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An APP-Physician Model Improves Risk Stratification and Palliative Care



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An APP-Physician Model Improves Risk Stratification and Palliative Care

By Jia Conway

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The Official Journal of the Association of Community Cancer Centers

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FROM THE EDITOR-----

Technology Solutions in Practice

BY SIBEL BLAU, MD



he past few years have reminded us that all humans are vulnerable, yet recent events have underscored the promise technology holds for some of our most vulnerable patients. When

people are compromised and face challenges to accessing healthcare, food, shelter, education, and other basic human needs, technology can help. Technology, such as automation and artificial intelligence, is becoming a part of daily life, especially in the fields of medicine and healthcare.

My practice, Northwest Medical Specialties in Tacoma, Wash., is always looking at ways to improve our operational efficiency and quality of care. When appropriate, we look to external partners to help us create these efficiencies or to introduce new clinical tools that allow our teams to maximize their time and improve direct patient care. As one of the first oncology practices to adopt medically integrated dispensing—a care model that focuses on keeping both medical and pharmacy care within patients' core care teams—our practice saw firsthand the impact this model has had on the patient experience and patient outcomes, including faster therapy initiation times, reduced financial burden, better patient education, and improved therapy adherence.

Yet we are only as efficient as the technology we use. And our practice needed more sophisticated technology to successfully optimize its medically integrated dispensing. We also needed visibility into how our practice was performing, such as prescribing patterns across providers, time to fill, payers that were causing treatment delays, etc.

Our solution was to partner with HouseRx, which offers technology tailored to the workflow of a community oncology practice. Yet technology is just one piece of the solution. Today a team of pharmacists and pharmacy technicians help our care teams get patients started on their therapy by removing

the operational burden associated with running a successful medically integrated dispensing program. They do this all while providing clinical consultations.

Our practice also operationalized artificial intelligence solutions. We chose Ivion's prescriptive analytics platform that combines artificial intelligence algorithms with machine learning techniques to identify at-risk patients (i.e., those with a higher chance of experiencing poor outcomes). Based on its analyses, Jvion generates patient-specific, dynamic, and actionable insights. Appropriate resource utilization and initiation of a downstream workflow are critical to the success of these insights. Our practice uses a patient care coordinator team to track insights and review flagged patients, electronic health records, risk factors, and recommended interventions for high- to medium-risk patients, as well as to consider additional needs or barriers for these patients. Once these data are reviewed, patient care coordinators schedule palliative care visits with an advanced practice provider. By using this process to identify patients at risk for mortality, we increased our palliative care utilization by more than 30 percent and significantly improved our hospice utilization

Human intervention in medicine is imperative, yet our care teams are exhausted and often overworked. Successful deployment of technology promises to improve the quality of patient care and the patient experience, while also alleviating excessive burdens on our clinicians and staff. The timing could not be better for ACCC to focus its efforts in this area through the 2022-2023 President's Theme, "Leveraging Technology to Transform Cancer Care Delivery and the Patient Experience." Learn more about these efforts in the "President's Message" on the next page. Then turn to page 36 to learn about a data analytics solution that streamlines revenue cycle management, provides greater clarity on insurance claims data, and collects and reports on business health key performance indicators. Though we work daily to improve the health of our patients, we must also focus on the health of our cancer practices and programs.

Tech Solutions Ahead!

BY DAVID R. PENBERTHY, MD, MBA



n my first column, l introduced the ACCC 2022-2023 President's Theme, "Leveraging Technology to Improve Cancer Care Delivery and the Patient Experience." Now I'd like to share the key components of this initiative.

including the information, resources, and education that will be heading your way over the next year.

Tech Talks

ACCC will host four 60-minute video calls where subject-matter experts lead small-group discussions on technology-related topics. The first of these Tech Talks took place on July 14 and focused on "The Home as a New Site of Cancer Care." The expansion in access to telehealth services during the COVID-19 public health emergency and Medicare coverage for remote patient monitoring have allowed patients to increasingly receive care at home. On a macro level, we discussed how technologies have revolutionized cancer care delivery, as well as regulatory and reimbursement barriers to long-term transformation. On a micro level, we focused on topics like models to provide care in the home, services that can be delivered safely at patients' homes, staffing requirements for these models, remote patient monitoring, virtual visits, payer and policy strategies, and more. Future Tech Talks will focus on "Technology Solutions to Mitigate the Workforce Shortage," "Digital Tools in Oncology," and "Big Data." More information is to come. If you want to be involved in these small-group discussions, email mparker@accc-cancer.org.

Institute for the Future of Oncology

This year, the Institute will be held immediately before the ACCC 39th National Oncology Conference on Oct. 11 in West Palm Beach, Fla. At this half-day meeting, ACCC will convene thought leaders, stakeholders, industry, and engaged members to discuss ways to leverage technology to support the oncology workforce. And, because ACCC members have shared across multiple platforms that workforce issues are the number one challenge they face, let me

invite you to stay for the National Oncology Conference (Oct. 12 to 14). Not only will the five ACCC Innovator Award winners share technology-related solutions like "Chemotherapy Care Companion: A Remote Patient Monitoring Program" and "Deploying Technology Across an Interdisciplinary Team to Improve Oral Oncolytic Compliance" but the second day of the conference will focus on solutions to workforce challenges with sessions on retention, recruitment, improving workplace culture and morale, succession planning, mentoring new leaders, and more.

Technology-Driven Solutions

In May, ACCCBuzz kicked off its coverage of the 2022-2023 ACCC President's Theme with a two-part blog series on optimizing cancer care delivery. The first blog discussed integrated care settings that include oncology-specialized urgent care centers, community paramedicine partnerships, telehealth, and remote patient monitoring. The second blog highlighted the use of artificial intelligence-specifically a prescriptive intelligence platform that pulls in massive amounts of data, including social determinants of health—to predict patient risk and proactively target interventions. If you missed it, go back and check it out at accc-cancer.org/prescriptive-intelligence. Other blog posts focused on the hospital-at-home model, including a spotlight on the University of Utah, Huntsman Cancer Institute's Huntsman at Home program.

The first in the series of Oncology Issues articles related to the 2022-2023 ACCC President's Theme appears in this issue. Turn to page 36 for an interview with long-time ACCC member Kim Woofter, who left her role as chief operating officer at Michiana Hematology Oncology to become executive vice president of strategic alliances at AC3, an oncology business intelligence platform. After a career spent building a successful oncology practice, Woofter was hooked by business information technology. "To have solutions that don't require more manpower, more expense, it was really exciting for me," she said.

We have an exciting year ahead. And if you have a large or small technology-driven strategy or idea, we want to hear from you! Be a part of the solution and send your story to mmarino@accc-cancer.org. Stay tuned!

Coming in Your 2022 ONCOLOGY ISSUES

- A Comprehensive Oncology Program for Elders (COPE)
- Best Practices for Development of a Successful Cardio-Oncology Program in a Community Hospital
- Improving Care of Patients with Lung Cancer and COVID-19
- Meeting Women's Sexual
 Health Needs After a Cancer
 Diagnosis and Treatment
- The Effect of the "Living Well After Cancer" Program on Physical and Metabolic Health: A Community-Based Feasibility Study
- Improving Cancer Care
 Teamwork: Five PatientCentered Strategies to
 Strengthen Care Coordination
- Establishing Best Practice
 Care Coordination for Breast
 Screening, Cancer Detection,
 and Diagnosis
- Developing a Comprehensive Arts in Medicine Program
- Digital Reasoning: An Innovative Lung Nodule Program
- Reimagining Healthcare for Lung Nodules
- Simulate and Educate: A Nurse-Led Pilot to Enhance Patient Education and Experience
- Changing the Tune for CAR-T:
 A Music City Experience in
 Remote Monitoring
- Genetic Navigation: Improving Patient Outcomes and Identification for Hereditary Cancers

*more online @ accc-cancer.org

The Promise of Prescriptive Intelligence

BLOG The second in the ACCCBuzz series focusing on the 2022-2023 ACCC President's Theme, Leveraging Technology to Transform Cancer Care Delivery and the Patient Experience, explains how an artificial intelligence platform to that pulls massive amounts of data, including social determinants of health, can help predict patient risk and proactively target interventions. accc-cancer.org/prescriptive-intelligence.

ASCO and ACCC Release Joint Recommendations

Based on an extensive literature review and consensus discussion by the ASCO-ACCC Steering Group and Patient Partners Advisory Group, comprising cancer research advocates and patients who represent racially and ethically diverse populations, these recommendations address the lack of equity, diversity, and inclusion in cancer clinical trials. The recommendations were published in the Journal of Clinical Oncology. ascopubs.org/doi/full/10.1200/JCO.22.00754.

ACCC Recognized by the Cancer Moonshot Initiative

In May, ACCC Executive Director, Christian Downs, JD, MHA, was invited to the White House Cancer Moonshot: Goals Forum to strategize with other healthcare leaders, providers, and private sector groups. ACCC was identified by the White House as one of the five private sector actions in response to the goal of Bringing Cancer Screening to More Communities. Read more about how ACCC and AstraZeneca have joined forces to launch the "Rural Appalachian Lung Cancer Screening Initiative" to develop and implement person-centered and sustainable approaches to increase lung cancer screening in rural America. accc-cancer.org/ACCA.

Digital Bridges: Optimizing Telewebinar health for Older Adults with Cancer

Gain insights into how the City of Hope's advanced advanced practice provider-led geriatric consult clinic developed a telehealth assessment tool geared toward the unique needs of older adults. accc-cancer.org/digital-bridges-webinar.

Biomarker Testing Panel

VIDEO A panel of multidisciplinary oncology experts discuss the hurdles cancer care teams face when implementing biomarker testing for patients and solutions to ease these burdens. Panelists explore the treatment landscape of non-small cell lung cancer, how comprehensive biomarker testing can inform decision-making, and effective practices to incorporate biomarker testing in a cancer program. accc-cancer.org/biomarker-testing-panel.



Metro Areas with the Highest Telemedicine Adoption Rates

- 1. Boston, Mass.
- 2. Baltimore, Md.
- 3. Charlotte, N.C.
- 4. Philadelphia, Pa.
- 5. San Francisco, Calif.
- 6. Birmingham, Ala.
- 7. Richmond, Va.
- 8. Raleigh, N.C.
- 9. Denver, Colo.
- 10. Portland, Ore.

Source. Doximity. State of Telemedicine Report: Second Edition. c8y.doxcdn.com/image/upload/Press%20Blog/Research%20Reports/Doximity-Telemedicine-Report-2022.pdf.

How Social Drivers of Health Impact Physician Practice

- While nearly 90% of surveyed physicians indicated that they
 would like a greater ability to effectively address their patients'
 social drivers of health, 61% feel they have little to no time
 and ability to effectively address these issues
- Physicians identified these challenges to addressing social drivers of health: limited time during patient visits (89%), an insufficient workforce to navigate patients to community resources (84%), and lack of reimbursement for screening for or addressing social drivers of health (57%).
- 68% believe managing patients' social drivers of health has a major impact on physician mental health and well-being.
- 63% report often having feelings of burnout when trying to address their patients' social drivers of health.



Source. The Physicians Foundation. 2022 Survey of America's Physicians. physiciansfoundation.org/physicianand-patient-surveys/the-physiciansfoundation-2022-physician-survey-part-1.

facts



- Nearly 85% of surveyed physicians indicate that they are currently using telehealth to care for patients
- Nearly 70% report their organization is motivated to continue using telehealth
- 95% report that patients are primarily located at their home at the time of the virtual visit
- Physicians identified the top 3 barriers to telehealth: technology, digital literacy, and broadband internet access.

Source. American Medical Association. ama-assn.org/practice-management/digital/telehealth-resource-center-research-findings.

Healthcare Workforce Shortages are Affecting Patients

- 80% of Americans are concerned about healthcare workforce shortages;
 78% are concerned about hospital bed shortages
- Half of respondents (51%) experienced one or more healthcare shortages, most centered around primary care
- 45% reported trouble with scheduling appointments
- 36% reported their physician's office operating on reduced hours
- 25% experienced delays in treatments or surgeries
- 21% reported their physicians stopped practicing; 13% reported their healthcare facilities closed completely
- 13% said community health initiatives have either stopped or decreased
- 1/3 of Black and 24% of Latinx Americans said they will prioritize going to the physician more than they did before the pandemic, but
 59% of Black and 54% of Latinx Americans are stressed about accessing quality healthcare compared to 43% of the general population.

Source. A CVS Health and Harris Poll Survey of 2,020 U.S. adults between Feb. 10 and Feb. 15. CVS Health-Harris Poll National Health Project.



A Framework for Coping with Moral Challenges In the COVID-19 Era

Exploring these three questions can provide clarity:

- What am I experiencing? Naming something allows you to categorize it in a familiar way, providing a sense of control and removing some fear of the unknown. Taking big experiences and examining their components makes it easier.
- What do I want to do with it? This question is empowering and actionable; one you can and want to do. This question is individualized; account for your own strengths and limitations.
- How do I approach it? Explore how best to implement your choices. Each experience or situation demands specific skills, tools, or frames of reference based on what it is and what you want to do with it.

Source. CAPC. A Framework for Coping with Moral Challenges In the COVID-19 Era. capc.org/documents/download/853/.



ISSUES

Study Highlights Need for Medicare Advantage Prior Authorization Reform

BY MATT DEVINO, MPH



nrollment in Medicare Advantage the commercial alternative to traditional fee-for-service Medicare has risen steadily since the early 2000s. With strong, bipartisan support for the Medicare Advantage program in Congress and the Biden administration finalizing earlier this year the largest rate increase to the program since the Bush presidency, the number of enrollees in Medicare Advantage is soon expected to surpass those in traditional Medicare. In fact, the Medicare Payment Advisory Commission reported to Congress that 46 percent of Medicare beneficiaries with both Part A and Part B coverage were enrolled in a Medicare Advantage plan in 2021.1 The Medicare Payment Advisory Commission noted that if the current trend continues, this figure will exceed 50 percent by next year.

However, prior authorization requirements tend to be much more strenuous for Medicare Advantage plans compared to traditional Medicare, which does not require prior authorization for most services. The biggest concern with these prior authorization requirements—aside from the administrative burden on providers—is that they can act as a barrier to patients accessing necessary services and treatments. This administrative hurdle can lead to delays in care and potential harm to patients. Provider groups have expressed concerns with excessive prior authorization requirements in the Medicare Advantage program for years

and pointed out the potential for their inappropriate use. Specifically, there is a concern with the misalignment of incentives in the Medicare Advantage payment model because these plans can increase their own profits by denying access to medically necessary care and reimbursement.

In response to these concerns, the Department of Health and Human Services' Office of Inspector General (OIG) conducted a study to examine the appropriateness of Medicare Advantage plans' prior authorization and payment denials. In its analysis, OIG found that among the prior authorization requests that Medicare Advantage plans denied, 13 percent met Medicare coverage rules, meaning that the services would have been approved if the patient had been covered by traditional Medicare.² OIG also found that among the payment requests that Medicare Advantage plans denied, 18 percent met Medicare coverage and plan-specific billing rules. In some of the identified cases, prior authorization or payment denials that met Medicare coverage and plan-specific billing rules were reversed, often following a beneficiary- or providerinitiated appeal or dispute process.

As a result of this study, it is more evident than ever that there is a need for reform around the use of prior authorization in the Medicare Advantage program. For this reason, ACCC supports the Improving Seniors' Timely Access to Care Act of 2021 (H.R. 3173/S. 3018), which would require

Medicare Advantage plans to standardize and streamline prior authorization processes and increase the transparency of their requirements to prevent unnecessary denials and delays in patient care. The legislation would also create an electronic prior authorization program to eliminate the need for faxes and would provide real-time determinations for items and services that are routinely approved.

Due to broad, bipartisan support for the Improving Seniors' Timely Access to Care Act, the bill is now poised for consideration by the full House of Representatives. Back in 2019, the House created a legislative process that allows bills with more than 290 co-sponsors to proceed to a floor vote without first going through a committee. On May 12, 2022, the House bill's sponsors—Reps. Suzan DelBene (D-WA), Mike Kelly (R-PA), Ami Bera (D-CA), and Larry Bucshon (R-IN)—announced in a joint press statement that it had crossed the 290-co-sponsor threshold.³ The lawmakers expressed their desire to bring the bill to the House floor for a vote, following the necessary 25 legislative days without committee action. Should the bill pass a House vote, the Senate version of the bill would still need to pass to get this legislation to the president's desk.

ACCC members encouraged their members of Congress to support this piece of legislation as part of ACCC's 2022 Virtual Hill Day on June 15, 2022.

The Oncology Nursing Society Releases New Oral Anticancer Medication Adherence Guidelines, a Scoping Review, and a Toolkit!

The toolkit features the following:

- Pretreatment assessment and patient and caregiver education
- Safety concerns, including drug-drug and drug-food interactions
- Financial and reimbursement resources
- Tips for motivational interviewing
- Follow-up monitoring and wallet card

ONS Guidelines™ to Support Patient Adherence to Oral Anticancer Medications

Developed by experienced oncology nurses and oncology pharmacists, the oral adherence guidelines incorporate published research with expert consensus on the certainty of the evidence, the balance of benefits and harms, and patient preferences and values.

Domains of Structured Oral Anticancer Medication Programs: A Scoping Review

This scoping review identifies oral anticancer medication programs in the literature to provide examples and propose a framework intended to improve adherence.

Oral Anticancer Medication Toolkit

The toolkit provides evidence-based strategies and resources to help clinicians facilitate adherence among patients prescribed oral anticancer therapy.

Learn more at ons.org/OAM-Guidelines



Matt Devino, MPH, is director of Cancer Care Delivery and Health Policy, Association of Community Cancer Centers, Rockville, Md.

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- U.S. Representative Suzan DelBene. Press release: prior auth reform legislation reaches critical milestone setting the stage for floor action.
 Published May 12, 2022. Accessed May 23, 2022. delbene.house.gov/news/documentsingle. aspx?DocumentID=3117

compliance

Is My E/M Visit Separately Billable?

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

ue to the nature of their disease, patients with cancer may have many touch points with providers and staff, including building relationships and sharing personal stories, triumphs, and struggles. As such, it can be confusing for providers to know when time spent with a patient is an informal interaction (i.e., a component of their relationship) or when it is considered a billable service—especially when the physician is spending time with their patient.

There are also instances when a provider will see a patient and perform a minor procedure or other primary therapeutic service in addition to an evaluation and management (E/M) visit. Again, the question comes up: are these additional services separately billable?

Complicating this issue are the 2021 coding changes that shifted E/M visit coding to medical decision making and time-based requirements, raising additional questions as to which services are included in an E/M visit and which are separate and, therefore, separately billable. To begin the process of determining if a visit is separately billable, ask yourself these two questions:

- Has there been a change in the patient since they were last seen by the provider, necessitating a visit with the patient today?
- Is this a routine check-in to ensure that the patient can safely proceed with their therapy today?

Not Separately Billable

If a physician is checking in with the patient as part of a routine interval between drug administrations and there are no new symptoms or side effects, the visit is not separately billable. There is no medical necessity to support billing for an E/M visit. Rather, this check-in is considered a "courtesy."

Similarly, if the visit is a routine check-in, maybe it has been a week or two since the initial visit, and the plan of care to perform the setup simulation for radiation therapy is unchanged, then the E/M visit is not separately billable. Physicians must participate in these simulations, so any check-ins to see how patients are doing are a "courtesy" and not separately billable.

When a physician management service, Current Procedural Terminology (CPT®) codes 77427 to 77435, is billed during the course of radiation therapy, the follow-up visit is considered part of the patient's ongoing management and therefore is not billable. The Medicare Claims Processing Manual, chapter 13, states that there are several services bundled into the physician management service.¹ The final bullet in the lengthy list of items includes: "Follow-up examination and care for 90 days after last treatment (whatever code billed)."

There is one exception to this rule. For certain brachytherapy treatments, when no physician management service is billed or if the patient presents for a new problem that was not previously known or symptomatic, the visit is considered "separately billable" and the provider can bill for an E/M visit.

Separately Billable

But what if there has been a change in the patient or there is no pre- or post-surgical period attached to the E/M visit? In these scenarios, providers may have an opportunity to bill for the E/M visit, in addition to any of the other services delivered on that same day. In the below scenarios, providers can bill a separate E/M visit, but they must also review new or recent diagnostic findings and/or results with the patient:

 The patient presents with a new problem or complaint. Examples include bone pain, dizziness, cognitive changes, deep vein thrombosis, or plural effusion symptoms.

- The patient presents with a side effect to their drug therapy, requiring assessment, intervention, or a new prescription.
 Examples include nausea, pain, fever, diarrhea, or mouth sores.
- There is a change in the drug therapy treatment plan that requires a discussion with the patient. Examples include need for new drug regimen, palliative care, or hospice.
- The patient has an adverse drug reaction, requiring assessment and/or intervention by the provider.

Documentation should clearly identify medical necessity to support the E/M visit and what about the patient has changed. To support billing for an E/M visit, the provider should select the CPT code that best represents the events and services that took place. Though the problem may be new, these patients are considered established to the physician or group, so the E/M visit is billed as an established patient visit.

Severe Drug Reactions

If a patient experiences a severe drug reaction, there is the potential for the physician to bill for their intervention and management of the patient on the same date the chemotherapy is administered. When drug administration codes were updated in 2005 and 2006, there was debate on how to bill these situations. At the time, a CPT Workgroup recommended that new codes be created to represent the physician intervention, but the CPT Editorial Panel did not agree. Instead, the panel said that physicians should bill using existing codes. The Centers for Medicare & Medicaid Services (CMS) indicated that the agency was aligning its guidance with the American Medical Association, publishing in the 2005 Medicare Physician Fee Schedule final rule that "physicians can bill existing codes that reflect the time, resources, and complexity of services they and their staff provide for management of significant adverse drug reactions. Note that this is in addition to the billing normally allowed for the physician's care of a cancer patient."²

CMS outlined the existing codes that would be most appropriate and would depend on the specifics of the scenario. For example, a physician could bill for an E/M visit if the patient has a reaction during the chemotherapy administration and the physician must intervene. In this scenario, an E/M visit could be billed in addition to the chemotherapy administration services. If a patient visit was supported prior to the administration of the chemotherapy, a physician could bill a higher-level visit code for the complexity and time spent to manage the drug reaction. It may also be possible for providers to bill a prolonged service code. For example, if the total time is used when billing and that time exceeds the threshold for prolonged outpatient services, providers could bill for the add-on code in addition to the E/M code (CPT 99417 or HCPCS G2212). Lastly, if the patient had a visit prior to the chemotherapy administration and experiences life-threatening adverse reactions to the drugs, critical care services may be supported and billable if specific criteria are met (CPT 99291 or 99292).

Note: if the chemotherapy administration is started and then stopped due to a severe drug reaction, payers may allow providers to bill the full amount of the drug. The claim should be reported using the appropriate International Classification of Diseases, Tenth Revision, Clinical Modification codes to identify what took place:

- Z53.09: Procedure and treatment not carried out because of contraindication AND
- T45.1X5A: Adverse effect antineoplastic drug, active treatment (the secondary or tertiary code).

If a drug reaction is due to a medication error on the part of a physician or staff and requires administration of a "rescue" protocol, the additional drugs and administration services *are not* separately billable. In this scenario, the drug reaction was the result of a provider error and, therefore, the responsibility of the facility. It cannot be billed to the payer and patient.

When Additional Services are Performed at Time of Visit

Beyond the examples presented above, there may be instances when another service, such as a minor surgical procedure, is performed during the E/M visit, and this service may be separately billable. An example of this scenario would be a radiation oncologist who performs a nasopharyngoscopy or flexible fiberoptic laryngoscopy during the same encounter as the E/M visit. Often, when a radiation oncologist is seeing a patient with head and neck cancer, they will also perform a scope during the encounter. When the physician administers an anesthetic and inserts a scope through a nasal or oral approach to examine the larynx, this service is separately billed as:

• **31575**: Laryngoscopy, flexible fiberoptic; diagnostic.

If the physician administers an anesthetic and inserts an endoscope through the nose and into the pharynx to determine whether there are any fixed blockages, this service is billed as:

• **92511**: Nasopharyngoscopy with endoscope (separate procedure).

Regardless of which approach is used, providers should be specific in the documentation of the service performed. First, the anatomy viewed must be clearly stated in the procedure note. This will determine the type of service performed and the correct code to bill. Next, document the scope itself (ideally in a separate note) to fully support the additional and separately billable service. If the physician does not document separately, at minimum the service:

- Must be documented in a section of the visit note that is not related to the exam portion of the E/M visit.
- Must specifically call out the work that was done.

Use of Modifier 25 with E/M Visits

When an E/M visit is supported and there are other services also billed by the same physician, providers will typically encounter an edit. This may not happen on every service combination, but in oncology it is quite common. If the E/M visit is "above and beyond" the work of the other procedure or

service performed, it is possible to add **modifier 25** (Significant, separately identifiable evaluation and management service by the same physician or other qualified healthcare professional on the same day of the procedure or other service) to the E/M visit code.

The use of modifiers when there is an edit does not guarantee payment. Additionally, because payers consider **modifier 25** to be overutilized, they look at it closely and require providers to document that the E/M visit was medically necessary and in addition to the procedure that was performed. As discussed previously, if the physician is simply checking in with the patient before their drug administration to assess how they are, explain the procedure, and obtain consent, payers *do not* consider this to be a separate patient encounter.

There are many specialties where most of the work provided is consultative and supported through an E/M visit. Much of the time, the work and services provided during a patient encounter are considered part of the criteria for the E/M itself; however, providers should understand what services are—and are not—separately billable. Recognizing opportunities to bill for additional services commonly performed during the same encounter as an E/M visit, but that are considered distinct and separate from the visit itself, ensures that providers are reimbursed for all of the services they performed.

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spotlight

Tennessee Oncology, Tennessee



ennessee Oncology is a physicianled private oncology practice based in Nashville. A partner of OneOncology, Tennessee Oncology operates 32 clinic locations across the state and one in northern Georgia and offers offers medical and radiation oncology, imaging, and lab services. Its seven imaging centers are accredited by the American College of Radiology, and the entire practice is certified by the Quality Oncology Practice Initiative (QOPI®). Additionally, Tennessee Oncology was selected to be 1 of 12 participating practices in the American Society of Clinical Oncology's (ASCO's) Oncology Medical Home certification pilot. This new ASCO certification combines its QOPI qualifications with an additional six care delivery standards and is designed to further promote coordinated, accessible, and evidence-based care delivery, including measurements to facilitate continuous quality improvement.1

Through OneOncology, Tennessee Oncology's providers are uniquely connected with their colleagues and experts, who can assist in informing and developing treatment plans. "The OneOncology network allows us to closely interact with community oncology practices around the different parts of the United States," says Susan Frailley, chief administrative officer of Front Office Operations at Tennessee Oncology. "The knowledge base and resources provided through the network really help us a lot with the challenges we're facing and how we can navigate around those." Providers can participate in and chair

OneOncology's committees, furthering their career development and the practice's work in quality improvement.

Tennessee Oncology hires and employs all clinical and non-clinical staff, who are then paid through the practice's partnership with OneOncology. Though staff may receive their checks from OneOncology, all work for Tennessee Oncology and deliver on its mission to provide access to high-quality cancer care for all patients within their community and close to their home.

An Adapting Model of Care

In widely covering the middle east area of the state, Tennessee Oncology faces a major challenge: location. While many patients live in more populated areas like Nashville and Chattanooga, others live in smaller, rural communities. Therefore, Tennessee Oncology leadership knew they needed to stand up clinics of various sizes in different locations, while optimizing practice resources and staff time. "Our challenge is: how do we bring care to the community and to the patient?" says Kathy McGee, chief clinic operations officer at Tennessee Oncology. "We want to provide care to the patient in the community where they live, so we have to think strategically about how we open clinics in those areas."

To serve patients in rural locations, Tennessee Oncology staff established adaptable clinic structures for their full-time and part-time locations. Its largest clinic sees about 4,000 patients a month, while its smallest clinic sees about 100 patients a month. And three clinics—in Smithville, Lawrenceburg, and Spring Hill, Tenn.—are

open one day a week, with staff traveling from other nearby locations to provide care to patients locally. With this flexibility, the practice ensures that traveling to appointments and navigating the healthcare system will not be a patient burden.

Multidisciplinary Cancer Care

Similarly, medical oncology and hematology services are available at Tennessee Oncology's clinics through various staffing models. At least 1 medical oncologist (up to 12 total), as well as medical assistants, lab staff, and nursing staff (ranging from 2 to 17), are on-site in each clinic every day. The practice employs APPs who assist oncologists with patient visits, orders, and more. Tennessee Oncology also employs patient service representatives at each of its clinics, who are tasked with greeting, checking-in and checking-out patients, and handling all medical records.

Additionally, the practice's infusion suites range in size, from 6 chairs to 37 chairs, totaling 550 chairs across all clinic locations. Pharmacy technicians mix patients' treatments on-site, and nurses are available to assist with infusions and injections when needed. Tennessee Oncology employs a central pharmacy-accredited by the Utilization Review Accreditation Commission and Accreditation Commission for Health Care—located in downtown Nashville that dispenses patients' oral prescriptions via mail-order or on-site pickup. This pharmacy is staffed by pharmacists, pharmacy technicians, and nurses, who support patients by filling their prescriptions and following them through treatment to

ensure therapy adherence and to provide education.

For patients requiring surgical services, all gynecologic and surgical oncology services are provided in partnership with oncologists and surgeons in the community. Radiation oncology treatments, including IMRT, IGRT, SRS, LDR, HDR brachytherapy, total body irradiation, and proton therapy, are offered at 16 of the practice's clinics. Each radiation oncology location is run in partnership with a local hospital that provides the support staff to run day-to-day operations and at least one radiation oncologist is on-site every day.

Tennessee Oncology developed a unique solution to support staffing and patient care needs across the practice: a float team of 20 to 30 professionals who can backfill clinic staff when necessary. Further, operator, triage, and new patient teams are centralized in Nashville, overseeing a territory of four to six clinics each.

Staff are proud to offer a variety of supportive care services like psychology, genetic counseling, integrative oncology, nutrition, care coordination, patient advocacy to assist with food and transportation needs, and financial counseling. Oncologists work closely with their patients to identify needs and make referrals to palliative care, integrative oncology, labs, etc. These supportive care services are offered in-person at Tennessee Oncology's larger locations and virtually through telehealth, so patients who cannot travel can access much-needed support in the comfort of their home. While any physicianprovided services are billable, many others are free to patients.

Serving the Communities' Needs

Tennessee Oncology sees a high incidence of lung cancer, as well as patients presenting with a secondary disease and comorbidities (e.g., diabetes, obesity). To address these needs, the practice partners with local hospitals and agencies to assist patients, especially when care is needed outside the practice's business hours. Tennessee Oncology can facilitate care with local partners when a need is identified, and some of these partners will provide services within patients' homes. Additionally, the





practice has implemented a lung cancer screening program that allows all Tennessee Oncology providers to refer appropriate patients for screening. This service is also offered to partnering pulmonologists in the community.

In prioritizing community partnerships to truly offer comprehensive cancer care, Tennessee Oncology partners with Sarah Cannon Research to host Phase II and Phase III clinical trials. These studies are available to qualifying patients regardless of which clinic they are receiving treatment, and research nurses work side-by-side with clinic staff to ensure patients are enrolled in an available study. In 2021, Tennessee Oncology enrolled 42 patients in its Phase I drug development unit and currently has about 1,700 patients on a clinical trial.

In opening clinic locations across the state (with one additional clinic in Georgia),
Tennessee Oncology staff take pride in their ability to deliver comprehensive oncology care to patients close to their home. "We're all very proud of how everyone comes together to take care of the patient," says Leah Owens, BSN, RN, BMTCN, OCN, executive director of Care Transformation at Tennessee Oncology. "Even though we are 30 plus locations, it still very much feels like it is just one big team providing care."

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tools



Approved Drugs

- On April 18, the U.S. Food and Drug Administration (FDA) approved Alymsys® (bevacizumab-maly) (Brand Institute and mAbxience, brandinstitute.com and mabxience.com)—a biosimilar to Avastin® (bevacizumab). Alymsys's approved indications include: 1) metastatic colorectal cancer in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment and 2) metastatic colorectal cancer in combination with fluoropyrimidineirinotecan- or fluoropyrimidineoxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen.
- On May 4, the FDA approved Enhertu®
 (fam-trastuzumab deruxtecan-nxki)
 (AstraZeneca and Daiichi Sankyo, Inc.,
 astrazeneca.com and daiichisankyo.com)
 for adult patients with unresectable or
 metastatic human epidermal growth
 factor receptor 2 (HER2)-positive breast
 cancer who have received a prior
 anti-HER2-based regimen either in the
 metastatic setting or in the neoadjuvant
 or adjuvant setting and who have
 developed disease recurrence during or
 within 6 months of completing therapy.
- On May 27, the FDA granted accelerated approval to Kymriah® (tisagenlecleucel) (Novartis Pharmaceuticals Corporation, novartis.com) for adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

- On May 27, the FDA approved Opdivo®
 (nivolumab) (Bristol Myers Squibb,
 bms.com) in combination with
 fluoropyrimidine- and platinum-based
 chemotherapy and Yervoy® (nivolumab)
 (Bristol Myers Squibb, bms.com) in
 combination with ipilimumab for the
 first-line treatment of patients with
 advanced or metastatic esophageal
 squamous cell carcinoma.
- On May 25, the FDA approved Tibsovo®
 (ivosidenib) (Servier Pharmaceuticals LLC, servier.us) in combination with
 azacitidine for newly diagnosed acute
 myeloid leukemia with a susceptible IDH1
 mutation, as detected by an FDA approved test, in adults 75 years or older
 or who have comorbidities that preclude
 use of intensive induction chemotherapy.
- On May 20, the FDA approved Vidaza® (azacytidine) (Bristol Myers Squibb, bms.com) for pediatric patients with newly diagnosed juvenile myelomonocytic leukemia.

Drugs in the News

- BriaCell Therapeutics Corp. (briacell.com) announced that the FDA granted fast track status to Bria-IMTTM for the treatment of metastatic breast cancer.
- AstraZeneca (astrazeneca.com) and Daiichi Sankyo (daiichisankyo.com) announced that the FDA accepted and granted priority review to the supplemental biologics license application (BLA) of Enhertu for the treatment of adult patients with unresectable or metastatic non-small cell lung cancer whose tumors have an HER2 mutation and who have

- received a prior systemic therapy. The companies also announced that Enhertu was granted breakthrough therapy designation for the treatment of adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-negative) breast cancer who have received a prior systemic therapy in the metastatic setting or developed disease recurrence during or within six months of completing adjuvant chemotherapy.
- Spectrum Pharmaceuticals (sppirx.com) announced that it resubmitted a BLA for eflapegrastim, which has been accepted by the FDA, seeking an indication to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.
- Gamida Cell Ltd. (gamida-cell.com)
 announced that the FDA cleared its
 investigational new drug application
 (NDA) and removed the clinical hold for a
 cryopreserved formulation of GDA-201—
 an off-the-shelf cell therapy candidate for
 the treatment of patients with follicular
 and diffuse large B-cell lymphomas.
- AstraZeneca (astrazeneca.com)
 announced that the supplemental BLA for
 Imfinzi® (durvalumab) in combination
 with standard-of-care chemotherapy
 was accepted and granted priority review
 by the FDA for patients with locally
 advanced or metastatic biliary tract
 cancer.
- ImmunoGen, Inc. (immunogen.com)
 announced that the FDA accepted and

granted priority review to the BLA for mirvetuximab soravtansine monotherapy for patients with folate receptor alpha-high platinum-resistant ovarian cancer who have been previously treated with one to three prior systemic treatments.

- Bayer (bayer.com) announced that the FDA accepted a supplemental NDA and granted priority review to Nubeqa® (darolutamide) in combination with docetaxel for the treatment of metastatic hormone-sensitive prostate cancer.
- ImmunityBio, Inc. (immunitybio.com)
 announced it has submitted a BLA to the
 FDA for N-803 plus Bacillus Calmette Guérin (BCG) for the treatment of
 BCG-unresponsive non-muscle invasive
 bladder cancer carcinoma in situ with or
 without Ta or T1 disease.
- VBL Therapeutics (vblrx.com) announced that the FDA granted fast track designation to ofra-vec (ofranergene obadenovec or VB-111) in combination with paclitaxel for the treatment of platinum-resistant ovarian cancer.
- Gamida Cell Ltd. (gamida-cell.com)
 reported that it has submitted a rolling
 BLA to the FDA for omidubicel for the
 treatment of patients who have blood
 cancer and need allogenic hematopoietic
 stem cell transplant.

- Fennec Pharmaceuticals Inc. (fennec-pharma.com) announced that the FDA accepted for filing the company's resubmitted NDA for Pedmark™ (a formulation of sodium thiosulfate) for the prevention of platinum-induced ototoxicity in pediatric patients one month to less than 18 years of age with localized, non-metastatic, solid tumors.
- Elevation Oncology, Inc.
 (elevationoncology.com) announced that
 the FDA granted fast track designation to
 seribantumab for the tumor-agnostic
 treatment of advanced solid tumors that
 harbor NRG1 gene fusions.
- SQZ Biotechnologies (sqzbiotech.com) announced that the FDA granted fast track designation to SQZ-PBMC-HPV for the treatment of HPV16+ advanced or metastatic solid tumors.
- AstraZeneca (astrazeneca.com)
 announced its BLA for tremelimumab
 has been accepted for priority review by
 the FDA, supporting the indication of a
 single priming dose of the anti-CTLA4
 antibody added to Imfinzi® (durvalumab)
 for the treatment of patients with
 unresectable hepatocellular carcinoma.
- Mersana Therapeutics, Inc. (mersana.com) announced that the FDA granted orphan drug designation to XMT-2056 for the treatment of gastric cancer.

Devices and Assays in the News

- Guardant Health, Inc. (guardanthealth. com) announced the availability of Shield™, a blood-based test for the detection of early-stage colorectal cancer.
- On June 9, the FDA approved
 FoundationOne®CDx (Foundation
 Medicine, foundationmedicine.com) as a
 companion diagnostic for two Rozlytrek®
 (entrectinib) (Genentech, Genentech.
 com) indications: 1) to identify patients
 with ROS1-positive non-small cell lung
 cancer and 2) to identify patients with
 neurotrophic tyrosine receptor kinase
 fusion-positive solid tumors.

Updated ASCO Guidelines

The American Society of Clinical Oncology (ASCO) has updated its 2022 Biomarkers for Adjuvant Endocrine and Chemotherapy in Early-Stage Breast Cancer guidelines to include **Oncotype DX Breast Recurrence Score®** test (Exact Sciences, exactsciences.com) in early-stage breast cancer.

An APP-Physician Model Improves Risk Stratification and Palliative Care





s the landscape of medicine changes in terms of treatment options, modalities, delivery methods, and patient populations, a failure to shift clinical thinking and practices can create a stagnancy that causes healthcare providers to miss the most basic patient needs—ones that impact their overall outcome while on treatment. Despite our efforts to offer our oncology patients the best possible treatment outcomes, quality of life, and disease control—if not cure—my practice (Cancer Care Associates of York in York, Pa.) came to understand that we were treating patients following a one-size-fits-all model. In 2018, as a newly enrolled practice in the Oncology Care Model (OCM), we quickly realized that our patients were not one-sizefits-all, and that each deserved individualized care tailored to his or her specific cancer diagnosis, treatment-related symptoms, existing comorbidities, age, social determinants of health, and high-risk disease and/or symptom status, including the need for palliative care to address treatment toxicities.

We assessed our goals of care to improve patient outcomes, all while providing cost-effective, care-initiated conversations between our advanced practice providers (APPs) and physicians. We began to reevaluate what our providers needed to do differently to improve patient outcomes, symptom management, and a fragmented healthcare system, while effectively identifying high-risk patients (with a goal of reducing hospitalizations). With limited resources in our community setting, our practice experienced delays in referrals to other disciplines (such as palliative care) and had a lack of understanding regarding the true benefits of early palliative care interventions, which often left some patients suffering and struggling. The solution to streamlining care and creating a solid foundation of cancer care management needed to begin with our practice.

The integration of APPs in our practice streamlined care in several domains and, as a result, improved continuity and transitions of care, team collaboration, and overall patient satisfaction.

Getting Started

The data the Centers for Medicare & Medicaid Services released via OCM's practice-based reports allowed us to understand our current practice patterns, benchmark these against other OCM practices, and identify areas for improvement, such as:

- Timely referral to hospice care
- Number of patients being sent to the emergency department
- Evaluation and management of depression
- Cost savings of chemotherapeutic treatment options.

What we found was eye-opening. The data showed us:

- Over- and underuse of resources
- Areas in which we failed to promote the overall well-being of our patients, specifically for patients who were suffering from treatment toxicities until their death
- Too many patients being sent to and treated in the emergency department because they were not seen in a timely manner in our clinic or referred to other disciplines for symptom management

A lack of assessment—and intervention—of social determinants of health that affect disease outcomes. Cancer is not a freestanding disease; cancer manifests itself in the setting of a pre-existing state of health. The burden of cancer care is impacted by race and ethnicity, socio-economic status, health insurance coverage (or lack thereof), existing comorbidities, and geography.¹

These data helped remind us that risk stratification and palliative care services should be at the forefront of care, not just at the end of life. Palliative care is a highly organized system for delivering care, as well as a philosophy of care that sets goals to prevent and relieve suffering and to support the best possible quality of life for patients and their families—regardless of disease stage or need for other therapies.² Yet due to the scarcity of comprehensive palliative care programs in community settings, a lack of internal education about palliative care and high-risk assessments, and a fragmented healthcare system that hinders continuity of care, our patients are not always receiving truly interdisciplinary cancer care.

Our New Care Model

The integration of APPs in our practice streamlined care in several domains and, as a result, improved continuity and transitions of care, team collaboration, and overall patient satisfaction. Our experience was not an anomaly: Studies have demonstrated that APPs help reduce the burden of oncology care by supporting other aspects beyond direct patient care.³

In collaboration with physicians, our APPs developed a primary model of care that allows them to see patients from initial diagnosis throughout the trajectory of their cancer care journey. The model's design promoted APP autonomy and decision making based on clinical guidelines, and it provided physician support to implement supportive care programs and assessment tools. This care model was one of the first steps to building better relationships with our patients and developing an internal dialogue with all disciplines involved in the treatment of our patients.

As our APPs assumed the management and monitoring of high-risk patients or those with complex treatment plans and increased toxicities, our practice was afforded more consistent decision making by our providers, better coordination with transitions of care, and reduced treatment delays and fragmented care for new and existing patients on active treatment. Simply put, this care model improved patient, APP, and provider satisfaction.

Our Palliative Care and High-Risk Model

With this APP-led model in place, we turned our attention to palliative care. Launching a palliative care initiative in our community practice setting required several steps:

 We developed internal consultations and an interdisciplinary approach to care through prolonged-scheduled visits with our APPs. At these dedicated 45- to 60-minute visits, our APPs addressed palliative and high-risk patients' needs. Patients were scheduled for these visits by internal referral after their initial consultation, at disease progression or when experienc-

- ing treatment-related symptoms, and following hospital discharge.
- We set up early symptom management that was comprehensive, focusing on patients' physical, emotional, social, financial, relational, and spiritual needs. Comprehensive visits allowed for detailed assessments and interventions as needed.
- We included families in decision making, which allows for establishment of support systems early in the disease course, not just at the end of life—often with potential complications.
 Family integration also provided a means of educating all involved family members about the patient's disease, treatment, and goals of care.
- We included advanced care planning and initiation of multidisciplinary referrals.
- We followed APP-led development of guidelines and processes to leverage data in our electronic health record (EHR) to identify at-risk patients based on specific criteria.

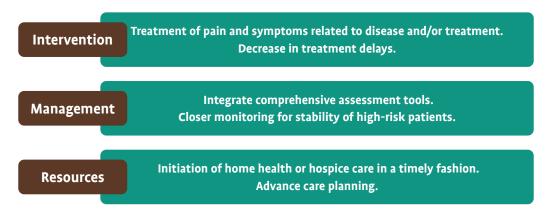
To answer the question, "Who's at risk?" we developed stratification assessment criteria based on:

- Select diagnoses (i.e., head and neck, lung, and pancreatic cancers)
- Treatment regimens with significant toxicities (i.e., doxorubicin plus cyclophosphamide, paclitaxel, and 5-fluorouracil plus irinotecan and oxaliplatin)
- Performance status at diagnosis
- Palliative needs identified at consultation or initial visit in the clinic or post-hospital discharge
- Palliative performance status of 50 percent or lower (i.e., patients unable to do work, patients with extensive disease).

Our second high-risk category focused specifically on our geriatric patients. Older oncology patients present with unique challenges related to economic well-being, pre-existing comorbidities, and independence, all of which increase mortality risk.³ They are at higher risk for chemotherapy intolerance, toxicity, and treatmentrelated toxicity.3 They also require a dedicated, comprehensive focus that highlights problems with daily activities, comorbidities, medications, nutritional status, cognitive function, psychological state, and social support system(s).^{2,3} Our APPs were tasked with integrating measures and assessment tools that gave special consideration to the needs of our geriatric patients with cancer and that were inclusive of their age but not exclusive of other factors, such as pre-existing comorbidities, mobility, Eastern Cooperative Oncology Group performance status, nutritional status, and cognition, to name a few. Figure 1, right, outlines the pillars of our palliative care and high-risk care model. Our APPs use three assessment tools for consistent monitoring, management, and equal criteria measurement for all high-risk and palliative care patients, and we are currently piloting a custom geriatric risk assessment tool:

• The Edmonton Symptom Assessment System⁴ rates the intensity of nine common symptoms experienced by patients with cancer, including pain, tiredness, nausea, depression, anxiety, drowsiness, loss of appetite, and well-being.

Figure 1. The Pillars of Our Palliative Care and High-Risk Model of Care



- *The Mini Nutritional Assessment*® is a nutrition screening and assessment tool used to identify patients aged 65 and older who are malnourished or at risk of malnutrition.⁵
- The Fulmer SPICES framework for assessing older adults focuses on six common "marker conditions"—sleep problems, problems with eating and feeding, incontinence, confusion, evidence of falls, and skin breakdown. These conditions provide a snapshot of a patients' overall health and quality of care.⁶
- Our custom geriatric risk assessment is currently being piloted for assessing geriatric patients (aged 65 or older and on active treatment). The tool evaluates medications, mobility, pain, nutrition, sleep, treatment adherence, anemia, and creatinine for risk of toxicities to treatment. This tool is being modified to include other assessment criteria and comorbidities for better high-risk scoring.

Using these tools, our APPs can better identify symptoms patients often did not think to discuss and healthcare needs that require referrals. These tools also provide a dynamic view of our patients over time, as it relates to decline in performance status that requires treatment adjustment.

Impact and Benefit of Our Palliative Care and High-Risk Model

Since program inception, we have improved the continuity and consistency of our patient care. Patients are now afforded the opportunity to be evaluated without delays in potentially lifesaving therapies. We have learned that the earlier we intervene in providing care that meets the complex and comprehensive needs of oncology patients, the better the outcomes are overall, including end-of-life care. We have witnessed our patients' appreciation for education on palliative care and the benefits of early intervention. Our patients also liked that this education was provided by their oncology care team.

As a practice, we appreciate and understand that palliative care cannot be viewed as an end-of-life measure—but should be seen as an adjunct to quality oncology care—and that early and timely palliative care visits with an APP prevent delays in hospice referrals and decrease the incidence of patients dying within three days of hospice. Data show that we improved patient referrals to hospice to greater than seven days of advanced illness and stopped active treatment for advanced disease sooner than two to three months before hospice enrollment. We also increased the number of patients completing their advanced directives sooner in their disease trajectory, as well as those obtaining follow-up in our clinic prior to use of the emergency department.

Geriatric Follow-Through

We had to address our geriatric patients with cancer independent of our other patient populations due to their dedicated needs and risks. We define our geriatric patients with cancer as those 65 years of age or older. Our practice has treated 3,723 of these patients (2,266 female; 1,457 male). Currently, we have 651 geriatric patients in active treatment, including combination chemotherapy regimens, immunotherapy, and oral oncolytics.

Since the initiation of our pilot geriatric risk assessment, we have gained a greater understanding of these patients' needs specifically as they relate to social determinants of health, which impact overall patient outcomes. APPs assess patients on active treatment at eight-week intervals, and scores are recorded in the EHR after provider review. To date, 543 patients (age 65 to 86 years old) have completed the assessment on at least one visit, with one or more risk factors identified—the most common being mobility and polypharmacy. This assessment has provided us greater details about other aspects of patients' lives that they often do not share or that we have not previously considered as impacting patient outcomes.

We have experienced some challenges. For example, we believe some of our patients may be underscoring the assessment. Further, patients often are not completely transparent and honest about what they need until they are sick or struggling to balance health-care needs with daily living needs. Finally, for some patients, we have missed out on key factors that impact initial decision making (i.e., active comorbidities, current side effects that are disease-and treatment-related, nutritional decline).

Practice Barriers

Given that Cancer Care Associates of York is a small community practice, we are often limited in resources, and the ability to collaborate with surrounding universities is not readily available. The limitations of what we can do internally are reflected in our data. Key indicators we observed directly or indirectly as barriers to fully assessing skilled needs include:

- Use of tool(s) that can miss the assessment of key indicators that influence decision making and impact patient outcomes
- Time constraints for patients completing the assessments in our current practice workflow
- Time constraints experienced by clinicians in assessing scores and applying interventions to patients' current clinical status
- Inadequate resources and staff for data capture and real-time information provided to physicians.

However, these barriers have empowered us to do better. Identifying barriers and outcomes showed that we must be willing to look at what is not working, engage patients in their own outcomes, and initiate practice changes that take our care from better to best in order to gain a true measurement and understanding of our patients' clinical status and risk score. To do so, our practice looks to:

- Provide practice education, training, and professional development regarding palliative care and risk stratification among nurses, APPs, and physicians
- Provide clinical time to see patients as a means of preventing delays in treatment and symptom management
- Engage in early transitions of care to a multidisciplinary approach
- Create a foundation and model that is supportive of the patient and provides a balance in continuity of care
- Make dose modifications and select choice of polychemotherapy treatments vs. single agent therapies based on risk-stratification tools and scores before patients experience treatment toxicities.

Where Do We Go from Here?

Oncology must never become stagnant but, instead, continue to innovate, improve patient outcomes and the patient experience, streamline cancer care delivery, and look for cost-saving opportunities. Specific to our practice, we plan on moving forward by:

- Implementing changes to our comprehensive geriatric assessment by adding categories with numerical values to measure risk, including:
 - Active comorbidity risk
 - Nutrition and malnutrition risk
 - Cognitive assessment risk
 - Frailty assessment risk
- Integrating the comprehensive geriatric assessment into our EHR for easier access, interpretation, and application of results
- Evaluating patients in a timely manner so that we can plan early intervention(s) to reduce complications and enhance quality of life.

Looking to the future, we can deliver person-centered, holistic care that is comprehensive and inclusive of the total person and not just the disease. High-risk patients require more time and resources, but care that is delivered in a coordinated manner makes the burden of cancer lighter. To attain this level of care coordination, our practice looks to:

- Improve communication with all disciplines involved in the care of oncology patients
- Improve and grow our high-risk and palliative care program
- Change the mindset of what patients believe about hospice care to one of understanding
- Change the culture of our practice to one of learning and expansion. •

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MAKING AND CT

ASSOCIATION OF COMMUNITY CANCER CENTERS

2021 IMPACT REPORT

The oncology community grappled with significant issues in 2021, from health disparities and delayed cancer screenings to the well-being of healthcare providers and workforce shortages.

Because every cancer program and practice were impacted differently, the Association of Community Cancer Centers (ACCC) listened to its stakeholders and responded with a wealth of tools, resources, and education initiatives based on expressed member needs.

ACCESS THE REPORT!



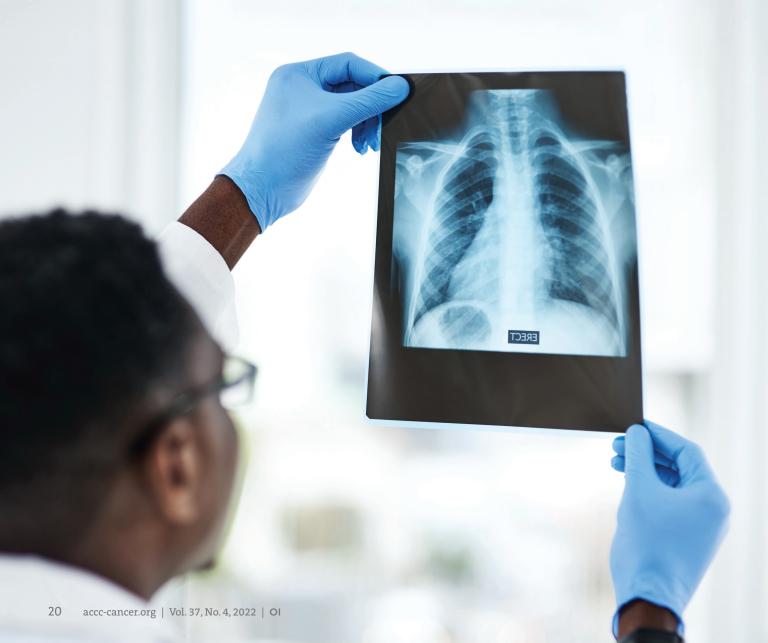
Scan this QR code or visit accc-cancer.org/impact2021

to scroll through the highlights, watch videos from ACCC volunteers,

and explore resources in key focus areas.



Oncology Capture of ED Patients with Incidental Radiologic Findings





Radiologic imaging (i.e., CT and MRI scans) is often used in emergency departments (EDs) to diagnose patients presenting to the hospital. Use of these imaging tools can lead to the discovery of incidental findings, defined as findings that are nonemergent and unrelated to the main concern for which patients sought care. According to one study, 27 percent of all CT scans performed in an ED show an incidental finding that is unrelated to the reason patients originally sought care. Examples of incidental findings discovered through imaging include adrenal masses² and pulmonary lung nodules. Some incidental findings are malignant and left unaddressed, often resulting in more extensive and expensive care. Most concerning, patients with unaddressed incidental findings have the potential to experience more adverse outcomes.

After being notified of an incidental finding by an ED provider and discharged, patients are generally left to seek follow-up care on their own. This care model (often called a "push" model of care) is not ideal, as patients may not understand the nature of their finding or know the medical specialty to contact for follow-up care. One study reported that incidental findings in the ED are common, yet only about 18 percent of patients who were notified of an incidental finding had evidence of follow-up care. It is no secret that patients find it hard to navigate the U.S. healthcare system, especially as it relates to oncology care. Patients who are informed about an adrenal nodule may not know where their adrenal gland is located or that they should follow up with an endocrinologist. These patients require a provider to help them navigate the healthcare system at large and to ensure they receive appropriate follow-up care.

Ultimately, our goal was to proactively offer appropriate care to patients with incidental findings, thereby removing the burden of patients having to search for this care.

Moving from a 'Push' to a 'Pull' Model of Care

Vanderbilt University Medical Center and Vanderbilt-Ingram Cancer Center in Nashville, Tenn., recognized that their current push model of care and referral processes for ED patients with incidental findings had significant opportunities for improvement.

Prior to 2020, Vanderbilt University Medical Center ED providers would receive an alert of a patient's incidental finding in the electronic health record (EHR). ED providers would then discuss the findings with the patient prior to his or her discharge, placing the burden of follow-up care on the patient. From there, oncology providers would receive messages about certain incidental findings via the EHR or by phone. However, these processes were undefined, and non-clinical oncology staff (e.g., schedulers) were unsure about which subspecialty patients should follow up with. These factors had the potential to delay follow-up care and result in inappropriate routing of patient cases.

With the opportunity to redesign our processes, we assembled a project team to evaluate the current and ideal state for assisting ED patients with incidental findings. This team included Vanderbilt-Ingram Cancer Center's associate nursing officer, chief surgical officer, nurse navigators, a project manager, and a business analyst, as well as ED stakeholders, such as the executive medical director, case managers, and a social worker. Bringing this interdisciplinary team together helped ensure representation of all perspectives and support of key stakeholders, who played a role in the development of the new processes. The ideal workflow depended on four essential cornerstones:

- Dedicating staff to follow up with ED patients after discharge and provide ongoing support
- Replacing the existing "push" model with a "pull" model
- Leveraging a technology solution in the EHR to ensure complete and consistent data capture
- Educating ED providers and staff on any process changes.

Ultimately, our goal was to proactively offer appropriate care to patients with incidental findings, thereby removing the burden of patients having to search for this care.

Implementing a New Workflow

The project team determined that radiology would continue to alert ED providers of incidental findings via the EHR, and ED providers would continue to notify patients of their findings prior to discharge. However, after notifying patients of their incidental findings, ED providers would now complete a follow-up form in the EHR to initiate the appropriate follow-up care. Depending on patients' insurance status, the EHR routes the message to one of two baskets—an in-network basket or an out-of-network and uninsured basket—that are monitored by dedicated staff. These staff then contact patients directly to facilitate the appropriate follow-up care.

With the new workflow, the project team understood that additional staff would be needed to ensure program success. Today, two ED case managers focus on patients who present to the ED and are considered out-of-network or uninsured. From an in-network perspective, two disease-specific nurses navigate patients with pancreatic- and pulmonary-related incidental findings, a dedicated physician sees all patients with liver findings, and a nurse manager (who also oversees the program) is responsible for all other incidental findings.

These dedicated staff not only are alleviating burdens from Vanderbilt's nurse navigators but are also establishing "hightouch" relationships with patients by providing a tailored experience, as patients are now interacting with staff who are dedicated to their disease site. Moreover, these staff have expertise in both the nature of the incidental finding and navigation of the health system's follow-up processes.

Upon receipt of an incidental finding EHR message, nurse navigators, ED case managers, or dedicated physicians review the medical chart and contact the patient to discuss the finding and to formulate a follow-up plan, whether it be through their primary care provider or a specialist. Because ED providers may see patients who are not local, not every patient referred to the program receives follow-up care within the Vanderbilt healthcare system. If a patient receives a call from our providers and already has a specialist in mind, staff are happy to forward the patient's medical records to an appropriate provider. This is an important aspect of our program, as patients can complete necessary follow-up with an appropriate healthcare professional even if they live outside of the state.

During the final step of our new workflow, the program's nurse navigators, ED case managers, and physician document their outreach and communication with patients in the EHR via the title "ED incidental finding." Providers use a patient list within the EHR, so all work can be located and tracked.

For this new workflow and for the program to succeed, it was imperative that ED providers were educated about the new processes and supportive of our changes. The project team developed and presented a standard operating procedure to ED providers at their regular meetings. Additionally, because Vanderbilt University Medical Center is a teaching hospital, residents were also informed of this process change during their weekly conferences. After ensuring physician buy-in, the new workflow and processes were presented via weekly emergency room update communications to make all ED staff aware of the program.

Celebrating Patient 'Wins'

Below are a couple of patient "wins" that illustrate our success with this new workflow.

Patient A, a 64-year-old male, presented to the ED with abnominal pain. After completing the necessary imaging, the ED provider found that the patient had a pancreatic mass with liver metastases. Once referred to our new program, the pancreatic-dedicated nurse navigator contacted the patient on the same day the incidental findings were discovered, scheduled an oncology appointment for the following day, and the patient began chemotherapy just six days later.

Patient B, a female traveling through Nashville on her way back to her home in Colorado, presented to the ED, and imaging found an incidental lytic lesion on her spine. When the nurse navigator contacted the patient, the patient said that she had a history of breast cancer and had a medical oncologist she saw regularly. The nurse navigator sent the ED reports to the patient's oncologist and made sure the patient had an appointment scheduled. The nurse navigator also called the oncologist's office prior to the patient's appointment to make sure they had the patient's reports and everything else they needed.

Patient C, a male patient, presented to the ED with a migraine. Imaging subsequently showed a mass on his spine. The nurse navigator made several phone calls and requests through the EHR and, within a week, was able to secure a neurosurgical appointment for the patient for evaluation.

Proving Program Efficacy

When evaluating the efficacy of any program, it is important to remember your goal(s). In our case, we had a two-part goal: 1) routing ED patients with incidental findings through the appro-

priate referral pathway and 2) improving patient engagement through dedicated nurse navigators and staff to initiate follow-up care. Since our program went live in May 2020 and through the end of June 2021, providers identified 1,663 unique ED patients with incidental radiologic findings, approximately 120 patients a month (Figure 1, below). More importantly, 100 percent of those patients were successfully routed via our newly established referral pathways, indicating that the first part of the program's goal is being accomplished.

Looking at the two-part goal, a total of 3,741 outpatient appointments were completed between May 2020 and June 2021, an average of 267 outpatient appointments per month (Figure 2, below). Less than half of those appointments occurred within the cancer center, meaning that most of our program follow-up occurs in non-oncology departments. Lab, radiology, and medicine patient care centers have all experienced a significant number of visits. This finding is important because it demonstrates a significant benefit beyond the cancer center, which helps inform future growth and resourcing for the program.

The data showed some delays in realized visits due to the nature of an incidental finding, which may warrant follow-up immediately or within three months, six months, or longer. Figure 2 shows the number of outpatient appointments completed per month. When comparing this with Figure 1, there were very few visits in May 2020, even though more than 100 unique ED patients were identified with incidental findings. These data suggest that appointments were scheduled out months later, resulting in higher visit totals during later months (e.g., September or October) and beyond. It is also possible that appointments were scheduled out months later due to appointment availability at the time of patients' ED visit, clinical need for follow-up, and provider recommendations.

Another key indicator demonstrating program efficacy is the number of surgeries and procedures that have resulted from these incidental findings. As outlined in Figure 3, page 24, from May 2020 to June 2021, almost 150 surgical procedures were completed, amounting to about 10 procedures per month. From a fiscal responsibility perspective, this is a critical metric, as surgical

Figure 1. Unique Incidental Findings Patients by Month

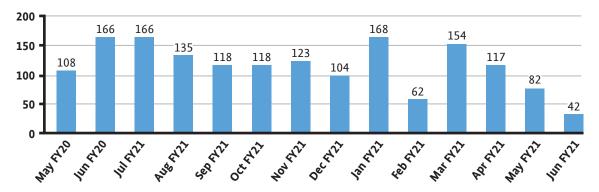
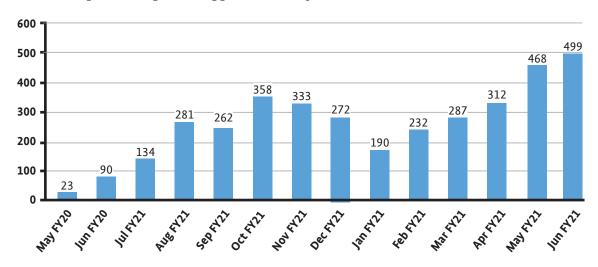


Figure 2. Total Completed Outpatient Appointments by Month



procedures are high revenue generators. Looking at organizational investment in terms of resources, return on investment (ROI) is essential to ensure the ongoing success of the program and future growth.

Learning from Successes and Challenges

Many factors were critical to the success of the program, including involving the appropriate stakeholders (e.g., leadership, nurse navigation, ED case management, and analytics) from the onset. Also, it was imperative to have providers with expertise in incidental findings and the skill to navigate our complex healthcare system—in our case, nurse navigators—who follow up with patients. The ability of staff to deliver these services was critical. Dedicated staff, like our nurse navigators, and resources (e.g., data analytics, program management, and information technology) were key to swift implementation and program success. Finally, engagement by physician leadership was essential to ensure necessary provider education and program advocacy that is carried out across the institution.

Ongoing program success can be credited to the consistent communication and collaboration between all team members, including nurse navigators, ED case managers, physicians, and other organizational leaders. Under the new workflow, all communication is done via the EHR; without this seamless and trackable platform, patients would undoubtedly fall through the cracks.

Even with our successes, we experienced and continue to work through several barriers. In particular, data validation was a significant barrier to demonstrating the efficacy of the program. It was not always apparent whether follow-up visits, labs, procedures, and surgeries were directly associated with a specific patient's incidental finding. Overcoming this barrier involved frequent and close collaboration between nursing, physician leadership, and data analytics to ensure data were attributed to the appropriate incidental findings and tracked to demonstrate ROI.

Other barriers included patient response rates to staff and appointment no-shows. Even though patients are contacted directly about their incidental findings through our "pull" model, they still bear responsibility and must reciprocate that engagement to obtain the follow-up care they need. This includes responding to and working with staff, as well as physically presenting for their scheduled appointments.

Finally, we are faced with a large number of patients with incidental findings and a limited number of navigational resources. Our nurse navigators and other staff can only do so much to engage with patients, including phone calls, online messages, and letters. Demonstrating the program's efficacy should allow us to grow and invest in additional navigational resources.

Exploring Growth Opportunities and Future Direction

Growth within the incidental findings program has been intentional. The program was first staffed by a single nurse navigator and two case managers. Two additional disease-specific nurse navigators (e.g., pancreatic and pulmonary) were later added. With the addition of this dedicated staff, our program's growth was able to align with Vanderbilt University Medical Center's growth. For example, the medical center recently established a lung institute and pancreatic cancer program, and the implementation of our lung-dedicated physician and pancreatic-dedicated nurse navigator helped support the growth of these new programs.

Work is actively taking place to expand the program to the inpatient setting, as our current structure is focused solely on patients who present to the ED and receive follow-up care in the outpatient setting. Opening these services to the inpatient setting will allow us to capture patients who present to the ED, have an incidental finding, and are admitted to the hospital for an unrelated need. Considering this opportunity, we established a work group to focus on this expansion, developing the appropriate processes and ensuring adequate resource allocations to follow-up with

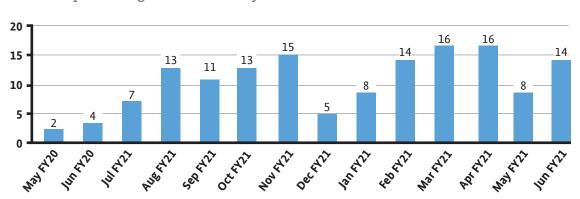
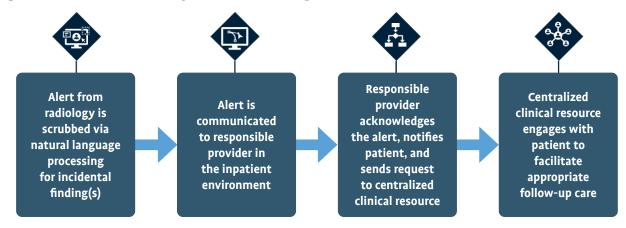


Figure 3. Total Completed Surgical Procedures by Month

Figure 4. Vanderbilt University Medical Center Inpatient Process



those admitted to the hospital. The goal is to cross-coordinate follow-up care for admitted patients with incidental findings with the inpatient care team(s) prior to discharge.

As a direct result, the work group established the process outlined in Figure 4, above. This process hinges on natural language processing as the catalyst for initiating follow-up. Therefore, an alert initiated through the EHR from radiology is scrubbed via a natural language processor, which was developed in-house at Vanderbilt University Medical Center. The processor looks for any coded language that relates to incidental findings. Once an incidental finding is identified, the alert is automatically communicated to the inpatient care team and responsible provider. The inpatient care team acknowledges the alert within the EHR, notifies the patient appropriately, and forwards the request to a new, centralized clinical resource to activate the follow-up process. This resource then engages directly with the patient—similar to our ED-based process—and facilitates next steps. A pilot of this program expansion is underway in a few of Vanderbilt's larger units, and we hope to expand this program into our entire inpatient operation in the future.

Finally, there are numerous opportunities to expand this program and share findings beyond the Vanderbilt University Medical Center and Vanderbilt-Ingram Cancer Center. These opportunities include expanding to other community hospitals within the Vanderbilt University Medical Center system that offer emergency or inpatient services, as well as to other service lines

with a high frequency of radiologic imaging. Moreover, there is opportunity to share these processes with other hospitals and health systems within the Vanderbilt Health Affiliated Network.

Finally, because this opportunity is not unique to the Vanderbilt University Medical Center and its patients, an important next step is to share these findings with the broader, national oncology community through publication in peer-reviewed journals like Oncology Issues.

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Holy Smokes!



Developing a cannabis clinic for patients with cancer

annabis use is becoming more prevalent among patients with cancer in large part due to the benefits the drug brings, like managing multiple symptoms and patients experiencing minimal treatment-related side effects. ¹⁻³ As more states legalize or decriminalize cannabis and the stigma on its use decreases, patients appear to have an increased interest in implementing cannabis into their treatment regimen. However, patients and healthcare providers often lack knowledge about cannabis, including its risks and benefits, specific dosing recommendations, and nationwide or state-based legality.

The Cannabis and Cancer Research and Education Clinic (CanCaRE) at HealthPartners Frauenshuh Cancer Center in St. Louis Park, Minn., looks to bridge this gap. The clinic was developed by Dylan Zylla, MD, MS, an oncologist and medical director of the HealthPartners Cancer Research Center, and Sarah Jax, APRN, CNP, an oncology and hematology advanced practice provider (APP). The initial goals of the clinic were twofold: 1) to provide education for patients with cancer interested in incorporating safe and effective cannabis use into their care plan and 2) to create a robust registry of patients with cancer who are actively using cannabis and leverage this real-world data to inform oncology providers and patients. The CanCaRE clinic offers virtual one-on-one consultations to educate patients about cannabisrelated questions and concerns; the clinic also provides updates on completed clinical trials and ongoing research opportunities regarding cannabis use in oncology.

In 2017 the National Academies of Sciences, Engineering, and Medicine concluded that there is substantial evidence that cannabis is a treatment option for chronic pain and chemotherapy-induced nausea and vomiting.⁷

Cannabis in Oncology

At a federal level, cannabis remains classified as a Schedule I drug with no known medical uses. However, the legalization of cannabis, both medically and recreationally, continues to expand at the state level across the United States. Approximately 25 percent of patients with cancer at one comprehensive cancer center in Seattle, Wash., used cannabis within the past year, with nearly two-thirds of patients expressing a moderate to high interest in education about cannabis use during their cancer treatment. Additionally, nearly 40 percent of patients believe that cannabis may have anticancer properties. These patients want information from trusted sources (i.e., their care team) but often report getting information from family, friends, and/or online.

Cannabis Use and Cancer-Related Symptoms

The growing popularity of cannabis use has increased efforts to study its impact on symptom management. Accumulating evidence suggests the cannabis can enhance quality of life through improvement of many cancer-related symptoms. In 2019, we published a comprehensive review article that addresses cannabis's availability and legality, as well as the safety and efficacy of the drug's use through review of completed clinical trials and observational studies. In addition, we analyzed the safety and efficacy of cannabis in a state-sponsored cannabis program (the Minnesota Medical Cannabis Program) and found that patients with cancer who used cannabis over a four-month period reported significant improvement in:

- · Chemotherapy-induced nausea and vomiting
- Depression
- Disturbed sleep
- Fatigue
- Lack of appetite
- · Pain.

In 2017 the National Academies of Sciences, Engineering, and Medicine concluded that there is substantial evidence that cannabis is a treatment option for chronic pain and chemotherapy-induced nausea and vomiting.⁷ Of particular interest is the impact cannabis may have on opioid requirements. For patients with cancer-related pain, opioids are often prescribed, but they can lead to troublesome side effects, such as constipation, mental fogginess, fatigue, and nausea. Furthermore, the opioid epidemic has made patients fearful of "becoming addicted" to opioids, and thus, patients inquire about alternative analgesic options. In chronic, non-cancerrelated pain, cannabis helps patients reduce or eliminate opioid use altogether. Large observational studies in patients with cancer have shown that 36 percent no longer use opioids while using medical cannabis, and nearly 10 percent of patients can reduce overall opioid consumption.2 Although cannabis may not completely omit the need for opioids in severe cancer-related pain, its ability to limit opioid use could have other beneficial impacts on patients' quality of life.

Educating Providers about Cannabis

Although patients want information from their cancer provider(s), less than 15 percent of patients actually receive this information from their cancer care teams. Over half of oncologists support the use of medical cannabis, yet most do not feel well-informed to make clinical recommendations. However, oncologists are interested in learning about cannabis. We conducted a statewide survey and discovered that 85 percent of oncology providers want more education about medical cannabis. Despite growing interest, barriers, such as perceived patient cost and inadequate data, limit these discussions with qualified patients. Patients and providers often face certain challenges when considering cannabis. A key goal of the CanCaRE clinic is to provide education and research updates on cannabis to enhance awareness and provide safe, effective, and cost-efficient product recommendations to interested patients.

Cost Considerations

The federal status of cannabis prohibits insurance coverage of medical cannabis unless it is one of the few approved prescriptions by the U.S. Food and Drug Administration (FDA) for synthetic delta-9-tetracannabinol (e.g., dronabinol, nabilone). However, these FDA-approved agents are infrequently prescribed given their poor tolerability, which may result from omitting the cannabidiol (CBD) that mitigates the unwanted "high" of tetrahydrocannabinol (THC). Similarly, state-based medical cannabis products are not covered by insurance. Therefore, all costs associated with using medical cannabis are out-of-pocket expenses for patients. Oncology providers report that one of the highest barriers to patient use of cannabis was perceived to be costs. Further, approximately 50 percent of patients indicate cost as a barrier to use.5 On average, patients with chronic, non-cancerrelated pain spend about \$3,000 in accessing and using cannabis per year.9 This potentially high expense can be prohibitive for patients already burdened by medical costs related to their cancer treatment. At CanCaRE, we strive to create cost-effective plans through individual dosing regimens for our patients.

Safety Considerations

Another consequence of the federal classification of cannabis is a lack of robust randomized and observational trial data. Cancer care teams can be apprehensive about the safety profile for cannabis, especially regarding its implications on current treatment and potential side effects. Although cannabis is generally perceived as a safe adjunct therapy for standard intravenous chemotherapies, its impact on metabolism of novel targeted agents is less clear. Furthermore, cannabis can have anti-inflammatory and immunomodulatory effects that might impact patients who are receiving immunotherapy. Small, retrospective studies have reported lower response rates and shorter survival in cannabis users who receive immunotherapy. 10,11 In our CanCaRE clinic, we review this data and generally advise patients to omit or severely limit cannabis use while they are on immunotherapy. Pharmaceutical-grade cannabis extracts may be safer than whole plant/smokeable products as they are tested for potency (i.e., exact amount of THC/CBD/other terpenes) and purity (e.g., toxic chemicals and heavy metals). While lung cancer risk is likely low, there is potential for fungal infection with inhaling raw plant.

State-Specific Laws and Regulations

In Minnesota, medical cannabis is legal through the Minnesota Medical Cannabis Program. Patients who reside in Minnesota and meet at least one of the qualifying conditions are eligible for the registry. For patients with cancer, qualifying conditions include, but are not limited to:¹²

- Cancer associated with severe or chronic pain, nausea or severe vomiting, and/or cachexia or severe wasting
- Terminal illness with a probable life expectancy less than one year and if illness or treatment produces severe or chronic pain, nausea or severe vomiting, and/or cachexia or severe wasting.

These qualifying condition(s) must be confirmed by a healthcare practitioner who is registered with the state to certify patients for the program.

However, medical cannabis and the associated costs for registering with the state program are not covered by health insurance. Annual enrollment in the Minnesota Medical Cannabis Program is \$200 (or \$50, if patients receive federally funded medical assistance, such as Medicaid or Supplemental Security Income). All cannabis products purchased through the program are out-of-pocket costs for patients.

Once a patient is certified by the state program, he or she can purchase up to a 30-day supply of medical cannabis through one of two state-sponsored dispensaries. At the dispensary, patients consult with a licensed pharmacist to determine the appropriate formulations of cannabis for their specific needs. Current state legislation only allows pharmaceutical-grade extracts. However, this summer, smokeable cannabis plant will be available for eligible adults in the program. Before each subsequent purchase, a self-evaluation is required.

Anticancer Properties

At CanCaRE, patients occasionally ask about using cannabis to treat cancer. We recently published a comprehensive review article on cannabis as an antitumor agent through assessment of case reports and clinical data. Additionally, we conducted a nation-wide survey to find patients who had an anti-tumor benefit after cannabis use. Although there are intriguing *in vitro* and *in vivo* studies to support this theory, no prospective clinical trials have shown the clear ability of cannabis to treat or control cancer in patients. However, our research center is developing pilot studies that will evaluate the use of high-dose CBD protocols in patients with refractory glioblastoma and other terminal cancers.

CanCaRE Clinic Referral Process

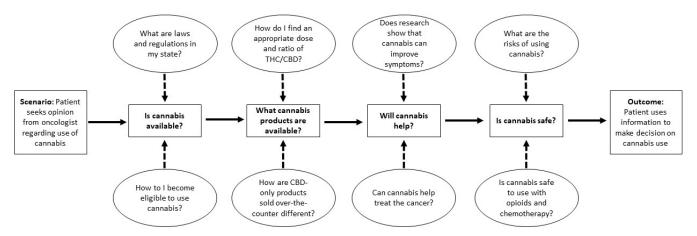
All oncology providers at the HealthPartners Frauenshuh Cancer Center are informed of the CanCaRE clinic and encouraged to refer patients who are interested in learning more about cannabis to the clinic. Information about the clinic is printed on small stick cards and fliers, which allows patients to self-refer. One of the cancer center's lead schedulers is assigned to coordinate all initial and follow-up visits to the CanCaRE clinic. Patients interested in one-on-one education are then scheduled for a video or phone consultation with a CanCaRE APP.

Our current staffing model involves one advanced practice provider (APP), who does all consults and follow-up visits four hours a week. Most CanCaRE patients request a follow-up visit within four to six weeks. Thus far, patient wait times for our consults have averaged less than two weeks. Our cancer center employs 15 oncologists who see about 2,904 new patients each year. This year, we plan to add one additional APP at four hours a week to expand our clinic's services to our affiliate, HealthPartners Cancer Center at Regions Hospital in St. Paul, Minn., which employs 10 full-time oncologists who see about 1,758 new patients each year.

Initial CanCaRE Visit and Education

In addition to addressing patients' questions, the CanCaRE APP reviews the many common concerns patients have about cannabis use (see Figure 1, below). During the initial 45- to 60-minute consultation, patients are educated on the compounds of medical cannabis (e.g., THC vs. CBD) and how different formulations and doses of these compounds can provide potential relief for different symptoms, such as cancer-related pain, insomnia, and appetite stimulation. The APP also discusses the enrollment process, including information on Minnesota's two medical

Figure 1. Important Questions to Address with Patients when Incorporating Cannabis into the Cancer Treatment Plan*



*Reproduced with permission from Current Oncology Reports.

cannabis dispensaries, and the costs of cannabis products. Safety of medical cannabis is reviewed, including potential side effects, as well as drug interactions of medical cannabis with patients' prescribed chemotherapy or immunotherapy regimen.

If a patient meets the criteria for participation in the Minnesota Medical Cannabis Program and wants to enroll, the CanCaRE team works with his or her primary oncologist on how best to get the patient certified by the program. Other costs associated with cannabis certification or product purchasing are discussed at the patient's consult visit, where we provide detailed pricing lists from each of the state's cannabis dispensaries.

The CanCaRE APP visits were modeled after our cancer center's integrated palliative care clinic, and these visits are billed to insurance.

CanCaRE Registry Data

A REDCap registry was created to assess patients' current symptoms, medication use, and cannabis history prior to their initial clinic consult (Figure 2, below). The 16-page CanCaRE Intake Survey is available online at accc-cancer.org/cancare-intake.

Creating the REDCap registry required assistance and input from a multidisciplinary team that includes CanCaRE clinicians, a research intern, staff from our Survey and Evaluation Research Department, and an oncology research coordinator. CanCaRE clinicians use this registry data to tailor patients' visits to their individualized needs and symptoms and to better inform product recommendations. An intake survey includes questions on patients' past medical history, including if they have high-risk conditions (e.g., heart disease or schizophrenia). We also obtain a detailed medication history with a focus on antiemetic and anti-anxiety medications, opioids, and other analgesia usage. Finally, patients answer questions about their past and current cannabis use to help determine their ideal product(s) and dosage of cannabis for their treatment.

The registry sends automatic reminders to patients so they complete the intake survey prior to their consult. Following the initial visit, emails are auto-generated for patients and include product and dosing recommendations, as well as their follow-up plans. Finally, a short survey on symptom management and cannabis use is sent via text or email (based on patient preference) every four weeks to capture longitudinal data on product use patterns, efficacy, and safety.

Metrics and Patient Satisfaction

CanCaRE welcomed patients in December 2020. As of October 2021, our clinic providers have completed initial consultations with 69 patients and follow-up visits with 12 patients. On average, each appointment takes 40 minutes, with 27 minutes of face-to-face interaction. In April 2021 we implemented the REDCap registry, and approximately 75 percent of our patients completed the intake survey.

CanCaRE patients average in age 62 years old. Ninety-three percent have a solid tumor, with 55 percent having Stage IV cancer (Table 1, right). Of the 80 percent of patients with a current treatment plan, over half have a palliative goal of care. In addition, 61 percent of patients are in their first year of treatment.

In July 2021 we conducted a brief patient satisfaction survey. Twenty patients were contacted six to eight weeks after their initial consult. Ten of the 11 patients who responded felt they had learned and benefited from their appointment and recommended CanCaRE to their family members and friends with cancer.

Future Directions

Although the CanCaRE clinic is relatively new, the high level of interest among our patients and clinicians requires strategic planning for future growth. The following are key areas to explore to ensure more patients with cancer can obtain adequate cannabis education:

Figure 2. CanCaRE REDCap Registry Data from Varying Timepoints

Pre-Visit

- Cancer diagnosis
- Potential confounding diagnoses
- Cancer treatment
- PRO-CTCAE® questionnaires
- · Previous cannabis use
- Current medications
- Demographics

Initial visit

- Review pre-visit information
- Current cannabis use/ products
- New recommendations

Follow-Up Visit

- Review/update medical history
- PRO-CTCAE questions from pre-visit survey
- Review/update cannabis
- Review/update medications

PRO-CTCAE = National Cancer Institute's Patient Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE®)

Table 1. CanCaRE Metrics and Patient Satisfaction Survey

| Patient Metrics | |
|----------------------------------|----|
| Average age (%) | 62 |
| Current treatment plan (%) | 80 |
| First-year treatment (%) | 61 |
| Palliative goal of treatment (%) | 55 |
| Solid tumor (%) | 93 |
| Stage IV (%) | 55 |
| Clinic Metrics | |
| Average time with patient (min) | 27 |
| Average total time (min) | 40 |
| Complete pre-visit survey (%) | 79 |
| Total follow-ups | 12 |
| Total patients seen | 69 |
| Patient Satisfaction Survey | |
| Learned/benefited (%) | 95 |
| Recommend CanCaRE (%) | 96 |
| Response rate (%) | 55 |

- Growth and expansion of CanCaRE to serve patients throughout Minnesota
- Analysis of CanCaRE registry data to improve our understanding of the patient experience and better tailor cannabis product recommendations
- Collaboration with other cancer centers across the United States to further enhance education and research opportunities to all patients living with cancer. Ol

Sarah Jax, APRN, CNP, is an oncology/hematology advanced practitioner; Katherine Schmiechen is research intern; and Dylan M. Zylla, MD, MS, is an oncologist and medical director of the HealthPartners Cancer Research Center at HealthPartners Frauenshuh Cancer Center in St. Louis Park, Minn.

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Supplemental Material

This article contains supplemental material that can be accessed on the publisher's website: http://dx.doi.org/10.10 80/10463356.2022.2079356

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Auricular Acupuncture for the Treatment of Cancer-Related Pain

Cancer-related pain is often challenging to manage when trying to ensure patients are comfortable as they experience treatment-related side effects. To improve patients' pain and psychological distress, auricular acupuncture—a treatment that stimulates points on the ear—may serve as a safe and effective complementary therapy. Therefore, in 2020, Vanderbilt-Ingram Cancer Center implemented Battlefield Acupuncture—an auricular acupuncture protocol developed by the U.S. military—in its pain and symptom management cancer care clinic.¹ Patients reported high satisfaction with the acupuncture treatment, in addition to their standard care treatments. Furthermore, positive impacts include cases of significant opioid reductions and improved patient quality of life. In line with current evidence, auricular acupuncture should be considered as an adjunct treatment for cancer-related pain.

ancer impacts millions of people across the globe daily as incidences grow. More than 17 million cancer cases were reported worldwide in 2016, resulting in more than 8 million deaths.² In a 10-year duration between 2006 and 2016, there was a 28 percent increase in cancer diagnoses.² Cancerrelated pain and psychological distress are unfortunate comorbidities that often remain undertreated during patients' care.3-5 The sequelae of uncontrolled cancer-related pain further impacts a person's quality of life and ability to cope with effective psychosocial interventions.6 Often, the use of pain-relieving medications, such as opioids, has undesired side effects that could further impact patients' function and quality of life. Commonly reported adverse effects of opioids include constipation, nausea and vomiting, sedation, pruritis (itchy skin), respiratory depression, and hypogonadism (a failure of the gonads, testes in men and ovaries in women, to function properly), which often lead patients

to discontinue use of these medications, resulting in uncontrolled pain.⁷⁻⁹

Given the prevalence and impact of cancer-related pain, optimal treatments must be pursued. A promising adjunctive intervention for pain management is auricular acupuncture, a type of acupuncture that uses thin needles inserted at specific locations on the outer ear, ¹⁰ following the Battlefield Acupuncture protocol. ¹¹ Many studies have demonstrated auricular acupuncture to be safe and beneficial in reducing pain intensity when combined with the standard of care. ^{12,13} Additionally, auricular acupuncture may improve psychological distress in patients experiencing pain. ¹⁴

Implementing Auricular Acupuncture at Vanderbilt-Ingram Cancer Center

Auricular acupuncture is less expensive for patients (\$31 per treatment) compared to full-body acupuncture, and it can be

easily implemented within the standard of oncology care. The pain and symptom management team at Vanderbilt-Ingram Cancer Center gathered current evidence for integrating auricular acupuncture and presented it to the cancer program leadership. Support from key stakeholders was secured and included executive physician, nursing, and business leaders. Once buy-in was secured, collaboration among scheduling specialists; nursing, advanced practice, physician, and administrative leadership; and billing consultants was key to ensuring successful implementation and operation of the program.

The acupuncturist was a specialty trained nurse practitioner currently practicing within the institution. Additional training, certification, and credentialing is required for this practice and was extended to this and other team members.

In collaboration with our coding teams, we developed a note template to collect documentation and bill for the service.

To ensure all providers and staff were made aware of the new auricular acupuncture service, we shared information at monthly operational and departmental meetings, as well as at town halls. Informational meetings with leaders from Vanderbilt's access centers were conducted, and decision trees were updated to alert specialists of this new service.

Finally, we updated our patient brochures, allowing for self-scheduling by patients online, and we placed advertisement banners in the cancer center's waiting room. Advertising materials included patient out-of-pocket fees and images of the nurse practitioners providing this treatment.

Vanderbilt-Ingram Cancer Center began offering auricular acupuncture for the treatment of cancer-related pain in 2020.

Results from Program Implementation

Overall, acceptance and use of auricular acupuncture by patients within our cancer center has been positive. Providers now refer to this service as a complementary therapy. Patients appreciate the additional treatment option without risk of side effects, and many have reported an improvement in their pain and comfort. Patients have also reported a reduced need for medication(s) prescribed for pain (e.g., muscle relaxers, benzodiazepines, anti-inflammatories, and neuropathic regimens in addition to opioids). The benefits of auricular acupuncture are highlighted in the case study below.

Patient Case Study

A 49-year-old male with a history of thyroid cancer and chronic cancer-related pain in his bilateral cheeks and the left side of the neck was referred to the clinic. Quality of life for this patient was significantly disrupted, as the pain was so severe when chewing, it prevented him from eating at times. He further reported multiple side effects from a prescribed opioid, impacting his quality of life and his ability to parent his young children. At the time of consultation, the patient was taking oxycodone (immediate release, 15 mg, four times per day [60mg/day]).

Our team administered Battlefield Acupuncture to the patient once a month for two months (a total of two sessions). Following the second auricular acupuncture treatment, the patient reported 100 percent relief from the pain on the right side of his face, 50 percent relief from the pain on the left side of his face, and significant improvement in comfort while eating. He was tearful when discussing his considerably increased ability to enjoy meals socially. Furthermore, the patient was also able to reduce his oxycodone intake to 5 mg for no more than three times a day (15 mg/day)—a 75 percent reduction—and had plans to continue weaning off the opioid completely.

Our institution evaluates patient satisfaction with validated surveys. ¹⁵ This patient reported 100 percent satisfaction with the overall auricular acupuncture care provided, including time spent with the provider and explanation of the procedure and medical condition. He said he was likely to recommend this service to others (Table 1, below).

Final Thoughts

Integration of auricular acupuncture is safe, feasible, and cost effective, and provides patients suffering from cancer-related pain an additional complementary treatment option. Use of auricular acupuncture as an adjunct to standard anti-cancer therapies may help mitigate adverse reactions associated with cancer treatments and pain medications. In the literature, patients have reported positive outcomes and, in some cases, significantly improved quality of life after auricular acupuncture. Our findings support existing studies and provide evidence to include auricular acupuncture as a treatment consideration for patients experiencing cancer-related pain and/or side effects from medications.

| Table 1. Patient Satisfaction with Auricular |
|--|
| Acupuncture Treatments |

| Survey Question | Satisfaction (%) | N |
|--|------------------|---|
| Care overall | 100% | 1 |
| Explanation of condition | 100% | 1 |
| Provider concern for questions/worries | 100% | 1 |
| Provider's efforts to include patient in decision making | 100% | 1 |
| Time spent with patient | 100% | 1 |
| Likelihood of recommending the therapy | 100% | 1 |
| Auricular acupuncture provider | 100% | 1 |
| Discussion of treatment | 100% | 1 |

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Data Analytics + Business Intelligence = Operations Insights



"Leveraging Technology to Transform Cancer Care Delivery and the Patient Experience" is the theme of 2022-2023 ACCC President David R. Penberthy, MD, MBA. As one component of Dr. Penberthy's president's theme, ACCC is developing resources on how technology can be used to identify ways to reduce disparities, to mitigate workforce shortages, and to improve efficiency and sustainability of quality cancer care delivery. Learn more at accc-cancer.org/presidents-theme.

s oncology practices work to succeed in today's environment of decreasing reimbursement and the increasing cost of new drugs, having an efficient and effective charge capture program in place is absolutely essential to practice success. Every oncology practice will readily admit that charge capture is an important process to perform in order to prevent lost charges for services provided."

Sound familiar? These are the opening sentences of a 2008 article, "Charge Capture: Does Your Process Ensure Accuracy of the Revenue Cycle?" published in the *Journal of Oncology Practice*.

Whether care is provided in an outpatient ambulatory clinic, in an independent oncology practice, virtually, or in person, optimizing revenue cycle management in oncology is both critical and complicated.

Over the past two decades oncology business operations—billing, coding, prior authorizations, denials, drugs costs, contracting, forecasting, and more—have continued to experience unchanging pain points. What has changed, however, is the availability of data analytics technology applications specific to the business of oncology. Today, oncology business intelligence (BI) platforms harness technology to perform those revenue cycle tasks best suited to automation, freeing business and revenue staff to tackle issues that require human intelligence and intervention.

And yet, as a recent article, "Leveraging Business Intelligence for Healthcare Management," explains, complexities remain: "Healthcare organizations have very quickly learned that they cannot simply snap their fingers and instantly access all of the data, reporting, and decision support they need to foster an intelligent business."²

Tackling the Pain Points

Kim Woofter has an insider's perspective on the critical role of data analytics in oncology practice management. Upon graduation from nursing school, Woofter began her nursing career in the oncology inpatient setting. In the mid-1990s, she transitioned to the business operations side of cancer care, managing Michiana Hematology Oncology, then a small medical oncology practice in South Bend, Ind. She found a passion for the work of building a practice with the mission of delivering high-quality patient care. Over time, the practice thrived and expanded, adding radiation oncology, radiology, and gynecologic oncology to medical oncology services; providing care in 11 locations; and growing from 4 physicians to 19.

About six years ago—in the midst of healthcare's evolution toward value-based reimbursement—Michiana Hematology Oncology recognized that data analytics were becoming essential to sustainability as an independent practice, Woofter recalled.



Kim Woofter, executive vice president, Strategic Alliances, AC3

"Initially we wanted analytics around the way we used our pharmaceuticals and moved them to different [practice] locations in our hub-and-spoke model, and to look at data utilization trends," she said. The practice engaged a local data analytics firm and the results from this first foray into integrating data analytics were "an eye-opening experience," Woofter said. The practice realized the advantages to automating specific, repetitive, backend tasks, such as identifying underpaid claims, and the ways in which technology could increase business staff efficiency and improve the bottom line.

The practice partnered with the data analytics firm Aunalytics, eventually spinning off an oncology business intelligence platform, AC3, as an independent company. After a career spent building a successful oncology practice, Woofter was hooked. "To have solutions that don't require more manpower, more expense, it was really exciting for me," she said. In 2016 Woofter left her role as chief operating officer at Michiana Hematology Oncology to become executive vice president of strategic alliances at AC3. In a conversation with *Oncology Issues*, Woofter shared her perspective on the versatile benefits cancer programs and practices can realize from leveraging data analytics solutions for streamlining revenue cycle management, for greater clarity on insurance claims data, and for more transparency on key performance indicators (KPIs) of cancer program business health.

Oncology Issues. We've seen so many clinical advances in oncology over the past two decades. But we haven't seen as much progress on revenue cycle challenges. Oncology programs and practices continue to struggle with recovering missing reimbursement, burdensome prior authorization processes, diverse payer plans with varying fee schedules, reducing costs for claims processing, and more.

Woofter. You're correct about what hasn't changed. We understand clinical practice. We've put a lot of energy into patient care with new technology—new ports, new pumps, new ways to deliver care. But if we're to keep community oncology sustainable, we must be able to bill and collect and do so with confidence to keep our business alive.

For example, a core problem for the oncology revenue cycle team is knowing exactly what you are supposed to be paid [under each patient's commercial plan]. Practices usually have contracts with a small number of payers. But in providing care for patients, you accept payment from payers from other states or elsewhere in the country. Medicare fee schedules are published publicly, but getting a handle on what you will be paid by private payers is challenging.

Oncology Issues. How does a BI platform, like AC3, help?

Woofter. Using business intelligence and technology, we are able to automate and build in these fee schedules and codify into the technology the business rules around billing so that the practice knows what the allowable amount is for more than 90 percent of its payers. That's the foundation you build on.

The goal and benefit of AC3's technology is that it empowers cancer programs to not only know what they will get paid—to be able to track and predict [revenue]—but also to look at 100 percent of transactions. Technology can do that; humans cannot. Combining business intelligence with data analytics, we can leverage technology to show what was paid and then apply business rules—for example, was the provider an NP [nurse practitioner]? An assistant surgeon? Was there a modifier? And through this automated process, we can identify underpayments.

What we have found is that practice management systems frequently use the EOB (Explanation of Benefits) statement as the source of truth—rather than the actual fee schedule. Because the EOB often lists differing amounts that are incorrect and understated when comparing exceptions, payers will often inappropriately adjust or write off partial amounts. What you were paid wasn't right and you don't know it because the practice management system automatically adjudicates that claim.

Oncology Issues. How is this information and data communicated back to the client?

Woofter. In our case, AC3 provides claims intelligence detailing the root cause of discrepancies and uses color codes to prioritize claims based on recovery probability and timeliness. It's hard to hire experienced staff. Color coding helps. New billing and revenue cycle staff, for example, who have never reprocessed claims, can be given items [flagged] in green that are easier to handle, allowing more experienced staff to handle harder items.

It's leveraging technology to provide staff with actionable insights versus staff searching through files for the "needle in the haystack." Technology serves up the exceptions. Ninety percent of claims are correct. It's that 10 percent that are not, and there is a lot of money in that 10 percent.

Oncology Issues. So it's leveraging machine intelligence to optimize the revenue cycle process and free up business and revenue staff to address those issues that require human intelligence to sort out.



Examples of Claims Dashboard-Pay Vs. Allowed MEDONC

Woofter. AC3 truly provides business intelligence, because you have the data set and the people who can build a dashboard for the cancer program as needed. Business intelligence can answer the questions that are most important to that cancer program.

Oncology Issues. Can you give an example?

Woofter. We have a pharma solution that provides intelligence when payer reimbursement does not cover the cost of the drug—what's commonly called an "underwater drug." An alert is triggered at the time of prior authorization. For patients on active therapy the solution looks forward [so that you can see] in the next 10 days which patients are coming in to receive a drug that is underwater. Rarely have I seen an active on-treatment plan changed [because of this information]. What it does is provide the intelligence and transparency we are all looking for.

Another example is when sequestration went away [during the pandemic]. The beauty of technology: you make one adjustment and every fee schedule that had a sequestration—it's now removed. Now sequestration is back, and all you have to do is tell the technology that sequestration is now 1 percent for these payers. It replaces a human having to go through all the fee schedules. You're able to make real-time adjustments quickly.

Oncology Issues. What does the AC3-client interaction look like? What's the onboarding process?

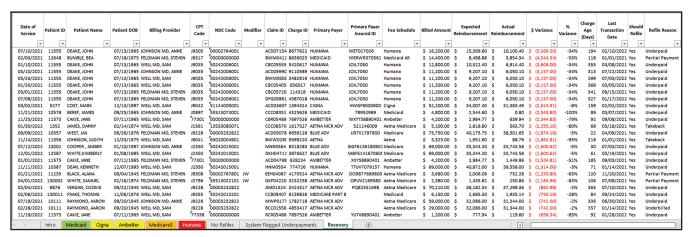
Woofter. Onboarding takes about 90 days—understanding, digesting, and researching all the fee schedules and contracts. We

AC3 has a quarterly executive business review with clients in which we go over what the technology has uncovered and highlight for the cancer program leadership that "in working with your team, this is what they've found." We are the silent partner that makes your billing team shine.

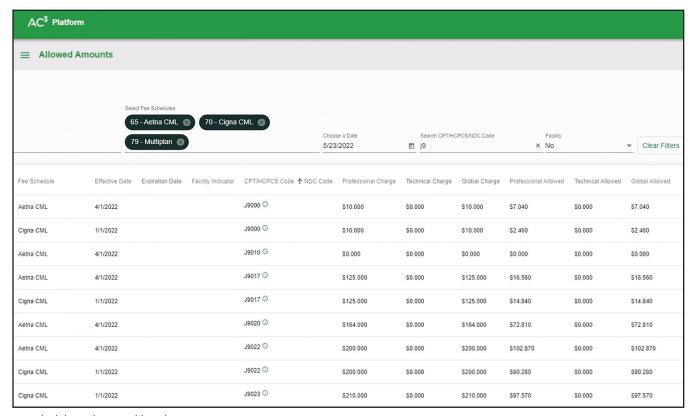
see ourselves as a tool for the billing and revenue cycle team. We are a long-term tool. Instead of staff digging through software [to find missing revenue], AC3's technology processes billions of data points a day and translates these into simplified, actionable insights for clients. It will show the team in real time what was underpaid and how to act on it.

AC3 has business intelligence "advisors" and "client success managers." Our advisors are always looking at the client's data. Another tool is a KPI dashboard that allows the revenue cycle director to see net collections, lag in charge entry, etc.—it's another set of eyes watching that [data].

The cancer program or practice should be able to reduce the cost per claim that it's processing. Let technology do what it does best and let humans do what they do best.



Claims Priority Intelligence Download Report



Fee Schedule Analyzer Dashboard

Oncology Issues. What's the average recovery practices see on underpaid claims?

Woofter. About 70 to 80 percent. It's money that the cancer program wasn't even addressing before. It's not like a denied claim. It's an underpaid claim. The practice does not have to validate why it's the wrong amount; AC3's technology and staff help with that.

Oncology Issues. What impact, if any, does implementation of the BI platform have on patients?

Woofter. The way it is impacting patients is the transparency around pricing. It helps the physician educate them [about costs] and make informed decisions. Now a physician is able to know what a treatment plan is really going to cost with that patient's payer—a good faith estimate that is pretty accurate because we have accurate fee schedules. So, you get accuracy and transparency. It helps billing teams to get it right and allows patients to resolve issues in a timely way with their payers.

Oncology Issues. What is the business office staff reaction to AC3 technology? Do revenue cycle staff ever feel threatened by potential job loss?

Woofter. This [issue] was important to all of us. We've all been in those shoes where new technology comes in and makes you look like you've been missing something and are not doing your job well. Our approach is that we are a tool for the revenue cycle team, and the cancer program is investing in a tool to streamline the team's workflow and results. AC3 routinely meets with the revenue cycle team to collaborate on the process for achieving the desired results.

AC3 has a quarterly executive business review with clients in which we go over what the technology has uncovered and highlight for the cancer program leadership that "in working with your team, this is what they've found." We are the silent partner that makes your billing team shine.

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Editor's Note

The images in this article contain fictitious demo data. No real personal identifiers (patient name, provider, date of birth [DOB], patient ID, date of service, claim ID, charge ID, payer ID, fee schedule, transaction date) are used in these images.

Insights Available in the AC3 Revenue Cycle Management KPI Dashboard

- Accounts receivable aging (A/R aging); billed A/R and allowed A/R
- Days in A/R, days to payment
- Allowed revenue and cash collections A/R (total allowed net sequester, cash as a percentage of allowed, cash collected by date of service)
- Charge entry success (claim and charge volume, days to bill)
- Financial assistance KPI
- Adjustments KPI
- Authorizations KPI

Technology in Practice

Highlands Oncology Group is a freestanding cancer center located in the northwestern corner of Arkansas. The multispecialty cancer center operates four clinical sites with a staff of 450 and sees nearly 6,000 patients annually. Highlands Oncology Group providers include 11 medical oncologists, 3 radiation oncologists, 2 supportive care physicians, 5 surgeons, 52 registered nurses, 4 oncology pharmacists, 2 genetic counselors, 4 social workers, 2 physical therapists, and 2 massage therapists. The cancer center uses OncoEMR for its electronic health record and the G4 Centricity practice management system.

At the end of August 2021 Highlands Oncology Group officially went live with AC3's oncology business intelligence platform.

One problem Highlands Oncology Group looked to the AC3 platform to resolve was missing reimbursement from payers, said business office manager Terry Cardona, RHIA. Keeping up with all of the payer fee schedules and updates manually was unmanageable. In addition to any fluctuations in fee schedules, the business office wanted to leverage the technology for alerts regarding drugs on which the group would be underwater.

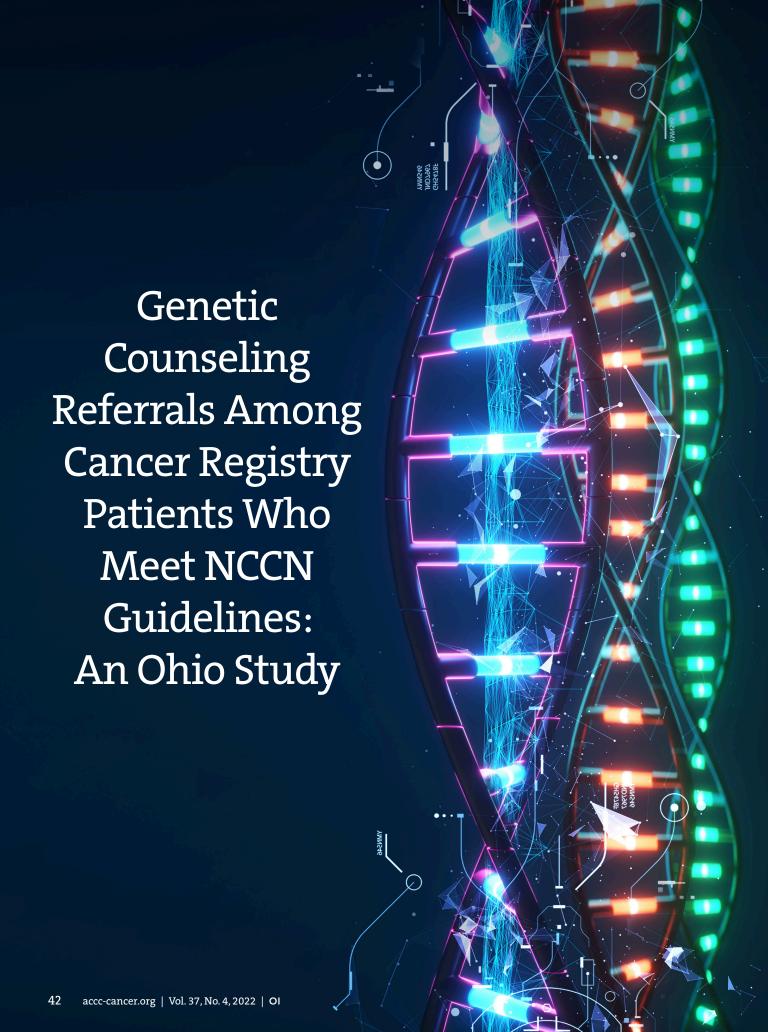
Six business office staff received the AC3 onboarding training, which went off without a hitch, Cardona said.

The AC3 team provides the business office team at Highlands Oncology with color-coded spreadsheets of audited information. At first, spreadsheet review can add to the workload Cardona said, because "you're seeing things you've not seen before." But the color coding helps by prioritizing those items that need to be addressed first. AC3 auditors provide notes and are available for Highland Oncology Group staff questions. Currently the practice has two business staff working with these spreadsheets, one in medical oncology and one in radiation oncology.

True to plan, one of the most important benefits of integrating the business intelligence platform has been automating the process for updating fee schedules and identifying missing reimbursement, she said. On occasion, the cancer center still encounters challenges in having the most up-to-date fee schedule on hand, but the team from AC3 will help by communicating what information needs updating. Once the updated schedules are obtained, the AC3 team works quickly to identify any underpayments.

Another AC3 feature that powers efficiency, Cardona said, is the dashboard generated by the AC3 platform, which she uses to identify billing trends and performance drivers. "The improved visibility from the dashboard allows us to act fast on implementing or changing workflows." Highlands Oncology Group continues to work with the AC3 team to develop additional dashboard solutions, which provide that "ready-to-view information" that business office staff need, Cardona said.

Bottom line: She would encourage other programs and practices to consider adopting an oncology business intelligence platform. "The data is always there, but we don't always have time to drill down. This is real-time information."



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he National Cancer Institute estimates that more than 519,000 women will be diagnosed with breast, colorectal, endometrial, or ovarian cancer in 2021, making up approximately 27 percent of all new cancer cases. 1,2,3,4 Although most cancers occur sporadically, approximately 10 percent of these cases will be due to a hereditary cancer predisposition syndrome caused by an inherited genetic variant. Therefore, an estimated 76,000 newly diagnosed patients with cancer will have a hereditary cause for their disease. Identifying these individuals early can have a significant impact on their future health by determining their risk for additional cancers, altering cancer-screening recommendations, offering risk-reducing options, and potentially identifying gene-based anticancer treatment options.

Genetic testing became available in 1996 for the *BRCA1/2* genes associated with hereditary breast and ovarian cancer syndrome for breast and ovarian cancers. These are the most widely recognized indications for testing. Another important milestone in cancer genetics occurred in 2000, as providers could now test for two of the five genes known to be associated with Lynch syndrome, a hereditary condition that accounts for up to 3 percent of all colon and endometrial cancers. Historically, clinicians have been more aware of guidelines for referral in breast and ovarian cancers than any other types of the disease, which is reflected in genetic counseling referral patterns.

To help clinicians identify individuals at risk for hereditary cancer, the National Comprehensive Cancer Network (NCCN) created its guidelines in 1999 that continue to be updated today.⁷⁻¹¹ Several studies have analyzed the efficacy and utility of the NCCN Guidelines® in clinical practice. One such study, by Febbraro et al., evaluated the number of women with breast, endometrial, or ovarian cancer who met NCCN Guidelines and who were referred for genetic counseling between 2004 and 2010.¹² The study found that the overall referral rate was 21.7 percent and that patients with breast cancer were more likely to be referred for genetic counseling than those with endometrial or ovarian cancer.¹²

The overall referral rate for genetic counseling increased from 36 percent in 2013 to 66 percent in 2018. The proportion of patients with breast cancer who were referred for genetic counseling showed a substantial increase, from approximately 49 percent in 2013 to 75 percent in 2018.

Numerous other studies and abstracts have looked at evaluating genetic counseling uptake. Bellcross et al. evaluated a large genetic counseling integrated site system and found that, of the 684 individuals considered at high risk for hereditary breast and ovarian cancer syndrome, only 20 percent were referred for genetic counseling. A 2012 Michigan study showed that only 23 percent of women with a family history of breast cancer diagnosed at age 50 or younger received genetic counseling. Additionally, a study in the *Journal of Clinical Oncology* found that only 15 percent of women with ovarian cancer discussed genetic testing, and only 11 percent had genetic testing done. 15

An Ohio Study

Ohio Partners for Cancer Control's Comprehensive Cancer Control Plan laid out the state's cancer genetics objective from 2015 to 2020, which was to increase the overall number of individuals who receive genetic counseling at an Ohio Cancer Genetics Network site by 20 percent. One strategy identified to help meet this goal included promoting collaboration among

genetic counselors and cancer registrars to identify individuals appropriate for genetic counseling. The Ohio Department of Health contracted with five Ohio-based health systems to gather registry data on individuals who meet NCCN genetic counseling referral guidelines for select cancer diagnoses. These participating health systems included the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute at The Ohio State University, OhioHealth, and Mount Carmel Health System in Columbus, as well as TriHealth in Cincinnati and ProMedica in Toledo, Ohio.

This study was created to support Ohio Partners for Cancer Control's state cancer plan objective and to determine a statewide benchmark for Ohio Cancer Genetics Network sites by evaluating genetic counseling referral data for individuals who meet NCCN criteria and who are identified by cancer registry data at the five participating health systems. In this article, we discuss our experience in collaborating with various cancer registrars and lessons learned on how to obtain accurate data. The information shared here may serve as a platform for future assessment of potential methods to increase genetic counseling referral and uptake of these services among populations who are at high risk for hereditary cancers.

Materials and Methods

This study is a continuous prospective quality review that will incorporate new data annually as they become available at each participating health system. This is an Ohio-based multicenter initiative, and data were shared only in aggregate form, without patient identifiers, among participating health systems. The study's population is listed below. Eligible individuals with cancer in 2013 to 2018 who met NCCN genetic counseling referral criteria and who were identified by a cancer registrar's database from the five participating health systems were asked to participate in the study. The study was approved by each participating health system's institutional review board (IRB) and the Ohio Department of Health's IRB.

Study Population

Based on NCCN 2013 referral criteria and adjusted with NCCN updates, the study's inclusion criteria were:

- Females with breast cancer ages 18 to 50 years old
- Females with triple-negative breast cancer ages 51 to 60 years
- Males with breast cancer ages 18 years or older
- Females and males with colorectal cancer ages 18 to 49 years old
- Females with fallopian tube, ovarian, or primary peritoneal cancer ages 18 years or older (these cancers are referred in combination as "ovarian cancer")
- Females with endometrial cancer who were diagnosed at 18 years to 49 years old.

Although there are numerous other criteria for genetic counseling referral, this study used only patients' cancer and age at diagnosis. This is because these criteria are the easiest for healthcare providers to identify and the most straightforward data for cancer registrars

to collect. Patients who did not meet the criteria were excluded from the study.

Statistical Analysis

Each participating health system requested data from their respective cancer registry annually from 2013 to 2018. The registry looked for patients who met the study's criteria and provided a list to the health system with patient identifiers. Each center used its own method to determine if a genetic counseling referral was made and whether or not the patient's appointment was completed. This process included query of the center's electronic health record (EHR) and/or use of internal genetics clinic databases. The patient identifiers were only used internally to match patients who had genetic counseling. For each year, the participating health systems recorded and collected in an aggregate spreadsheet the de-identified number of eligible patients referred to genetic counseling and the number of eligible patients seen for genetic counseling. Table 1, right, shows the formulas each healthcare center used to calculate percentages.

The proportions of eligible patients who were referred to genetic counseling, eligible patients who were seen by a genetic counselor, and those seen by a genetic counselor for each cancer diagnosis were summarized by year. Generalized linear mixed models were used to estimate mean predicted probabilities and evaluate trends from these referral statistics. These data were summarized over time from 2013 to 2018 for patients with breast cancer, triple-negative breast cancer, ovarian cancer (fallopian tube, ovarian, and primary peritoneal cancers), colorectal cancer, and endometrial cancer. Cancer sites were used as a random effect in our models to account for repeated measures. The mean predicted probabilities summarized in tables and plots represent the model's estimated proportion of eligible patients who were referred to genetic counseling, eligible patients seen by a genetic counselor, and those referred patients who were seen for genetic counseling across all centers for a given year. Statistical analysis was performed using statistical software SAS/STAT (version 9.4 of SAS for Windows by SAS Institute Inc. in Cary, N.C.) and RStudio (R version 3.6.0 by The R Foundation for Statistical Computing).

Patients Referred for Genetic Counseling

Data for eligible patients referred to genetic counseling are summarized in Figure 1, page 46, and Table 2, page 47. From 2013 to 2018, the five participating health systems identified 8,945 patients who met NCCN criteria for genetic counseling referral, including:

- 477 patients with breast cancer (477 females; 136 males)
- 1,956 patients with ovarian cancer
- 968 patients with colorectal cancer
- 636 patients with triple-negative breast cancer
- 475 patients with endometrial cancer.

The overall referral rate for genetic counseling increased from 36 percent in 2013 to 66 percent in 2018. The proportion of patients with breast cancer who were referred for genetic counseling showed a substantial increase, from approximately 49 percent in 2013 to 75 percent in 2018 (p < .001). Similarly, the proportion

Table 1. Mean Predicted Probabilities of Eligible Patients Referred for Genetic Counseling

| Mean predicted probability of eligible patients referred for genetic counseling | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 |
|---|------------|------------|------------|------------|------------|------------|
| | n | n | n | n | n | n |
| | Mean (SE) |
| | [95% CI] |
| Breast cancer (female) | 581 | 841 | 785 | 829 | 912 | 826 |
| | .49 (.08) | .54 (.08) | .62 (.07) | .67 (.07) | .7 (.06) | .75 (.06) |
| | [.33, .65] | [.38, .69] | [.47, .76] | [.51, .79] | [.55, .81] | [.6, .85] |
| Triple-negative breast cancer | 65 | 96 | 155 | 120 | 96 | 104 |
| | .30 (.11) | .48 (.12) | .73 (.09) | .67 (.11) | .67 (.11) | .66 (.11) |
| | [.12, .56] | [.25, .72] | [.5, .88] | [.42, .85] | [.42, .85] | [.41, .84] |
| Breast cancer (male) | 19 | 28 | 23 | 18 | 19 | 29 |
| | .57 (.19) | .61 (.14) | .87 (.09) | .46 (.16) | .69 (.15) | .59 (.14) |
| | [.2, .87] | [.31, .85] | [.57, .97] | [.17, .77] | [.34, .91] | [.3, .83] |
| Ovarian cancer | 210 | 328 | 373 | 320 | 353 | 372 |
| | .3 (.08) | .35 (.08) | .39 (.08) | .46 (.09) | .51 (.09) | .5 (.09) |
| | [.16, .49] | [.2, .53] | [.24, .58] | [.29, .65] | [.33, .69] | [.32, .68] |
| Colorectal cancer | 91 | 155 | 171 | 185 | 162 | 204 |
| | .22 (.06) | .29 (.05) | .33 (.05) | .33 (.05) | .44 (.06) | .51 (.05) |
| | [.12, .36] | [.2, .4] | [.24, .45] | [.23, .44] | [.33, .56] | [.4, .62] |
| Endometrial cancer | 43 | 69 | 89 | 80 | 101 | 93 |
| | .1 (.05) | .27 (.06) | .29 (.06) | .39 (.07) | .45 (.06) | .51 (.06) |
| | [.03, .27] | [.16, .42] | [.18, .42] | [.26, .53] | [.33, .58] | [.37, .64] |

CI = confidence interval; SE = standard error.

of patients with triple-negative breast cancer who were referred for genetic counseling increased from 30 percent in 2013 to 66 percent in 2018 (p = .002), and the proportion of patients with ovarian cancer who were referred to genetic counseling increased from 30 percent in 2013 to 51 percent in 2018 (p = .001). Increases in referrals over the same period were also seen among patients with colorectal cancer (22 percent to 44 percent, p = .001) and patients with endometrial cancer (10 percent to 51 percent, p = .006).

Patients Seen for Genetic Counseling

The overall rate of eligible patients who were seen for genetic counseling increased from 29 percent in 2013 to 57 percent in 2018. Proportions of female patients with breast cancer who were seen for genetic counseling gradually increased from 43 percent to 68 percent from 2013 to 2018 (p < .0001). Similarly, the proportion of patients with triple-negative breast cancer who were seen for genetic counseling showed a substantial increase from 27 percent in 2013 to 60 percent in 2018 (p = .001). Proportions of male patients with breast cancer seen for genetic counseling fluctuated between 33 percent to 52 percent from

2013 to 2018, with no overall difference detected in mean predicted probability seen across time (p = .859). Increases in proportions from 2013 to 2018 were also observed among patients with ovarian cancer (19 percent to 44 percent, p = .001), patients with colorectal cancer (15 percent to 35 percent, p = .021), and patients with endometrial cancer (4 percent to 30 percent, p = .045). See Table 2, page 47, and Figure 2, page 48.

Percentage of Referred Patients Seen for Genetic Counseling

The overall proportion of referred patients seen for genetic counseling increased slightly (from 82 percent to 87 percent) from 2013 to 2018. Generally, trends in the mean predicted probabilities of referred patients seen for genetic counseling fluctuated over the study period, with no definitive increases over time. Among female patients with breast cancer, there was a slight increase (83 percent to 90 percent) from 2013 to 2018 (p = .078). There was no clear trend over time in the proportion of patients with triplenegative breast cancer who were referred and seen for genetic counseling; mean predicted probabilities fluctuated between 70 percent to 89 percent from 2013 to 2018 (p = .047). Similar

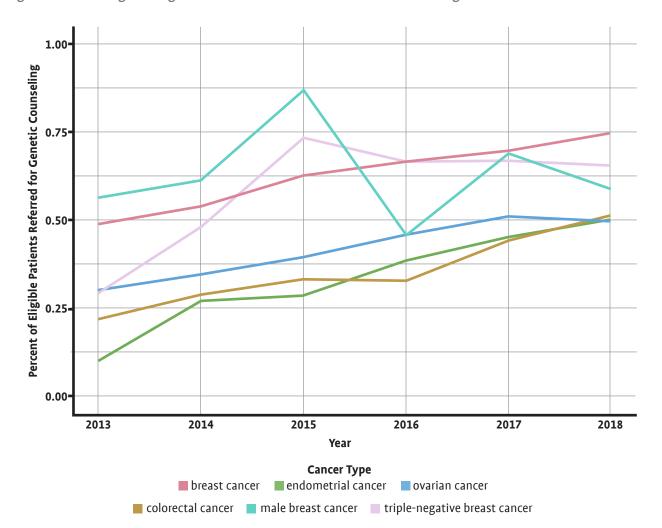


Figure 1. Percentage of Eligible Patients Referred for Genetic Counseling

fluctuating trends with no clear increase overtime were observed among patients with ovarian cancer (68 percent to 90 percent, p = .047), colorectal cancer (50 percent to 80 percent, p = .061), endometrial cancer (41 percent to 71 percent, p = .061), and male patients with breast cancer (59 percent to 85 percent, p = .047). See Table 3, page 49, and Figure 3, page 50.

Referral Increases by Cancer Type

From 2013 to 2018, all cancer sites showed an increase in patient referral, and by 2018, all cancer sites had 70 percent or more patients who completed genetic counseling when referred. Exactly what contributed to these increases were not measured as part of this study. However, our team considered factors, such as:

- Adding genetic counselors to a cancer program or practice
- Embedding genetic counselors within oncology point-of-care clinics
- Screening patients with colorectal and/or endometrial cancer universally for Lynch syndrome

- Using genetic test results for determining targeted therapies
- Increasing discussion of genetic counseling at tumor board meetings
- Performing genetic counseling grand rounds presentations
- Requiring genetic counseling for site accreditation (e.g., National Accreditation Program for Breast Centers).

Additional factors like improved insurance coverage and reduced out-of-pocket costs for genetic testing may have also played a role in increased genetic counseling appointments and follow through.

A Focus on Breast Cancer

Breast cancer started with the highest genetic counseling referral rate (49 percent) and had the highest overall increase: 75 percent by 2018. This increase excludes the study's rate increase found among patients with triple-negative breast cancer (66 percent) and male patients with breast cancer (87 percent) because these

Table 2. Mean Predicted Probabilities of Patients Seen for Genetic Counseling 2013 2014 2015 2016 2017 2018 Mean predicted probability of n n n n eligible patients seen for Mean (SE) Mean (SE) Mean (SE) Mean (SE) Mean (SE) Mean (SE) genetic counseling [95% CI] [95% CI] [95% CI] [95% CI] [95% CI] [95% CI] 581 841 785 829 912 826 .43 (.06) **Breast cancer (female)** .46 (.06) .52 (.06) .61 (.06) .64 (.06) .68 (.05) [.31, .55] [.34, .58][.4, .64][.48, .72][.52, .75] [.56, .78]65 96 155 120 96 104 Triple-negative breast cancer .27 (.07) .36 (.08) .61 (.07) .53 (.08) .59 (.08) .6 (.08) [.45, .74][.15, .45][.22, .53][.37, .68][.42, .74][.43, .75]19 28 23 18 19 29 .52 (.1) Breast cancer (male) .47 (.11) .5 (.09) .33 (.11) .47 (.11) .52 (.09) [.25, .7][.31, .69][.31, .72][.15, .59][.25, .7][.33, .7]210 328 373 320 353 372 Ovarian cancer .19 (.06) .24 (.07) .31 (.08) .34 (.09) .37 (.09) .44 (.09) [.09, .35][.12, .41][.17, .5][.19, .53][.21, .56][.27, .64]155 204 91 171 185 162 .15 (.05) .19 (.06) .21 (.06) .35 (.08) **Colorectal cancer** .25 (.07) .21 (.06) [.06, .3][.09, .34][.11, .37][.14, .42][.11, .37][.2, .53]93 43 69 89 80 101 **Endometrial cancer** .04 (.03) .14 (.06) .17 (.06) .24 (.08) .16 (.06) .3 (.08) [.01, .2][.06, .3][.08, .33][.11, .43][.07, .32][.15, .5]

CI = confidence interval; SE = standard error.

are much smaller patient populations. An average of 6 male patients with breast cancer and 21 patients with triple-negative breast cancer were included in the study in 2018 across all five health systems, resulting in more significant changes to the study's percentages by even just one patient. There were fluctuations in percentages of patients with breast cancer who were referred and seen across the individual health systems, possibly due to genetic counselor and physician staffing; the more physicians and genetic counselors on staff, the more patients can be referred and seen.

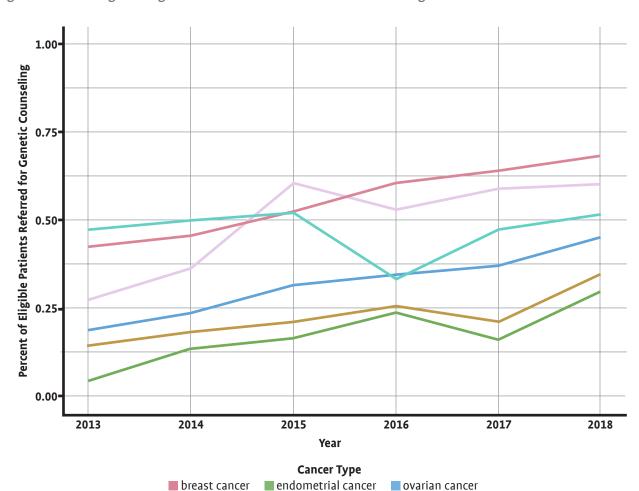
Data among patients with breast cancer also show an increase in genetic counseling appointments, with an average of 68 percent in 2018, and the highest average for referred patients who were seen by genetic counseling was at 90 percent in 2018. This study did not analyze the reasons why an individual declined a genetic counseling appointment. However, a prior study by OhioHealth looked at referral rates of newly diagnosed patients with breast cancer and existing barriers to genetic testing. ¹⁸ The study found that the biggest limiting factors for patients referred to genetic counseling included physicians' not referring, timing, stress, and patients not wanting to know about their testing results. ¹⁷ This study was published in 2017 and may have contributed to Ohio-

Health now having the highest overall referral rate for patients with breast cancer (94 percent in 2018).

A Focus on Ovarian Cancer

Studies have shown that fewer than 34 percent of patients with ovarian cancer are referred to genetic counseling and testing in the United States. ^{13,18,19} Our ovarian cancer referral data showed an increase across all participating health systems from 30 percent to 51 percent, which is above the U.S. average. ^{13,18,19} Low genetic counseling referral rates for ovarian cancer are perplexing given the straightforward guidelines stating that all patients with ovarian cancer meet referral criteria regardless of age and therapeutic implications.⁹

In 2013, Bednar et al. implemented a universal genetic testing initiative that included physician-coordinated testing; genetic counselors being embedded into gynecology oncology clinics; and tracking for patients with high-grade, nonmucinous epithelial ovarian cancer. This initiative surpassed an 80 percent increase in referrals.²⁰ Additionally, the initiative reviewed reasons for failure to complete genetic testing, and the most common reasons were that patients elected to pursue genetic testing elsewhere,



colorectal cancer male breast cancer triple-negative breast cancer

Figure 2. Percentage of Eligible Patients Seen for Genetic Counseling

declined genetic counseling and testing, or had financial concerns or lack of health insurance coverage for testing.²⁰

In 2014, the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute at The Ohio State University evaluated whether having a genetic counselor embedded in the gynecologic oncology clinic would increase referrals and patient uptake of their appointment.²¹ Data found that only 21 percent of patients were being referred, and after the genetic counselor was embedded in the clinic (from 2014 to 2016), the referral rate increased to 44 percent.²¹ The data from our study reflects this steady increase of referrals and patients that were seen at the James Cancer Hospital.

An additional factor that could have influenced ovarian cancer referrals was the approval for PARPs in December 2014 for patients with advanced ovarian cancer who have germline *BRCA1*/2 pathogenic variants. The rise in patients referred and

seen during this time may have been because providers recognized that genetic testing posed implications for anticancer therapy. Our data show that there is an increase in patients with ovarian cancer being seen by genetic counseling over time when referred. However, there is room for improvement, and sharing these data help us think about the factors that are involved in getting closer to a 100 percent rate.

A Focus on Colorectal Cancer

Our data reflects that Lynch syndrome genetic counseling referrals have lagged behind hereditary breast and ovarian cancer syndrome. Colorectal cancer had a starting overall referral rate of 22 percent that increased to 44 percent by 2018, compared to breast cancer's 50 percent starting referral rate. As Lynch syndrome testing continues to evolve and incorporates universal tumor screening by immunohistochemistry and next-generation tumor profiling,

Table 3. Mean Predicted Probabilities of Referred Patients Seen by Genetics 2014 2015 2013 2016 2017 2018 Mean predicted probability of n n n n n referred patients seen by Mean (SE) Mean (SE) Mean (SE) Mean (SE) Mean (SE) Mean (SE) genetics [95% CI] [95% CI] [95% CI] [95% CI] [95% CI] [95% CI] 479 268 509 585 666 642 **Breast cancer (female)** .83 (.04) .86 (.03) .86 (.03) .88 (.03) .9 (.02) .9 (.02) [.84, .94] [.73, .9][.79, .92][.78, .91][.81, .93][.84, .94] 23 48 105 78 65 67 .7 (.08) .87 (.05) Triple-negative breast cancer .75 (.1) .89 (.03) .72 (.06) .88 (.04) [.52, .83][.76, .95][.74, .94][.5, .9][.8, .94][.58, .83]19 20 14 18 Breast cancer (male) .76 (.16) .77 (.1) .61 (.12) .59 (.2) .68 (.13) .85 (.09) [.31, .96][.48, .92][.34, .83][.2, .9][.36, .89][.57, .96]47 131 168 168 200 203 Ovarian cancer .77 (.07) .68 (.06) .82 (.05) .76 (.05) .74 (.05) .9 (.03) [.59, .89][.54, .8][.7, .89][.64, .85][.62, .83][.82, .95]42 52 100 16 56 68 **Colorectal cancer** .75 (.15) .64 (.17) .69 (.15) .8 (.11) .5 (.17) .75 (.12) [.34, .94] [.28, .89][.34, .91][.49, .95][.19, .81][.42, .92]4 45 45 19 25 31 **Endometrial cancer** .66 (.27) .58 (.19) .63 (.18) .71 (.15) .41 (.16) .61 (.16) [.13, .96][.21, .88][.25, .89][.33, .92][.14, .74][.26, .87]

CI = confidence interval; SE = standard error.

genetic counselors became involved in reviewing testing results and helping direct appropriate referrals at all five of this study's participating health systems. Thus, genetic counseling referrals increased at TriHealth Cancer Institute and Mount Carmel Health System.

An additional impact on colorectal cancer data comes from an Ohio-wide study called the Ohio Colorectal Cancer Prevention Initiative, which overlapped with our study period. From 2013 to 2016, the initiative enrolled patients with colorectal cancer for a large-scale, universal Lynch syndrome screening protocol that used genetic counseling and testing at no charge to patients. As a result of this initiative, Pearlman et al. found that 16 percent of individuals with colorectal cancer before age 50 had inherited cancer susceptibility.²² Thus, this initiative highlighted the importance of genetic counseling and testing in patients with colorectal cancer diagnosed before age 50.²²

However, our study's colorectal cancer data are potentially skewed because patients enrolled in the Ohio Colorectal Cancer Prevention Initiative and underwent genetic counseling and testing, but may not have been referred to our participating centers' genetics program unless testing identified a pathogenic variant.

Thus, patients participating in the Ohio Colorectal Cancer Prevention Initiative could have contributed to a lower percentage of eligible patients with colorectal cancer being referred and seen by genetic counseling.

Since the addition of universal tumor screening, genetic counseling involvement in universal tumor screening, and the Ohio Colorectal Cancer Prevention Initiative study publication, our data show a rise in colorectal referrals across all five participating health systems. We also anticipate that colorectal cancer referrals will continue to increase with somatic tumor profiling and as therapeutics are approved for individuals with Lynch syndrome-related colorectal cancer.

A Focus on Endometrial Cancer

The lowest starting referral rate among all cancer types in this study was for endometrial cancer (10 percent), but this disease site also saw an overall increase from 10 percent to 51 percent, which was the greatest increase in referral rates across all cancer sites. This increase could be attributed to participating health systems adding universal tumor screening for Lynch syndrome by immunohistochemistry on all endometrial cancers with genetic

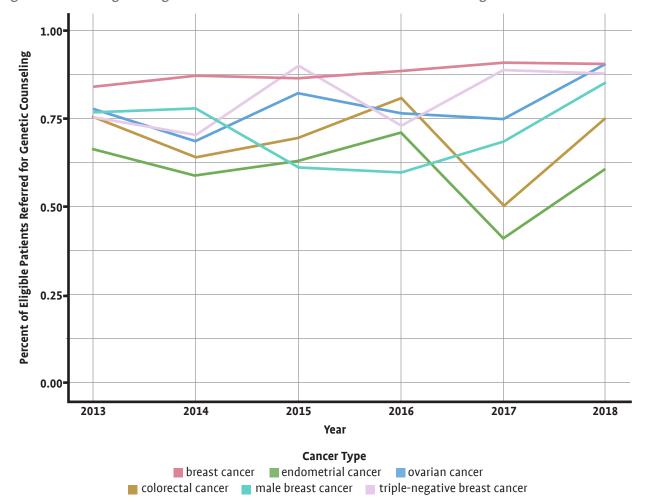


Figure 3. Percentage of Eligible Referred Patients Seen for Genetic Counseling

counselor involvement. Additionally, the James Cancer Hospital had a study called Ohio Prevention and Treatment of Endometrial Cancer (OPTEC) from 2017 to 2020, in which all patients with endometrial cancer were enrolled and received germline and somatic genetic testing. Three centers (the James Cancer Hospital, TriHealth Cancer Institute, and OhioHealth) enrolled patients in the OPTEC study. This reduced overall endometrial cancer referrals to genetics, yet it increased the rate of patients who underwent genetic testing and could explain the inconsistent increase in referrals at these three cancer centers, as patients were not being counted for referrals to genetics.

Study Limitations

This study was performed within five Ohio-based cancer centers that had strong cancer genetics programs within major medical centers and that were led by board-certified genetic counselors. The authors acknowledge that there are cancer centers that do not have genetic counselors on staff and that may face greater barriers to genetic service uptake. Study data may not reflect

genetic counseling data for all cancer centers in Ohio. Our inclusion criteria were based on factors that could be readily identified using cancer registry data (e.g., cancer type, age). Family history of cancer and Ashkenazi Jewish heritage were not indications that could be applied accurately as a criterion for inclusion in the study due to lack of consistency in reporting this type of information and cancer registrars' inability to abstract this data consistently.

These factors contributed to a lack of uniformity within medical records and how data were gathered or stated differed among the participating cancer centers and their registrars. Patients referred to genetic counseling may not have been seen due to a multitude of reasons, including transfer of care to another health system, death before completing appointment, or patients declining their appointments. Whether these data were available to participating cancer centers or how they incorporated this information into their reporting could have differed. Additionally, due to the de-identified nature of the shared data between participating cancer centers, we could not assess if a patient was being captured

as an eligible patient at more than one cancer center. The James Cancer Hospital, OhioHealth, and Mount Carmel Health System are all in Columbus, Ohio; therefore, there is a possibility that patients may have received care at more than one location or sought a second opinion from another center due to their geographic location.

Additionally, genetic testing results can be scattered throughout the EHR and are often scanned in, as opposed to being entered in the EHR as discrete, searchable fields. Thus, tracking patients who had previous genetic counseling and testing at another cancer center was a challenge.

Another limitation of this study was that we did not stratify for triple-negative status in patients with breast cancer diagnosed at ages 18 to 50. To avoid counting twice those individuals with triple-negative breast cancer who overlapped with a breast cancer diagnoses at ages 18 to 50, triple-negative breast cancer was only specifically assessed for those diagnosed at ages 51 to 60. Therefore, we are not able to compare referral rates and appointment uptake for patients with triple-negative breast cancer at ages 18 to 60 versus patients with non-triple-negative breast cancer at ages 18 to 50. We also did not look at income, race, or other demographics to assess the level of health equity in genetic services, as these data were outside the scope of the study. It would be interesting to evaluate demographic factors in future studies on genetic testing and counseling in oncology.

Concluding Thoughts

The experience from these five Ohio-based cancer centers showed that partnering with cancer registrars can provide impactful genetic counseling data and lessons learned to improve referrals and appointment uptake among patient populations at high risk for hereditary cancer. By providing a benchmark, these data allow institutions to compare and use their cancer registry and a referral and appointment model to track their own data trends over time.

This study also revealed challenges with data not capturing patients who were enrolled in research that provided genetic counseling and testing; shared patients between participating institutions; and, most importantly, the inability to track genetic testing information within the EHR.

Furthermore, it is important to share our data with the genetic counseling community as we work to increase the number of individuals who receive these much-needed services. The participating five cancer centers will continue to collect data on all the cancers described above, in addition to other cancers (e.g., prostate and pancreatic cancers), in concordance with NCCN referral guidelines.

Finally, using these data will help further evaluate whether lack of genetic counseling compliance at an institution is at the point of referral or appointment uptake, in order to implement targeted interventions.

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Formulas Used to Calculate Percentages

Eligible patients referred for genetic counseling = Number of patients referred for genetic counseling

Number of eligible patients for that category

Eligible patients seen for genetic counseling = Number of patients seen for genetic counseling

Number of eligible patients for that category

Referred patients seen for genetic counseling = Number of patients seen for genetic counseling

Number of referred patients for that category

Ethics Declaration

This study was carried out under approved protocol #2017-05 by the Ohio Department of Health Institutional Review Board. This study includes data provided by the Ohio Department of Health, which should not be considered as an endorsement of this study or its conclusions. Additionally, this publication is supported by the OSU CCTS CTSA grant number UL1TR002733 from the National Center for Advancing Translational Sciences and funded by a voucher CTSA citation.

Declarations of Interest and Data Availability

The authors declare no conflict of interest. Data available upon request from the authors, with appropriate institutional approvals.

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A MULTIDISCIPLINARY CONSORTIUM TO ADVANCE GENETIC COUNSELING IN ONCOLOGY

Findings from the Iowa Oncology Society

INTRODUCTION

As cancer clinicians develop increasingly complex treatment plans, the results from somatic testing (i.e., testing done on cancerous cells after a person has been diagnosed) and/or germline tests (i.e., testing done on non-cancerous cells to see if a person has a gene mutation known to increase the risk of developing cancer) are guiding personalized treatment decisions. To ensure that cancer clinicians are following the latest clinical recommendations around genetic testing, the Iowa Oncology Society (IOS) leadership started discussions in November 2020 and then launched a multidisciplinary consortium in the spring/summer of 2021 to advance genetic counseling and testing in oncology. This project focused initially on patients diagnosed with cancer who are eligible for genetic counseling and testing. Working with a diverse group of stakeholders, IOS held a focus group to explore the current landscape, conducted three educational Lunch and Learn sessions, produced a podcast, and hosted a working group meeting.

In an era of precision cancer care delivery, the role of germline genetic testing has rapidly increased to identify patients with hereditary cancer syndromes. Today, the term "genetic testing" may refer to somatic testing for targetable gene mutations, or it may refer to identifying germline variants. The term may also refer to pharmacogenomic testing, a study of the ways in which DNA variants influence how individuals metabolize medications. More than ever, it remains crucial to clearly differentiate somatic vs. germline genetic testing. Using terms such as "molecular testing," "genomic profiling,"

"next-generation sequencing," or "gene testing" may not clearly communicate whether these tests are being conducted on somatic vs. germline samples. Moreover, patients may be confused by hearing variations in testing terms.

Commonly used terms in this paper:

- "Biomarker testing" will refer to tests performed on malignant tissue or blood to identify somatic genomic alterations.
- "Genetic testing" will refer to germline testing for inherited variants.
- At times, the term "paired testing" may be used when referring to the combination of somatic and germline testing in the same patient.
- Terms like "next-generation sequencing," "molecular testing," and "genomic profiling," describe laboratory techniques that are utilized for germline and somatic tests.
- Alterations in the genome may be called "variant" or "mutation," and these may be found in germline or somatic tissue. While these terms are not technically synonymous, they are often used interchangeably by cancer clinicians to simplify communication with patients. Some examples of other terms found in the literature include chromosome rearrangement, base substitution, gene deletion, gene insertion, point mutation, missense mutation, frameshift mutation, etc.

Variant vs. Mutation vs. Polymorphism

Variant: A change in the DNA or RNA. The term does not imply frequency or causality.

Mutation: A change in the DNA or RNA that has been proven to cause disease (e.g., BRCA1185delAG).

Polymorphism: A change in the DNA that is found in at least 5% of the general population and is considered

to be frequent.1

Historically, genetic testing was largely performed to assess people for cancer susceptibility attributable to hereditary cancer syndromes. Genetic testing also provided important prognostic information that directly impacted cancer treatment decisions (e.g., prophylactic mastectomy among BRCA mutation carriers). Certain genetic test results, such as a transformation-related protein 53 or tumor protein p53 (TP53) pathogenic variant, may indicate that radiation therapy is relatively contraindicated due to the increased risk of developing radiation-induced secondary cancers.

Recently, the landscape of genetic testing has intersected with the rapidly expanding area of

predictive biomarker testing to identify patients who may be eligible for targeted anti-cancer therapies. For example, germline BRCA mutations now identify patients who may be eligible for treatment with poly (ADP-ribose) polymerase (PARP) inhibitors. Lynch syndrome screening using microsatellite instability (MSI) or DNA mismatch repair (MMR) testing in patients with colorectal or endometrial cancer may also identify patients who may benefit from immune checkpoint inhibitor therapy. The presence of MSI represents the phenotypic evidence that MMR is not functioning properly and presents opportunities for making different therapeutic decisions for patients with these types of cancers.

Project Elements

This project included the following elements:

Focus Group (Jul 2021) Lunch and Learn Series (Aug - Oct 2021) Working Group Meeting (Nov 2021)

Podcast (Nov 2021) White Paper (Jun 2022)

Lunch and Learn Series and Podcast

For this project, IOS hosted and recorded a series of three virtual Lunch and Learn sessions. These sessions were designed to spark conversations with local providers and stakeholders about challenges and solutions around genetic testing, counseling, and screening for patients diagnosed with cancer and their family members. Those sessions were titled:

- Tips and Tricks to Optimize Genetic Testing at Your Cancer Program
- Genetic Testing Approaches to Improve the Identification of Hereditary Cancer Syndromes

 Genetic Counseling and Testing in Community Cancer Centers: Perspectives, Challenges, and Opportunities.

A mini-podcast was also recorded to cover policy changes that can help ensure access to genetic counseling across diverse patient populations. These recorded resources may be found on the project webpage of the IOS website: accc-cancer. org/iowa-genetic-counseling.

Genetic Counseling and Testing Referrals

Many patients with cancer who meet criteria for genetic testing are not referred for pre-test genetic counseling and testing. During the IOS focus group held in July 2021, participants discussed some of the key reasons eligible patients with cancer may not be receiving genetic counseling or testing in a timely manner:

- Perceived "shortage" of genetic counselors. Some oncologists may falsely perceive that there is a shortage of genetic counselors in lowa and may be reluctant to refer patients. In reality, the genetic counselor workforce in lowa is very strong, but oncologists in private practice may lack partnerships with these individuals since most genetic counselors work for hospitals or health systems.
- Difficulty finding genetic counselors. Oncologists may not be sure how to find a licensed certified genetic counselor or may not know that certain telehealth companies offer genetic counseling services.
- Misunderstanding about the role of genetic counselors. Members of the cancer care team may not understand the role of the genetic counselor. They may not be aware of the professional credentialing requirements and scope of practice laws that affect licensed genetic counselors.
- Confusion around genetic testing criteria. Recent updates in clinical practice guidelines have expanded the criteria around which patients with cancer should undergo genetic testing. However, guidelines do not always provide the same recommendations, and this may confuse clinicians. For example, the American Society of Breast Surgeons recommends genetic testing for all patients with breast cancer. In contrast, the National Comprehensive Cancer Network (NCCN) Guidelines® provide specific criteria for testing based on the patient's age, ancestry, family history, and type of cancer.² The lack of guideline concordance may make it difficult for cancer centers to standardize their approach around referrals for genetic counseling and testing.

- Patients are not discussed at tumor boards. Multidisciplinary meetings (e.g., tumor boards) are often where patient risk factors are evaluated and discussed. During these meetings, clinicians determine who should be referred for genetic counseling and testing. However, many patients with cancer are not discussed at a tumor board and may not be identified as candidates for genetic counseling and testing.
- Suboptimal coordination around genetic test ordering. Different medical specialists, such as general surgeons, urologists, and gastroenter-ologists, are often the ones making the initial diagnosis of cancer. Some of these specialists will also initiate a genetic testing referral, but others may assume that medical oncologists will handle this task. Breakdowns in communication and coordination across different medical specialists may cause some patients to miss an opportunity for genetic testing.

How Are Variants Classified?

The American College of Medical Genetics (ACMG) recommends a five-tier classification system for classifying variants:⁴

- Pathogenic
- Likely pathogenic
- Uncertain significance
- Likely benign
- Benign

A VUS, or "variant of unknown significance," is a variation in a genetic sequence for which the association with disease risk is unclear.⁵

- Patients may perceive that genetic testing is cost-prohibitive. Patients may think that genetic testing is expensive, or they may be confused by direct-to-consumer testing options.
- Patients may think that genetic testing does not apply to them. Some patients may think that certain tests, such as BRCA 1/2 genetic testing, are only relevant for female family members like daughters and aunts.

Focus group members also discussed some of the challenges associated with the fact that gene variants are constantly being reclassified. A patient who underwent genetic testing many years ago may have been told that their test result included a "variant of unknown significance." However, that variant may now be classified as "likely pathogenic," but the patient may not know this information if they lose contact with the provider who ordered their genetic test. Additionally, the field is constantly finding new hereditary cancer conditions and improving technology. People who underwent genetic testing many years ago may not know that updated testing is available to them. Some clinical guidelines also recommend retesting patients who received genetic testing prior to a certain year. For example, genetic testing prior to 2014 most likely would not have included *PALB2* or other relevant genes.³

Certified Genetic Counselors

What is a Certified Genetic Counselor?

The American Board of Genetic Counseling (ABGC) Certified Genetic Counselor (CGC®) credential is an internationally recognized professional credential for the specialty. Professionals who have been awarded the CGC credential have completed a rigorous academic program, including supervised clinical experience, and have passed the ABGC national certification exam. Individuals who have earned the CGC credential have also met established standards of knowledge, skills, and practice for their profession. These individuals have demonstrated a commitment to excellence by meeting the standards required to achieve and maintain their professional credential.

When the Government Accountability Office (GAO) did a workforce study in 2019, it found that lowa had 34 genetic counselors for its population of 3,155,070, resulting in a ratio of 5.388 genetic counselors per 500,000 people.⁷ The National Society of Genetic Counselors (NSGC) reports that there are 5,629 CGCs in the United States as of April 2021.⁸

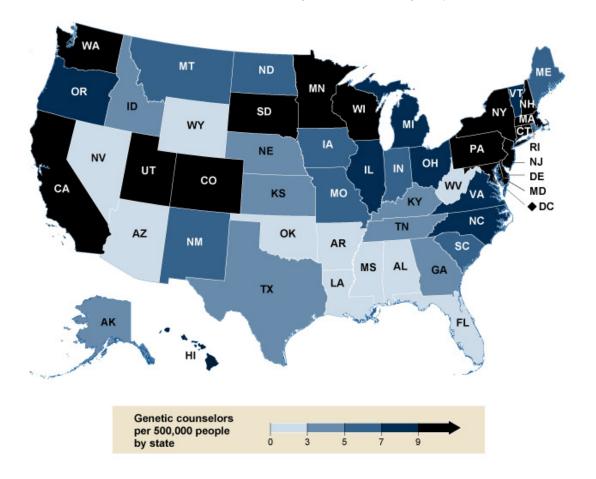
Currently, 29 states require CGCs to be licensed to practice. In Iowa, CGCs are licensed by the Iowa Board of Medicine, and their scope of practice includes, but is not limited to, the ability to "identify, order, and coordinate genetic laboratory tests and other diagnostic studies as appropriate for the genetic assessment of a patient."

Most CGCs work in academic medical centers or other hospital settings, but some work in group practices or are employed by companies that offer genetics services. Since many CGCs also provide services via telehealth, it is easier than ever before for patients to receive genetic counseling. While the COVID-19 pandemic has led to an increased adoption of telehealth across the United States, many people living in rural areas still struggle with limited access to video-based devices or the lack of broadband internet.¹⁰

How Do I Find a Genetic Counselor?

The Find a Genetic Counselor directory offers access to over 3,300 genetic counselors (in the U.S. and Canada). Find a local or telehealth certified genetic counselor at: findageneticcounselor.nsgc.org.⁶

Distribution of Genetic Counselors per 500,000 People by State, 2019⁷



Who Is Eligible for Licensure to Practice Genetic Counseling in Iowa?

To be eligible for licensure to practice genetic counseling in Iowa, an applicant must hold and maintain active certification as a genetic counselor by the American Board of Genetic Counseling, as a genetic counselor by the American Board of Medical Genetics and Genomics, as a medical geneticist by the American Board of Medical Genetics and Genomics, or the successor to any of the aforementioned organizations.

A genetic counselor licensed under Iowa Code chapter 148H may use the words "genetic counselor," "licensed genetic counselor," or the corresponding abbreviation "LGC" after the person's name. Persons who possess a provisional license should add the designation "provisional licensed genetic counselor" after their name.

Access to Genetic Counselor Services Act of 2021

As more patients with cancer are referred to CGCs for counseling and testing, the current healthcare system struggles with the fact that CGCs are not recognized as healthcare providers by Medicare. As such, Medicare does not reimburse CGCs for the services they provide to Medicare beneficiaries. In March 2021, the Access to Genetic Counselor Services Act of 2021 bill (H.R.2144) was introduced in the House of Representatives. ¹¹ A similar bill, S.1450, was introduced in the Senate in April 2021. ¹² Prior versions of these bills were introduced in 2018 (H.R.7083) and 2019 (H.R.3235). Under these

proposed bills, Medicare would recognize CGCs as healthcare providers and enable these professionals to provide telehealth services. As previously stated, CGCs do not have provider status under Medicare, even though genetic counseling is a covered benefit.

The NSGC continues ongoing advocacy efforts and encourages stakeholders to send endorsement letters to congressional representatives in support of the Access to Genetic Counselor Services Act. Federal advocacy resources are available on the NSGC website (nsqc.org).

Cascade Testing

Genetic testing has the potential to identify high-risk individuals before they develop cancer. While the scope of the IOS 2021 project did not specifically address ways to screen and identify people before they develop hereditary cancer syndromes, there are numerous opportunities to promote cascade testing once a patient is diagnosed with cancer. Cascade testing involves counseling and testing biological relatives once a patient is diagnosed with a pathogenic variant. In an ideal healthcare system, every at-risk biological relative would be informed and referred to a genetic counselor. Currently, the burden of contacting at-risk biological relatives often falls on the patient, and many relatives may not be informed about their potential risk of harboring a

pathogenic mutation. Research has suggested that a peer support model may improve cascade testing by providing role models for addressing emotional concerns as family members contact their blood relatives to speak with them about genetic testing.¹³

By improving the uptake of genetic screening in people at high-risk for cancer, clinicians may help prevent certain cancers or provide early treatment. Several large research projects are currently underway to inform evidence-based strategies to identify those at risk for inherited cancer syndromes and implement appropriate clinical management.

Ongoing Debates: Genetic Testing in Patients with Breast Cancer

The debate continues about optimal genetic testing criteria for identifying patients with high-risk breast cancer genes. According to one study, the criteria outlined by the NCCN Guidelines may miss about half of people with a genetic variant. ¹⁴ In a 2021 editorial published in the *Journal of Clinical Oncology*, Tung and Desai wrote whether we should be shifting the paradigm from "whom to test" to "whom not to test" since there is much clinical value in identifying a high-risk breast cancer gene mutation among the 3 percent of patients with breast cancer who have a pathogenic or likely pathogenic variant in a high-risk breast cancer gene. ¹⁵ One potential approach the article's authors suggest is to test all patients diagnosed by age 60 or 65 years and those with triple-negative breast cancer at any age. ¹⁶

Opportunities to Improve Cancer Genetic Testing in Iowa

Based on multi-stakeholder input throughout this project, members of the consortium made the following ideas and recommendations:

- Support the Access to Genetic Counselor Services Act by sending endorsement letters to congressional representatives. Advocacy resources are available on the NSGC website. The passage of this act will enable certified genetic counselors to be recognized as healthcare providers under Medicare. To learn more, listen to the ACCC mini-podcast "Ep 72: Genetic Counseling Advocacy" at accc-cancer. org/genetic-counseling-advocacy.
- Organize a process for collecting family history that includes information about first-, second-, and third-degree blood relatives. Examples of family history collection strategies and tools are covered in the Lunch and Learn session: "Tips and Tricks to Optimize Genetic Testing at Your Cancer Program" at accc-cancer.org/iowa-lunch-and-learn.
- Develop processes and procedures to track genetic counseling referrals in patients with cancer. Based on this information, conduct a quality improvement (QI) project aimed at increasing genetic testing in eligible patients with a specific type of cancer (e.g., prostate). Engage all members of the multidisciplinary team to ensure that referrals for genetic counseling are coordinated at the time of diagnosis. Ensure there is someone on the team to champion this effort.
 - Identify gaps in genetic testing rates by performing audit/feedback and discussing these findings with members of the multidisciplinary cancer care team.
 - Develop a map of the referral process to determine why eligible patients are not being referred or tested.
 - Review and update universal genetic testing policies for specific types of cancers (e.g., all patients with exocrine pancreatic cancer should receive germline testing).
- Refer patients to genetic counselors who can provide clear information about insurance coverage for genetic testing. This can help clear up any misconceptions patients may have about

- insurance coverage and out-of-pocket costs for genetic testing. Remember that some health insurance companies may require pre-test genetic counseling prior to testing.
- When referring patients to genetic counselors, provide them with education materials like handouts or pamphlets that clearly explain the importance of genetic counseling and testing for patients with cancer. Examples of resources include the MD Anderson "Genetic Counseling" handout in English (mdanderson.org/patient-education/Genetics/Genetic-Counseling.pdf) and Spanish (mdanderson.org/patient-education/Genetics/Genetic-Counseling-(Spanish).pdf) and NSGC's About Genetic Counselors wepage at: aboutgeneticcounselors.org.
- Develop partnerships with local or regional genetic counselors or telehealth genetic counseling companies and streamline the referral process. Every member of the multidisciplinary cancer care team should know how to refer patients to these genetic counselors. Examples of different genetic service delivery models were covered in the Lunch and Learn session: "Genetic Testing Approaches to Improve the Identification of Hereditary Cancer Syndromes" at accc-cancer.org/ iowa-lunch-and-learn.
- Provide continuing education to members of the multidisciplinary team about genetic testing updates. For example, ensure that urologists who are treating patients with prostate cancer are knowledgeable about germline testing and the role of PARP inhibitors. Also, confirm that gastroenterologists are coordinating MSI/MMR tests in patients who are diagnosed with colorectal cancer.
- When discussing or documenting test results in the patient's chart, clearly differentiate whether "molecular" or "genetic" test reports reflect somatic and/ or germline test results. Remember that circulating tumor DNA (ctDNA) tests have the potential to identify somatic and/or germline variants.
- To reduce confusion about somatic vs. germline testing, consider using consistent terms outlined by the Consistent Testing Terminology Working Group.¹⁶ "Biomarker testing" refers to somatic test results originating from malignant tissue or blood.

- "Genetic testing for an inherited mutation" and "genetic testing for inherited cancer risk" refers to tests that identify germline pathogenic variants.
- Work with pathology to review abnormal somatic biomarker test results. Some results may suggest a potential germline finding since pathogenic variants reported in the tumor may be of somatic or germline origin. Somatic pathogenic variants seen in tumor specimens may be more common in genes with germline implications (e.g., TP53, STK11, PTEN, etc.). Remember that the sensitivity of many tumor (somatic) genetic tests is lower than germline tests.
- Examine the clinical workflow for genetic testing when patients are being considered for targeted therapies (e.g., PARP inhibitor). Is the process for referral and genetic testing the same as biomarker testing? Specific case examples are covered in the Lunch and Learn session: "Genetic Counseling and Testing in Community Cancer Centers: Perspectives, Challenges, and Opportunities" at accc-cancer.org/iowa-lunch-and-learn.
- Explore ways to work with organizations like the lowa Cancer Consortium to track and improve genetic counseling and testing in patients with cancer.

Examples of Universal Genetic Testing in Patients with Cancer:

- NCCN Guidelines recommend genetic risk evaluation and germline and somatic testing for all patients with ovarian cancer, fallopian tube cancer, or primary peritoneal cancer.¹⁷
- NCCN Guidelines for pancreatic adenocarcinoma recommend germline testing for any patient with confirmed exocrine pancreatic cancer.¹⁸
- NCCN Guidelines for colon cancer recommend universal mismatch repair (MMR) or microsatellite instability (MSI) testing for all patients newly diagnosed with colon cancer.¹⁹

CONCLUSION

As the landscape of cancer genetics continues to evolve, the Iowa Oncology Society (IOS) leadership remain committed to providing education and resources to its members and the general public. IOS sponsored this program in 2021 and committed time and resources to this important effort.

IOS is a Chapter Member of the Association of Community Cancer Centers (ACCC), the leading education and advocacy organization for the cancer care community. Additional tools and resources focused on genetic testing and precision medicine may be found on the ACCC website: accc-cancer.org/precision-medicine.

Additional tools and resources

A full listing of consortium members and individuals who graciously contributed their time to this effort is available in the digital version of this publication at accc-cancer.org/iowa-genetic-counseling.



A publication from the IOS education project, "A Multidisciplinary Consortium to Advance Genetic Counseling in Oncology." To access the full compendium of resources that support genetic counseling in lowa, visit accc-cancer.org/iowa-genetic-counseling or scan this ΩR code.

The Iowa Oncology Society is the largest oncology professional organization in the state and comprises a powerful community of oncologists, nurse practitioners, physician

assistants, pharmacists, and other multidisciplinary care providers involved in the treatment of patients with cancer. For more information, visit ios-iowa.com.



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The Association of Community Cancer Centers (ACCC) is the leading education and advocacy organization for the cancer care community. Founded in 1974, ACCC is a powerful network of 28,000 multidisciplinary practitioners from 2,100 hospitals and practices nationwide. As advances in cancer screening and diagnosis, treatment options, and care delivery models continue to evolve – so has ACCC – adapting its resources to meet the changing needs of the entire oncology care team. For more information, visit accc-cancer.org. Follow us on social media; read our blog, ACCCBuzz; tune in to our CANCER BUZZ podcast; and view our CANCER BUZZ TV channel.

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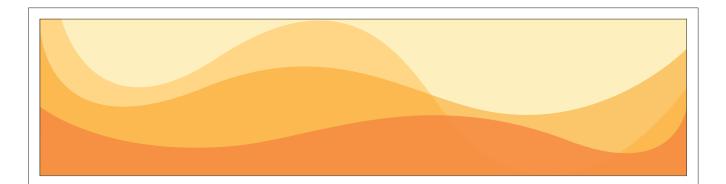
Making the Business Case for Hiring an Oncology Pharmacist

Olalekan Ajayi, PharmD, MBA; Melody Chang, RPh, MBA, BCOP; and Kirollos S. Hanna, PharmD, BCPS, BCOP

The Hematology/Oncology Pharmacy Association (HOPA) describes oncology pharmacy practice as encompassing a "broad range of expertise and levels of practice, skill, and responsibilities." A comprehensive detailing of the evolving role of oncology pharmacists is provided in "Further Defining the Scope of Hematology/Oncology Pharmacy Practice," published by HOPA in 2019.² Licensed oncology pharmacists may have responsibility for interpreting, evaluating, and implementing medication orders; dispensing and administering prescribed drugs; drug utilization review; medication-related research; medication therapy management; patient education and counseling; inventory management and safe storage; and direct patient care through participation in collaborative practice agreements, among other duties.^{1,2} Across the oncology ecosystem, licensed oncology pharmacists are team members in the delivery of quality care—in the inpatient clinical setting, ambulatory outpatient clinic, infusion center, specialty pharmacy, practice management, and clinical research.2 In the context of costly cancer therapies, "the oncology pharmacist is often a clinician who understands both the clinical and financial components" of patient care.¹

THE PROBLEM

The Institute for Healthcare Improvement (IHI) Triple Aim challenges healthcare organizations to strive for an enhanced patient experience while reducing costs and maintaining quality.³ As knowledge of the biology underlying the many diseases comprising cancer expands, practice-changing advances in diagnosis and treatment continue to accelerate. More patients are diagnosed with more nuanced disease and, in many cases, are living longer and experiencing an improved quality of life due to new therapies and approaches to treating cancers. These include new classes of drugs, combination therapies (doublet, triplet, quadruplet), immunotherapies with checkpoint inhibitors, targeted therapies with companion diagnostics, CAR T-cell therapies, and for some disease types, multiple sequential lines of therapy. As treatments for cancer have grown in number, complexity, and cost, U.S. demographics have continued to shift. Over the past decade, the number of individuals over age 65 has increased by more than one-third (34.2 percent); by 2030 all of the baby boomer generation will be older than 65.4,5 The oncology community is aware of the approaching "perfect storm"-increased patient volumes, projected shortage of medical oncologists, more complex treatment regimens, and unsustainably high costs of care. As value-based payment becomes predominant, cancer programs and practices must implement new care delivery models. Oncology pharmacists are the health practitioners with training and skills that include the operational, clinical, and financial aspects of cancer care. As such, oncology pharmacists play an integral role in today's complex, dynamic cancer care delivery environment.



THE SOLUTION

Oncology pharmacists bring to clinical teams needed support for the management of patient symptoms and comorbidities to improve patient care and quality of life. With knowledge of therapeutics, pharmacology, and drug interactions, clinical oncology pharmacists can provide "management of pain, nausea, vomiting, diarrhea, anemia, depression, and other symptoms" for patients with cancer throughout the care continuum.¹ Where collaboration between pharmacy and revenue cycle teams exists, oncology pharmacists can be instrumental in ensuring that pharmacy workflows and operations optimize drug procurement and value-based contracts. Oncology pharmacists are a key clinical resource for cancer program financial navigators seeking to lessen the financial burden and ensure access to treatment for patients-by answering clinical questions to secure prior authorizations and overcome denials. (See case studies below.)

A growing body of evidence supports the value and versatility of oncology pharmacists in cancer care. In "Demonstrating the Value of the Oncology Pharmacist within the Health Care Team," Eve M. Segal and colleagues present results of a systematic literature review spanning 1951 to 2018.6 The study examined existing research focused on measuring the value and impact of oncology pharmacists in the areas of patient satisfaction, improvement in medical safety, improvement in quality care and outcomes, economics, and intervention acceptance. Of the more than 400 papers identified, 66 met the study criteria, demonstrating the value of oncology pharmacists in four areas: clinical care, patient education, informatics, and cost savings.

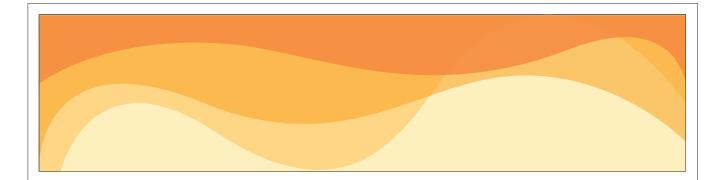
One example of oncology pharmacist versatility is through participation in a collaborative practice agreement. These agreements "create formal relationships between pharmacists and physicians or other providers. Collaborative practice agreements define certain patient care functions that a pharmacist can autonomously provide under specified situations

and conditions."⁷ Through this type of agreement, oncology pharmacists can extend their clinical expertise to conduct patient assessments, order drug-therapy-related lab tests, administer drugs, and under a defined protocol select, initiate, monitor, and adjust drug regimens.

Oncology pharmacists lead and participate in medically integrated pharmacy models. One such example is a dispensing pharmacy within the cancer program enabling patients to obtain their oral oncolytics where they receive their cancer care. This model offers patient convenience, enhances care coordination and communication, allows for closer monitoring of patients on oral agents, and facilitates more costeffective care. In 2010, St. Luke's Cancer Institute in Idaho initiated a medically integrated pharmacy model to manage patients on oral oncolytics, starting with two oral agents. Today, the cancer institute's oral oncolytic medically integrated pharmacy is staffed by several pharmacists and pharmacy technicians who manage the care of more than 500 patients. A study conducted over a six-month period, showed that St. Luke's Cancer Institute had an annual estimated net cost avoidance of \$1,730,416 through in-office dispensing as compared to an estimated net annual waste of \$119,794 for prescriptions filled through a mail order pharmacy.^{7,8} Developing, piloting, and implementing an oral oncolytic collaborative practice agreement at St. Luke's Cancer Institute's medically integrated pharmacy resulted in reduced treatment delays and improved pharmacist and provider workflows.^{8,9} Details on the St. Luke's experience are available at accccancer.org/Pharmacist-Collaborative-Practice.

BILLING & REIMBURSEMENT

Since pharmacists do not currently have provider status, CPT codes higher than Level 1 are not routinely allowed by most payers. However, depending on the state scope of practice or the specific payer, pharmacists may bill for certain evaluation



and management (E&M), education, and training codes, for example.¹⁰

VALUE, QUALITY, AND SAFETY

Hiring oncology pharmacists brings value to cancer programs, patients, and oncology physicians across multiple domains—institutional, cancer program-specific, education (for patients and staff), and outreach. In 2020, HOPA and the Academy of Managed Care Pharmacy published a white paper highlighting takeaways from a joint forum on value in cancer care that emphasized how—in the value-based environment—oncology pharmacist involvement in optimizing acute cancer care adds value to "patient-focused and clinician-focused care delivery."¹¹

Oncology pharmacists have many potential roles in the implementation of value-based care models. From serving on an organization's Pharmacy & Therapeutics (P&T) Committee to managing cancer medication inventory, from patient education at the chairside to direct patient care through a collaborative practice agreement model, from establishing and administering an in-house specialty pharmacy to in-depth medication expertise, oncology pharmacists have a skill set that is well suited to the fast-changing oncology landscape. The capacity to understand both the clinical and economic implications of cancer therapies is critically important in the value-based reimbursement environment. Oncology pharmacists have the training and expertise to help cancer programs evolve strategically toward the IHI Triple Aim goals-improve the patient experience and reduce costs while maintaining quality.

CASE STUDY ONE ONCOLOGY PHARMACIST AS NAVIGATOR

2018 ACCC Innovator Award recipient Legacy Cancer Institute integrated the role of oncology pharmacy navigator as an innovative approach to medication and side effect management,

to assist patients in accessing medications, to address patient financial concerns, and to standardize medication reconciliation, while achieving an annual cost savings, collecting quality metrics, and receiving recognition from an accrediting organization.¹² In the first year of this new position, the oncology pharmacy navigator was directly responsible for more than \$237,000 of cost savings. 12 Most of those savings resulted from accessing patient support programs, grants, foundations, and free drug programs through pharmaceutical companies to help offset the high co-pays often incurred by their patients; additional savings were realized from formulary changes and the revenue generated by selling supplements in the hospital-based retail pharmacies. The oncology pharmacy navigator position continues to realize cost savings of more than \$200,000 annually.12 Details on Legacy Cancer Institute's experience are available at accc-cancer.org/ The-Oncology-Pharmacy-Navigator.

CASE STUDY TWO PHARMACY-LED PRE-CERTIFICATION & DENIALS MANAGEMENT

2019 ACCC Innovator Award recipient Lineberger Cancer Institute at UNC Medical Center initiated a pharmacy-managed, closed-loop medical benefit pre-certification and denials management program that includes a continuous quality improvement component. Leaders in oncology pharmacy worked collaboratively across various health system teams involved in the cancer drug pre-certification and denials process. With denials management transferred to a pharmacy-led denials team, the new workflow reduced institutional revenue loss and patient financial toxicity through development of an institutional precertification policy, a streamlined process, engagement of pharmacy operations, optimization of manufacturer-supported patient assistance programs, and development of proactive medical necessity policy review. Oncology

pharmacy stepped up to take the lead in this endeavor, through which the institution realized millions of dollars in cost savings and patients experienced increased attention to and mitigation of financial toxicity.¹³ Details on Lineberger Cancer Institute's experience are available at accc-cancer.org/Pharmacy-Managed-Pre-Certification-and-Denials-Program.

CASE STUDY THREE TRANSITIONING DRUG ADMINISTRATION FROM THE INPATIENT TO OUTPATIENT SETTING

2020 ACCC Innovator Award recipient University of Arizona Cancer Center, Banner University Medical Center, Tucson brought together a multidisciplinary team of physicians, pharmacy staff, finance specialists, social workers, nursing staff, and information technologists to identify chemotherapy regimens administered in the inpatient setting that could be safely administered in the outpatient setting, and then implemented a transition plan that included provider and patient education. ¹⁴ Benefits included reduced inpatient medical resources and chemotherapy costs, decreased inpatient bed stay, lower infection rates, improved quality of life, and decreased overall cost of care—conservatively estimated at almost \$6 million. ¹⁴ Details on the University of Arizona Cancer Center's experience are available at accc-cancer.org/Transitioning-Select-Chemotherapeutics.

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A publication from the President's Theme of 2021-2022 ACCC President Krista Nelson, MSW, LCSW, OSW-C, FAOSW, "Real-World Lessons from COVID-19: Driving Oncology Care Forward." Learn more at accc-cancer.org/learn/presidents-theme.

The Association of Community Cancer Centers (ACCC) is the leading education and advocacy organization for the cancer care community. Founded in 1974, ACCC is a powerful network of 28,000 multidisciplinary practitioners from 2,100 hospitals and practices nationwide. As advances in cancer screening and diagnosis, treatment options, and care delivery models continue to evolve—so has ACCC—adapting its resources to meet the changing needs of the entire oncology care team. For more information, visit accc-cancer.org.

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action

ACCC Recommits to Cancer Moonshot

On May 11, ACCC Executive Director Christian G. Downs, JD, MHA, was invited to the White House to attend the "Cancer Moonshot: Goals Forum," where the President and First Lady announced a call to action to jumpstart cancer screenings across the nation.

ACCC and AstraZeneca were recognized at the event for their joint effort—the Rural Appalachian Lung Cancer Screening Initiative—to develop and implement person-centered and sustainable approaches to increase lung cancer screening in underserved Appalachian communities. ACCC will bring together an Advisory Committee, composed of ACCC and Oncology State Society stakeholders, American Society of Clinical Oncology (ASCO) leaders, LUNGevity and other patient advocacy representatives, Appalachian Region public health experts, and local lung cancer screening program staff to:

- Identify and address challenges in implementing lung cancer screening programs in rural communities.
- Implement innovative approaches to increase guidelineconcordant lung cancer screening among rural Appalachian communities.



 Assess patient-centered screening education and communication strategies to overcome informational, literacy, and cultural barriers.

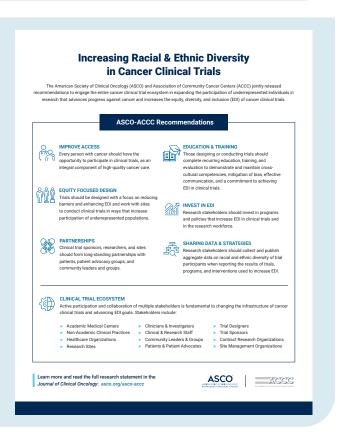
Success will be measured by changes in provider attitudes, their self-reported changes in behavior, and patient-reported outcomes. These efforts are part of ACCC's broader Appalachian Community Cancer Alliance, which is made possible by support from Bristol Myers Squibb. Read more at accc-cancer.org/ACCA.

ACCC and ASCO Release Joint Recommendations

On May 19, ASCO and ACCC jointly released recommendations to address the lack of equity, diversity, and inclusion in cancer clinical trials. Published in the *Journal of Clinical Oncology*, "Increasing Racial and Ethnic Diversity in Cancer Clinical Trials: An American Society of Clinical Oncology and Association of Community Cancer Centers Joint Research Statement" details specific actions that would engage the entire cancer clinical trial ecosystem in expanding the participation of under-represented individuals in research to advance progress against cancer. Summarized in an infographic, these recommendations focus on key areas, such as:

- 1. Access to clinical trials
- 2. Equity-focused design
- 3. Partnerships among stakeholder groups
- 4. Continuous education and training
- 5. Equity, diversity, and inclusion investment
- 6. Sharing data and strategies.

Access the guidelines online at ascopubs.org/doi/full/10.1200/ JCO.22.00754. Access the infographic online at accc-cancer.org/ asco-accc-2022.



2022 ACCC Virtual Hill Day

As Congress continues to consider legislation to improve access to care after the COVID-19 pandemic, it is more important than ever to share with your congressional representatives the real-world impact that federal health policy has had on patients with cancer and care delivery. ACCC members from 14 states participated in more than 40 virtual meetings with their congressional representatives, sharing the challenges they—and their patients—face and allowing them to help ensure that future legislation reflects the reality of cancer care delivery. Among the 2022 policy asks ACCC members discussed were:

- The **Telehealth Modernization Act** to permanently expand access to Medicare telehealth services by removing geographic and originating site restrictions, which require a patient to live in a rural area and be physically in a doctor's office or clinic to use telehealth services.
- The **Improving Seniors' Timely Access to Care Act of 2021** to standardize and streamline prior authorization processes within the Medicare Advantage program by establishing an electronic prior authorization system that can increase transparency and provide real-time decisions.
- The **DIVERSE Trials Act** to lessen financial burdens for patients participating in clinical trials.
- The Safe Step Act to protect patients from step therapy protocols that delay access to necessary anti-cancer treatments.
- The Medicare Multi-Cancer Early Detection Screening Coverage Act to allow the Centers for Medicare & Medicaid Services to cover these blood-based screening assays.

ACCC Showcases Six Abstracts at ASCO Annual Meeting

The ASCO Annual Meeting, June 3 to 7, 2022, showcased six ACCC abstracts that address some of the current barriers to and disparities in comprehensive cancer care:

- Data for Screening, Offering, and Consenting Patients to Cancer Clinical Trials: Report from an ASCO-ACCC Collaboration
- 2. Generating Meaningful
 Peer-to-Peer Engagement
 Through a Mentor-Led, Small
 Group Social Learning
 Experience on the Evolving
 Standards of Care for
 Advanced HER2+ Breast Cancer
- 3. Building a Multidisciplinary Consortium in Iowa to
- Background

 The 2021-2022 Association of Community Cancer Centers (ACCC) President's Theme centered on strengthering a work culture that supports professional week-leveling and entertained in the control of the community cancer can deliver, ACCC an education and advocacy organization for the multidisciplinary oncology care team (MOT)—designed a multifacted principlinary oncology care team (MOT)—designed and multifacted principlinary oncology are steam (MOT)—designed and multifacted principlinary oncology are steamed.

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- Advance Genetic Counseling and Testing in Patients with Cancer
- 4. Assessing Feasibility and Utility of an Implicit Bias Training Program for Addressing Disparities in Cancer Clinical Trial Participation
- 5. National Organization Addresses Multidisciplinary Oncology Team Burnout and Resiliency Through Multifaceted Presidential Theme Education Initiative
- 6. Using Real-World Data to Assess Variations in Cost and Healthcare Utilization for Patients Diagnosed with Bladder Cancer.

VIEWS

Introducing the New Digital ACCC Patient Assistance & Reimbursement Guide

BY JORDAN KARWEDSKY



have been a financial counselor in oncology for 12 years and searching for medication assistance is something that I do daily. In the past, this search was quite cumbersome, because there was no one website that financial navigators could rely on to find available financial assistance programs for an oncology-related medication that was on the market. Having one website to search for these available programs and also links to the correct enrollment webpage has streamlined this process. With that, I am excited to share a little more about the interactive and fully digital ACCC Patient Assistance & Reimbursement Guide.

Today, this guide is a tool that cancer programs and practices across the country can use every day at no charge. It does not matter if your cancer program or practice's financial navigation program is well established or just getting off the ground because the ACCC Patient Assistance & Reimbursement Guide is a one-stop-shop that makes finding and accessing financial assistance programs from manufacturers and independent foundations quick and easy. This digital tool was created for everyone, from financial counselors or navigators to pharmacy staff, social workers, or any other member of the multidisciplinary care team.

As a member of ACCC's Financial Advocacy Network, I was asked to be a part of the Patient Assistance and Reimbursement Guide Task Force in 2020 and have been a member since. This opportunity allowed me to provide valuable insight to help revamp and shape the guide into the interactive search tool that it is today. But before getting into that, below is a little context on the guide's history and design process.

Setting the Scene

Since 2012, ACCC has produced its Patient Assistance & Reimbursement Guide as a print publication. A hardcopy was sent to all ACCC members every January and the guide's digital version (then a PDF document) was updated on a quarterly basis throughout the year. Users could find the guide on ACCC's website and would scroll through the ever-expanding document to find the information they needed. The resource is one of ACCC's most valuable member benefits and has grown over the years to include 45 companies and almost 200 oncology-related products.

Creating a Fully Digital Tool

This year, ACCC debuted it's all new and interactive Patient Assistance & Reimbursement Guide. As a member of the task force, I was heavily involved in quarterly Zoom meetings and email conversations where we discussed what this digital search tool should be, including how it should be organized and function. ACCC aimed to make this digital guide as user-friendly as possible and something that cancer programs and practices could use as their go-to resource when searching for financial assistance for their patients. While discuss-

ing how we wanted the digital guide to look and function, it was not uncommon for one person's idea to snowball into even more ideas. The task force threw everything out on the table—no idea was too crazy to consider. And every time we had a new idea, ACCC quickly researched feasibility and options. The resource was ready to be tested in late summer 2021, and we were finally able to see all our ideas and suggestions come to life!

As a member of the task force, I was given time to play with the new fully searchable guide and was asked to complete a list of tasks to ensure the tool was working as we anticipated. In testing, it was clear that the filters we decided to include were easy to understand and that any added descriptions for functionality were helpful. I walked through example case studies, doublechecking to make sure that the correct quick links appeared after my search, that program descriptions were readable and helpful, and that any links to websites and/or portals were working. These links are vital as they take users directly to the right program portal and/or enrollment form(s).

After testing was complete and any bugs worked out of the digital guide, it was time to launch. Since then, I have bookmarked the guide's website (accc-cancer.org/patient-assistance-2022) so that it is always one click away. I find myself accessing the digital guide multiple times a day now to search for financial assistance programs for our patients in need, and I have been using this resource more than I ever did before.

Navigating the New Digital Guide

When you arrive at the ACCC Patient Assistance & Reimbursement Guide homepage, you are given a quick overview on how it works. Once in the digital guide, you will see the new search function front and center. The first search option you have is by oncology-related product name, and you can search by either brand or generic name. Once you start typing, drop-down list of products will appear that you can select from. We also included an option just underneath the product name box that allows you to select to see all products with the same active ingredients or biosimilars in your results. By checking this box, you can easily compare various products' assistance programs to see which is a better fit for your patient, especially if your cancer program or practice allows biosimilar substitutions.

Once you click "Search," the guide will list all available manufacturer-based assistance programs for the product. Because there can be a lot of different programs available, you can also apply optional filters that help narrow down your search results. These filters can be applied based on patients' insurance coverage type (e.g., commercial, government, uninsured), the type of assistance program you are looking for (e.g., patient assistance programs, co-pay cards, etc.), or both. You can select as many filters as you want. If you are unsure about what filter you should use, just click on the question mark to the right of a filter's name to read a brief description.

Once your search results appear and if you have opted to include biosimilars, you can easily remove any unwanted oncology-related products from your search by simply clicking the "X" option. For all search results, available programs appear below the list of included oncology-related products. A quick overview of the financial assistance program is provided, along with its qualifying type of coverage and the assistance type that is available, the product the program supports,

| Search by Oncology-Related Product or Company | | | | | |
|---|---------------------------------------|---|--|--|--|
| Oncology-Related Product | Company | | | | |
| | 8 | 8 | | | |
| Show products with the same active ingredient or biosimilar | 9 | | | | |
| Apply Filters (optional) | | | | | |
| Coverage | Assistance Type | | | | |
| Commercial/Private ③ | Co-Pay Card/Out-Of-Pocket Cost Assi | Co-Pay Card/Out-Of-Pocket Cost Assistance ① | | | |
| Government ② | ☐ Dose Exchange Program ⑦ | ☐ Dose Exchange Program ② | | | |
| Uninsured/Underinsured ③ | ☐ Independent Charitable Foundations | /Organizations ③ | | | |
| | ☐ Insurance Coverage-Related Delay Pr | rogram ③ | | | |
| | ☐ Patient Assistance Program ③ | | | | |
| | Product Replacement Program ③ | | | | |
| | Reimbursement Assistance ③ | | | | |

Screenshot of the Search by Oncology-Related Product or Company function.

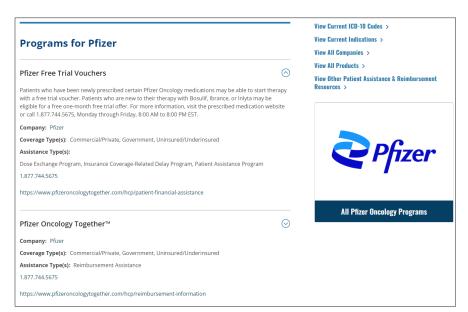
and a phone number and link. For a deeper dive into a program, including patient qualifications and how to enroll, just click on the drop-down arrow to the right of its name.

The second search option available to you is to search by a manufacturer company's name. Just like searching for an oncologyrelated product, as you begin to type in the name of the company, a drop-down list appears from which you can select the correct company name. You are then able to use the same coverage- and assistance-type filters to narrow down search results. Just like an oncology-related product search, a company name search provides a list of the available financial assistance programs and coverage and assistance types supported, as well as applicable phone numbers and links. There is a drop-down arrow to the right of each company name that opens a deeper dive into its programs. Note that this search option does not include the oncologyrelated product(s) supported by the resulting program(s).

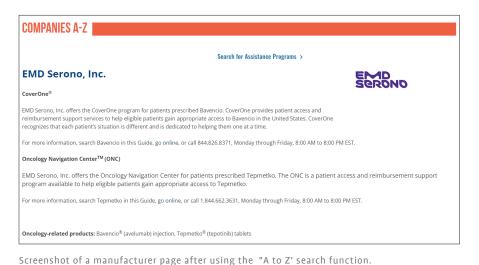
Other Search Options

If you are unsure on the spelling of the oncology-related product or company name. do not worry. We have you covered. On the left-hand side of the digital guide, you will see links that allow you to alphabetically search for products and/or companies. Either search function pulls up a complete list, where you select the first letter of a company or product name to narrow down the list. The "Products A-Z" page allows you to search by either brand or generic name. The alphabetical company search lists companies' products, as well as their phone numbers and program websites. Both the "A to Z" company and product searches provide you with brand and generic product names, the company name, and a program's phone number and website link.

On the left-hand column, the guide includes a search option for other patient assistance and reimbursement resources, including those from independent foundations. This option provides an "A to Z" listing of non-pharmaceutical company assistance



Screenshot of a Manufacturer Information page.



programs and national foundations like the Patient Advocate Foundation and Leukemia & Lymphoma Society. This list includes the name of each program, a brief description of the support it offers, how to enroll, a phone number, and a link to its website.

Finally, the guide includes links to resources for the most up-to-date International Classification of Diseases, Tenth Revision codes and oncology-related product indications that can be accessed from the left or via a search. Also included is a Financial Navigation Flowchart, which is a great tool to print and keep handy at your desk or save as a browser bookmark. This flowchart provides a step-by-step process for navigating potential financial assistance needs you may encounter for any type of insurance coverage patients may have.

In Closing

I hope that you find the digital ACCC Patient Assistance & Reimbursement Guide as user-friendly as I do and that it makes finding and applying for financial assistance on behalf of your patients more efficient. I hope it becomes a staple in your day-to-day work like it has in mine.

Jordan Karwedsky is a financial counselor at Green Bay Oncology in Green Bay, Wisc. She is also an ACCC Financial Advocacy Network Advisory Committee member, a member of its Network Task Force, and an ACCC Patient Assistance & Reimbursement Guide Task Force member.

ASSOCIATION OF COMMUNITY CANCER CENTERS

Improving Patient Communication Using the Ask Me 3® Tool

Ask Me3® encourages patients to ask 3 simple questions each time they talk to their care team. ACCC has created a video to demonstrate how the cancer care team can most effectively use this tool with patients.



Visit accc-cancer.org/ask-me-3-tool to view this video

In partnership with:















The Association of Community Cancer Centers (ACCC) is the leading education and advocacy organization for the cancer care community. Founded in 1974, ACCC is a powerful network of 25,000 multidisciplinary practitioners from 2,100 cancer programs and practices nationwide. As advances in cancer screening and diagnosis, treatment options, and care delivery models continue to evolve—so has ACCC—adapting its resources to meet the changing needs of the entire oncology care team. For additional strategies to improve patient-provider communication, please visit accc-cancer.org/health-literacy.

Funding and support provided by Lilly Oncology.

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ACCC PRECISION MEDICINE

TRANSFORMING

COMPLEX



CLEAR

ACCC has developed a comprehensive precision medicine resource library that aims to put personalized cancer care into focus–transforming the complex into something clear, actionable, and impactful–for multidisciplinary providers and their patients.

No matter your learning style–podcasts, on-demand webinars, videos, blogs, or publications–the ACCC Precision Medicine Library provides essential knowledge that bring clarity to complex patient care decisions.



Explore the Library at ACCC-CANCER.ORG/Precision-Medicine or Scan this QR Code

