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ONCOLOGY ISSUES

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

Vol. 36 | No. 4 | 2021

This Lyrical Life

Music therapy in oncology

ACCC
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CONGRATULATIONS
2021 ACCC INNOVATOR AWARD RECIPIENTS

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DEPARTMENTS

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ONCOLOGY ISSUES
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FROM THE EDITOR

The Masking Conundrum

BY SIBEL BLAU, MD

The COVID-19 virus entered our lives quickly, and almost no one could have predicted that several vaccines would be available less than a year after the public health emergency was declared. After the U.S. Food and Drug Administration issued the first emergency use authorization on Dec. 11, 2020, many Americans rushed to get in line for the first vaccine. While there was much concern that there would not be enough vaccine, almost half of the population was vaccinated by the spring of 2021. However, patient demand dropped considerably. To increase vaccination rates, federal and local governments asked clinicians to give and encourage vaccines in their clinics. Though many oncologists joined this effort, we also saw a decline in patient demand. We find ourselves now explaining the importance of the vaccine, as well as the benefits and risks.

The Quality Cancer Care Alliance Network (QCCA) held its biannual meeting on May 14, the day after the Centers for Disease Control and Prevention issued new guidelines on mask use, which stated that vaccinated individuals could remove their masks inside or outside—regardless of group size. However, masking is a more nuanced issue for immuno-compromised individuals, like patients with cancer. Vaccines are highly effective, but they are not 100 percent effective. Further, not all immuno-compromised vaccinated individuals are developing enough immunity. Data on how vaccinated patients with cancer will fare are not well understood because accrual of these patients to vaccine clinical trials was extremely low.

During the QCCA meeting, we listened to experts in the field of infectious disease and vaccine development, as well as an update from the COVID-19 and Cancer Consortium. It is clear from the Consortium's huge data set that patients with cancer are at a higher risk of mortality from COVID-19. Moreover, some patients with cancer are very immuno-compromised, and their responses to the vaccine may be inadequate.

Though many Americans are happy to stop wearing masks and resume pre-pandemic activities, others are wary about going out in public without a mask because so many people are still not vaccinated. The level of uncertainty and stigma that can arise from wearing a mask—whether it implies one is not vaccinated or that one is worried about infection—creates a social dilemma.

Many patients ask when masking requirements will be relaxed or withdrawn at our practice. Some cancer care team members feel the same way. At QCCA, our practices came together to respond quickly to these questions. Until herd immunity is achieved and the rates of infection drop to a very low level in the community, we must continue to protect the most vulnerable, including our patients with cancer and others who are deeply immuno-compromised.

The oncology community made real-time adjustments to mask policies throughout the pandemic as we learned more about COVID-19. We now face another challenge. And this social and emotional challenge must be answered in a scientific and practical manner. Now is not the time to let our guard down. Instead, we must be methodical about developing new ways and policies to prevent infection among our patients with cancer. The message we need to communicate to our patients and staff is simple: we care for our most vulnerable citizens whose immune systems may not be robust enough to overcome a COVID-19 infection—despite vaccination. The oncology community must put in place special guidelines for these patients, and it is our job as oncology providers to do so swiftly. OI

Choose Gratitude

BY KRISTA NELSON, MSW, LCSW, OSW-C, FAOSW

I want to start my second column by saying, "Thank you." A strength and a reason I love ACCC is because we are a community of people caring for those with cancer and their families. I am more aware than ever of all of the individuals, disciplines, and roles it takes to ensure that these patients and families have access to comprehensive cancer care services. Each of you is important, and I want to thank you for your efforts. As ACCC President, I am thrilled to represent all members of the multidisciplinary cancer care team—across all clinic sites.

Whether you provide care at an academic program, community cancer center, or physician practice, you have experienced great suffering this past year. *Burnout. Exhaustion. Fatigue. Stress.* These were the words most frequently used by your colleagues who participated in the ACCC *Trending Now in Cancer Care 2020* focus groups.

So, what can ACCC do to help?

On May 24, I held my first Coffee Chat with new ACCC Delegate Representatives from across the country. Not surprising, one theme that emerged during our informal conversation was an overall feeling of distress in cancer program leaders and staff. Though some hesitate to share this emotion in front of colleagues, as a clinician, I believe that we must acknowledge this grief before we can heal from the challenges of the past 12 months. One way to heal is to connect with others who shared the same experience and who have come out stronger on the other side.

Another key finding in ACCC's *Trending Now in Cancer Care 2020* report is that cancer care staff showed great resilience during the global pandemic. From this resiliency came new ways of delivering care to patients, strategies to improve processes and workflows, and innovative ways to support colleagues. What better way to share these successes than during a virtual Coffee Chat with other ACCC members? Sign up for the next one today by emailing lgardner@accc-cancer.org.

If a Coffee Chat is not your "cup of tea" (excuse the pun), then join me for a Mindfulness Meditation. To help members of the cancer care team better manage stress and improve their overall well-being, ACCC is developing a Mindfulness Meditation series that will start at the end of June and run throughout my tenure as ACCC President. For more information about these opportunities to connect personally with others in the ACCC community, log on to accc-cancer.org/home/learn/presidents-theme.

Personally, I have come to realize that the COVID-19 pandemic magnified my awareness of the community I have served over the past decades. Living with uncertainty became a lens that I looked through this past year. In an online support group for people with advanced cancer, one member shared that though they felt like others now had a sense of what it was like to live with uncertainty, they were also aware that eventually things would go back to normal for most people. For others, especially patients with cancer, when the threat of COVID-19 is over, the uncertainty remains.

Recently, I have been working with a young man who was told that there are limited options for him to fight his cancer. This patient has gone through two stem cell transplants; his providers have tried multiple treatments. Nothing has kept his cancer from returning. Watching this young man embrace the uncertainty of when he will die—knowing that his cancer will take his life—has been an honor for me. We can learn so much from the strength of those we serve.

I share his story because it is why we do what we do. We are present with people in their most vulnerable moments and witness not only the suffering but the joy that those individuals with cancer bring to everyone around them. We may not be able to "fix" their problems, but we celebrate their moments of happiness and offer support during the difficult times.

For me, looking for things to be grateful for is one of the ways that I cope during hard times. June is National Cancer Survivor Month and an opportunity to be grateful for and celebrate the nearly 17 million cancer survivors across the country. I am also grateful to you—my colleagues—for supporting these 17 million cancer survivors.

Join me and choose gratitude. It's a wonderful and healthy place to be. OI

Coming in Your 2021 *ONCOLOGY ISSUES*

- Integrating Spiritual Care in the Outpatient Oncology Setting
- Use of Pharmacy Informatics to Standardize Pharmacist Review of Oral Oncolytic Medications for Hospitalized Patients
- Medication Transitions in Patients with Hematologic Malignancy at a Safety Net Hospital
- Timing Distress Screening in Surgically Resectable Esophageal Cancer
- An Investigation of Self-Determined Work Motivation Among Young Adult Central Nervous System Cancer Survivors
- Improving Oncology Nurse Knowledge of Delirium Through an Interprofessional, Patient-Centered Simulated Case Scenario
- Mixed-Method Study Examining Initial Interactions of Oncology Patients with Multidisciplinary Cancer Care
- A Virtual Integrative Oncology Program Supports Patients with Cancer Throughout the Treatment Continuum
- A Model for Integrating APPs in a Radiation Oncology Satellite Clinic
- Creating an Oncology Practice That Can Change Through the Times
- A Computerized Population Tracking System to Support Colon Cancer Survivorship
- Cannabis in Cancer Research and Patient Education Clinic

more online @ accc-cancer.org

PUBLICATION

Shared Decision-Making: Effective Practices for Optimal Patient Engagement

Patients who are actively involved in making treatment decisions are more likely to be confident about their choices, satisfied with their treatment, and trust their providers. This ACCC publication identifies a wide range of methods for building engagement with patients, with a special focus on shared decision-making in the context of metastatic disease, geriatric oncology, and limited health literacy. accc-cancer.org/shared-decision-making.

BLOG

New Patient Education Tools for Skin Cancer Awareness

Patient information on advanced skin cancers is not readily available, leading to confusion for newly diagnosed patients. To help the Cancer Support Community released two patient guides for talking to physicians about treatment options for skin cancer, including questions for patients to ask their dermatologist and oncologist about their disease; patient tips for taking control of their care; information about side effects; contact information for financial and community support; and lists of suggested questions to help patients determine their personal and treatment goals. Read more at accc-cancer.org/skincare-awareness-month.

RESOURCE

Geriatric Oncology Gap Assessment Tool

ACCC's evidence-based Geriatric Oncology Gap Assessment covers nine domains: functional status; cognition; comorbidities; decision making; pharmacy and medication management; psychological health; nutrition; patient goals and needs; and communication and workforce training. After taking the assessment, cancer programs receive a personalized report with scores in each domain, as well as an aggregate score. With this report, cancer programs can then develop short- and long-term improvement goals. accc-cancer.org/gerigap.

PODCAST

Two CANCER BUZZ Podcasts Explore the Impact of COVID-19

As a follow up to ACCC's *Trending Now in Cancer Care 2020* report, Douglas B. Flora, MD, LSSBB, shares how the pandemic impacted his cancer program in Kentucky, including lower patient volumes, declines in screening interventions, and decreased revenue. Then listen to Una Hopkins, RN, FNP-BC, DNP, talks about the dramatic changes in care delivery that New York City's Montefiore Health System underwent during the pandemic, lessons learned along the way that can help pave the way forward, and how the spirit of collaboration and innovation that emerged in 2020 will remain long after the pandemic. Find both podcasts at accc-cancer.org/podcast.

fast

Has COVID-19 Put Older Adults at Increased Risk of Cancer?

Cancer screening, diagnosis, and treatment for older adults dropped considerably in 2020, including:

- An **85%** decline in breast cancer screenings.
- A **75%** decline for colon cancer screenings.
- While data has shown an improvement in cancer screening rates, average screening rates for the top **4** cancer types remain down **25%** across the country.

Source. Patt D, Gordan L, Diaz M, et al: The impact of COVID-19 on cancer care: how the pandemic is delaying cancer diagnosis and treatment for American Seniors. *JCO Clin Cancer Informatics*. DOI: 10.1200/CCI.20.00134.

ASCO Post-Pandemic Telemedicine Recommendations

- Ensure robust reimbursement and coverage of telemedicine at the state and national level.
- Develop new products to inform guidelines, standards, and models that improve the quality of care.
- Create training for providers on delivering high-quality cancer care via telemedicine.
- Develop new measures to assess the quality of telemedicine and adapt existing ones to reflect the virtual delivery of care.

Source. ASCO. Road to Recovery Report: Learning from the COVID-19 Experience to Improve Clinical Research and Cancer Care. Available online at http://bit.ly/ASCO-R2R.

facts

No Relief from Prior Authorizations

Almost **70%** of 1,000 practicing physicians reported that health insurers had either reverted to past prior authorizations policies or never relaxed these policies in the first place during COVID-19. More than **9** in **10** physicians (**94%**) reported care delays while waiting for health insurers to authorize necessary care, and nearly **4** in **5** physicians (**79%**) said patients abandon treatment due to authorization struggles with health insurers. Other critical physician concerns:

- **9** in **10** physicians (**90%**) reported that prior authorizations have a negative impact on patient clinical outcomes.

- A significant majority of physicians (**85%**) said the burdens associated with prior authorization were high or extremely high.
- Medical practices complete an average of **40** prior authorizations per physician, per week, which consume the equivalent of two business days (**16** hours) of physician and staff time.
- To keep up with the administrative burden, **2** out of **5** physicians (**40%**) employ staff members who work exclusively on tasks associated with prior authorization

Source. A December 2020 survey by the American Medical Association. ama-assn.org/system/files/2021-04/prior-authorization-survey.pdf.

About 3 in 10 healthcare workers have considered no longer working in healthcare because of the COVID-19 pandemic.

Washington Post-Kaiser Family foundation poll. washingtonpost.com/health/2021/04/22/health-workers-covid-quit.

Nutrition Expert Shares 5 Tips for "Burning off" the Pandemic

1. Perform a 15 to 20-minute meditation first thing in the morning to reduce stress and stress-related hormones.
2. Do 3 sessions per week of deep yoga breathing to increase habitual breathing volume, oxygenate the body, and provide the necessary oxygen to help burn fat.
3. Set a proper sleep schedule. A full 8 hours of sleep can burn between 400-700 calories.
4. Eat more protein and fewer carbohydrates.
5. Lift weights three times per week.

Source. Paul Jenkins, qualified chemist, sports coach, nutritionist, and founder of DNA Lean. dna-lean.co.uk/blogs/news.

The Need for Increased Access to Genetic Counselors

BY KRISTIN MARIE FERGUSON, DNP, RN, OCN

Precision medicine uses information about a person's own genes, proteins, and personal environment to prevent, diagnose, and treat cancer. The same type of cancer can be different from person to person, depending on genetic variability. For years scientists have tried to determine why some patients respond to certain treatments whereas others with the same diagnosis do not respond to the same treatment. There are many factors to consider, but looking at both hereditary genetics and tumor DNA sequencing (i.e., biomarkers) is essential for oncology teams to tailor patient treatment recommendations and achieve the best potential outcomes.

About 5 to 10 percent of all cancers are attributed to inherited variants. Genetic counselors work in and with cancer programs to:

- Meet with patients and educate them about potential benefits, risks, and limitations on genetic testing.
- Order testing best suited for a specific diagnosis and patient.
- Communicate genetic testing results to both patients and providers.

Not every person with cancer requires genetic testing, but those who do benefit from meeting with certified genetic counselors (CGC®)—experts with advanced training in offering comprehensive genetic counseling services. As with many healthcare services, insurance only covers genetic testing if the payer deems it "medically necessary."

Currently, the Centers for Medicare & Medicaid Services only covers genetic testing for a known mutation in a family if an individual has "signs and/or symptoms of cancer. Testing of an unaffected Medicare eligible individual or family member is not a covered Medicare benefit."[1] To many in the cancer advocacy community, it is unacceptable that individuals with Medicare who have a relative with the BRCA1 or BRCA2 gene mutation with breast, ovarian, pancreatic, or prostate cancer cannot get their genetic testing covered until they have a diagnosis of cancer themselves—especially considering that risk reduction strategies, such as increased screening, chemoprevention, and risk-reducing surgeries can be performed.

Currently, Medicare does not cover testing for patients without signs and symptoms of breast or ovarian cancer. Though some people who are positive for BRCA1 or BRCA2 variants never develop breast cancer, there is an increased risk. Consider these data: 13 percent of women in the general population will develop breast cancer in their lifetime.[2] By contrast, between 55 and 72 percent of women who inherit a BRCA1 variant and 45 to 69 percent of women who inherit a BRCA2 variant will develop breast cancer by age 70 to 80.[2]

Recent Legislation Impacting Access to Genetic Counselors

The National Comprehensive Cancer Network recommends genetic testing services for patients with many cancer types. Earlier this year, S.1450/H.R. 2144 were introduced in both the Senate and House to increase access to genetic counseling for Medicare beneficiaries. ACCC, along with other stakeholders, signed a letter of support for this legislation, which would recognize certified genetic counselors as healthcare providers, giving beneficiaries improved access to the services these professionals provide. Currently, genetic counselors must provide services under "direct" supervision, which means that genetic counselors are only available to beneficiaries when they are supervised by a Medicare-certified healthcare provider (i.e., physician or nurse practitioner). This legislation would allow genetic counselors to bill Medicare directly and be reimbursed for their services at 85 percent of physician billing.

Trends Impacting Access to Genetic Counseling

Currently the Government Accountability Office estimates that there are about 4,700 genetic counselors and 1,240 medical geneticists certified to provide care in the United States.[3] Though both numbers have increased in recent years, many have raised concerns about whether there are enough providers to meet current and future demand for genetic testing and counseling services. A map on the Government Accountability Office website shows the distribution of genetic counselors per 500,000 people by state in 2019, and several states have three or fewer trained genetic counseling staff per 500,000 people (see Figure 1, right).[3]

Telehealth expansion prompted by the COVID-19 pandemic has increased the availability and job satisfaction of genetic counselors in many areas, as well as increased access in rural areas where physically seeing a genetic counselor in

person is more difficult due to travel time and specialist availability. Many cancer advocates are hopeful that telehealth services for genetic counseling will continue to be reimbursed to maintain and potentially improve access to these services in the future.

Another factor affecting patient access: currently, only 27 states issue licenses for genetic counselors.[4] According to the Centers for Disease Control and Prevention, "State licensure ensures that genetic counselors who are trained through accredited programs and are certified through the American Board of Genetic Counseling are able to provide genetic counseling and order genetic testing."[4] The National Society of Genetic Counselors has a state licensure map on its website and notes that many states are making progress in advancing state licensure.[5]

An increased focus on workforce growth, state licensure, and reimbursement for genetic counseling services is needed to continue to advance precision medicine and quality oncology care. Please feel free to email me at KFerguson@accc-cancer.org about any workforce, reimbursement, or cancer care delivery trends you are seeing. I look forward to hearing your thoughts and learning more about how ACCC can play a role. OI

Kristin Marie Ferguson, DNP, RN, OCN, is senior director, Cancer Care Delivery & Health Policy, Association of Community Cancer Centers, Rockville, Md.

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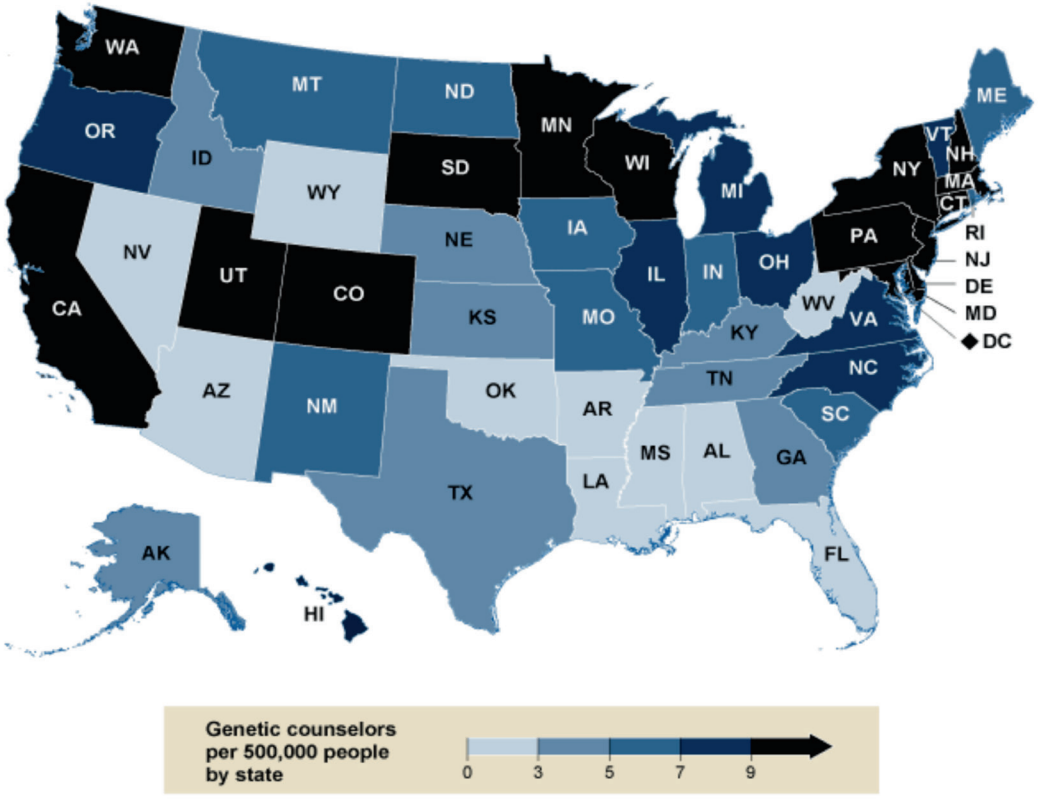
Figure 1. Geographic Distribution of Genetic Counselors



Source: GAO analysis of data from the American Board of Genetic Counseling and Census Bureau: Map Resources | GAO-20-593

Telehealth After the Public Health Emergency

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

Though the current public health emergency (PHE) is anticipated to be extended through the end of 2021 by Health and Human Services Secretary Xavier Becerra, the fate of telehealth after the PHE remains a concern for providers. The most recent extension of the PHE signals the Centers for Medicare & Medicaid Services' (CMS) intent to continue the extensions and waivers for beneficiaries initiated in March and April 2020. Even with the understanding that telehealth reimbursement may remain status quo for the rest of the year (for CMS at least), many questions remain.

- What happens after the PHE ends?
- Will CMS still cover telehealth services for beneficiaries as it did during the PHE?
- What about private payers—are they even covering telehealth services in 2021?
- What about after 2021? How do providers prepare for what is coming next for telehealth?

Some of these questions may be answered through federal legislation—with the reintroduction of two bills that appear to have some traction to move forward.

The first is the Telehealth Modernization Act, S.368.[1] This rather brief bill focuses primarily on the continuation of certain waivers and extensions established in response to COVID-19 relief. If passed, this bill would allow rural health clinics and federally qualified health centers to be designated as "distant sites," the location where the physician is present for the telehealth visit. Additionally, this bill would allow for the patient's home to serve as an originating site—for all services not just specifically designated ones—and for all types of practitioners to be able to furnish telehealth services as defined by CMS. This bill was one of two keys "asks" at the May 12 ACCC Virtual Hill Day (read more on page 83).

The CONNECT for Health Act of 2021 is a similar but more comprehensive bill originally introduced in October 2019.[2] Similar to the Telehealth Modernization Act, the CONNECT for Health Act proposes to remove all geographic restrictions for telehealth services and expand sites that can be designated as originating sites. The bill also addresses how to report telehealth services and how to monitor for fraud and abuse and expands the healthcare professionals permitted to provide telehealth services.

If either of these bills is passed into legislation, it would expand telehealth services beyond the PHE and more closely mirror services allowed during the pandemic. But a big question remains: what about private payers?

Several state governors established regulations directing private payers operating within their states to cover telehealth services beyond the federal requirements. To know what states designated telehealth service coverage—and the status of these designations—one must review every state's guidelines and all contracted payers. Providers can begin their search by reviewing the information provided by the Center for Connected Health Policy at cchpca.org. This organization's interactive website provides information at various levels, including private payers at the state level and their associated telehealth policies updated as of Feb. 28, 2021. For example, the Center for Connected Health Policy indicates that the state of California established access to telehealth services and this access is active until the end of the California state of emergency.[3] In the state of Colorado, coverage of telehealth services has expired.[3] Generally, at the state level, it appears that if telehealth services are still covered, that coverage ends either at the end of the state's PHE or at the end of the federal PHE.

Prior to the pandemic most private payers provided some type of coverage for telehealth services. Many of these payers looked to CMS to establish a baseline or standard from which the private payers have built their policies. Below is information from a recent website review of the top private payers to help understand how they are addressing ongoing coverage for telehealth services:

- **United Healthcare (UHC).** According to its website, UHC will reimburse appropriate claims for telehealth services in accordance with a member's benefit plan. Some markets and plans may also match the waiver on the originating site requirements to those currently in effect by CMS. More information from UHC can be found at uhcprovider.com/en/resource-library/news/Novel-Coronavirus-COVID-19/covid19-telehealth-services.html.

- **Humana**. At a minimum, Humana is following CMS telehealth guidelines or state-specific requirements for telehealth coverage for the duration of the PHE. Learn more at humana.com/provider/coronavirus/telemedicine.
- **Cigna**. According to its website, Cigna established a Virtual Care Reimbursement Policy, which went into effect Jan. 1, 2021. This policy includes services such as routine checkups, general wellness visits, new patient exams, and behavioral assessments—all provided virtually. More information about Cigna's telehealth coverage can be found online at static.cigna.com/assets/chcp/resourceLibrary/medicalResourcesList/medicalDoingBusinessWithCigna/medicalDbwCVirtualCare.html.
- **Blue Cross Blue Shield Association (BCBS)**. This association includes a system of 35 independent, locally operated companies. To understand telehealth service coverage in any given state, one must review each BCBS company separately. BCBS does provide an interactive map to help you access the appropriate contact for a given state at bcbs.com/coronavirus-updates.
- **Aetna**. Per the Aetna website, this payer is encouraging the use of telehealth visits to limit exposure. Some of the cost share waivers ended Jan. 31, 2021, but other coverage components may be available, depending on the member's plan. Aetna provides a COVID-19: Telemedicine FAQs site, which provides updates to coverage for patients at aetna.com/health-care-professionals/covid-faq/telemedicine.html#acc_link_content_section_responsivegrid_responsivegrid_accordion_1.

Knowing for certain what any private payer will do post-PHE or in the years to come is anyone's guess. Ask healthcare professionals or patients and they will likely say they believe that telehealth services are here to stay—in some form or fashion. Though telehealth existed prior to the COVID-19 pandemic, the experiences during the PHE have given a light and direction to where healthcare is going, including telehealth post-PHE. Two big questions remain. From a payment perspective, what value do payers (public and private) place on telehealth? How do we ensure equitable access to technology needed to provide telehealth—for providers and patients alike? OI

Teri Bedard, BA, RT(R)(T), CPC, is executive director, Client & Corporate Resources, Revenue Cycle Coding Strategies, Cedar Park, Tex.

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3. Center for Connected Health Policy. Policy Finder. Available online at: cchpca.org/all-telehealth-policies. Last accessed June 21, 2021.

tools

Approved Drugs

- On Mar. 26, the U.S. Food and Drug Administration (FDA) approved **Abecma® (idecabtagene vicleucel)** (Bristol Myers Squibb and bluebird bio, bms.com and bluebirdbio.com) for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.
- On Apr. 6, the FDA approved a new dosage regimen of 500 mg/m^2 as a 120-minute intravenous infusion every two weeks for **Erbitux® (cetuximab)** (Eli Lilly, lilly.com) for patients with K-Ras wild-type, epidermal growth factor receptor (EGFR)-expressing colorectal cancer or squamous cell carcinoma of the head and neck.
- On Apr. 22, the FDA granted accelerated approval to **Jemperli (dostarlimab-gxly)** (GlaxoSmithKline, us.gsk.com/en-us) for patients with recurrent or advanced endometrial cancer that has progressed on or following prior treatment with a platinum-containing chemotherapy and whose cancers have a specific genetic feature known as dMMR, as determined by an FDA-approved test.
- On May 5, the FDA granted accelerated approval to **Keytruda® (pembrolizumab)** (Merck, merck.com) in combination with trastuzumab and fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma.
- On May 28, the FDA granted accelerated approval to **Lumakras™ (sotorasib)** (Amgen, amgen.com) for adult patients with KRAS G12C mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.
- On Apr. 16, the FDA approved **Opdivo® (nivolumab)** (Bristol Myers Squibb, bms.com) in combination with certain types of chemotherapy for the initial treatment of patients with advanced or metastatic gastric cancer, GEJ cancer, and esophageal adenocarcinoma. On May 20, the FDA approved Opdivo for patients with completely resected esophageal or GEJ cancer with residual pathologic disease who have received neoadjuvant chemoradiotherapy.
- On May 21, the FDA approved **Rybrevant™ (amivantamab-vmjw)** (The Janssen Pharmaceutical Companies of Johnson & Johnson, janssen.com) for adult patients with NSCLC whose tumors have specific types of genetic mutations: EGFR exon 20 insertion mutations.
- On Mar. 31, the FDA approved **Sarclisa® (isatuximab-irfc)** (Sanofi Genzyme, sanofi.com/en) in combination with carfilzomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.
- On Apr. 7, the FDA granted regular approval to **Trodelvy® (sacituzumab govitecan-hziy)** (Gilead, gilead.com) for patients with unresectable locally advanced or metastatic triple-negative breast cancer who have received two or more prior systemic therapies, at least one of them for metastatic disease. On Apr. 13, the FDA granted accelerated approval to **Trodelvy** for use in adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and either a programmed death receptor-1 or a programmed death-ligand 1 inhibitor.
- On May 28, the FDA granted accelerated approval to **Truseltiq (infigratinib)** (QED Therapeutics, Inc., qedtx.com) for adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 fusion or other rearrangement as detected by an FDA-approved test.
- Jazz Pharmaceuticals (jazzpharma.com) announced that the FDA approved a revised label for **Vyxeos® (daunorubicin and cytarabine)** to include a new indication to treat newly diagnosed therapy-related acute myeloid leukemia or acute myeloid leukemia with myelodysplasia-related changes in pediatric patients aged one year and older.

- On Apr. 23, ACD Therapeutics (ir.adctherapeutics.com) announced FDA approval of **Zynlonta™ (loncastuximab tesirine-lpyl)** for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma not otherwise specified, diffuse large B-cell lymphoma arising from low grade lymphoma, and high-grade B-cell lymphoma.
- On May 13, Heron Therapeutics, Inc. (herontx.com) announced that the FDA approved **Zynrelef™ (bupivacaine and meloxicam)** extended-release solution for use in adults for soft tissue or periarticular instillation to produce post-surgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy, and total knee arthroplasty.

Drugs in the News

- AffyImmune Therapeutics, Inc. (affyimmune.com) announced that the FDA granted fast track designation to **AIC100** for the treatment of anaplastic thyroid cancer and refractory poorly differentiated thyroid cancer.
- Agenus Inc. (agenusbio.com) announced the submission of a biologics license agreement (BLA) to the FDA for the accelerated approval of **balstilimab (AGEN2034)** for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.
- Amgen (amgen.com) announced that the FDA granted breakthrough therapy designation to **bemarituzumab (anti-FGFR2b)** as first-line treatment for patients with fibroblast growth factor receptor 2b (FGFR2b) overexpressing and human epidermal growth factor receptor 2-negative metastatic and locally advanced GEJ adenocarcinoma in combination with modified FOLFOX6 (fluoropyrimidine, leucovorin, and oxaliplatin), based on an FDA-approved companion diagnostic assay showing at least 10 percent of tumor cells overexpressing FGFR2b.
- BeiGene, Ltd. (beigene.com) announced that the FDA accepted a supplemental new drug application (NDA) and granted priority review to **Brukinsa® (zanubrutinib)** for the treatment of adult patients with marginal zone lymphoma who have received at least one prior anti-CD20-based therapy.
- Foresee Pharmaceuticals (foreseepharma.com/en-us/index) announced that the FDA approved the NDA for **Camcevi® (leuprolide)** as a treatment for advanced prostate cancer.
- Legend Biotech Corporation (legendbiotech.com) announced that the FDA accepted for priority review the BLA submitted by the Janssen Pharmaceutical Companies of Johnson & Johnson (janssen.com) for **ciltacabtagene autoleucel (cilta-cel)**, an investigational B-cell maturation antigen-directed chimeric antigen receptor T-cell therapy.
- Immutep Limited (immutep.com) announced that it received FDA fast track designation for **eftilagimod alpha (IMP321)** for first-line recurrent or metastatic head and neck squamous cell carcinoma.
- Taiho Oncology, Inc. (taihooncology.com) announced that the FDA granted breakthrough therapy designation for **futibatinib (TAS-120)** for the treatment of patients with previously treated locally advanced or metastatic cholangiocarcinoma harboring FGFR2 gene rearrangements, including gene fusions.
- Merck (merck.com) and Eisai Inc. (eisai.com/index.html) announced that the FDA has accepted and granted priority review for applications seeking two new approvals for the combination of **Keytruda® (pembrolizumab) plus Lenvima® (lenvatinib)** for the first-line treatment of patients with advanced renal cell carcinoma.
- Takeda Pharmaceutical Company Limited (takeda.com) announced that the FDA accepted an NDA and granted priority review to **maribavir** for the treatment of post-transplant cytomegalovirus infection in those that are refractory, with or without resistance, in solid organ transplant or hematopoietic cell transplant recipients.
- Mustang Bio, Inc. (mustangbio.com) announced that the FDA accepted its investigational NDA for **MB-106**, a CD20-targeted chimeric antigen receptor T-cell therapy for relapsed or refractory CD20+ B-cell non-Hodgkin's lymphoma and chronic lymphocytic leukemia.
- Takeda Pharmaceutical Company Limited (takeda.com) announced that that the FDA granted priority review to the NDA for **mobocertinib (TAK-788)** for the treatment of adult patients with epidermal growth factor receptor Exon20 insertion mutation-positive (insertion+) metastatic NSCLC, as detected by an FDA-approved test, who have received prior platinum-based chemotherapy.
- Bristol Myers Squibb (bms.com) announced that the FDA accepted the supplemental BLA for **Opdivo® (nivolumab)** for the adjuvant treatment of patients with surgically resected, high-risk muscle-invasive urothelial carcinoma.
- Astellas Pharma Inc. (astellas.com) and Seagen Inc. (seagen.com) announced FDA acceptance and priority review for two supplemental BLAs for **Padcev® (enfortumab vedotin-ejfv)** in locally advanced or metastatic urothelial cancer.
- CTI BioPharma Corp. (ctibiopharma.com) announced that it has completed a rolling NDA submission to the FDA seeking approval of **pacritinib** as a treatment for myelofibrosis in patients with severe thrombocytopenia. The NDA has been accepted by the FDA for priority review.

- Fennec Pharmaceuticals Inc. (fennecpharma.com) announced the resubmission of an NDA to the FDA for **Pedmark™ (sodium thiosulfate)** for the prevention of ototoxicity induced by cisplatin chemotherapy in patients one month to less than 18 years of age with localized non-metastatic solid tumors.
- BeyondSpring Inc. (beyondspringpharma.com) announced that the FDA accepted for priority review the NDA seeking approval for use of **plinabulin in combination with granulocyte colony-stimulating factor** for the prevention of chemotherapy-induced neutropenia.
- Innovent Biologics, Inc. (innoventbio.com/en) and Eli Lilly (lilly.com) jointly announced that the FDA accepted for review a BLA for **Tyvyt® (sintilimab)** in combination with pemetrexed and platinum chemotherapy for the first-line treatment of people with non-squamous NSCLC.
- Hutchmed (hutch-med.com) announced that it completed the rolling submission of an NDA to the FDA for **surufatinib** for the treatment of pancreatic and extra-pancreatic (non-pancreatic) neuroendocrine tumors.
- Kite (kitepharma.com) announced that it has submitted a supplemental BLA to the FDA for **Tecartus® (brexucabtagene autoleucel)** for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia.
- The Janssen Pharmaceutical Companies of Johnson & Johnson (janssen.com) announced that the FDA granted breakthrough therapy designation to **teclistamab** for the treatment of relapsed or refractory multiple myeloma.
- Servier Pharmaceuticals (servier.us) announced that the FDA accepted the supplemental NDA for **Tibsovo® (ivosidenib tablets)** as a potential treatment for patients with previously treated IDH1-mutated cholangiocarcinoma.
- Seagen Inc. (seagen.com) and Genmab A/S (genmab.com) announced that the FDA accepted for priority review the BLA seeking accelerated approval for **tisotumab vedotin** for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.
- TG Therapeutics, Inc. (tgtherapeutics.com) announced that the FDA accepted the BLA for **ublituximab (TG-1101) in combination with Ukoniq® (umbralisib)** as treatment for patients with chronic lymphocytic leukemia and small lymphocytic lymphoma.
- Verastem, Inc. (verastem.com) announced that the FDA granted breakthrough therapy designation for the combination of its investigational RAF/MEK inhibitor, **VS-6766**, with **defactinib**, its FAK inhibitor, for the treatment of all patients with recurrent low-grade serous ovarian cancer regardless of KRAS status after one or more prior lines of therapy, including platinum-based chemotherapy.
- Exelixis, Inc. (exelixis.com) announced that the FDA accepted its investigational NDA for **XB002** in patients with advanced solid tumors.

Devices and Assays in the News

- Avenda Health (avendahealth.com) announced that the FDA has awarded breakthrough device designation to the **Avenda Health Focal Therapy System** for treating prostate cancer in-office while preserving patients' quality of life.
- Guardant Health, Inc. (guardanthealth.com) announced that the FDA approved the **Guardant360® CDx liquid biopsy test** to identify patients with locally advanced or metastatic NSCLC who harbor the EGFR exon 20 insertion mutation and may benefit from targeted treatment with Rybrevant™ (amivantamab-vmjw) after progressing on or after platinum-based chemotherapy. The test has also received FDA approval as a liquid biopsy companion diagnostic for Lumakras™ (sotorasib) in advanced NSCLC.
- IceCure Medical Ltd. (icecure-medical.com) announced that it has been granted FDA designation as a breakthrough device for **ProSense™** for use in the treatment of patients with T1 invasive breast cancer and/or patients not suitable for surgical alternatives for the treatment of breast cancer.
- Roche (roche.com) announced FDA approval of the **Ventana MMR RxDx Panel** for patients with advanced or recurrent endometrial cancer patients. Testing can identify patients eligible for treatment with Jemperli (dostarlimab-gxly) monotherapy.
- QIAGEN (qiagen.com/us/) announced the launch of an expanded scope of companion diagnostic claims for the ***therascreen*® KRAS RGQ PCR Kit** after it received U.S. regulatory approval as a companion diagnostic to aid in the identification of patients with NSCLC who may be eligible for treatment with Lumakras™ (sotorasib). OI

- The FDA announced that it has authorized marketing of the **GI Genius™** (Cosmo Pharmaceuticals, cosmopharma.com), a device that uses artificial intelligence-based machine learning to assist clinicians in detecting lesions in the colon in real time during a colonoscopy.
- Vysioneer (vysioneer.com) announced that the company received FDA clearance for **VBrain**, an artificial intelligence-powered tumor auto-contouring solution in radiation therapy.

ASSOCIATION OF COMMUNITY CANCER CENTERS

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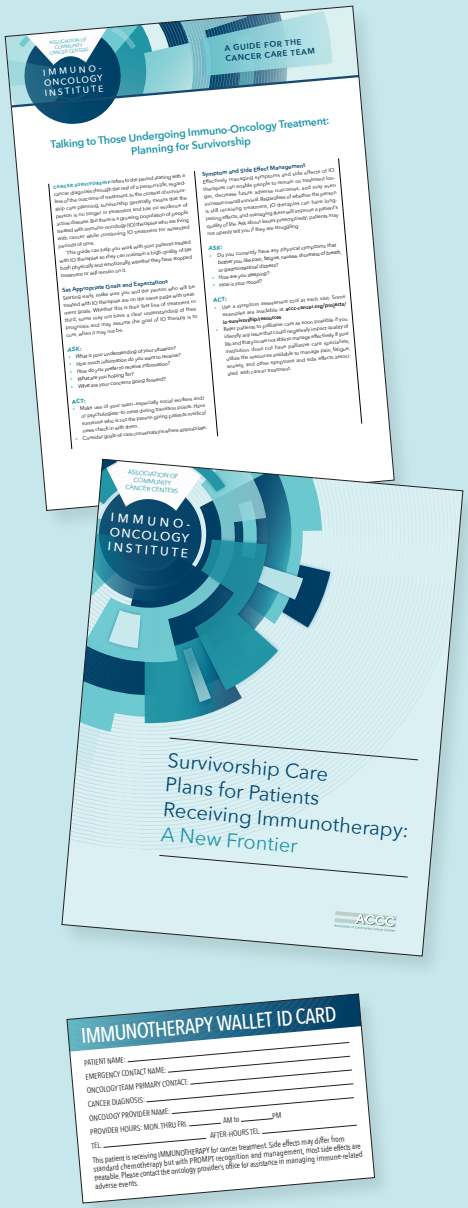

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The ACCC Immuno-Oncology Institute is supported by Bristol Myers Squibb (charitable donation) and Merck & Co. (Care Coordination educational grant).

The **Association of Community Cancer Centers** (**ACCC**) is the leading education and advocacy organization for the cancer care community. Founded in 1974, ACCC is a powerful network of 25,000 multidisciplinary practitioners from 2,100 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 or call 301.984.9496. Follow us on Facebook, Twitter, and LinkedIn; read our blog, ACCCBuzz; and tune in to our podcast, CANCER BUZZ.

The **ACCC Immuno-Oncology Institute** is the leader in optimizing the delivery of cancer immunotherapies for patients by providing clinical education, advocacy, research, and practice management solutions for cancer care teams across all healthcare settings.

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Association of Community Cancer Centers

spotlight

Roger Williams Cancer Center
Providence, Rhode Island

Roger Williams Cancer Center offers a unique approach to multidisciplinary cancer care for patients in and near Providence, R.I. It is an outpatient department of Roger Williams Hospital and is located across the street from the hospital in its own building. The cancer center is part of CharterCare Health System, which is comprised of Roger Williams Hospital and Our Lady of Fatima Hospital in North Providence, R.I. CharterCare began as an initiative of the two hospitals to bring patients in the city high-quality care in multiple locations. It has since been purchased by Prospect Medical Holdings—a large, multi-state health system that operates Roger Williams Cancer Center and Hospital as a for-profit entity.

With the resources to serve many patients in their region, the staff at Roger Williams Cancer Center take pride in their ability to offer high-quality cancer services in the community setting that are tailored to meet the needs of its patients. The cancer center holds many accreditations, including those from the Foundation for Accreditation of Cellular Therapy, National Marrow Donor Program, and American Society for Transplantation and Cellular Therapy. It is also designated by the Commission on Cancer as an academic comprehensive cancer center. Through these accreditations and an affiliation with the Boston University School of Medicine, the cancer center offers comprehensive cancer care that enables patients to stay in their communities while they receive treatment.

Comprehensive Community-Based Care

A majority of the cancer center's oncologists are employed by Roger Williams Hospital, and a few are employed by Charter Care Medical Associates—a medical group practice in the community. All remaining clinical and non-clinical staff are employed by the hospital, with the exception of radiation oncology staff. The cancer center offers its radiation oncology services on its first floor in partnership with GenesisCare—the largest radiation oncology provider in the United States, which employs all of the cancer center's radiation oncology staff. Most patients with cancer who receive radiation are referred by Roger Williams' clinicians, and others are referred from other providers in the community. To further its dedication to providing patients the newest treatment technology, an Elekta Versa HD™ will soon be added to the radiation oncology department, allowing radiation oncologists to use a MRI-guided system to make real-time adjustments to individual treatment plans.

Due to the nature of many oncology treatment plans and the cancer center's radiation oncology model, care coordination is vital to ensure that patients receive the appropriate treatment in a timely fashion. Roger Williams Cancer Center and GenesisCare staff prioritize communication and collaboration to ensure that patients are scheduled and adhere to treatment. Two nurse navigators—one dedicated to breast health and the other to the geriatric program—ensure that individual patients' needs are met. The cancer center also makes sure that patients' medical information is shared with all pertinent parties and coordinates appointment scheduling, particularly for those who are receiving adjuvant therapy. Scheduling staff are available on the first floor and work for all departments within the cancer center. This staff tracks treatment plans and schedules patients right away, eliminating lengthy wait times.

The Roger Williams Cancer Center medical oncology department is on the second floor and is staffed by three medical oncologists, one nurse practitioner, three medical assistants, two administrative assistants, and six fellows from the fellowship program. Each medical oncologist is paired with a medical assistant who helps with the overall operation of the medical-oncology clinic and provides support in obtaining patients' pre-certifications, imaging, and genetic testing. Next to the clinic, a 10-chair infusion suite is set up in a horseshoe shape with the nursing station at the center, allowing nurses to see everyone and quickly help if patients have an adverse reaction to their treatment. Both oncology and non-oncology infusions are administered at the cancer center, with a 6-chair area now reserved for patients receiving non-oncology infusions.

A dedicated 797-certified pharmacy on the first floor of the main hospital is staffed by two pharmacists and multiple pharmacy technicians. Due to the structure of

pharmacy services in Roger Williams hospital, staff are dedicated to the cancer center but report to the main hospital.

All surgical oncology services are performed in coordination with the cancer center and main hospital. With four surgical oncologists on staff, the cancer center offers general and breast surgical oncology, as well as surgical immunotherapy. Pre-operative work is done in the cancer center, and all surgeries and post-operative care are completed in the hospital. Patients return to the cancer center for follow-up care. The cancer center also has a dedicated laboratory, bone marrow infusion area staffed by two certified nurses, and minor procedure rooms for bone marrow biopsy restorations.

To keep patients close to home during treatment, the cancer center provides consultative services for medical and surgical oncology at four hospital-based satellite clinics in Lincoln, East Providence, Cumberland, and East Greenwich, R.I., all within a 25-mile radius of the cancer center. Each satellite location is staffed by an administrative assistant scheduler, a medical assistant, and a medical or surgical oncologist.

The East Providence clinic also provides infusion services in an eight-chair suite staffed by three oncology certified nurses. One pharmacist and one pharmacy technician make up the clinic's dedicated pharmacy.

Meeting Patients' Needs

Because Rhode Island is small and several nearby cancer centers share a catchment area, Roger Williams Cancer Center collaborates with its local competitors to ensure that its community receives a unified message on cancer care and prevention for melanoma, which is seen frequently in this state—a popular destination for outdoor recreation. The cancer center collaborates with other programs to develop a central message on skin care and melanoma prevention, promote community outreach, and participate in melanoma screening throughout the state.

Rhode Island is also a popular state for retirees; patients 65 years and older make up about one-third of the cancer center's patient population. To tailor its care to best meet these patients' needs, Roger Williams created and implemented the Comprehensive Oncology Program for Elders. This program addresses the unique needs of older patients with cancer. It incorporates a comprehensive pre-treatment assessment that evaluates older patients in terms of their ability to maintain activities of daily living, their nutritional status, their cognitive deficiency, and their mobility. Intervention protocols exist for each of these clinical criteria, and, when necessary, patients are quickly referred to the necessary service(s) to ensure their access to care is seamless. Roger Williams Cancer Center is proud to be the only in the state to offer a comprehensive program for older adults with cancer.

The cancer center also offers its patients a variety of supportive care services, including occupational therapy, physical therapy, speech therapy, social work, nutrition, navigation, behavioral health, and support groups. All are available at its main location. Support groups and social work services are free to patients, and the other psychosocial services are billable. Patients can be referred to these services by their oncologist, medical assistant, or nurse or they can self-refer.

An Immunotherapy Research Focus

Roger Williams Hospital houses a protocol office and research office within its research department to offer clinical trials to eligible patients in the cancer center. It recently began offering immunotherapy clinical trials in collaboration with its onsite Core Lab Facility. All oncology patients complete a screening form with medical assistant fellows and protocol nurses as part of their initial consult. If an appropriate clinical trial is available to a patient, the medical assistant fellows explain the benefits of participation and what is required to take part. Roger Williams Cancer Center currently offers Phase Ib and II immunotherapy clinical trials for breast, prostate, gastrointestinal, and solid tumors. It will be offering a human epidermal growth factor receptor 2-positive solid tumor chimeric antigen receptor T-cell trial. The cancer center enrolled 104 patients in a clinical trial from January 2019 to January 2020.

The Roger Williams Cancer Center staff take pride in the variety of services they offer patients and their ability to keep patients close to home while they receive treatment.

Richard Ballard, MS, executive director of cancer services at Roger Williams Cancer Center says that, even through the COVID-19 pandemic, all staff continued to work within the cancer center. They did not stop the necessary clinical and supportive care their patients needed. "I think that the compassion and the skill in which our staff takes care of our patients is very impressive," says Ballard. "Even when everybody else was working from home, our staff came in every day. They knew what we needed to be done, and they were just as compassionate as before." The Roger Williams Cancer Center staff take pride in the variety of services they offer patients and their ability to keep patients close to home while they receive treatment. OI

This Lyrical Life:
Music Therapy in Oncology

BY DEAN QUICK, MT-BC AND SUSAN YAGUDA, MSN, RN

You have likely heard this saying before, but by the end of this article we hope you will have a deeper understanding of what it means: music heals. In early human evolution, dance, rhythm, and singing preceded language. Shamans sang—and continue to sing—songs to heal. You may even get chills when you hear a specific song at the right moment. As we know, music soothes and restores.

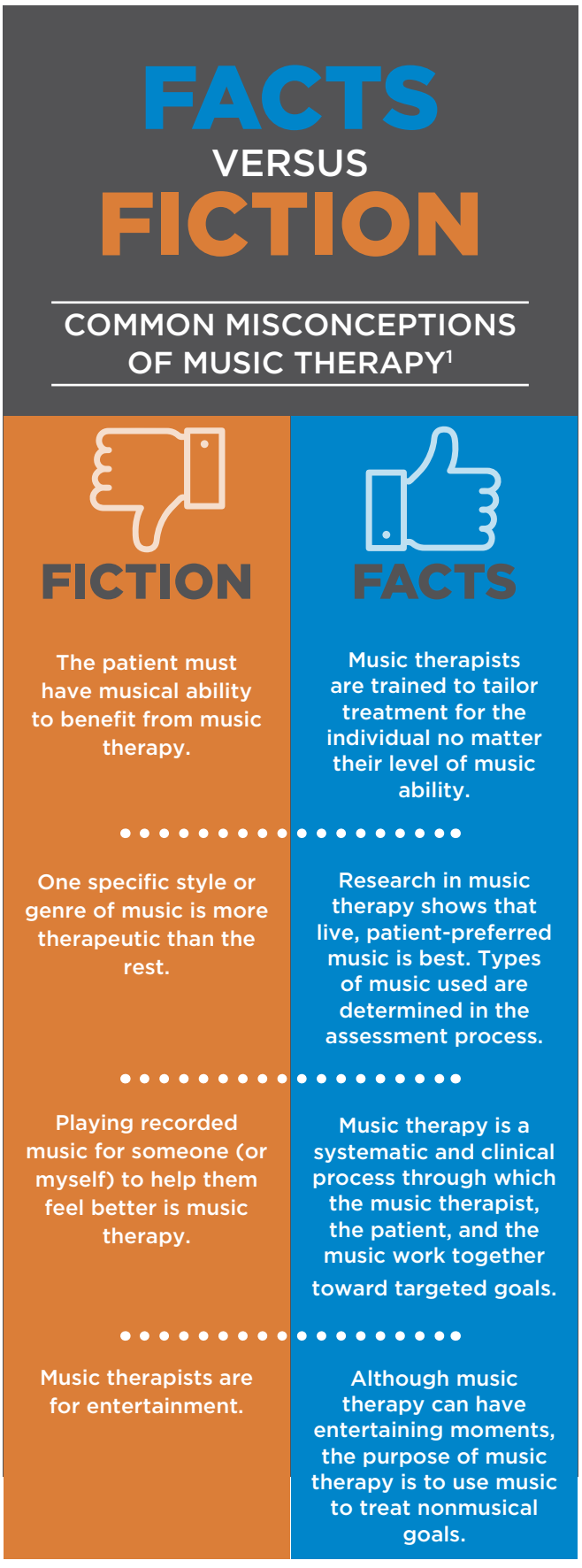
Music is built into our daily lives—mothers sing to babies, adolescents blast their stereos in self-expression, people work out to music for motivation, a couple chooses a song for their first dance, and a son sings to his dying mother, not only to comfort her but to soothe himself as she did for him as a baby. Music is something people connect with deeply. This understanding of music as a healing tool is one of the many reasons why music therapy is widely used in healthcare and other settings.

In the United States, music therapists are board certified and carry the MT-BC credential. This credential means that the therapist has at least a bachelor's degree in Music Therapy, has completed at least 1,200 hours of supervised clinical work, and has passed the board certification exam. Music therapists work in many different medical and educational settings, all of which use music in clinical ways to help people overcome or accept their psychological, physical, cognitive, and social challenges. This article discusses the benefits of music and music therapy in cancer care and specifically at my institution, Atrium Health Levine Cancer Institute.

> Music therapy is an evidence-based treatment modality supported by a substantial body of quantitative and qualitative research. The effects of music therapy are easily measurable, and progress is documented in patients' medical charts.

Music Therapy at Levine Cancer Institute

Our Department of Supportive Oncology consists of nine sections working together to help mitigate the symptoms and side effects of cancer and cancer treatment. Within the department, the section of integrative oncology uses evidence-based complementary and integrative interventions to support patients and care partners at all stages of their cancer journey. Music therapy is part of that section, along with acupuncture, Healing Touch therapy, meditation, oncology massage, a physician consult clinic, spiritual care, Tai Chi, therapeutic art, yoga, and other integrative supportive services.



The music therapy position at Levine Cancer Institute was funded originally through a grant from the Livestrong Foundation (livestrong.org) in September 2014. This funding enabled the cancer institute to hire a part-time music therapist to provide services to the outpatient infusion area and on occasion in the bone marrow transplant inpatient unit. Within six years, the position expanded to full time, and the cancer institute is now hosting a full-time music therapy intern as of January 2021.

As music therapy services expanded, in addition to the above, the music therapist now provides treatment to the acute inpatient hematology unit, to the pre- and post-surgical solid tumor inpatient unit, and to bone marrow biopsy procedural support. There is a monthly group drumming, various groups using songwriting and relaxation techniques, and a YouTube channel with livestream music therapy weekly.

What is Music Therapy?

Music therapy is an evidence-based treatment modality supported by a substantial body of quantitative and qualitative research. The effects of music therapy are easily measurable, and progress is documented in patients' medical charts. The American Music Therapy Association defines music therapy as "the clinical and evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship by a credentialed professional (MT-BC) who has completed an approved music therapy program."[1] The goals of music therapy in oncology include, but are not limited to:[2,3]

- Symptom reduction of pain, nausea, or sleep disturbance
- Procedural support
- Emotional validation, support, and release
- Improved coping
- Better familial cohesion
- Greater physical ability
- Distraction from the cancer treatment process or life with cancer.

Music therapy treatments are grounded in peer-reviewed and evidence-based research. The process involves ongoing assessment of clinical needs and progress toward established individual goals. Though most music therapy is not standardized, it follows clinical and systematic processes. This allows for maximum individualized care. While often viewed as a "feel good" therapy, music therapy does not always feel good for the patient—the music therapist will sometimes challenge difficult emotions within patients and help them work through their emotional processes. We allow for vulnerability in these moments with music to support and engage processing. The experience of listening to and creating music can bypass patients' thinking and go straight to their emotional and feeling states.[4] Therefore, the music therapist engages patients and effects change.

Listening to music alone can effect positive change, too, though it is different than music therapy. Music therapists are trained and highly skilled in creating music with clinical intention for and with patients. The music created with the patient is goal driven. A stranger playing Bach in a lobby or other public space may have a calming effect, but this music is not driven by a clinical

process or individualized goals. Though there is great value in volunteer musicians playing in public spaces for patients and staff, volunteers should not create music with or for patients in a clinical capacity.

Music therapists follow a treatment process like related treatment modalities. On referral, every patient receiving music therapy has an initial assessment session (or period) to determine how and if music therapy can be used to help treat their needs. The process will vary depending on the patient's need(s); however, the following always remains true:

- The music therapist is board certified (MT-BC). Only those with the MT-BC credential may practice music therapy and can call themselves music therapists in the United States. Canadians hold the music therapist accredited (MTA) credential.
- Needs are assessed by the therapist, and goals and objectives are developed with the patient.
- The relationship between the therapist, the patient, and music is equilateral. None outweigh the others in importance.

Music Therapy in Treatment

Music therapists facilitate many clinical interventions that are either active or receptive methods. Live, patient-preferred music is typically used, which research shows is most effective.

Active Interventions[4]

Patients do not have to be musicians or have any musical experience to fully participate in and benefit from music therapy. Non-musicians can sometimes be intimidated by the notion of playing on strange instruments, some of which they may have never seen before. Music therapists are trained to support patients' music no matter their musical ability. It is through the act of creating music that a music therapist can help patients progress.

Receptive Interventions[5]

It is common to think of music therapy as a tool for relaxation when listening to specific music. Treatment often includes methods for mood modification, relaxation, or for uplifting and can be adjusted as the situation demands. Music-assisted relaxation techniques are used to address multiple symptoms while the patient engages in minimal physical involvement (other than listening to live music and responding to prompts). Since the intervention does not rely on a recording, this affords the music therapist the opportunity to adjust based on patients' response in real time. For example, a music therapist will slow the music's tempo down to reflect a slowing respiratory rate. Table 1 (page 20) and Table 2 (page 20) provide examples of music therapy interventions for oncology along with the symptoms typically treated. Note that this list does not include all interventions, but those that are most frequently used in the oncology setting.

Treatment Goals

Typical goals in music therapy are:[2,3]

- *Pain management*. This could include music therapy (active or receptive) to decrease pain perception and efforts to target decreased opioid use.

(Continued on page 21)

A patient and wife singing and recording their original song.

Group Drumming event for the LCI Healing Arts Celebration 2018.

Overhead view of Quick's telehealth set up in his personal studio.

Table 1. Common Active Music Therapy Interventions

Active Music Therapy		Symptoms				
Intervention	**Descriptions**	**Pain**	**Nausea**	**Sleep**	**Fatigue**	**Mental Health**
Dyadic music making	Music created between the patient and one other person, usually a family member or care partner or the music therapist. The music serves as means of bonding, communication, meaning making, and self-expression.	X			X	X
Exploratory music making[6]	Music created evokes emotional responses that will be discussed, analyzed, and sometimes interpreted with the music therapist.	X			X	X
Symbolism and existentialism[7]	Identification of symbols in patient-created music (or the music they listen to) to determine if it holds meaning to the patient's experience.				X	X

Table 2. Common Receptive Music Therapy Interventions

Receptive Music Therapy		Symptoms				
Intervention	**Descriptions**	**Pain**	**Nausea**	**Sleep**	**Fatigue**	**Mental Health**
Progressive muscle relaxation	A systematic process to guide patients through tensing and releasing muscles in every large muscle group in tempo with the live music from the music therapist.	X		X		X
Autogenic relaxation	The music therapist creates music congruent with the patient's current emotional state (if they want that to change) and guides them through breathing, light and color imagery, or focused attention on the body. The music therapist gives broad guidance, but it is up to the patient to decide the level at which they engage in the process.	X	X	X		X
Music and imagery	Typically, patients are led in a scripted experience with personal imagery chosen beforehand. The music therapist choses music to enhance and guide the imagery. Recorded music is frequent.	X	X	X	X	X

(Continued from page 19)

- *Nausea control*. This treatment typically uses receptive methods.
- *A strategy to help patients process emotions and explore feelings evoked by the music used or discussed in the treatment.*[8] This can include improved patient outlook on their treatment progress and mood modification.
- *A process to help patients create meaning*. This could include creating recordings, songwriting, or experiences that validate patients' experiences in life.
- *Strategies to support sleep health*. For example, receptive music therapy interventions combined with typical relaxation methods can target insomnia due to medication(s) or other psychological reasons.

Digital Music Instruments and Mobile Recording Studios

With the greater availability of professional recording studio software, most music therapists now use digital instruments. This use is not just to recreate or create music for the younger generation or to meet their desire for electronic sounds; digital instruments produce a high-quality sound sometimes indistinguishable from acoustic instruments. As technology advances, so do music therapists' instrument carts as they become fully digital. Though you will always find acoustic instruments, instrument carts now look like mobile recording studios.

At Levine Cancer Institute, the shift to digital music therapy was of necessity to protect those who wanted to sleep (or deferred music therapy) during their infusions. Most infusion suites are relatively public with chairs next to each other, sometimes separated with a full or half wall for patient privacy. Often, patients receiving music therapy are near others. Because of these spatial considerations, the cancer institute saw a need to increase patient privacy. The music therapist also has an ethical responsibility to respect patients who indicate that they do not want music during their treatment or who are sleeping. Though digital music making requires more preparation than acoustic instruments, the benefits of individualizing treatment within a shared space are important.

Headphones protect patients from external sounds. Additionally, headphones also keep music at the individual level, while not disturbing others close by. Headphones help to change the environment of sound for patients. For some, the noises of machines beeping and the bustling noises on a hospital floor can create anxiety that music therapy with headphones may alleviate. Even with no musical experience, and with the help of the music therapist, patients can design soundscapes to use in the moment (or at home) to address symptoms such as anxiety, nausea, pain, and sleep challenges.

Digital instruments also improve accessibility for those with physical limitations. Many, such as keyboards and electronic drums, have sizable silicone pads that can be programmed or assigned virtually any sound imaginable. For example, because of the flexibility of digital instruments, someone with neuropathy affecting their hands could benefit from music therapy. They might not be able to strike the keys of a typical keyboard, but they can strike a larger silicone pad assigned a sound of their choosing when using digital music. This flexibility allows them to create a similar experience of playing hand drums, but with different and more comfortable hand motions.

Quick and a patient engaged in dyadic music-making.

Music Therapy During COVID-19

With the onset of the COVID-19 pandemic, all remote sessions now rely on equipment from a mobile recording studio to deliver an experience like an in-person session, but one that practices safe distancing. This has opened the opportunity to see patients at home and target symptoms from cancer treatment that typically occur within 24 to 48 hours after treatment. Patients unable to participate in music therapy due to distance (or fear of COVID-19) can participate in virtual group and individual sessions.

Although there are key differences in virtual music therapy compared to in-person sessions, the increased access has been beneficial. Challenges of music therapy in the virtual setting include delayed audio and difficulty seeing a patient's breathing pattern. Several technical considerations keep the music therapist and patient from truly creating music together. Audio delay and syncing issues make it difficult and unreliable to create music over an Internet connection. During in-person treatments, the music therapist often adjusts the music tempo to match the

In one 45-minute treatment session, a music therapist can treat pain, validate and engage patients to understand a depressed mood, and work to improve their fine motor skills. Music therapy is non-threatening and engaging, especially when patients seek answers and ways to process their experiences.

respiratory or heart rate of the patient. Because of the inability to move camera angles in some computer or phone setups, the music therapist may be unable to see a patient's breathing pattern. This limits traditional music therapy in a virtual environment.

Overall, the experience of virtual music therapy treatment during the pandemic has been positive and appreciated by patients and other clinicians. The obstacles that bar virtual care from being identical to in-person care have created opportunities for growth and sometimes new ways for patients to find comfort.

Why Use Music Therapy?

Music therapy can be fun and can distract patients and their caregivers from cancer treatment. It is a clinically relevant and effective treatment modality with lasting, impactful positive change in patients' lives. Cancer programs understand that the whole individual—and their family—is affected by cancer. Modalities like music therapy address these holistic concerns with few, if any, side effects.

In one 45-minute treatment session, a music therapist can treat pain, validate and engage patients to understand a depressed mood, and work to improve their fine motor skills. Music therapy is non-threatening and engaging, especially when patients seek answers and ways to process their experiences.

Another value of music therapy to healthcare settings is better patient satisfaction scores for those who employ a music therapist (MT-BC).[9] We effect positive clinical change for patients at all stages of their disease. Music therapists are board-certified professionals and should be an integral part of the interdisciplinary team. Patients respond positively to music therapy with less use of opioids, improved outlook on treatment and life, shorter length of stay in the hospital, and lower anxiety—just to name a few clinical benefits.[2,3]

Music therapists are professionals, not volunteers. The lobby and other public places in your institution are well suited for volunteer musicians. Music therapists work alongside other medical professionals in treatment settings throughout the hospital.

Music therapy is valued not only by the patients at Levine Cancer Institute, but by our colleagues as well. Working in groups and teams with a music therapist can improve morale, foster team building, and ease compassion fatigue and burnout. A music therapist can change the environment at your facility in many positive ways—just as music can be a positive influence in your personal life. It is the hope of these authors that you can now listen more intently to the music in your life, that you will sing with a loved one and laugh when you hit a "wrong" note, and that ultimately you will see the value of the music all around you. Experiences in music are transformative and they heal.

To find a MT-BC near you to assist with that journey, visit CBMT.org. OI

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2020 IMPACT REPORT

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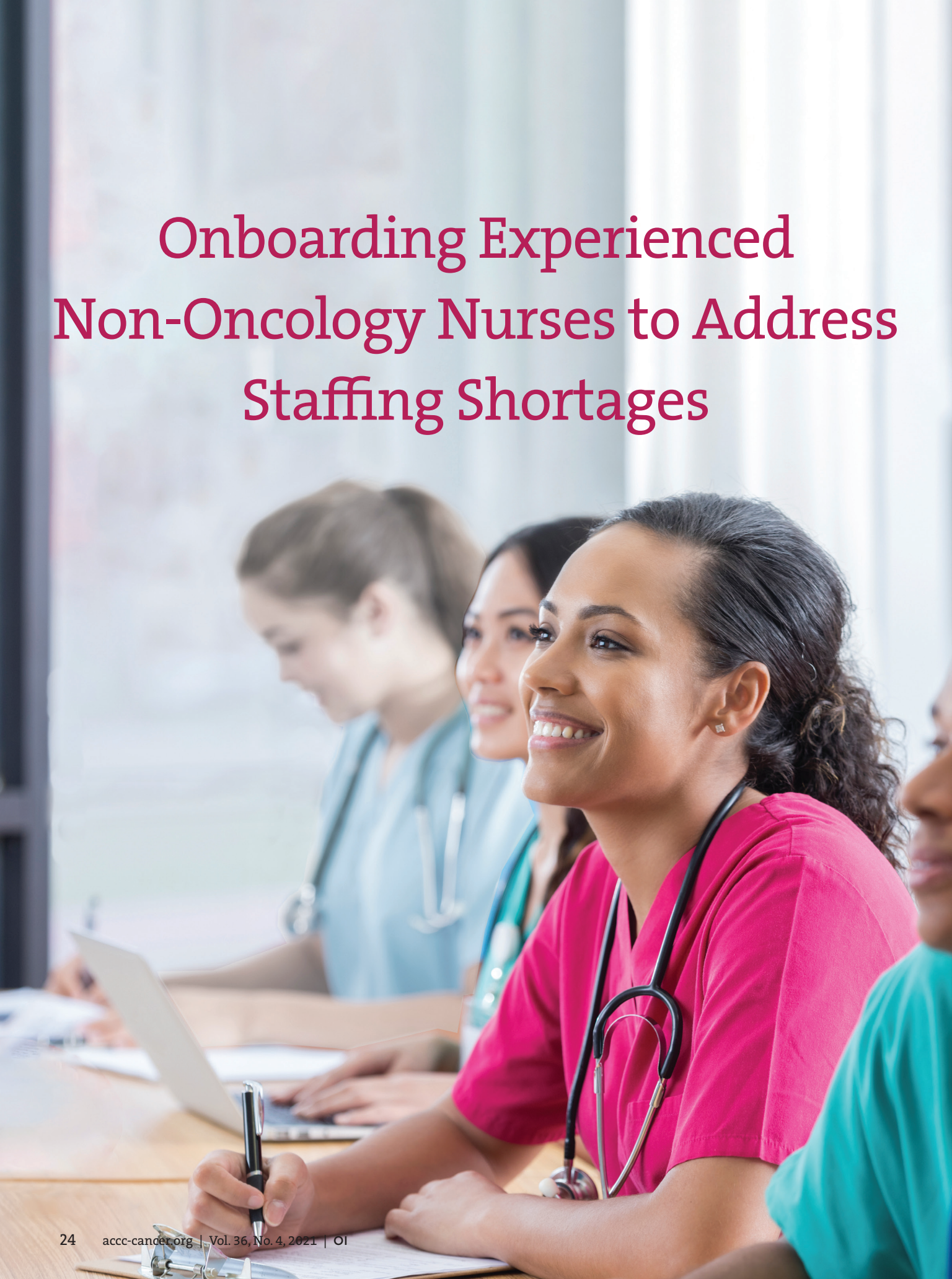
Onboarding Experienced Non-Oncology Nurses to Address Staffing Shortages



BY MICHELE RYDER, MSN, MSHSA, RN, CENP; MARGUERITE ROWELL, MSN, MBA, MSM/ HM, ONC, SCRN; NOAH ZANVILLE, PHD, BSN, BA; HOLLIE GOW, DNP, ARNP, ACNP-BC, CCRN, CPHQ; AND CATHY OLLOM RN, MSN, OCN, AOCNS

Development of a transitional oncology training program

In Brief

Over the past few decades, the demand for oncology services has skyrocketed in the United States,[1] propelled by a steady stream of advances in diagnosis, treatments, and survival from cancer.[2] Unfortunately, the pipeline of oncology nurses nationally has not kept pace with demand[3-8] and continues to be a major issue.[9] This is particularly true in specialized areas of cancer care, such as blood and marrow transplantation (BMT) and precision medicine (Phase I-III clinical trials), which require considerable experience, knowledge, and skill. In 2017 nursing leaders at Miami Cancer Institute, a comprehensive community cancer center located in Miami, Fla., found themselves facing this exact dilemma. Building off their experience designing programs in the inpatient setting, these nurse leaders developed a 12-week Transitional Oncology Nursing Academy designed for experienced, non-oncology nurses to orient and receive the oncology-specific knowledge, skills, and mentoring needed to transition successfully into the ambulatory oncology setting. In 2020, Miami Cancer Institute won an Association of Community Cancer Centers (ACCC) Innovator Award for this program, which has a 97 percent graduation and retention rate and has supplied 13 percent of the nursing workforce of the cancer program. Below, the authors present data from the first two years of the program, along with the program's history, structure, metrics, and initial outcomes, as well as helpful hints and lessons learned for cancer programs looking to implement a similar program.

Miami Cancer Institute, a 405,000-square-foot comprehensive and academic community cancer center, opened its doors in January 2017, offering a wide range of specialty services, including blood and marrow transplantation (BMT), proton therapy, a robust research program with precision medicine that includes Phase I-III clinical trials, and a Patient Cancer Support Department. In the years leading up to Miami Cancer Institute's opening, one of the many important challenges we had to contend with was the national shortage of nurses, with recent data suggesting that South Florida has actually been one of the regions hardest hit by the national nursing shortage.[10] As leaders well versed in oncology, we were highly attuned to the possibility that we might not be able to hire enough nurses with the high-level knowledge and skills needed to work in oncological specialties. We also knew that to meet our mission to deliver "the most innovative, evidence-based care" anywhere, we needed to ensure that the nurses we hired were prepared to care for our patient population.[11,12] Finding nurses with the blend of skills, experiences, knowledge, and certifications needed to care for our patients would pose a big challenge.

Nursing shortages in any clinical specialty can influence job satisfaction, job stress, burnout, and the quality of patient care.[13-15] We knew that, in most cases, even Bachelor's prepared nurses receive minimal education in specialty areas such as oncology and the operating room during their programs.[2] While helping to develop the next generation of oncology nurses is an important focus for Miami Cancer Institute, we recognize that experienced nurses represent an opportunity to build a strong base of nurses from those we have locally.[2]

Making the business case to senior leadership that our sustainable nurse training and onboarding program would supplement outside recruitment, eliminate agency costs, and attract experienced nurses to outpatient oncology made approval of the Transitional Oncology Nurse Academy a "no brainer."

Origin Story

The idea for a Transitional Oncology Nurse Academy originated from two executive RN administrators: Michele Ryder, MSN, MSHSA, RN, CENP, Miami Cancer Institute's vice president, chief operating officer, and chief nursing officer; and Marguerite Rowell, MSN, MBA, MSM/HM, ONC, SCRN, assistant vice president of nursing. Our collective years of experience working as leaders in the inpatient setting at hospitals, such as Baptist Hospital of Miami, and creating training programs for specialties, such as orthopedics and neuroscience, made developing a transitional nursing program in oncology a natural fit. Over the years, we have learned that preparing nurses to work in subspecialties often requires additional education, training, and resources. By developing academies for the various oncology specialties, nurses are provided the resources needed to competently work in high-stress, highly specialized clinical areas and feel confident providing safe, quality patient care.

Building Support for the Initiative

One the first steps we took to develop the Transitional Oncology Nurse Academy was to obtain buy-in from our chief executive officer (CEO) and chief medical officer (CMO). For any institution, nurse staffing is a complex process that requires careful solutions hardwired into an organization and flexible enough to evolve over time. We knew that program development would require ongoing financial commitment to be successful, along with strong support from executive leadership who recognized the benefits this type of program could bring to the organization overall. Making the business case to senior leadership that our sustainable nurse training and onboarding program would supplement outside recruitment, eliminate agency costs, and attract experienced nurses to outpatient oncology made approval of the Transitional Oncology Nurse Academy a "no brainer."

Understanding Current Opportunities

Before we started formally designing the Transitional Oncology Nurse Academy, our team evaluated the current education and training available to oncology nurses in our healthcare system and developed a gap analysis. A gap analysis is critical before designing any program to ensure you do not spend time recreating processes and resources that already exist, and you can focus your energy adding training where it is needed most. Our gap analysis showed that our health system's onboarding process for new nurses was structured and well organized; however, an opportunity existed to strengthen onboarding, education, and training of experienced nurses seeking to transition into the oncology ambulatory setting.

During the early stages of program development, we worked closely with our Human Resource Department's Recruitment Team, as well as the system-level Clinical Learning Department, who were instrumental in internally marketing the academy, helping support initial screening of program applicants, and providing faculty support as needed.

Assembling Our Team

With the design for the Transitional Oncology Nurse Academy mapped out, our next challenge was staffing the program. After attending a required preceptor and mentorship program, existing staff were prepared to precept and mentor the new preceptees. We used our institute's internal clinical experts—clinical nurse educators, advanced practice providers (APPs), physicians, nurse scientist, pharmacists—to develop and teach the didactic program. We allocated funds for classroom supplies and resources that we would need for the academy, including laptops, poster boards, and training binders. In addition, because we did not want cost to be a barrier for our potential graduates, we included the cost of Oncology Nursing Society (ONS)/Oncology Nursing Certification Corporation (ONCC) Chemotherapy Immunotherapy Certification as part of the academy program.

Developing Our Candidate Selection Process

Another component essential to the success of the Transitional Oncology Nurse Academy were the nurse candidates themselves. Candidates had to demonstrate leadership, critical thinking, collaboration and teamwork, adaptability, compassion, and empathy throughout the interview process. Final candidates were required to have greater than one year of nursing experience and to have successfully completed a behavioral-based panel interview with department leaders and specialty educators.

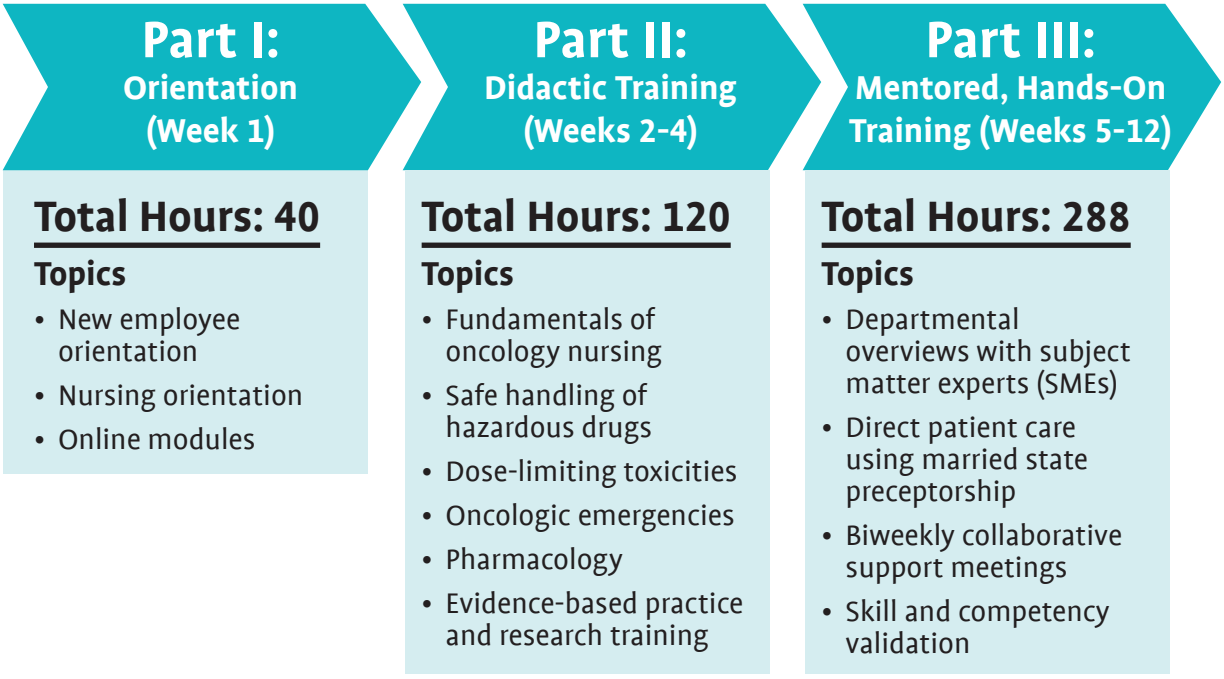
Program Structure and Launch

Our first Transitional Oncology Nurse Academy launched in October 2018. The program took carefully selected nurses from other nursing areas and gave them the oncology-specific knowledge, skills, and onboarding training needed to successfully transition to the ambulatory oncology setting. The program is 12 weeks long and divided into three phases (Figure 1, right).

Phase I. Orientation

During Phase I of the Transitional Oncology Nurse Academy, external nurses completed an initial week of orientation designed to welcome them to Baptist Health South Florida. During the first week, nurses received a tour of Miami Cancer Institute and instruction on:

Figure 1. Structure and Components of Transitional Oncology Nurse Academy



- Practice
- Norms and values
- Electronic medical record (EMR)
- Infection control practices
- Patient experience
- Patient safety
- Human resources and employee relations
- Emergency response
- Cultural diversity and other vital information.

Phase II. Didactic Training

Next, during Phase II of the Transitional Oncology Nurse Academy, nurses began their didactic training, which continued over a three- to four-week period. Didactic content was taught by a multidisciplinary team and covered topics ranging from the fundamentals of oncology nursing, safe handling of hazardous drugs, dose limiting toxicities, preventing and addressing oncologic emergencies, and pharmacology.

In designing the Transitional Oncology Nurse Academy, we aligned didactic content with the most current evidence and standards. For years ONS has emphasized the need for oncology nurses to be "educated in the latest technologies and emerging cancer therapies" to help them stay current.[15] To ensure we met this goal, our team developed a state-of-the-art curriculum based on the latest standards from the American Society of Clinical Oncology (ASCO),[16] ONS,[17] the Commission on Cancer (CoC),[18] ASCO's Quality Oncology Practice Initiative (QOPI®),[19] and the Infusion Nursing Society,[20] as well as research on how to implement effective preceptorship programs.[12] By the end of the program, academy graduates not only would have additional oncology knowledge and skills to safely care for our patients, but also a greater understanding of current oncology evidenced-based standards.

In addition, because research and evidence are the cornerstones of safe oncology nursing,[21] during the academy, trainees received four hours of training in research, evidence-based practice, and quality improvement from our PhD prepared nurse scientist. The goal of this training, which included basic skills such as how formulate a PICO(T) (patient, intervention, comparison, outcome and, sometimes, time) question, perform a literature review, structure a unit-based performance improvement project, and evaluate evidence strength and quality, was to ensure all trainees had the basic skills needed to practice evidence-based oncology nursing.

Phase III. Hands-On Training

Following completion of the initial 120-hour didactic immersion, nurses began approximately 300 hours of hands-on training within different clinical areas with experienced oncology mentors. We used the Married State Preceptorship Model to assess learning readiness during the mentoring portion of the academy.[22, 23] The model is a partnership between the preceptor and preceptee and is designed to help transition the preceptor role over time to a resource role. Instead of the preceptor taking a group of patients and the preceptee taking their own set of patients, preceptors and

Since the launch of the Transitional Oncology Nurse Academy, we have learned that candidate selection is crucial to your program's success and retention rate. Leaders must be actively involved in the selection process, and candidates must have a desire to learn and want to care for oncology patients.

preceptees manage their patients together, with the preceptor providing continuous feedback and coaching to ensure that that preceptee thoroughly understands how to care for oncology patients and helping preceptees learn their strengths and opportunities for improvement.[22]

We had successfully used the Married State Preceptorship Model in the inpatient setting and found it quite effective for onboarding and developing confident, competent new nurses, as well as retaining staff. The preceptor, preceptee, department educators, and leaders met biweekly to collaboratively support the new nurses and validate the skills they were developing. These touch bases also helped us identify competences that required more education or exposure.

Program Metrics and Goals

To determine if the Transitional Oncology Nurse Academy was successful, we developed and tracked outcomes in eight areas:

1. *Graduation rates:* measured by the total number of admitted nurses that successfully graduated from the program.
2. *Initial readiness for oncology practice:* measured by the percentage of nurses that successfully earned their ONS/ONCC Chemotherapy Immunotherapy Certification within 30 days of completing the academy.
3. *Job placement rates:* measured by the percentage of graduates placed in an oncology unit post-graduation.
4. *Nurse retention rates:* measured by one-year retention on an oncology unit.
5. *Nursing quality:* measured by nursing quality data such as extravasations and central-line associated blood stream infection rates.
6. *Impact on oncology nursing workforce:* measured by the percentage of our total workforce we were able to fill with academy graduates.
7. *Estimated cost savings:* measured by estimated savings to our organization associated with reduced hiring costs and reductions in staff turnover. This outcome was key to the program's sustainability.
8. *Number of internal transfers versus external hires.* This outcome was measured to see if the program met its goal to serve as an early or mid-career bridge for experienced non-oncology nurses (inside and outside our organization) to transition to oncology.

Program metrics and goals are summarized in Table 1, right.

Initial Outcomes

Since we launched the Transitional Oncology Nurse Academy four years ago, we have graduated a total of 35 nurses from 4 cohorts. Currently, the program's graduation rate is 97 percent. Of the graduates, 100 percent successfully earned their ONS/ONCC Chemotherapy Immunotherapy Certification within 30 days of completing the program and were placed in oncology units. Together, these nurses now make up 13 percent of Miami Cancer Institute's total oncology nursing workforce.

In addition, over the two years, we have maintained a 97 percent one-year retention rate, with only one RN leaving their position due to medical reasons. Review of nursing quality data, such as extravasations rates and central-line associated blood stream infection rates, indicate that experienced non-oncology nurses who graduate from the transitional academy perform in a similar fashion to oncology nurses. Internal data from our Human Resources Department suggest that we have saved approximately $80,000, per nurse, in advertising, sign-on bonuses, and associated work time by preparing existing nurses to transition to oncology rather than seeking outside candidates. Interestingly, approximately 80 percent of the graduates were experienced RNs from outside of our organization with a desire to transition into oncology and only 20 percent of the program's final residents consisted of internal candidates (Figure 2, page 30).

To better understand our cohort characteristics, we sent out an electronic survey, asking participants to share information on previous nursing experience. Results of the survey, which included responses from 22 of our 35 academy graduates (62.9 percent), found that the mean age of program graduates was 35.1 ± 8 years with ages ranging from 26 to 52 years. On average, while nurses with only one year of experience were technically eligible for the transitional academy, the survey found that our nurse graduates had 7.8 ± 5.5 years of previous experience, on average (range: 2 to 25 years) and brought experience in from multiple non-oncology areas.

The most common non-oncology specialities nurse graduates reported having experience with prior to entering oncology were medical/surgical, cardiac/telemetry, intensive care unit/step-down, maternity/labor and delivery, and emergency department nursing. However, graduates also reported experience in other potentially useful areas, including pain management, endoscopy, hospice/palliative care, neurology, quality assurance, infection prevention, public health, and bioethics.

Without question, one of the strongest—and most important—indicators we have used to guide us during the first few years of the transitional academy is feedback from our nurse graduates themselves. Over the past three years, we received feedback on the ways that the Transitional Oncology Nurse

Table 1. Transitional Oncology Nurse Academy Metrics and Goals

Domain	Metrics	Goals
Program graduation rates	Percentage of nurses admitted to transitional academy who successfully graduate	> 90% graduation rate
Initial readiness for oncology practice	Percentage of graduates completing ONS Chemotherapy and Immunotherapy Certification	100% of graduates earn ONS certification course within 30 days of graduation
Job placement rates	Percentage of graduates placed in oncology unit postgraduation	> 90% job placement in oncology
Impact on nursing workforce	Percentage of total oncology nurses at Miami Cancer Institute	To increase total number of oncology nurses
Nurse retention rates	Percentage retention at 1 year	> 90% academy graduate retention at 1 year
Nursing quality	Internal quality metrics	Graduate nurses who provide high-quality care and service
Estimated cost savings	Estimated recruitment and retention costs	Reduce hiring costs through increased nurse retention and reduced staff turnover
Career bridge	Percentage of internal vs. external hires	N/A

ONS = Oncology Nursing Society

Academy prepared them to enter the world of cancer care. Many of our nurse graduates tell us that that the curriculum, carefully chosen teaching staff, and close mentorship helped students feel "confident working while beginning their careers in oncology."

Overall, these results are consistent with the results of the survey we performed, in which we asked nurses to rate "the quality of the training" they received and "how prepared they were to begin oncology practice after graduating from the Miami Cancer Institute Transitional Oncology Nurse Academy," respectively, on a scale from 1 to 10 (with 10 being the highest or the most prepared). On average, results showed that respondents rated the quality of their instruction at a 9.4 (median: 9.95) and their preparedness to begin oncology practice at 8.0 (median: 8.0).

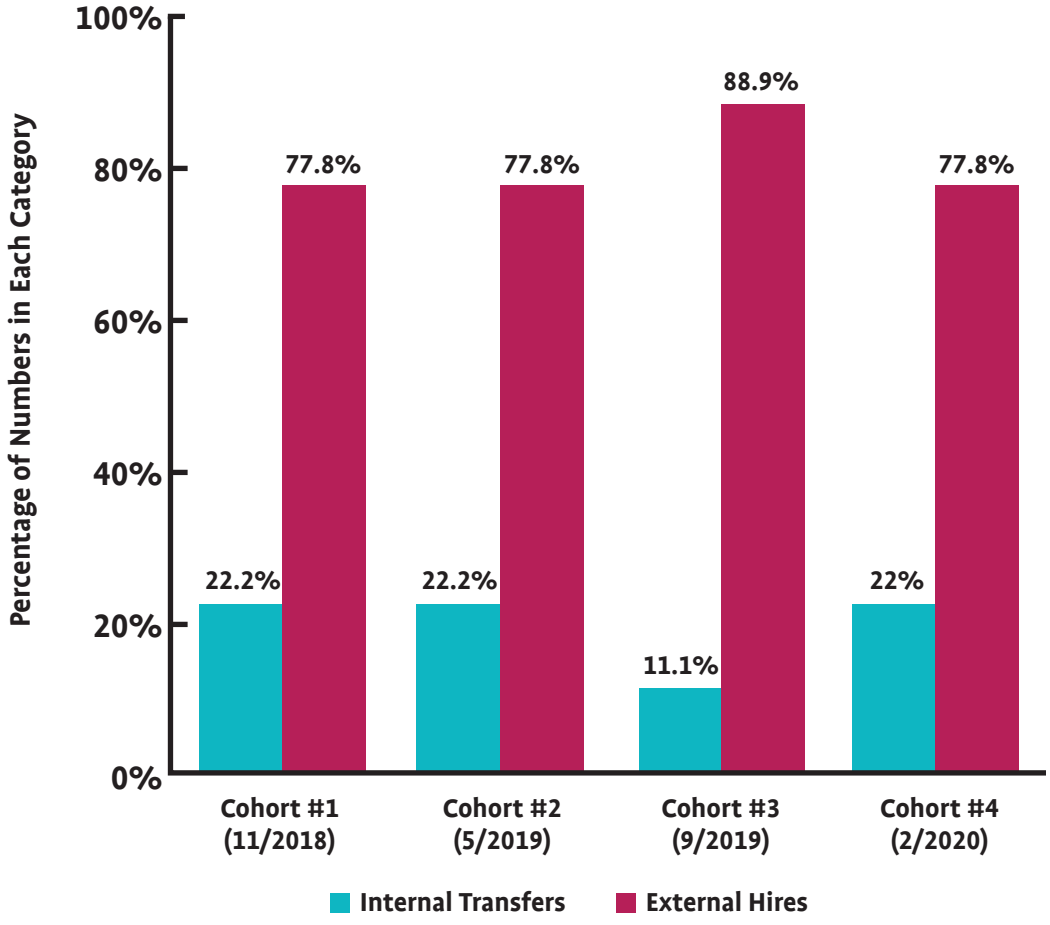
Lessons Learned

Since the launch of the Transitional Oncology Nurse Academy, we have learned that candidate selection is crucial to your program's success and retention rate. Leaders must be actively involved in the selection process, and candidates must have a desire to learn and want to care for oncology patients. Staff trained on how to precept and mentor new staff are also key to standardizing how staff are trained. To reduce faculty cost, tap into your multidisciplinary experts (specialty educators, APPs, physicians, pharmacists, etc.) and plan out the program far in advance to avoid running into scheduling conflicts. Also, be sure to have backup presenters in case of emergencies. Additionally, integrate organizational policies and procedures into the program, so new staff have a good understanding of processes and policies before completing their onboarding. Finally, conduct the program at minimum, three to four times during the year to keep the groups small and foster learning, engagement, and group bonding and socialization.

Next Steps and Concluding Thoughts

The next step for the Transitional Oncology Nurse Academy is to expand the program and provide oncology education and training to all entities. In 2020 we completed our first onboarding and residency program for BMT nurses. In the upcoming year, we would like to launch a clinical trials residency onboarding program and an APP fellowship program. Additionally, we will continue to incorporate feedback from our residency students to

Figure 2. Percentage of Internal Transfer (Within Our Organization) Versus External Hire Graduates from the Transitional Oncology Nurse Academy Acquired (November 2018 to February 2020)
n=36.



make the program more robust for the next group.

To develop Miami Cancer Institute's Transitional Oncology Nurse Academy, we needed to "think big" and push ourselves to find a sustainable, long-term solution that would help address the ongoing shortage of oncology nurses. The goal of the Transitional Oncology Nurse Academy was to develop a solution that would continually attract experienced nurses to the ambulatory oncology setting. Three key steps were necessary to achieve this goal: 1) assessing the need for the program; 2) presenting a clear and convincing business case of the cost savings and potential benefits to key stakeholders; and 3) ensuring financial and organizational support for the program. To track our success, we developed metrics for success, monitored our outcomes, and communicated our results to drive support for the initiative and help us improve the program. We are extremely proud of our 97 percent graduation and retention rate at one year, and we hope this article encourages other cancer programs to move forward in developing similar programs. OI

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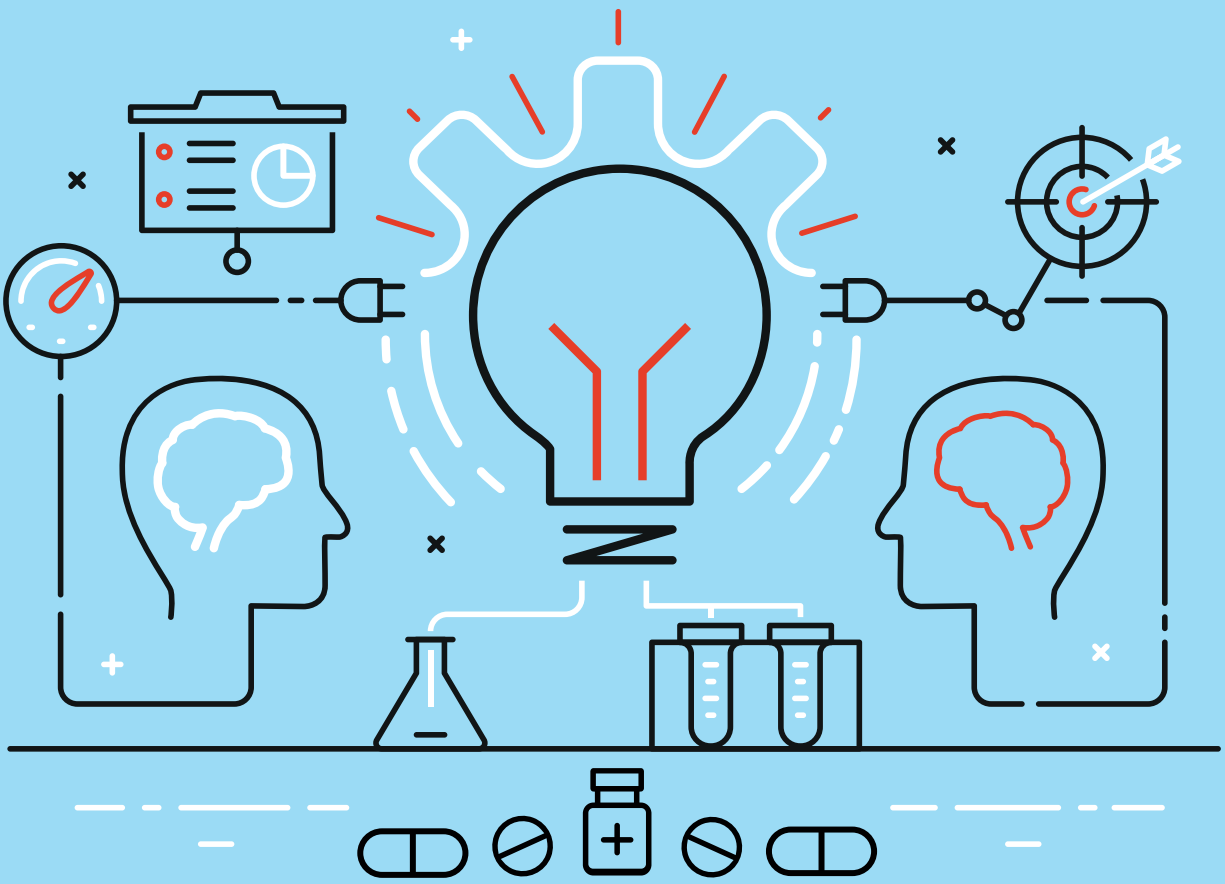
A Pharmacist Collaborative Practice Agreement Improves Oral Oncolytic Workflow and Reduces Treatment Delays



BY AMANDA L. WRIGHT, PHARMD; STEPHANIE F. MATTA, PHARMD, BCOP; AND JULIA R. KERR, PHARMD

Rapid development and utilization of oral oncolytics over the past several decades has led to a paradigm shift in the management of patients with cancer. The substantial challenges associated with this shift in care have prompted cancer programs and practices to enlist the assistance of clinical pharmacists to manage treatment and supportive care for patients receiving oral therapies. Through clinical integration, pharmacists can improve medication access, provide chemotherapy order review and medication reconciliation, identify significant drug interactions, monitor patient adherence and side effects, provide patient education, and enhance onsite outpatient pharmacy revenue, among others.[1] Another advantage for pharmacist integration in oncology clinics is the opportunity to dispense prescriptions at provider appointments. This in-office dispensing service is typically provided by a medically integrated pharmacy, defined as "a dispensing pharmacy within an oncology center of excellence that promotes a patient-centered, multidisciplinary team approach."[2] A medically integrated pharmacy is "an outcome-based collaborative and comprehensive model that involves oncology healthcare professionals and other stakeholders who focus on the continuity of coordinated quality care and therapies for cancer patients."[2]

The National Community Oncology Dispensing Association, Inc. (NCODA) is among the major associations advocating for the value of this model. Patient satisfaction surveys collected through NCODA from more than 350 practice sites revealed that patients favored obtaining their oral oncolytics from their physician's offices given the convenience, timeliness, care coordination, and satisfaction with staff interaction.[3] Not only can medically integrated pharmacies provide closer and timely management of patient therapies, but they can also offer the advantage of more cost-effective care. A study conducted at St. Luke's Cancer Institute over a period of six months revealed an annual estimated net cost avoidance of $1,730,416 through in-office dispensing as compared to $119,794 for prescriptions filled through a mail order pharmacy.[4]

> Originally, prior authorizations were completed by the nursing-managed triage department, but in the past year the oral oncolytic medically integrated pharmacy assumed responsibility of this process.

St. Luke's Cancer Institute, formerly known as Mountain States Tumor Institute, established its medically integrated pharmacy in 2010 to manage patients on oral oncolytics. This service was initiated with the dispensing of only two oral oncolytics to patients being managed by a select number of oncology providers. The significant impact of this service on patient care led to the

quick expansion of the program to dispense and manage multiple medications prescribed by all St. Luke's medical oncology providers. Oral oncolytics were originally prescribed using a paper order form that was faxed to the medically integrated pharmacy; however, this process was automated in 2016 with the sitewide transition of St. Luke's Health System to the Epic electronic medical record (EHR). Providers now enter oncology treatment plans in the EHR and then communicate with the medically integrated pharmacy by sending the plans to an assigned oral oncolytic message pool, seamlessly integrating pharmacists into the care of all corresponding patients.

Our Medically integrated Pharmacy At-a-Glance

St. Luke's Cancer Institute's oral oncolytic medically integrated pharmacy is staffed by several pharmacists and technicians who manage the care of more than 500 patients. Pharmacist services are primarily telephone based, as our five clinics serve patients from southwest Idaho, eastern Oregon, and northern Nevada. The filling process for oral oncolytic prescriptions was refined over several years since the establishment of the medically integrated pharmacy. Once the treatment plan is received by the medically integrated pharmacy, technicians initiate a tracking sheet (Word document) for each patient in their individual folder. The patient tracking sheet details the patient's medication dosing and the start date for each cycle to assist in following their treatment. Technicians will also run a drug interaction report with the patient's current medication list, which is saved in the patient's folder. After these steps are completed, pharmacists review the oral oncolytic prescription.

Our review process follows these steps. Patient charts are reviewed for diagnosis and medication indication, followed by a review of the prescription for appropriate dosing based on treatment guidelines and patient specific factor such as renal and hepatic function. The patient's drug interaction report is reviewed to note medications with possible interactions that may need to be addressed with the patient or provider. The patient is then contacted via telephone to introduce the oral oncolytic medically integrated pharmacy and discuss the filling process for a specialty medication, including prior authorization through insurance and possible co-pay assistance. Any outstanding questions regarding medications or appointments for baseline exams are addressed with the patient and the provider, when necessary, to complete the prescription review.

A test claim is then run to determine if the patient's insurance requires the completion of a prior authorization. Originally, prior authorizations were completed by the nursing-managed triage department, but in the past year, the oral oncolytic medically integrated pharmacy assumed responsibility of this process. Pharmacists use the EHR to answer clinical questions related to prior authorization and provider notes are attached for reference. If a prior authorization is denied, pharmacists send the paperwork to the provider to complete for appealing the decision. Once the prescription is approved through the insurance, the claim is run again to determine the patient's co-pay.

If a patient's co-pay is deemed unaffordable, pharmacists contact St. Luke's Cancer Institute's patient financial advocates. These advocates work with patients to find co-pay assistance or patient assistance programs, depending on their financial situation. Once the lowest co-pay for the medication is identified, the prescription is filled by the St. Luke's Boise retail pharmacy, which is associated with St. Luke's Cancer Institute. After the prescription is filled, our medically integrated pharmacy contacts the patient to provide counseling and arrange pickup. When possible, our pharmacists provide this counseling in person. The pharmacist uses the documented start date for the patient's oral oncolytic to schedule weekly follow-up calls through the first cycle—unless the patient has a scheduled appointment with their provider. After this appointment, pharmacists review all provider notes for patient updates and possible changes in therapy.

For subsequent cycles, pharmacists contact patients when they have just over a week of medication on hand to begin the refill process and coordinate delivery or pickup. This conversation with the patient includes review of side effects, adherence, and changes in their medication list. EHR reminders send notifications to the St. Luke's Boise retail pharmacy to fill oral oncolytic prescriptions. A reminder message within the EHR is also created and sent to the medically integrated pharmacy when a new prescription is received. Along with treatment details, these EHR reminders are used by pharmacists and technicians to track and complete tasks related to patient care.

Pharmacists also assist patients who are required by their insurers to use mail order pharmacies or patients enrolled in patient assistance programs. Our oral oncolytic medically integrated pharmacy continues to follow these patients until they have been contacted by the mail order pharmacy or free drug program and have received their medication. After receiving medication counseling, these patients are discharged from the medically integrated pharmacy and followed up by their provider's primary nurse. The only exception to this process is mail order patients treated at the Boise St. Luke's Cancer Institute clinic; these patients are followed by a nurse who works with the medically integrated pharmacy.

Laying the Foundation for Change

Transitioning to electronic entry of oral oncolytic prescriptions in the EHR brought new challenges to the order entry process for providers—who often consulted pharmacists for entry of treatment plans or to make changes to prescriptions. Any time a change in dose, quantity, renewal of refills, or a monthly prescription for Celgene products was needed, the new prescription would be sent back to the provider for signature through the Send Plan function in the EHR. Depending on when the signature request was sent and provider workload, it could take a few hours to several days for prescriptions to be signed. Pharmacists would spend time each day, occasionally multiple times per day, reviewing patient charts for signed prescriptions as providers would not always send notifications when this action was completed. If prescriptions were not signed within a few days of the request

for signature, additional messages are sent to the provider. This process significantly impacted the workflow of the medically integrated pharmacy, causing interruptions in the prescription review or refill processes and, sometimes, even delays in treatment.

To improve the workflow in the medically integrated pharmacy and assist busy providers with patient care, St. Luke's Cancer Institute's pharmacy management team discussed opportunities to expand pharmacist responsibilities, including the implementation of a collaborative practice agreement (CPA). The concept of a CPA dates back many decades to when the American College of Clinical Pharmacy (ACCP) issued a position statement regarding collaborative medication management by pharmacists.[5] In turn, the American Pharmacists Association (APhA) issued consortium recommendations to define CPAs and advanced pharmacist practice. Collaborative practice agreements are documents intended to "create formal relationships between pharmacists and physicians or other providers. CPAs define certain patient care functions that a pharmacist can autonomously provide under specified situations and conditions."[6] Several examples of successful CPAs are currently in practice across the nation. For several years, St. Luke's Cancer Institute pharmacists have been involved in prescribing and managing antiemetics for oncology patients through a CPA. Pharmacists use patient history to assist in selecting the appropriate antiemetic at treatment initiation and communicate with patients through their treatment to further tailor the antiemetic therapy. Based on the success of the antiemetic CPA and the good rapport between providers and pharmacists, St. Luke's Cancer Institute decided to pursue implementation of an oral oncolytic CPA in the medically integrated pharmacy.

Developing the CPA

A pharmacy resident project was designed to assist our medically integrated pharmacy create, implement, and evaluate an oral oncolytic CPA. A literature search revealed that although CPAs are being used in several settings, the practice was not commonplace in oncology pharmacy, especially to the extent at which we were aiming. In other words, creation of an oral oncolytic CPA would be a novel approach to pharmacist assistance with oncology medications.

Based on observations in the medically integrated pharmacy, we compiled a list of clinical activities that oral oncolytic pharmacists would be responsible for under the CPA. Clinical activities included the pharmacist intervention requests sent most often to providers. The most common request to providers was for signature on refill renewals for continuation of therapy, including Celgene products that require a new prescription with each cycle. Dose adjustments based on renal and hepatic function at initiation of and during therapy were included as these labs are reviewed by pharmacists prior to each fill. And because pharmacists are more familiar with available strengths, we included under the CPA the ability for pharmacists to round medications to the nearest tablet size for ease of patient administration and possible cost savings. Allowing pharmacists to renew prescriptions based on provider notes indicating continuation of therapy would have a large impact on workflow, so that was included under the CPA. Dose adjustments for toxicities based on guidelines, the pharmacist's clinical judgment, and provider notes were also included in the clinical activities. Note that a staff message is still sent to providers to confirm dose adjustments for toxicities that are reported to pharmacists or not clearly addressed in provider notes. Another intervention that pharmacists occasionally see is adjustments to the appropriate dose in medications where dosing varies based on indication, which must be addressed before completion of the initial review and can result in treatment delays. Because pharmacists monitor the patients closely, the ability to order lab tests and exams that are recommended for baseline and continued monitoring during treatment was a valuable addition. Inclusion of these clinical activities in the CPA responsibilities would decrease workflow interruptions and allow pharmacists to practice at the top of their license. Table 1, page 36, lists the clinical activities we proposed under the draft CPA.

Improvements in pharmacist workflow at St. Luke's Cancer Institute due to significantly reduced turnaround times of prescriptions has allowed the medically integrated pharmacy to keep up with a rapidly growing patient population.

The draft CPA and the idea of a pilot project involving a small subset of providers was presented to the oncology pharmacy and therapeutics (P&T) committee for provider approval. The pilot project would allow us to evaluate improvements in medically integrated pharmacy workflow, possible patient cost savings, and provider satisfaction prior to CPA implementation in all clinics. Following P&T committee approval of the oral oncolytic CPA and pilot project, 4 providers were approached to request their participation in the pilot as a subset of the 15 St. Luke's Cancer Institute's providers. The pilot providers, or pilot group, were selected based on oral oncolytic workload and their physical proximity to the medically integrated pharmacy to enhance communication. The other 11 providers were considered to be the control group.

Pilot group providers received education on the clinical activities that pharmacists would be able to perform under the CPA. These providers were also notified that they would receive a weekly email detailing the interventions completed for their patients. Education was also provided to the pharmacists in the medically integrated pharmacy on the clinical activities that could be performed with the oral oncolytic CPA, and how to address interventions for patients depending on whether their provider was in the pilot or control group.

Table 1. Clinical Activities Included in Our Draft Collaborative Practice Agreement

Signature on refill renewals for continuation of therapy.
Dose adjustments based on renal and hepatic function at initiation of and during therapy.
The ability to round medications to the nearest tablet size for ease of patient administration and possible cost savings.
Renewal of prescriptions based on provider notes indicating continuation of therapy.
Dose adjustments for toxicities based on guidelines, the pharmacist's clinical judgment, and provider notes.
Adjustments to the appropriate dose in medications where dosing varies based on indication.
The ability to order lab tests and exams that are recommended for baseline and continued monitoring during treatment.

The pilot was designed to allow comparison of interventions made by pharmacists through the CPA in the pilot group with suggested interventions sent to the control group. Data collection for the pilot group included type of intervention required, turnaround time of prescriptions, patient cost savings, and provider satisfaction. Data collection in the control group was designated as interventions recommended, turnaround time of prescriptions, and delays in new orders. The pilot planned for two months of data collection before results would be presented to the oncology P&T committee.

In the pilot group, once the need for an intervention was identified, pharmacists would make prescription adjustments and then sign on behalf of the provider, with reference to the CPA in the comments section of the signature screen in the EHR. Pharmacists would then proceed with the normal workflow in addition to documenting the intervention in a shared pilot group spreadsheet. The pilot group spreadsheet was then reviewed by the data collector to assign time values based on the type of intervention. Interventions were assigned a value of the time it would take the pharmacist to complete the task to avoid any additional impact on their workflow. Simple tasks such as refill renewals or dose adjustments were given a value of 5 minutes to identify the intervention and enter a new prescription. Interventions that were given a value of 10 minutes included those that required a more detailed review or Celgene renewals due to the added documentation with the risk evaluation and mitigation strategy (REMS) program requirements. A value of 15 minutes was assigned to prescriptions where multiple interventions were completed.

In the control group, the normal medically integrated pharmacy process was followed once interventions were identified. Pharmacists would update the prescription in the treatment plan and then send a staff message to the provider informing them of the suggested intervention, upcoming start date, and requesting a signature if they would like to proceed. These messages were also sent to the medically integrated pharmacy message pool to provide visibility of the response to all team members. The data collector was included on these staff messages during the pilot to update the control group Excel spreadsheet with the time the pharmacy message was sent to the provider; the time the prescription was signed and received was also recorded. These values were used to show the amount of time it took for a prescription requiring an intervention and provider signature to be ready for a pharmacist to review.

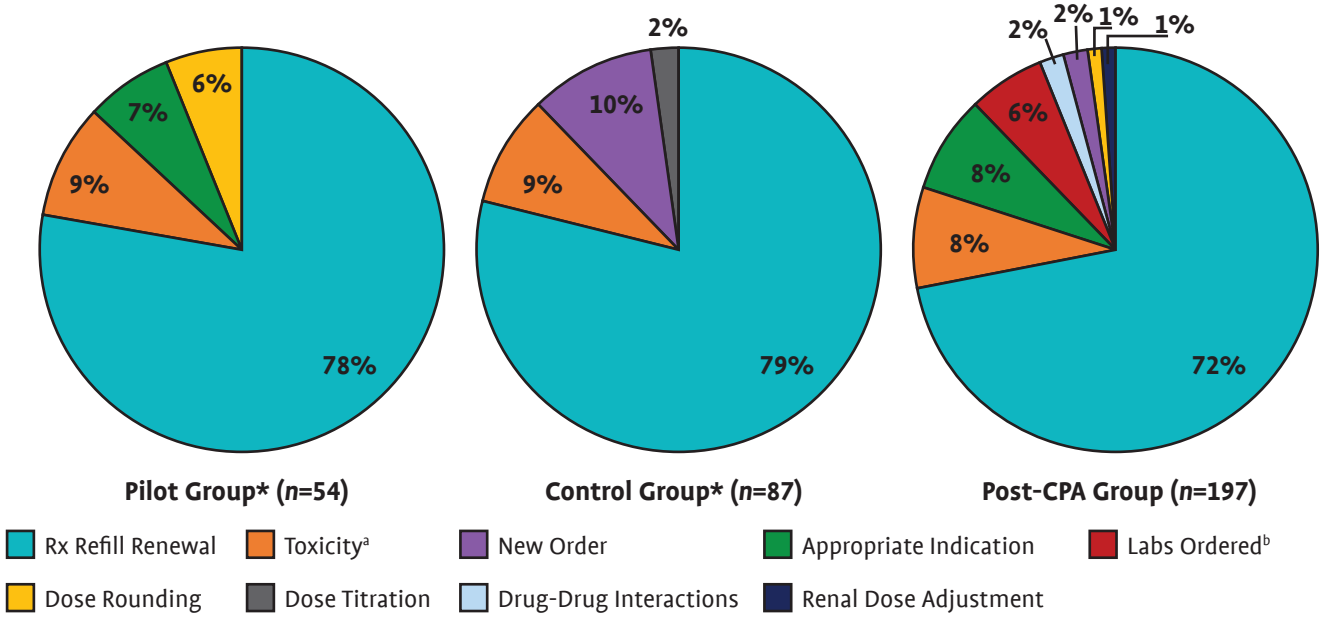
Study Results

At the end of two months of data collection, preliminary data was finalized for presentation to the oncology P&T committee. A survey was also conducted in the pilot group to show data on provider satisfaction with the oral oncolytic CPA. Based on these data, the oral oncolytic CPA was approved for sitewide implementation in all St. Luke's Cancer Institute clinics. Due to the timing of the P&T meeting, three months of pilot data collection was completed, which allowed time to educate to St. Luke's Cancer Institute providers before the oral oncolytic CPA was implemented systemwide. We decided to continue data collection for an additional three months following systemwide implementation of the CPA to further evaluate the impact on workflows. To distinguish between the data collected before and after CPA implementation, results were discussed as part of the pilot phase or the post-CPA phase.

Pilot Results

In the pilot phase, data was collected on 141 total interventions, with 54 in the pilot group and 87 in the control group. Interventions recorded in the pilot group included prescription refills, adjustment for toxicity, adjustment for appropriate indication, and dose rounding. The control group interventions included refill renewals, adjustment for toxicity, new orders, and dose titration. Breakdown of these interventions can be seen in Figure 1, page 37. The total turnaround time for the 54 pilot group interventions was 365 minutes, with the average time spent on each intervention at 7 minutes. In the 87 control group interventions, the total turnaround time was 399,999 minutes with an average of 3,311 minutes per intervention. Three outliers were identified in the control group for prescriptions unsigned after an extended length of time and were removed from the data prior to statistical analysis. The oral oncolytic CPA was shown to have a statistically significant ($p < 0.0001$) impact on decreasing prescription turnaround times, as seen in Table 2, page 38. Dose rounding that resulted in patient cost savings was reported on two prescriptions. Suggested wholesale prices for capecitabine and temozolomide were used to determine cost savings. Dose rounding for capecitabine and temozolomide resulted in savings of $9,858.24 per year ($547.68 per cycle) and $3,281.85 per year ($252.45 per cycle), respectively.

Figure 1. Intervention Results of Pilot, Control, and Post-CPA Groups



NOTES: *Pilot phase (*n* = 141): pilot group (*n* = 54) and control group (*n* = 87). CPA = collaborative practice agreement. [a]Hand-foot syndrome (*n* = 8), diarrhea (*n* = 6), neutropenia (*n* = 5), nausea (*n* = 4), and neuropathy (*n* = 3) were the most commonly observed reasons for dose reductions due to toxicity in all groups. [b]Complete blood count (CBC, *n* = 4), complete metabolic panel (CMP, *n* = 5), phosphorus (*n* = 3), uric acid (*n* = 3), and pregnancy test (*n* = 4) were ordered in the post-CPA group.

A three-statement survey using a Likert scale measured provider satisfaction with the interventions and support of systemwide CPA implementation. Three of the pilot group providers strongly agreed and one provider agreed with all the statements, with all verbally expressing support of the oral oncolytic CPA after the survey.[7]

Post-CPA Results

In the weeks prior to systemwide implementation of the oral oncolytic CPA, education was provided to all 15 providers. Pharmacists in the medically integrated pharmacy were also given further education on order entry for labs and exams, and instructed on plans for data collection in the post-CPA phase. Pharmacists were instructed to use the same method for completing prescription interventions per the CPA as in the pilot group. Reference to the CPA was still included in the comments section of the EHR when signing prescriptions. For data collection, pharmacists sent a reminder with a brief description of the intervention completed, and the data collector filled in the Excel spreadsheet for the post-CPA data. Time values for interventions made in the pilot group were also applied to data from the post-CPA group.

Over three months, 197 interventions were made in the post-CPA group. The interventions completed were similar in breakdown to the pilot and control groups for the pilot phase, as seen in Figure 1, above.[7] Total turnaround time for the post-CPA group was 1,190 minutes, averaging 6 minutes per intervention. Comparison of the post-CPA group to the control group also showed statistical significance for decreased turnaround times on prescriptions when interventions are signed on behalf of the provider per the CPA (Table 2, page 38). Provider feedback was requested through an email sent to each of the providers detailing the interventions made with the oral oncolytic CPA in the post-CPA phase. Only one provider responded with a question regarding future notification of interventions.[7] An official survey was not completed in the post-implementation phase; however, provider approval of the oral oncolytic CPA was heard by word of mouth throughout the clinic locations.

A noted limitation of data collection in both phases is that all data may not be represented. Due to delays in pharmacist education (based on their schedule), some of the possible interventions in the pilot and control groups may have been missed. Some instances of forgotten notifications to the data collector were also observed in the pilot, control, and post-CPA groups. Despite this limitation, the data still showed a significant difference in the turnaround time of prescriptions.

Table 2. Turnaround Times from Pilot, Control, and Post-CPA Groups

Pilot Group (*n*=54)	Control Group (*n*=87)	Post-CPA Group (*n*=197)
Total Turnaround Time: 365 minutes	Total Turnaround Time: 399,999 minutes	Total Turnaround Time: 1,190 minutes
Turnaround Time Range: 5–15 minutes (Average 7 minutes)	Turnaround Time Range: 10 – 20,565 minutes (Average 3,311 minutes) Outliers: 30,075, 41,549, & 50,245 minutes	Turnaround Time Range: 5 – 15 minutes (Average 6 minutes)
Mean Turnaround Time* (p<0.0001)		*Excluding outliers

CPA = collaborative practice agreement.

There were 141 interventions completed in the pilot phase. Comparison of turnaround times between the pilot and control groups showed a statistically significant decrease in turnaround times in the pilot group with interventions made through the CPA. The turnaround times for prescriptions in the post-CPA group were also decreased by a statistically significant margin when compared to the control group.

Importance of a Team Approach in Implementing a CPA

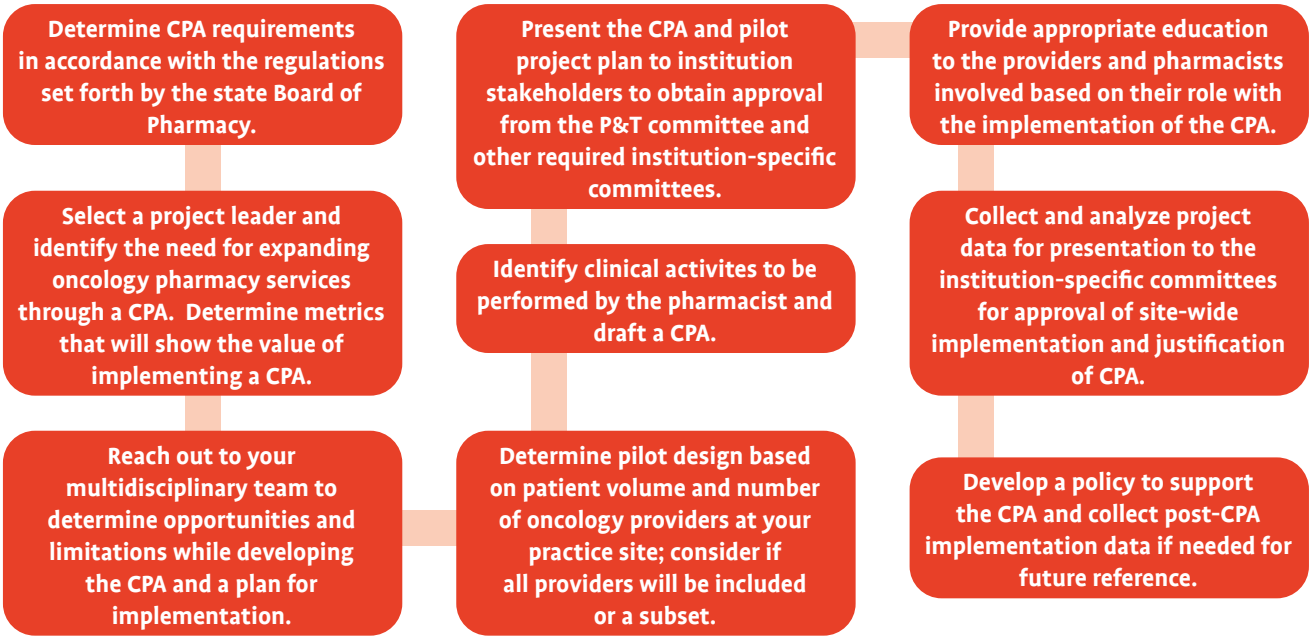
As healthcare continues to evolve and specialties continue to play an integral role in patient care, cancer programs and practices are embracing a multidisciplinary team-based approach. Leveraging the expertise of every member of the healthcare team not only assists providers, but also results in more comprehensive care for patients. With continued medical advances and expansion of medication options in oncology treatment, pharmacists are recognized as valuable resources within the clinic for drug information and management. Cancer programs interested in implementing a CPA can follow the key steps outlined in Figure 2, right.

Pharmacists should consult their state Board of Pharmacy for regulations in place on pharmacist practice with CPAs. It is important to identify a project leader and discuss what the team hopes to achieve by implementing a CPA. Building good rapport within the multidisciplinary team is key to effective communication in discussions about expanding pharmacist services in the cancer program. Open discussions with the oncology team can help identify areas of medication management where providers require additional assistance, or that pharmacists know would increase support to both patients and providers. Whereas all cancer programs and practices may not have a medically integrated pharmacy associated with their clinic, this should not be considered a barrier to implementing a similar oral oncolytic CPA. Pharmacists can still assist with reviewing and adjusting prescriptions based on the clinical activities agreed on by the multidisciplinary team before prescriptions are sent to specialty pharmacies to be filled.

Once you have an outline of your CPA goals, create a draft following your institution's policies that will be shared with the oncology team. Determining the ideal design of a pilot project for your cancer program is another important step to allow for the appropriate evaluation of CPA outcomes. The drafted CPA and plans for a pilot project should be shared with various stakeholders at your institution for approval. It is important to note if there will be any changes in cost to the institution with implementation of the CPA. Following approval of the CPA and pilot, all team members involved will need education. Education should be timely to ensure your data collection is not impacted. Preliminary evaluation of data as you are collecting can assist in identifying limitations and determining what steps can be taken to assist in improving data collection, especially if related to education. At the conclusion of data collection, be sure to report the results to the same stakeholders that approved the pilot to show the impact the CPA had on your endpoints. This will also provide an opportune time to initiate implementation of your CPA with all providers if a subset was used during the pilot. The decision on whether further data collection after the CPA is implemented will be up to the discretion of your institution.

Pharmacist assistance with oral oncolytic prescriptions can have a large impact in any oncology clinic. Improvements in pharmacist workflow at St. Luke's Cancer Institute due to significantly reduced turnaround times of prescriptions has allowed the medically integrated pharmacy to keep up with a rapidly growing patient population. Provider workflow improvements were also noted as they are now able to focus on other patient care responsibilities and entrust the management of the finer details of medications to the pharmacists. Moreover, CPAs allow pharmacists to practice at the top of their license, providing greater job satisfaction. OI

Figure 2. Guide to Implementing a CPA.



Notes: CPA = collaborative practice agreement; P&T = pharmacy and therapeutics.

Stepwise guide based on St. Luke's Cancer Institute's experience to assist with creation, implementation, and evaluation of a CPA.

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Reducing ED Visits and Hospital Admissions After Chemotherapy with Predictive Modeling of Risk Factors

BY MICHELLE SMITH, DC, AND JAY CARLSON, DO

Approximately 1.76 million people were diagnosed with cancer in the United States in 2019, and new technology and treatments have helped to increase our national five-year survival rates to 70 percent, up from 39 percent in 1960.[1] To better meet the needs of this growing patient population, providers have changed how they manage oncology patients. The most common patient concern today is the fear of financial toxicity from increasing drug costs and associated treatment costs; too many patients with cancer are concerned about going bankrupt or, even worse, taking their families into bankruptcy with them due to these high costs of care. Patients are also highly concerned about how their cancer diagnosis, treatment, and side effects will impact their quality of life and ability to work and care for their family. So, in addition to working to cure or manage cancer, today's oncology providers must also work to mitigate these patient stressors.

Rising Cost of Cancer Care

On average, in the 10 years from 2004 to 2014, the United States has seen a 62 percent increase for commercial healthcare plans and a 73 percent increase for Medicare-associated healthcare costs.[2] Oncology is unique compared to other diseases as patients often have at least two and up to five specialty areas (e.g., medical oncology, radiation oncology, surgery, cardiology) involved in their care. In 2015, the United States spent an estimated $80.2 billion on all cancer care—with 52 percent spent on hospital outpatient and clinic services and 38 percent on inpatient admissions.[2] A reduction in inpatient admissions or emergency department (ED) visits would significantly improve the quality of life for patients with cancer while also reducing the cost of their care.

> CMS developed the OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure to help quantify and reduce ED visits and inpatient admissions of patients with cancer, as well as improve their quality of life.[5]

Increased Usage of ED and Inpatient Admissions to Manage Oncology Patients

Several studies have evaluated ED utilization of patients with cancer. A Fred Hutchinson Cancer Research Center study of 5,853 adults with solid tumors who had been treated with chemotherapy, radiation, or both, determined that 53 percent of

Measure OP-35 requires change. To effect positive change and meet this quality measure, cancer programs and practices need to ask and find answers to the right questions…

these patients had an ED visit(s) related to symptom management that could have been managed in an outpatient setting.[3] The study also found that the average cost of an ED visit was higher for oncology patients than those of non-oncology patients—$1,047 compared to $335.[4] Extrapolating these data, if providers could impact only half of the 3,100 patients requiring ED care, 1,550 patients might have avoided an ED visit.[4] Another study evaluated 87,025 patients with cancer who had 197,886 ED visits within one year of diagnosis and averaged 2.27 ED visits per patient, per year.[4] Of these, 35 percent had more than one ED visit per year, and approximately 51 percent of oncology patients who presented for an ED visit had an inpatient admission.[5] The potential cost-savings for managing these patients in the outpatient setting is clear.

Implementation of a New Medicare Outpatient Quality Measure

The Centers for Medicare & Medicaid Services (CMS) reviewed the 2007 commercial claims of 14 million patients with cancer and found that these patients averaged one inpatient admission and two ED visits per year.[6] Forty percent of inpatient admissions and 50 percent of ED visits were related to their chemotherapy treatment.[6] The study showed that patients have unmet needs and experience gaps in care that, if addressed, could reduce ED visits and inpatient admissions and improve quality of life.[6] Based on these data, CMS developed the OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure to help quantify and reduce ED visits and inpatient admissions of patients with cancer, as well as improve their quality of life.[5]

CMS used claims data from October 2015 through September 2016 to provide a "dry run" of OP-35 in oncology programs and practices across the United States. The agency used 2018 claims data to establish benchmark metrics for ED visits and inpatient admissions as part of its Hospital Outpatient Quality Reporting Program. Initial benchmarks were 6.1 percent for ED visits and 12.9 percent for inpatient admissions.

OP-35 went into effect January 1, 2020, and the measure was designed to evaluate the rate of ED visits (EDV) and inpatient admissions (IPA) within 30 days of hospital-based outpatient chemotherapy treatment for patients 18 years and older with cancer, not including those with leukemia. The measure consists of two scores—one for EDVs and one for IPAs. The rates are determined by the hospital's current and expected IPAs and EDVs, as well as national observed rates on both metrics. In addition, rates are risk-adjusted for factors such as patient demographics, cancer type, comorbidities, treatment type, and possibly socio-demographic status. CMS provided oncology programs with data to compare their performance on these measures to national benchmarks.

Although OP-35 recognizes two outcomes—ED visits and inpatient admissions—a single patient can be assigned only a single outcome. Thus, patients experiencing both an EDV and an IPA will count as having only an IPA. The numerator is 1 or more EDV or IPA for 1 of 10 diagnoses (anemia, nausea, dehydration, neutropenia, diarrhea, pain, emesis, pneumonia, fever, or sepsis) within 30 days of receiving hospital-based outpatient chemotherapy for cancer treatment. The denominator is Medicare fee-for-service patients 18 years and older with a diagnosis of cancer (except leukemia) who have received at least one outpatient chemotherapy treatment during the 30-day performance period.

For the first year (2020), participating institutions that shared data for disclosure avoided a 2 percent penalty imposed on their CMS oncology claims. The 10 diagnoses associated with an EDV or IPA are all common side effects of most chemotherapy agents, and most patients with cancer experience them at some point in their journey. CMS's rational for OP-35 was multifold and included:

- Assessing the care provided to patients with cancer by publishing an institution's metrics on the CMS website
- Increasing the quality of care provided to and the quality of life of patients with cancer
- Encouraging quality improvement efforts to reduce the number of potentially avoidable EDVs and IPAs for patients with cancer
- Promoting the use of evidence-based interventions to prevent and treat common side effects and complications of chemotherapy.

What Should Cancer Programs and Practices Be Thinking About?

Measure OP-35 requires change. To effect positive change and meet this quality measure, cancer programs and practices need to ask and find answers to the right questions, including:[8]

- Do patients have easy access to care? Think in terms of your office location(s) and hours of operation.
- What are we doing to improve the patient's quality of care and quality of life?
- Are we proactively addressing symptom management?
- Do patients know what to expect and how to address symptoms?
- How are we monitoring outcomes for our patients receiving cancer treatment?
- What interventions do we have in place to identify patients who are having difficulty with treatment?
- What interventions do we offer? How are patients educated on these interventions?
- What happens to our patients after hours?
- How can we meet the needs of our patients in the moment—yet at a convenient time for them?

How We Addressed Measure OP-35

We were an early adopter of the Epic electronic health record (EHR). Over the past 12 years, Mercy Cancer Care has accumulated more than 700 million separate inpatient and outpatient Epic encounters. Our response to OP-35 was to develop an internal report that predicted the metrics for one of our larger oncology practices. While the clinic was doing well with the ED benchmark, its metric for IPAs was too high. This initial work led Mercy Cancer Care to develop an internal review board protocol to review all the health system's data. Initial study objectives were twofold: 1) to use the EHR to identify the risk factors associated with EDVs and IPAs within 30-days of chemotherapy; and 2) to use these data to build a predictive model to prevent such future encounters by focusing on key factors and at-risk patients.

We defined chemotherapy based on CMS metrics. For example, the OP-35 measure excluded oral chemotherapy as CMS identified challenges with oral chemotherapy administration without using pharmacy claims data. CMS data also found that oral agents had fewer adverse reactions and side effects, which resulted in lower numbers of EDVs and IPAs.

Mercy Cancer Care's review included approximately 100,000 chemotherapy encounters within 30 days of the infusion encounter. The study identified that 16.8 percent of the encounters resulted in an IPA and 11.8 percent experienced an EDV. Both metrics exceeded CMS's initial published benchmarks. With the understanding that many of the targeted diagnoses in OP-35 can be managed in the outpatient setting, our next step was to identify our at-risk patients.

Now, How to Make the Data Usable?

Mercy Cancer Care decided to use predictive algorithm methodology and machine learning to identify patients at risk for potential EDVs or IPAs. We split our retrospective patient data into a training cohort (70 percent) and testing cohort (30 percent) and applied the algorithm. The final algorithm model was applied to our live patient data set, assigning a probability of an ED visit or being admitted as an inpatient to all active chemotherapy patients. Based on modeling, "at-risk" patients were divided into high, intermediate, and low risk categories. Every 24 hours, Mercy Cancer Care assessed the pertinent EHR variables within the model, including natural language processing where appropriate.

Implementing a Reporting Process

Mercy Cancer Care has a web-based oncology dashboard of multiple oncology-related quality metrics, including:

- Preferred regimen compliance
- Performance score documentation
- Discrete staging documentation
- Chemotherapy within 14 days of end of life (EOL)
- Survivorship care plan completion rate.

The dashboard also includes Commission on Cancer (CoC) Standards, such as automated tracking for clinical research accruals, genetic testing and risk assessments, and distress screening.

Mercy Cancer Care established the world's first Virtual Care Center in October 2015. Our Virtual Care Center offers approximately 12 programs, one of which is our Nurse on Call program.

The oncology dashboard was the obvious tool to collect and monitor OP-35 risk scores for every patient who had received chemotherapy. The dashboard displayed patients at high risk for EDV or IPA; data were summarized and are searchable by region, community, clinic, and provider. OP-35 dashboard reports are updated daily to generate the most recent score for each patient. Automated reports are delivered daily to essential personal within each clinic, including medical oncology, radiation oncology, and surgery, to minimize the clicks required at the clinic level while still allowing providers to use these data in intake assessments. When medical assistants room patients, they use a questionnaire to assess patients and alert providers to potential areas that need further assessment.

The automated OP-35 report is also sent to navigators, triage nurses, infusion nurses, and clinic managers. It is especially critical that these reports go to infusion nurses who educate patients on side effects, review home medications, and teach patients and caregivers best practices for handling side effects. Mercy Cancer Care developed an Epic Smart phrase to assist its infusion nurses with documentation related to OP-35 status and planned intervention(s) of high-risk patients.

Our Nurse on Call Program

Mercy Cancer Care established the world's first Virtual Care Center in October 2015. Our Virtual Care Center offers approximately 12 programs, one of which is our Nurse on Call (NOC) program. Available 24/7, NOC uses Schmitt-Thompson evidence- and symptom-based protocols.[7] NOC protocols are reviewed and updated every year and are standardized across the ministry. The NOC team has access to Epic for scheduling appointments quickly, and nurses document every encounter and communicate with the clinic or provider on call. Providers have access to all the notes entered from the NOC, which means potentially more cost-effective care management as patients are proactively captured before they require EDV or IPA interventions. NOC data have shown an 80 percent reduction in unnecessary ED visits for oncology patients in two Mercy communities.

Next Steps and Future State

While our current proactive OP-35 management dashboard is a huge success, it requires our clinical team to assess patients. Under Mercy Cancer Care's planned future state, currently in development, this assessment process will be automated. Patients at higher risk will be identified through smart texting for electronic navigation (eNavigation). Initiation of the oncology texting project

was delayed due to COVID-19. By automating the assessment process and directly interfacing with patients, Mercy Cancer Care may be able to reduce care variations. Accordingly, we developed algorithms for common diagnoses amendable to eNavigation such as pain, fever, diarrhea, nausea and vomiting, and fatigue. eNavigation will be used in conjunction with Mercy Cancer Care's Nurse on Call program to escalate issues to a nurse who is available 24 hours a day. Based on the smart text response, the NOC can contact the patient directly. If the response indicates an escalation threshold was not met, the NOC sends a message acknowledging that patients are doing well.

Best Practices for Reducing Unplanned Acute Care for Patients with Cancer

Mercy Cancer Care's OP-35 quality improvement initiative allows us to identify our high-risk patients and their needs in a proactive manner. We improved our care coordination by running daily real-time reports of these at-risk patients, standardizing their symptom management, and establishing a process to escalate care, when appropriate, to the NOC. For cancer programs and practices looking to develop a similar quality improvement initiative, Mercy Cancer Care suggests following these best practices:[9]

1. Develop a process to identify patients at high risk for unplanned care.
2. Look at ways to improve access and care coordination.
3. Standardize clinical pathways for symptom management.
4. Develop urgent care tactics.
5. Use palliative care earlier.

CMS's intent for establishing OP-35 was to reduce IPAs and EDVs for oncology patients. One way the agency thought to do this was by publishing how well each institution is doing to meet this metric. As a result, many institutions changed their care or made efforts to improve care coordination and patient outcomes because they knew their performance was being tracked and monitored. Mercy Cancer Care is no different, but we used this impetus to change our care model to proactively treat patients with cancer, improve their outcomes, and most importantly improve their quality of life. OI

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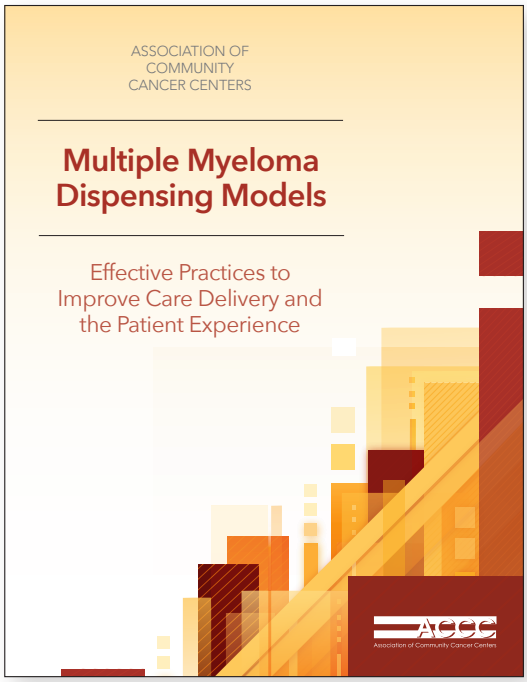

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Integrating Prehabilitation, Rehabilitation, and Prospective Surveillance into Cancer Interdisciplinary Teams

BY CHRISTOPHER M. WILSON, PT, DPT, DSCPT; JANNIFER S. STROMBERG, MD; AND JANET WIECHEC SEIDELL, PT, MPT

In Brief

A growing body of evidence finds that prehabilitaton, rehabilitation, and prospective surveillance can improve clinical outcomes, quality of life, and functional performance. To achieve these gains, rehabilitation services must first be purposefully and strategically integrated into the cancer program or practice. Individuals with cancer can experience a variety of impairments and functional limitations from the disease and its treatments; these may include fatigue, pain, loss of range of motion, weakness, balance impairments, cognitive issues, urinary or fecal continence issues, or lymphedema. A structured approach to periodic assessments, termed *prospective surveillance*, can proactively address these issues, identifying and treating emerging impairments. Purposeful integration of rehabilitation services into a cancer program should include strategic planning meetings, a fiscally responsible pro forma, clinical pathways for efficient referrals, and a process for monitoring patient outcomes. In addition, a means to train rehabilitation professionals on the basics of cancer care and anticipated side effects is needed. After the cancer rehabilitation program is up and running, ongoing data collection is necessary to monitor clinical and financial outcomes, as well as a marketing and communication plan to sustain and grow the program.

Innovations in cancer care have resulted in more people surviving the disease, more people living longer with the disease being treated as a chronic condition, fewer side effects, and improved tolerance to cancer treatments. At the same time, more individuals diagnosed with cancer aspire to have a better quality of life in addition to a longer life. Strategically leveraging the unique skills of the entire interdisciplinary team, including rehabilitation professionals, can help improve quality of life (QoL) before, during, and after cancer treatment. Specifically, licensed healthcare providers, such as physical therapists (PTs), occupational therapists (OTs), and speech language pathologists (SLPs), can help mitigate the side effects of cancer or its treatments.[1] There is emerging evidence that rehabilitation professionals' involvement in cancer care across the entire care continuum helps improve health outcomes and treatment compliance, reduce

Because physical issues can increase the risk of delaying or disrupting cancer treatment, prospective surveillance also has the potential to improve cancer clinical outcomes, shorten hospital length of stay (LOS), and contain healthcare costs.

healthcare costs, and facilitate reintegration into the workforce and community.[2,3] To achieve these outcomes, prehabilitation and prospective surveillance must become part of routine cancer care.

Defining Prehabilitation

Silver and Baima define *prehabilitation* (or prehab) as "a process on the continuum of care that occurs between the time of cancer diagnosis and the beginning of acute treatment. It includes physical and psychological assessments that establish a baseline functional level, identifies impairments, and provides targeted interventions that improve a patient's health to reduce the incidence and the severity of current and future impairments."[4] Although prehab is a relatively novel concept to oncology, one of the initial clinical applications of prehab was within sports medicine and orthopedic surgery.[5,6] This early use involved the foundational supposition that if a surgical limb (and the rest of the body) had better strength and endurance going into surgery, these gains would be appreciated postoperatively. To achieve these gains, the patient is prescribed a series of exercises or activities to complete before surgery, including muscular strengthening as well as cardiovascular, balance, and flexibility activities.[7,8] A holistic prehab program includes adoption of healthy behaviors such as smoking cessation and nutritional modifications.[9] As cancer and its treatments often result in similar physiologic insults to the system, prehab can be used help optimize patients' functional status during cancer treatment.

Defining Prospective Surveillance

Stout et al. describes the concept of *prospective surveillance* as a "proactive approach to periodically examining patients and providing ongoing assessment during and after disease treatment, often in the absence of impairment, in an effort to enable early detection of and intervention for physical impairments known to be associated with cancer treatment."[10] Specific to breast cancer, a physical therapist or other healthcare provider would periodically screen a patient to monitor for subtle changes in strength, range of motion, fatigue, lymphedema, pain, or difficulties performing activities of daily living (ADLs). Instead of waiting until these issues worsen and result in substantial dysfunctions for the patient with breast cancer, these issues are identified early and appropriate referrals are initiated; conditions are addressed proactively, resulting in shorter, more cost-effective care. Because physical issues can increase the risk of delaying or disrupting cancer treatment, prospective surveillance also has the potential to improve cancer clinical outcomes, shorten hospital length of stay (LOS), and contain healthcare costs.

Making the Case for Prehab and Rehabilitation

Poor preoperative fitness and physical status are risk factors for serious postoperative complications and prolonged disability in individuals with cancer.[9] Recognizing the physical benefits that exercise has for individuals with cancer, the American Cancer Society (ACS) recommends: 150 minutes of moderate and 75 minutes of vigorous intensity exercise per week and 2 to 3 sessions or weeks of resistance training of major muscle groups.[9]

Despite this recommendation, too few patients with cancer are prescribed prehab services. One reason may be that healthcare providers are reluctant to "pile on" and add another appointment or task for patients already experiencing a multitude of treatment appointments, life changes, and stressors. While this decision may be well intentioned, the benefits of prehab often outweigh the risk of additional stressors. In fact, in our experience, many individuals newly diagnosed with cancer are eager to adopt exercise and healthy behaviors. Many patients express that at a time in their lives when many things are beyond their control, exercise and healthy behaviors are life choices that they can make to have some semblance of control.

As noted above, the reluctance to overwhelm patients with cancer may prompt some providers to suggest only one or two health behavior changes; however, multimodal, structured prehab protocols have proven more beneficial than using a single approach.[9] In 2017 Chen et al. assessed whether a four-week prehab program would improve functional capacity of older adults scheduled for colorectal cancer surgery.[11] Participants demonstrated an increased amount of physical activity and improvement in distance ambulated on the six-minute walk test; an increased number of patients also met current ACS physical activity guidelines. In a study by Mayo et al., 33 percent of participants diagnosed with colorectal cancer who participated in a prehab program demonstrated improvements in their physical function with a significant increase seen in their mental health, vitality, self-perceived health, and peak exercise capacity.[12] Minnella et al. reported that the distance walked over six minutes in a prehab group was higher compared to those who participated in an exercise program only after colorectal cancer surgery.[13] Finally, as it relates to time to return to ADL performance, Carli, Gillis, and Scheede-Bergdahl demonstrated that participation in prehab programs before cancer surgery enhanced postoperative functional capacity and patients' ability to return to ADLs more quickly than those who did not participate in a prehab program.[9]

In 2016 the National Institutes of Health (NIH) convened a group of subject matter experts in cancer rehabilitation to outline a variety of recommendations to improve integration of rehabilitation services within cancer care.[1] A key recommendation is: rehabilitation screening and assessment should be performed as a part of a comprehensive cancer care plan. The consensus group also recommends that functional status be evaluated objectively at regular intervals, including prior to commencement of active cancer treatment, periodically during cancer treatment, and throughout survivorship. These assessments are aimed at preserving and optimizing function, as well as monitoring for late effects of treatment. In addition, the consensus group recommends a thorough assessment of the content and psychometric properties of existing clinical measurement tools to establish validity with key cancer diagnoses, as well as to establish reliability, minimally clinically important difference, and sensitivity to change. The consensus group found that integration of rehabilitation services within the cancer care continuum helps address and proactively mitigates common side effects of cancer and its treatment, includ-

ing pain, fatigue, distress, balance impairments, and limitations to ADLs and functional activities.

Ensuring Sustainability and Growth

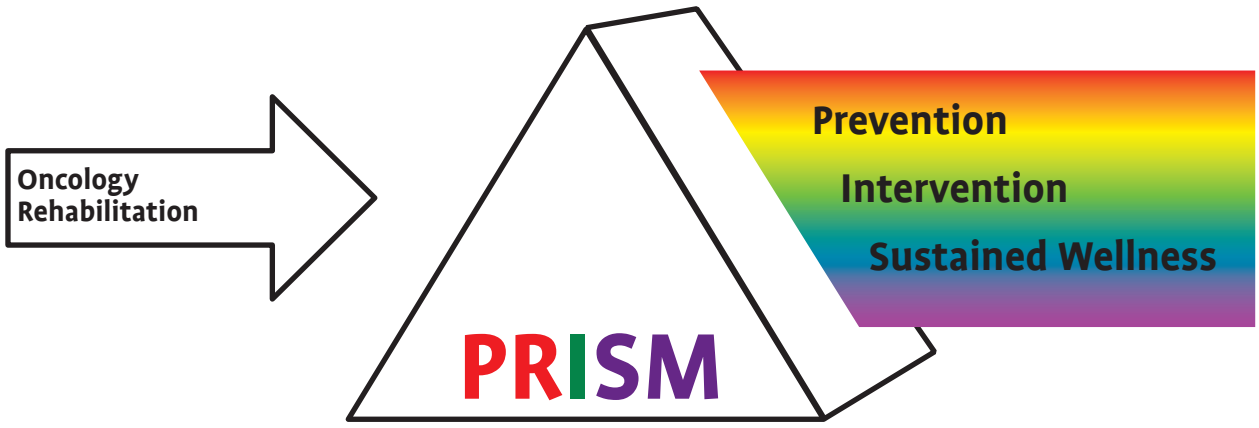
It is estimated that between 60 to 90 percent of people surviving cancer have impairments and meet criteria for participating in rehabilitation services.[2] Thorsen et al. reported that 43 percent of patients with cancer require physical therapy.[3] Despite growing evidence, many cancer programs experience challenges integrating rehabilitation services within routine cancer care. One challenge is reimbursement. Because rehabilitation services are traditionally episodic, reimbursement of these services is optimized for patients already with impairments severe enough to require a referral. This reimbursement model often limits routine preventative or early intervention rehabilitation, as well as community- or population-health activities (e.g., community health fairs). In addition, because most oncologists experience extensive time demands with multiple highly technical and critical healthcare decisions during patient care, providers may focus on addressing chief complaints as opposed to employing a holistic, population health approach, which includes prehab or rehabilitation. Other challenges are technology related; specifically, how well the electronic health record (EHR) is integrated within the healthcare system so that providers can quickly refer patients for these services based on evidence-based measures.[14] In addition, there may be a poorly integrated patient registry for managing patient care plans or the patient's plan of care (POC) is not consistently integrated in the continuum of care.

Cancer rehabilitation is not a novel concept. In 1969 Dietz introduced classifications for cancer rehabilitation, which include preventative, restorative, supportive, and palliative approaches.[15] In 2015 Colombo and Wilson introduced the **PR**evention, **I**ntervention, **S**ustainable wellness **M**odel (PRISM) concept as a means to educate healthcare providers, rehabilitation therapists, and patients about the expanding role of rehabilitation within cancer care, including with patients with advanced cancers.[16] PRISM is a visual depiction of the preventative and wellness roles that rehabilitation therapists can provide across the cancer care continuum in addition to their traditional role as rehabilitative interventionists (Figure 1, page 50). Prevention includes activities related to health promotion and wellness such as early detection and health screening for at-risk populations. Care activities focus on managing comorbidities and their complications, as well as initiating prehab to strengthen the body before cancer treatment.

Within the acute hospital setting, preventative care activities can be safely and effectively employed to shorten LOS and reduce the risk and extent of complications (e.g., venous thromboembolism, debility, falls). An important component to this approach is the employment of clinical pathways to facilitate and expedite referrals. For example, at Beaumont Cancer Institute in Royal Oak, Mich., when a medical oncologist initiates chemotherapy orders during a hospitalization, physical therapy and occupational therapy are automatically included within that order set to begin hospital-based prehab activities (e.g., walking programs, energy

(Top): Beaumont's Rehabilitation and Dialysis Center building is a key location for oncology rehabilitation services in coordination with the the Beaumont Cancer Center. (Bottom): Beaumont's Survivorship Exercise and Wellness Program shares space with the cardiopulmonary rehabilitation gym.

Figure 1. PRISM Model of Care



conservation techniques, fall prevention). In addition, Beaumont Cancer Institute implemented medical executive protocols to facilitate initiation of a PT/OT order with clear inclusion and exclusion criteria. The protocol allows nurses, discharge planners, and even therapists to begin PT/OT services once needs are identified and if there are no exclusion criteria. This practice is most effectively applied when rehabilitation therapists participate in tumor boards, daily huddles, and rounds where physical and/or occupational therapy needs are identified. Because regulations vary by institution and locale, some medical executive protocols may require physician co-signature; this can be accomplished by routing the order to the attending physician's EHR inbox. A similar process can be implemented in the ambulatory or outpatient setting where a rehabilitation therapist attends a tumor board or multidisciplinary clinic and identifies prehab or rehabilitation needs. The rehabilitation therapist sends referrals to the physician for authorization and then schedules outpatient therapy.

On the other end of the PRISM spectrum is *sustained wellness*, which is often aligned with the survivorship phase of cancer care (after cancer treatment has concluded or stabilized). Rehabilitation professionals can initiate sustainable and individualized exercise programs for patients with cancer to help them achieve and maintain a healthy lifestyle.[17] Exercise may be carried out independently by the patient at home or in a community fitness center. Because some patients with cancer may not feel comfortable performing these activities independently or in a community setting, hospitals and cancer programs should consider development of a medical fitness center (e.g., an exercise gym supervised by medical professionals). At Beaumont Cancer Institute, the rehabilitation department established a Cancer Survivorship Exercise and Wellness program to fill this need. Provided as an out-of-pocket service, every patient with cancer receives an individualized exercise session and these exercises are performed under the supervision of a licensed physical therapist assistant (with specialty cancer training) in a group setting. This allows individuals to begin their exercise program in a controlled setting under the guidance of a trained health professional to minimize the risk of injury, incorrect performance, or other health risks.

A cancer survivorship care plan (as required by the Commission on Cancer [CoC]) offers another opportunity to systematically establish ongoing rehabilitation involvement within the survivorship phase of care. This might include activities, such as an annual visit with a physical therapist (as endorsed by the American Physical Therapy Association), to employ prospective surveillance to identify and proactively address emerging issues before they result in extensive debility.[18] Surveillance can be carried out at survivorship clinics, patient education classes, or support groups. Finally, staff who coordinate cancer survivorship programs are an optimal resource for identifying needed referrals to rehabilitation.

Integrating Rehabilitation into Cancer Care

In addition to the traditional interventionist approach to rehabilitation, cancer programs screen patients for common physical, cognitive, or psychosocial impairments. Specifically, during cancer treatment, patients should be screened and observed on a periodic basis for pain, difficulty with ADLs, cognitive impairments, balance issues, weakness, limited range of motion (ROM), and fatigue. If no formal interventions are required, patients should be prompted to start or continue an exercise routine.

Below are examples of how Beaumont Cancer Institute has integrated rehabilitation within the cancer care continuum. At Beaumont, physical therapists travel to the cancer center to attend tumor boards and perform screenings on patients who participate in the breast multidisciplinary clinic. In general, the screenings last about 15 minutes and, because these individuals are newly diagnosed, some do not present with substantial impairments or functional limitations; however, many initially present with fatigue. This screening provides an opportunity to prescribe exercise or

offer referrals to other services, such as occupational therapy or speech-language pathology. Some patients participate in the breast multidisciplinary clinic after surgical excision. These patients may present with mobility restrictions, increased girth, pain, fatigue, or lymphatic cording, which often require more immediate referral. Attendance at the multidisciplinary breast clinic allows the physical therapist to screen patients for their ability to achieve and maintain a set position for completing radiation therapy. If patients are not able to achieve this positioning, physical therapy is initiated to restore appropriate shoulder range of motion or body positioning to successfully complete their radiation therapy regimen. In collaboration with the surgeons who attend clinic, the physical therapist can discuss postoperative weight-lifting restrictions and how to slowly institute a weight-lifting program after surgical intervention. These proactive discussions help minimize the risks of lymphedema, especially for patients who increase their activity levels too quickly following surgery or radiation.[19]

An underutilized role for physical therapists is integration within the care processes for gastrointestinal, gynecological, and genitourinary cancers. In addition to prescribing exercise and addressing movement disorders, pelvic floor physical therapy may be beneficial to treat pelvic and abdominal pain, constipation, sexual dysfunction, or urinary and fecal incontinence.[20] Because this specialty service requires advanced certification and training, the first step is to establish a relationship between oncology team members and pelvic health physical therapists.

Beaumont Cancer Institute stations a PT in the hospital's radiation oncology department to provide consults to patients. Once the radiation oncologist or nurse navigator identifies a patient who needs a consult, the individual is screened and monitored by the physical therapist each week while undergoing radiation treatment and then again at 3-, 6-, and 12-month follow-up visits. Key diagnoses that have benefited from screenings in radiation oncology include individuals with breast, head/neck, lung, prostate, glioblastoma, sarcoma, and cervical cancers.

Finally, Beaumont Cancer Institute has integrated rehabilitation within the survivorship care team, and rehabilitation is a key consideration when a patient's survivorship care plan is developed. Within the Beaumont Health System, rehabilitation services are offered in a variety of

Members of the Beaumont Oncology Rehabilitation Leadership Team. Left to right: Cindy Marsili, PT, Board Certified Oncology Specialist; Chris Wilson, PT, DPT, DScPT, Residency Program Director; Jannifer Stromberg, MD, Radiation Oncology and Medical Director of the Wilson Cancer Center; and Janet Seidell, PT, MPT, CLT, Senior Manager Rehabilitation Services.

Left to right: Stromberg, Marsili, Wilson, and Seidel.

Integrating prehab, rehabilitation, and prospective surveillance into a cancer program requires an interdisciplinary commitment and ongoing dedicated support from administration, oncology providers and staff, inpatient providers and staff, and the rehabilitation team.

settings, including dedicated multidisciplinary survivorship clinics and support groups. In these settings, in addition to receiving consultations from nurse navigators, social workers, and dietitians, patients are screened by the physical therapist. Common findings include fatigue, weakness, deficits in range of motion, increased limb girth, and difficulty performing some ADLs. Regardless of the setting or screening method, integrating rehabilitation therapists into the interdisciplinary cancer care team provides another set of skilled eyes to identify, treat, and cross-refer to optimize patients' clinical outcomes and quality of life.

Ensuring Program Sustainability

Integrating prehab, rehabilitation, and prospective surveillance into a cancer program requires an interdisciplinary commitment and ongoing dedicated support from administration, oncology providers and staff, inpatient providers and staff, and the rehabilitation team. At Beaumont Cancer Institute, key stakeholders work as a team to educate oncology leadership and administration on the value that rehabilitation services provide to patients and providers alike. Education is also provided on the changing landscape of cancer survivorship and the desires of patients and their families to move forward into survivorship in the healthiest way possible. In our experience, it helped to first identify the oncology providers at our institution who were already referring patients to rehabilitation services, as well as the oncology providers most interested in rehabilitation and survivorship resources. We also looked at the rehabilitation services that were most frequently requested for patients with cancer. This information was behind our decision to start first with a proactive lymphedema prevention program and our breast multidisciplinary clinic discussed previously. These were both high volume areas and the surgeons, radiation oncologists, and medical oncologists were interested in becoming more proactive in preventing lymphedema in their patients.

Our pilot program, integrating rehabilitation services into a breast multidisciplinary clinic, was previously published[21] and involved a physical therapist being present at the clinic visit to complete limb girth measurements and discuss healthy exercise behaviors with patients. Patients were then automatically referred to physical therapy after completing their oncologic treatments or at the 12-month mark to repeat measurements. In addition to this systematic evaluation process, providers monitored patients on an ongoing basis to screen for early signs of lymphedema so that appropriate patients could receive a prompt referral to a lymphedema certified physical therapist. Based on the success of this pilot program and the ensuing enthusiasm from oncology providers, rehabilitation team members, and patients and families, we developed additional workflows and processes throughout the oncology program for referring patients to appropriate rehabilitation services.

During implementation of the oncology rehabilitation program, our oncology team noted that patient enthusiasm for these early interventions was reflected in improved patient satisfaction scores. This included comments that showed the appreciation our patients had for gaining knowledge on how to proceed effectively through their cancer care. For example, once the physical therapist in the breast multidisciplinary clinic met with patients, they could cross-refer or direct patients to other supportive care services.

In addition to the patient benefits of prehab and rehabilitation, our oncology providers also recognized the role these services play in CoC and other accreditations. In 2020 the CoC updated its standards to include compliance guidelines for cancer rehabilitation services: "1. The cancer committee develops policies and procedures to guide referral to appropriate rehabilitation care services on-site or by referral. 2. The process for referring or providing rehabilitation care services to cancer patients is monitored and reviewed by the cancer committee and documented in the cancer committee minutes."[22]

Our rehabilitation team members and oncology providers brainstormed other ways to further integrate these services to provide a seamless experience for our patients with cancer and empower them to regain control of their wellness. We developed workflows and referral processes to make it easier for staff, nurses, physicians, and patients to access resources and appointments. We leveraged the strengths of many teams, both inpatient and outpatient, and built enthusiasm among team members to share brochures and information regarding prehab and rehabilitation services. In this way, our pilot program grew to become a comprehensive program with seamless integration of prehab, rehabilitation, and prospective surveillance services into the oncology program.

Internal and External Environmental Factors

Those looking to implement a similar comprehensive oncology rehabilitation program must consider many internal and external factors. Buy-in from oncology and administrative leadership is necessary early in the process to ensure that resources are in place, including staffing, physical space, equipment, and educational resources for staff and patients alike. The oncology rehabilitation program's mission and goals must be closely assessed (and updated as needed) to align with the mission of the oncology program.

Identify key stakeholders and champions to advance the concept and initial program development. Education and meetings with staff and providers help build enthusiasm and commitment prior to embarking on oncology rehabilitation program devel-

opment and integration. Development of a comprehensive, realistic financial pro forma and patient volume estimates are critical. Consider piloting a smaller program at first to demonstrate value and success before implementing a more comprehensive, permanent program.

In our experience, it was important to identify strengths and related programs already available at Beaumont Cancer Institute; existing programs and referral relationships helped raise awareness and build additional referral relationships and subsequent workflows.

Concurrent with the development of our cancer rehabilitation program, Beaumont Cancer Institute was also developing and growing oncology nurse navigation services and a cancer survivorship program. This meant that workflows were evolving and fluid, as opposed to attempting to integrate a new service within a long-established and deeply rooted workflow.

Every institution has its own organizational and administrative structure, and we tried to align our ideas and vision to build our interdisciplinary oncology rehabilitation program within these existing structures. For example, the rehabilitation department expressed a desire to build an oncology rehabilitation residency program, and we realized that our oncology rehabilitation program would grow patient volumes by leveraging resources available as a teaching institution.

When developing a comprehensive oncology rehabilitation program, there are many external factors to consider. For example, in Beaumont Cancer Institute's geographic region, value-based purchasing programs are underway for many conditions, and we anticipate these will continue to evolve for oncology services as well. We want to be well positioned as these bundled payments are developed and have services in place to help improve patient outcomes and lower costs and unwarranted readmissions across the cancer care continuum.

Beaumont Cancer Institute engaged community and philanthropic support as it developed its cancer supportive care resources, including the oncology rehabilitation program.

We collaborated with our hospital-employed and private practitioner physicians and advanced care providers, as well as our cancer survivorship program staff members, to keep rehabilitation referral patterns steady. In addition, efforts are ongoing to ensure that new providers in the Beaumont Health System are aware of the breadth of our services and engage these providers in our workflows and referral patterns.

Oncology Rehabilitation Program Components

To establish an oncology rehabilitation program, several core components need to be in place, including financial accountability and sustainability, administrative accountability, ongoing education, and effective communication.

Financial Accountability

Financial components include creating the aforementioned pro forma, which forecasts a neutral budget (when the program is expected to break even) and a return on investment (when the program is expected to bring in revenue). Administrators use the pro forma to evaluate added costs or expenses and whether these can be absorbed in the operational budget during initial implementation. Pro formas are also important when scheduling time for therapists to be available for patient screenings, which often are not billable procedures. Although patient screenings are not revenue producing, downstream revenue is realized from new referrals for subsequent episodes of care. Tracking these metrics is crucial to first establish a neutral budget and then demonstrate resulting downstream revenue. Key measures to track are the number of new referrals produced from rehabilitation screening and revenue produced in relation to costs (mainly the salary cost of the therapist provider).

As it relates to billing insurance companies for cancer rehabilitation, the rehabilitation department will follow conventional billing methods and guidelines for individual payers to obtain reimbursement for exercise prescription or traditional rehabilitation services. A key consideration in billing is clear documentation linking impairments or functional limitations to the cancer diagnosis to establish medical necessity for these services.

To help ensure adequate reimbursement and return on investment, monitor all charges, charge capture (payments), and charge reconciliation for all administered rehabilitation interventions. Doing so will allow for a collaborative relationship with the cancer program or health system's financial team to establish processes for tracking these financial metrics. Include these financial analysts early in program development to avoid having to re-engineer any processes that do not ultimately result in financial sustainability.

Administrative Accountability and Ongoing Education

Oncology rehabilitation program logistics include issues, such as identifying staff that will perform screenings, establishing clinical assessment procedures (direct interventions) and documentation, and developing referral mechanisms to prehab and rehabilitation services (inclusive of PT, OT, or SLP).

Staff providing prehab and rehabilitation services must be educated and receive specialty certifications or advanced training in oncology. Beaumont Cancer Institute has found that while oncology training for rehabilitation staff is important, it may not be the best use of their time to do patient screenings. Instead, their skills may be better employed treating patients referred for services. For example, although a pelvic floor specialist may be qualified to provide screenings at a colorectal multidisciplinary clinic, these screenings can be performed just as proficiently by a general oncology therapist. This frees up the pelvic floor specialist to provide direct treatments for those with pelvic pain or dysfunctions. Regardless of which staff members perform screenings, administrators need to establish a tracking mechanism to capture results from prospective surveillance screenings, including referrals for exercise prescription, for traditional rehabilitation, and for those patients who might need medical clearance before exercising, such as individuals with chemotherapy-induced cardiotoxicity. In addition to ensuring appropriate training for screening and referrals, administrators must ensure that all members of their rehabilitation team have a foundational education and clinical

When prehab, rehabilitation, and prospective surveillance models are integrated within the cancer care continuum, patients will experience an improvement in cancer-related health outcomes and a better quality of life, as well as reducing overall healthcare costs.[23-25]

skill set to provide prehab and rehabilitation services to this patient population. This includes assessment of staff competency, initial and continuing education, and integration of prehab and rehabilitation services, so all patients diagnosed with cancer have access to basic rehabilitative care. In our experience, individuals diagnosed with cancer may require prehab or rehabilitation at any point in their disease trajectory and in many different settings. Accordingly, staff may need to provide "generalist" level of cancer rehabilitation at acute care or intensive care units, inpatient units, skilled nursing facilities, home care settings, and outpatient ambulatory clinics. Our advice is to designate one person as the "cancer therapist" at each location or setting. Administrators must also develop a clear mechanism for referral from the generalist cancer therapist to a specialist cancer therapist, if needed.

Administrators should perform a gap analysis to identify the oncology rehabilitation program's strengths and where additional opportunities exist. This should include an action plan to address identified care gaps. In Beaumont's initial gap analysis, we identified a knowledge gap among staff as it relates to the basics of cancer care. The administrative team developed an action plan for training and education, developed platforms to provide ongoing education, created a cancer program website, and hosted symposiums and conferences for staff as well as outside clinicians to generate revenue to reinvest back into staff education. Opportunities for staff to gain oncology education include participation in tumor boards and multidisciplinary clinics; attendance at continuing education events; specialty certifications in cancer rehabilitation, lymphedema, and pelvic health; and board certification as an oncology specialist physical therapist. To meet staff education and training needs, Beaumont Cancer Institute developed a comprehensive, robust educational curriculum on cancer rehabilitation. As a result of this curriculum development, Beaumont established a clinical residency for physical therapists in cancer rehabilitation and was the first program in the United States to achieve accreditation by the American Board of Physical Therapy Residency and Fellowship Education (abptrfe.org).

Marketing and Communication Efforts

All providers should be able to speak to the value of prehab and rehabilitation, including front office staff who answer the phones, therapists at all levels of care, and all members of the multidisciplinary cancer care team, including but not limited to physicians, nurse navigators, and social workers.

Marketing starts with developing a plan for internal and external communication. At Beaumont Cancer Institute, marketing efforts included brochures, emails, newsletters, flyers, and showcases, as well as rounding in physician offices and presenting at leadership meetings within the organization. Social media is an important part of the marketing plan, but it can be challenging for large healthcare organizations with tighter controls on posting to the organization's social media accounts. The administrator needs to work closely with the marketing and communications department on key messaging and delivery mechanisms, including website development, media kits and press releases, community calendars, and community-facing events and classes. A key component to marketing oncology rehabilitation services is the collection of patient testimonials (with appropriate consent) to share with key stakeholders and use in communications. In addition to traditional marketing, cancer rehabilitation staff should be supported and encouraged to attend and be active at community service events.

A Look to the Future

When prehab, rehabilitation, and prospective surveillance models are integrated within the cancer care continuum, patients will experience an improvement in cancer-related health outcomes and a better quality of life, as well as reducing overall healthcare costs.[23-25] As many healthcare institutions shift focus to population health management, cancer rehabilitation administrators should connect with institutional leaders to be part of a comprehensive population health management plan. Know the community that the healthcare system serves and establish processes and mechanisms to keep these community members engaged in the wellness trajectory. This will help the institution and its providers partner with patients, families, and caregivers in shared decision making and the development of patient-centered care plans. Involve patients and families in planning for the oncology rehabilitation program to gather valuable feedback and input from these healthcare stakeholders.

Creating a plan for sustainability is key for ongoing success and growth of any oncology program and must be constantly updated and modified based on the fluctuating healthcare climate.[12] Sustainability requires ongoing communication between team members, including the establishment of professional relationships across the acute to postacute continuum of care. Establish clinical pathways, guidelines, and protocols as well as standards and quality metrics, monitor performance, and implement continuous process improvement. Communicate metrics and outcomes regularly to leadership teams, physicians, and providers, and to patients, families, and caregivers. Embrace flexibility and adaptability to adjust the oncology rehabilitation program as the needs of physician providers and patients change. OI

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Transitioning Select Chemotherapeutics to the Outpatient Setting Improves Care and Reduces Costs

BY ALI MCBRIDE, PHARMD, MS, BCOP; AND DANIEL PERSKY, MD

As those of us in oncology have seen over the years, the cost of chemotherapy across the board continues to rise. In some cases, oncology drug prices increased at an exponential rate. Looking at anti-cancer drug costs at time of U.S. Food and Drug Administration approval from 2014 to 2019, these costs surpassed the $10,000 range and are close to a cost of $100,000 per one month of treatment.[1]

But anti-cancer medication prices are not the only healthcare-related costs. Some patients with cancer also incur costs related to inpatient bed stays for chemotherapy administration. In some cases, patients who are treated in the inpatient setting may be admitted to the hospital and must wait before treatment can start—adding to an already high bill. Due to scheduling mishaps or late arrivals, patients may also end up paying for extra days spent in the hospital for treatments that can be safely administered in the outpatient setting. Figure 1, page 58, shows the average costs of inpatient bed stays per day across the United States and within Arizona.[2] Since the cost of cancer care continues to rise and many patients now face financial toxicity, we, as members of the cancer care team, need to address costs across the care continuum to help patients achieve better outcomes and to decrease costs to patients and to cancer programs and practices. This includes addressing inpatient stays and transitioning administration of certain chemotherapeutic agents to the more cost-effective outpatient setting.

> Outpatient chemotherapy administration also reduces costs to the cancer program or practice and our overall healthcare system. Patients no longer need to pay for unnecessary bed stays, and inpatient beds will be available in the hospital for those who truly need them.

Why the Move to the Outpatient Setting?

Moving chemotherapy administration from the inpatient to the outpatient setting has been a popular conversation in oncology for decades. Since 1996, various justifications were made to keep patients in the hospital when they receive chemotherapy treatment; for example, special procedure chemotherapy, high-dosage chemotherapy, and induction therapy.[3] We can see how oncology has changed in the past 25 years because many of these inpatient chemotherapy regimens can now be safely given in the outpatient setting. More so, appropriate chemotherapy administration in

Figure 1. Average Cost of Inpatient Bed Stay[2]

United States

- State/local government hospital: $1,878 in 2015 and $2,052 in 2020.
- Non-profit hospital: $2,289 in 2015 and $2,488 in 2020.
- For-profit hospital: $1,791 in 2015 and $1,889 in 2020.

Arizona

- State/local government hospital: $2,089 in 2015 and $2,034 in 2020.
- Non-profit hospital: $2,474 in 2015 and $2,675 in 2020.
- For-profit hospital: $1,035 in 2015 and $1,959 in 2020.

the outpatient setting has many benefits to patients and the cancer program, including:

- Reducing the cost of chemotherapy.
- Relieving inpatient bed crunch.
- Making patients eligible for patient assistance options (e.g., pharmaceutical patient assistance programs or co-pay assistance programs).
- Allowing cancer programs and practices to bill for waste.
- Improving overall patient satisfaction.

Outpatient chemotherapy administration also reduces costs to the cancer program or practice and our overall healthcare system. Patients no longer need to pay for unnecessary bed stays, and inpatient beds will be available in the hospital for those who truly need them. This benefit was especially true during the COVID-19 pandemic.[4] Oncology patients are often immune compromised and face the risk of infection, especially when admitted into the hospital. By keeping these patients in the outpatient setting, we reduce their risk of infection and remove costs associated with expensive inpatient stays.

In the outpatient setting, more patients are also eligible and qualify for patient assistance and co-pay programs offered by drug manufacturers or independent foundations. Therefore, with help from your financial navigation team, you can continue to reduce patients' cost of care.

Drug waste cannot be billed in the inpatient setting. Revenue is often lost from inpatient chemotherapy administration because payments are subject to diagnosis related groups (set rates established by Medicare for the operating costs of hospital inpatient stays under Medicare Part A),[5] and high-cost chemotherapies often are not adequately reimbursed. Because of the "buy-and-bill" philosophy that many inpatient settings follow, a cancer program or practice ends up eating the costs of drug waste because they are not reimbursable.

Chemotherapy administration in the outpatient setting has been shown to be safe and effective, and some providers find it to be a much easier setting in which to treat patients. The outpatient setting also respects patients' wishes to avoid hospitalization and provides patients immediate and direct control of their therapy administration. In addition, outpatient chemotherapy administration decreases the overall costs of inpatient chemotherapy, reduces overnight stays or avoids hospital admissions, and can lead to an improvement in long-acting nausea and vomiting control, infusion pump use, and supportive care medication administration to prevent overnight stays.

For certain patients, however, it is still best to administer chemotherapy in the inpatient setting, such as those with acute lymphocytic leukemia (ALL) or acute myeloid leukemia (AML), those who have been newly diagnosed, or those with urgent conditions for solid tumors or allogeneic transplant and some chimeric antigen receptor (CAR) T-cell therapies. This way patients receive around-the-clock acute care management in case of toxicity.

What Do Patients Want?

Providers and staff at the University of Arizona Cancer Center, along with published literature, report that patients want to receive their therapies in the outpatient setting when possible. Below are examples of patient feedback we received:

- "I get no sleep when I'm admitted, so I hate staying inpatient."
- "I waited eight hours for a bed to get admitted and start chemotherapy the next day."
- "I have kids, so I do not have time for an inpatient stay."
- "I have a line attached to my arm for three days for only two days of chemotherapy."

Patient feedback and the need to improve patient satisfaction were the main reasons why we began looking at chemotherapy regimens that could be safely administered in the outpatient setting. Based on these clinical and patient needs, our first task was to determine the right patients and the right chemotherapy regimens to administer in the outpatient setting.

Selecting the Outpatient Chemotherapy Regimens

When choosing which chemotherapies to transition to the outpatient setting, we first looked at rituximab and clofarabine.[6,7] In 2013, we were using a lot more clofarabine and, in these cases, patients did not have access to patient assistance programs, there was drug waste that we could not bill for, and patients often had to wait until the next day to start chemotherapy due to their arrival time. In some cases, there was need for 24-hour observation prior to starting treatment and we sometimes experienced a lack of signed chemotherapy orders on the day of treatment. Patients who did arrive on time would sometimes have to wait until the next day to be treated so a physician could evaluate them and sign the order.

High dose cytarabine (HiDAC) is a chemotherapy regimen used to treat patients with acute myeloid leukemia and can be

used in combination or as a monotherapy.[8] In the outpatient setting, we provide HiDAC under a general infusion schedule to patients who are deemed to be reliable, are compliant, and have suitable transportation. It is a multi-day regimen, so we usually begin treatment on a Monday morning to ensure treatment completion occurs during normal infusion center hours. Originally, transition of this chemotherapy regimen was done in phases (e.g., we started by providing the third or fourth cycle in the outpatient setting), but now we provide all four cycles of treatment in the outpatient setting (Table 1, below).

Looking at rituximab, we decided to adopt a hybrid inpatient-outpatient administration model, similar to our phased approach of administering HiDAC in the outpatient setting. A typical example of a rituximab chemotherapy is the rituximab, ifosfamide, carboplatin, and etoposide in combination (R-ICE) regimen (Table 2, page 60). We administer ifosfamide, carboplatin, and etoposide (ICE) in the inpatient setting and when patients are discharged, and then on day three or four patients come in to get their rituximab and pegfilgrastim or its biosimilar in the outpatient clinic. An example of an outpatient rituximab hybrid regimen with inpatient chemotherapy is listed in in Table 3, page 60.

Since 2015 when we transitioned certain rituximab administrations to the outpatient setting, we decreased our inpatient bed stays, reduced our inpatient chemotherapy costs, and increased the use of our own specialty pharmacy for patients receiving intravenous rituximab combination regimens, as well as an increased use of this model post-implementation for standard order sets. However, not every patient receiving rituximab can be treated in the outpatient setting. Accordingly, we have developed patient restrictions for rituximab in the outpatient setting, including:

- Immune thrombocytopenic purpura—dose-reduced rituximab, 100 mg[9].
- Cold agglutinin disease.
- Post-transplant lymphoproliferative disease.
- Autoimmune hemolytic anemia.
- Prolonged chemotherapy inpatient stays requiring continued treatment.
- Infusion reaction or need for rituximab desensitization.

A third example is the etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin in combination (EPOCH) chemotherapy regimen (Table 4, page 61). EPOCH is given for numerous indications, including diffuse large b-cell lymphoma. In transitioning this chemotherapy regimen to the outpatient setting, we developed a workflow utilizing our smart pump technology—a major change from what was previously done.

(Continued on page 61)

Table 1. The University of Arizona Outpatient HiDAC Workflow

	Monday	Wednesday	Friday
Days of therapy	1	3	5
07:00	Neuro-check/antiemetics	Neuro-check/antiemetics	Neuro-check/antiemetics
07:30	HiDAC	HiDAC	HiDAC
Infusion	1 hour	1 hour	1 hour
Discharge	—	—	—
16:00	Neuro-check	Neuro-check	Neuro-check
16:30	HiDAC	HiDAC	HiDAC
Infusion	1 hour	1 hour	1 hour
Pegfilgrastim	—	—	+/- Pegfilgrastim or pegfilgrastim-cbqv
Premedications (30 minutes before infusion)	Ondansetron 8 mg (IV) Dexamethasone 10mg (PO)	Ondansetron 8 mg (IV) Dexamethasone 10mg (PO)	Ondansetron 8 mg (IV) Dexamethasone 10mg (PO)
At home medications	Acyclovir, promethazine, dexamethasone ophthalmic suspension		

Table 2. Transitioned Ifosfamide-Based Regimens[a]

Disease State	Chemotherapy Regimen
Sarcoma	AIM
	IE
	AEWS 1031/1221
Germ cell tumors	TIP
	VIP
	ACNS 1123
	TI
	VeIP
Lymphoma	IGEV
	ICE
	R-ICE
	IVAC
	VIPD
	SMILE
	GIFOX
Lung cancer	Ifosfamide (monotherapy)

Note: AIM = doxorubicin, ifosfamide, mesna; IE = ifosfamide, etoposide; TIP = paclitaxel, ifosfamide, cisplatin; VIP = etoposide, ifosfamide, cisplatin; IGEV = ifosfamide, gemcitabine, vinorelbine; ICE = ifosfamide, carboplatin, etoposide; R-ICE = rituximab, ifosfamide, carboplatin, etoposide; IVAC = ifosfamide, etoposide, cytarabine; SMILE = dexamethasone, methotrexate, leucovorine, asparapinase, etoposide; AEWS1031/1221 = vincristine, doxorubicin, cyclophosphamide, ifosfamide, etoposide; ACNS1123 = carboplatin, etoposide, ifosfamide; TI = paclitaxel, ifosfamide.

[a]Some patients had alternating ifosfamide-containing regimens.

Table 3. Hybrid-Based Regimens with Rituximab[a]

Disease State	Chemotherapy Regimen
Lymphoma	CHOP-R (cyclophosphamide, doxorubicin, vincristine, prednisone, rituximab)
	Mini-CHOP-R (cyclophosphamide, doxorubicin, vincristine, prednisone, rituximab)
	COEP-R (cyclophosphamide, vincristine, etoposide, prednisone, rituximab)
	CHOEP-R (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone, rituximab)
	CVP-R (cyclophosphamide, vincristine, prednisone, rituximab)
	ICE-R (ifosfamide, carboplatin, etoposide)
	ESHAP-R (etoposide, methylprednisolone, cytarabine, cisplatin, rituximab)
	DHAP-R (dexamethasone, cytarabine, cisplatin, rituximab)
	CVAD-R (cyclophosphamide, vincristine, doxorubicin, dexamethasone, rituximab)
	EPOCH-R (etoposide, vincristine, doxorubicin, cyclophosphamide, prednisone, rituximab)
	CODOX-M-R (cyclophosphamide, vincristine, doxorubicin, cytarabine, high-dose methotrexate, rituximab)
	MPV-R (high-dose methotrexate, procarbazine, vincristine, rituximab)
	BR (Bendamustine Rituximab)
	PBR (Bendamustine Polatuzumab Rituximab)
	MATRix regimen (methotrexate, cytarabine, thiotepa, rituximab)
Acute Lymphocytic Leukemia (ALL)	HCVAD-R (course A regimen: cyclophosphamide, vincistine, doxorubicin, dexamethasone, rituximab; course B regimen: high-dose methotrexate, cytarabine, rituximab)
	CD20+ ALL regimens

[a]Patients who required combination chemotherapy were administered the backbone chemotherapy regimen inpatient, and then administered rituximab outpatient the following day.

(Continued from page 59)

Therefore, we needed to address monitoring parameters and eventually decided to do labs at the initiation of chemotherapy. (In the inpatient setting, patients get labs done every day, which increases their costs.) Our clinical ambulatory oncology pharmacists ensure that patients receive the correct take-home medications prior to treatment initiation. So, by administering the full EPOCH regimen in the outpatient setting, we are realizing cost savings for patients and the hospital.

Selecting the Patients to Treat in the Outpatient Setting

As mentioned with the rituximab regimens, not every patient should receive their chemotherapy treatment in the outpatient setting. When looking at our patients, we developed criteria that continue to be refined today to make sure we are treating the appropriate patients with outpatient chemotherapy (Table 5, page 62). For example, at the University of Arizona Cancer Center, we treat patients who travel across the state, so we did not want to move these patients to the outpatient setting if they have excessive travel time or unreliable transportation. We chose patients who have a good support system at home and who are often accompanied by their caregiver(s) during treatment. Finally, to provide the quality care that patients with cancer need, we set up after-hours care since patients would no longer receive the 24-hour care they had gotten in the inpatient setting. We used oncology fellows and nurses to address triage calls and the pharmacy clinical coordinator to address urgent chemotherapy issues.

We also introduced an on-call service for patients using infusion pumps. This was key to developing our outpatient chemotherapy orders because pumps are required for certain chemotherapy regimens such as EPOCH; vincristine, doxorubicin, and dexamethasone in combination (VAD); doxorubicin 24-hour infusions; cytarabine infusions; and ifosfamide orders. We evaluated our workflows to include the necessary steps for administering and checking infusion pumps, as well as using our rental pumps on-call service number. Pumps are often controlled by the state's board of pharmacy law, which required some research. For example, in Arizona, every time a pump leaves the clinic, we must complete a regulatory check. Therefore, we included this step in our outpatient workflows. We also did education with patients and caregivers on their infusion pumps and any issues that could arise, including information about the on-call service for needs that came up after hours. To this day, infusion pumps continue to pose challenges, so we set up a workflow for four oncology fellows to call a pharmacist on staff to address any issues that crop up after hours. Our outpatient treatment utilizes same-day pegfilgrastim or pegfilgrastim-cbqv for ease of use in our patients and previous studies in lymphoma showed similar efficacy without undue febrile neutropenia risk.[10,11] In our studies, we evaluated same-day versus next-day pegfilgrastim and found similar outcomes of febrile neutropenia incidence, regardless of the originator or reference product. Recent studies have yielded equivocal outcomes of febrile neutropenia incidence with same-day versus next-day administration.

Developing Our Practice Model

When looking at designing and implementing any new models of care, you first need to develop a practice model, which takes teamwork. In our case, we first evaluated our high-cost inpatient chemotherapy regimens (e.g., R-ICE, EPOCH) (Table 4, below). This was done via weekly and then monthly meetings with pharmacy leadership: the pharmacy manager and clinical pharmacy team. In these meetings, we evaluated inpatient and outpatient chemotherapy trends and identified in what settings certain chemotherapies were being administered. We came to realize that chemotherapy was often administered in the inpatient setting just because it could be—and that trend was consistent across the board. Finally, we reviewed our pharmacy budget every month, so we could calculate costs and the impact of transitioning certain

Table 4. Outpatient Dose-Adjusted Etoposide, Prednisone, Vincristine, Cyclophosphamide, Doxorubicin, and Rituximab (DA-EPOCH +/- ¬R) Regimena (Dosages Are Based on Dose Level One)

Drug	Dose and Route	Given on Day(s)
Rituximab	37 mg/m^2 IV	1
Etoposide	50 mg/m^2 per day IV	1-4 (96 hours)
Doxorubicin	50 mg/m^2 per day IV	
Vincristine	0.4 mg/m^2 per day IV (dose not capped)	
Cyclophosphamide	75 mg/m^2 IV	5
Pegfilgrastim or pegfilgrastim-cbqv	6 mg	5

Table 5. Criteria for Patient Selection for Outpatient Chemotherapy[a]

Criteria	Patient and Caregiver Evaluation
Patient	Able to understand chemotherapy and supportive care management
	Has a caregiver or caregiver support during chemotherapy infusion and support visits
Location	Patient must live within approximately 30 minutes of our infusion center sites
Transportation	Patient must have transportation to and from the infusion center for treatment
Clinical management in outpatient clinic	Patient must be able to be assessed by the physician or advanced practitioner at least once a week in the outpatient clinic
	Lab monitoring done twice a week or more frequently if needed
Supportive care medication	Patient must have treatment/supportive care medications prior to start of infusion and before therapy (HiDAC dexamethasone eye drops; EPOCH prednisone therapy)
After hours care	Patient or caregiver must be able to recognize toxicity profiles of chemotherapy (HiDAC neurotoxocity, clofarabine infusion reaction/cytokine release)
	Patient or caregiver must understand pump infusion and support services for home administration of infusion therapies

[a]Patients are evaluated for outpatient care based on several criteria to ensure adherence to therapies and maintain patient safety with chemotherapy issues that were set up prior to the transition for outpatient chemotherapy treatments.

chemotherapeutic administrations from the inpatient to outpatient setting.

In moving administration of select chemotherapy regimens to the outpatient setting, we wanted to improve patient care overall at our facility. This required buy-in from the multidisciplinary cancer care team—physicians, advance practitioners, fellows, nursing staff, pharmacy staff, and the financial team. We had to address these outpatient options early and educate staff on these treatments. Our nurse coordinators in the clinic needed to evaluate the treatments we wanted to move to the outpatient setting, which included addressing each anti-cancer drug, any supportive care needs, and any follow-up lab tests. Our financial team was one of the critical pieces in the early assessment discussions. They knew that they would have to address outpatient chemotherapy with payers and, in some cases, pharmacists and physicians would need to step in and educate payers about which treatments could be given safely in the outpatient setting. The finance team worked on denials and addressed them quickly. Our clinical pharmacists and staff pharmacists addressed patient eligibility for outpatient chemotherapy and supportive care services. These pharmacists review all medications, including any supportive care medicines, or any relevant lab tests.

Beginning in 2013, we began transitioning administration of select chemotherapy regimens to the outpatient setting. We first implemented this transition into our electronic health record (EHR), creating the necessary order sets for the selected chemotherapies and establishing these processes as a formal workflow using our EHR. Because we started this project in 2013, shortly after moving to a new EHR, we had to set up these processes—regardless of access to an EHR. These processes included the use of standardized antiemetics and appropriate tests.

As mentioned above, implementation of this model was a team effort. It included our medical director, physicians and providers, nurse coordinators, oncology ambulatory specialists, finance team, financial counselors, nurse navigators, infusion center management, staff pharmacists, information technology team, and risk management. Everyone was involved in the process and everyone had a part to play, which speaks to the diversity and strength of our healthcare team at the University of Arizona Cancer Center when addressing and implementing practice change.

Our medical director addressed any patient-related issues for those who needed inpatient chemotherapy, as well as any other resolutions needed for larger program-wide issues. Our physicians and nurses ensured there was housing available for patients who had to travel, working with our supportive staff to address housing and fuel assistance. One of the more amazing pieces of this project was seeing our infusion nurses drive home the need for this transition. Because many were former bone marrow transplant

nurses, they made the transition from inpatient to outpatient easily and were already aware of some of the chemotherapies they would be working with. The clinical ambulatory pharmacists also set up an education opportunity for our nurses to ensure they knew about treatment toxicities and side effects of the chemotherapies that would now be administered in the outpatient setting. Our nurse coordinators then addressed any issues related to outpatient chemotherapy timing and scheduling.

Other key members of the team included our clinical pharmacy staff. They addressed some of the educational pieces for other staff and patients, worked with supportive care, and led treatment adherence. Pharmacists also worked on some of the chemotherapy regimen builds within the EHR. Finally, our staff pharmacists addressed any billing issues, performed dose rounding, billed for waste, and helped with the overall transition from the inpatient to the outpatient setting. Additionally, the staff pharmacists established our outpatient care hours for early morning administration. Today, we open earlier than the hospital for our outpatient high-dose cytarabine-containing regimens. Since the transition of cytarabine to the outpatient setting, we have been able to move several other AML regimens to the outpatient setting (Table 6, right).

Figure 2, right, shows an example checklist for transitioning administration of selected chemotherapy to the outpatient setting. Following this checklist will ensure that you have financial approval, including:

- Coverage of infusion pumps.
- Infusion hours set up in case a schedule prohibits the administration of certain chemotherapy agents.
- Nursing staff to lead the education of any coordinators or infusion nurses.
- Pharmacy and specialty pharmacy to educate staff on regimens and supportive care treatments.

Measure, Measure, Measure

As you should for any new program, measuring outcomes and cost savings proves the impact that your innovation has on your patients and cancer program. As my former University of Arizona Cancer Center director Peter Drucker used to say, "If I can't measure it, I can't manage it." In developing this program, our team knew it needed to gather metrics and identified the following areas to measure:

- High-cost chemotherapy regimens administered in the inpatient setting.
- Chemotherapy administration transitioned from the inpatient to the outpatient setting.
- Inpatient days per admission.
- Medication assistance program dollar amounts.
- Patient outcomes.
- Miscellaneous data, such as emergency department (ED) visits, hours between inpatient admission and chemotherapy start, and length of time for each day of outpatient chemotherapy.

Table 6. Transitioned Outpatient Myeloid Regimens, Including Outpatient Acute Myeloid Leukemia and Acute Lymphocytic Leukemia

Disease State	Chemotherapy Regimen
AML	5+2
	ME/MEC
	FLA/FLAG
	CLA/CLAG
	HiDAC
	Clofarabine
	Clofarabine/HiDAC
ALL	Clofarabine

Figure 2. Example Outpatient Chemotherapy Transition Checklist

- **Selected chemotherapy available to be administered outpatient**
- **Financial approval**
  - **Infusion pumps covered**
- **Infusion center hours**
  - **Current schedules prohibit administration of certain chemotherapeutic agents**
- **Nursing staff**
  - **Education with nurse coordinators**
  - **Education with infusion nurses on administration and side effect monitoring**
- **Pharmacy/specialty pharmacy**
  - **Education on regimens and supportive care treatments**
  - **Large focus on anti-infective prophylaxis**

For rituximab, our original benchmark goal at implementation was 90 percent outpatient administration. Since then, we transitioned 137 of 173 (79 percent) patients receiving rituximab to the outpatient setting. Initial inpatient rituximab savings to our cancer program include drug cost savings between $400,000 and $450,000, and an average inpatient bed stay decrease of approximately nine hours. Therefore, our cancer program and hospital are saving about $950,000 annually for administering rituximab in the outpatient setting.

For patients who received an EPOCH-based chemotherapy regimen, out of 175 cycles, there were 18 cycles that were administered inpatient for a total cost of $89,857. With the transition of 67 cycles to a hybrid inpatient/outpatient setting, we realized a cost savings of $180,453 and saved 67 hospital bed days. Ninety cycles were transitioned fully to the outpatient setting with a cost savings of $1,454,398 and 540 hospital bed days. Overall, by transitioning to a hybrid inpatient/outpatient or outpatient setting, the updated total cost savings for hospital stay, drug cost and labs, under an alternative payment model, was $3,523,174 with 607 hospital bed days saved.

Looking Toward the Future

We continuously work to safely transition more chemotherapy regimens to the outpatient setting, especially as our hospital and patients have realized cost savings and improved satisfaction. Our next list of chemotherapies to consider for transition, includes:

- HyperCVAD, Part A.
- Dexamethasone, cyclophosphamide, etoposide, and cisplatin in combination (DCEP); and bortezomib, thalidomide, dexamethasone, cisplatin, doxorubicin, cyclophosphamide, and etoposide in combination (VTD-PACE).
- Outpatient stem cell transplant conditioning regimens, including thiotepa/carmustine; melphalan; and carmustine, etoposide, cytarabine, and melphalan in combination (BEAM). OI

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BY BARBARA A. GABRIEL, MA

Real-Life Stories of Ordinary People with Extraordinary Bravery

A conversation with the author of *Between Life and Death*

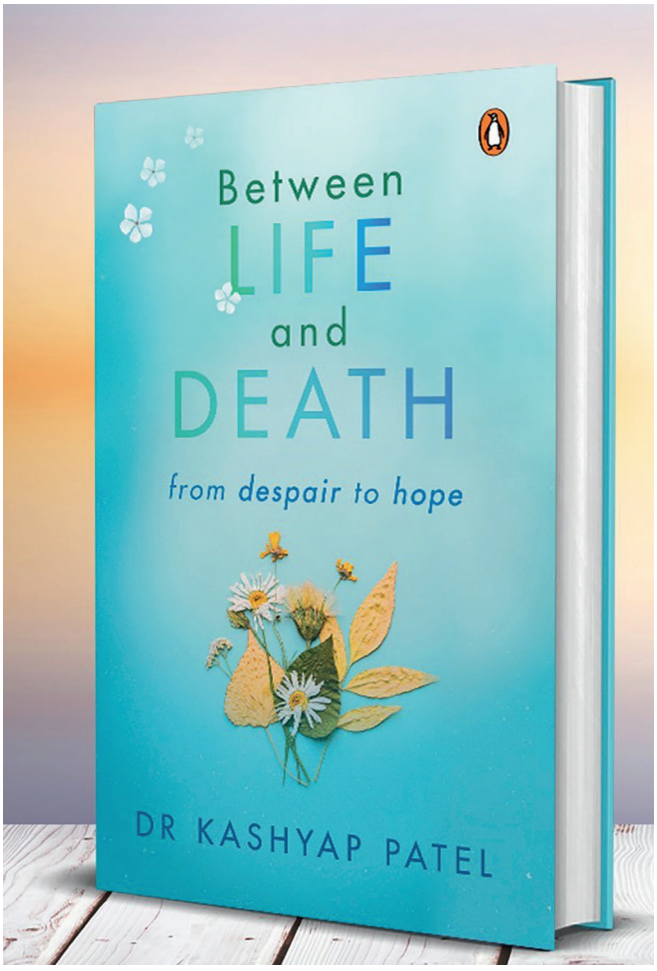
Between Life and Death is a collection of real-life stories of ordinary people who displayed extraordinary bravery as they approached the end of their lives. By acknowledging death as a necessary transition rather than an unknown to be feared and avoided, these patients embraced their end days by living each day they had remaining to the fullest. The patients profiled in this book provide guidance not only to other patients with cancer, but also to oncologists seeking insight into how best to help their patients approach the end of their cancer journey.

The book's author, Kashyap Patel, MD—CEO of Carolina Blood and Cancer Care Associates in South Carolina, vice president of the Community Oncology Alliance, former member of the Association of Community Cancer Centers (ACCC) Board of Trustees, and chair of the ACCC Clinical Affairs Committee—says he wrote *Between Life and Death* to capture his 30-year journey as a practicing oncologist across 4 countries and 11 cities.

Dr. Patel explains that his book is a response to the struggle he and his and his colleagues often face when treating patients with cancer for whom a cure is no longer an option. He has come to believe that great harm has been done to patients and their loved ones by framing cancer, the suffering it causes, and its frequent termination in death as a battle to be won or lost. This dominant paradigm, explains Dr. Patel, has led to the inevitable conclusion that cancer creates winners and losers, and death is an enemy to be battled until the bitter end.

> When I see advanced patients for their first consultation, I explain to them that palliative care will be an option at some stage, that, at some point, we'll have to sit down and talk about changing gears from trying to prolong life to focusing on quality of life.

Dr. Patel explains in his book that while death is indeed inevitable, fear of it is not. "While most published literature focuses on cancer as a battle and celebrates stories of cancer survivors, this compilation highlights the altruistic and humanistic aspect of the struggle against cancer," he says. "My book reveals that the true reason death causes so much insecurity is our fear of it."



Dr. Patel's book narrates the stories of individual patients with cancer who have chosen to approach death as a transition on a longer journey rather than as a terminus to be feared. "We have the capacity of choosing how we react to the fear and challenges death brings," explains Dr. Patel. In *Between Life and Death*, he shares his conversations with several extraordinary patients about their attitudes toward death as they approach the end of their lives. Through those conversations, Dr. Patel seeks answers to questions such as: How do people perceive their own death? What impact does their fear of death have on their cancer journey? How can we best spend the end of our lives with our loved ones? Is there an afterlife or a soul?

Below, *Oncology Issues* talks to Dr. Patel about the origins and aims of his book.

OI. How do oncologists generally learn to help their patients deal with death and dying?

Dr. Patel. In all the places I've practiced, I've seen very little training in death and dying for physicians. In U.S. medical schools, there still is no curriculum. Less than 10 percent of U.S. medical schools offer any classes in death and dying. Students may have 10 hours total in their five years of medical school, which is hardly sufficient.

Why is this? It may be because physicians have a sense of guilt about "failing" their patients who have not gotten well. Patients may pick up on that and feel that they are disappointing their physicians. It's like the relationship been a coach and his players. Even though the players may know that they are losing the game, they do not want to disappoint their coach.

But we have an obligation as physicians to help patients make their transition. It's a comfort for patients when they realize that death is an inevitable part of their life journey. This book is a telling of stories about life and death from the point of view of patients who have encountered their own mortality. It's a complex issue, and the more we shy away from talking about it, the more complex the problem becomes.

OI. What do you perceive as the most problematic ways oncology deals with the death and dying of patients with cancer?

Dr. Patel. We are consistently taught that our goal is to stop death through any means possible. When we develop new medications for cancer, we talk about them as a new way to defeat death. So, when a patient improves or recovers, we brag about stopping death. When death becomes inevitable, we feel like we have failed. Little attention is given to end-of-life care, as we have been programmed to believe that when our patients reach that stage, there is little we can do.

A big problem is that our medical system does not give patients adequate time to prepare to die. The average length of stay in hospice is three days, which is considered adequate. I think we should enable patients to spend six to nine months in hospice, so they have time to come to a peaceful end of their lives. We celebrate many things in life: weddings, birthdays, major milestones. The one thing we don't celebrate is saying goodbye to our loved ones by enabling them to transition to the unknown.

OI. What roles should members of the cancer care team outside of physicians (e.g., nurses, social workers, navigators) play when working with terminal patients?

Dr. Patel. I spend approximately 20 minutes with my patients in the consulting room, but my infusion nurses might spend 6 hours at a time with them. Nurses and other caregivers in the office can take that time to engage patients in conversation and share examples of how people can have excellent quality of life, even if they decide not to receive curative treatment. They can explain to them how their relationships with their family members continue. Together, we are a team caring for all of our patients' needs.

OI. Do you want to highlight any of the specific patient stories you relate in your book?

Dr. Patel. In my effort to better care for my terminal patients, I studied different spiritual practices, religions, and perceptions of death and dying, going back to ancient Egypt and Rome. I studied Christianity, Judaism, and Islam. And I saw a commonality in beliefs about death and the process of dying.

Then, I met a patient who changed my way of perceiving death. He had been perfectly fine when he was diagnosed with Stage 4 cancer. He told me that he did not want treatment, but he did want me to help him and his family prepare for his death. He said he had read about dying, but he didn't feel fully prepared for it. During the next three months, our team had continual conversations with this patient and his family about death and dying, and we prepared him to leave.

My experience with this patient taught me so much. I decided to tell his story, as well as the stories of several other patients, in my book. All these patients are real people I met in my practice in South Carolina. From my interactions with a 29-year-old woman to an 85-year-old man, I was able to help these patients in their spiritual journeys and help them prepare for their transitions, and it was an incredible journey for me as well.

Another patient of mine had multiple myeloma. She was 85 years old, and she used to jokingly call me "her boyfriend." When she was ready to transition to hospice care, I placed her there. One day, her son called me and said, "I know that you're not on call, and forgive me if I entered into your personal life. But my mother is dying, and she keeps muttering your name." She had been in a coma for the past three days, and she just opened her eyes and said, "Dr. Patel, my boyfriend, where is he?"

I was going to attend a wedding that evening, but I told my wife that I had to go and see this patient. I went to the room she was in, and she was surrounded by her son, daughter-in-law, and grandchildren. I put my arm around her, and she opened her eyes, almost like she was waiting for me. And then she died in my arms. Her son told me he could not believe what he witnessed. "It's almost like if you did not come, she would have continued to suffer," he said. "She would have continued to struggle, and eventually she would have died. But you helped put closure to her life."

OI. What do you most want people to take away from this book?

Dr. Patel. We need to better prepare our patients for death. When I see advanced patients for their first consultation, I explain to them that palliative care will be an option at some stage, that, at some point, we'll have to sit down and talk about changing gears from trying to prolong life to focusing on quality of life. That sets the expectation that the aim is not a cure, that the aim is to extend quality of life. To say that, at some point, it will become necessary to make a compromise between quality and quantity is just ridiculous. I want this book to serve as a guide to teach all providers across all tiers how to effectively communicate with patients about end-of-life care.

This book is for everyone because all of us are going to die. Even though it's focused on stories of cancer patients, it's for anyone who wants to know about their ultimate journey toward the finish line. It's for anyone who does not want to approach dying as a hopeless situation. We all have a choice to make: Do I want to be afraid of death and lose every moment to fear, or do I want to live life to the fullest? I don't know when my time will come, but I do know that I can choose to live my life to the fullest, and I can make that choice today.

We all have a choice to make: Do I want to be afraid of death and lose every moment to fear, or do I want to live life to the fullest?

OI. I've heard that you intend to donate the royalties from this book. Can you talk about the charity you selected?

Dr. Patel. I am giving it to a foundation that helps the marginalized, orphaned children of India learn acting skills. I have a friend in the theater in Mumbai, and I donated a small amount of money to this foundation several years back. Later, my friend invited me to see the impact of my donation. I saw a child perform, and he was dressed in rags because he had no money. He told me afterward that he saw water come out of a faucet for the first time that day. In the slums, they have shantytowns, and there is no plumbing.

I was moved. In general, these kids have no future other than begging on the street. But one child who was trained there did actually go on to Hollywood to act professionally. That is an inspiration for so many, and I want to help other children believe they could also do that. It gives them some sense of hope. All proceeds from this book will support this foundation for orphaned children in Mumbai who may have no hope of living beyond the slums they grew up in. I will also match all proceeds with my own personal savings. OI

Kashyap Patel, MD, is a practicing oncologist and has been working directly with cancer patients for the past 20 years. He is the CEO of Carolina Blood and Cancer Care Associates; vice president of the Community Oncology Alliance; former member of the ACCC Board of Trustees; chair of the ACCC Clinical Affairs Committee; medical director at the International Oncology Network; and past president of the South Carolina Oncology Society. A certified trainer for physicians with Education in Palliative and End-of-Life Care (EPEC), Dr. Patel has been a speaker at several continuing medical education events. Dr. Patel has led committees in numerous South Carolina hospitals and has extensive research experience in the field of oncology. In August 2020, Dr. Patel published Between Life and Death. *Read more about Dr. Patel and his book at betweenlifeanddeath.org.*

Barbara Gabriel, MA, is associate editor, Oncology Issues.

An Optimal Care Coordination Model for Medicaid Patients with Lung Cancer:

Finalization of the Model and Implications for Clinical Practice in the United States

BY RANDALL A. OYER, MD; CHRISTOPHER S. LATHAN, MD, MS, MPH; MATTHEW P. SMELTZER, PHD, MSTAT; AMANDA KRAMAR; LEIGH M. BOEHMER, PHARMD, BCOP; AND THOMAS M. ASFELDT, MBA, RN, BAN

In 2016 the Association of Community Cancer Centers (ACCC) embarked on a three-year, multiphase initiative to design, test, and refine an Optimal Care Coordination Model (OCCM) for Medicaid patients diagnosed with lung cancer.[1] Disparities between Medicaid and non-Medicaid or privately insured patients, such as underutilization of systemic treatments with bevacizumab combinations or targeted therapy with tyrosine kinase inhibitors for advanced-stage cancers[2] and lack of survival advantage,[3] emphasize the need for special considerations in this socio-economically disadvantaged population to ensure equitable outcomes with other patients diagnosed with lung cancer. The aim of the OCCM is to help U.S. cancer programs identify and reduce the effects of such disparities between Medicaid and non-Medicaid patients through assessments that facilitate and expand access to the appropriate use of multidisciplinary coordinated care, and ultimately help strengthen care delivery systems for lung cancer.[1]

Phase I of the OCCM initiative involved the design and development of the Model from January 2016 onward by a Technical Expert Panel, with guidance from the Advisory Committee, ACCC staff, and consultants. An environmental scan was conducted, which identified six broad barriers to optimal care delivery that were found uniformly among Medicaid patients diagnosed with lung cancer.[1] The barriers, not ordered by frequency or priority, were as follows:[4]

- Financial and social barriers, such as access to reliable transportation, lost income, provision of childcare or other family support, and out-of-pocket expenses for services and medications.
- Unequal access to high-quality cancer care, including appropriate diagnostic and referral pathways at the first point of care, and restrictive healthcare provider networks.
- Limited patient empowerment due to a low level of health literacy, a distrust of the healthcare system, and the perceived stigma of lung cancer.
- Inadequate integration of patient navigation into care teams.
- Underdeveloped care coordination within multidisciplinary teams.
- Delayed access to supportive services to address bio-psychosocial needs, palliative care, survivorship, and hospice services and end-of-life care.

Phase II involved the selection of seven community-based cancer programs between March and June 2017 to pilot test the Model.[5] Phase III involved the implementation of quality improvement projects by these seven testing sites between October 2017 and September 2018.[5] As part of this process, testing sites conducted self-assessments of their care delivery systems for Medicaid patients with lung cancer and advanced multidisciplinary coordinated care.

In this article, we discuss revisions to the Model following beta testing to develop the final version, rationale for significant revisions, and nationwide dissemination of the OCCM. Dissemination is intended to foster and accelerate the adoption of multidisciplinary coordinated care delivery among a wider network of U.S. cancer programs and ensure optimal clinical outcomes for patients with lung cancer, especially among underserved populations.

Methods

As part of the OCCM beta testing, each of the seven testing sites was asked to provide feedback on the Model and suggestions for revision. Qualitative feedback was provided through quarterly reports and included direct feedback on the Model, process-level challenges and opportunities, key transferable lessons, and how application of the Model uncovered misinterpretation of certain terms or assessment areas. Quantitative results included the OCCM self-assessments conducted by the testing sites before and after beta testing and patient-level results that were reported by individual testing sites in their final reports. Crosscutting feedback was considered, irrespective of OCCM assessment area selection(s) by individual testing sites and other suggested changes. In addition, consultants and ACCC staff who worked with all seven testing sites provided feedback on how the sites interpreted the Model and used it to inform their quality improvement projects. Based on these experiences and results, revisions to the Model were made to enhance clarity of intent and ensure ease of use and reproducibility, specificity, and uniformity across the OCCM assessment areas. The Technical Expert Panel, Advisory Committee, ACCC staff, and consultants further refined the Model as part of a two-stage revision process, which involved an in-person meeting followed by a remote followup, where a lead person was designated for each OCCM assessment area, and a consensus approach was used for decision making. For each OCCM assessment area, efforts were made to identify current and targeted quality metrics and to provide a defined list in the final Model.

Results

Beta testing of the OCCM demonstrated the ability of the Model to offer practical guidance to cancer programs on prioritizing the unique care and treatment needs of Medicaid patients and improving care coordination to achievable target levels across a variety of high-impact areas, including patient access to care, prospective multidisciplinary case planning, and tobacco cessation.[5] The experiences and results of beta testing at the sites demonstrated key successes such as enhanced collaboration within cancer programs and improved lung cancer programming for patients, site-specific challenges in implementation of the OCCM such as inadequate staffing at project start and lack of centralized data collection and coordination, and transferable lessons such as maintaining a patient-centered focus.[5] Additionally, opportunities were identified to improve care coordination beyond lung cancer to other tumor types.

Refinements to the Beta OCCM

Refinements were implemented with the goal of clarifying vague terms, such as tobacco education, navigation, and multidisciplinary treatment planning, and the pre-condition that progress to higher and improved levels of care coordination implied that lower-level requirements continued to be met. These refinements were intended to ensure specificity and uniformity across OCCM assessment areas and corresponding metrics and to promote further ease of use by cancer programs. The overall number of high impact assessment areas was reduced in the final Model—emphasis was specifically placed on patient navigation, to align with findings of the environmental scan. Furthermore, Management of Comorbid Conditions was excluded as an assessment area since it was perceived to be outside the scope of work for the beta testing contract period and, therefore, not selected for beta testing by any of the sites. The sites also reported that descriptions of some assessment areas in the beta OCCM were vague, while the corresponding list of quality metrics for each assessment area was extensive. In response, efforts were made to include specific language or detailed descriptions that could lead to measurable benchmarks and identify current and targeted quality metrics, which helped provide a shorter and more precise selection for the final version.

Composition of the Final OCCM

The final OCCM, a patient-focused framework for cancer programs to evaluate care coordination for lung cancer and

plan quality improvements, is composed of 12 interrelated assessment areas (see Figure 1, page 74), each with 5 levels.[6] The 12 assessment areas to be evaluated synergistically are as follows:

1. ***Patient entry into lung cancer program,*** which addresses factors such as referral sources, referral processes, and timely access to appropriate care.
2. ***Multidisciplinary treatment planning,*** which addresses factors such as patient evaluation and inputs on treatment planning and recommendations provided by a range of healthcare providers
3. ***Clinical trials,*** which addresses factors related to overcoming cultural, financial, and logistical barriers encountered by patients in accessing clinical trials.
4. ***Supportive care,*** which addresses factors related to the evaluation of physical, emotional, mental, and spiritual symptoms, and the infrastructure and resources available in the cancer program to manage these symptoms across the continuum of care.
5. ***Survivorship care,*** which addresses factors related to the ongoing surveillance for recurrence of primary cancer, prevention and early detection of new health problems, management of latent and long-term toxicities associated with cancer treatments, and overall patient wellness across the continuum of care.
6. ***Financial, transportation, and housing needs,*** which addresses factors related to the financial barriers to care and mechanisms to identify and eliminate such barriers.
7. ***Tobacco education,*** which addresses factors related to the evaluation of tobacco use and provision of tobacco education, including cessation strategies for patients with lung cancer.
8. ***Navigation,*** which addresses factors related to the identification of patient needs and barriers to care, and strategies to minimize gaps in service among vulnerable and underserved groups.
9. ***Treatment team integration,*** which addresses the depth, breadth, and effectiveness of team collaboration through the care continuum.
10. ***Physician engagement,*** which addresses factors related to disease expertise, availability to the patient and care team, effectiveness in team science and communication, and leadership roles.
11. ***Electronic health records (EHRs) and patient access to information,*** which addresses factors related to the facilitation of interdisciplinary communication along the continuum of care through the capacity to access clinical information from physician practices, hospitals, outpatient clinics, and diagnostic centers through optimized EHR platforms.
12. ***Quality measurement and improvement,*** which addresses factors related to quality metrics that can reveal potential disparities in coverage type, socioeconomic status, and gender, race, and ethnicity, and help monitor these to ensure minimal variation in patient outcomes.

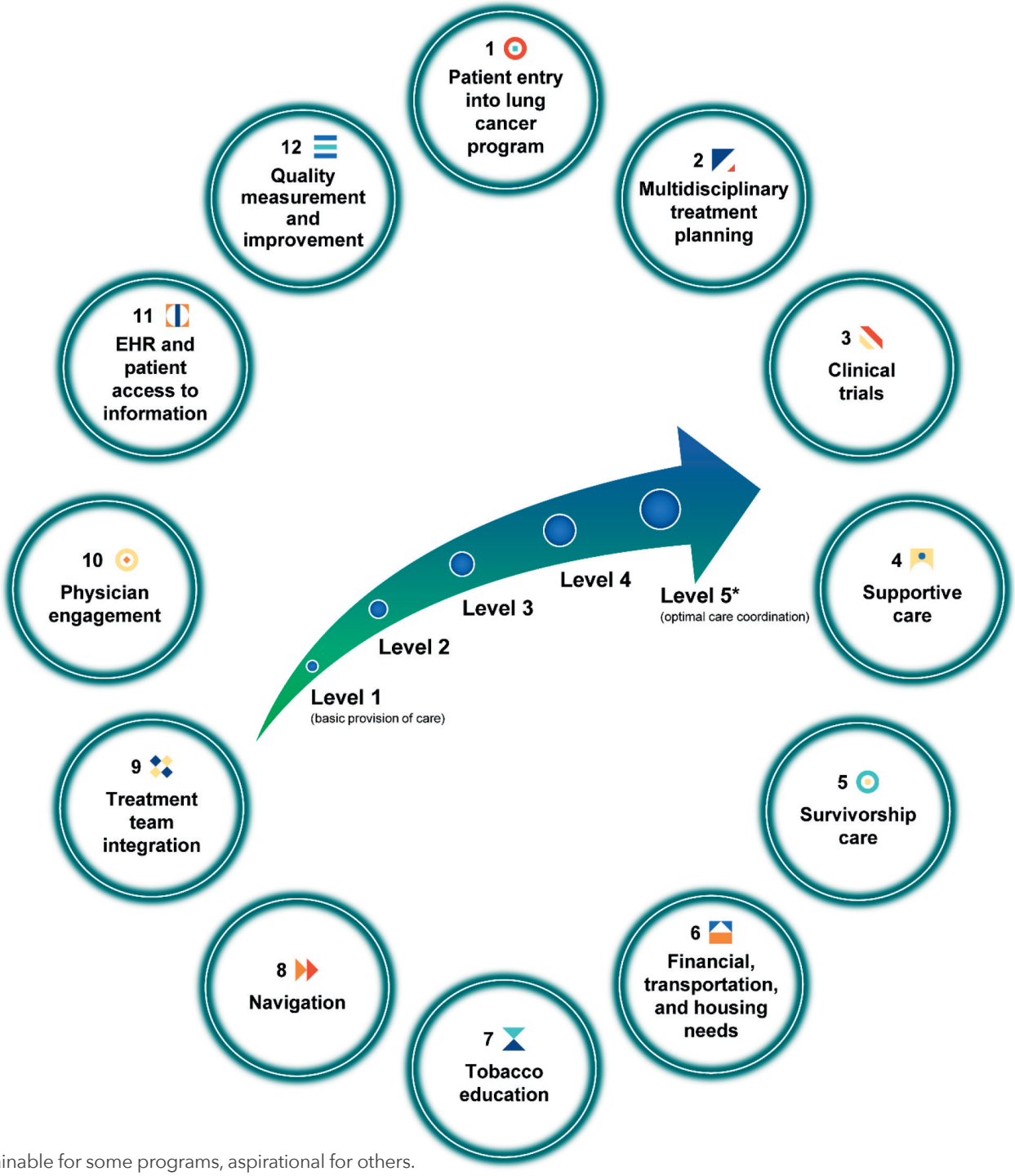
The OCCM can be deployed by any cancer program, regardless of size, setting, or resource level, to help identify disparities, strengthen and expand access to optimal lung cancer care, and articulate aspirational goals.

The levels of care coordination for lung cancer in the OCCM (Figure 1, page 74) are rated from 1 (indicative of fragmented care and a low focus on optimal care coordination) to 5 (indicative of optimal care coordination with a patient-centered focus that requires education and engagement with patients and their caregivers to facilitate shared decision making and increased participation). Progress to a higher level of care coordination implies that all conditions for the lower level(s) of care coordination continue to be met. Depending on the OCCM assessment area and contextual factors, achieving Level 5 may be attainable for some cancer programs and aspirational for others. Each OCCM assessment area requires the selection of at least one specific and measurable parameter as an evidence-based and institution-specific benchmark for continuous monitoring of quality improvement. The OCCM can be deployed by any cancer program, regardless of size, setting, or resource level, to help identify disparities, strengthen and expand access to optimal lung cancer care, and articulate aspirational goals.

The model is available in its entirety online at accc-cancer.org/care-coordination. Cancer programs should strongly consider taking the online assessment at accc-cancer.org/6-steps to get a downloadable customized report of their results in each assessment, as well as a crosswalk to more than 100 quality measures.

(Continued on page 75)

Figure 1. Assessment Areas[a] for Lung Cancer Care Delivery in the Final Optimal Care Coordination Model



[a]Attainable for some programs, aspirational for others.
EHR = electronic health record.

(Continued from page 73)

Dissemination of the Final OCCM

The final OCCM is being disseminated nationwide by ACCC through its vast network of U.S. cancer program members. The proposed use of the final OCCM is as a Model offering institutional guidance on conducting self-assessments of care delivery capabilities for Medicaid patients diagnosed with lung cancer (especially across the 12 high-impact assessment areas), identifying areas for improved care coordination in this patient population, and implementing improvements through varied approaches in support of multidisciplinary coordinated care delivery for lung cancer. The final package includes a web-based benchmarking tool for the 12 OCCM assessment areas and other resources, including online and print versions of the model,[6] the environmental scan[4] access to a quality improvement project planning tool, a podcast and publication highlighting the experiences of several testing sites, and the literature review bibliography compiled in 2016,[7] to enable expanded use by cancer programs and practices. ACCC worked with an external web design team to develop an optimal user experience with revised webpages and the web-based benchmarking tool for the OCCM assessment areas (Figure 2, page 76).[8] Additionally, a brochure highlighting the benefits of using the Model will be sent to 50,000 cancer program professionals, and a series of blogs and a podcast promoting the model will be released. Project leadership will also participate in interviews on the OCCM to be published in a variety of relevant print and online publications.

Discussion

Advances in systemic and targeted cancer therapies have not benefited all patient populations equally, with a higher burden of disease often experienced by socio-economically disadvantaged subgroups and other vulnerable populations.[2-3,9-11] The goals of high-quality care delivery across the cancer continuum include timely access to optimal, evidence-based care; coordination and communication among providers, including primary care and specialty care; promotion of a patient-centered management approach, including effective communication between patients and their providers; and implementation of value-based payment models with incentives to reduce health disparities.[12] Therefore, special considerations are needed to ensure that patient subgroups, such as those with Medicaid insurance, receive timely access to high-quality care across the cancer continuum and, ultimately, achieve equitable outcomes when compared with other patients. The first step is to describe and quantify processes in existing care delivery systems. The OCCM, with its special focus on Medicaid patients diagnosed with lung cancer, has the potential to address the dichotomy between the disproportionate disease burden in vulnerable patient subgroups and their limited access to appropriate, high-quality, and timely cancer care, ultimately improving clinical outcomes. The OCCM provides cancer programs with a resource to evaluate their care delivery practices, especially for underserved and vulnerable patient subgroups. This includes the ability to conduct baseline assessments that, in turn, help identify disparities and inequities; prioritize areas for improvements that require additional time, efforts, and resources; and facilitate access to multidisciplinary coordinated care. The Model supports a comprehensive approach to optimal care delivery across the cancer continuum, spanning timely access from diagnosis to survivorship, supportive care, and end-of-life care.

The medical and care coordination needs of Medicaid patients with lung cancer are likely to have important implications on lung cancer care delivery in the future. This initiative focused on Medicaid patients as the target population; however, the distribution of patients by payer status during beta testing was proof that many non-Medicaid patients at each testing site were also able to participate in and benefit from quality improvement projects implemented for lung cancer care delivery.[5] This included beneficiaries eligible for both Medicare and Medicaid programs who may have more complex care needs resulting in higher costs compared with nondual eligible beneficiaries.[13-15] In clinical practice, defining value-based cancer care is essential, preferably through the use of evidence-based and institution-specific metrics that evaluate structure, process, or patient outcomes across the cancer care continuum.[12] In this regard, the OCCM can be transformative for cancer programs and can contribute significantly to value-based care. Evidence-based quality metrics, including those from the Centers for Medicare & Medicaid Services Merit-based Incentive Payment System (CMS MIPS), the American Society of Clinical Oncology Quality Oncology Practice Initiative (ASCO QOPI), the National Committee for Quality Assurance Patient-Centered Specialty Practice Recognition (NCQA PCSP), the Agency for Healthcare Research and Quality Consumer Assessment of Healthcare Providers and Systems (AHRQ CAHPS®), and the Commission on Cancer (CoC) 2020 Cancer Program Standards, the National Comprehensive Cancer Network Guidelines®, and the National Committee for Quality Assurance's Oncology Medical Home Recognition Program, are important components of the OCCM framework and assessment tool to promote continuous monitoring for quality improvement by cancer programs.[6]

(Continued on page 77)

Figure 2. Online Assessment Tool for the Final Optimal Care Coordination Model

OVERVIEW

The Association of Community Cancer Centers (ACCC) has created a model framework (the Model) for cancer care providers to use in improving care coordination for lung cancer patients covered by Medicaid. A three-year grant from the Bristol Myers Squibb Foundation provided funding for development of the Model.

Guided by an interdisciplinary **Advisory Committee**, led by physician champion co-principal investigators, and a **Technical Expert Panel**, ACCC developed the Model in three phases:

Phase One—Research and Beta Model Development
Learn More

Phase Two—Testing the Beta Model
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Phase Three—Data Analysis and Outcomes
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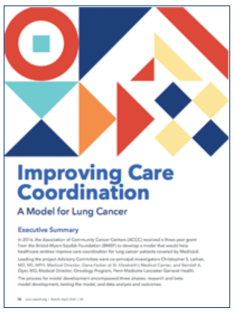

Read Executive Summary

THE MODEL

ACCC is pleased to make available the Model for Improving Care Coordination, which is designed for programs and practices of all sizes and resource levels. In addition to being a **comprehensive PDF report**, the Model has been transformed into a free, interactive online tool to evaluate the current state of care coordination for lung cancer patients and identify focus areas for improvement and actionable next steps.

Beyond a framework for evaluation and setting quality improvement priorities, the Model aligns quality improvement (QI) with existing quality measures, including those from the Centers for Medicare & Medicaid Services Merit-based Incentive Payment System (CMS MIPS), the American Society of Clinical Oncology Quality Oncology Practice Initiative (ASCO QOPI), the National Committee for Quality Assurance Patient-Centered Specialty Practice Recognition (NCQA PCSP), the Agency for Healthcare Research and Quality Consumer Assessment of Healthcare Providers and Systems (AHRQ CAHPS®), and the Commission on Cancer (CoC) 2020 Cancer Program Standards.

The Model has 12 assessment areas, each with a high impact on optimal care coordination for lung cancer patients. The assessment areas start at the time of initial patient referral to cancer services and continue through survivorship and end of life. Each assessment area is divided into 5 levels. Level 1 attributes represent basic care and coordination; Level 5 attributes represent optimal best practice. The Model includes a crosswalk of assessment areas to quality measures.

Assess Your Cancer Program with the Model

Source: Association of Community Cancer Centers. Improving care coordination: overview, 2020. Available online at: accc-cancer.org/projects/improving-care-coordination/overview.

(Continued from page 75)

Application of the OCCM framework and assessment tool by a cancer program at the point of care can be used to identify specific gaps and barriers that prevent healthcare systems from being able to deliver care equitably and efficiently to their constituencies. Asking complex, in-depth questions about the quality of care given and how that care is accessed is the first step in attempting to address barriers to care. Given the current societal examination of structural racism, many cancer programs are asking, "How can we better serve our traditionally underserved communities?" While this question is important, without an accurate evidence-based evaluation of the cancer program's current care delivery system, the question remains rhetorical and devoid of action. Health disparities are created and maintained long before the lung cancer point of care. To eliminate disparities evident for Medicaid and non-Medicaid patients with cancer, facilitation and expansion of access to appropriate care is essential. This expansion must be inclusive of all community identities, including but not limited to those based on race, ethnicity, indigenous groups, religion, sexual orientation, rural residence, and recent immigrant status. A true assessment of the cancer program is necessary for any quality improvement and expansion effort, and programs should judge themselves by how well they treat their most vulnerable patients, not just their most resourced patients.

The OCCM also has important implications for Medicaid policy related to the delivery of cancer care. The expansion of Medicaid eligibility and statewide coverage brings into focus the need for delivery system– and payment-related reforms to improve the quality of care, reduce duplicative or unnecessary services, and control program costs through managed care and other initiatives that coordinate care across the continuum of services.[15]

In conclusion, refinements to the OCCM were informed by the experience and results of beta testing at seven cancer programs and led to improved clarity of intent, ease of use and reproducibility, specificity, and uniformity before wider dissemination. The final Model can be utilized by cancer programs and practices to conduct objective self-assessments of their capabilities across 12 high-impact areas of care delivery for lung cancer that will prioritize the unique care and treatment needs of Medicaid patients as an important step toward ensuring equitable health outcomes with non-Medicaid patients. Dissemination of the final Model across the wider network of U.S. cancer programs has high potential to advance multidisciplinary coordinated care delivery, define value-based care delivery metrics, and improve clinical outcomes for patients nationwide, regardless of cancer type. OI

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Bristol Myers Squibb™ Foundation

A publication from the ACCC education program, "Improving Care Coordination: A Model for Lung Cancer Patients on Medicaid." **Learn more at accc-cancer.org/care-coordination** or scan this QR code.

The **Association of Community Cancer Centers (ACCC)** is the leading education and advocacy organization for the cancer care community. Founded in 1974, ACCC is a powerful network of 28,000 multidisciplinary practitioners from 2,100 hospitals and practices nationwide. As advances in cancer screening and diagnosis, treatment options, and care delivery models continue to evolve—so has ACCC—adapting its resources to meet the changing needs of the entire oncology care team. For more information, visit accc-cancer.org or call 301.984.9496. Follow us on Facebook, Twitter, and LinkedIn; read our blog, ACCCBuzz; and tune in to our podcast, CANCER BUZZ.

Association of Community Cancer Centers

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Association of Community Cancer Centers

Collaborative Learning Workshops Explore Best Practices for Implementing Cancer Immunotherapies in the Community

To help community oncology programs and practices across the United States better integrate immunotherapies to treat cancer, the Association of Community Cancer Centers (ACCC) hosted a day-long, expert faculty-driven workshop with three Member Programs: Grand Valley Oncology in Grand Junction, Colo.; Medstar Franklin Square Medical Center in Baltimore, Md.; and PIH Health in Whittier, Calif. These workshops provided guidance on practical issues related to optimal integration of immunotherapies into practice, including coordination and communication within the multidisciplinary cancer care team, coverage and reimbursement, and patient education and engagement.

Workshop participants engaged in discussion with expert faculty to assess their own immuno-oncology practices and to build an action plan to address challenges and barriers at their respective locations. "We participated in the workshop in November 2019. At the time, we had onboarded several new nurses to our oncology practice, and we were starting to see more and more of these immunotherapies come through, including the side effects of those therapies," says Tara Bebee, RN, BSN, OCN, oncology nurse educator at Grand Valley Oncology. "We participated in this program because we wanted to provide an education program for staff that gave us a well-rounded overview of immunotherapies, and to get our nursing staff more experience with these treatments. Exposure to the expert faculty and their experience was really valuable."

Staff Education and Management of irAEs

Grand Valley Oncology staff identified the need to implement tools (e.g., patient wallet cards, reference sheets, and checklists for staff) to improve patient education on immunotherapies, and to help nursing staff across the hospital better identify patients who experience toxicities or immune-related adverse events (irAEs) due to their treatment. Grand Valley Oncology is located near Community Hospital in Grand Junction, Colo., and is an outpatient department of the hospital, so ensuring inpatient and emergency department (ED) staff are educated about immunotherapies and irAE symptoms is a challenge. "It's hard for clinical staff in those settings to look at the anti-cancer drug regimens patients are on and know that their patient may be experiencing toxicity to treatment," explains Bebee. "Immunotherapies are coming out so quickly, and it's still an emerging field. It can be difficult for clinical staff to stay up to date on every new development—especially for providers in the ED setting who do not specialize in oncology."

To help ED and inpatient staff, Bebee developed binders to share information and education on all types of oncology emergencies, including irAEs. This resource is helpful for hospital staff since the oncology department is not within the walls of the main hospital but a phone call away. In turn, Bebee's nursing staff benefitted most from ACCC's education opportunity. "I believe our triage nursing assessment skills have been positively impacted and even improved by exposure to cutting-edge

education about immuno-oncology and what nurses should watch for," says Bebee. Since completing the workshop, Grand Valley Oncology nursing staff use reference sheets to educate patients and a checklist to better assess patients who are on an immuno-oncology treatment regimen.

Located just outside Baltimore, Md., Medstar Franklin Square Medical Center provides oncology services at eight community-based locations. Pallavi Kumar, MD, director of Immuno Oncology at Medstar Franklin Square Medical Center, The Harry and Jeanette Weinberg Cancer Institute, also sees a great need to ensure ED and hospital staff are educated on immunotherapies. "There is never enough education to go around to ED staff and hospitals," says Dr. Kumar. She explains that patients can continue to experience toxicity long after completing their immunotherapy treatment, so a need also exists to educate primary care providers (PCPs) along with ED and hospital physicians.

In response to the varying toxicities immunotherapy patients experience and lessons learned from the ACCC workshop, Dr. Kumar developed an immunotherapy side effect team within her program. This team is made up of a physician lead within each relevant discipline (e.g., endocrinology, pulmonology, and gastroenterology). "I've done this partly to increase the physicians' experience with identifying and treating immunotherapy toxicities," says Dr. Kumar. "If you get to see more than one case, then it becomes much easier for you to identify toxicity symptoms." If a patient's symptoms are identified to be immunotherapy-related, Dr. Kumar contacts the necessary physician lead directly to discuss the best course of treatment for the patient. Staffing has also been enhanced since participating in the workshop to address the need for tracking patients who are being treated with immunotherapies. A nurse dedicates their time to monitor and track these patients via a simple spreadsheet and algorithm to establish follow up timing. During follow up, after the team checks up on patients at each cycle of treatment and if no symptoms are reported, the nurse calls patients once a month per cycle. If patients report mild symptoms, the nurse follows up with them weekly. If patients experience any autoimmune toxicity, the nurse calls daily until treatment and symptoms stabilize. Monitoring and tracking patients help ensure their symptoms are addressed and treated right away.

Patient and Caregiver Education

While it is critical to educate healthcare staff on immunotherapies, patient and caregiver education is also key. When patients experience symptoms after treatment(s), they often visit the ED or hospital, which results in higher costs to patients and the healthcare system due to ED or hospital admission and possible misdiagnosis of patients' symptoms or toxicities because staff are unaware of patients' cancer history. Bebee shared that the ACCC patient immuno-oncology wallet card implemented after participating in the workshop has greatly helped with their patient education, and her nursing staff continue to use the immunotherapy quick facts sheet in new patient teaching appointments. But staff use of these tools is an ongoing effort. "In my opinion, if cancer programs want to successfully implement these types of tools for process improvement, the use of the tools should be mandatory," explains Bebee. "I think making the tools available to staff is a great start, but it's also one of those things that if it's out of sight, it's out of mind. Putting the emphasis on needing to use these tools versus the choice being left up to staff will make a big difference."

At Medstar Franklin Square Medical Center, patients being treated with immunotherapies will spend time at their first visit learning the autoimmune effects of their treatment with their oncologist. Before treatment begins, patients are also required to attend a 90-minute group education session. (During the COVID-19 pandemic, these group sessions were replaced with individual conversations with patients when they came in for treatment.) Dr. Kumar takes an extra step with her immunotherapy patients by sitting down with them to provide further education and answer questions. During treatment, she will also meet with patients on a three- to four-week basis, depending on the prescribed therapy, and on a weekly basis with those patients who have also been prescribed a steroid.

Coverage and Reimbursement

Even with the existing differences between participating cancer programs, workshop faculty noticed similar challenges and barriers to immuno-oncology implementation and effective practices. Faculty member Sarah Hudson-DiSalle, PharmD, RPh, pharmacy manager, medication assistance and reimbursement services at the Arthur G. James Cancer Hospital and Richard J. Solve Research

Institute at The Ohio State University, explains that a key step for ensuring reimbursement on immunotherapies is packaging payer pre-determination/pre-authorization information (e.g., patients' previous treatments, labs, etc.). "There is a need to streamline this process," says Dr. Hudson-DiSalle. "Cancer programs use a lot of resources upfront to get immunotherapies to patients. And if everything is ready upfront, there is no lag or delay in payment or reimbursement, and patients can continue to receive treatment."

For many cancer programs and practices, this process is initiated with a simple ask for permission from payers, which allows more formal payer requests to be completed later. Dr. Hudson-DiSalle suggests that cancer programs and practices should hire or commit a full-time staff member dedicated to the pre-determination process and tracking of these agents. "You need to ensure that you have a dedicated staff member just because immuno-oncology agents are so expensive and so specialized," she explains. "Healthcare is evolving, and our payers are evolving too—whether that means site of care restrictions, benefit restrictions, or out-of-pocket expenses. When it comes to immunotherapies, all of these different nuances can contribute to a negative patient experience." A dedicated staff member can make certain the pre-determination process is done in a streamlined and unified fashion, This dedicated staff member can ensure the pre-determination process is completed in a streamlined and unified fashion. This allows treatment for the patient in a timely and expedited manner while helping to increase the likelihood of timely reimbursement for the facility or practice.

Continued Learning

Learning at these ACCC workshops was bi-directional. Meaning, as workshop participants learned effective practices for implementing immuno-oncology into their practice, workshop expert faculty learned from participants' experiences. Since immuno-oncology is not a one-size-fits-all solution, a cancer program or practice's setting and patient population plays a key role in the design and implementation of necessary tools and/or staff to best treat patients with cancer who are on an immunotherapeutic regimen. "It's refreshing to see a smaller operation because they can be much more personalized and really do the right things for their patients," explains Dr. Hudson-DiSalle. "For me, it was nice to see what their barriers had been and what they had done to overcome those barriers. Sometimes there were things that I may have not thought to try, and sometimes I could share other ideas or avenues to help them remove those barriers."

Like many areas of oncology, immuno-oncology faces a unique set of implementation barriers and challenges often driven by the cancer program's patient population. But the common denominator to optimizing the integration of immunotherapies into practice, Bebee shares, is the continued learning and exposure by healthcare staff. "I definitely advocate for participating in these types of workshops," she says. "I believe it is important to introduce clinical staff to this type of education because continued exposure is what helps people keep this information at the forefront of their minds when they are assessing their patients and administering immunotherapies." Similarly, Dr. Kumar shares that since participating in the ACCC workshop, she has felt more confident in her cancer program's ability to provide quality care to patients. "These types of forums [workshops] are so important," says Dr. Kumar. "I found that it reinforced and strengthened my ability to provide the best care to patients."

This activity is supported by educational grants from AstraZeneca Pharmaceuticals LP, and Merck & Co., Inc.

This article is produced as part of the "Best Practices for Implementing Cancer Immunotherapy" education program. You can learn more at accc-cancer.org/projects/implementing-cancer-immunotherapy/overview

ACCC Hosts First Virtual Hill Day

On May 12, 2021, ACCC hosted its 2021 Virtual Hill Day. Forty-three members from 24 states attended more than 70 meetings with U.S. House and U.S. Senate offices. ACCC member participants came from all different backgrounds and included physicians, financial advocates, social workers, nurses, pharmacists, and cancer program administrators.

In the past, ACCC Hill Day has been an in-person event held in conjunction with the ACCC Annual Meeting and Cancer Center Business Summit. With restrictions on in-person visits to federal buildings due to the COVID-19 pandemic, ACCC decided to bring this experience to a virtual format. Pivoting to a virtual format allowed members who were unable to travel in previous years the opportunity to engage with policymakers from their state at a federal level.

To help prepare its members, ACCC hosted two webinars, one in April and one in May, with training on the ACCC policy and advocacy platform, how to interact with policymakers at legislative meetings, and key "asks" for the ACCC 2021 Virtual Hill Day. Other tools ACCC developed and provided to Virtual Hill Day participants include:

- One-pagers on each "ask," including the main points of each Congressional bill.
- A sample script of how a meeting with a congressional office typically goes, including talking points.
- A sample thank-you note that members could personalize and send after their virtual meetings to thank legislative offices for their time and remind them of the key advocacy points discussed.
- A social media toolkit to share their advocacy efforts via Twitter and LinkedIn.

The two keys "asks" at the ACCC 2021 Virtual Hill Day were:

- Support for the Telehealth Modernization Act (H.R. 1332/S.368). Prior to COVID-19, telehealth services were largely non-reimbursable and restricted to the use of patients in remote and rural areas who had existing relationships with a medical provider. New policies enacted in response to the pandemic allowed providers to offer telehealth services to patients living outside of designated rural areas and across state lines. This bipartisan legislation addresses concerns about the continuity of telehealth after the pandemic resolves and proposes to extend telehealth flexibilities, such as "permanently removing Medicare's geographic and originating site restrictions, which require a patient to live in a rural area and be physically in a doctor's office or clinic to use telehealth services."
- Support for the Safe Step Act (H.R. 2163/S. 464). The use of step therapy for people with cancer is inappropriate, creating barriers to appropriate, necessary, and timely care. This bipartisan legislation would require ERISA governed health plans—that is, group health plans or health insurance coverage offered in connection with such a plan—that provide coverage of a prescription drug pursuant to a medication step therapy protocol, "to implement a clear and transparent process for a participant or beneficiary (or the prescribing healthcare provider on behalf of the participant or beneficiary) to request an exception to such medication step therapy protocol."

If time was available during their legislative meetings, ACCC members were asked to advocate for three additional issues:

- Support for the Access to Genetic Counselor Services Act (H.R. 2144/S.1450).
- Support for the Research Investment to Spark the Economy (RISE) Act (H.R. 869/S.289).
- Support for the Medicare Multi-Cancer Early Detection Screening Coverage Act of 2021 (H.R. 1946).

A Reminder from ACCC's Bylaws Committee

Dec. 1, 2021, is the deadline for submission of any proposed amendments to the ACCC bylaws. Proposed recommendations should be sent to Betsy Spruill at bspruill@accc-cancer.org. The ACCC bylaws are available online at: accc-cancer.org/bylaws.

Developing and Studying the Investigational City of Hope COVID-19 Vaccine

BY SANJEET DADWAL, MD

City of Hope is a National Cancer Institute-designated comprehensive cancer center and founding member of the National Comprehensive Cancer Network. Its mission is centered on transforming the future of healthcare through advancing research and quality patient care for people with cancer, diabetes, and other serious illnesses. In huge part, this mission is carried out in its research program, which now includes the development and study of an investigational City of Hope COVID-19 vaccine known as COH04S1.

The investigational City of Hope COVID-19 vaccine is important because it was designed with immunocompromised patients in mind, including transplant patients and those with cancer. As chief of the division of infectious diseases and co-chair of the infection control committee at City of Hope, I have seen first-hand the unique situation immuno-compromised patients face with the COVID-19 vaccines currently under emergency use authorization by the U.S. Food and Drug Administration.

The current recommendation led by the Centers for Disease Control and Prevention is for everyone to get vaccinated—regardless of patients' immune status. Though the COVID-19 pandemic is a great example of the benefits of vaccine research and development, little research has been done to show a more positive response in patients with cancer and other immuno-compromised people. This was made apparent in data released by Johns Hopkins University on the Pfizer-BioNTech and Moderna COVID-19 vaccines.[1] Researchers at Johns Hopkins conducted a multicenter study in which they looked at the antibody response of these vaccines and found that they produce very low rates of detectable antibodies in patients with solid organ transplants and others who are immuno-compromised. These findings identified a need to study and evaluate a COVID-19 vaccine that induces a much better response in these patients.

That is not to say that patients with cancer or others who are immuno-compromised should forgo COVID-19 vaccination. Instead, those who receive a COVID-19 vaccine should be told that their chance of responding to the vaccine varies depending on their disease—those with solid tumors respond better than those with a blood cancer. All immuno-compromised patients with a history of or active cancer should be advised to continue practicing social distancing and to wear masks to stay safe even after they are vaccinated.

I work with Don J. Diamond, PhD, professor in the Department of Hematology & Hematopoietic Cell Transplantation, who leads research on vaccine development for hematologic malignancies, solid tumors, and cytomegalovirus human immunodeficiency virus and who led development of City of Hope's investigational COVID-19 vaccine. When the COVID-19 pandemic first began, Dr. Diamond and his team quickly began developing a vaccine for the virus. Based on the track record of the investigational vaccine platform, we believe that people, especially those who are immuno-compromised, may have a better response. But that hypothesis needs to be investigated.

Vaccine Design

Dr. Diamond and his team used the Modified Vaccinia Ankara (MVA)—a vaccine delivery system for antigens—as the vehicle for City of Hope's investigational COVID-19 vaccine. MVA technology has been around for a long time and has been tested extensively in patients who have received hematopoietic cell transplants. Studies have found that these MVA-based vaccines are very safe, effective, and able to induce a good immune response even in patients who are immuno-compromised. The investigational City of Hope COVID-19 vaccine is novel because it is the only one in study in the United States that uses the SARS-CoV-2 spike protein and nucleocapsid proteins to induce an immune response in the host. By using both the spike and the nucleocapsid proteins, we believe that the vaccine will be more immunogenic and will induce antibody responses and a very strong T-cell response.

T-cells are the immune cells that linger behind after vaccine injection and can be recalled by the body when you are exposed to the SARS-CoV-2 infection. So even when the antibody count decreases, these T-cells can still fight the virus. We believe the vaccine should work by inducing an immune response to two different targets and may have a lasting, more durable response in people. We also believe that side effects should be less severe and that the investigational vaccine could have a more robust and positive effect on the immune system, especially in immuno-compromised patients.

Animal studies are being done now in Dr. Diamond's lab to look at the vaccine and the COVID-19 variants we have seen so far. We have targeted the two major COVID-19 components recognized by the immune system, namely, the spike and the nucleocapsid proteins, and we believe that it could be effective against known variants (because most of the mutations are in the spike protein). But it is still too early to truly make this determination, because research data will prove the effectiveness of the vaccine on COVID-19 variants. City of Hope began animal studies in April 2020, in May we developed the investigational COVID-19 vaccines, and the optimal vaccine candidate was chosen in June. The animal studies showed a good antibody and cellular immune response to the vaccine candidate. Manufacture of the new investigational COVID-19 vaccine was completed by August 2020, and applications were filed with the U.S. Food and Drug Administration by October 2020 to begin the phase I clinical trial.

Josh Jenisch is executive director of content at City of Hope.

Josh Jenisch receives the investigational City of Hope COVID-19 vaccine.

Our Phase I Clinical Trial: A First-Person Perspective

We are still conducting the phase I clinical trial for the City of Hope investigational COVID-19 vaccine, whose principal investigator is Dr. John Zaia, director of City of Hope's Center for Gene Therapy. This phase I study is designed to evaluate safety and optimize the effective dosage. We began with a lower dose, followed by a medium dose, and then a high dose to study the immune response with a small selection of participants. These first set of studies gave us the dosing mechanism for this vaccine: two doses per individual. Patients get the first dose at day zero and the second dose at day 28. As a co-investigator from a clinical standpoint, I help enroll patients in the study and follow up with them in the clinic.

Josh Jenisch is executive director of content at City of Hope. He often speaks with and shares the amazing stories of the patients we treat on our website and through our social media channels. As part of City of Hope's initiative to increase trial accrual, we offered the opportunity to join the clinical trial to those who work with us, as well as those in the broader community. Jenisch was one of the first to volunteer to take part in the phase I trial.

"I had been sitting at home since March, really just frustrated with my inability to do anything about this virus," Jenisch said. "I go to work every day, and I work alongside some of the smartest folks on the planet. I was unable to help them, even in the most rudimentary way."

We sent out an email to all City of Hope staff offering the opportunity to participate in the phase I clinical trial in December 2020.

"I just had this realization that this is the one thing I could do right to push the science forward," Jenisch explained. He received the investigational COVID-19 vaccine in December and continues to come in for follow-up as we continue to study it. He experienced no symptoms himself and found the process easy and straightforward.

"It was almost exactly like getting a flu shot," he says. "I didn't have any side effects whatsoever. But the best part of this experience for me was getting to work from inside the science. I'm in communications, so I'm always hearing about these things after the fact. This was a chance for me to be in that background space with doctors like Dr. Dadwal, Dr. Zaia, and Dr. Diamond. These really smart scientists. For someone who loves science and discovery, it was a perfect opportunity."

The situation is improving in the United States. More people are getting vaccinated, and the federal government has said that vaccinated individuals need not wear masks when indoors except where required by local guidance. However, the story is different for people who are immuno-compromised. Even after COVID-19 vaccination, these individuals are advised to continue to wear masks because it is unclear how effective the current vaccines are for them. Their treatment blunts the immune system so that it doesn't produce as many antibodies as the vaccines are designed to stimulate. The hope is that further clinical trial data on City of Hope's investigational COVID-19 vaccine will result in a viable option for patients with cancer or who are immuno-compromised. OI

Sanjeet Dadwal, MD, is chief of the Division of Infectious Diseases and co-chair of the Infection Control Committee at City of Hope in Duarte, Calif.

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