management and data tracking may help navigators be most efficient and accurate with documentation critical for billing.

Next Steps for the Field

First, future research should include analyses of which states include navigators under the community health worker terminology for purposes of payment credentialing as well as the degree to which state-level requirements for community health worker credentialing fit with oncology patient navigators' scope of practice. Studies on implementing the payment codes—including barriers, facilitators, and lessons learned—will also be valuable.

Second, the workforce of community health workers and navigators cannot be sustained without skills-based pay that reflects the experience, knowledge, and expertise of those performing navigation services. Additionally, skills-based pay is essential to avoid the common paradox of an inequitably paid community health worker or health navigator who struggles to pay for basic life expenses while helping patients access much-needed resources. It also should be emphasized that the degree to which current reimbursement rates are sufficient to cover the salary and programmatic costs of providing community health worker and patient navigation services is yet to be determined. More research is needed to optimize appropriate reimbursement rates for patient support that optimally advances health equity based on patient need, navigator training and experience, and costs of providing services.

Third, while these new codes are an important step forward for navigation sustainability, cost-sharing is a real and serious limitation for patients. Based on current CMS policy, patients will need to consent to PIN services, since there will be a 20% cost-share. There is a real risk that those individuals most in need of services could decline assistance due to inability to pay. Additionally, cost-sharing will likely come as a surprise to patients who previously received navigation services free of charge. The field will benefit from research describing reasons for and extent of patient nonconsent for services and the amounts patients pay due to cost sharing. Advocacy to close the cost-share gap as well as proactive philanthropy to cover costs for needy patients should be pursued and lessons learned should be shared with the field.

Fourth, feasibility of effective caseload management that supports the health of patients and the navigation workforce should be further studied to ensure appropriate expectations.[33-36] Appropriate caseload management can be achieved using an acuity-based case weight system.[32] This system provides for equitable distribution of community health worker and patient navigator caseloads considering the navigator's time allocation based on individual patient needs, severity of illness, and social determinants. Smaller caseloads are needed for more complex navigation—such as support for patients who have been historically excluded, marginalized, stigmatized, and/or traumatized. These individuals are more likely to have significant and numerous barriers to care, necessitating more time and resources from the auxiliary health professional to find culturally-, economically-, legally-, and socially-affirming supports.

Fifth, ongoing training, support, mentorship, and counseling for navigation roles on the front line of care should be prioritized, and best practices to accommodate navigators with disabilities should

be shared and implemented. As the navigation workforce continues to professionalize, ongoing training and education should support deepening the proficiency of navigators beyond the baseline required by CMS.[27] Institutions should also seek to model supports that allow navigators to actualize their own optimal health while assisting those in need.

Finally, while payment for patient navigation is a thoughtful and laudable start to support much-needed and health-related social needs support to people affected by cancer and other serious illnesses, future research on barriers and facilitators to implementation of the new G codes for SDOH, CHI, PIN, and PIN-PS will be needed to share lessons learned for cancer programs and practices in the years to come. ■

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Additional Resources

GW School of Medicine & Health Sciences. 2021 Updates to the Oncology Patient Navigator Training.

GW School of Medicine & Health Sciences. Financial Navigation Lesson for Oncology Patient Navigators.

GW School of Medicine & Health Sciences. Patient Navigation Guide (English and Spanish) and Companion Resources.

GW School of Medicine & Health Sciences. Reducing Financial Toxicity: Tips for Patient Navigators.

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National Comprehensive Cancer Network. Evidence-based Resources for Patients and Navigators.

National Comprehensive Cancer Network. Measuring and Addressing Health Related Social Needs in Cancer: Working Group Recommendations.

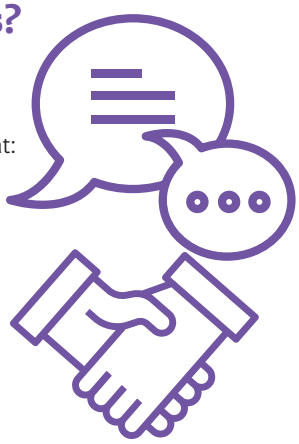
fast facts

4 Community Engagement Recommendations to Reduce Racial Disparities in Access to Cancer Care

- Reflect community demographics in practice leadership
- Use culturally and linguistically appropriate wording
- Partner formally and equitably with community-based organizations
- Develop programs based on community health needs assessments

Source. National Comprehensive Cancer Network. Health Equity Report Card.

Do Providers Need More Honest Dialogue with Patients?



A City of Hope study of patients with advanced neuroendocrine tumors found that:

- Only **30%** of patients say their top goal for treatment is living longer; **70%** of patients selected other treatment goals as most important, including maintaining the ability to do daily activities, reducing or eliminating pain, or reducing or eliminating symptoms like fatigue.
- **67%** of those surveyed agreed with the statement, "I would rather live a shorter life than lose my ability to take care of myself."
- Respondents felt that their providers were more singularly focused on extending overall survival, even if it impacted other outcomes; only **52%** of patients perceived that they had the same treatment goals as their physician.

Source. Li D, Can-Lan S, Kim H, et al. Patient-defined goals and preferences among adults with advanced neuroendocrine tumors. JNCCN. 2022;20(12):1330. doi:10.6004/jnccn.2022.7059

Nearly Half of American Women Forgo Preventive Care Services

A survey of more than 3,000 American women found nearly half (**45%**) are forgoing preventive care services like check-ups, screenings, and vaccines; the inability to afford out-of-pocket costs is the most common reason women cite for skipping this critical care. Other survey findings include:

- 3 out of 4 women (**76%**) have received a cervical cancer screening at some point in their lifetime
- White women are more likely to have received a cervical cancer screening (**81%**) than Black women (**65%**), Asian women (**66%**), and Hispanic women (**68%**)
- Women who are insured (**79%**) are more likely to have received a screening than uninsured women (**51%**)
- **72%** of women are likely to get a cervical cancer screening if it is recommended by their provider
- Only **34%** are likely to get a cervical cancer screening if it is not covered by their insurance.

Source. Alliance for Women's Health and Prevention Poll conducted online from Nov. 18-Dec. 8, 2022 by Ipsos. womenshealthandprevention.org/wp-content/uploads/2023/01/AWHP-Ipsos-Survey_Topline-Results.pdf.

5 Negative Effects of Prior Authorizations

1. ***Delayed Care***. More than 9 in 10 physicians (**94%**) reported that prior authorization delayed access to necessary care.
2. ***Bad Outcomes***. Nearly nine in 10 physicians (**89%**) reported that prior authorization had a negative impact on patient clinical outcomes.
3. ***Disrupted Care***. 4 in 5 physicians (**80%**) said patients abandoned treatment due to authorization struggles with health insurers.
4. ***Lost Workforce Productivity***. More than half of physicians (**58%**) who cared for patients in the workforce reported that prior authorizations had impeded a patient's job performance.
5. ***Patient Harm.*** 1/3 of physicians (**33%**) reported that prior authorization led to a serious adverse event for a patient in their care, including hospitalization, permanent impairment, or death.

Source. American Medical Association. 2022 AMA Prior Authorization Physician Survey. ama-assn.org/system/files/prior-authorization-survey.pdf.

What Frustrates Patients the Most About Medical Bills

- 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 responsibility—**20%**

Source. An AKASA survey conducted by You.Gov. prnewswire.com/news-releases/nearly-40-of-americans-confused-by-medical-bills-301705347.html.

more online @ accc-cancer.org

TOOL | Guideline-Based Care Plans for Providers and Patients

ACCC, in partnership with the Center for Business Models in Healthcare, is making 4R Care Sequences® available at no cost to ACCC members. These guideline-based care plans are personalized for specific patient populations at each point in care, for example, at diagnosis and during transitions between treatments. The 1-page templates are available in hard copy or electronically.

PODCAST | Beyond the Brush: Navigating Dental Care in Head & Neck Cancer

While advancements in oral medicine are improving the treatment landscape for head and neck cancer, routine dental care and preventative oral cancer screenings can help identify head and neck cancers early. This CANCER BUZZ podcast explains the proactive role dentists can play in early identification of cancer—as well as the need for equitable access to dental care—and explores how a cross-disciplinary cancer care team and patient education work in tandem to better manage complications from head and neck treatment.

PUBLICATION | Multidisciplinary Approaches to Addressing the Needs of Patients with Gynecologic Cancers

This executive summary of ACCC's September Gynecologic Oncology Summit addresses issues like care equity, gynecologic cancer awareness, social drivers of health, workforce challenges, and patient advocacy. Explore discussions held during the summit regarding barriers in the management of gynecologic cancers and potential next steps to further improve treatment of this patient population.

BLOG | Unite for HER's Vision for Equitable Cancer Care

This national nonprofit organization has spent the last 14 years enriching the health and well-being of those affected by breast and ovarian cancers. In this blog, learn how collaboration lies at the heart of its efforts. By forming strategic partnerships with hospitals, nonprofits, and advocacy groups, Unite for HER works collectively to ensure that underserved communities receive equitable access to integrative services, education, and support.

2024 ACCC Hill Day

BY CJ IKE

On February 28, a day before the ACCC 50th Annual Meeting & Cancer Center Business Summit (#AMCCBS), ACCC members traveled to Capitol Hill for the Association's first in-person Hill Day in 5 years. Understanding the importance and influence of policy to delivering comprehensive cancer care, ACCC concentrated its advocacy efforts on 4 integral issues identified by its membership and the patients they serve:

- Oncology drug shortages
- Financial toxicity
- Oncology patient navigation
- The Inflation Reduction Act.

Oncology Drug Shortages

"Therapies are so expensive, and we want to make sure we keep cancer care affordable and accessible to patients," said Sarah Hudson-DiSalle, PharmD, RPh, assistant director of Infusion Reimbursement Services at the Arthur G. James Cancer Hospital at The Ohio State University, in a conversation with Matthew Williams, correspondence manager for Senator James David Vance (R-OH). "That takes everyone, and we want to ensure we are providing solutions for the issues the cancer care continuum faces."

Dr. Hudson-DiSalle explained to Williams that in 2023, the U.S. experienced the highest rate of drug shortages in its modern history and expressed ACCC's desire to develop a solution. "We want to fix it systematically...at the root of the cause and would like to partner with Senator Vance on some initiatives."

Williams shared Dr. Hudson-DiSalle's desire to collaboratively develop initiatives that prevent or at the very least minimize the effects of future oncology drug shortages. "The system needs streamlined, coordinated communication processes...and I think we can have a fruitful relationship," Williams said.

To address the oncology drug shortage, ACCC asks that Congress use the Association's 41,000+ membership as a resource. Further, ACCC requests that Congress identify, evaluate, and propose transparent policies to address future drug shortages when they occur.

Financial Toxicity + Patient Navigation

Among The Hill Day contingent were members of the Financial Advocacy Network (FAN) sub-committee. They shared compelling stories that highlighted the effects of financial toxicity and the expressed the need for patient navigation.

Other members of the FAN sub-committee shared the value of oncology patient navigation with Members of Congress. Angie Santiago, CRCS, senior business manager, Medical Oncology, Sidney Kimmel Cancer Center at Jefferson Health, and Aimee Hoch, MSW, LSW, OSW-C, oncology financial navigator, Grand View Health Cancer Center, met with the offices of Senator John Fetterman (D-PA), and Congressman Brendan Boyle of Pennsylvania's 2ND district, to share their excitement for the new Healthcare Common Procedure Coding System patient navigation codes. These codes went into effect on January 1,

Hudson-DiSalle (left) and Williams (right).

2024, and represent a historic new level of Medicare reimbursement for patient navigation services.

Inflation Reduction Act

President Joseph Biden signed the Inflation Reduction Act of 2022 (IRA) into law on August 16, 2022.[1] The law contains multiple provisions aimed at reducing prescription drug prices and costs for patients. Further, it sought to lower prescription drug spending in the federal Medicare program. Some of the IRA's drug pricing-related provisions include:

- Medicare Part D benefit redesign with a cap on beneficiary out-of-pocket-costs
- Medicare Drug Price Negotiation Program (Medicare Part D Effective in 2026 and Part B Effective in 2028)
- Rebates to Medicare: pharmaceutical manufacturers must pay rebates to Medicare if prices for Medicare Part B or Part D rise faster than inflation.[2]

ACCC believes the IRA's Drug Pricing, Medicare Part D Benefit Redesign, and Medicare Part B and D rebate provisions have the potential to provide real savings for Medicare beneficiaries. Consequently, ACCC asks that Congress, together with policymakers at the Department of Health and Human Services and the Center for Medicare & Medicaid Services, continue to listen to healthcare providers and patients as IRA implementation moves forward.

In conclusion, ACCC members shared with their respective representatives that the Association has endorsed the Protecting Patient Access to Cancer and Complex Therapies Act (S.2764/H.R.5391). This proposed legislation seeks to mitigate the impact of any reduced Medicare reimbursement under Medicare Part B on the providers and healthcare organizations that administer such therapies—including programs serving patients with cancer. OI

CJ Ike is ACCC associate editor, Rockville, Maryland.

(Left to right) Molly Kisiel, MSN, FNP-BC, ACCC director of Clinical Content; Senator Reverend Raphael Warnock (D-GA); and Francinna Scott-Jones, CPAR, ROCC, FACCC, a financial coordinator at Northside Hospital Cancer Institute.

(Left to right) Hoch, Santiago, Senator Cory Booker (D-NJ)., and Rifeta Kajdić Hodžić, a senior program manager at ACCC.

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1. Inflation Reduction Act. U.S Department of the Treasury. Inflation Reduction Act. Accessed March 22, 2024. https://home.treasury.gov/policy-issues/inflation-reduction-act

2. CMS Releases Revised Guidance for Medicare Prescription Drug Inflation Rebate Program. Centers for Medicare & Medicaid Services. December 14, 2023. Accessed March 22,2024. https://www.cms.gov/newsroom/press-releases/cms-releases-revised-guidance-medicare-prescription-drug-inflation-rebate-program#:~:text=As%20a%20result%20of%20President%20Biden%E2%80%99s%20historic%20prescription,Medicare%20increase%20faster%20than%20the%20rate%20of%20inflation

Place of Service Codes
Key to Compliant Billing

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

Billing appropriately for services provided to oncology patients is not limited to the procedure codes themselves. In fact, key pieces of information on the claim submitted to the payer tell more of the patient story. One of these key components is the place of service (POS) code.

POS codes are 2-digit numeric characters reported on the professional component services claim; they identify the setting in which a service was provided to the patient. The national POS code set is maintained by the Centers for Medicare & Medicaid Services (CMS), but it was the 1996 Health Insurance Portability and Accountability Act (HIPAA) that outlined standards on protection of patient information and established guidelines for communication of POS codes.[1] HIPAA requirements, which went into effect October 16, 2003, apply to all covered payers and not just Medicare and Medicaid. Additionally, the Health Insurance Reform: Standards for Electronic Transactions final rule published August 17, 2000, established a standard for how to use POS codes to electronically communicate the place where services were provided to patients.[2]

The POS code is entered into box 24B of the CMS1500 claim form for services provided by the physician or another qualified health care professional. The POS code corresponds to the provider address that is credentialed with the payer and the location where services were delivered; the only exception is telehealth services as the POS, which may indicate the location of the patient relative to the qualified health care professional.

In addition to information about where the patient received services, the POS codes also contain information about payment rates. The Medicare Physician Fee Schedule establishes payment rates for professional services provided in the facility and nonfacility setting, and the POS code on the claims form identifies the appropriate payment rate. Facilities are locations such as hospitals (inpatient or outpatient), ambulatory surgical centers, and observation and emergency departments. Nonfacility settings are office-based settings (private practices) and independent diagnostic testing facilities.

When a practitioner provides services in the facility setting, the practice expense is lower than if services were provided in the nonfacility setting, this results in a lower professional payment rate. Payment is only established for the physician's work and fractions of practice and malpractice expenses. In the nonfacility setting—where physicians often own the practice, building, equipment, and supplies and directly employ staff—this additional overhead is factored into reimbursement, resulting in a higher professional payment rate.

It is possible that practitioners may provide services in multiple settings over a given date of service. When this situation occurs, separate claims for each POS must be submitted to the payer. It is also common for oncology patients to receive inpatient care in the hospital but receive medical or radiation oncology outpatient services in either the hospital outpatient department (outpatient provider-based department) or office-based setting. When this situation occurs, billers must remember that the hospital status follows the patient. So, for example, the claim billed to the payer for professional services when a patient is transported to the outpatient department or outpatient office setting will use the inpatient **POS code 21** for inpatient or **POS 31** for skilled nursing facility and not the outpatient POS code. Services provided are paid at the facility rate even though the patient may have been treated in the nonfacility office setting. This rate is based on how hospitals bill for inpatient services under the diagnostic-related group (DRG) with all provided services paid under a single payment per the assigned DRG. (Please note that the transfer agreement between the nonfacility setting and facility setting [inpatient hospital] should outline the payment for the technical services provided to the patient. This process is reviewed in Chapter 26 of the *Medicare Claims Processing Manual*.[3])

Additionally, since November 2, 2015, outpatient provider-based departments are recognized based upon 2 factors. The first is how long the outpatient provider-based department has been established with CMS; the second is how close the outpatient provider-based department is to the main building of the hospital. Any outpatient provider-based department within 250 yards of the main hospital building is considered an on campus-outpatient hospital **(POS 22)**. Outpatient provider-based departments more than 250 yards from the main hospital building are considered off campus-outpatient hospitals **(POS 19)**. In both settings, the practitioner is paid at the facility rate; however, payment for technical services may vary based on payment policy.

Telehealth POS codes also result in some reporting variances, and they may change again following the end of the waivers and extensions that are effective through December 31, 2024. For example, **POS 02** is recognized for Medicare claims adjudication when the patient is located

somewhere that is not their home. Typically, **POS 02** indicates an originating site, which is considered to be a facility setting; any practitioners providing services to patients in this location while physicians are in their office will be paid at the facility rate. **POS 10** identifies that patients were located in their homes when services were provided. Physicians providing services from their office location will report **POS 10**, and they will be reimbursed for services at the nonfacility rate.

Table 1 outlines some of the available POS codes most commonly used by oncology providers. The full list can be accessed on the CMS website.[4]

Ensuring accurate reporting of services, providers, diagnoses, quantities, dates of service, and place of service codes are all components of health care reimbursement. Each component is a layer that works in tandem to report the whole picture. This interconnection also serves as a reminder to billers and coders that sometimes the smallest action can impact the bottom line. Ensuring that staff responsible for billing and submitting claims are educated about the most up to date and current payment policies is key to compliance.

Teri Bedard, BA, RT(R)(T), CPC, is executive director of client and corporate resources at Revenue Cycle Coding Strategies in Des Moines, Iowa.

Table 1. POS Codes Most Commonly Used by Oncology Practitioners

Place of Service Code(s)	Place of Service Name	Place of Service Description
01	Pharmacy*	A facility or location where drugs and other medically related items and services are sold, dispensed, or otherwise provided directly to patients. (Effective October 1, 2003.)
02	Telehealth provided other than in patient's home	The location where health services and health-related services are provided or received through telecommunication technology. Patient is not located in their home when receiving health services or health-related services through telecommunication technology. (Effective January 1, 2017; description change effective January 1, 2022, and applicable for Medicare April 1, 2022.)
10	Telehealth provided in patient's home	The location where health services and health-related services are provided or received, through telecommunication technology. Patient is located in their home (which is a location other than a hospital or other facility where the patient receives care in a private residence) when receiving health services or health-related services through telecommunication technology. (Effective January 1, 2022; available to Medicare April 1, 2022.)
11	Office	Location, other than a hospital, skilled nursing facility, military treatment facility, community health center, State or local public health clinic, or intermediate care facility, where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
13	Assisted living facility	Congregate residential facility with self-contained living units providing assessment of each resident's needs and on-site support 24 hours a day, 7 days a week, with the capacity to deliver or arrange for services including some health care and other services. (Effective October 1, 2003.)
19	Off campus-outpatient hospital	A portion of an off-campus hospital provider-based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Effective January 1, 2016.)
20	Urgent care facility	Location, distinct from a hospital emergency room, an office, or a clinic, whose purpose is to diagnose and treat illness or injury for unscheduled, ambulatory patients seeking immediate medical attention. (Effective January 1, 2003.)

(Table continues on next page)

(Continued from previous page)

Place of Service Code(s)	Place of Service Name	Place of Service Description
21	Inpatient hospital	A facility, other than psychiatric, which primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by, or under, the supervision of physicians to patients admitted for a variety of medical conditions.
22	On campus-outpatient hospital	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Description change effective January 1, 2016.)
23	Emergency room-hospital	A portion of a hospital where emergency diagnosis and treatment of illness or injury is provided.
24	Ambulatory surgical center	A freestanding facility, other than a physician's office, where surgical and diagnostic services are provided on an ambulatory basis.
31	Skilled nursing facility	A facility which primarily provides inpatient skilled nursing care and related services to patients who require medical, nursing, or rehabilitative services but does not provide the level of care or treatment available in a hospital.
32	Nursing facility	A facility which primarily provides to residents skilled nursing care and related services for the rehabilitation of injured, disabled, or sick persons, or, on a regular basis, health-related care services above the level of custodial care to other than individuals with intellectual disabilities.
34	Hospice	A facility, other than a patient's home, in which palliative and supportive care for terminally ill patients and their families are provided.
72	Rural health clinic	A certified facility which is located in a rural medically underserved area that provides ambulatory primary medical care under the general direction of a physician.
81	Independent laboratory	A laboratory certified to perform diagnostic and/or clinical tests independent of an institution or a physician's office.

*Revised; effective October 1, 2005

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A Purpose-Driven Visit to Puerto Rico

BY DOUGLAS FLORA, MD, LSSBB, FACCC

Marking its 50th anniversary, the Association of Cancer Care Centers (ACCC) finds itself at a significant crossroads, commemorating a history rich with advancements in oncology while looking forward to a future filled with potential. This golden jubilee is more than a moment of celebration; it is a reaffirmation of our deep-seated commitment to ensuring access, advocacy, education, and equity in cancer care across all communities. Our network spans over 2,100 member programs, ranging from small practices to comprehensive cancer centers, embodying a collective strength and diversity that drives our mission towards a future where equitable cancer care is a universal reality.

A Purpose-Driven Visit to Puerto Rico

This year, ACCC's leadership journeyed to Puerto Rico, aiming to connect with pioneering institutions and learn from their experiences in providing exceptional care under challenging circumstances. In Puerto Rico, a territory where 3.2 million Hispanic citizens reside, with an additional 5.8 million Puerto Ricans living in the mainland US, the landscape of cancer care is uniquely comprehensive, spanning private, federal, and public health systems. Facilities such as the Veterans Hospital, Hospital Oncológico Dr. Isaac González Martínez, Auxilio Cancer Center, and HIMA Cancer Center, along with the Centro Comprensivo de Cáncer de la Universidad de Puerto Rico (University of Puerto Rico Comprehensive Cancer Center), highlight the region's commitment to oncologic excellence.

"The ACCC delegation site visit continues to reap rewards. From this visit, I connected my colleague, Yhana Chavis, DO, a PGY3 radiation oncology resident, with Dr. Padilla and others I met in San Juan. As a result, Dr. Chavis will be working with a team of radiation oncologists on a rotation in Puerto Rico."

DAVID PENBERTHY, MD, MBA
ACCC PRESIDENT, 2022-2023

Despite facing economic and systemic challenges, Puerto Rico's health care professionals maintain standards on par with the largest cancer programs in the US, exemplifying remarkable expertise and dedication. However, the journey to provide consistent, accessible care is fraught with obstacles, including a fragmented health care system and the lingering effects of Hurricane Maria's devastation in 2017. Yet, the resilience and collective effort to overcome these challenges are truly inspiring.

An ACCC delegation (left) had the fantastic opportunity to tour facilities in San Juan, including the Centro Comprensivo de Cáncer de la Universidad de Puerto Rico. The tours revealed a

profound dedication to patients—from cutting-edge offerings like phase 1 clinical trials, PET/CT imaging, da Vinci robotic surgery, and comprehensive radiation oncology, to grassroots community outreach spanning the entire island.

Innovative Collaborations Leading the Way

The establishment of PanOncology Trials in 2018, in partnership with Hospital Oncológico Dr. Isaac González Martínez, represents a significant stride toward expanding clinical trial access in Puerto Rico. This collaboration has not only increased the availability of clinical trials but has also fostered a network of medical professionals dedicated to transforming patient care across the island. With units now in Mayagüez, Cayey, Dorado, and San Juan, and plans for further expansion, PanOncology exemplifies a successful model for decentralizing clinical trials, ensuring that innovative treatments are accessible to a broader patient population.

We extend our deepest gratitude to Marcia Cruz-Correa, MD, PhD, AGAF, FASGE, (bottom right picture, far right) and her team for their invaluable contributions to cancer care in Puerto Rico. Their work with PanOncology and the broader oncology community stands as a testament to what can be achieved through dedication, innovation, and a commitment to serving all patients with the highest standards of care. Their efforts are a source of inspiration for ACCC and its members as we strive to fulfill our mission.

The insights gained from this visit have profoundly impacted our understanding and approach to cancer care advocacy and delivery. Witnessing firsthand the seamless integration of high-quality care, advanced research, and community outreach in Puerto Rico has provided us with a clearer vision of how to address the challenges faced by patients with cancer and their health care providers. It underscores the importance of fostering collaborations that extend beyond traditional boundaries, ensuring that every patient—regardless of their geographic location or socioeconomic status—has access to the best possible treatments and support.

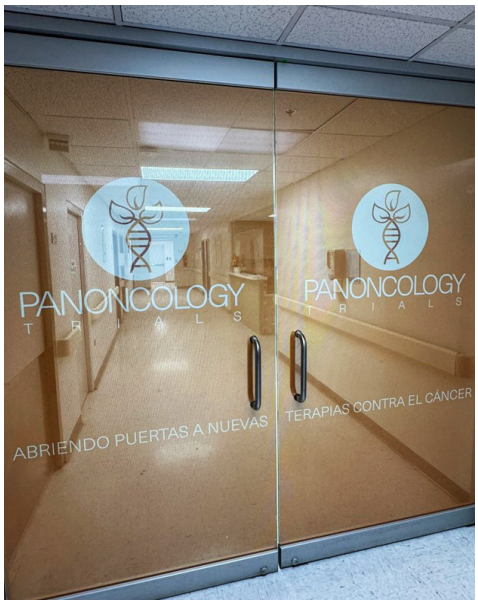
Looking to the Future

The example set by our colleagues in Puerto Rico will continue to guide and inspire our efforts. Their ability to provide world-class cancer care amidst economic challenges and natural disasters is a powerful reminder of the resilience and potential within the oncology community. It encourages us to think creatively, act compassionately, and work tirelessly to break down barriers to care.

In this moment of reflection, celebration, and renewed purpose, ACCC is more committed than ever to advancing its mission. Our journey to Puerto Rico is just one step in a broader endeavor to ensure that cancer care is defined by its excellence, inclusivity, and impact on patients' lives. We are invigorated by the challenges and opportunities that lie ahead and are dedicated to continuing our work with the same passion and dedication that have characterized ACCC for the past 50 years.

As we move forward, let us carry the lessons and inspirations from Puerto Rico with us, working together to shape a future where every individual facing cancer can do so with the highest level of support, care, and hope. Our journey toward improving cancer care for all is ongoing, and together we can make a significant difference in the lives of patients, families, and communities worldwide.

ACCC invites all members and the broader cancer care community to join us in this vital mission. Together, we can build on the foundation laid by pioneering efforts in Puerto Rico and beyond, striving for a world where the intersection of love and science defines the cancer care experience for everyone. OI



"The cancer care teams [in Puerto Rico] have worked hard to be trustworthy to their patients and communities, and it shows. The community is their advocate and raises significant funds to support the cancer program and the expansion of cancer services. There is much to be learned from—and be inspired by—our incredible colleagues in Puerto Rico."

NADINE J. BARRETT, PHD, MA, MS
ACCC PRESIDENT, 2024-2025

Douglas Flora, MD, LSSBB, FACCC, is ACCC Treasurer and Executive Medical Director, Oncology Services at St. Elizabeth Healthcare in Edgewood, Kentucky.

Maroone Cancer Center Cleveland Clinic Weston,Florida

Since its inception in 1921 as a not-for-profit multispecialty group practice, Cleveland Clinic has been at the forefront of modern medicine. Founded by George Crile Sr, MD; Frank Bunts, MD; William Lower, MD; and John Phillips, MD, the institution was established with a mission to provide exceptional patient care, conduct groundbreaking research, and educate future generations of medical professionals. The inaugural dedication of its offices on February 26, 1921, featured a keynote address by renowned physician William Mayo, MD, setting the stage for a legacy of innovation and excellence.

Over the past century, Cleveland Clinic has evolved from a small outpatient clinic into an integrated international health system. With more than 65,000 providers spread across over 200 locations worldwide, the institution now serves nearly 6 million patients annually. Among its notable expansions is the establishment of the Maroone Cancer Center in Weston, Florida, in 2015, which has emerged as a comprehensive cancer center under the leadership of its director, Zeina A. Nahleh, MD.

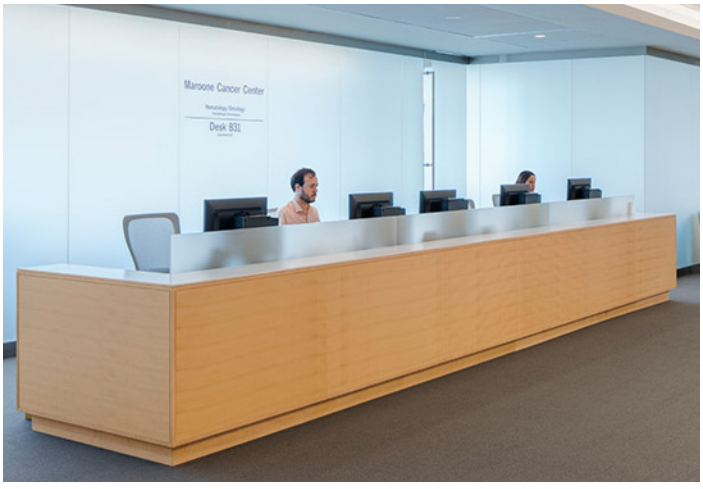
Dr. Nahleh, a breast oncologist and chair of the Department of Hematology-Oncology at the Maroone Cancer Center, brings a deeply personal understanding of patient care to her role. Born and raised in Beirut, Lebanon, amidst civil unrest, she recognized early on the importance of empathy and sensitivity in delivering cancer care. This patient-centered ethos lies at the heart of the cancer center's mission, where every individual's well-being is prioritized above all else in the delivering of hematology, medical, radiation, and surgical oncology services.

Delivering Patient-Centered Care

"We pride ourselves on providing the best experience because we constantly focus on a patient-centered approach," Dr. Nahleh said. "We have a great culture here at Cleveland Clinic, Maroone Cancer Center, because we have built a team of professionals who do care and who are passionate, and that is something you don't find everywhere."

The Maroone Cancer Center's designation as a Center of Excellence by the Florida Department of Health in 2022 underscores its commitment to delivering exemplary cancer care. According to Dr. Nahleh, the designation was created in 2013 by the Florida Legislature and recognizes hospitals and treatment centers that demonstrate excellence in delivering comprehensive, patient-centered care for patients receiving anticancer treatment in Florida.

"We are 1 of 6 programs with this designation," she said. The center also boasts accreditations from the American College of Surgeons (ACS) Commission on Cancer, the American College of Radiation Oncology, and the College of American Pathologists. "We have also been accredited by the National [Accreditation] Program for Breast Cancer[s], and the National [Accreditation] Program for Rectal Cancer," (both administered by ACS) Dr. Nahleh said. She



believes that these accreditations exemplify the cancer center's unwavering commitment to upholding the highest standards of care, as does their patient intake process and practice layout.

"Patients come to us through many channels and the main one is the call center," Dr. Nahleh explained. "We focus on 2 main goals when it comes to patient access. First, we like to book an appointment for all the new patients with cancer within 7 days. The other [initiative] is called *appointment when wanted*. For all patients with cancer, we try to closely fit their preferred time and date." Dr. Nahleh believes urgency is key in delivering comprehensive cancer care, to ensure patients maintain a positive outlook on treatment. "We make sure we [providers] are accessible, because patients with cancer are very anxious, and they want to make sure they get in as soon as they are diagnosed," she said. "If you delay treatment, the outcome is not the same."

Delivery Care That Is Convenient

Through the doors of the Maroone Cancer Center, patients will find a layout built to maximize their convenience. The radiation oncology department is located on the first floor and offers a wide range of treatments, such as advanced and precise stereotactic radiotherapy, using state-of-the-art technology that boasts submillimeter precision and real-time tumor monitoring. In addition, the department offers image-guided radiotherapy services, a specialized CT simulator, 4D treatment planning, and high-dose-rate radiotherapy. The second floor houses support services, administrative, and research, while the infusion clinic is on the third level.

"Our infusion clinic has a dedicated pharmacy and 36 infusion chairs. There are currently plans to add 10 more," Dr. Nahleh said. "It is important that patients don't have to go to different buildings or places to get the care they need."

The cancer center is organized based on specialty, as they have 10 disease-specific cancer teams. According to Dr. Nahleh, each team is staffed with an expert in their field as Maroone Cancer Center's 200-person physician and nonphysician staff—all of whom are employed by the cancer center—work in multidisciplinary teams. This includes providing patients with tailored support services as they navigate the cancer care continuum.

"We have established several support services that are geared toward improving the mental and physical health of the patient," Dr. Nahleh said. "Our navigators are subspecialized; [care] is not just one-size-fits-all."

Support Services and Clinical Research

The cancer center provides patients access to social workers, genetic counseling, a wig boutique, a patient education center, a book club, art and music therapy, massage therapy, and an in-house psychologist. All services are available in person or virtually, and Dr. Nahleh believes they provide patients with an environment of healing.

In addition to an expansive array of psychosocial care options, the Maroone Cancer Center remains at the forefront of cancer research, with over 35 active clinical trials spanning various diseases. "We started a vaccine trial for head and neck cancer, which is amazing because patients are responding positively," Dr. Nahleh said. "We also engage in quality-of-life outcome[s] research." All patients are screened for available clinical trials by a research team that shares their findings during weekly subspecialty tumor boards.

According to Dr. Nahleh, meeting the standard of care that Maroone Cancer Center prides itself on has not been devoid of challenges. However, she credits the resiliency of its staff with ensuring that patients receive the best care possible. "We strive for excellence in quality care but also [in our] service," she said. "Despite many challenges, we have stayed focused on our mission of providing the best patient experience. We are a resilient program, always growing and innovating, steadfast in our mission to provide the best experience for every patient we serve." OI

ACCC 50th Annual Meeting & Cancer Center Business Summit

Galvanized by a productive February 28 Capitol Hill Day, ACCC members convened in Washington D.C. on February 29 for the second day of #AMCCBS. Through a compelling keynote address, general sessions, deep dive workshops, and many networking opportunities, attendees explored cutting-edge solutions to persistent challenges in the oncology landscape.

The day began with an address from members of ACCC leadership, as they shared their excitement for the Association's rebranding. "Words matter, and our new name [the Association of Cancer Care Centers] truly reflects who we are and where we are going," said ACCC president-elect, Nadine J. Barrett, PhD, MA, MS, senior associate dean for Community Engagement and Equity in Research at Wake Forest University School of Medicine and Atrium Health and associate director, Community Outreach and Engagement at Wake Forest Comprehensive Cancer Center and Levine Cancer Institute. "It is exciting how much the organization has grown, and I am looking forward to the next 50 years."

Building on Dr. Barrett's insight, ACCC president Olalekan Ajayi, PharmD, MBA, chief operating officer at Highlands Oncology Group, PA, said, "Over the coming weeks you will witness updates to the ACCC branding and communications as we implement this change seamlessly. As president and president elect of ACCC, Nadine and I would like to thank you for your support, and we look forward to the future."

As the leading education and advocacy organization for the cancer care community in the United States, ACCC's history in the past half-century has been built on pioneering innovations. These accomplishments were highlighted in an evocative video presentation that drew a rousing applause from attendees.

Empathy & The Oncology Workforce

"It is an incredible honor to be here with you today," Mila Felder, MD, FACEP, enterprise vice president, Well-Being for All Teammates at Advocate Health, said to begin her keynote address. "I was moved as I listened to the incredible video documenting how you all in the community, small or big, work to deliver comprehensive cancer care...in the next 40 minutes, I will give you a little path on improving your organizational wellbeing."

Through a series of carefully curated pieces of art created by clinicians, Dr. Felder illustrated to the audience that clinicians are much more than their job description. Even in the current health care landscape—inundated by workforce shortages, burnout, and workplace violence. "Workplace violence is not normal, even though members of the multidisciplinary cancer care team try to downplay it," she said. "Let's create a health care culture that embraces our humanity."

According to Dr. Felder, the idea of "embracing our humanity" begins with health care professionals caring for each other as they care for their patients. "Ask yourself, how can I support me and my team, so we are not only here to save the world, but enjoy the day?"

Further, Dr. Felder advises that health care workers remember what "grounds them to where they come from." For Dr. Felder, it is her journey as an immigrant who had to leave her family to pursue a career in medicine. It is the pain of losing her 17-year-old daughter following a long-drawn-out illness. Dr. Felder believes these experiences connect her to both sides of the care continuum—understanding the trauma of the patient, and the resiliency of the physician.

"I have held the hand of the patient who died when I was a medical student, and I have held the hand of the parents who lost their child like

Olalekan Ajayi, PharmD, MBA, chief operating officer at Highlands Oncology Group, PA.

Mila Felder, MD, FACEP, enterprise vice president, Well-Being for All Teammates at Advocate Health.

Research and Clinical Trials #AMCCBSM deep dive.

Attendees asked questions and participated in lively interactive discussions in the #AMCCBS deep dives.

EHR Integration: A Key Component to Precision Medicine #AMCCBS deep dive.

Left to right: ACCC president-elect Una Hopkins, RN, FNP-BC, DNP, FACCC; 2020–2021 ACCC president Randall A. Oyer, MD; 2023–2024 ACCC president Olalekan Ajayi, PharmD, MBA, FACCC; and 2021–2022 ACCC president Krista Nelson, MSW, LCSW, OSW-C, FAOSW.

I did," she said. Her story is what makes her human, and she argues organizational well-being can be improved by cancer programs and practices capturing that essence in their daily activities. "I hope that our time together has inspired you to bring back that community and sense of belonging at your organization," Dr. Felder concluded.

Diving Deep into Cancer Care Challenges

Back by popular demand, ACCC hosted 8 deep dive workshops throughout the day, allowing invited expert facilitators and attendees to partake in interactive conversations. These workshops aimed to identify challenges ACCC members are experiencing and brainstorm practical solutions to mitigate or resolve them. Areas of focus included:

- Collaborative Care Delivery Models
- Research and Clinical Trials
- Payer, Manufacturer, and Supply Challenges
- EHR Integration: A Key Component to Precision Medicine
- Artificial and Business Intelligence Technology
- Community Engagement in Cancer Education and Prevention
- Oncology Workforce Challenges

Discussion from these workshops will be captured and used to develop a comprehensive report for ACCC-members post-conference, scheduled for publication in the Volume 39, Number 3 *Oncology Issues*.

The 2024-2025 ACCC President's Theme

The final day of #AMCCBS on March 1, began with the ACCC House of Delegates meeting and the announcement of Nadine J. Barrett, PhD, MA, MS, senior associate dean for Community Engagement and Equity in Research at Wake Forest University School of Medicine and Atrium Health and associate director, Community Outreach and Engagement at Wake Forest Comprehensive Cancer Center and Levine Cancer Institute, as the 2024–2025 ACCC president.

"As the incoming ACCC president, I am excited to announce my theme: *Reimagining Community Engagement and Equity in Cancer*," Dr. Barrett said. "With this theme, I am encouraging all of us as ACCC to ensure that the work we are doing engages our community's and puts our patients at the center as we continue to move forward in advancing equity in cancer."

Award Presentations

Following the ACCC House of Delegates Meeting, attendees heard presentations from the 2024 ACCC Award winners. The Clinical Research Award, which recognizes individuals whose research has significantly and positively impacted the oncology patient, family, and/or community was presented to Robert Winn, MD, director, and Lipman chair in Oncology, VCU Massey Comprehensive Cancer Center.

"Dr. Winn walks the walk, all day, every day, with his commitment to advancing equity. He ensures that we look at our patients and our communities as experts in their own right," Dr. Barrett said. "I am truly humbled to introduce and welcome up to the stage, my friend, my colleague, and my champion, our champion for the cause, Dr. Robert Winn."

"I want to thank ACCC for all the work that you do," Dr. Winn said as he accepted the award. Then he asked the audience an important question: Why the need for change and why now? "It is easy to figure out why folks don't trust us. They see all these organizations working to eradicate cancer, and they don't feel included in the process," he said. "If you want to change a system, don't just do something different, do a different thing."

It is difficult to care for a community that experiences medical mistrust. Dr. Winn believes trust is built by creating informed, collaborative partnerships, in which the patient is respected as an equal and expert. "ACCC allows us to do a different thing," Dr. Winn said. "Our organizations need to have a different type of talk, not about what will be taken, but what will be brought to the table."

Regarding the issue of trust, Dr. Winn argues that the cancer care community has been asking the wrong question. "The question should not be how do we get trust, but how do we as an institution become more trustworthy," he said. Dr. Winn believes trust is especially important in recruiting clinical trial participants. "We have to rethink how we are conducting clinical trials," he said. "We must recognize blind spots, reflect, and figure out how we can do better."

Dr. Winn reminded a captivated audience that while health care workers discuss medical illiteracy among their patients, they too must be aware of their own community illiteracy that needs to be addressed. "What if we do a

Association of American Cancer Institutes (AACI) president Robert Winn, MD, and ACCC president Nadine J. Barrett, PhD, MA, MS.

Left to right: ACCC president Nadine J. Barrett; ACCC immediate past president Olalekan Ajayi; Dr. Christa M. Braun-Inglis; ACCC executive director Christian Downs, JD, MHA; and ACCC president-elect Una Hopkins, RN, FNP-BC, DNP, FACCC.

Katherine A. Meese, PhD, assistant professor, Department of Health Services Administration at the University of Alabama at Birmingham.

different thing by training the next generation [oncology workforce] to not only know about the science of clinical trials, but about the communities they take place in," he said. "Our organizations need to realize that while we exist, we exist as a group. If we start having a different conversation within our communities, what will be possible?"

In concluding his address, Dr. Winn shared his optimism for the future of community engagement across the cancer care continuum and left attendees with a call to action. "Let us remember that through grace and humility, there is power. We are much more powerful together than we are separate."

The David King Community Clinical Scientist Award, which recognizes individuals who have demonstrated leadership in the development, participation, and evaluation of clinical studies and/or active in the development of new screening, risk assessment, treatment, or supportive care programs for patient with cancer was presented to Christa M. Braun-Inglis, DNP, APRN, FNP-BC, AOCNP, nurse practitioner and assistant researcher at the University of Hawaii Cancer Center.

"Thank you to everybody at ACCC, who thought enough of me to receive this award," Dr. Braun-Inglis said upon accepting the award. Like Dr. Winn, Dr. Braun-Inglis highlighted the importance of engaging the community in clinical research and trials. Further, she finds that advanced practice providers add value to clinical research teams in all aspects of clinical trials. Thus, cancer programs and practices must reassess the lens through which they view clinical research staff.

Improving Leadership

The second keynote address at #AMCCBS was delivered by Katherine A. Meese, PhD, assistant professor, Department of Health Services Administration at the University of Alabama at Birmingham. Dr. Meese shared insights on how leaders can strengthen their workforce by focusing on "the human margin." According to Dr. Meese, leaders must equip their employees with the tools to navigate independently, for as she puts it, "autonomy without skills is cruelty." Further, Dr, Meese argues that to maximize productivity, employees must understand the end goal, priorities, and values of their organization. "When they can see the map, they can get to the destination," she said.

Dr. Meese believes the benefit of clear and open communication cannot be overstated. "According to a Gallup poll, employees are 73% less likely to feel burned out at work when they strongly agree that the leadership of their organization communicates effectively with the rest of the organization," she said. "Employees are also 2.8 times more likely to be engaged when they speak with their manager regularly about their goals and progress."

To improve communication at their organizations, Dr. Meese shared these conversations starters leaders can adopt:

- I work for you, what do you want me to work on?
- What worries you the most?
- What do you find most rewarding about your work?
- What challenges are you currently facing in your work?

With the oncology workforce experiencing an unprecedented level of burnout, having these conversations must become a standard procedure at cancer programs and practices. "Seventy-five percent of healthcare executives were burned out in 2022 compared to 60% in 2018," Dr. Meese said. "The suicide rate for female physicians is 1.46 times higher and approximately 4,800 years' worth of education and training is lost to physician suicide each year."

Dr. Meese argues that these figures emphasize the importance of improving the wellbeing of the oncology workforce. "Creating a healthy workforce is not just important for meeting the broader goals of the organization but for improving the health of the community," she said. "Employees who strongly agree that their employer cares about their overall wellbeing are: 3 times more likely to be engaged, 69% less likely to search for a new job, 71% less likely to report burnout, and 36% more likely to be thriving in their overall lives."

Thus, as the broader cancer care community pushes to consistently innovate, it must ensure that those who make that possible are healthy in mind and body, to carry on the life-changing work they do. Through meetings like #AMCCBS, ACCC hopes to create an environment where that goal remains a priority. OI

ACCC Meets with Swedish Delegation

On Tuesday, March 12, Molly Kiesel, MSN, FNP-BC, ACCC director of clinical content joined Jennifer Bires, LCSW, OSW-C, CST, FACC, executive director of Life with Cancer and Patient Experience at Inova Schar Cancer Institute and newly elected member of the ACCC Board of Trustees, for a meeting with delegates from the Swedish Ministry of Health and Social Affairs. During the meeting—which happened at Inova's Life with Cancer clinic in Fairfax, Virginia—Kiesel provided an overview of ACCC's efforts to expand access to cancer care and alleviate the financial burdens on patients, highlighting recent advocacy initiatives on Capitol Hill. While Bires shared Inova's innovative approach to person-centered cancer care, with an emphasis on the invaluable psychosocial support offered by its Life with Cancer program.

This exchange of ideas and experiences between the United States and Sweden serves as a testament to the importance of global cooperation in advancing cancer care and research, which will ultimately benefit patients worldwide. ACCC expresses its thanks and gratitude to everyone at Inova Schar who made this visit possible.

One notable topic of discussion centered around the use of advanced practice providers (APPs) to expand the availability of healthcare providers—a practice integral to the multidisciplinary oncology care team in the United States. The absence of APPs in Sweden sparked interest among the delegates, with 1 expressing their admiration for the role of nurse practitioners based on prior experiences in the U.S. and a desire for a similar expansion in Sweden.

Both the U.S. and Sweden face challenges in cancer care access, albeit with different underlying causes. Sweden grapples with a shortage of oncologists as does the U.S., with the latter also confronting challenges rooted in social drivers of health, including financial barriers to the cost of treatment.[1]

A panel consisting of 4 members from the Life with Cancer program, including 2 nurse navigators, Laura Kaminski, BSN, RN, OCN, and Eva Ruiz Olivares, BSN, RN; an oncology behavioral therapist, Anna Harkins-Joseph, LCSW; and an oncology dietitian, Marion Irvin, RD, CSO, LD, CNSC, elaborated on their pivotal roles in providing continuous support to patients and their families from diagnosis to survivorship. Robust discussions ensued between the Swedish delegates and Inova staff regarding potential research opportunities focusing on the impact of psychosocial care on patient outcomes.

Stephanie Van Bebber, senior director of the Inova Schar Clinical Trials Office within the Inova Health System, provided an insightful overview of the ongoing research endeavors at the program—highlighting the expanding reach of trials into the Northern Virginia community. Van Bebber mentioned the enrollment rate of patients into cancer clinical trials at the cancer program currently stands at between 1% to 5%, but with a concerted effort to raise this figure over the next 3 years. Swedish delegates expressed a desire for all patients with cancer to be enrolled in trials, emphasizing the importance of maximizing participation rates. This aspiration aligns with several initiatives spearheaded by ACCC, such as the Just ASK training program in partnership with the American Society of Clinical Oncology (ASCO), aimed at enhancing clinical trial awareness and diversifying participation. Additionally, the ACCC Community Oncology Research Institute (ACORI)—launched under the tenure of past ACCC president, Randall A. Oyer, MD, FACC, executive medical director, Penn Medicine Lancaster General Health, Ann B. Barshinger Cancer Institute—endeavors to broaden access to clinical trials within community settings and reflects ACCC's commitment to advancing research and improving patient outcomes.

Kathleen Harnden, MD, MBA, director of Breast Medical Oncology at Inova Health System, provided valuable insights into the integration of cancer clinical trials within her program. Notably, she highlighted Inova's significant contribution as one of the leading enrollers in an ongoing clinical trial investigating a promising new approach to hormone therapy for patients with breast cancer. Dr. Harnden emphasized the importance of clinical trials in advancing treatment options and improving outcomes for patients. Further, she discussed how participation in such

trials not only offers patients access to cutting-edge therapies but also contributes to the advancement of medical knowledge and the development of more effective treatments.

Bires led the Swedish delegation on a tour of Inova Schar Cancer Institute and provided insights into the patient-centric design of Inova Schar Cancer spaces. The delegation then visited the Inova Saville Cancer Screening and Prevention Clinic, where Elizabeth Hatcher, MSN, FNP-BC, outlined the clinic's services and ongoing trials. Finally, the group explored the Radiation department on a tour led by Ann Miner, senior director of Radiation Oncology at Inova Health System, observing cutting-edge technologies, such as a proton beam, and facilities designed to cater to the needs of pediatric and adolescent patients.

As the meeting concluded, members of the Swedish delegation expressed their admiration for witnessing "words put into actions" during their visit. They conveyed their anticipation of bringing back valuable insights and learnings to their country, inspired by the innovative approaches and collaborative efforts witnessed today. This exchange of ideas and experiences serves as a testament to the importance of global cooperation in advancing cancer care and research, which will ultimately benefit patients worldwide.

References

1. Ladan, M. The doctor exodus – with focus on the Scandinavian context. BMG Global Health. April 23, 2023. Accessed March 22, 2024. https://blogs.bmj.com/bmjgh/2023/04/13/the-doctor-exodus-with-focus-on-the-scandinavian-context/

(Top left) Molly Kiesel shares information about ACCC, its mission, and its membership with delegates from the Swedish Ministry of Health and Social Affairs.

(Top and bottom right) Delegates from the Swedish Ministry of Health and Social Affairs toured Inova Schar Cancer Institute and its Life with Cancer program.

(Bottom left) Elizabeth Hatcher, MSN, FNP-BC, speaking to the Swedish delegation at the Inova Saville Cancer Screening and Prevention Clinic.

Celebrating 50 Years of Service

Recognizing ACCC's 50 years of Innovation and Contributions to the Field of Oncology

As ACCC celebrates 50 years of serving its member programs and practices and looks ahead to the next 50 years of innovation, education, and advocacy, we'd like to share the association's key accomplishments.

We are grateful to the members, providers, and supporters who have contributed to these achievements and are excited about continued collaboration to advance cancer care delivery in the future.

▼ 1974

The Beginning

ACCC (Association of Community Cancer Centers) was founded to challenge the notion that community physicians were uninterested in and incapable of delivering in state-of-the-art cancer care, including participation in research and clinical trials.

▼ 1978

Emphasis on Community Care

ACCC actively advocated for increased government funding for the National Cancer Institute's Cancer Centers Program, creating a network of community oncologists to educate Congress. This effort led to the renewal of the National Cancer Act, which was amended to include, for the first time, an emphasis on community care.

▼ 1980s

Multidisciplinary Growth

ACCC's membership diversified to include all oncology professionals. ACCC became the only national organization promoting the collective concerns of the multidisciplinary oncology team.

▼ 1986

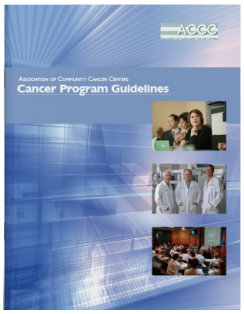
ACCC Creates The Journal of Cancer Program Management

The official journal of the Association is published quarterly until 1989 when goes bi-monthly with a rebrand as *Oncology Issues*. To this day, *Oncology Issues* remains the only journal focused on issues impacting the multidisciplinary cancer care team.

▼ 1988

ACCC Publishes its Standards for Cancer Programs

This publication (later re-named ACCC Cancer Program Guidelines) established a set of standards that would provide members with guidance on how to go about setting up oncology programs.



▼ 1990s

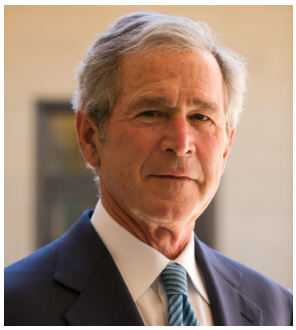
Advocating for Access to Therapies

ACCC worked tirelessly to overcome reimbursement difficulties related to off-label uses of FDA-approved drugs and advocated for patients who were denied access to therapies.

▼ 2003

Medicare Modernization Act

Years of advocating for policy and regulatory changes to improve cancer care delivery paid off when President Bush signed the Medicare Prescription Drug, Improvement, and Modernization Act into law, revamping the program and introducing average sales price (ASP) methodology for drug reimbursement.



▼ 2004

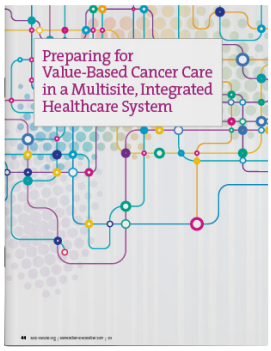
Advocacy for Adequate Drug Reimbursement

ACCC celebrated 30 years of service. With adequate drug reimbursement top of mind for its membership, ACCC recognized that pharmacists were critical to these efforts and created the Oncology Pharmacy Education Network (OPEN), guided by founding member Steven D. D'Amato, BScPharm, BCOP.

▼ 2007 to 2010

Resources for Comprehensive Cancer Care

Building on the success of its Cancer Program Guidelines, ACCC developed comprehensive education programs and resources on topics like patient navigation, cancer survivorship, and nutrition in cancer care.



▼ 2010

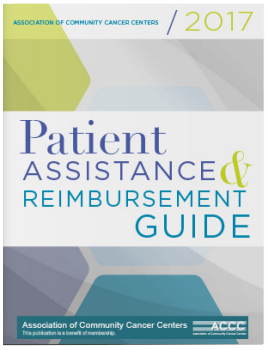
Transition to Value-Based Care

The Patient Protection and Affordable Care Act (ACA) was signed into law by President Obama on March 23, 2010, kicking into high gear the transition to value-based care. ACCC members lead the way as early supporters and adopters of this methodology.

▼ 2010

Patient Assistance and Reimbursement Guide

Recognizing that the skyrocketing costs of cancer treatment were affecting patient access to care, ACCC developed its first Patient Assistance and Reimbursement Guide, which quickly become an important resource for cancer care professionals across the country.



▼ 2011

ACCC Innovator Awards Program

ACCC launched its Innovator Awards program to honor Cancer Program Members for ingenuity and pioneering achievements in oncology. These peer-reviewed innovations advanced the goals of improving access, quality, and value in cancer care delivery.

▼ 2012

Financial Advocacy

Building on the success of its annual Patient Assistance and Reimbursement Guide, ACCC launched its Financial Advocacy Network to develop education, tools, and resources to support cancer program staff responsible for helping patients navigate the financial issues surrounding cancer care delivery.

▼ 2014

40 Years of Service

ACCC celebrated 40 years of service, continuing its focus on helping its membership improve the delivery of patient-centered care, developing resources and education in areas like adolescent and young adult cancer care, distress screening, oncofertility, geriatric care, and palliative care.

▼ February 3, 2014

ACCCBuzz Posts It's First Blog

Lessening the financial side effects of cancer was the first topic covered on ACCC's official blog, sharing that ACCC's most recent Trends in Community Cancer Centers survey found that 88% of cancer programs reported seeing more patients needing help with prescription drug expense and co-pays.

▼ 2015

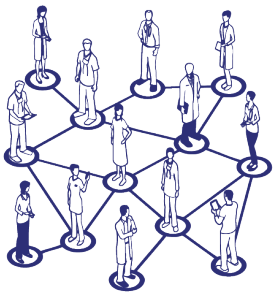
Immuno-Oncology

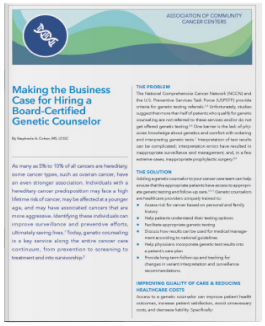
ACCC launched the Institute for Clinical Immuno-Oncology, the first initiative to guide the multidisciplinary care team's adoption of immuno-oncology in community cancer settings.

▼ 2016

The Oncology Care Model

ACCC launches the OCM Collaborative to help members succeed under the Oncology Care Model—the first specialty care model implemented by the Center for Medicare & Medicaid Services.





▼ 2019

Advocacy for Reimbursement of Comprehensive Cancer Care Services

ACCC continues to develop resources to help its members deliver comprehensive cancer care services, including business case studies for hiring supportive care staff, and advocating for reimbursement for these services.

OPEN celebrated 15 years, and ACCC continued its advocacy efforts around key issues like brown- and white-bagging, step therapy, and pharmacy benefit managers.

▼ June 26, 2019

CANCER BUZZ Hosted Its First Guest

The inaugural episode of ACCC's award-winning podcast focused on why and how some cancer programs are working to provide 24-hour access to oncology-specific emergent care services.

▼ 2020

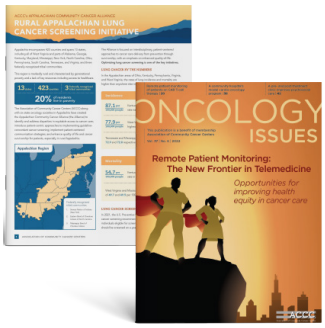
Responding to the Pandemic

ACCC adapted quickly to the COVID-19 pandemic, developing tools and resources to help members redefine how they work while keeping their patients and staff safe during a global pandemic.

▼ 2021

The Launch of ACORI

ACCC established the ACCC Community Oncology Research Institute (ACORI) to strengthen oncology research and engage patients and caregivers. A Research Site Self-Assessment tool, an Increasing Diversity in Clinical Research training module, a Research Review e-newsletter, and a clinical trials glossary are among the many resources developed under this initiative.



▼ 2022

Leveraging Technology to Transform Cancer Care Delivery

ACCC developed tools and resources to help its members use technology and digital tools to help mitigate workforce shortages, reduce health disparities, and improve care efficiency.

After President Biden announces efforts to revamp the Cancer Moonshot Program, ACCC works with the White House on efforts around increasing screening rates post-COVID-19 and improving health equity with projects like ACCC's Rural Appalachian Lung Cancer Screening Initiative.

▼ 2023

A Focus on the Oncology Workforce

ACCC develops resources to help rebuild the oncology workforce after a 3+year global pandemic in areas like building a pipeline of future workers, improving recruitment and retention, and identifying and mentoring diverse leaders.

ACCC is 1 of 3 organizations asked to testify at the President's Cancer Panel in support of the National Cancer Plan released on April 3, 2023.

tools

Approved Drugs

- On February 16, the U.S. Food and Drug Administration (FDA) granted accelerated approval to **Amtagvi® (lifileucel)** (Iovance Biotherapeutics, Inc., iovance.com) for adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 positive, a BRAF inhibitor with or without a MEK inhibitor.
- On January 19, the FDA approved **Balversa® (erdafitinib)** (Janssen Biotech, janssen.com) for adult patients with locally advanced or metastatic urothelial carcinoma with susceptible FGFR3 genetic alterations, as determined by an FDA-approved companion diagnostic test, whose disease has progressed on or after at least 1 line of prior systemic therapy.
- On March 6, the FDA approved **Besponsa® (inotuzumab ozogamicin)** (Pfizer, pfizer.com) for pediatric patients 1 year and older with relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia.
- On March 7, the FDA granted accelerated approval to **Brukinsa® (zanubrutinib)** (BeiGene, Inc., beigene.com) **in combination with obinutuzumab** for relapsed or refractory follicular lymphoma after 2 or more lines of systemic therapy.
- On March 22, the FDA approved **Elahere® (mirvetuximab soravtansine-gynx)** (AbbVie, abbvie.com) for adult patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received 1 to 3 prior systemic treatment regimens.
- On March 19, the FDA granted accelerated approval to **Iclusig® (ponatinib)** (Takeda Pharmaceuticals Inc., takeda.com) in combination with chemotherapy for adult patients with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia.
- On March 6, the FDA approved **Opdivo® (nivolumab)** (Bristol Myers Squibb, bms.com) **in combination with cisplatin and gemcitabine** for first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma.
- On February 13, the FDA approved **Onivyde® (irinotecan liposome)** (Ipsen Biopharmaceuticals, Inc., ipsen.com) **in combination with oxaliplatin, fluorouracil, and leucovorin**, for the first-line treatment of metastatic pancreatic adenocarcinoma.
- On March 1, the FDA approved **Rybrevant® (amivantamab-vmjw)** (Janssen Biotech, janssen.com) **in combination with carboplatin and pemetrexed** for the first-line treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor exon 20 insertion mutations, as detected by an FDA-approved test.
- On February 16, the FDA approved **Tagrisso® (osimertinib)** (AstraZeneca Pharmaceuticals LP, astrazeneca.com) in combination with platinum-based chemotherapy for patients with locally advanced or metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
- On February 15, the FDA approved **Tepmetko® (tepotinib)** (EMD Serono, Inc., emdsereno.com) for adult patients with metastatic NSCLC harboring mesenchymal-epithelial transition exon 14 skipping alterations.

Drugs In the News

- A2 Biotherapeutics, Inc. (A2bio.com) announced that the FDA has granted orphan drug designation to **A2B530** for the treatment of germline heterozygous HLA-A*02(+) patients with colorectal cancer that expresses carcinoembryonic antigen and has lost HLA-A*02 expression.
- Adaptimmune Therapeutics plc (adaptimmune.com) announced that the FDA has accepted for priority review its biologics license application (BLA) for **afami-cel**, an investigational engineered T-cell therapy, for advanced synovial sarcoma.
- RadioMedix, Inc. (radiomedix.com) and Orano Med (oranomed.com) announced that the FDA has granted breakthrough therapy designation to **AlphaMedix™ (212Pb-DOTAMTATE)** for the treatment of adult patients with unresectable or metastatic, progressive somatostatin receptor expressing gastroenteropancreatic neuroendocrine tumors who are naïve to peptide receptor radionuclide therapy.
- Bristol Myers Squibb (bms.com) announced that the FDA has accepted the supplemental new drug application (NDA) for **Augtyro™ (repotrectinib)** for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase gene fusion and are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity.

- Verastem Oncology (verastem.com) announced that the FDA granted orphan drug designation to **avutometinib**, alone or **in combination with defactinib** for the treatment of all patients with recurrent low-grade serous ovarian cancer. The company also announced that the FDA granted fast track designation to **avutometinib** in combination with Amgen's (amgen.com) **Lumarkas® (sotorasib)** for the treatment of NSCLC.
- BioNTech SE (biontech.com) announced that the FDA granted fast track designation to **BNT325/DB-1305** for the treatment of patients with platinum-resistant ovarian epithelial cancer, fallopian tube cancer, or primary peritoneal cancer who have received 1 to 3 prior systemic treatment regimens.
- Biosyngen (biosyngen.com) announced that the FDA granted fast track designation to **BST02** for the treatment of various liver cancers, including hepatocellular carcinoma and cholangiocarcinoma.
- AstraZeneca Pharmaceuticals LP (astrazeneca.com) and Daiichi Sankyo (daiichisankyo.com) announced that the FDA has accepted their BLA for **datopotamab deruxtecan** for the treatment of adult patients with locally advanced or metastatic nonsquamous NSCLC who have received prior systemic therapy.
- AstraZeneca Pharmaceuticals LP (astrazeneca.com) and Daiichi Sankyo (daiichisankyo.com) announced that the FDA has accepted and granted priority review to their supplemental BLA for **Enhertu® (trastuzumab deruxtecan)** for the treatment of adult patients with unresectable or metastatic HER2-positive (immunohistochemistry [IHC] 3+) solid tumors who have received prior treatment or who have no satisfactory alternative treatment options.
- Xcovery Holdings, Inc. (xcovery.com) announced that the FDA has accepted the NDA for **ensartinib**, an anaplastic lymphoma kinase inhibitor (ALK) for the treatment of adult patients with metastatic ALK-positive NSCLC.
- Indapta Therapeutics, Inc. (indapta.com) announced that the FDA has granted fast track designation for **IDP-023** for the treatment of patients with non-Hodgkin's lymphoma and multiple myeloma.
- Immune-Onc Therapeutics Inc. (immune-onc.com) announced that the FDA has granted orphan drug designation to **IO-202** for the treatment of chronic myelomonocytic leukemia.
- Bristol Myers Squibb (bms.com) announced that the FDA has accepted for priority review the supplemental NDA for **Krazati® (adagrasib) in combination with cetuximab** for the treatment of patients with previously treated KRASG12C-mutated locally advanced or metastatic colorectal cancer.
- Citius Pharmaceuticals, Inc. (citiuspharma.com) announced that the FDA has accepted the resubmission of the company's BLA for **Lymphir™ (denileukin diftitox)** an IL-2-based immunotherapy for the treatment of patients with relapsed or refractory cutaneous T-cell lymphoma after at least 1 prior systemic therapy.
- PureTech Health plc (purehealth.com) announced that the FDA has granted orphan drug designation to **LYT-200** for the treatment of acute myeloid leukemia.
- Nuvalent, Inc. (nuvalent.com) announced that the FDA has granted breakthrough therapy designation to **NVL-520** for the treatment of patients with ROS1-positive metastatic NSCLC who have been previously treated with 2 or more ROS1 tyrosine kinase inhibitors.
- Autolus Therapeutics plc (autoplus.com) announced that the FDA has accepted its BLA for **obecabtagene autoleucel** for patients with relapsed/refractory adult b-Cell acute lymphoblastic leukemia.
- Bristol Myers Squibb (bms.com) announced that the FDA accepted its supplemental BLA for neoadjuvant **Opdivo® (nivolumab)** with chemotherapy followed by surgery and adjuvant Opdivo for the perioperative treatment of resectable stage IIA to IIIB NSCLC.
- Poseida Therapeutics, Inc. (posieda.com) announced that the FDA has granted orphan drug designation to **P-BCMA-ALLO1**, a novel BCMA-targeted allogeneic, T stem cell memory-rich chimeric antigen receptor-T therapy candidate, for the treatment of multiple myeloma.
- Terns Pharmaceuticals, Inc. (ternspharma.com) announced that the FDA granted orphan drug designation for **TERN-701** for the treatment of chronic myeloid leukemia.
- BeiGene, Ltd. (beigene.com) announced that the FDA has accepted a BLA for **Tevimbra® (tislelizumab) in combination with fluoropyrimidine** and platinum-containing chemotherapy, for the treatment of patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma.

Device and Assays

- DermaSensor Inc. (dermasensor.com) announced that the FDA approved **DermaSensor**, a handheld device that uses artificial intelligence to non-invasively detect skin cancer.
- Amadix (amadix.com) a Spanish biotech company, announced that **PreveCol®**, its colorectal cancer screening blood test, has received breakthrough device designation from the FDA.