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ONCOLOGY ISSUES

This publication is a benefit of membership
Association of Community Cancer Centers

Vol. 38 | No. 1 | 2023

Advancing cancer prevention, detection, diagnosis, treatment, and precision medicine

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Association of Community Cancer Centers

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FROM THE EDITOR

Remembering Our "Why"

BY MARK LIU, MHA

The COVID-19 pandemic put us all to the test—a test for which we had little to no preparation. As we continue to move forward, we cannot ignore how this global pandemic changed us all. And so, for my first column, I want to focus on the importance of remembering our "why" and take the opportunity to share a little bit about myself.

When I reflect on why I chose to work in healthcare and, more specifically, oncology, my interest started when I signed up to be an EMT (emergency medical technician) and a hospice volunteer in college. As an eager student, I wanted more experience in care delivery and completing the training to become a certified EMT was one way to gain critical life skills. When I showed up on the first day of hospice training, I was the youngest volunteer in the room. The time I spent learning how I could best support patients and their caregivers at their end of life was both an honor and life changing experience.

Unfortunately, it is rare to come across anyone today who has not been impacted by cancer. My "why" for working in healthcare was cemented in my work as a care coordinator at Memorial Sloan Kettering Cancer Center in New York City. Reminiscing on my time in that role, it remains one of my favorite jobs. My days started as early as 6:45 AM, which required me to wake up at 4:30 AM due to my long commute. Despite these early starts, a wave of purpose came over me each day when I walked into the building and worked alongside my colleagues.

I felt privileged that patients, caregivers, and family members trusted me at such a sensitive time in patients' lives. With all the patients coming through our cancer center each day, the job came with a roller coaster of emotions—"highs" like the high-fives we shared at good news and "lows" like the gentle hand holding or hugs we shared at difficult news. The stories and experiences. The faces and personalities. They remain with me today, informing my understanding of the disparities and challenges faced by those trying to manage their cancer care. These memories continue to fuel my passion to work in oncology. In my current role at Mount Sinai Health System & Tisch Cancer Institute, also in New York City, I call on all my past experiences to strategically plan and implement initiatives that ensure equitable cancer care for patients, caregivers, and clinical teams.

As we move forward in the aftermath of the COVID-19 pandemic, we will continue to operate within a complex environment that is complicated by many different pressures and constraints on cancer care delivery. As editor-in-chief over the next two years, my hope is that *Oncology Issues* continues to be your go-to resource to help unravel these complexities and serve as a source of inspiration to provide the high-quality care for which we all strive. I would love to hear from you—our readers—about the issues you face, as well as the innovative solutions and best practices you have implemented. You can do so by applying for a 2023 ACCC Innovator Award at: accc-cancer.org/innovator), contributing to *Oncology Issues* (email the managing editor, mmarino@accc-cancer.org), or attending the upcoming ACCC 49th Annual Meeting and Cancer Center Business Summit, March 8-10, in Washington, D.C. These engagement opportunities help highlight the extraordinary work you are doing at your cancer program or practice and elevate our entire field.

ACCC PRESIDENT'S MESSAGE

Remote Patient Monitoring and Health Equity

BY DAVID R. PENBERTHY, MD, MBA

More than 40 ACCC members registered for the November 10 Tech Talk, "Applying a Health Equity Lens to Remote Patient Monitoring." When asked to describe where their cancer program was in its use of remote patient monitoring technology, the majority (61 percent) indicated that they currently do not use but are actively researching this tech-nology. Twenty percent identified their program as "new users" of remote patient monitoring technology, with an additional 11 percent identifying themselves as "experienced users."

This Tech Talk (the third in a series) was driven by the ACCC *Digital Tools in Cancer Care* education program, with three members of the project's Advisory Committee serving as panelists.

Amanda Dean Martin, DNP, CNEP, ACNP-BC, RNFA, chief, Division of Advanced Practice and Clinical Integration at Banner MD Anderson Cancer Center, kicked off the talk with a brief history of remote patient monitoring and its transition from capturing only objective data like blood pressure to subjective data like the information being collected through ePROs. Dean Martin discussed the growing use of medical devices to capture these data and how oncology is using these technologies to successfully manage patients' symptoms and monitor treatment compliance.

Cardinale B. Smith, MD, PhD, chief quality officer, Cancer Services, and vice president, Cancer Clinical Services at Mount Sinai Health System & Tisch Cancer Institute, shared how COVID-19 changed remote patient monitoring. "Telehealth and virtual care are here to stay," she told Tech Talk participants. "We now have the opportunity to envision how we want this care to be delivered going forward." For those looking to select a remote patient monitoring technology partner, Dr. Smith suggested a focus on six key areas: 1) patient vitals you want to track; 2) access to video visits; 3) user web interface—the technology must be easy for clinical staff and patients to use; 4) connectivity, including solutions for patients without broadband access; 5) home set-up and orientation; and 6) tech support, as vendors must be available to troubleshoot with patients.

The use of tablets to perform remote patient monitoring "opens up the opportunity to collect ePROS and push out surveys to at-risk and underserved patients," Dr. Smith suggested, concluding that "there is no roadmap for this type of care. Engaging patients is challenging, and it took us some time to develop the right patient education." The other challenge is cost. While Mount Sinai Health System used a grant from the Federal Communications Commission to fund a pilot remote patient monitoring program aimed at improving care of Black and Latinx patients with cancer, questions regarding how to pay for this technology and bill for these services going forward remain.

Yet, "technology itself is not the number one cost. There are a lot of platforms available at different price points," pointed out panelist Adam Dicker, MD, PhD, FASTRO, FASCO, senior vice president, Radiation Oncology at Thomas Jefferson University Hospitals, Bodine Center for Cancer Treatment. "Instead, figure out how to deploy your human capital because that is the costliest asset [in remote patient monitoring]."

At the start of the Tech Talk, I asked this question: Does technology help or hinder health equity?

"The healthcare community was prepared for the COVID-19 pandemic," Dr. Dicker told participants. "Not all of our patients were prepared."

It is clear then that there is still work to be done to ensure that all patients with cancer—regardless of race, ethnicity, and socio-economic status—benefit equitably from remote patient monitoring technology.

Listen to this Tech Talk in its entirety at: accc-cancer.org/techtalk3. OI

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- Addressing Social Determinants of Health through a Medical-Legal Partnership
- Chemotherapy Care Companion: A Remote Patient Monitoring Program
- Expediting Cancer Treatment Through a Rapid Access APP-Led Diagnostic Clinic
- Deploying Technology Across an Interdisciplinary Team to Improve Oral Oncolytic Compliance
- Acupuncture for Cancer Patients at St. Elizabeth Cancer Center
- Interprofessional Collaboration with EHR to Optimize Oncology Navigation Efficiency and Value

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PUBLICATION

Best Practices in Expanding Access to Antibodies and Adverse Event Management

With more than 50 bispecific antibodies currently in clinical trials, this resource looks to optimize care for patients treated with bispecific antibodies and explore early identification and management of adverse events common in these patients. Download today at accc-cancer.org/bispecific-antibodies-brief.

BLOG

Manipulating Data to Make Precision Medicine Magic

John Strickler, MD, medical oncologist and associate professor of Medicine at Duke Cancer Institute, discusses molecular profiling and data, including development of Duke's Precision Cancer Medicine Initiative, which seeks to maximize the interoperability of key clinical and tumor genomic information of patients. Read more at accc-cancer.org/manipulating-data.

WEBINAR

Accruing Patients with Small Cell Lung Cancer to Clinical Trials

David Waterhouse, MD, MPH, medical oncologist and hematologist at the Dana-Farber Brigham Cancer Center, shares strategies to address barriers and engage patients in clinical trials. accc-cancer.org/engaging-patients-sclc.

PODCAST

Multi-Cancer Early Detection 101

Thought leader Chetan Bettegowda, MD, PHD, associate professor, Department of Neurosurgery and Oncology, Johns Hopkins University School of Medicine, discusses the latest advances in blood-based multi-cancer early detection screening platforms. Learn more at accc-cancer.org/mced101.

fast

Physician Burnout Rate Spikes to New Height

Landmark studies conducted at regular intervals between 2011 and 2021 by researchers from the American Medical Association, Mayo Clinic, and Stanford Medicine found the overall prevalence of burnout among U.S. physicians was **62.8%** in 2021, compared with **38.2%** in 2020, **43.9%** in 2017, **54.4%** in 2014, and **45.5%** in 2011.

Source. Shanafelt TD, West CP, Dyrbye LN, et al. Changes in burnout and satisfaction with work-life integration in physicians over the first 2 years of the COVID-19 pandemic. Mayo Clinic Proceedings; 2022. doi.org/10.1016/j.mayocp.2022.09.002.

Priorities & Challenges for U.S. Healthcare System

A survey of physicians, practice management staff, billers, and coders found:

- Patient satisfaction is the highest priority, with **62%** of physicians and **40%** of practice managers ranking it **#1**.
- The rising cost of healthcare is the biggest challenge report **70%** of physicians, **64%** of practice managers, and **58%** of billers and coders.
- Staying up to date on financial policies and reimbursement takes up the largest portion of work hours; practice managers spend **23%** of their time and billers and coders spend **27%** of their time on these activities.

Source. Clarivate survey for RxVantage. prnewswire.com/news-releases/patient-satisfaction-remains-most-important-even-as-rising-costs-are-biggest-challenge-to-healthcare-practices-rxvantage-study-reveals-301531316.html.

facts

The Future of Telemedicine

- In 2020, **58%** of patients report an intention to use telemedicine "more" frequently or at "the same" frequency after the end of the COVID-19 pandemic.
- In 2021, more than **73%** of patients report they planned to receive "some" or "all" of their care through telemedicine after the pandemic. Notably, this percentage was consistent across race and ethnicity, reinforcing that historically marginalized groups will use telemedicine when it is accessible. Optimizing solutions that allow, rather than impede access will be an important part of equitable telemedicine delivery.
- The percentage of patients who reported that telemedicine provides the same or better quality of care as compared with in-person visits increased from **40%** in 2020 to **55%** in 2021.
- While in-person appointments require patients to spend time in a waiting room, virtual care offers alternatives. Approximately **79%** of patients report they would prefer to receive a call or text when their doctor is ready to see them, versus standing by in a virtual waiting space.

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

Caregiving Needs Causing Family Strains?

New survey results from Family First reveal:

- Caregiving needs and challenges are impacting mental health. **65%** of respondents say their caregiving needs increased during the pandemic, leading many to face mental health challenges. Since the onset of the COVID-19 pandemic, **59%** also experienced suicidal thoughts, another **59%** increased their substance abuse, and **62%** suffered from depression.
- Family dynamics associated with caregiving are strained. More than half (**57%**) of respondents feel like a burden to their family, and **61%** say that their caregiving needs had a negative impact on their relationship with the family caregiver. In addition to receiving care, **62%** of respondents also provide caregiving support to another member of their family, which can be extremely overwhelming.
- Health plans are not offering enough clinical caregiving support. **66%** of respondents feel that caregiving support should be an essential benefit offered by health plans, and another **66%** would consider switching to a health plan that provides better caregiving support. Making medical appointments and managing medications were listed as the most difficult aspect of healthcare to navigate.

Source. Family First. family-first.com. prnewswire.com/news-releases/the-majority-of-medicare-and-medicaid-members-feel-their-caregiving-needs-caused-family-strain-new-family-first-survey-finds-301459254.html.

10 Things Gen Z and Millennial Nurses Want from Their Hospitals

1. On-the-job training and support
2. Mental health support
3. Financial support
4. Respect and recognition
5. Improved working conditions
6. Long-term workforce solutions
7. Patience
8. More flexible working hours
9. To be fulfilled
10. Continuing education support

Source. Bean M, et al. 10 things Gen Z, millennial nurses want from their hospitals. Becker's Hospital Review. beckershospitalreview.com/nursing/10-things-gen-z-millennial-nurses-want-from-their-hospitals.html?origin=BHRE&utm_source=BHRE&utm_medium=email&utm_content=newsletter&oly_enc_id=5512G9513589G9J.

First Look: What to Expect in Health Policy 2023

BY MATT DEVINO, MPH

The 118th United States Congress, which officially meets from January 3, 2023, through January 3, 2025, is poised to be a case study in 21st century American bipartisanship. Following the 2022 midterm elections, Democrats will maintain control of the Senate, while the House of Representatives will be controlled by Republicans. A divided Congress, with very slim majorities in both chambers, means that any legislation able to clear both chambers will require significant negotiation across the aisle and ultimately agreement between both parties.

There is precedent for significant pieces of healthcare legislation passing in a divided government. The Balanced Budget Act of 1997,[1] which created the Children's Health Insurance Program (CHIP) and introduced what later became the Medicare Advantage program, and the Medicare Access and CHIP Reauthorization Act of 2005 (MACRA),[2] which drastically changed how Medicare reimburses providers, were both passed by Republican-controlled congresses and signed into law by Democratic presidents. To pass these laws, significant bipartisan cooperation was necessary between Congress and the Administration. Early indications, however, suggest that members of Congress may be more interested in campaigning on policy differences ahead of the 2024 presidential election rather than compromising and legislating on major policy issues in the 118th Congress.

In looking at the current state of health policy, this means that we are unlikely to see any sweeping changes to the U.S. healthcare system in 2023 and 2024. I think it's safe to say at this point that the Affordable Care Act is here to stay. And the Inflation Reduction Act of 2022,[3] which passed with Democrat-only support in August 2022, is unlikely to see any significant alterations over the next two years. However, there are policy proposals that have bipartisan support and are likely to be considered in some form over the course of the 118th Congress. My predictions for these areas of progress in health policy are outlined below.

Extension of Medicare Telehealth Flexibilities

It seems likely that the COVID-19 public health emergency (PHE), which has been ongoing since January 2020, will end at some point in 2023. While this date is not yet known, the Biden administration has indicated that it will provide 60 days' notice prior to letting the PHE expire. This means that the COVID-19 PHE will likely be renewed at least once more through at least April 2023.

Congress acted in early 2022 to extend Medicare telehealth waivers and flexibilities for 151 days beyond the end of the COVID-19 PHE, whenever that may be. These flexibilities were originally granted because of the PHE determination and have allowed for Medicare beneficiaries to access telehealth services from their homes and any geographic area across the country for the duration of the pandemic. This simple expansion of Medicare coverage was not permitted prior to COVID-19, but now most of these telehealth flexibilities have strong bipartisan support in Congress.

Recognizing that telehealth has become a critical component of healthcare delivery, the House of Representatives overwhelmingly passed the Advancing Telehealth Beyond COVID-19 Act of 2021[4] in July 2022, to uncouple the duration of Medicare telehealth flexibilities from the PHE determination entirely and extend those flexibilities through December 31, 2024. Congress included these provisions to extend all telehealth flexibilities through the end of 2024 in its fiscal year 2023 omnibus package, which was signed into law on December 29, guaranteeing telehealth availability for Medicare beneficiaries for at least another two years. There is a strong likelihood that Congress will re-examine this issue in its new session and may even consider making this expansion of Medicare telehealth coverage permanent.

Renewed Efforts for Healthcare Transparency and Oversight

In recent years, both Congress and the Biden administration have pursued an agenda to increase transparency into healthcare costs and the pricing of medical services. To date, hospital and payer pricing transparency requirements are in effect, as well as regulations around surprise medical billing, following the passage and subsequent implementation of the No Surprises Act.[5] With Republicans retaking control of the House and its various committees, it is likely these efforts to increase healthcare transparency will be redoubled in the 118th Congress.

In fact, the incoming chairman of the House Oversight Committee, Rep. James Comer (R-KY), has already promised to aggressively pursue transparency in the federal government and host frequent hearings on topics relevant to the U.S. healthcare system. Following policy developments in 2022, there is already bipartisan support to increase transparency around pharmacy benefit managers (PBMs) and the 340 Drug Pricing Program in the coming year. The Federal Trade Commission has already initiated a formal inquiry into six of the largest PBMs in the country, and Senators have introduced bipartisan legislation to increase drug pricing transparency and hold PBMs accountable for unfair business practices that drive up the cost of prescription drugs.[6,7] This momentum for transparency at the federal level is likely to continue in 2023.

As Republicans regain control of what topics each committee will prioritize in the new Congress, they are likely to also explore hospital finances and non-profit status, consolidation in the healthcare ecosystem, prior authorization in the Medicare Advantage program, the origins of COVID-19, and the Biden administration's COVID-19 response.

Support for Public Health Initiatives and Pandemic Preparedness

Congress has made significant progress to pass bipartisan legislation addressing mental and behavioral health challenges over the past several years, particularly as these issues have been exacerbated by the COVID-19 pandemic. Most recently, Congress passed the Bipartisan Safer Community Act[8] in June 2022 to improve access to mental healthcare and additional funding to expand and enhance the 988 suicide and crisis response hotline. The law also temporarily extended funding for mental health services through block grants, but further action will be required in the coming year to reauthorize the Mental Health Reform Act of 2016.

A Republican-controlled House will also bring substance use disorders, particularly fentanyl-related overdoses, into the spotlight as they seek to focus on how illegal substances are entering the country and find legislative solutions to address increasing overdose-related deaths. Additionally, the reauthorization of the Pandemic and All Hazards Preparedness Act will be a likely vehicle in the 118th Congress for additional legislation to support the public health and healthcare workforce and ensure supply chain resiliency for medical equipment and supplies.

Wrap-Up

While much is certainly still up in the air with a split Congress, and the dynamics of new party leadership is still unknown, I believe that the issues summarized above will factor in some way into policy conversations and potentially legislation in the 118th Congress. Republicans assuming committee leadership in the House will also likely elevate discussions around the insolvency of the Medicare trust fund as a means to influence Medicare policy in the years ahead. As healthcare stakeholders turn to Congress to address supply chain issues, labor shortages, and inflationary concerns, the topic of broader Medicare payment reform may bubble to the surface. OI

Matt Devino, MPH, is the director of Cancer Care Delivery and Health Policy at ACCC.

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2023 Oncology Coding Update

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

The coding updates for 2023 were released by both the American Medical Association (AMA) and the Centers for Medicare & Medicaid Services (CMS). While there are not a significant number of coding updates, providers should understand the changes that were made. This column outlines coding changes specific to the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM); Current Procedural Terminology (CPT®); and Healthcare Common Procedure Coding System (HCPCS) for services that may be provided by or related to the services of oncology specialties. Items in orange indicate changes for 2023.

Revised ICD-10-CM Guidelines

As these updates run on a fiscal year calendar, the following ICD-10-CM guidelines went into effect Oct. 1, 2022. Note: due to the change to a biannual update to diagnosis coding, additional updates are expected for implementation on April 1, 2023.

Many of the 2022 guideline updates focus on the need to code the diagnosis to the highest level of specificity. Language was added in several sections of the *ICD-10-CM Official Guidelines*, including:

Conventions for ICD-10-CM

- **Code assignment and clinical criteria.** The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis. If there is conflicting medical record documentation, query the provider.

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

- **Documentation of Complications of Care.** Code assignment is based on the provider's documentation of the relationship between the condition and the care or procedure, unless otherwise instructed by the classification. The guideline extends to any complications of care, regardless of the chapter in which the code is located. Note: not all conditions that occur during or following medical care or surgery are classified as complications. There must be a cause-and-effect relationship between the care provided and the condition, and the documentation must support that the condition is clinically significant. It is not necessary for the provider to explicitly document the term "complication." For example, if the condition alters the course of the surgery as documented in the operative report, then it would be appropriate to report a complication code. Query the provider for clarification if the documentation is not clear as to the relationship between the condition and the care or procedure.

Chapter 2: Neoplasms (C00-D49)

- **Admission/Encounter for treatment of primary site.** If the malignancy is chiefly responsible for occasioning the patient admission/encounter and treatment is directed at the primary site, designate the primary malignancy as the principal/first-listed diagnosis. The only exception to this guideline is if the administration of chemotherapy, immunotherapy, or external beam radiation therapy is chiefly responsible for occasioning the admission/encounter. In that case, assign the appropriate **Z51-code** as the first-listed or principal diagnosis, and the underlying diagnosis or problem for which the service is being performed as a secondary diagnosis.
- Secondary malignant neoplasm of lymphoid tissue. When a malignant neoplasm of lymphoid tissue metastasizes beyond the lymph nodes, a code from categories C81 to C85 with a final character "9" should be assigned, identifying "extranodal and solid organ sites," rather than a code for the secondary neoplasm of the affected solid organ. For example, for metastasis of B-cell lymphoma to the lung, brain, and left adrenal gland, assign code C83.39, diffuse large B-cell lymphoma, extranodal and solid organ sites.

Chapter 5: Mental, Behavioral and Neurodevelopmental Disorders (F01-F99)

- Dementia. The ICD-10-CM classifies dementia (categories F01, F02, and F03) on the basis of the etiology and severity (unspecified, mild, moderate, or severe). Selection of the appropriate severity level requires the provider's clinical judgment and codes should be assigned only on the basis of provider documen-

tation (as defined in the *ICD-10-CM Official Guidelines for Coding and Reporting*), unless otherwise instructed by the classification. If the documentation does not provide information about the severity of the dementia, assign the appropriate code for unspecified severity. If a patient is admitted to an inpatient acute care hospital or other inpatient facility setting with dementia at one severity level and it progresses to a higher severity level, assign one code for the highest severity level reported during the stay.

Chapter 19: Injury, Poisoning, and Certain Other Consequences of External Causes (S00-T88)

- The occurrence of drug toxicity is classified in ICD-10-CM as follows. Underdosing refers to taking less of a medication than is prescribed by a provider or a manufacturer's instruction. Discontinuing the use of a prescribed medication on the patient's own initiative (not directed by the patient's provider) is also classified as an underdosing. For underdosing, assign the code from categories T36 to T50 (fifth or sixth character "6"). Documentation of a change in the patient's condition is not required to assign an underdosing code. Documentation that the patient is taking less of a medication than is prescribed or discontinued the prescribed medication is sufficient for code assignment.

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

- Social determinants of health. Codes describing problems or risk factors related to social determinants of health (SDOH) should be assigned when this information is documented. Assign as many SDOH codes as are necessary to describe all the problems or risk factors. These codes should be assigned only when the documentation specifies that the patient has an associated problem or risk factor. For example, not every individual living alone would be assigned code Z60.2, Problems related to living alone.

Revised ICD-10-CM Codes

These codes continue to expand to allow for specificity with diagnosis coding. The following are highlights of ICD-10-CM coding changes for 2023.

Neoplasms (C00-D49)

- **C61** Malignant neoplasm of prostate. "Previous–Use additional code to identify" was replaced with "New—Use additional code, if applicable, to identify."
- Under **C84** Mature T/NK-cell lymphomas:
  - **C84.0** Mycosis fungoides. "Previous—Excludes1: peripheral T-cell lymphoma, not classified (C84.4-)" was replaced with "New—Excludes1: peripheral T-cell lymphoma, not elsewhere classified (C84.4-)."
  - **C84.4** Peripheral T-cell lymphoma. "Previous—C84.4 Peripheral T-cell lymphoma, not classified" was replaced with "New—**C84.4** Peripheral T-cell lymphoma, not elsewhere classified."
  - Note: The codes listed under **C84.4** for peripheral T-cell lymphoma are all adjusted as listed above from "not classified" to "not elsewhere classified." Only one example is included for brevity.
- **C94** Other leukemias of specified cell type:
  - **C94.6** Myelodysplastic disease, not classified. "Previous–C94.6 Myelodysplastic disease, not classified" was replaced with "New–**C94.6** Myelodysplastic disease, not elsewhere classified." "Myeloproliferative disease, not classified" was deleted. "Myelodysplastic/myeloproliferative neoplasm, unclassifiable" and "Myeloproliferative disease, not elsewhere classified" were added.

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

- **D75** Other and unspecified diseases of blood and blood-forming organs.
  - **D75.8** Other specified diseases of blood and blood-forming organs.
    - **D75.82** Heparin induced thrombocytopenia (HIT). Use additional code, if applicable, for adverse effect of heparin (**T45.515-**):
      - **D75.821** for non-immune heparin-induced thrombocytopenia, non-immune HIT, and type 1 heparin-induced thrombocytopenia.
      - **D75.822** for immune-mediated heparin-induced thrombocytopenia, immune-mediated HIT, and type 2 heparin-induced thrombocytopenia.
      - **D75.828** for other heparin-induced thrombocytopenia syndrome, autoimmune heparin-induced thrombocytopenia syndrome, delayed-onset heparin-induced thrombocytopenia, and persisting heparin-induced thrombocytopenia.
      - **D75.829** for heparin-induced thrombocytopenia, unspecified.
    - **D75.84** for other platelet-activating anti-PF4 disorders for spontaneous heparin-induced thrombocytopenia syndrome (without heparin exposure), thrombosis with thrombocytopenia syndrome, and vaccine-induced thrombotic thrombocytopenia. Use additional code, if applicable, for adverse effect of other viral vaccine (T50.B95-).

A large section of codes was added to identify long-term drug therapy. As factors influencing health status, these codes are only added to the claim form if documented

in the encounter by the physician. If there is no documentation to support their use, the codes are not utilized.

Z79 Long term (current) drug therapy

- **Z79.63**, Long term (current) use of chemotherapeutic agent.
  - **Z79.630** Long term (current) use of alkylating agent for: Long term (current) use of chlorambucil, Long term (current) use of cisplatin, and Long term (current) use of cyclophosphamide.
  - **Z79.631** Long term (current) use of antimetabolite agent for: Long term (current) use of 5-fluorouracil, Long term (current) use of 6-mercaptopurine, Long term (current) use of cytarabine, and Long term (current) use of methotrexate.
  - **Z79.632** Long term (current) use of antitumor antibiotic for: Long term (current) use of bleomycin, Long term (current) use of doxorubicin, and Long term (current) use of mitomycin C.
  - **Z79.633** Long term (current) use of mitotic inhibitor for: Long term (current) use of paclitaxel, Long term (current) use of plant alkaloids, Long term (current) use of vinblastine, and Long term (current) use of vincristine.
  - **Z79.634** Long term (current) use of topoisomerase inhibitor for: Long term (current) use of etoposide, Long term (current) use of irinotecan, and Long term (current) use of topotecan.
  - **Z79.64** Long term (current) use of myelosuppressive agent for: Long term (current) use of hydroxyurea.
  - **Z79.69** Long term (current) use of other immunomodulators and immunosuppressants.
- **Z79.8**, other long term (current) drug therapy.
  - **Z79.84** Long term (current) use of oral hypoglycemic drugs. Excludes: long-term (current) use of injectable non-insulin anti-diabetic drugs (**Z79.85**).
  - **Z79.85** Long-term (current) use of injectable non-insulin antidiabetic drugs. Excludes: long term (current) use of insulin (Z79.4) and long term (current) use of oral hypoglycemic drugs (Z79.84).

Evaluation and Management Deleted Codes

In 2023, several codes were deleted for evaluation and management (E/M) services to align with the overhaul of "other" E/M services (i.e., inpatient, observation, and critical care). The following codes were deleted effective Jan. 1, 2023: **99217, 99218, 99219, 99220, 99224, 99225, 99226, 99241, 99251, 99318, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99339, 99340, 99343, 99354, 99355, 99356,** and **99357.**

E/M Revised Codes

Inpatient and observation visit codes are revised for 2023, the changes mirror those made for outpatient visits in 2021. Inpatient and observation codes are now based on medical decision making (MDM) or total time on date of encounter.

The following are the inpatient and observation visit codes for initial and subsequent patient visits.

Initial Visits

- **99221**: Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straight forward or low-level medical decision-making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.
- **99222**: Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level medical decision-making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded.
- **99223**: Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high-level medical decision-making. When using total time on the date of the encounter for code selection, 75 minutes must be met or exceeded.

Subsequent Visits

- **99231**: Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low-level medical decision-making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.
- **99232**: Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level medical decision-making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.
- **99233**: Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high-level medical decision-making. When using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded.

New Codes

As in 2021, CMS and AMA did not agree on the use and application of prolonged services with the new E/M guidelines. Due to this, the AMA has a CPT code and the HCPCS (CMS) has three codes for prolonged services, but only one specific to inpatient and observation services. When reporting,

the appropriate code will depend on the payer.

- **AMA CPT Code 99418**: Prolonged inpatient or observation evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time. (List separately in addition to the code of the inpatient and observation evaluation and management service.)
- **HCPCS Code G0316**: Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact. (List separately in addition to CPT codes 99223, 99233, and 99236 for hospital inpatient or observation care evaluation and management services.)

Nuclear Medicine Revised Codes

In 2023, the radiopharmaceutical localization codes were updated to expand more on the acquisition variances in the code levels/selections:

- **78803**: Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), single area (eg, head, neck, chest, pelvis) or acquisition, single day imaging.
- **78830**: Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, single area (eg, head, neck, chest, pelvis) or acquisition, single day imaging.
- **78831**: Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), minimum 2 areas (eg, pelvis and knees, chest and abdomen) or separate acquisitions (eg, lung ventilation and perfusion), single day imaging, or single area or acquisition over 2 or more days.
- **78832**: Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, minimum 2 areas (eg, pelvis and knees, chest and abdomen or separate acquisitions (eg, lung ventilation and perfusion), single day imaging, or single area or acquisition over 2 or more days.

Nuclear Medicine Category III Codes

Three codes were created for cardiac focal ablation utilizing radiation therapy for arrhythmia. Currently, there is little guidance or information on the application of these codes relative to other radiation therapy treatment delivery codes. CMS does not recognize these codes for payment in the outpatient setting; for physicians, these codes are contractor priced.

- **0745T**: Cardiac focal ablation utilizing radiation therapy for arrhythmia; noninvasive arrhythmia localization and mapping of arrhythmia site (nidus), derived from anatomical image data (eg, CT, MRI, or myocardial perfusion scan) and electrical data (eg, 12-lead ECG data), and identification of areas of avoidance.
- **0746T**: Cardiac focal ablation utilizing radiation therapy for arrhythmia; conversion of arrhythmia localization and mapping of arrhythmia site (nidus) into a multidimensional radiation treatment plan.
- **0747T**: Cardiac focal ablation utilizing radiation therapy for arrhythmia; delivery of radiation therapy, arrhythmia.

HCPCS Code Changes: Added Modifiers

- **JZ**: Zero drug amount discarded/not administered to any patient.
- **LU**: Fractionated payment of CAR T-cell therapy.
- **JG**: Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes.
- **TB**: Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities.

HCPCS Code Changes: Added Codes

- **G0317**: Prolonged nursing facility evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact. List separately in addition to CPT codes **99306** and **99310** for nursing facility evaluation and management services. Do not report **G0317** on the same date of service as other prolonged services for evaluation and management **99358**, **99359**, and **99418**). Do not report **G0317** for any time unit less than 15 minutes.
- **G0318**: Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified

healthcare professional, with or without direct patient contact. List separately in addition to CPT codes **99345** and **99350** for home or residence evaluation and management services. Do not report **G0318** on the same date of service as other prolonged services for evaluation and management **99358**, **99359**, and **99417**). Do not report **G0318** for any time unit less than 15 minutes.

- **J1954:** Leuprolide acetate for depot suspension (lutrate), 7.5 mg
- **J9046:** Injection, bortezomib, (Dr. Reddy's), not therapeutically equivalent to j9041, 0.1 mg
- **J9048:** Injection, bortezomib (Fresenius Kabi), not therapeutically equivalent to j9041, 0.1 mg
- **J9049:** Injection, bortezomib (Hospira), not therapeutically equivalent to j9041, 0.1 mg
- **J9314:** Injection, pemetrexed (Teva) not therapeutically equivalent to J9305, 10 mg
- **J9393:** Injection, fulvestrant (Teva) not therapeutically equivalent to J9395, 25 mg
- **J9394:** Injection, fulvestrant (Fresenius Kabi) not therapeutically equivalent to j9395, 25 mg OI

CY 2023 HOPPS Final Rule Highlights

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

CMS released its Hospital Outpatient Prospective Payment System (HOPPS) final rule[1] on Nov. 1, 2022, but it was not published in the Federal Register until later that week. This article outlines several key HOPPS changes and updates that impact oncology outpatient hospitals.[1] Note: the below payment impacts are outside the agency's authority to change:

- The 2 percent sequestration reduction was fully reimplemented on July 1, 2022, after suspension due to the COVID-19 public health emergency (PHE)
- The 4 percent reduction in payments due to the pay-as-you-go rule (PAYGO) begins Jan. 1, 2023. While this decrease is intended to recoup the economic relief provided as part of the federal government's COVID-19 response, there are rumblings that Congress will waive the PAYGO decrease. These reductions would apply to Medicare payments for each code and would be in addition to the payment policies finalized by CMS for calendar year (CY) 2023.

HOPPS Payment Rates

The Hospital Outpatient Prospective Payment System provides the regulatory information and payment rates for facility-based settings, outpatient hospitals, and ambulatory surgical centers. CMS proposed a 2.7 percent increase and, in the end, finalized a 3.8 percent increase to the Outpatient Department fee schedule. However, due to a Supreme Court ruling filed on June 15, 2022, related to the 340B Drug Discount Program, CMS had to adjust final payments for CY 2023 to account for the shift from average sales price (ASP) -22.5 percent to ASP +6 percent for certain drugs. This adjustment affected services differently, but most saw a decrease of 2 percent from the proposed rates. Specifically, some services decreased and will be reimbursed at a lower payment rate in CY 2023 than CY 2022, while other services saw an increase overall in CY 2022, which was less than the increase proposed. The big unknown is what the additional five years of payment adjustments (2018 to 2022) that CMS must make will do to future rate setting. The agency indicated that it is still working through how to distribute the payback of monies from the remaining five years, but it is likely that more reductions will follow.

Cancer Hospital Payment Adjustment

There are 11 designated cancer hospitals in the United States. CMS provides additional payments to these hospitals, which are a "hold harmless" amount, as they are exempt from payment under the Inpatient Prospective Payment System. Each year, CMS calculates the factor of payment above the annual finalized rate hospitals will receive. For CY 2023, CMS finalized its proposal to continue to use the CY 2021 and CY 2022 target PCR (pre-claim review) of 0.89 for the 11 designated cancer hospitals without modification.

Procedures Assigned to New Technology APC Groups for CY 2023

When new technology is assigned a billing code, it can be difficult for CMS to establish a payment rate because there is no claims data to determine utilization and cost by hospitals. Due to this, the agency created New Technology Ambulatory Payment Classifications (APCs), which are like pass-through payments for new drugs, biologicals, radiopharmaceuticals, and devices. The new technology is assigned to a temporary APC until claims data is available. Typically, this assignment is a minimum of two years, but it can be less if there is sufficient data available sooner. Once there is sufficient data, the new technology is moved to a clinically appropriate APC.

Scalp cooling is a fairly new technology that became effective July 1, 2021. It is used to describe initial measurement and calibration of a scalp cooling device for use during chemotherapy administration to prevent hair loss. The scalp cooling device is included in Medicare's national coverage determination (NCD) policy: **NCD 110.6** (scalp hypothermia during chemotherapy to prevent hair loss). The scalp cooling cap is classified as a supply and not paid separately under HOPPS.

CMS received comments that indicate there was substantial resource costs, ranging from $1,900 to $2,400, for calibrating and cap fitting for scalp cooling services. The Category III code **0662T** (scalp cooling, mechanical; initial measurement and calibration of cap) is billable once per chemotherapy session,

which CMS interprets to be once per course of chemotherapy. As scalp cooling was new under the CY 2022 HOPPS final rule, CMS finalized its assignment to **New Technology APC 1529** for CY 2023, with a national payment rate of $1,850.50.

Brachytherapy Sources

CMS finalized the use of costs derived from CY 2021 claims data to set the CY 2023 payment rates and base the payment rates for brachytherapy sources on the geometric mean unit costs for each source. Brachytherapy sources, unless otherwise noted, are assigned status indicator (SI) "U." Codes with SI "U" are not packaged into C-APCs (comprehensive APCs); the sources are paid separately, in addition to the brachytherapy insertion code in the hospital setting.

CMS will also continue to use recently established low-volume APCs (i.e., when there are fewer than 100 single claims) in CY 2021 for CY 2023 rate setting. When a brachytherapy source meets this criterion, CMS will use up to four years of claims data to establish a payment rate using the greatest of the arithmetic mean cost, median cost, or geometric mean cost. CMS finalized the designation of four brachytherapy sources' APCs as low-volume APCs for CY 2023.

Payments of Drugs, Biologicals, and Radiopharmaceuticals

CMS finalized the following payment policies for drugs, biologicals, and radiopharmaceuticals:

- Packaged drugs and biologicals estimated at a per-day administration cost less than or equal to $135, in CY 2022 this was set at less than or equal to $130.
- Continued separate payment for items with an estimated per-day cost greater than $135, except for diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies or devices when used in a surgical procedure.
- Continued policy of making packaging determinations on a drug-specific basis rather than by HCPCS code for those codes that describe the same drug or biological but in different dosages.
- Continued policy of making all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product.
- Continued payment for diagnostic and therapeutic radiopharmaceuticals granted pass-through payment status based on ASP methodology, as CMS considers these to be drugs under HOPPS.
- For drugs or biologicals without sufficient data on sales price during the initial sales period, CMS will base payments on their wholesale acquisition cost (WAC) +3 percent.

The Inflation Reduction Act of 2022,[2] signed into law on August 16, 2022, includes a required temporary increase—8 percent (from 6 percent) of the reference biological's ASP— for the add-on payment of qualifying biosimilar biological products, beginning Oct. 1, 2022. This increase applies for a 5-year period, as required by the Act.

The Act also defines a qualifying biosimilar biological product as a biosimilar with an ASP that is not more than the ASP of the reference biological. For qualifying biosimilar biological products paid using an ASP as of Sept. 30, 2022, the 5-year period began on Oct. 1, 2022. For qualifying biosimilar biological products with first payments made using an ASP between Oct. 1, 2022, through Dec. 31, 2027, the 5-year period will begin on the first day of the calendar quarter during which the first payment is made.

This change, as well as others, are related to the Inflation Reduction Act, and implementation of these changes are not fully detailed within the HOPPS final rule.

CMS clarified that further details on the implementation of the Act are forthcoming and will be communicated through a vehicle other than its CY 2023 HOPPS final rule.

Manufacturer Refunds for Discarded, Single-Use Vial Amounts

Drugs and biologicals ("drugs") are administered to patients in varying amounts, and the amount administered is often less than the total amount in the product's vial or package. Some of these drugs are only available in single-dose vials or single-dose packages. The U.S. Food and Drug Administration (FDA)-approved labeling for a drug packaged in a single-dose container typically states that any extra amount of the drug remaining after the dose is administered must be discarded. Based on this FDA language, Medicare has established under Part B that the unused and discarded amount from a single-dose vial or single-dose package would be paid when reported on the claim with use of **modifier JW**, which is not for use with drugs that are not separately paid, such as drugs packaged into outpatient hospital services or other designated settings.

Due to the nature of these changes, CMS proposed to codify certain billing requirements within the CY 2023 Medicare Physician Fee Schedule (MPFS) proposed rule[3] for HOPPS and ambulatory surgical centers. CMS directed interested parties to the full description of the proposed changes via the MPFS rulemaking. Similarly, CMS directed readers interested in the policy's finalization to the CY 2023 MPFS final rule,[4] which is available on the CMS website. Highlights of the CY 2023 MPFS final rule can be found on pages 21 to 24.

In addition, after the CY 2023 proposed rule, the Inflation Reduction Act[2] was signed into law and includes sections 11101 and 11102, which relate to rebates by manufacturers of drugs covered under Part B and D. The Act specifies an effective date of January 1, 2023. Per CMS policy established on Jan. 1, 2017, providers are required to report the

amount of the administered drug on one claim line with the applicable HCPCS code and units, and the waste amount with the applicable drug code, number of wasted units, and **modifier JW** on a separate claim line. 2020 claims data support that Medicare paid nearly $720 million for discarded drug amounts billed with modifier JW under Part B for single-dose vials or single-dose packages. These payment amounts track with yearly totals between 2017 and 2019, which ranged from approximately $700 million to $750 million each year.

340B Drug Discount Program

In the CY 2018 HOPPS final rule, CMS finalized the policy to pay for drugs purchased under the 340B Drug Discount Program (not including drugs on pass-through payment status or vaccines) at the rate of ASP -22.5 percent—a significant reduction from the previous rate of ASP+6 percent. Since this payment policy was updated in CY 2018, there has been significant litigation, which has resulted in varying decisions, some which favored the plaintiff and some which favored the defendant (CMS). In response to those rulings, the payment policy for the 340B Drug Discount Program has had some back-and-forth adjustments between ASP+6 percent and ASP -22.5 percent. On June 15, 2022, the Supreme Court filed a decision in the *American Hospital Association v. Becerra case*.[5] The Supreme Court reversed the D.C. Circuit Court's decision, citing that the Department of Health and Human Services Secretary may not vary payment rates for drugs and biologicals among groups of hospitals in the absence of having conducted a survey of hospitals' acquisition costs. The Supreme Court's decision involved payments for CYs 2018 and 2019, but it has implications for CY 2023.

Utilizing the separately paid line items with modifier "JG" in the CY 2021 claims available for HOPPS rate setting, which is the modifier used to identify drugs purchased under the 340B Drug Discount Program, the estimated payment differential would be an increase of approximately $1.96 billion in HOPPS drug payments. To ensure budget neutrality, CMS applied a decrease to HOPPS payments by factoring in a 0.9691 adjustment for a revised CY 2023 conversion factor of $85.585.

On Sept. 28, 2022, after the publication of the proposed CY 2023 HOPPS rule, the district court ruled on the first motion, vacating the 340B reimbursement rate for the remainder of CY 2022. CMS took steps to implement the court's ruling, which was clarified as a final judgement.

CMS is maintaining its requirement for 340B hospitals to report the "JG" and "TB" modifiers for informational purposes for CY 2023. The application of the modifiers will have no effect on payment rates. The presence of modifier "JG" on a claim indicates a drug is acquired under the 340B program, but it will not trigger a payment reduction and will only be used for informational purposes. Claims for 340B drugs and biologicals identified with modifier "JG" will be paid at the statutory default rate as non-340B drugs and biologicals. For CY 2023, CMS directs rural sole community hospitals, children's hospitals, and Prospective Payment System (PPS)-exempt cancer hospitals to continue to report modifier "TB" on claim lines for drugs acquired through the 340B Program. All other 340B providers are directed to continue to bill the modifier "JG."

In response to a comment within the final rule for CY 2023, CMS states the following, "We note that while the original intent of this policy was not to benefit rural hospitals financially, we recognize that ending this policy means that payment rates for non-drug items and services will decrease, which will lead to lower total payments for all hospitals, including non-340B hospitals or hospitals that were exempt from the 340B payment policy for which the 340B policy had a positive financial effect…since the Supreme Court invalidated the previous payment rate of ASP -22.5 percent for 340B acquired drugs and biologicals, we must decrease other rates to offset the increase in 340B drug payment. We believe the best interpretation of the statute is to require budget neutrality across the program."[1]

References

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2. Congress.gov. Public Law 117–169—Aug. 16, 2022. Accessed December 13, 2022. congress.gov/117/plaws/publ169/PLAW-117publ169.pdf

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CY 2023 MPFS Final Rule Highlights

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

CMS released its 2023 Medicare Physician Fee Schedule (MPFS)[1] on November 1, 2022, but it was not published in the Federal Register until later that week. This column outlines several of the key items for MPFS that impact oncology practices and providers.[1] Note: the below payment impacts are outside the agency's authority to change:

- The 2 percent sequestration reduction was fully reimplemented on July 1, 2022, after suspension due to the COVID-19 public health emergency (PHE)
- The 4 percent reduction in payments due to the pay-as-you-go rule (PAYGO) begins Jan. 1, 2023. While this decrease is intended to recoup the economic relief provided as part of the federal government's COVID-19 response, there are rumblings that Congress will waive the PAYGO decrease. These reductions would apply to Medicare payments for each code and would be in addition to the payment policies finalized by CMS for calendar year (CY) 2023.

MPFS Payment Rates

The Medicare Physician Fee Schedule provides the regulatory information and payment rates for physicians—across all care settings (facility and non-facility). In its final MPFS rule, CMS made some changes to what was proposed, for example, to the conversion factor, which is the value multiplied to the assigned relative value units (RVUs) of physician work, practice expense, and malpractice codes to determine payment. CMS finalized a conversion factor of $33.0607, a decrease of 4.5 percent from CY 2022 ($34.6062) and slightly less than what was proposed. CMS provided a breakdown of the payment impacts to each specialty to identify where changes will be the greatest (non-facility vs. facility). This breakdown only reflects the impact to estimated RVUs and does not reflect other changes, such as the 4.5 percent decrease to the conversion. Table 1, below, illustrates the estimated impact these RVU changes will have on oncology/hematology specialties.

CMS finalized updates to malpractice RVUs for next year; these were last updated in CY 2020 and are required to be updated every three years. Based on the malpractice

Table 1. CY 2023 MPFS Estimated Impact on Total Allowed Charges by Setting

SPECIALTY	TOTAL NON-FACILITY/ FACILITY	ALLOWED CHARGES (MILLIONS)	COMBINED IMPACT
Hematology/Oncology	TOTAL	$1,713	-1%
	Non-facility	$1,134	-2%
	Facility	$579	1%
Radiation oncology and radiation therapy centers	TOTAL	$1,615	-1%
	Non-facility	$1,545	-1%
	Facility	$69	-1%

or practice liability insurance data collected from all 50 states, CMS is changing the risk index values that are used to calculate the malpractice RVUs at the code level. Malpractice RVUs reflect the risk of the primary specialty assigned to the service to perform the service. For CY 2023, the risk index value for hematology/oncology will decrease from 0.765 to 0.743 for CYs 2023 to 2025, and the risk index value for radiation oncology will increase from 0.840 to 0.907 for CYs 2023 to 2025.

Evaluation and Management Changes

Effective Jan. 1, 2023, there will be updates to the next set of evaluation and management (E/M) codes. These codes are the "other E/M" visits (inpatient and observation visits, emergency department [ED], nursing facility, domiciliary or rest home, and home visits, including cognitive impairment assessment). While these codes exclude critical care services, they match the framework (medical decision-making or time-based) of the outpatient and office E/M visits that changed in 2021. CMS is moving forward with the AMA CPT Editorial Panel changes, with a few minor exceptions like coding for prolonged services. The agency did finalize amendment of its definitions for "initial" and "subsequent" in relation to E/M visits for inpatient services. CMS does not recognize subspecialties, as is outlined in the CPT manual, so CMS proposed the following language:

- An initial service would be defined as one that occurs when a patient has not received any professional services from a physician or other qualified healthcare professional or another physician or other qualified healthcare professional of the same specialty who belongs to the same group practice during the stay.
- A subsequent service would be defined as one that occurs when a patient has received any professional services from a physician or other qualified healthcare professional or another physician or other qualified healthcare professional of the same specialty who belongs to the same group practice during the stay.

CMS proposed three new Healthcare Common Procedure Coding System (HCPCS) codes to be used in place of the AMA-created CPT code **99418** for prolonged services: one code for hospital inpatient or observation care, one for nursing facilities, and another for home or residence. The code to be used with Medicare beneficiaries for prolonged services of inpatient time-based visits in 2023 is:

- **G3016:** Prolonged hospital inpatient or observation care E/M service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact. List separately in addition to CPT codes **99223**, **99233**, and **99236** for hospital inpatient or observation care E/M services. Do not report **G0316** on the same date of service as other prolonged services for E/M codes **99358**, **99359**, and **99418**. Do not report **G0316** for any time unit less than 15 minutes.

As with outpatient prolonged services, CMS did not agree with the AMA on how time was counted to meet the threshold for billing new codes. In addition, the prolonged service code **G0316** can only be used with the highest-level hospital inpatient or observation care visit codes (CPT codes **99223**, **99233**, and **99236**) when the time-based method is used.

The prolonged service period described by **G0316** begins 15 minutes after the total time (as established in the physician time file) for CPT codes **99223**, **99233**, and **99236** have been met. Additionally, CMS finalized that the G0316 prolonged code would be used for a 15-minute increment, and that the entire 15-minute increment must be completed to bill **G0316**.

Code **G0316** will apply to both face-to-face and non-face-to-face time spent on a patient's care within the survey timeframe. For CPT codes **99223** and **99233**, this would be time spent on the date of encounter. For CPT code **99236**, this would be time spent within three calendar days of the encounter.

CMS said that split (or shared) visits for new and established patients will be fully integrated in policy beginning in CY 2023 (a one-year delay) to allow full acquaintance and implementation of the other E/M visit changes.

Telehealth after the PHE

As of writing this article, the COVID-19 PHE is scheduled to end mid-January 2023. Any extension to the PHE would require the Secretary of the Department of Health and Human Services to notify the governors of each state with 60 days' notice and an extension is very likely. The provisions and waivers in response to the COVID-19 pandemic will continue for 151 days post the PHE's end.

CMS reiterated that any codes that are not part of the telehealth list of services identified as continuing permanently or temporarily as a Category 3 telehealth service will end on day 152 post-PHE. The services to be removed include:

- CPT code **77427** for radiation oncology physician management
- Initial inpatient E/M CPT codes **99221**, **99222**, and **99223**
- Audio-only CPT codes **99441**, **99442**, and **99443**.

Billing for telehealth services will return to pre-PHE guidelines, with some exceptions, and no longer require use of **modifier 95**; the appropriate place of service (POS) code (02 or 10) must be applied to process payment.

Another change: telehealth visits will no longer be allowed for patients in their homes or anywhere outside of an originating site other than the statutory exceptions for the diagnosis, evaluation, and treatment of mental health disorders, home dialysis, end-stage renal disease-related visits,

and the diagnosis, evaluation, and treatment of acute stroke symptoms.

CMS also addressed that there are certain types of services, when provided incident to the billing physician or practitioner, that require direct supervision. The agency reiterated that "...outside the circumstances of the PHE, direct supervision requires the immediate availability of the supervising physician or other practitioner, but the professional need not be present in the same room during the service." CMS has clarified that the "immediate availability" requirement means in-person (physical) availability—not virtual—in two different recent rulemakings (April 6, 2020, interim final rule with comment period and CY 2022 MPFS final rule).[2,3]

CMS also reminded stakeholders that after Dec. 31 of the year in which the PHE ends, the pre-PHE rules for direct supervision will apply. The agency is not making the temporary exception to allow immediate availability for direct supervision through virtual presence permanent. Instead, CMS is continuing to seek comments on whether to allow flexibility to meet the immediate availability requirement for direct supervision using real-time, audio/video technology. The agency also reminded stakeholders that supervising practitioners continue to be required to append the "**FR**" modifier on any applicable telehealth claim when they provide direct supervision for a service using virtual presence through real-time, audio and video telecommunications technology.

Manufacturer Refunds for Discarded Single-Use Vial Amounts

Drugs and biologicals ("drugs") are administered to patients in varying amounts, and the amount administered is often less than the total amount in the vial or package. Some of these drugs are only available in single-dose vials or single-dose packages. The U.S. Food and Drug Administration (FDA)-approved labeling for a drug packaged in a single-dose container typically states that any extra amount of the drug remaining after the dose is administered must be discarded. Based on this FDA language, Medicare has established, under Part B, that the unused and discarded amount from a single-dose vial or single-dose package would be paid when reported on the claim with use of **modifier JW**, which is not for use with drugs that are not separately paid, such as drugs packaged into outpatient hospital services or other designated settings.

CMS finalized enacting section 90004 of the Infrastructure Investment and Jobs Act[4] and provided details of how it plans to do this for the following areas:

- How discarded amounts of drugs are determined
- Defining which drugs are subject to refunds (and exclusions)
- When and how often CMS will notify manufacturers of refunds
- When and how often payment of refunds from manufacturers to CMS is required
- Refund calculation methodology (including applicable percentages)
- A dispute resolution process
- Enforcement provisions.

In addition, after the CY 2023 proposed rule, the Inflation Reduction Act was signed into law on August 16, 2022, which includes sections 11101 and 11102 relating to rebates by manufacturers for drugs covered under Part B and D.[5] The Act also specified an effective date of January 1, 2023. The details below were finalized:[5]

- Use of **modifiers JW** (drug amount discarded/not administered to any patient) and **JZ** (zero drug amount discarded/not administered to any patient) to identify discarded billing units of a billing and payment code to calculate the refund amount.
- For dates of service on or after Jan. 1, 2023, **modifier JW** will be required on claims for all single-dose container or single-use drugs when any amount is discarded, as part of the current policy.
- A six-month delay in the requirement to use the **JZ modifier** would allow healthcare providers sufficient time to incorporate necessary updates to their claims systems to report JZ data. If a provider cannot report the **JW** or **JZ modifiers** as required by Oct. 1, 2023, they should hold their claims until they are able to do so. Claims submitted without required modifier data will not be accepted.
- The definition for refundable single-dose container or single-use package drug would apply "to drugs paid under Medicare Part B (that is, under any payment methodology) that are described as being supplied in a 'single-dose' container or 'single-use' package based on FDA-approved labeling or product information. This definition also includes drugs described in FDA-approved labeling as a 'kit' that is intended for a single dose or single use."
- Excluded drugs would be radiopharmaceuticals, imaging agents, drugs requiring filtration during the drug preparation process, and drugs approved on or after the date of the Act's enactment (Nov. 15, 2021), for which payment under Part B has been made for fewer than 18 months.
- Exclusion of drugs requiring filtration during the drug preparation process specifically pertains to those drugs in which the dosing and administration instructions included in the labeling require filtration during the drug preparation process, prior to dilution and administration, and require any unused portion of the drug after the filtration process be discarded.
- While CMS did not finalize that initial reports be sent no later than Oct. 1, 2023, the agency finalized the proposed timeline for sending reports to manufacturers. The effective date of the provision remains Jan. 1, 2023, as required by the statute, and reports will be sent at each calendar quarter, beginning on or after this date.

- Refunds by drug manufacturers will be due no later than Dec. 31 of the year in which the report was delivered.
- Establishment of a dispute resolution process, civil monetary penalties, and periodic review of Part B medication claims to ensure **modifier JW**, **modifier JZ**, and discarded drug amounts are billed appropriately, as part of the already developed claims audit policy and process.

The Radiation Oncology Model

Due to the indefinite hold on the Radiation Oncology (RO) Model, CMS is evaluating the radiation oncology treatment delivery and image guidance (IGRT) G-codes. Specifically, the agency is looking to determine if current coding and payment policies for the services represented by the G-codes in the outpatient hospital setting can be adopted in the office-based setting. If any changes are made, they would be finalized through a rulemaking process like MPFS and HOPPS. OI

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tools

Approved Drugs

• On November 10, the U.S Food and Drug Administration (FDA) approved **Adcetris® (brentuximab vedotin)** (Seagen, seagen.com) **in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide** for pediatric patients 2 years of age and older with previously untreated high-risk classical Hodgkin's lymphoma.

• On November 14, the FDA granted accelerated approval to **Elahere® (mirvetuximab soravtansine-gynx)** (Immunogen, immunogen.com) for adult patients with folate receptor alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens.

• On October 21, the FDA approved **Imjudo® (tremelimumab)** (AstraZeneca, astrazeneca.com) **in combination with durvalumab** for adult patients with unresectable hepatocellular carcinoma. And on November 10, the FDA approved Imjudo in combination with Imfinzi® (durvalumab) (AstraZeneca, astrazeneca.com) and platinum-based chemotherapy for adult patients with metastatic NSCLC with no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

• On Nov. 2, Amneal Pharmaceuticals, Inc. (amneal.com) announced that it received abbreviated new drug application (NDA) approval from the FDA for **leuprolide acetate** in the palliative treatment of ad-vanced prostatic cancer.

• On November 8, the FDA approved **Libtayo® Inc., (cemiplimab-rwlc)** (Regeneron Pharmaceuticals, Inc., regeneron.com) **in combination with platinum-based chemotherapy** for adult patients with advanced NSCLC with no EGFR, ALK, or c-ros oncogene 1 (ROS1) aberration.

• On December 1, the FDA approved **Rezlidhia® (olutasidenib)** (Rigel Pharmaceuticals Inc., rigel.com) capsules for adult patients with relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase 1 (IDH1) mutation, as detected by an FDA-approved test.

• On November 18, the FDA approved a new dosing regimen for **Rylaze® (asparaginase erwinia chrysanthemi** (recombinant)-rywn) (Jazz Pharmaceuticals, jazzpharma.com). Under the new regimen, patients should receive 25 mg/m2 intramuscularly on Monday and Wednesday mornings, and 50 mg/m2 intramuscularly on Friday afternoon.

• On October 25, the FDA granted accelerated approval to **Tecvayli® (teclistamab-cqyv)** (Janssen, Janssen.com) for adult patients with relapsed or refractory multiple myeloma, who have received at least four prior lines of therapy, including a proteasome inhibitor, immunomodulatory agent, and anti-CD38 monoclonal antibody.

Drugs in the News

• Aravive Inc. (aravive.com) announced that the FDA granted fast track designation to **batiraxcept** for the treatment of patients with advanced or metastatic clear cell renal cell carcinoma, who have progressed after 1 or 2 prior lines of systemic therapy that include both immuno-oncology-based and vascular endothelial growth factor tyrosine kinase inhibitor-based therapies (either in combination or sequentially).

• Caribou Biosciences, Inc. (cariboubio.com) announced that the FDA granted regenerative medicine advanced therapy designation to **CB-010** for relapsed or refractory large B-cell lymphoma and fast track designation for relapsed or refractory B-cell non-Hodgkin's lymphoma.

• Citius Pharmaceuticals, Inc. (citiuspharma.com) announced that the FDA accepted its biologics license application (BLA) for **denileukin diftitox (E7777)** for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma.

• Pfizer Inc. (pfizer.com) announced that the FDA granted breakthrough therapy designation to **elranatamab** for the treatment of relapsed or refractory multiple myeloma.

• Myeloid Therapeutics, Inc. (myeloidtx.com) announced that the FDA granted fast track designation to **MT-101** for patients with refractory or relapsed CD5+ peripheral T-cell lymphoma.

• Ipsen (ipsen.com) announced its intent to file a supplemental NDA with the FDA for **Onivyde® (irinotecan liposome injection) in combination with oxaliplatin plus 5- fluorouracil/leucovorin** for the treatment of patients with previously untreated metastatic pancreatic ductal adenocarcinoma, following the fast track designation granted in 2020.

• Oncolytics Biotech Inc. (oncolyticsbiotech.com) announced that the FDA granted fast track designation to **pelareorep in combination with Tentriq® (atezolizumab)** (Genentech, gene.com), **Abraxane® (nab-paclitaxel)** (Bristol Myers Squibb, bms.com), **and nab-paclitaxel** for the treatment of advanced/metastatic pancreatic ductal adenocarcinoma.

• Gilead Sciences, Inc. (gilead.com) announced that the FDA accepted for priority review the supplemental BLA for **Trodelvy® (sacituzumab govitecan-hziy)** for the treatment of adult patients with unresectable, locally advanced, or metastatic hormone receptor positive (HR+), HER2- (IHC 0, IHC 1+, or IHC 2+/ISH–) breast cancer, who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.

• Tvardi Therapeutics, Inc. (tvarditherapeutics.com) announced that the FDA granted fast track designation to **TTI-101** for the treatment of relapsed/refractory locally advanced, unresectable, or metastatic hepatocellular carcinoma.

• Daiichi Sankyo (daiichisankyo.com) announced that the FDA accepted and granted priority review to the NDA for **quizartinib in combination with standard cytarabine and anthracycline induction, as well as standard cytarabine consolidation chemotherapy**, as continuation monotherapy following consolidation, for the treatment of adult patients with newly diagnosed acute myeloid leukemia that is FLT3-ITD+.

Assays and Devices in the News

• Genmab A/S (genmab.com) announced that the FDA accepted and granted priority review to the BLA for **enporitamab (DuoBody®—CD3xCD20)** for the treatment of patients with relapsed/refractory large B-cell lymphoma after two or more lines of systemic therapy.

• Roche (roche.com) announced that the FDA approved the **VENTANA FOLR1 (FOLR1-2.1) RxDx Assay** to aid in identifying epithelial ovarian cancer in patients who are eligible for targeted treatment with Elahere. OI

spotlight

St. Anthony Regional Cancer Center

Carroll, Iowa

Amid the trees, farmsteads, and rolling hills of Carroll, Iowa, resides St. Anthony Regional Cancer Center, a full-service oncology-hematology hospital-based department of St. Anthony Regional Hospital, offering radiation and medical oncology, hematology, and infusion therapy services. While faith-based healthcare organizations are common, this cancer center's dedication to providing high-quality care to its small, rural community makes it unique and serves as a foundation for constant innovation. A facility planning evaluation that occurs every decade is emblematic of this philosophy. Following the most recent strategic facility evaluation in 2011, St. Anthony Regional Hospital's goals for the future included building a new cancer center—one equipped with state-of-the-art facilities and equipment.

The groundbreaking for the new cancer center was in April of 2019, and the building was completed in December 2020. The project cost was estimated at $19 million. Of that amount, the Building Hope Capital Campaign raised $11 million through charitable donations. "That is what people in Iowa do. They stand behind what is going to benefit them and their neighbors," said Lori Pietig, MHA, CT, RT(R), director of Cancer Services at St. Anthony Regional Cancer Center. "Every dollar mattered, and every donor was acknowledged for their commitment to improving care across west central Iowa."

Redesigning with Patients in Mind

The level of commitment demonstrated by donors is likely a result of the quality of care the cancer center and its staff have provided to patients for the last 30 years. "We are not treating a group of individuals; we are treating our family, neighbors, and former schoolteachers," Pietig said. "Having a recognizable face makes a difference to our patients. They have a sense of connection."

The relationship St. Anthony Regional Hospital developed with its community ensured the patient perspective was included when designing the new cancer center. "None of our current [treatment] areas had windows and natural light," Pietig said. "The existing patient care spaces were very small and cramped. The patient care needs exceeded the space available in our current setting." A study of the Carroll County region also served as a source of inspiration for the new center. "We wanted to see what cancer [care] would look like in the future," Pietig explained.

Upon the study's conclusion, St. Anthony Regional Hospital found it needed to update its equipment. "Our linear accelerator was at the end of its life, and we did not have a secondary vault," Pietig said. The study also revealed the need to expand the health system's cancer service line. "The staff saw an increase in patient volumes because other local facilities were cutting back on cancer services, increasing patient volumes in the specialty clinic that was used by multiple providers," Pietig said.

The Cancer Center Today

The first floor is home to the radiation oncology clinic. The clinic is staffed by a radiation oncologist, registered nurse, dosimetrist, and three radiation therapists who are all employed by the hospital. The medical oncology and infusion therapy clinics can be accessed on the second floor. The infusion therapy clinic is staffed by nine registered nurses, with most being oncology certified. The medical oncology and hematology clinics are staffed by three oncologists, each of whom are contracted by the hospital. They also employ the services of a registered nurse, certified medical assistant, phlebotomist, and two licensed nurse practitioners, who are employed by the hospital.

"Our staffing model allows for consistency but also flexibility when dealing with ever changing patient volumes," Pietig said. "We also cross train staff throughout the cancer center to assure coverage for vacation and sick leave."

On patients' recommendations, St. Anthony Regional Cancer Center created three infusion suite options in the cancer center. Within the infusion space, there are thirteen chairs in a communal infusion setting, three chairs in a semi-private space, and two in the private rooms. "This allows patients to choose the setting they best see fit to receive treatment that day," Pietig said. Staff provide chemotherapy, immunotherapy, specialty injections, and blood transfusions in these infusion suites. Additionally, the nursing staff use portable computers to chart at the bedside—allowing them more time to be with patients.

The cancer center currently works with the St. Anthony Regional Hospital pharmacy team to support patient care needs. In the coming months, Pietig expects that the infusion suites' dedicated pharmacy will be fully operational. Following its launch, the pharmacy will be staffed by a full-time pharmacist and technician. "We have installed and are in the process of commissioning the Equashield® fully enclosed chemo mixing robot," Pietig said.

The cancer center's radiation oncology team offers IMRT, SBRT, EBRT, and radium Ra 223 dichloride injections. In addition, surgical oncology services are available for colon and breast cancer through a partnership with local physicians who offer services on-site. "We also work with patients if surgical options are available closer to home," Pietig said.

With the new building and services came a new patient referral form, developed by the staff at the cancer center, which is shared with local providers. "This form outlines what [information] is needed for a referral. From the time of referral to appointment, we are looking at less than five business days," Pietig said.

Supporting the Whole Person

Every Friday morning, cancer center staff discuss the care plans for each new patient, as well as their individual needs—both physical and spiritual. "Our facility was founded by Father Joseph Kuemper who had a vision, and he enlisted the Franciscan Sisters of Perpetual Adoration to build a hospital in Carroll," Pietig said. "Being a Catholic hospital, the spiritual aspect of care has been a part of us since the first brick was laid on the ground." St. Anthony Regional Hospital's current chaplain has been part of the care team for five years, and the facility also enlists help from retired priests and community members to provide spiritual guidance to those in need organization-wide.

Dedicated expansion of the supportive care services offered was a major focus when developing the new cancer center.

"The nurse navigator, social work, financial navigator, and dietitian [positions], those were areas we had opportunity to expand, and we have been able to add them as we grow." Today, St. Anthony Regional Cancer Center employs a full-time nurse navigator, social worker, financial navigator, and a part-time dietitian. Through a partnership with contracted medical oncology physicians, patients can also meet with a genetic counselor and receive genetic testing. Further, patients can access physical therapy, in-person or virtual support groups, as well as enrollment in clinical trials.

Pietig considers herself lucky because most of the patients being treated by St. Anthony Regional Cancer Center staff have insurance coverage. However, if they are underinsured, patients are referred to the patient finance department to evaluate support options from the hospital's charity program.

Unique Challenges to Rural-Based Healthcare

St. Anthony Regional Cancer Center does not currently have any accreditations, but it is one of five oncology programs enrolled in a five-year grant program that is funded by the National Cancer Institute and the University of Iowa. This opportunity is designed to help rural cancer centers in Iowa achieve Commission on Cancer accreditation. In 2021, the cancer center treated patients from 17 counties and 4 states—a significant expansion of its catchment area. "We have a saying here at the center: 'We, as caregivers, take more from our patients than we can ever give back to them.' We are humbled that each day they choose St. Anthony," Pietig said. "It is with great pride that we serve the patients that walk through our doors." OI

Advancing Cancer Prevention, Detection, Diagnosis, Treatment, and Precision Medicine

BY AMANDA PATTON, MA

> "While AI [artificial intelligence]-based systems are currently unable to discern a grimace, notice sweating, or hear a tremor in a patient's voice—skills at which humans excel—these systems offer the unique opportunity to augment clinician performance by creating order and transforming vast amounts of mostly unstructured data into clinically actionable information to support optimal care. This field, although nascent, is rapidly advancing."
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> –ABERNETHY ET AL. [1]

Artificial intelligence (AI) is running in the background and foreground of our lives. Whether it's the fitness app counting our daily steps, the "you may also like" recommendations on our screens, or the GPS telling us where to turn next—AI is everywhere.

Healthcare is no exception. On the business side, AI tools power increasingly sophisticated business intelligence (BI) platforms. In hospitals, as well as oncology programs and practices, AI-based software streamlines operational functions, such as staffing and appointment scheduling, virtual visits, and processes for safety and quality. In cancer research, AI brings together the expertise of biomedical engineers, computer scientists, oncology clinicians, and researchers to imagine, develop, study, and test AI-based solutions to advance early cancer detection, diagnosis, drug development, clinical decision-making, and the boundaries of precision medicine. Consider, for example, the capacity of AI tools to "look" at datasets of images and identify actionable patterns, which are uncovering new ways to "see" cancers with greater granularity and opening the door to the development of non-invasive processes for assessing cancer prognosis and targeting anti-cancer therapeutics.[2]

AI-driven cancer research is uncovering potential approaches for achieving the precision medicine goal: targeting the right treatment to the right patient at the right time.[3] In particular, research on the integration of AI in oncology imaging is progressing with implications for radiology, pathology, and clinical decision-making support for cancer diagnosis, prognosis, and treatment planning.

Anant Madabhushi, PhD, is a professor in the Wallace H. Coulter Department of Biomedical Engineering at the Georgia Institute of Technology and Emory University. He holds a primary faculty appointment at Emory University in the Department of Biomedical Engineering, as well as secondary appointments in the Departments of Radiology and Imaging Sciences, Biomedical Informatics, and Pathology. Dr. Madabhushi joined Emory University in July 2022, coming from Case Western Reserve University where he was director of the Center for Computational Imaging and Personalized Diagnostics and Donnell Institute Professor in the Department of Biomedical Engineering. He is also a research health scientist at the Atlanta Veterans Administration (VA) Medical Center.

In 2017, Dr. Madabhushi received the Institute for Electrical and Electronic Engineering in Medicine and Biology Society award for technical achievements in computational imaging and digital pathology. His work on the use of AI to address health disparities—including identifying differences in prostate cancer "appearance" between Black and White patients—earned national recognition. Dr. Madabhushi co-founded three companies, one of which is Picture Health, where he serves as chief scientific officer.

In a recent conversation with *Oncology Issues*, Dr. Madabhushi and his colleague Trishan Arul, chief executive officer at Picture Health, discussed the expanding role of AI and healthcare professionals in the fields of biomedical engineering and computer science to advance cancer prevention, detection, diagnosis, and treatment, as well as tailor precision medicine for patients with cancer.

OI: Can you share your perspective on AI in cancer research?

DR. MADABHUSHI: I've been working in the biomedical engineering space for about 18 years and [over that time] there have been a lot of developments in AI. Most of those developments have tended to be in diagnostics. That is, thinking about the role of AI for disease diagnosis and disease detection, and that's really good. It's critical. We need technologies to look non-invasively at imaging data to identify presence or absence of disease, but, having said that, our group has also been looking at some of the questions that emerge post-diagnosis.

Nearly 40 percent of the American population will be diagnosed with cancer at some point in their lifetime.[4] In the United States, 1 in 2 men and 1 in 3 women will be diagnosed with cancer during their lifetime.[5] This is a staggering statistic. To me, as we think about diagnosis, we also have to be thinking about how we address the issue of management and care for such a large population of patients.

> One way AI may play a significant role is by identifying which patients really require those more aggressive treatments versus patients who will not benefit from aggressive treatment.

OI: Specifically, how can AI tools applied to cancer imaging support clinical decision-making?

DR. MADABHUSHI: Something I feel very passionately about is the development of decision support tools, not just for the radiologist and pathologist to help in diagnosis, but for the clinician to help answer the question: "How should the disease be managed? More aggressively or less aggressively?"

My group and I spend a lot of time thinking about the kinds of AI approaches we can develop that integrate groupings of data that have been acquired as part of routine clinical workup—the initial pathology images, CT [computed tomography] scans, MRI scans. What can we do with these data so that we can really move the needle forward in terms of the decision-making process?

What do I mean by that? For example, figuring out which patients have more aggressive cancer versus less aggressive cancer. We know that in the U.S., unfortunately, there are many, many patients who end up with toxicity, not only because of aggressive anti-cancer therapies, but also from the very real issue of financial toxicity. Something like 42 percent of Americans with cancer will lose their life savings within two years of their cancer diagnosis.[6,7]

Anant Madabhushi, PhD

Trishan Arul, CEO, Picture Health

We think that one way AI can play a significant role is by identifying which patients really require those more aggressive treatments versus patients who will not benefit from aggressive treatment. AI can help advance our ability to more precisely identify which patients need more aggressive therapies and increase precision in treatment selection. Improvements in each area could help patients avoid drug-specific toxicity and treatment-related financial toxicity.

We are also thinking about treatment response. We know that even the best drugs today are not yielding the response rates we would like. So another area our group has been looking at is how can we move forward in terms of early response prediction and monitoring of the changes in the disease and, again, doing this [using] routinely acquired data—off of pathology images or other radiology scans. I think the opportunities here are tremendous.

These tools will no doubt benefit the radiologist and pathologist from a diagnostic perspective. If you think about radiation, medical, and surgical oncology, the ability of these tools in terms of helping provide risk stratification—who to treat more aggressively, who to treat less aggressively, predicting treatment response—to try to identify the right treatment for a given patient. This is where I think AI can really move the needle forward for cancer care providers.

ARUL: With any new technology, concern about integration with existing workflow arises. Picture Health's AI utilizes routine clinical images that already exist [as part of the diagnostic process]. We're not asking anyone to do anything special. We're not asking them [healthcare professionals] to send it [data] out for a specialized test or anything else.

Broader adoption of AI tools will require integration into the [clinical] workflow. We've seen early indications of this with many PACS [picture archive and communication systems] providers. They are building in APIs [application program interfaces] to allow outside AI vendors to plug in to [one's

We are trying to build decision-support tools for the oncologist. Tools for the treating physician to make important decisions, i.e. moving someone off a particular treatment regimen and putting them on another.

electronic health record,] acquire an image, apply their proprietary AI algorithm, and send back the annotated image with additional reporting. It's available in the workflow, but right now it's still fairly clunky. Other AI providers are developing their own cloud-based solutions. But these approaches require users to download and upload images to and from the cloud. We obviously have to solve that workflow challenge in order to achieve wide adoption.

OI: What does the business model look like for implementation of clinical AI tools into oncology practice?

ARUL: AI vendors are still figuring out the business model. It seems to be coalescing around subscription agreements with pay-for-use type arrangements. It's not surprising because it mimics the insurance reimbursement model we have in the U.S. You do something; you get paid for it. That said, Picture Health's AI utilizes routine clinic images like CT images. You can envision a world where all the images come in, we do the AI processing, we send the images back, and there are only alerts on certain images where the AI tool has identified something actionable or something that we can provide a report on. Then, that's a pricing model we've got to sort out. From the AI vendor's perspective, AI applications use a lot of computing horsepower. We have to absorb the cost of the cloud computing to run everything, but, for the clinician, results are available immediately.

OI: Can you say more about Picture Health's goals for its AI tools under development?

DR. MADABHUSHI: We are trying to build decision-support tools for the oncologist. These are AI tools for the treating physician to make some pretty heavy decisions. Moving someone off a particular treatment regimen and putting them on another—these are not trivial decisions. Picture Health is very deliberate and intentional with the AI features invoked in developing its decision support tools.

One of the criticisms around a lot of AI today is that it is very "black box." There is a lack of interpretability. We don't know what's under the hood, how it's working, or how it [the AI tool] got to its prediction. I think clinicians—in particular when it comes to making treatment decisions—set the bar for AI interpretability significantly higher because they are making these life-changing decisions. Because of that, Picture Health has focused on features from both pathology and radiology images that are intuitive and tethered more directly to the biology of the disease. The "anti-black box" if you will. But the beauty of what we are doing is that it also connects within the current paradigm of biomarkers and the way biomarkers are being invoked for treatment management.

Let's talk about immunotherapy, as an example. We all recognize—and I'm not saying anything that is controversial—that PD-L1 [programmed death-ligand 1] is not a good biomarker. And yet it is the status quo for how patients end up getting immunotherapy today. In lung cancer, I think we've gone in some ways beyond PD-L1, where in many cases—independent of the PD-L1 status—patients will end up getting immunotherapy. Four years ago, I think it was different. If you had low PD-L1, you might not be offered immunotherapy. I think it now represents first-line therapy across almost all lung cancers. If it's not there, it's moving toward first-line therapy in many cases.

One of the things we recognized is that in patients with low-PD-L1, even though they are getting immunotherapy, they are probably getting a combination of chemotherapy and immunotherapy. We've done a lot of work around better risk stratification of patients (i.e., seeing how AI tools can add more granularity within patient groups stratified by PD-L1 [low and high PD-L1 status]). These AI tools that we are developing can add further specificity within those buckets to allow further stratification of patient populations.[8,9] Further, compartmentalization of patients within those existing biomarker-defined buckets will add huge value. Now you have the opportunity to look at patients who may have low PD-L1 but potentially have favorable prognosis as determined by our AI tool. Or patients who are candidates for chemotherapy and immunotherapy—the AI application may indicate those patients who are likely to do well and can be given immunotherapy alone. We can avoid chemotherapy for these patients. That is game changing.

It's also valuable because, [although] we know in medicine things are going to change, approaches that try to disrupt the status quo have typically not fared very well. But if you try to be creative and innovative within the context of the existing status quo, I think you can have an impact. That's the way we're thinking about it.

ARUL: If you look at pathology-based AI companies, they are looking at replacing genomic-based biomarkers, doing alternative genomic biomarkers, and recomputing genomic biomarkers

without having to take a molecular test. Picture Health is not necessarily taking that approach. We see this [Picture Health's AI approach] as another layer of information on top of what's already there. As Anant said, [a tool to] further stratify the patient population and give the oncologist—and the other physicians, radiologists, pathologists—additional information with which to make these life-saving decisions for their patients.

OI: Is variation in image quality due to site-to-site variation among CT scanners, MRIs, etc., an issue?

ARUL: Much of what we're doing right now is based on the lowest common denominator—the standard H&E (hematoxylin and eosin) slide. The beauty of it is—yes, there is variability across sites—but certainly the variability for H&E slides is significantly lower compared to immunohistochemistry and lower than immunofluorescence, where you have more pre-analytic variations.

Picture Health is unique in that we look at both radiology and pathology. And so, on the pathology side, we are looking at the standard H&E because that's more widely available, with less variability. One of the tools that we've licensed is an algorithm called HistoQC, which is widely used by AI researchers to assess the quality of pathology images.[10] It provides a powerful way for assessing fidelity and computational worthiness. We have ideas on how to use that as a standard quality control mechanism—not just for our AI but for anyone's AI.

DR. MADABHUSHI: There is some variability, but, again that is where these very interpretable features that we've developed are also resilient to variations across sites and scanners. We've been intentional in the way that we've developed these features. Not only are they interpretable, but they are also discriminating, stable, and resilient across variations. So yes, CT scans will be different as a function of the vendor, as a function of the site—there are some sources of variation. But because of the way in which we've constructed our AI tools, they are imbued with more robustness and resilience than a lot of the "black box", non-interpretable AI tools.

OI: ACCC's multidisciplinary membership includes all members of the cancer team—radiation oncologists, medical oncologists, pathologists, molecular pathologists, interventional radiologists, palliative care physicians, and other specialists and subspecialists, including biomedical engineers and data scientists. Can you share your thoughts on how AI may be leading to further integration of the disciplines engaged in diagnosing and treating cancers along the care continuum?

DR. MADABHUSHI: For too long, medicine has been siloed. I think it just goes back to how traditional medicine tends to be. Disciplines were defined decades and decades ago, and they still tend to operate in those departments and siloes. But I think there is also acknowledgement, certainly in many academic medical centers, that this practice has to change. We're hearing terms like "integrated diagnostics" coming up. It is an appreciation that diagnostics is not about radiology or pathology—it's fundamentally about the patient. What you have to be able to do is provide the best decision for the patient. That is where this concept of integrative diagnostics—leveraging the totality and plurality of information—is gaining a lot of traction. It's still a buzzword. It hasn't truly been implemented in practice, but it's something that Picture Health has embraced. Frankly, it's a travesty for us not to be able to use the totality and plurality of information that is being acquired from the patient [for the best possible prognosis]. Philosophically, that's what we've embraced at Picture Health.

As a company, we are unique in being able to meld information together across pathology and radiology to provide a more holistic, integrated prediction of outcome and treatment response for a given patient. The hope is that this will align with changes that are taking place. There is more and more appreciation, certainly within academic medical centers, that the departments of tomorrow will not be radiology or pathology; it will be a diagnostics department. That's the way a lot of the thought leaders and KOLs [key opinion leaders] in the field are thinking. The infrastructure and framework are also starting to change. For the longest time—since the early '90s—radiology has been where the PACS resided. But now, with pathology starting to digitize slides and images becoming available, I think vendors are starting to think about integrated PACS, where you can have radiology and pathology.

Picture Health is very well positioned to take advantage of this coming wave of integrated diagnostics because we think about data differently. We don't think about data in terms of radiology or pathology. We are thinking about data in a more integrated, consolidated fashion. And that, I'd say, is probably the most distinguishing feature of what we do, compared to AI companies that solely leverage either radiology or pathology.

OI: A recent American Society of Clinical Oncology (ASCO) article describes "Artificial Intelligence in Oncology: Current Capabilities, Future Opportunities, and Ethical Considerations."[11] The authors point out that "a major limitation to the broad application of AI algorithms and CDSS [clinical decision support software] in cancer care delivery is the requirement for diverse and inclusive data sets for training."[10] Put another way: the need to address the potential for bias and ethical issues arising with the utilization of AI in oncology.

DR. MADABHUSHI: This something that we've been very deliberate and intentional about. There was a fabulous paper that came out last year that showed that the Oncotype DX® multi-gene assay was actually not accurate in [use among] Black women.[12] That was quite a stunning publication. But when you think about it, it's not that stunning because of the data that Oncotype DX was trained and validated on. The proportion of Black women [who were included] in those data sets for developing and validating that assay was extremely small compared to the number of White/Caucasian women included.

In fact, more and more evidence is coming out, revealing the complexities surrounding health disparities. The worse mortality that we see in underrepresented populations, such as the Black population, has to do with a complex set of socio-political factors, including racism, but apart from social determinants of health, there is also growing evidence that there are fundamental morphological and molecular differences in disease appearance across different populations. This is where I think we have the opportunity to be very deliberate and intentional to make sure those differences are accounted for as we are developing our AI models. It's something I'm very passionate about. It's something I've published on,[13,14] and Picture Health is committed to making sure that we are intentional and deliberate as we develop these models. We don't want to develop models based on a single population; we must be intentional so that models are validated across a plurality of populations.

OI: In your opinion, what are the next steps for community oncology?

ARUL: We think it's important to start the education process through ASCO, ACCC, and other oncology professional organizations to help build understanding for what these AI tools can do. We imagine an AI report that delivers information to end-users that is truly actionable—with a section of the report aimed at each specialty, so that an inter-specialty team can discuss the report in a similar process to a molecular tumor board.

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TREATMENT & LOGISTICAL SUPPORT
FINANCIAL & INSURANCE NAVIGATION
COMMUNICATION & LANGUAGE BARRIERS
EDUCATION & INFORMATION
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BY CARLA STROM, MLA

Population Health Navigators

An Innovative Approach for Supporting Underserved Patients

The patient navigation world has a new kid on the block. Just when we thought we knew everything there was to know about navigators, the role has been reinvented by a concept so intuitive, it is difficult to believe that these navigators are not standard practice in oncology. By now, most cancer programs and practices across the United States have introduced at least one type of navigator into their ecosystem—whether as nurse, lay, patient, clinical, disease-specific, or financial—navigators have become an integral component of comprehensive, high-quality patient care. Yet the trailblazing team at the Office of Cancer Health Equity at Atrium Health Wake Forest Baptist's comprehensive cancer center in Winston-Salem, N.C., introduced an approach that has the potential to reshape the navigation landscape.

Meet population health navigators—individuals who are dedicated to supporting a specific underserved population, including rural, Black (African American), and Hispanic populations, through culturally and linguistically competent navigation services for patients with cancer, their families, and their caregivers. These navigators share a cultural connection and language with their patients and are non-clinical professionals—legal specialists, social workers, advocacy experts—who bring valuable, real-world skills and experiences to patients' cancer journey and help break down barriers more effectively by understanding the nuances of a patient's culture, language, and identity.

Making the Case for Population Health Navigators

Far too often, underserved populations face inequities during their cancer care journey and encounter unique barriers. Atrium Health Wake Forest Baptist's novel approach addresses these health disparities by designating population health navigators who assist patients with cancer in overcoming healthcare system- and social-related barriers, facilitate timely access to quality medical and supportive care, and educate our underserved and underrepresented patients with critical information about the role of research and clinical trials in cancer care. While other cancer programs and practices may have bilingual navigators, Atrium Health Wake Forest Baptist is the only comprehensive cancer program in the U.S. with population health navigation—support services focused on the specific patient population being served, rather than focusing on a specific disease and attuning navigation services with all the linguistic, cultural, and societal implications that impact a patient's cancer experience. A Black patient being helped by a Black navigator will have a different impact because of their shared culture and community; there is a higher level of initial trust that can be bridged between these two. If we really want to address underserved populations and health equity, instead of expecting patients to meet us at the level that we operate, even with basic things like the language and word choices we make, we need to meet patients where they are at.

If we really want to address underserved populations and health equity, instead of expecting patients to meet us at the level that we operate, even with basic things like the language and word choices we make, we need to meet patients where they are at.

And that, we have done. Our latest comprehensive review of underserved patients navigated by Atrium Health Wake Forest Baptist's population health navigators between September 2019 and August 2022 revealed that 773 patients (231 Hispanic, 239

Table 1. Underserved Patients Navigated, Sept. 1, 2019 to Aug. 31, 2022 (n=773)

CATEGORY	Rural Patients n=303		Black Patients n=239		Hispanic Patients n=231	
	Number	Percentage	Number	Percentage	Number	Percentage
GENDER						
Female	148	49%	143	61%	142	61%
Male	155	51%	96	39%	89	39%
AGE						
0-17	1	<1%	1	<1%	5	2%
18-34	11	4%	17	7%	19	8%
35-59	95	31%	98	41%	150	65%
60+	196	65%	123	51%	57	25%w
TYPE OF CANCER						
Brain	13	4%	7	3%	7	3%
Breast	30	10%	53	22%	46	20%
Gastrointestinal	38	13%	15	6%	41	18%
Genitourinary	16	5%	4	2%	12	5%
Gynecologic	15	5%	17	7%	30	13%
Head & Neck	23	8%	13	5%	10	4%
Hematologic	69	23%	43	18%	54	23%
Thoracic	92	30%	53	22%	16	7%
Other	7	2%	34	14%	15	6%

Black, and 303 rural) were successfully navigated (Table 1, above). Our population health navigators have assisted patients across a broad spectrum of issues specific to their needs. While the most common barriers were related to treatment logistics, including transportation and financial and/or insurance issues for all patients, communication was the next most significant barrier for Hispanic patients, practical needs for Black patients, and information and education for rural patients (Figure 1, page 36).

Furthermore, the rates of participation in clinical trials for navigated patients are higher than for unnavigated patients with cancer prior to program implementation: 36 percent of rural patients, 32 percent of Black patients, and 31 percent of Hispanic patients with population health navigators are participating in clinical trials (Figure 2, page 36)—a tremendous achievement among patient populations that are underrepresented in clinical research in general.

Our team is making the business case for population health navigation and proving that there is a place for this unique comprehensive cancer care service at the navigation table.

The Evolution of Population Health Navigators

The program started out as a single position. When I joined the cancer center almost 11 years ago, one of my tasks was to do outreach in the Hispanic community and address the challenges and barriers to cancer care this community faced. What came up—repeatedly—were challenges around language and culture, as well as barriers in the clinic when trying to get treatment and work through the health system. When there are immigration status or insurance-related issues, patients experience even more barriers to care. Thus, the first population health navigator position was our Hispanic patient navigator.

The early days of the population health navigator program looked vastly different from what it has become today. The first population health navigator, grant-funded and working primarily independently, was focused simply on connecting with each Hispanic patient that came through the cancer center to determine if they had needs or potential barriers to care; there were no other models or programs from which our first navigator could draw direct experience. In fact, at the time, the concept of "navigators" in the local area was limited to clinical navigators, primarily for

(Continued on page 37)

Figure 1. Patient Barriers to Care by Underserved Population

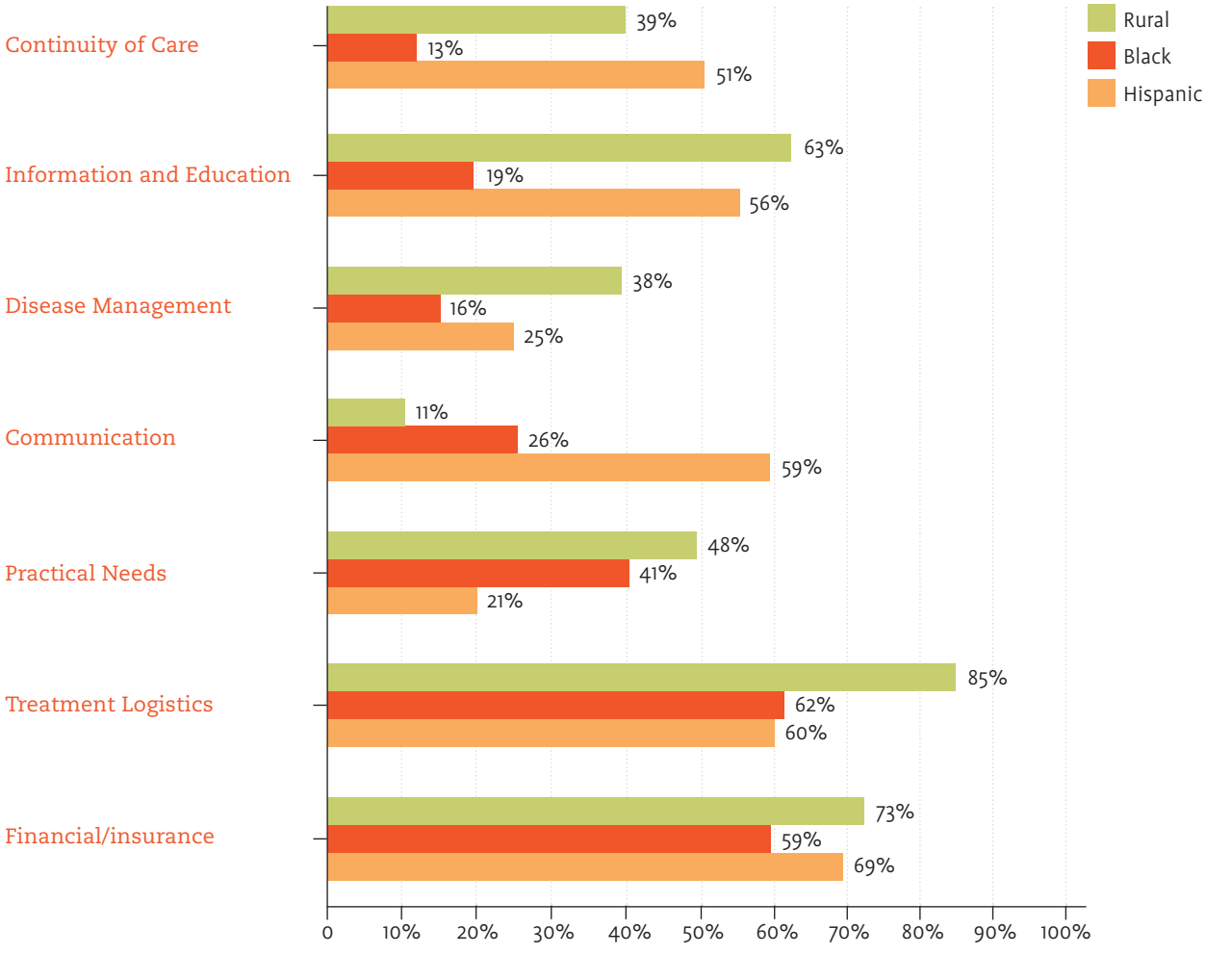
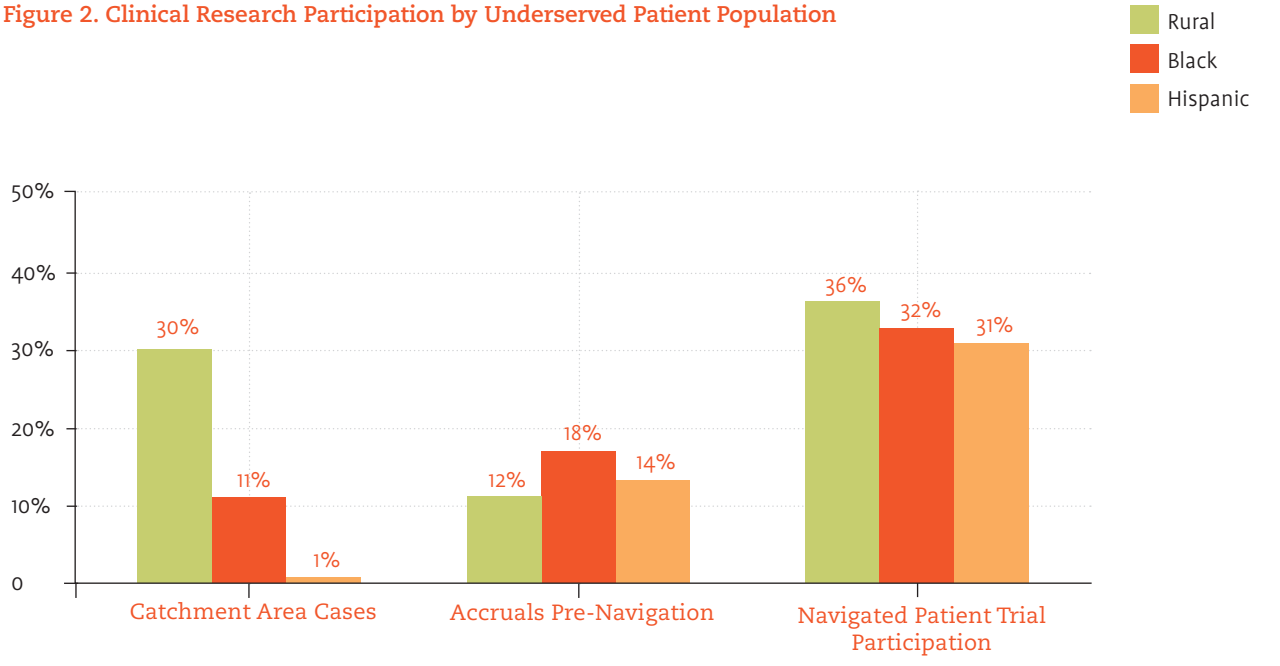


Figure 2. Clinical Research Participation by Underserved Patient Population



(Continued from page 35)
breast health. Most providers had no idea what a population health navigator was or what exactly they could do. Even now, because population health navigation may not be easily understood, we sometimes refer to it as underserved patient navigation.

Yet by 2018, under the tutelage of our previous leader—Karen Winkfield, MD, PhD, professor in the Department of Radiation Oncology at Vanderbilt University Medical Center, Vanderbilt-Ingram Cancer Center—who served as the director of the Office of Cancer Health Equity at the time, the program flourished. Building on the initial success of the inaugural Hispanic population health navigator and by obtaining grants to fund additional full-time equivalents, Dr. Winkfield advocated for the development and growth of our program.

From a Person to a Program

To understand the direction the population health navigation program took next, it is important to understand the geographic and historical identity of Winston-Salem. As a gateway city, Winston-Salem connects the mountainous, Appalachian region of North Carolina and predominantly homogenous rural communities with the more urban northwest Piedmont region of the state. In contrast, Winston-Salem and its surrounding county, according to 2021 U.S. Census Bureau estimates, are home to a diverse population of nearly a quarter of a million people that identify as Black or African American (34.2 percent), Hispanic or Latino (15.1 percent), or as two or more races (5 percent).[1] Moreover, 17.5 percent of the population speak languages other than English at home.[1] Additionally, the area is a historical hub for tobacco production and cigarette manufacturing, one of several elevated cancer risk factors, which, along with limited access to healthcare and other social determinants of health, contribute to significant racial, ethnic, and geographic disparities in the region.

Recognizing the diversity of our catchment area and understanding how these specific populations intersect with cancer (e.g., significantly higher rates of cancer, including colon cancer mortality, exist among the Black community), our team tailored their population health navigation strategy around these diverse characteristics.

As the boots on the ground office for our Community Outreach and Engagement program, the population health navigation program is charged with making sure that the work of the cancer center is reflective of and responsive to the needs of our catchment area. After staffing the Hispanic patient navigator, we prioritized an expansion to include a rural patient navigator to address the unique needs of our very large, geographically rural catchment area. In contrast, Winston-Salem is a majority-minority city with a long, southern-based history that includes the Black community and their role in building the area, so we also added a navigator dedicated to serving this population.

As the program developed, we worked with our informatics experts to create a daily data pull that compiled all new patients from Hispanic, Black, and rural backgrounds, who had appointments scheduled in the next two weeks. Our population health navigators would then methodically filter through this list of patients and reach out to conduct an initial assessment—a tailored acuity scale created for the program around identified patient characteristics and potential barriers to care that indicate the expected level of navigation intensity required (i.e., no navigation, low level of support, medium level of support, and high level of support needed) to best assist patients. These levels provide a structure for our proactive navigation services and their respective timelines needed to guide the work of the navigators. Historically, our rural patients have needed lower levels of support, while most of our Black patients have needed medium levels support and our Hispanic population has had the largest percentage of high levels of support needed (see Table 2, page 38).

In just a short span of time, the popularity of the population health navigation program soared. Emily Copus, MSW, OPN-CG, manager of the Office of Cancer Health Equity's population health navigation program at Atrium Health Wake Forest Baptist, described this evolution. "Originally, we were proactively going through those lists and looking to see who was coming within the next week, who [we] could call and reach out to offer an initial assessment. But now people know who we are, [so] we don't have to utilize it anymore. Now we get referrals from

everyone—physicians, ambulatory nurses, PAs [physician assistants], our nurse navigators, front desk folks. For the most part, it is providers calling us saying 'Hey, we met this person in clinic, and they had to scrape together two pennies to get here today. Can you reach out and do an assessment?'"

Today, our population-focused program has grown to include five navigators, and they are busier than ever. With a dedicated Hispanic navigator, African American navigator, rural navigator, adolescent and young adult navigator (an underserved population with very unique age-related barriers), and a financial navigator (for patients in lower socio-economic populations), we have effectively built a dream team of navigators who serve very specific patient populations.

> Our population health navigators educate every patient about the role of research in cancer care, and we are very intentional about those words. Our navigators never represent a specific study or consent a patient; they advocate for informed decision-making.

The Mechanics of the Program

So what exactly does a population health navigator do? How is this role different from a nurse navigator? Because our navigators are population specific, rather than disease specific, every workday looks different. Population health navigators may begin their day in clinic, and, while they are part of the multidisciplinary care team, they are there to address the health-related social needs of patients by focusing on social determinants of health. This allows other team members, such as nurse navigators, to focus on the clinical aspects of patient care and work to the highest level of their licensure. Below are some examples of a population health navigator's day-to-day activities:

- Arranging a ride to and from treatment appointments
- Providing a meal voucher to address food insecurity
- Overcoming language and literacy barriers by ensuring patients' understanding of their treatment plan
- Helping patients communicate their clinical needs to their care team.

Population health navigators spend time in multiple tumor boards, gathering vital information that will be used to better assist their patients through the duration of their care. These navigators return patient phone calls to provide much-needed resources and information, including everything from budgeting and financial assistance to logistical barriers like transportation and household management. In a few words, population health navigators support and provide solutions to address barriers to care.

As Copus described, "We are multi-disease site navigators, so one of the puzzle pieces we must put together when looking at our day and our week is which patients are coming to which clinic on which day. [For example,] I just left a new patient visit, and, while the physician is explaining what kind of cancer [the patient] has and what the treatment protocols look like, I know I have voicemails that I need to return for patients asking about food pantries or transportation for next week."

The number of patients the program supports is also as variable as the navigators' scope of work. "Just yesterday, I had 11 patients that I somehow talked to, whether they were in clinic or on the phone. But today, I've worked with just 3 patients and spent over 2 hours with a single patient," Copus explained.

With the popularity of the program and referrals growing each day, our acuity scale has become more important than ever in helping guide our population health navigators in triaging patients' needs and services, allocating their time, and balancing their caseload. A rural patient with a cancer type who has a standard treatment protocol and who also has stable insurance, great family support, and lives an hour away may not require as much support as a patient who is uninsured, undocumented, and lives in West Virginia with no caregiver.

And the population health navigation program works. As an example, a Black patient who needed a feeding tube was vehemently refusing it despite appeals by several members of the clinical team. "He kept saying over and over, 'No way, no way.

Table 2. Intensity Level by Underserved Population

Intensity Level	Total (n=434)	Rural (n=170)	Black (n=122)	Hispanic (n=142)
No navigation	28 (6%)	10 (6%)	6 (5%)	12 (8%)
Low	177 (41%)	95 (56%)	38 (31%)	44 (31%)
Medium	183 (44%)	62 (36%)	66 (54%)	65 (46%)
High	36 (8%)	3 (2%)	12 (10%)	21 (15%)

I don't want this feeding tube.' So they asked Alexis, our Black navigator, to talk with him. She went up to the clinic and said, 'Give me a minute, I got this.' She went in and spoke to the patient, addressing his concerns and explaining what he needed to understand about it that he wasn't getting from the clinical team. She had her conversation and then less than 15 minutes later she walked out and said, 'He's ready for his tube." While it is not always as simple as this, Alexis' story truly paints a picture of why it matters who is talking to patients, who patients trust, and who is helping them understand with the words and language that resonate best with them.

A common question we are asked is how we fund the program since navigation services are not reimbursable. In the early years, our navigators were primarily grant-funded, and, at our cancer center, we accomplished this by linking our population health navigators to research and clinical trials. As a National Cancer Institute-designated comprehensive cancer center and academic medical center, research is a big part of what we do at Atrium Health Wake Forest Baptist's comprehensive cancer center. Rather than trying to keep things separate, we were very intentional about bringing research and navigation together.

One of the pieces that we built into the role of our navigators was education; our population health navigators educate every patient about the role of research in cancer care, and we are very intentional about those words. Our navigators never represent a specific study or consent a patient; they advocate for informed decision-making. This way, whether patients participate in a clinical trial as part of their initial treatment or years later in survivorship, if they are asked to participate in a study, the concept and conversations around research and trials in cancer care are normalized and patients have an increased likelihood to participate. The first time patients learn about research studies or clinical trials should not be when they're being asked to participate in one.

As a result, the clinical research participation rates at Atrium Health Wake Forest Baptist are significantly higher than the general oncology patient population as our data have shown (Figure 3, page 8). Moreover, these increased rates of participation are among underserved populations, which traditionally have been underrepresented in clinical research.

Over time, we have moved beyond clinical trial participation and have been successful in making the business case for population health navigation through the lens of a value-added service. Thus, we seed fund each population health navigator position with a grant, show the success of the position and what it has accomplished, and, in turn, the cost of the position is absorbed by the cancer center. Thanks to ongoing support, today we have a full complement of nurse navigators, financial navigators, student navigators, and population health navigators, who work collaboratively side-by-side in a sustainable model.

Figure 3. Clinical Research Participation by Underserved Population

Catchment Area Cases
Rural: 30%
Black: 11%
Hispanic: 1%
Accruals Pre-Navigation
Rural: 12%
Black: 18%
Hispanic: 14%
Navigated Patient Trial Participation
Rural: 42%
Black: 19%
Hispanic: 23%

We are also looking ahead at other underserved populations with unique needs where we can take the program next. We have identified a clear need for support and care for patients within the prison population, which in Winston-Salem represents more than 240,000 people across five jails and prisons.

Looking Ahead—the Future of Population Health Navigation

What we have built at Atrium Health Wake Forest Baptist is strong and thriving. Our program has been largely successful due to the hard work and vision of everyone involved in the Office of Cancer Health Equity and from support by key stakeholders, including Dr. Winkfield, our former director, and A. William Blackstock, MD, chair of Radiation Oncology and interim director of the comprehensive cancer center at Atrium Health Wake Forest Baptist, as well as our local community partners, such as our regional chapter of the American Cancer Society, who have been instrumental in providing key resources and support to our program.

The potential to grow this innovative population health navigation program is great and well within our reach. In fact, Atrium Health Wake Forest Baptist recently integrated with Atrium Health Levine Cancer Institute in Charlotte, N.C. With this integration, we have the potential to impact more than twice as many patients, and our team in the Office of Cancer Health Equity is working closely with our colleagues in Charlotte to expand the program.

We are also looking ahead at other underserved populations with unique needs where we can take the program next. We have identified a clear need for support and care for patients within the prison population, which in Winston-Salem represents more than 240,000 people across five jails and prisons. We see many patients with an additional health factor that complicates their cancer experience, such as blindness or deafness. We have worked with patients suffering from a significant psychiatric illness, which requires a different set of skills and increased collaboration with psychiatry. And with the growing recognition that we should be asking about and recognizing sexual orientation and gender identity to serve the whole patient, we are also exploring the needs of LGBTQ+ patients with cancer.

In the Office of Cancer Health Equity at Atrium Health Wake Forest Baptist, we believe everyone, regardless of age, gender, race, religion, financial status, or geography, should have an equal chance of surviving cancer and surviving it well. This belief is why our navigation program is truly a game-changer. Our novel approach for population-specific navigation—culturally and linguistically concordant support for patients, families, and caregivers that is not disease specific but tailored to the diverse needs of our patient populations—breaks down barriers to care and helps achieve health equity in oncology. As a two-time bilingual, bicultural cancer survivor, I am especially proud to be part of a team of incredible professionals and the guardian of this unique program, and I look forward to the endless possibilities, as we move our population health navigation forward into its next stage of evolution.

Carla Strom, MLA, is assistant director, Office of Cancer Health Equity, Atrium Health Wake Forest Baptist, Winston-Salem, N.C.

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The State of Access and the Healthcare Experience for Patients with Cancer

BY KELLEY D. SIMPSON, MBA

Results from a national survey

In October 2019, prior to the COVID-19 pandemic, Chartis (chartis.com) conducted a national survey of 21 academic, community-based, and freestanding cancer programs. Survey findings at that time suggest that cancer programs are employing a variety of models to increase patient access, such as legacy models to expand capacity by growing the workforce or increasing productivity expectations, more novel approaches by opening urgent care centers, or models that transition patients in survivorship to create capacity for new patients.

In its latest survey conducted in the summer of 2022, Chartis offers new perspectives about how cancer programs function today, what is different from its 2019 survey results, and what remains important when optimizing access channels, reducing time to treatment, and improving the patient experience. Cancer program leaders must double down on their oncology ambulatory strategy in recognition of the following:

1. Patient expectations of timeliness to care are at an all-time high, particularly in the digital age.

2. Access and the patient experience serve as competitive advantages in the oncology ecosystem, considering for-profit market entrants.

3. Government regulatory and reimbursement trends are better supporting telehealth and hospital-at-home programs.

4. Even if cancer diagnostics and treatment timing do not always require immediate attention given scientific evidence, these things matter to patients and their caregivers who have a choice as to where they receive treatment.

Survey Overview

The COVID-19 pandemic ushered in workforce shortages, cost pressures, and patient re-engagement dilemmas. Layered on top of these new realities are ever-present access challenges that are exacerbated by continued growth of newly diagnosed cases, expansion of the survivors of cancer population, and the looming oncology physician shortage, which is projected to hit 2,250 needed physicians by 2025.[1] To explore how cancer programs and practices are addressing patient access today, Chartis surveyed a total of 36 organizations, including 22 academic and National Cancer Institute (NCI)-designated comprehensive cancer centers (inclusive of two freestanding centers) and 14 community-based cancer programs. The survey intent was to better understand participants' patient access goals, current challenges, systems and processes, performance metrics, and initiatives. Like the 2019 survey, broad survey topic areas included patient access, care team considerations, and supportive care programs. In 2022, survey questions were broadened to capture more details regarding each participant's care delivery model.

The survey intent was to better understand participants' patient access goals, current challenges, systems and processes, performance metrics, and initiatives.

Access Goals for Newly Diagnosed Patients

Although most cancer programs surveyed express a goal of seeing newly diagnosed patients with cancer within 7 days, there was a significant shift over the past 3 years, with more than 40 percent aiming to get newly diagnosed patients consulted within 3 days, compared to 10 percent in 2019.

In the 2022 survey, nearly 70 percent of community-based cancer programs aim to get newly diagnosed patients seen within 3 days; comparatively, about 60 percent of academic medical centers aim to see newly diagnosed patients within 7 days.

When surveyed about benign hematology patients, 44 percent of all cancer programs and practices indicate an aim to see these patients within 3 to 7 days (compared to 35 percent in 2019).

Despite more ambitious performance expectations for many cancer programs and practices, 1 in 5 participants say they do not have an organizational goal around benign hematology patient access.

So how well are these organizations performing to reach their goal? Less than half (14 of 33, 42 percent) of those surveyed believe that most or all patients receive care within their expected timeframe. A little more than half indicate that meeting this goal is highly dependent on the independent oncology/hematology clinic and/or department, with some being more successful than others. Only 2 respondents indicate that all patients are offered an appointment within their established targeted timeframe.

Records Collection

New to the 2022 survey was a question about medical records collection prior to scheduling. A little more than half of the cancer programs surveyed (56 percent) collect patients' records prior to scheduling, with 1 in 5 reporting they collect records on "select patient populations" before scheduling. This is an area of improvement, as a lack of patient records can delay patient confirmation of an appointment, which potentially leads to leakage and/or patient dissatisfaction with time to consultation.

Scheduling Systems

When asked, "What best describes the scheduling systems at your cancer center?" nearly half (16 of 36, 44 percent) report using a hybrid scheduling approach, where some areas employ centralized scheduling and others remain decentralized. This is a significant change compared to 2019 results, where 43 percent used a centralized cancer-specific contact center; only 28 percent report using this type of scheduling system in the 2022 survey.

The shift to a hybrid model and away from centralization was a surprise, but it may signal how challenging it can be to standardize elements of a centralized healthcare program. One organization described an extremely effective practice that includes robust training of contact center personnel, in-person introductions of new providers during onboarding, and weekly in-person meetings with call center and clinic physician and administrative leadership. In our experience, this practice style does not happen as often as it could or should and is often coupled with a comprehensive management and communication plan.

Of the 30 cancer programs with some centralized call functions, more than 80 percent offer new patient scheduling and second opinion scheduling. Figure 1, below, provides a list of the centralized services offered, including appointment reminders. Note: 50 percent of these cancer programs employ access analytics to measure success.

New to the 2022 survey were insights about patient access through self-service options like app usage, website, and patient portals. The survey found that most cancer programs offer online bill-pay, access to medical records, and the ability to message their provider online. However, very few offer self-scheduling (23 percent allow return patient scheduling), and 3 of 36 (8 percent) offer no self-service options. Not surprisingly, no cancer programs offer online infusion scheduling.

Access Metrics

Leadership from most surveyed cancer programs track similar access metrics, including new patient volumes, patient satisfaction, no-show rates, lag time, schedule utilization, and cancellation rates (Figure 2, page 44). In 2019, 38 percent of cancer programs

Figure 1. Appointment Scheduling and Support Services Provided by the Centralized Call and/or Contact Center

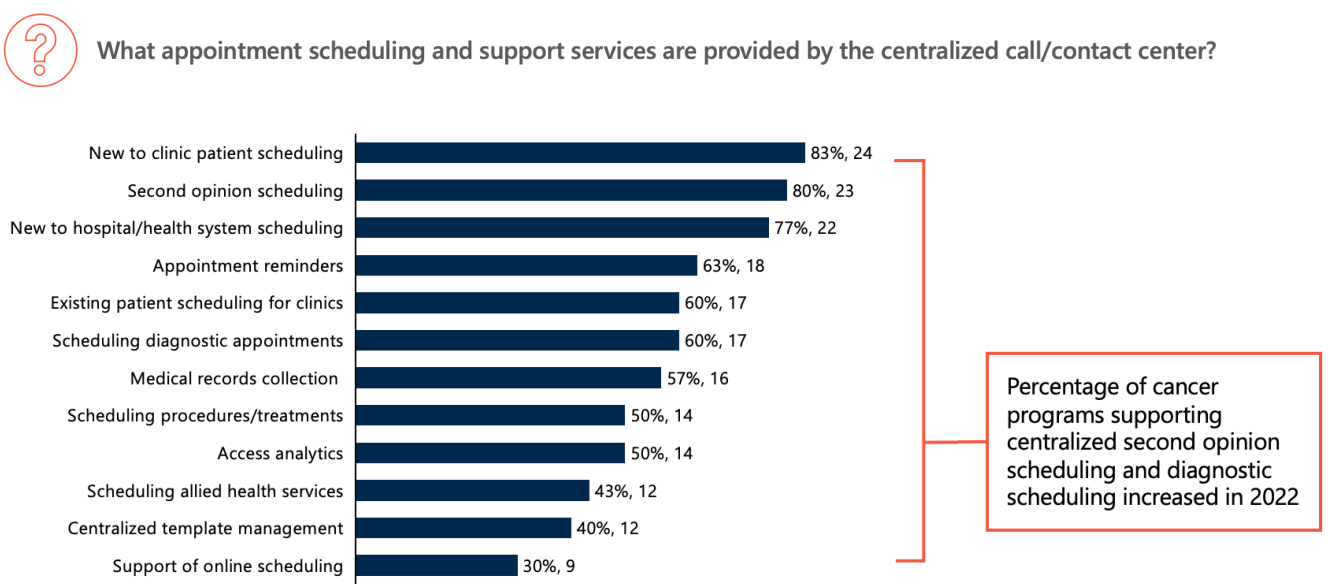
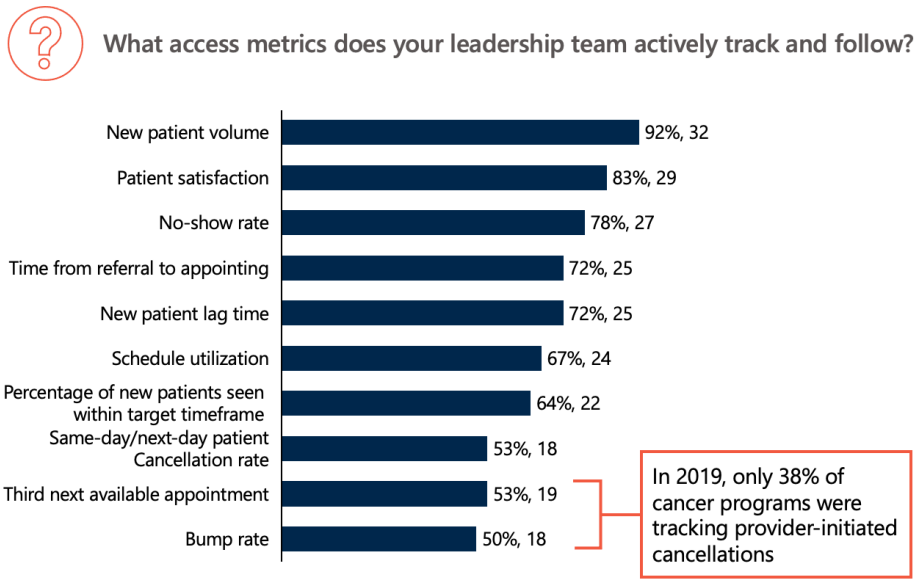


Figure 2. Patient Access Metrics Tracked



were tracking provider-initiated cancellations, and this number jumped to 50 percent in 2022. These metrics are actively being used to drive performance initiatives. Cancer programs are looking to meet their access goals through efforts to improve capacity by optimizing provider templates and call centers, elevating the patient experience by building and expanding cancer navigation programs, and addressing health disparities for the communities they serve.

Use of Advanced Practice Providers and Panel Sizes

The number of cancer programs tracking advanced practice provider (APP)- and medical assistant (MA)-to-provider ratios increased between 2019 to 2022. Fifty-three percent track APP-to-provider ratios (compared to 33 percent in 2019), and 33 percent track MA-to-provider ratios (compared to 24 percent in 2019). When asked about APP- and MA-visit ratios, 22 percent report tracking these metrics.

While we continue to find role ambiguity for APPs across organizations, many of those surveyed are actively working to promote independent visits for their APPs. A little more than 40 percent report that they are using APPs at "top of training," with 22 percent (up from 14 percent in 2019) using APPs predominately for independent visits (e.g., within an APP intake clinic and/or during active treatment). An additional 22 percent report that APPs perform shared visits with physicians, provide assessments, conduct ordering, etc.

APPs are increasingly being positioned to conduct initial visits with patients. Often this practice is done in highly competitive markets where "rapid access" is a priority and at academic programs where wait times to see a specific specialist are particularly high.

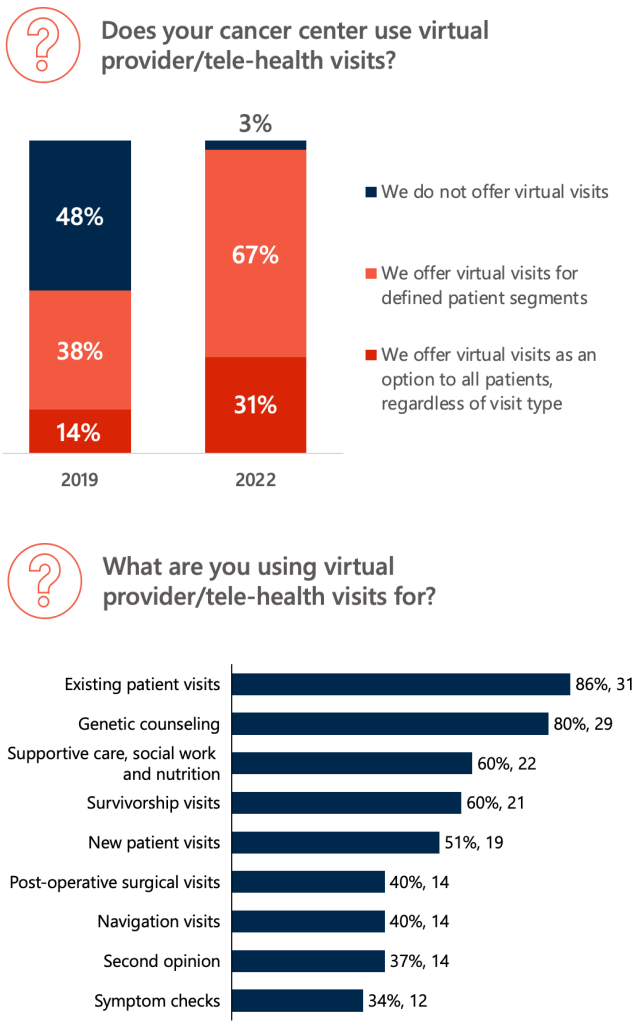
The Role of Navigators

There is variability in how surveyed cancer programs use care navigators. In the 2022 survey, almost 60 percent (21 of 36) of surveyed participants connect "all new patients" (25 percent) or "select new patients" (33 percent) with a navigator prior to their first visit. Only 1 in 5 have navigators wait to connect with patients until after they are seen in the clinic. Chartis is seeing growth in navigation programs across the country, including "top of training" use of clinical navigators very early in the access and intake process to:

- Provide provisional clinical review, working with patient access representatives to guide "matched scheduling" for first consultations with needed oncology sub-specialists and/or multidisciplinary clinics, enhancing the patient experience, and driving patient and care team satisfaction.
- Conduct barriers to care assessments to provide the care team with a patient summary before their initial consultation, making recommendations about accessing potential support services to abate these barriers.

Navigators then follow patients on their care journeys with templatized touchpoints to help patients understand how best to access supportive services. When access questions or issues arise, navigators act as internal advocates for patients, working with schedulers and clinicians to create an efficient treatment schedule that ensures patients receive all required treatments and services.

Figure 3. Services Provided Via Virtual and/or Telehealth Visits



Cancer Survivorship Programs

An estimated 18 million individuals with a history of cancer were living in the United States on January 1, 2022.[2] Considering the expected number of 1.9 million newly diagnosed cancer cases in 2021[3], this equates to approximately 9.5 survivors for every newly diagnosed cancer case. Since 2011, the population of individuals living with cancer has grown to include 4.3 million persons who are actively surveilled in the cancer care ecosystem.[3]

In recognition of this need, 75 percent of the cancer programs surveyed in 2022 have formal survivorship programs, whether supported by independent clinics, embedded within specialty-specific clinics, or delivered using a hybrid approach. (This percentage is comparable to 2019 survey data.) Survivorship programs serve patients' physical and emotional needs after treatment with the added benefit of expanding provider capacity for newly diagnosed patients and those in active anti-cancer treatment. On the flip side, 1 in 4 cancer programs report the lack of a formal survivorship program (also unchanged from 2019 survey data).

Oncology Urgent-Care and Symptom Management Clinics

In the 2022 survey, 42 percent of surveyed cancer programs (15 of 36) have a dedicated oncology urgent-care center, and another 33 percent (12 of 36) have plans to design and build one. Nearly 20 percent of survey participants offer extended hours for expedited symptom management and patient care, including infections, shortness of breath, nausea and vomiting, and neutropenic fever. Survey respondents indicate their urgent-care centers help reduce unnecessary hospitalizations and emergency department visits, while improving patient convenience and their overall experience.

Second Opinion Services

More cancer programs indicate having a formal second opinion program in 2022 (50 percent), compared to 2019 (33 percent). Some respondents reported offering additional services, such as:

- Patients can submit records with the cancer program that is providing written documentation to the patient (and/or their referring provider) about recommended treatment
- Patients can submit records with the cancer program that is providing a video visit for the patient (and/or their referring provider) about recommended treatment.

Chartis continues to see a growing number of organizations that partner with external vendors to offer second opinion services. These third parties act as the primary interface between the patient and cancer program by collecting patient records, working with a select group at the cancer program to evaluate records and gather patient results, and educating patients about their treatment options.

Virtual Care Visits

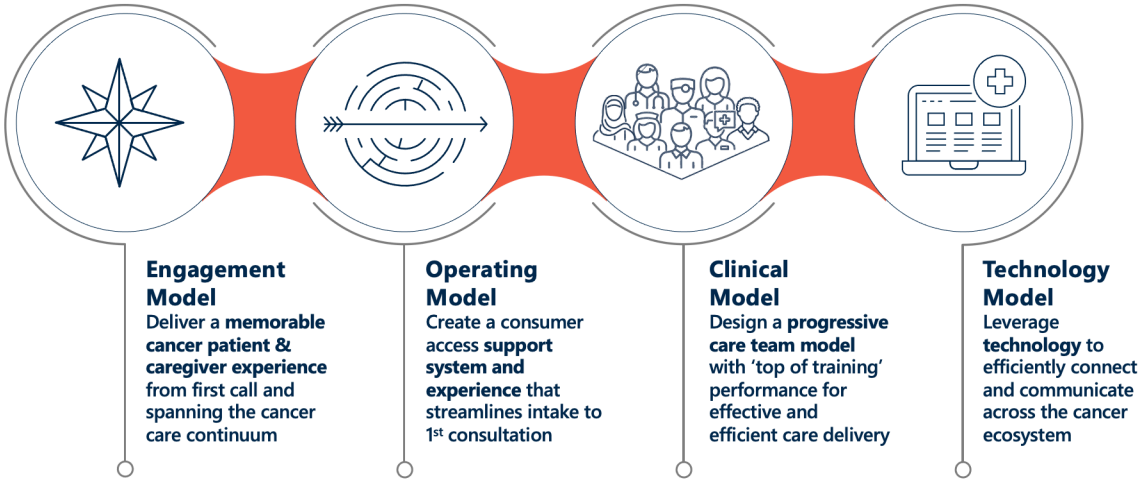
In 2019, most respondents (52 percent) reported using virtual care visits, either across or within select sub-specialties, or were planning to roll them out within the next year for patients who did not require a physical exam or procedure (e.g., symptom checks, return visits, navigation visits). Conversely, a notable 48 percent of respondents were not offering and had no plans to offer virtual care within the next year.

Fast forward to 2022, survey results found that nearly all respondents (35 of 36, 97 percent) offer virtual and/or tele-health visits, either across or within select sub-specialties, which is an exponential increase from 2019 survey results. The majority of 2022 survey respondents report using virtual or tele-health visits for existing patients, genetic counseling, survivorship visits, and supportive care interactions (Figure 3, left).

The Patient Experience Reimagined

Like never before, individuals accessing cancer care demand and deserve a seamless experience, with their preferences considered every step of the way. Patients with cancer have an array of

Figure 4. Reimagining the Patient Experience: Key Capabilities and Processes



provider options, both locally and across the U.S., within academic and NCI-designated comprehensive cancer centers, so reimagining patient access is a mandate. What do cancer programs need to do today to position their organization as a market leader in cancer care access for years to come? The answer: understand that delivering the best patient experience requires a team, as cancer care is a team sport, involving access, navigation, and care team transformation. The synergistic nature of these elements cannot be underestimated and advancing one in misalignment with the others leads to implementation delays. Figure 4, above, illustrates how cancer programs must develop key capabilities and processes across quaternary dimensions to successfully maximize the patient experience.

Engagement Model

Many cancer programs employ navigation services at varying levels, but we often find, despite good intentions, that providers overuse the term "navigator" and inconsistently manage these services, leading to overwhelmed navigators taking on tasks that would be more appropriately completed by access or other care team colleagues. Patient navigation suffers from definitional ambiguity, moving from "holistic" intent (Figure 5, right) to functional activities to describe any task in the patient journey. Examining your own navigation program for fit and effectiveness within the access and clinical care delivery model construct is essential. This assessment should include a review of five core elements:

1. *Foundation*. Vision and goals, model, general/disease assignment, span of role
2. *Operation*. Organizational structure, caseload targets, orientation and competencies, standard operating procedures
3. *Education*. Value proposition, organization education, resources, continuing education
4. *Integration*. Tumor conference participation, communication, care transitions, outreach, collateral
5. *Performance*. Technology enablement, documentation, metrics and patient surveys, key performance indicator reporting.

Using a scoring rubric to assess your navigation program against leading navigation practices will inform alignment with access and clinical care models to solidify the role of navigation in the patient experience. The assessment then leads to redesign needs

Figure 5. Overarching Goals of Navigation

and performance improvement initiatives that move in concert with other access and care team initiatives. Navigators can then lead in their intended roles to deliver a memorable experience spanning the patient care journey.

Operating Model

While navigation is an emotive and advocacy connection for patients and caregivers, the process of moving through the access realm can be complex and often frustrating. Leaning into design with key constituents in mind—patients and caregivers, physicians and APPs, and the broader clinical and supportive care team—is essential. The primary goal of operating model redesign is to enable a system that provides patients with exceptional customer service, while allowing providers to focus on cancer care delivery. The operating model should facilitate timeliness to care. With these goals at the center, cancer programs should follow the below approach to assess, design, stabilize, and implement their access strategy:

- **Step 1.** Patient acquisition and referral management linked to navigation
- **Step 2.** Curated access solutions for disease-specific populations and care teams
- **Step 3.** Integrated digital solutions across the cancer access journey
- **Step 4.** Capacity management linked to care team "top of training" and optimization practices
- **Step 5.** Access strategy supporting a technology roadmap
- **Step 6.** Performance analytics to drive continuous improvement.

Transforming patient access squarely involves people, processes, and technology. Strategies and implementation must stay intimately aligned with navigation and clinical models as well as care team initiatives. While the task of access redesign is not for the weary, a comprehensive change management and communications plan to overlay initiatives is important and can help break down barriers like legacy thinking and behaviors. Successful access redesign efforts can expect the below results:

- Improved use of existing capacity to serve about 15 percent to 30 percent more patients
- Acquisition of new patients to the oncology service line
- Retention and sustained activation of existing patients
- Strengthened relationships with referring providers
- Provider and care team commitment and engagement
- Enhanced adoption and use of information technology (IT) investments
- Transformed patient experience and greater satisfaction.

Clinical Model

With an often overwhelming patient volume, it is difficult for cancer programs to dive deep into their day-to-day operations and workflows to embark on re-design efforts. But to be more successful tomorrow, oncology professionals need to fundamentally rethink how they approach supply and demand today. Access initiatives are about supplying services to meet a demand—it is also increasingly about creating a demand. The connective tissue then becomes care team transformation.

This is critically important for oncology professionals, considering the ever-growing newly diagnosed and survivorship populations and an impending shortage of oncologists that is expected to be greater than 2,200 providers by 2025.[1] The COVID-19 pandemic has brought extreme workforce challenges to the broader cancer ecosystem, making employee engagement and satisfaction competitive advantages in many markets. Care team transformation will be a critical focus area to support providers and obtain optimal use from every allied healthcare professional. So how do cancer programs transform their clinical model to meet these market realities?

The first step is to optimize your current oncology provider base. The second step is successful development and deployment of next-generation care teams, which includes leveraging APPs in ways that expand the provider base rather than being duplicative. The third step is to focus on technology and digital solutions to support these efforts (this will be addressed in the following section). Here, let's focus on care team transformation with the goal of providing care to more patients with process ease and the timeliness to care they need.

Cancer care providers should map out the end-to-end patient journey, including necessary touchpoints throughout, taking stock of every touchpoint. What one attends to first, second, and third will be different for each organization. Additionally, understand what those priorities need to be. Then create a plan that overlays the broader team-based clinical model strategy. Focus on understanding the organization's supply—how much capacity the cancer program actually has—and then understanding demand, including both how many patients are walking through the doors and how many new patients one can generate. These data will provide a baseline. From there, one can grow and think differently about how their organization manages supply and demand within the broader care team context, including access colleagues, up-front clinical triage, navigation to first visit, and ongoing care throughout the continuum for MDs, APPs, MAs, and RNs, support services, survivorship roles, and responsibilities at "top of training."

Technology Model

The fourth and final pillar of access and the patient experience looks at leveraging technology to efficiently connect and communicate across the cancer ecosystem. Digital transformation requires two equally essential components:

1. A comprehensive understanding of an organization's underlying engagement and adoption for cultural, clinical, and operational technology
2. A technology-forward, break-the-rules perspective of digital transformation to revolutionize cancer care delivery and the patient experience.

The first step is optimization of current capabilities. Before any dream-big digital transformation, cancer programs must look to current provider-based supply, while simultaneously developing digitally enabled care models, to position their organization to

meet demand in a cost-efficient manner. Planning a digitally forward care delivery model requires thoughtful, purposeful alignment between the way health services are delivered and experienced—that is, the work that needs to be done, which roles do what work, when and where the work is done, and which tools are required to do it.

Fortunately, virtual care learnings and the case for change that many organizations successfully navigated early in the pandemic should allow them to determine the requirements, scale, and workflows necessary to intentionally operationalize a digitally forward care delivery model. A strategic focus on benefit realization, combined with an intentional and programmatic approach to execution, will truly transform a cancer program's care delivery platform.

Healthcare organizations need a methodology to apply across the oncology service line from defining, developing, and

Figure 6. Innovation In Oncology

Enhancing Access...

Solutions to speed patient intake, appointments, and on-demand access to care team while under treatment.

- **24-hour Promise** – CTCA (COH) use online chat/portal to offer appointment in <24 hours
- **AccessHope™** – Remote evaluation and expert review for 1.9 million members/employers (City of Hope).
- **Reimagine Care** – 24/7 APP command center for symptom triage (UC Health)

Wiring a Medical Home...

Solutions to cancer medical home requirements—remote monitoring, 24/7 symptom management, distress screening, etc.

- **PatientPing** – Real-time notifications to care team if patient is admitted.
- **Conversa Health** – AI chat-bots for post-discharge follow-up (Northwell)
- **Canopy Health** – Remote patient monitoring and symptom management.

Digitally Enabled Navigation...

Solutions for payors needing immediate access to a care navigator when members are faced with a cancer diagnosis.

- **Thyme Care** – Bring tech-enabled cancer navigation to Clover's Medicare Advantage members across New Jersey.
- **Jasper Health** – Use "smart planner" to connect patients with certified oncology social workers and to triage symptoms.

Improving End-of-Life Episode...

Solutions to patients and providers seeking early palliation, timely hospice transition, and a new approach to end-of-life care management

- **Vynca** – Early patient engagement and software to optimize ACP workflow and documentation (Intermountain)
- **Vital Decisions (Evolent)** – Define and document care goals and advanced care plans through high-engagement platform.

Source. Research by Chartis Oncology Solutions.

operationalizing the model to engaging clinical leadership and making the case for change. Grounding this methodology in a set of operating model principles like the ones identified below creates insight and ensures that a holistic care model emerges:

- Disease-specific patient segmentation and navigation are vital to ensure the right care.
- Digital capabilities are leveraged to their fullest potential.
- APPs and nurses drive lower-cost, digitally enabled care.
- Care options expand and extend beyond traditional hours and locations.
- Care teams are configured to support access and the provider experience.

These operating model principles articulate the requirements that must be met by technology-leveraged and digitally forward care models. The clinical, service-specific work steps test each principle, as care models are designed and implemented. Based on these operating model principles, healthcare organizations should consider five workplan components, while optimizing the use of technologies, to make cancer care delivery more efficient and effective:

1. Intentionally match patient encounter types to a provider and modality
2. Create use cases to illustrate and discuss how care should be triaged to providers and the care team
3. Evaluate the care team complement
4. Create the case for change
5. Address organizational- and service-specific supporting capabilities.

Start the work with eager and amenable oncology clinical leadership to refine the approach and templates, as well as to understand support requirements and capabilities. To be a truly valuable and scalable integrated facet of cancer care delivery, change management and communications will be critical.

Dreaming Bigger

The accelerated shift to digitally driven care delivery, demand for a person-centric experience, and COVID-19 pandemic-propelled pressures have made digital transformation an essential and existential requirement for stakeholders across the healthcare delivery ecosystem. Digital cancer care is the overarching spectrum of experience and capabilities required for the material transformation of care delivery beyond specific patient-provider interactions. Cancer programs (and new technology entrants) are increasingly focused on creating fast, frictionless, and seamless care experience with an emphasis on patient access and digital enablement. "Winning in access" is a common cancer program strategy theme.

Cancer programs are transforming oncology through patient access, agency, and the patient experience in three distinct ways. Reconfiguring the care delivery model to be digitally forward requires integrating clinicians' roles with digital tools to create a deliberate impact—optimizing clinical effectiveness, patient-centricity, provider experience, and net income. Chartis predicts oncology industry innovations for 2023 will include:

- Digital, cancer-specific care management platforms that proliferate, often with payers as the customer.
- Healthcare organizations will seek to activate and retain patients through mobile "medical home" technologies.
- Consumer innovation will go hand-in-hand with developing toolsets needed to deliver value-based care.

Several examples of the digital innovation being realized in cancer care range from enhancing access; enabling oncology medical home programs; providing digitally enabled support services; and managing end-of-life episodes of care. Figure 6, page 48, illustrates just a few examples of where innovation is showing up on the oncology landscape across provider and biotech platforms.

A Look to the Future

Oncology care is unique in its far-reaching impact on healthcare professionals, requiring a high level of coordination. Like oncology care itself, designing the roadmap for transformation—access, navigation, care team transformation, and technology—is one of the toughest tactical jobs of healthcare organizations. To navigate these complexities and ensure legacy culture and siloed behaviors coalesce into a symphony of team-based care delivery for patients and providers, organizations must act now to craft or optimize their cancer ambulatory strategy. OI

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Sue Fletcher, RN, is a Chartis Partner and Principal of its Performance Practice.

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BY AMANDA PATTON, MA

ePROs: Lighting the Way to Improved Outcomes, Efficiency, and Patient Experience

Patient-reported outcomes (PROs) and electronic patient-reported outcomes (ePROs) are not a new concept in healthcare. Until recently, a key obstacle to more widespread utilization of PROs in oncology was a lack of evidence of clinical benefit. Over the last 10 years, however, this situation has changed. Multiple studies, including large randomized trials, have demonstrated clinical benefit from the use of PROs and ePROs in patients with cancer.[1–10] Research has shown that asking patients undergoing anticancer treatment to self-report their symptoms and taking prompt action to address these patient-reported concerns has led to improved clinical outcomes, reduced emergency department utilization and unplanned hospitalization, and improved patient quality of life, when compared to non-PRO patients. An additional incentive for ePRO use in clinical practice is the Center for Medicare and Medicaid Innovation (the Innovation Center) Enhanced Oncology Model (EOM), released in August 2022, which requires that participants utilize ePROs and screen for health-related social needs.[11]

Most of the research on ePROs in oncology has been conducted in academic medical centers and large health systems. Over the last several years that, too, has changed. Innovative independent oncology practices have launched ePRO platforms and engaged in studies that are yielding evidence of the feasibility, sustainability, and economic benefits to ePRO integration into their care delivery process.[12–16] Highlands Oncology Group is an early contributor to this evidence base. An independent 25-physician oncology group in northwest Arkansas, the practice moved forward with implementation of the Canopy oncology-specific platform in June 2020. In collaboration with Michael Kolodziej, MD, head of Medical Oncology at Canopy, Highlands Oncology Group shared results from the practice's ePRO implementation with the wider oncology community in presentations at both the 2021 and 2022 ASCO Annual Meetings.[12,13]

> ...the most compelling argument in favor of implementing patient reporting into oncology practice is that it allows patients to actively participate in their own care by providing the information they know best.[1]

Founded in 1996, Highlands Oncology Group is a multispecialty oncology practice providing medical, radiation, and surgical oncology services and clinical trials access to a large geographic region that includes northwestern Arkansas, southwest Missouri, and southeast Oklahoma. This article details the impact of ePRO implementation on the practice's patients, providers, and clinic staff.

Evidence and Opportunity Align

Introducing a new ePRO platform to everyday clinical operations amid the unfolding uncertainties of the COVID-19 pandemic might seem counterintuitive. Yet, as the evidence of clinical benefit mounted and aligned with the opportunity to partner with Canopy, an "intelligent care platform,"[17] Highlands Oncology Group CEO Jeff Hunnicutt said, "The decision to move forward was pretty easy." Compelling study data reported in 2017 by Ethan Basch, MD, MSc, and colleagues that demonstrated outcomes benefits and cost savings from ePRO utilization was the tipping point, Hunnicutt said.[2,3] Further support for the decision derived from the practice's experiences as an Oncology Care Model

Highlights from Highlands Oncology Group's 2021 and 2022 ASCO Annual Meeting Presentations [12,13]

From Highlands 2021 ASCO Poster Abstract

- From June 2020 through January 2021, 769 patients were offered ePRO enrollment
- 569 patients (73.9 percent) offered ePRO were successfully enrolled
- 89.1 percent opted to use the mobile app; 10.1 percent reported using the interactive voice response interface
- 73.6 percent of ePRO-enrolled patients were in an OCM episode

Engagement & Retention

- 88 percent of patients engaged with ePRO two or more times per month
- More than half of patients were still reporting after three months.

Alert & Intervention Rates

- 50 percent of reports exceeded the practice-defined notification threshold
- 78.8 percent of notifications were followed by a nursing phone call
- Only 7 percent of reports required an acute office visit

From Highlands 2022 ASCO Poster Abstract

- Observational study conducted from September 30, 2020, through November 30, 2021. Analysis includes all patient treatment at HOG during study period.
- From September 2020 through November 2021, 855 patients were enrolled in the ePRO system; non-ePRO patients totaled 1,773. Reasons for non-enrollment included patient's opting not to participate and timing (i.e., patients not yet offered ePRO option due to rolling enrollment)
- The non-ePRO cohort was slightly older (66.7 years vs. 63.3 years, p <.001), more commonly male (47.3 percent vs. 39.3 percent, p <.001), and less likely to be White (85.3 percent vs. 89.4 percent, p = 0.003).
- Cancer site distribution was comparable between cohorts, as was the proportion of patients with metastatic disease (ePRO 52.9 percent vs. non-ePRO 51.6 percent, p = 0.55).
- Health resource utilization rates were lower for patients in the ePRO cohort: ER visits: 1.72 vs 2.34 per 100 patient-months, rate ratio and 95 percent CI = 0.74 (0.60, 0.92), p-value = 0.005; hospitalizations: 4.76 vs 5.41 per 100 patient-months, rate ratio and 95 percent CI = 0.87 (0.77, 0.99), p-value = 0.04.
- Findings support the substantial benefits of using an ePRO tool in reducing healthcare resource utilization, and futher the initial findings of previous publications in the academic clinical trial setting to the real-world community practice setting.

(OCM) participant; ePRO implementation appeared to be a next logical step in value-based practice transformation, fostering greater patient engagement with the potential to even further reduce avoidable ED and hospital utilization, lower the cost of care burden to patients, and improve outcomes.

With support from physician champion J. Thaddeus Beck, MD, Highlands Oncology Group, partnered with Canopy, in spring 2020 for integration of the ePRO platform into clinical operations. A deciding factor in vendor selection was the opportunity to collaborate with Canopy, "a development partner that was willing to work side-by-side with the practice to ensure that the product would work for patients but also for the workflow inside the clinic," Hunnicutt said.

Looking back, both Highlands Oncology and Canopy describe the ePRO implementation process as worth the commitment. Good communication and teamwork—between the practice and Canopy—were essential pieces of the two-to-three-month process. "It took a lot of teamwork, but [members of] the Canopy team were on site with us," said Tracy Thurow, RN, OCN, chief clinical officer at Highlands Oncology Group. "The Canopy team would take our feedback and make changes to the app or the [provider-facing] dashboard in real-time. They were part of our daily huddles. Canopy truly listened. They incorporated our needs and the needs of our patients into their technology, while taking into consideration our workflows."

Important takeaways for the Canopy team: The clinic needed an ePRO patient enrollment process that fit seamlessly into existing

clinical workflows, that did not create any additional burdens for providers or patients (and where possible further streamlined care), and that would be sustainable. "We worked closely with the team at Highlands, who were remarkable in their ability to truly conduct an open dialogue and a true sense of partnership, to explain their challenges and their workflows," said Canopy Founder and CEO Lavi Kwiatkowsky.

Eligibility to Enroll

Highlands Oncology planned to implement the Canopy ePRO platform at three practice sites simultaneously. Initially, the option to enroll in the ePRO platform (i.e., download the app) would only be offered to patients receiving anti-neoplastic IV therapy.

Staff Training

One day was set aside for staff training before the ePRO launch. On-site Canopy staff trained the designated Highlands Oncology Group team members on the ePRO platform in one-hour sessions. Comprising the initial training groups were nursing supervisors, office managers, chemo receptionists, and infusion and triage nurses. This training was repeated at all clinic sites.

Launch: Engaging Patients

The Canopy platform launched the day after staff training. The initial focus was on enrolling established patients. To accomplish this, Highlands Oncology Group used a simple, three-step enrollment process that integrated into the practice's existing clinical workflow:

1. Chemo receptionists briefly introduced ePROs when patients checked in.
2. Patients who agreed to reporting through the ePRO app were then educated on the app by their infusion nurse.
3. The infusion nurse taught the patient how to download the Canopy app and completed a trial run with the patient.

At first, the practice found that established patients were "somewhat hesitant" to use the ePRO app. "Most likely because they'd already gone through treatment without this option," Thurow said.

To enroll patients new to the practice in the Canopy app, Highlands Oncology Group developed an efficient process that introduces ePRO earlier, before the start of treatment. The medical oncology practice is structured so that all new patients attend "chemo class" before beginning IV therapy. Now, ePRO is introduced to patients and their family members during "chemo class," they are taught how to download the Canopy app, and practice using it. Highlands Oncology Group has a patient-friendly introduction to the Canopy platform on the practice website at highlandsoncology.com/canopy.

Transforming Triage

Patients report on Canopy's app using a 10-point well-being scale, as well as a problem list that includes physical symptoms, emotional issues, and practical problems (i.e., health-related social needs). The frequency of patient reports is determined, at least initially, by the care team on the basis of the disease and treatment protocol. Patients can work with their care team to adjust their reporting interval. Self-reporting via the app can take as little as 30 seconds up to several minutes, depending on the patient's circumstances, said Kwiatkowsky.

We want to meet patients where they are. So, we support both native iPhone and android apps, but also interactive voice response [IVR]... IVR is an option for patients who lack access to smart phones or a high-speed internet connection.

"When we talk about patient experience and driving higher quality care, we have to address accessibility. Different patients have different backgrounds and needs," said Kwiatkowsky. "We want to meet patients where they are. So, we support both native iPhone and android apps, but also interactive voice response [IVR)]." IVR is an option for patients who lack access to smart phones or a high-speed internet connection. To date, about 10 percent of Highlands Oncology Group's patients have chosen to report via IVR. Canopy also has multi-language support. "We try to simplify reporting," he said. "Instead of asking 100 questions, we ask: *How are you feeling today? 0–10 what is your sense of well-being? Are you suffering from any of the following issues?*" Patients can then select any issues they are experiencing: physical, practical, emotional, financial needs, spiritual, or other concerns.

When patients report through the app, the report is received by a Highlands Oncology Group triage nurse. The triage nurse views the report on Canopy's practice-facing clinical dashboard. Each symptom has a threshold trigger that alerts the nurse based on severity. Symptoms are divided into three categories: physical, emotional, and spiritual/family. Patients rate what they are experiencing as *mild*, *moderate*, *severe*, or the *worst possible*. Patient-reported symptoms appear in the dashboard's centralized work queue; symptoms rated as *severe* or the *worst possible* are elevated to the top of the triage dashboard.

The practice's staff of five triage nurses monitor the dashboard in real-time during business hours (7 days a week, 8 am to 5 pm). Triage nurses will initiate interventions as needed, e.g., calling the patient, bringing the patient in for an urgent office visit, and, when necessary, referring the patient to an emergency department. After business hours, patients are asked to call Highlands Oncology Group and speak with the physician on call.

Since implementation of the ePRO platform, the practice has seen a slight increase in acute care visits, and a significant (22

Highlands Oncology Group triage nurses monitor the ePRO dashboard in real time.

percent) decrease in hospitalizations and ED visits, Kwiatkowsky said. The ePRO integration has not disrupted providers' workflow, Dr. Beck confirmed. When a triage nurse determines that a patient needs a same-day, acute care visit, they are seen by one of the practice's advanced practice providers (APPs). Highlands Oncology Group is well-equipped to handle most episodes of acute care—the practice has on-site lab, infusion, and imaging services—all under one roof, Thurow said. "We encourage patients to report what they are experiencing and discourage the use of the ER. We know our patients and can see, assess, work-up, and treat almost any issue they may be experiencing."

ePRO Clinical Integration

Among obstacles to wider ePRO adoption, "alert fatigue" and lack of ePRO integration with patients' electronic health records (EHRs) are recognized concerns.[10] The Canopy platform addresses both issues. "We think it is critical that everything is integrated, not only for the nurse to avoid any sort of double charting or manual entry or to keep the medical record complete and in sync, but also to bring information for clinical rich context from the medical record into the ePRO dashboard and system," said Kwiatkowsky.

Working with Highlands Oncology Group and other oncology practices has taught Canopy: "It's not enough to just triage and have rules and alerts around ePROs. If you can't efficiently streamline the resolution of those problems, you've done nothing," Kwiatkowsky said. Having a single clinical work queue streamlines information for the triage nurses so that they do not have to look at information in multiple places—the EHR, chat messages, emails, voicemails, etc. "What we strive to do is take the work and put it all in one place and prioritize it," he said. "We try to bring the critical items in full view…to reduce the visual and cognitive burden so staff is able to work more efficiently and, I hear, enjoy the work more."

Using the triage tool, nurses can quickly determine the appropriate site of care for the patient—home, an urgent clinic visit, or the ED. The tool provides a standardized question list and decision support to guide the nurse's conversation with the patient. "The triage tool helps nurses chart, so they don't also need to take notes. They just click through," Kwiatkowsky said.

A feature of the ePRO platform that Highlands Oncology staff appreciates is the power to show trends, which supports intervention before a patient's symptoms begin to escalate. "We like that ePRO is proactive. It prompts patients to report," said Thurow. "When triage depends solely on patients to call [the practice], it is a reactive process." Since implementing the ePRO platform, "we learned many patients were not reporting or were under-reporting their symptoms despite having access to triage nurses who can communicate directly with the patient's physician. The app opened up a line of communication with patients that we previously didn't have."

At Highlands Oncology Group, ePRO is proving to be a patient and provider satisfier. "Our patients like this option. They

Select Oncology ePRO Resources

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can report on their time and on their terms," said Thurow. "Our providers like it because patients are more forthcoming in reporting issues that they are experiencing—issues that may have caused treatment delays or hospitalization." In this practice's experience, ePRO enhances provider-patient communication, connection, and care.

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INSTITUTION-DIRECTED QUALITY IMPROVEMENT OF GENETIC COUNSELING AND TESTING FOR COMMUNITY ONCOLOGY PATIENTS WITH BREAST CANCER

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ACCC
Association of Community Cancer Centers

Hereditary breast cancer accounts for 10 percent of all breast cancers currently diagnosed in the United States.[1] About 30 percent of the known inherited breast cancers are associated with pathogenic (or likely pathogenic variants) in *BRCA1/2,*[2,3] the most understood germline mutations. These cancers occur earlier in life and more often in patients with cancer susceptibility genes. The mean age of patients with germline *BRCA1/2* pathogenic variants who develop breast cancer is considerably lower, compared to the mean age of patients with sporadic breast cancer (42 years vs. 64 years, respectively), which clearly factors into decision making. There is a higher prevalence of triple-negative breast cancer (estrogen receptor [ER]-, progesterone receptor [PR]-, human epidermal growth factor receptor 2 [HER2]-) among those with a pathogenic *BRCA1* variant, while individuals with a pathogenic variant in *BRCA2* more commonly develop ER+ breast cancer and lower grade tumors.[4] Additionally, patients with a pathogenic variant in *BRCA1/2* have a higher risk of developing a second primary breast cancer and other cancers, including pancreatic cancer, ovarian cancer in women, and prostate cancer in men.[3,4]

Evidence-based guidelines continue to evolve, with current National Comprehensive Cancer Network (NCCN) Guidelines® for genetic/familial high-risk assessment in breast, ovarian, and pancreatic cancers emphasizing comprehensive family history assessment in deciding on who is eligible for testing. Current NCCN Guidelines recommend that women who are diagnosed with breast cancer at age 45 years or younger be considered for germline testing, even in the absence of family history or other risk factors.[5] At the time of data collection for this study (Jan. 1, 2018, through Oct. 10, 2020), the NCCN Guidelines for high-risk assessment of breast and ovarian cancers recommended that patients 60 years or younger with triple-negative breast cancer and those with metastatic HER2-negative breast cancer be tested for high-penetrance breast cancer susceptibility genes, including *BRCA1* and *BRCA2*.[5] Other organizations advocate for comprehensive testing of all women with breast cancer, citing the lack of significant family history in many patients with a pathogenic variant and omission of criteria that would identify carriers of non-BRCA variants.[6-8] These guidelines continue to evolve annually and currently include other cancer susceptibility genes.[5]

The presence of *any* pathogenic germline mutation, especially a *BRCA1/2* mutation, has the potential to influence primary treatment choices for patients with breast cancer. For example, when choosing between bilateral mastectomy vs. breast conserving surgery, the provider and patient should consider a shared decision-making model by discussing the chance of developing contralateral breast cancer after breast-conserving surgery because second (synchronous and metachronous) cancer rates are considerably higher in patients with germline *BRCA1/2* mutations.[3,9] Despite this association and the presence of recommendations to test early, the timeliness of genetic counseling and the completion of testing prior to primary surgical decision-making remains an ongoing issue in the U.S.[10-13]

Many academic medical centers and large community health systems have hereditary cancer risk assessment programs that are fully staffed by board-certified medical geneticists, genetic counselors, and other highly trained genetic professionals. Objectives of such programs often include providing patients with comprehensive information about hereditary cancer and the process of genetic testing. Since 85 percent of patients with cancer receive treatment in community-based oncology programs, these services may not be as readily accessible.[14,15]

Development of an Institution-Directed QI Initiative

In 2018, the Association of Community Cancer Centers (ACCC)[16] surveyed community oncology practitioners to assess the status of *BRCA1/2* testing for patients with breast cancer. Most respondents (approximately 80 percent) reported that less than

half of their patients with early onset (age 45 years or younger) or metastatic breast cancer had undergone germline *BRCA1/2* testing. Identified barriers to genetic testing included:[17]

- Patient-related barriers
- Challenges with respect to identification of patients who meet testing criteria
- Reimbursement for genetic counseling and testing
- Limited access to genetic counselors geographically
- Timeliness for genetic counseling
- Systems-based challenges related to ordering tests and communicating results
- Lack of clarity regarding the clinical benefits of testing.

While most respondents indicated that board-certified genetic counselors most often ordered genetic testing at their cancer program, 16 percent of practitioners did not routinely utilize a genetic counselor, often due to lack of access or long wait times.

As genetic counseling and testing has become more relevant in precision medicine and critical to treatment decision-making, it is important to gain a better understanding of the different models that are used by various cancer programs in community settings and implement quality improvement interventions to improve rates of genetic counseling and testing. To increase rates of guideline-concordant genetic counseling and testing in patients with Stage 0 to III breast cancer where results could impact care, ACCC coordinated a national, institution-directed quality improvement (QI) initiative for community oncology programs and practices. The aim of this project: to determine the impact of QI efforts on the rates and timeliness of genetic counseling and testing compared to baseline and the availability of genetic test results for providers prior to surgery.

Study Methods

ACCC sent a request for proposals (RFP) to address issues related to genetic counseling and testing for patients with Stage 0 to III breast cancer to 694 cancer program members. The RFP included the previously collected background data on rates of genetic counseling and testing, as well as the various barriers to these services. Forty-three cancer programs (6.2 percent response rate) from across the U.S. submitted QI proposals to increase genetic counseling and testing; 15 community cancer centers (institutions) were awarded grants based on criteria set by the ACCC-appointed peer review committee. Applications were graded based on how the implemented change(s) would directly affect patient care and provide sustainability (e.g., integration with an electronic health record) and scalability (e.g., plan for dissemination/applicability beyond the proposed institution) within the specified timeframe. Successful applicants were expected to describe specific clinical practice gaps for their own providers, healthcare system, or patient community and what they would do to close or overcome these challenges. The RFP highlighted the following specific areas of interest:

1. Systems-based challenges related to ordering genetic tests and communicating test results
2. Access to genetic counselors
3. Turnaround time for genetic testing
4. Patients' emotional needs, psychosocial support, and advocacy issues
5. Coordination of care within the multidisciplinary cancer care team.

Each institution implemented and conducted a unique QI project based on their own identified gaps and needs. Baseline and post-QI data were collected on adult, female patients at least 18 years old with a diagnosis of Stage 0 to III breast cancer. Patients with Stage IV disease were not included in this report, although some institutions provided this data. Baseline cohort data was provided for patients diagnosed between Jan. 1, 2018, and Dec. 31, 2018, and the QI cohort data included those diagnosed starting on the QI launch date at each institution and ending Oct. 10, 2020. Participating institutions provided patient-level data that was de-identified with a non-meaningful study ID; no protected health information was submitted. Prior to sending data to ACCC, each institution modified dates by adding or subtracting by a factor of seven. The factor of seven was determined independently by each institution and was not shared with ACCC. Baseline cohort data was submitted by July 31, 2019, and post-QI cohort data was submitted by Jan. 31, 2021, to maximize full registry data capture following the Oct. 1, 2020, cut-off date.

To facilitate aggregate data reporting, ACCC provided a data collection sheet for each institution to collect baseline and post-QI data. Data collection was voluntary and not a condition of the grant award. Each institution that chose to collect data went through its own internal quality committee and/or secured investigational review board approval.

Statistical Analysis

Descriptive statistics were used to evaluate de-identified demographic information. Differences in rates of genetic counseling appointments, documentation of genetic test results, and availability of genetic testing results before surgery between the baseline cohort and post-QI cohort were evaluated using two-tailed Fisher's exact tests, calculated using GraphPad QuickCalcs; a p-value less than 0.05 was considered statistically significant.

Participating Cancer Programs

Participating institutions varied in size and geography. The smallest cancer program was a critical access hospital in rural North Carolina, and the largest was a university medical center in Kansas. Nine of fifteen (60 percent) participating institutions in

Table 1. Institution QI Efforts, Rate of Genetic Counseling by Institution (Baseline to Intervention)

Institution	Type of QI Effort					Baseline Cohort n=2,691			QI Cohort n=3,530		
	Process to ID Patients	Add GC Capacity	Virtual GC/GC Support	Provider Education	Patient Education	Genetic Counseling			Genetic Counseling		
						n	No.	%	n	No.	%
1	Y	Y	N	N	Y	749	140	19	794**	507	64
2	N	Y	Y	N	Y	48	30	63	128	60	47
3	Y	N	Y	Y	N	490	204	42	206	97	47
4	Y	Y	Y	Y	Y	41	27	66	89*	79	89
5	Y	Y	N	Y	Y	7	4	57	45*	45	100
6	Y	Y	Y	N	Y	105	23	22	121*	51	42
7	Y	Y	Y	Y	Y	478	243	51	920	438	48
8	Y	Y	N	N	N	134	71	53	129**	108	84
9	Y	Y	Y	Y	N	639	203	32	1098**	661	60

*p<0.05, **p<0.001

Abbreviations: Institution, Cancer Program; GC, Genetic Counseling; ID patients, identification of patients who meet criteria for hereditary cancer genetic counseling/testing; Add GC Capacity, addition of clinicians that are able to conduct genetic counseling; Tele-GC or Tele-GC support for providers, the addition of telephone/video based genetic counseling for patients and/or telephone/video based support of healthcare providers; Provider education, education for clinicians on NCCN Guidelines® for genetic/familial high risk assessment for patients with breast cancer; Patient education, specific materials or education regarding genetic risk/counseling directed to patients with breast cancer.

this QI program voluntarily shared project data with ACCC, which forms the basis of this report. The nine institutions conducted two or more types of QI interventions to impact the rate of genetic counseling and testing for eligible patients (Table 1, above).

Patient Characteristics

The baseline cohort contained 2,764 patient records; 73 records were excluded due to incomplete information, resulting in a total of 2,691 analyzable patients. The post-QI cohort contained 3,845 patient records; 315 records were excluded due to incomplete information, resulting in a total of 3,530 patient records. Baseline and post-QI cohorts had significant differences in stage of breast cancer, with 3 times more patients with Stage II or III disease in the QI cohort than the baseline cohort (Table 2, page 61). Cohorts were similar in age and familial breast and ovarian cancer risk as defined by NCCN Guidelines.[18] There were significant differences in the rate of ER and PR positivity (e.g., 84 percent ER+ at baseline vs. 78 percent in the QI cohort), but similar rates of HER2+ and triple-negative breast cancer among the cohorts. Both cohorts had broad representation across patient characteristics, allowing for analysis by characteristic subgroups other than disease stage.

QI Interventions

QI efforts were grouped into five broad categories to allow measure of impact by type of intervention:

1. Telephone genetic counseling
2. Patient educational interventions about the need for genetic counseling and testing
3. Provider education about ways to improve testing
4. Added capacity (e.g., hiring more genetic counselors)
5. Identification of patients' genetic counseling needs though some other process improvement.

Timing of Genetic Counseling

The rates of genetic counseling were analyzed to measure the impact of the specific intervention as shown in Figure 1, page 60, for each institution. The time interval from date of diagnosis of Stage 0 to III breast cancer to the date of genetic counseling averaged 37.3 days in the baseline period (of those referred) and 21.8 days post-QI for all patients collectively, reflecting an improvement of 15.5 days. The largest impact was a reduction by an average of 17 days from diagnosis to genetic counseling among the institutions that implemented telephone genetic counseling, followed closely by an average reduction of 16.3 days by the institutions that focused on patient education. The least impactful intervention, increasing the capacity of genetic

counselors, still improved the time from diagnosis to genetic counseling by an average of 9 days.

Genetic Counseling Appointment Rates

Nine institutions submitted data measures of genetic counseling rates pre-intervention and post-intervention. Six of the nine institutions (67 percent) that provided data on its intervention demonstrated significant improvements in the rates of genetic counseling conducted for patients with Stage 0 to III breast cancer. Rates at baseline increased:

- From 19 percent to 64 percent for institution 1
- From 66 percent to 89 percent for institution 4
- From 57 percent to 100 percent for institution 5
- From 22 percent to 42 percent for institution 6
- From 53 percent to 84 percent for institution 8
- From 32 percent to 60 percent for institution 9.

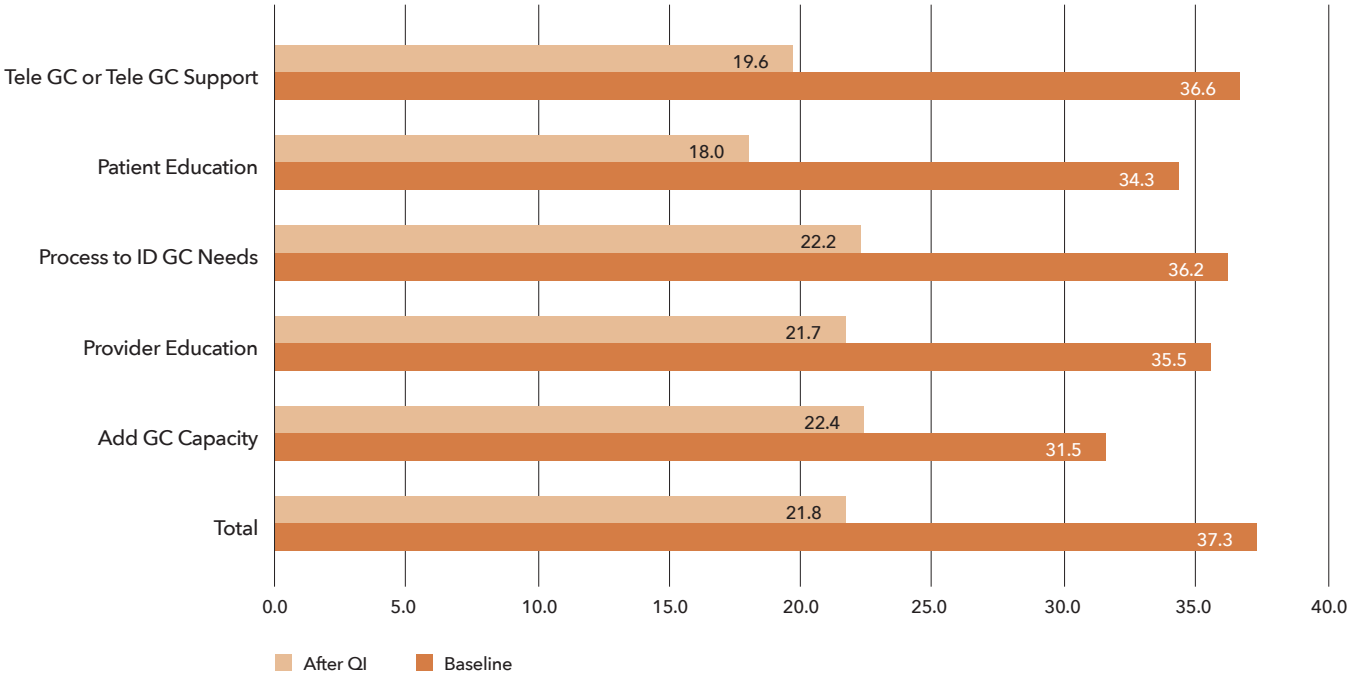
Institution 3 also increased genetic counseling rates from 42 percent to 47 percent, which was not statistically significant. Two institutions had lower genetic counseling rates following intervention.

Table 3, page 62, compares the impact of specific QI categories on genetic counseling rates, the documentation of a test result (i.e., testing was done), and whether the results were made available before patients' primary surgery. Results were analyzed in relation to:

1. Positive family history risk
2. No family history risk
3. Unknown family history
4. Age at diagnosis (45 years or younger)
5. Triple-negative receptors.

The various QI interventions statistically increased the number of genetic counseling appointments that were completed in total and in four of five of the specific genetic counseling measures. Proportions of patients in the post-QI cohort receiving genetic counseling ranged from 24 percent to 85 percent. The only group that was not statistically impacted was the triple-negative breast cancer group, which had pre-intervention and post-intervention rates of 56 percent and 64 percent, respectively, which were not significantly increased. The interventions significantly impacted all six genetic counseling measures for the

Figure 1. Average Days from Breast Cancer Diagnosis to Genetic Counseling Referral, QI Compared to Baseline by Type of QI Effort



Abbreviations and description of types of quality improvement efforts: Tele-GC or Tele-GC support, the addition of telephone/video based virtual genetic counseling for patients and/or tele/video based support and mentoring of providers; Patient education, specific materials or education regarding genetic risk/counseling directed to patients with breast cancer; Process to identify a patient's genetic counseling needs; Provider education for clinicians on genetic counseling indicators/needs for patients with breast cancer; Add GC Capacity, addition of clinicians that are able to conduct genetic counseling; Total, the total days across all participating institutions regardless of what QI interventions they used.

Table 2. Patient Characteristics

Characteristic	Baseline Cohort (n=2,691)		QI Cohort (n=3,530)	
	No.	%	No.	%
Stage**				
0	394	15%	403	11%
I	1,025	38%	1,666	47%
II	248	9%	970	27%
III	85	3%	387	11%
Stage I to III, specific stage missing	939	35%	104	3%
Age (Years)				
45 and younger	278	10%	377	11%
46-49	180	7%	252	7%
50-64	1,039	39%	1,294	37%
65-74	746	28%	1,013	29%
75-89	423	16%	560	16%
90 and older	25	1%	34	1%
Genetic Markers				
ER+**	2,248	84%	2,762	78%
PR+*	1,927	72%	2,404	68%
HER2+	305	11%	444	13%
Triple negative	219	8%	346	10%
Genetic/Familial Breast Ovarian Risk				
High risk	1,284	48%	1,680	48%
Not high risk	778	29%	1,144	32%
Unknown HBOC Risk	629	22%	706	20%

*p<0.05, **p<0.001

Abbreviations: BC, Breast Cancer; ER+, Patients with Estrogen Receptor Breast Cancer; PR+, Patients with Progesterone Receptor Breast Cancer; HER2+, Patients with HER2 positive Breast cancer; Triple Negative, Patients with ER negative, PR negative and HER2 negative breast cancer, Genetic/Familial Breast Ovarian Risk, patients with a risk factor(s) as defined by NCCN Guidelines® and/or history for hereditary breast or ovarian cancer

sub-groups that implemented a process to identify genetic counseling needs and added genetic counseling capacity. The intervention significantly impacted five of six genetic counseling measures for the subgroup that added patient education. The subgroups that added virtual genetic counseling visits and/or continuing medical education focused on cancer genetics in practice showed a significant impact on total number of genetic counseling appointments.

Genetic Test Results

All QI interventions were able to significantly improve documentation of genetic test results, which held true across all intervention subtypes. Rates improved overall from 25 percent documented at baseline to 49 percent after intervention, a relative improvement by a factor of about 2.

Genetic Test Results Available Before Surgery

All QI interventions improved the number of patients for whom genetic test results were available before surgery, regardless of

(Continued on page 63)

Table 3. Comparing Impact on Guideline-Indicated Measures, between QI and Baseline (B) Cohorts, in Total and by QI Intervention

Measure	Total		Process to ID Patients' GC needs		Add GC Capacity		Virtual GC or Support		Provider Education		Patient Education	
	B % N=2691	QI % N=3530	B % n=2643	QI % N=3402	B % n=2201	QI % n=3324	B % n=1801	QI % n=2562	B % n=1655	QI % n=2358	B % n=1428	QI % n=2097
Genetic Counseling Appointment	35	**58****	35	**58****	34	**59****	41	**54****	41	**56***	33	**56****
Familial high risk with GC appointment	57	**85****	56	**86****	51	**87****	75	**89****	78	**91****	41	**84****
Not Family high risk with GC appointment	23	**39****	23	**40****	29	**41****	25	**34****	25	**37****	24	25
Unknown family risk with GC appointment	6	**24****	6	**24****	6	**24****	0	**14****	0	**14****	15	**46****
Age 45 and younger with GC appointment	72	**81***	71	**81***	71	**82***	85	81	85	81	61	**82****
Triple negative (ER-, PR-, HER2-) with GC appointment	56	64	10	**64****	54	**64***	66	58	66	60	47	**62***
Genetic Test Result Documented	25	**49****	24	**49****	23	**50****	28	**46****	29	**47****	19	**49****
Age 45 and younger with genetic test result	49	**75****	48	**74****	47	**77****	56	**75****	54	**74****	27	**76****
Triple negative (ER-, PR-, HER2-) with genetic test result	26	**56****	26	**56****	22	**56****	18	**50****	16	**50****	26	**56****
Genetic Test Result Available Before Surgery	12	**27****	12	**27****	11	**27****	15	**28****	15	**28****	9	**28****
Age 45 and under with genetic test result before surgery	28	**45****	27	**44****	24	**47****	36	**50***	34	**47***	11	**48****
Triple negative (ER, PR-, HER2-) with genetic test result before surgery	13	**28****	13	**28****	10	**28****	13	**30****	13	**29****	10	**29****

*p<0.05, **p<0.001

Abbreviations: Familial High Risk is based on NCCN Guidelines® for Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic; GC, Genetic Counseling; Triple Negative, Breast Cancer with negative results for Estrogen Receptor (ER), negative results for Progesterone Receptor (PR) and negative human epidermal growth factor receptor 2 (HER2) results; id GC needs, identification of a patient's genetic counseling needs; Add GC Capacity, addition of clinicians that are able to conduct genetic counseling; Tele-GC or Tele-GC support, the addition of telephone/video based genetic counseling for patients and/or tele/video based support and mentoring of providers; CME on GC, provider education for clinicians on genetic counseling indicators/needs for patients with breast cancer; Patient education, specific materials or education regarding genetic risk/counseling directed to patients with breast cancer. G-Test, Genetic test.

(Continued from page 61)
intervention type (Table 3). Results were available at surgery in 27 percent of patients after intervention, compared to only 12 percent at baseline, a relative improvement by a factor of 2.25. Eleven of the 12 genetic counseling and testing measures that were evaluated improved within all 9 institutions.

Study Discussion

ACCC evaluated the impact of institution-directed QI interventions at 9 community cancer programs and practices across the U.S. to address guideline-concordant utilization of genetic counseling and testing in patients with Stage 0 to III breast cancer. The QI interventions were designed to improve rates of genetic counseling, genetic testing, and timeliness of test results relative to surgery. Prior background data pointed to the need to increase access to genetic counseling and testing and increase timeliness, as it potentially impacts primary shared decision-making.

Despite the various improvements demonstrated by this collective, several areas did not achieve "standard" practice. Genetic test results were available (i.e., done) for only 75 percent of patients 45 years old and younger and for only 56 percent of patients with triple-negative breast cancer regardless of age. While the message of *young age* at diagnosis was a positive predictor of genetic counseling (81 percent) and testing (75 percent), it was not enough to predict that germline BRCA (gBRCA) testing would be done. This is one of the reasons why a more broad-based testing guideline may help improve testing rates, especially in a younger population where the impact of breast conservation vs. mastectomy may depend on gBRCA mutation status.

While there was also significant improvement in the percentage of available genetic results before primary surgery because of QI efforts, total rates remained low (27 percent). If primary shared decision-making is designed to fully inform providers and patients of the risks and benefits of various treatment choices, this information is advantageous earlier in patients' care. One cancer program that participated in this project found that the majority of its patients with high-risk (BRCA) mutations chose bilateral mastectomy over breast conserving surgery when they had their genetic testing information up front, which also potentially affects other primary therapies. In the same institution, with 100 percent prospective genetic counseling and testing post-QI, 85 percent of patients with pathogenic germline variants with significantly increased breast cancer risk chose bilateral mastectomies up front.

The overarching goal of this project was to increase germline testing over an established baseline for each institution and highlight how different this can be throughout the oncology community. The lowest percentage of testing at baseline was 19 percent, and the highest was 66 percent of eligible patients prior to intervention, which highlights the differences in community institutions' readiness to offer genetic counseling and testing.

One of the strengths of this project was the ability of each institution to choose its own QI initiatives based on existing resources. One institution within the smallest community hospital in North Carolina used a genetics extender model to increase access to counseling and testing where there are few formally trained genetic providers. This was accomplished by training a registered nurse through the "Intensive Course in Cancer Genetic Risk" facilitated by City of Hope and training a physician through additional online professional education resources that are updated annually. That institution increased cancer risk assessment, genetic education, and testing to include 100 percent of all affected patients with breast cancer, which improved overall concordance with guidelines and was done in an environment with limited resources. As a result of this same grant, the same institution also increased genetic education, counseling, and testing for its at-risk screening (unaffected) population using extenders, expanding its counseling and testing to potentially include more than 5,000 individuals a year as a population health initiative. It has plans to integrate this into an EPIC-based platform for its entire health system, including 8 other community hospitals in eastern North Carolina.[19]

As a collective of community participants in this study, 7 of the 9 institutions that provided data from specific interventions were able to increase genetic counseling rates, with 6 of 7 of these being statistically significant. Rates following intervention ranged from 42 percent to 100 percent of eligible patients with breast cancer.

Another practice changing result of this project was the increased use of expanded panel (next-generation sequencing) testing. Although the proposal was focused on *BRCA1/2* genes due to the highly penetrant nature of these well-known germline mutations, most investigators in practice used expanded testing with larger panels that include other moderate- to high-risk genes like *ATM, BARD1, CDH1, CHEK2, PALB2, PTEN, RAD51C, RAD51D, STK11, TP53*, and others. Although not emphasized as part of this study, half or more of the pathogenic variants reported by the participating institutions were in non-BRCA genes. Future research should examine how knowledge of germline variants impact primary therapy, specifically if primary therapy for Stage 0 to III breast cancer is altered for patients with a highly penetrant gene, more than those who carry a pathogenic variant in a low penetrant gene. This would include

the use of poly ADP ribose polymerase (PARP) inhibitors for metastatic breast cancer and high-risk non-metastatic gBRCA+ mutated breast cancers that are HER2-,[20] a recent development since this study was conducted. A third future research topic is the possible use of shared decision-making regarding radiotherapy use based on genetic test results. Guidelines for radiotherapy avoid recommending accelerated partial breast irradiation stipulate as an option for patients with germline mutations in certain genes, such as *TP53*.[21]

An unanticipated event during this project was the increased use of virtual genetic counseling and testing as a result of the COVID-19 pandemic. Most institutions reported heavy use of telephone- or tele-video-based genetic counseling during 2020 in response to the pandemic. Counseling pre- and post-testing lends itself nicely to a virtual platform, and this study found these practices to be the case at many institutions. Additionally, vendors were happy to mail test kits to patients' homes, removing the need for clinic contact for those individuals concerned about COVID-19 and other potential infections.

Study Limitations

This study analyzed the impact of a self-directed QI project conducted at 9 of 15 total institutions who were awarded grant money; these institutions voluntarily chose to share baseline and post-intervention data with ACCC. Study authors do not know how data from the remaining 6 institutions may have impacted genetic counseling and testing rates. It is possible the that the 9 institutions that provided data did not have typical results that could be expected widely in community practices, but, as the study had a range of providers from a National Cancer Institute-directed program to a critical access hospital, they are somewhat representative. Larger studies could therefore include broader representation. Additionally, all 9 institutions that voluntarily provided data utilized two or more QI projects that were customized to their cancer program, so it is difficult to isolate the specific impact of each initiative.

The QI interventions, while focused on addressing the same problem, were designed and implemented uniquely at each institution. In addition, baseline data included a substantial portion of patients that did not have a specific breast cancer stage noted, other than "Stage 0 to III," which made comparisons between disease stages not analyzable at baseline compared to post-QI (Table 2). This is not something the study was specifically interested in comparing, as the overall goal was to increase genetic counseling and testing for all eligible patients.

Study Conclusions

Significant improvements in guideline-concordant genetic counseling and testing were achieved with institution-directed QI initiatives that were specifically designed to target easily identified populations of patients with Stage 0 to III breast cancer. Despite results indicating improvements in testing rates, there is a long way to go to meet national recommendations. This project demonstrates the importance of practice-directed strategies aimed at improving identification of high-risk patients and follow through to genetic counseling and testing. Further work is needed to understand the decision to undergo or forgo genetic testing and the timing of testing relative to surgical decision-making. Opportunities exist to examine additional facilitators and barriers to community-based and/or tele-genetic services to increase access to guideline concordant genetic counseling and testing for all eligible patients. ■

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Disclosures

Authors have no additional relevant interests to disclose.

Data Availability

The datasets generated and analyzed during the study are not publicly available but are available from the corresponding author on reasonable request.

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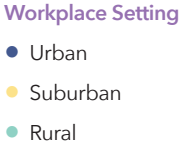
ASSOCIATION OF COMMUNITY CANCER CENTERS

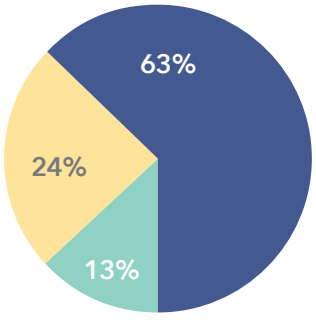
Exploring Current Perceptions of Multi-Cancer Early Detection Testing Among Healthcare Providers

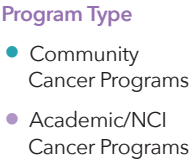
Multi-cancer early detection tests are designed to identify the presence of cancer for multiple cancer types with a single, blood-based test so that the disease can be diagnosed in early, more treatable stages. In combination with existing standard of care recommendations, multi-cancer early detection tests hold the potential to revolutionize cancer screening, in part by detecting cancers for which no routine screening exists, including liver, ovarian and pancreatic cancers, as well as detecting cancers earlier in the disease trajectory. In 2022, the Association of Community Cancer Centers (ACCC) conducted a comprehensive survey and a series of four focus groups with ACCC members to explore current attitudes, beliefs, and concerns related to multi-cancer early detection and the capacity to integrate this testing into cancer programs and practices.

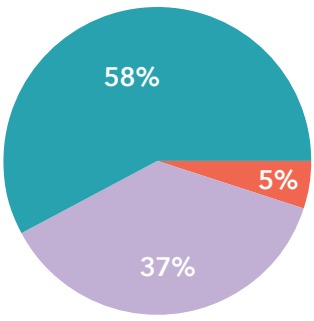
The survey, conducted between June 2002 and August 2022, included 108 providers representing diverse multidisciplinary roles from institutions in 34 states. Focus groups, conducted in October and November 2022, included 27 providers and aimed to collect more in-depth, qualitative data around perceptions, attitudes, beliefs, and potential impact of multi-cancer early detection testing.

Who Took the ACCC Survey?









Cancer Prevention, Screening & Surveillance Services

Members were asked several questions about the current landscape of cancer prevention, screening, and surveillance services, which set the stage to explore how multi-cancer early detection testing could integrate into current services offered. Most survey respondents (96 percent) confirmed that their program offered cancer screening services as described below:

- 92 percent offered screening and surveillance of cancer survivors who have completed treatment
- 91 percent offered diagnostic services to confirm cancer, such as laboratory tests (e.g., CBC or urine) and/or imaging tests (e.g., PET, MRI, CT, ultrasound, X-ray, or tissue biopsy)
- 87 percent offered screening for new primary cancers (e.g., mammography, colonoscopy, pap test, LDCT)
- 87 percent offered genetic counseling and testing for hereditary cancers.

ACCC members also suggested strategies to support adherence to screening and/or increase screening, including:

- Building trust among healthcare organizations and communities through faith- and community-based partnerships, community health workers, and direct outreach at community gatherings
- Using mobile screening for increased accessibility
- Linking underutilized screening programs with more successful screening programs
- Creating opportunities for screening to be a family event
- Leveraging patient navigators to increase completion of screening
- Reviewing EHR data, contacting patients who are over-due for a screening and scheduling the screening at that time.

Respondents felt that these strategies could be leveraged and/or adapted as multi-cancer early detection testing becomes more widely available in community settings.

Awareness, Confidence & Beliefs

Since multi-cancer early detection testing is an emerging screening tool, nearly **1/3** of respondents indicated that they were unsure or did not have enough information to answer questions about their awareness, confidence, attitudes, and beliefs related to this testing. This finding underscores the clear need for education and building awareness around multi-cancer early detection. Of those that were able to respond:

- **63%** agreed or strongly agreed that multi-cancer early detection testing will improve outcomes for patients diagnosed with cancer
- **51%** agreed or strongly agreed that this testing will improve existing disparities in cancer screening
- **65%** were concerned about access to follow-up diagnostics and treatment after this testing

Knowledge, Awareness & Perceptions of Multi-Cancer Early Detection Testing

Survey and focus group data findings showed that there were varying degrees of awareness of multi-cancer early detection testing among ACCC members, ranging from very aware to not aware at all. The current use of this testing in practice was limited, and only a handful of ACCC members indicated that their cancer program or practice was participating in a multi-cancer early detection clinical trial.

> "We just caught a positive cancer. We do not know how early it was caught, but I am really glad we found it because it is proof of principle that there is something here."
>
> ONCOLOGY ADMINISTRATOR AT A HEALTH SYSTEM OFFERING A MULTI-CANCER EARLY DETECTION TESTING THROUGH A CLINICAL TRIAL

Potential to Improve Cancer Screening & Outcomes

A majority of survey respondents (63 percent) indicated that they believed multi-cancer early detection testing will improve outcomes for patients diagnosed with cancer. About half of respondents (51 percent) also believed that multi-cancer early detection testing will improve existing disparities in cancer screening. Focus group participants also noted the potential benefits of using multi-cancer early detection as a screening tool, which included acceptability of a blood test, the ability to screen for cancers where there is currently no screening tool available, and the hope of downstaging more cancers.

While multi-cancer early detection testing offers the possibility of catching cancer early, ACCC members expressed concerns surrounding accessibility of testing. They discussed the need to proactively address the risk of widening disparities, to ensure that all individuals can access and benefit from these advances, rather than only individuals with higher incomes or more resources.

> "I think a benefit is the ease of having a blood test. And the fact that we have the infrastructure in this country that allows us to get blood tests so close to people's communities is tremendous. Plus, if these tests are effective and with the right guidelines in place (and the tests are not widening disparities), I think that is a tremendous benefit."
>
> GENERAL INTERNIST AND ADMINISTRATOR

Potential to Incorporate Multi-Cancer Early Detection Testing into Screening

More than half of survey respondents (57 percent) indicated multi-cancer early detection testing would fit within existing processes used to care for patients. This finding suggests that many respondents feel they have infrastructure and resources that could support multi-cancer early detection testing. However, most focus group participants also noted the need for U.S. Food and Drug Administration (FDA) approval and clear clinical guidelines to support the implementation of this testing into practice.

In addition to guidelines and/or workflows, focus group participants had a more in-depth discussion about whom should conduct multi-cancer early detection testing as part of primary screening. While there was a lack of clear consensus from survey participants on whether this testing should be conducted at a cancer program and/or by an oncology care team, most indicated that primary care providers should conduct multi-cancer early detection tests.

Focus group participants agreed there is a role for the field of oncology around multi-cancer early detection tests, particularly in supporting the development of patient and provider education and advising on the development of workflows. Participants also discussed the importance of transdisciplinary and multidisciplinary healthcare approaches as screening continues to evolve, and the need to involve community health workers and health communication experts to incorporate evidence-based health literacy and equity strategies to support educating the public about multi-cancer early detection.

> "It would be unlikely that I am going to be the person requesting a multi-cancer early detection test, but maybe I need to be thinking about that differently. We are currently involved in starting a lung cancer screening program with an advanced practitioner. But maybe we need to think outside the box and part of that discussion becomes more of a collaboration of multi-cancer screening all at once. Perhaps we need to consider a cancer screening clinic as being run more by mid-levels and being more multidisciplinary, and multi-cancer early detection is part of the clinic."
>
> PULMONOLOGIST

Implementation Considerations

ACCC members were asked to provide open-ended feedback regarding key considerations to successful implementation of multi-cancer early detection testing. Common themes that emerged were clinical implications, cost and coverage, and patient support services.

Clinical Implications

Clinical implications related to patient care, clinical workflow, and integration of the test into clinical practice were the most frequently cited considerations among survey participants. Participants also indicated the need for a coordinated plan throughout the entire testing process. Other considerations included management of false positives, unnecessary procedures, overdiagnosis, and lead time bias. ACCC members called for more evidence on clinical utility and effect on patient outcomes, and subsequent public health policy interventions to fully support multi-cancer early detection rollout, including FDA approval and Medicare coverage. There were also concerns that if testing is rolled out without clear clinical guidelines, it will be implemented with varying degrees of fidelity and may cause confusion in the interpretation of results and follow-up diagnostic process.

"Key decision makers need actual data that shows multi-cancer early detection benefits outweigh the potential risks—overdiagnosis, false positives and negatives, unnecessary psychosocial distress, morbidity from follow-up diagnostic tests, potential to widen disparities. And we need clinical practice guidelines in place before rolling this out."

PRIMARY CARE PHYSICIAN

Cost and Coverage

Cost was a frequently cited implementation consideration for both the healthcare system and especially for patients. The cost of the actual test and potential financial toxicity from the follow-up diagnostics was mentioned regularly. Participants pointed to current financial toxicity patients can face, such as high out-of-pocket costs for MRI screenings for individuals who are at high-risk for breast cancer. Participants noted that some state-level policies are being enacted to reduce out-of-pocket costs. Yet, as multi-cancer early detection testing moves forward, policies at both a federal and state level will be key to reduce financial toxicity for patients and ensure testing is accessible to all, while also balancing the cost to the healthcare system.

"Multi-cancer early detection testing needs a reimbursement structure to allow it to occur without being a cost burden to programs. Such reimbursement must attempt to include funding for covering the complexities of getting this new technology into the hands of cancer programs—with the need for deep education, working with false positives and follow up, navigation, etc."

CANCER PROGRAM ADMINISTRATOR

ACCC members also noted the need for potential polices to protect patients' rights, similar to the Genetic Information Nondiscrimination Act of 2008. Members were concerned that if an indolent cancer was found through testing and there was no treatment available, it could impact patients' health insurance and life insurance coverage.

Patient Support Services

There was a resounding call from ACCC members for the need for patient support services to be in place for the successful rollout of multi-cancer early detection testing. Support services included the need for education, particularly around potential out-of-pocket diagnostic costs that may not be covered because of a positive multi-cancer early detection test compared to coverage for current standard of care screenings; appropriate tools and resources to support shared decision-making; resources to manage patient anxiety during the waiting period or following a positive result; and peer to peer support.

"We know testing is anxiety provoking, and we know genetic counselors are trained to handle these situations. They are good at educating people about things that are hard to understand on a level they can understand. Genetic counselors understand the importance of consent and ensuring patients are thoroughly educated. So, that's why I feel genetic counselors are a good fit for this [education about multi-cancer early detection]. They have the tools and training. But how do you scale that up? A genetic counselor will not be able to meet with everyone, so providers will need to have the tools in place to help because it is always going to be anxiety provoking."

GENETIC COUNSELOR AND ADMINISTRATOR

Future Directions

As ACCC members look to the future of multi-cancer early detection testing, they provided the following recommendations for the healthcare field to both recognize the potential of this emerging screening tool and proactively address implementation considerations:

- Offer multi-cancer early detection clinical trials to advance the research and/or connect patients with multi-cancer early detection clinical trial opportunities
- Collaborate with interdisciplinary teams to provide guidance on workflows and the use of multi-cancer early detection testing
- Advocate for advancements in research to treat early detected, incurable cancers
- Advocate for policies at the state and federal level to ensure accessibility of tests as they become more widely available
- Promote and support the use and uptake of the current standard of cancer care screenings. ■

> "We all want to put the patient first. We also get very excited about innovations—whether it's medicine or a new screening tool. But we do not want to harm the patient, whether it's physically or emotionally. We also need to make sure that the cost is not outstanding, so it is not just for the elite few, but for all humans. There is a lot on the horizon and things are happening so quickly. I think we are going to get some answers faster than we used to, which is exciting. One thing that drives me to medicine is how fast things are changing and all the innovation—so I am really excited to see what the next few years will bring."
>
> NURSE NAVIGATOR

This is a publication from the ACCC education program, "Multi-Cancer Early Detection." Learn more at accc-cancer.org/mced.

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 30,000 multidisciplinary practitioners from 1,700 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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EXACT SCIENCES

ACCC
Association of Community Cancer Centers

ACCC Convenes 2022 ACCC Institute for the Future of Oncology at the 39th National Oncology Conference

ACCC leadership, key stakeholders, and thought influencers came together on October 11 for the ACCC Institute for the Future of Oncology—an event dedicated to ACCC President Dr. David Penberthy's 2022-2023 theme: "Leveraging Technology to Transform Cancer Care Delivery and the Patient Experience." The question posed to attendees: what does the future of cancer care delivery look like?

In presenting industry's perspective, Scott Penberthy, director of applied AI (artificial intelligence) at Google, shared one question Google Health is trying to answer: "How can we take all available healthcare data, feed it into a machine, and turn it into a tool for providers to use?" On partnering with providers, Penberthy said that Google has the science and technology expertise to understand and analyze patterns in big data, but it must partner closely with physicians and hospitals who have the medical expertise and who are the "keepers" of patient data.

Additionally, "patients want to know about the newest technologies and treatments available to them, and social media is one tool we can use to deliver that information," suggested Sanjay Juneja, MD, chief of Oncology Service at Baton Rouge General Hospital and co-founder and chief operating officer at MedFluencers. While active on his own social media accounts, Dr. Juneja shared how apps like Facebook, Twitter, and Instagram, among others, are digital platforms that can be helpful for cancer-related education efforts like busting commonly believed myths about this disease.

Moving into the business and operational perspective of cancer care in 2040, Jennie Kung, senior director at Mayo Clinic Innovation Exchange, detailed how Mayo is replicating, as close as possible, the capabilities of a brick-and-mortar hospital in its Advanced Care at Home Program.

"We saw this program as an opportunity to rethink the patient experience and reduce or even eliminate hospitalizations," said Kung. "When operationalizing the program, we took a step back and listened to the voice of the patient." Mayo Clinic believed that its program would not only address patient concerns and dissatisfiers but also reduce costs. This last goal was particularly important, considering the average cost of a three-day hospital stay is about $30 thousand and that 66 percent of all bankruptcies in the United States are tied to medical care, said Kung. To date, more than 1,000 patients have been admitted into the Advanced Care at Home Program and more than 3,000 bed days were saved.

The Institute then moved on to the most important voice at the table, when Adam Hayden—writer, speaker, and patient advocate—shared how genomic sequencing improved his quality of life after being diagnosed with brain cancer in 2016. Completing a patient's "genomic sequencing and then giving them that information is so important," he said, adding that it can help patients plan their lives. While patients may not be able to read lab results or interpret scans, Hayden shared: "We do know how we feel and how we want to feel."

He then discussed the need for multi-stakeholder engagement. "Being a patient is a job. We have responsibilities like completing insurance paperwork and applying for disability benefits. We [patients] are working together with providers in a therapeutic partnership."

Closing out the Institute for the Future of Oncology, attendees learned about several successful grant opportunities that required a partnership between clinicians, researchers, industry, and the federal government, including the National Institutes of Health's AIM-AHEAD Initiative. This initiative is dedicated to improving patient outcomes and their healthcare experience in the Appalachian Region through technology and data, with findings being shared with the broader oncology community. "We're here to talk about how a business plan with a contribution margin can save lives and ensure we are delivering value-based care," concluded Doug Flora, MD, LSSBB, executive medical director of Oncology Services at St. Elizabeth Cancer Center. OI

ACCC Welcomes its Newest Members

CoxHealth, Hulston Cancer Center
Springfield, Mo.
Delegate Rep: Lori Matthews, MBA
Website: coxhealth.com/our-hospitals-and-clinics/our-locations/hulston-cancer-center

Ivinson Memorial Hospital Meredith and Jeannie Ray Cancer Center
Laramie, Wyo.
Delegate Rep: Cheryl Rodgers, BSN
Website: ivinsonhospital.org/cancer-center

Central Georgia Cancer Care, P.C.
Macon, Ga.
Delegate Rep: Kevin Svoboda
Website: centralgacancercare.com

AdventHealth Cancer Institute Hinsdale
Hinsdale, Ill.
Delegate Rep: Kimberly Schram
Website: https://www.adventhealth.com/hospital/adventhealth-hinsdale/cancer-care

HIGHLIGHTS FROM ACCC 39TH NATIONAL ONCOLOGY CONFERENCE


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1. Approximately 500 cancer care professionals and industry attended the ACCC 39th National Oncology Conference (#ACCCNOC), Oct. 12-14, in West Palm Beach, Fla. During the opening keynote, attendees participated in a bias activity which revealed that innovations are not always the first ideas that come to mind.

2. Opening the meeting, innovation and tech-xpert Julie Holmes acknowledged that healthcare—especially oncology—is rife with competing demands that make it particularly challenging to engage oncology staff in innovation. Her message to attendees: even when your days are already packed, budgets are limited, and ideas are either non-existent or overwhelming, innovation is possible through "little big bangs" or micro-innovations.

3. Continuing the theme of innovation, Thursday morning's sessions featured presentations from the five 2022 ACCC Innovator Award winning programs. ACCC president David R. Penberthy, MD, MBA, (far left) and ACCC executive director Christian Downs, JD, MHA, (far right) pose with the 2022 ACCC Innovator Award presenters (left to right) Erin Heuser, MBOE, RT(R)(T), LSSBB, CCMP, senior process engineer at the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute; Zoe Larned, MD, system chair of Hematology & Oncology at Ochsner Health, Ochsner Cancer Institute; Morgan Nestingen, MSN, APRN, AGCNS-BC, NEA-BC, OCN, ONN-CG, director of nursing, Patient Intake and Navigation Services at Baptist Health's Miami Cancer Institute; Allison L. Held, JD, associate general counsel & director at Medical-Legal Partnership at VCU Health System, Virginia Commonwealth University Health System, VCU Massey Cancer Center; and Debra Delaney MSN, FNP-BC, primary care nurse practitioner at ChristianaCare's Helen F. Graham Cancer Center & Research Institute.

4. Friday morning's sessions kicked off with presentations from three ACCC Award Winners: 2022 Clinical Research Award recipient Carmen Guerra, MD, MSCE, FACP, the Ruth C. and Raymond G. Perelman Professor of Medicine at the Perelman School of Medicine at the University of Pennsylvania and vice chair of Diversity and Inclusion for the Department of Medicine and the associate director of Diversity and Outreach for the Abramson Cancer Center (left) and 2022 David King Community Clinical Scientist Award recipient Leana Cabrera Chien, MSN, RN, GCNS-BC, GNP-BC, a nurse practitioner at the City of Hope Center for Cancer and Aging (right). Not pictured is 2022 Annual Achievement Award recipient Lola A. Fashoyin-Aje, MD, MPH, a medical oncologist and deputy director in the Division of Oncology 3 in the Office of Oncologic Diseases at the U.S. Food and Drug Administration's Center for Drug Evaluation and Research.

5. After Friday's award presentations, meeting attendees attended concurrent sessions on a wide range of topics,including leveraging data analytics to mobilize the workforce and prepare for the future; preparing for population health in oncology; developing a leadership pipeline within cancer care teams; navigating the Great Resignation: rebuilding the oncology workforce; recruitment and retention of community-based general surgical oncology services; and more.

NOC Keynote Focuses on Innovation and Technology

During her keynote to the ACCC membership, innovation and tech-xpert Julie Holmes used live polling to engage with the audience, get to know who was in the room, and identify common challenges, including staffing and retention and recruitment, staff engagement and morale, fatigue and burnout, patient access to care, billing efficiencies, time constraints, and more.

To assist attendees in how to best approach innovation before putting solutions into action, Holmes shared some guiding principles she uses to identify and implement "little big bangs." First, and foremost, Holmes shared that everyone, everywhere needs to "take a time out." By not allowing the time and space to really step back from a problem and evaluate truly helpful solutions, you can stifle creativity. And by constantly being in a rush to complete your laundry list of work, you lose time in the day that could be dedicated to

Holmes' next lesson centered on bias—the beliefs, interpretations, assumptions, and stories that affect our daily lives and interactions. In an activity where Holmes asked audience members to "draw a flying horse," many sketched out a Pegasus, which is, in fact, a horse with wings. To drive her point home, Holmes shared that one's biases could be so clear they impacted this activity. While a Pegasus is quite literally "a flying horse," Holmes shared how more thoughtful (and perhaps easier) solutions to her direction would be drawing a horse with a cape or a horse on a plane. "We are burned by our bias," she said, adding that innovations aren't necessarily the first ideas that come to mind like the Pegasus mentioned above. Instead, the more thoughtful solutions are often creative, potentially resource saving, and may better address challenges in the long term.

Finally, Holmes shared how technology—even simple technology that auto populates and automates tedious staff processes and workflows—is often the answer to the problem. With the question, "What are you asking your staff to repeat?" Holmes challenged attendees to re-evaluate their daily processes to think about how technology could be used to ease workloads and effectively address morale and burnout rates. Additionally, Holmes suggested that everyone "stretch their tech," meaning that they look at what technology is already in use but isn't being utilized to its full potential. This could mean dedicating staff members to specialize in specific platforms, who can address how new features can be used to innovate care delivery. When implementing these practices, Holmes emphasizes the need to adjust for the future and announce these "little big bangs" in advance (before applying them into practice). This will ensure the successful implementation of any innovation.

Holmes closed with this uplifting message, "Innovation is viable and attainable," she said. "Your teams have incredible ideas if you give them the space to innovate."

Continuing the theme of "Innovation," the rest of the morning's sessions featured presentations from the five 2022 ACCC Innovator Award winners.

Expressing Life's Inexplicable Events Through Art

BY SUSAN PATRICIA COOPER, ATR-BC, LCAT

White Plains Hospital, Center for Cancer Care is a comprehensive, community-based outpatient cancer center located in White Plains, N.Y. In 2018, a part-time art therapist position was added to the cancer program's existing Integrative Services department. As the hired art therapist, I offered a range of activities through group and individual sessions in the cancer center's infusion suite, main conference room, and (a few times a week) main lobby. Initially, I supervised several volunteers and students, who assisted with organizing supplies, creating sample projects, and providing general support to the program.

Then, in March of 2020 with the emergence of the novel corona virus (SARS- CoV-2), the volunteer program was paused hospital-wide for the unforeseeable future. During this time, the cancer center restricted visits from family members and caregivers, who previously accompanied patients to their appointments. Suddenly, patients were required to visit the cancer center alone for treatment—while many were also experiencing prolonged isolation from their friends and family throughout their daily lives.

In response to these and other restrictions during the COVID-19 pandemic, the art therapy program at White Plains Hospital underwent several adaptations to continue offering therapeutic art making opportunities for both patients and caregivers. These adaptations included incorporating iPad painting for patients receiving infusions and the development of a yearly calendar for the cancer center, featuring and celebrating the art and craft work of patients and families. These innovations allowed our patients to continue to be involved in a creative process that is adjunctive and complementary to their medical treatments.

How Art Therapy Can Help

In response to the difficulties that occur in life, art and other creative pursuits can act as tools to express what might not always be available in language. The arts offer us the ability to communicate what is important, give a voice to express our experiences, and provide solace in times of duress.

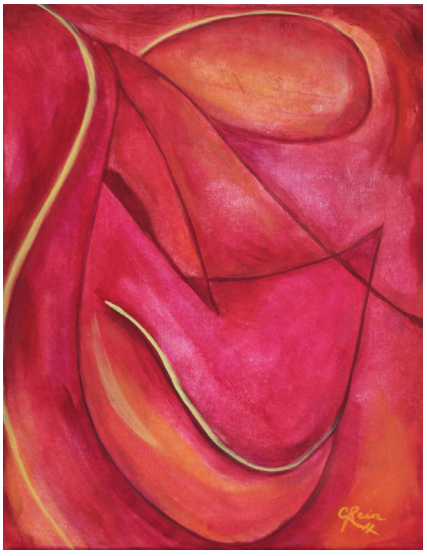
During the initial phase of the COVID-19 shutdown, many patients either returned to previous hobbies or started exploring ways to occupy their time when they were not able to socialize, travel, or go to the grocery store. I had ongoing discussions with patients around developing new interests or returning to previous hobbies to reduce stress and build an ongoing, relaxing experience that would provide respite and encourage self-care during this time.

While many of the events that occur in life are beyond our control, there are ways in which we can modify how we respond. My focus as a creative arts therapist is to emphasize an individual's strengths,

Seashells by Vincenzo
"I take walks in the morning to collect branches to carve and paint into walking sticks, and I create assemblages with seashells."

Rabbit Looking at a Butterfly by Lou
"I started painting while my wife was receiving treatment. It helped both of us to have something to focus on and talk about."

Campanula by Aurora
"These Campanula bloomed for the first time in my spring COVID-19 garden and filled me with hope."



Calm and Concern (left) and *Rise and Reach* (right) by Carmen
"Painting reduces stress for me. These pieces came through me trying to sleep and worrying and not worrying. That's where these two paintings come from. One is *Calm and Concern*, a dichotomy that is likely in all of us. The other is *Rise and Reach*, about moving on."

interests, abilities, and what is personally meaningful to them by engaging in purposeful activities. These activities can add meaning to life amid a serious illness and concurrent global pandemic.

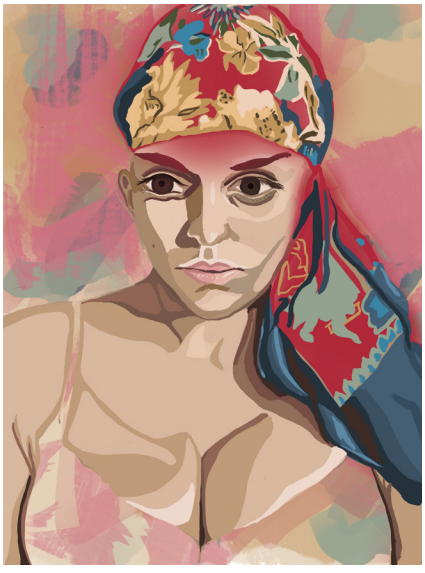
White Plains Hospital's Annual Calendar

Titled "The Art of being Exceptional," this calendar is created using images submitted by patients, caregivers, and family members. The artwork is accompanied by statements and thoughts from the contributing artist about what inspired the project and/or image. Prior to the start of 2022, the calendar was disseminated throughout the hospital and cancer center and to staff and patients. To increase community involvement, the annual calendar was shared widely with extended family and others in the community.

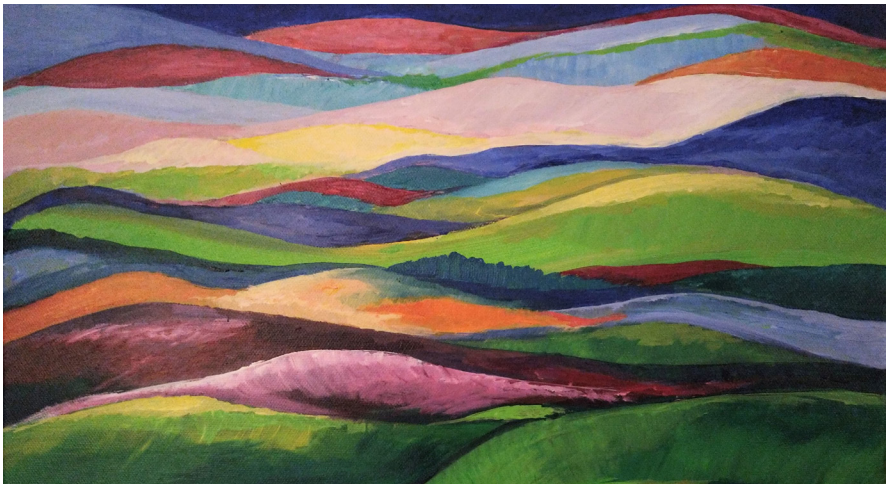
I hope readers enjoy the featured artwork as much as our staff, patients, and community. The narratives shared from the contributing artists contain much that pertains to the human condition and helps explain why humans have created visual symbols (art) since the era of cave painting. The experience of making art can deepen the understanding of ourselves, our relation-

Magnolia by Carol
From the family: "Being included in this calendar meant so much to our mother. Her art inspired and supported her both through her illness and through COVID-19. She discovered she could still learn to grow and surprise herself, even later in her life and with all the losses that she'd experienced. She was so very proud of this newly discovered talent and so motivated to see what she was capable of and to share her gift with friends and family."

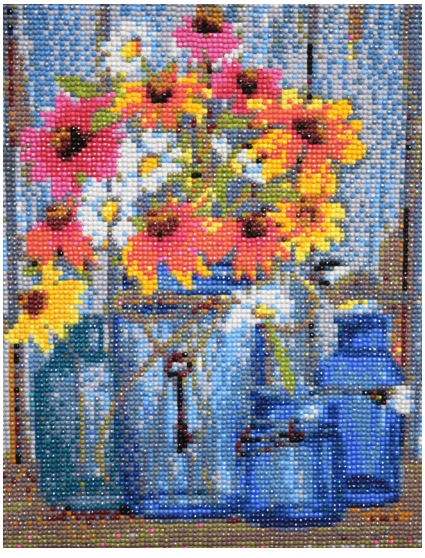
Winter by Miquel
"Paint is a very good medium for distraction...[from] your illness. You can imagine anything, a winter scene, a placid beach, or [an] abstract painting. You make an effort to forget your condition for a few hours and, at the end, you will see the results."



Digital iPad Self Portrait by Taylor
"Creating art took away the pain and side effects I felt from chemo[therapy] and gave me something to look forward to."



Dream Terrains by Miriam
"I'm hoping to visit Ireland someday. I created this abstract landscape as a reminder of my dream and an escape to a different reality where I don't have restrictions and diagnoses—only the freedom to run freely on fresh colorful grass."



Still Life with Flowers by Barbara
"Craftwork and using color in painting can put your mind at ease."

ships, nature, and the world, including a global pandemic and cancer diagnosis.

Susan Patricia Cooper, ATR-BC, LCAT, is a licensed creative arts therapist at the White Plains Hospital, Center for Cancer Care in White Plains, N.Y. She is also a practicing and exhibiting artist, which she has found to be personally important to her understanding of art's function as a tool for visual and symbolic expression that can circumvent the limitations of language. Susan works with patients both individually and in groups, where a range of creative arts activities are utilized to promote personal exploration, stress alleviation, choices, a sense of control, and emotional resilience within a psychotherapeutic relationship. She has worked in hospital and outpatient settings for more than 25 years with both adults and children with medical and mental health challenges.