# ONCOLOGY ISSUES

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

July | August 2020

## Multidisciplinary Conference Case Planning in the Virtual Space

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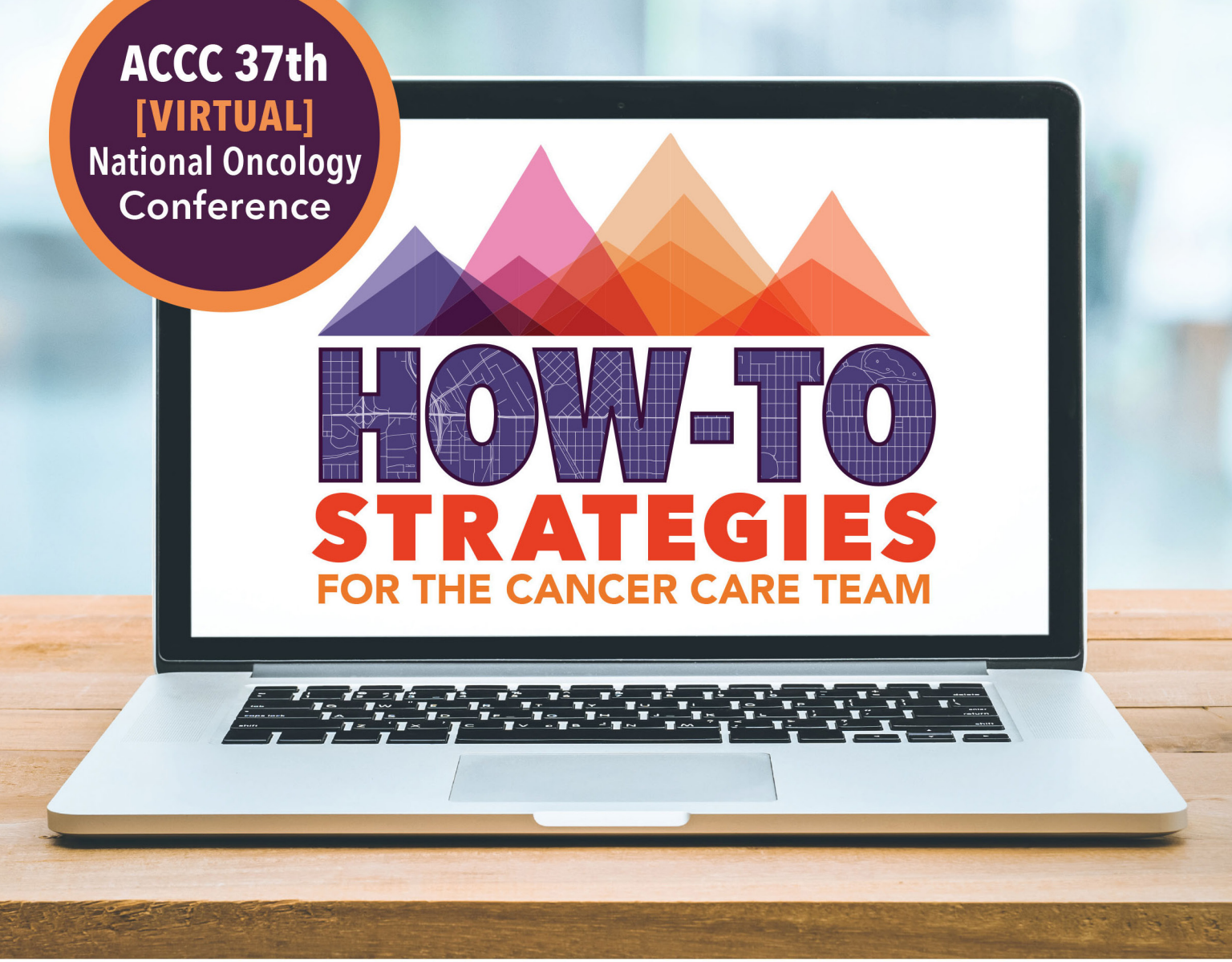


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July | August 2020
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## DEPARTMENTS

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FROM THE EDITOR

# Go Viral with Compassion and Kindness

BY JENNIE R. CREWS, MD, MMM, FACP,
AND KRISTA NELSON, MSW, LCSW, OSW-C, BCD

As we approach the sixth month of the SARS-CoV-2 (the virus that causes COVID-19) pandemic, so much has changed about the way we work and live. Screening, masking, testing, and virtual meetings and appointments are standard operating procedure. We now turn our attention to the future and wonder how long these procedures will remain routine, whether immunity from exposure or from a vaccine will become a reality, and how we will survive the psychological and economic toll of COVID-19. The fear and uncertainty related to the spread of COVID-19 is real, and we are all feeling it, both personally and professionally. We are being called upon to support each other and our patients in new and different ways.

Dealing with such uncertainty is daunting for many of us, but I am reminded that our patients have faced uncertainty long before there was COVID-19. A diagnosis of cancer suddenly shifts the futures that our patients imagined for themselves and their families. The effects of cancer and its treatment limit their participation in activities they once enjoyed. The cost of cancer care threatens their financial security. Now many of us are experiencing some of these same losses.

What can those experiencing cancer and its overwhelming unpredictability teach us about dealing with COVID-19?

- Take a moment to mindfully identify what emotion you are feeling.
- Acknowledge that we all need help sometimes. We chose oncology because we are givers. Givers have a hard time being receivers, but asking for help is not a sign of weakness or an imposition.
- Find connection. Stay connected to family, friends, and co-workers and don't worry alone. Share and listen to concerns, communicate openly, and provide professional services that support one another. Some cancer programs are offering peer counselors, care packages, video support groups, and special break areas.
- Embrace activities to alleviate anxiety, such as meditation, exercise, music, art, or creative hobbies.
- Consider limiting social media and news after 6:00 pm. These can trigger worry and impact sleep.
- Focus on what you can control. Slow down and consider what you *can* do, or focus on, in this moment to help you feel better. This may be your breath, a gratitude practice, or helping a neighbor.
- If you feel overwhelmed, seek out resources in human resources or community programs to provide financial counseling and emotional support.

Resources are also available from national organizations. For example, the Centers for Disease Control and Prevention offers online resources on coping with stress, helping children cope, and reducing stigma at cdc.gov/coronavirus/2019-ncov/daily-life-coping/stress-coping. The Substance Abuse and Mental Health Services Administration offers tools like *Coping with Stress During an Infectious Disease Outbreak* (store.samhsa.gov/sites/default/files/d7/priv/sma14-4885.pdf) and *Taking Care of Your Mental Health During an Infectious Disease Outbreak* (samhsa.gov/sites/default/files/tips-social-distancing-quarantine-isolation-031620.pdf). Share the resources you find most useful by posting them to ACCCeXchange at accc-cancer.org/COVID-19.

Our challenge is to remember to be gentle with each other and ourselves while acknowledging that we are suffering alongside our community. One unique outcome from our shared experience with COVID-19 is that we may now understand a cancer patient's perspective in a new way. This trying time will likely bring our community closer than ever. Let our compassion and kindness be the energy that goes viral in our community. OI

# ACCC Pivots to Provide COVID-19 Information and Resources

BY RANDALL A. OYER, MD

COVID-19 has brought an unexpected, unwelcome, and unwanted disruption to oncology care, as it has to every other facet of life. ACCC has met this unprecedented pandemic, however, with its characteristic "how to" approach.

Very soon after ACCC members began to report in with their experiences and to reach out for help, ACCC staff and member volunteers began to produce a series of high-level programs designed to share experience among the membership, to survey members about challenges they are facing, and to provide strategies and helpful evidence-based information where this exists.

ACCC's COVID-19 Resources (accc-cancer.org/COVID-19) is a landing webpage that offers thoughtfully curated information, including:

- A series of 30-minute, moderated, and member-driven webcasts on a broad range of topics such as Financial Assistance Amid COVID-19; Telehealth Billing and Coding; Clinical Trials Amid COVID-19; Managing COVID-Positive Patients in the Clinic; Planning Your COVID-19 Testing Strategy; and more.
- A series of mini-podcasts (less than 10 minutes in length) on topics like Urban Cancer Care During COVID-19; COVID-19 & Rural Cancer Care; Drive-Thru COVID-19 Screening; COVID-19 Conversations with Patients; COVID-19 Self-Care; and more.
- A blog series, including Creating a Safe Workplace During COVID-19; Immunotherapy Trials Amid COVID-19; Patient Financial Toxicity as a Result of the Pandemic; and more.
- Evidence-based COVID-19 information and resources from professional associations (i.e., ASCO, ASHP, ASTRO, ONS, etc.) and government organizations (i.e., CDC, CMS, FDA, NIH, etc.).
- Medicare and Medicaid pandemic-related coverage and payment updates.
- Peer resources.

With all the challenges that we have individually and collectively faced, it behooves us to take a moment and recognize all of the extraordinary work done by our teams, and all of YOU! In oncology practices, cancer centers, hospitals, and other healthcare settings all over the world, multidisciplinary oncology teams have transcended difficulties, demonstrated tremendous bravery and skill, and continued to provide life-saving therapies in a severely constrained and at times dangerous environment. We must all share the pride that we can do this—and do it well! It is nothing short of extraordinary.

We were not ready for this virus, but we were (and remain) ready to face any new problem together. We have done hard work together before and we have what it takes. Our cancer care teams share the absolute commitment that our patients always come first and that we will do whatever it takes to care for them.

We work tirelessly across disciplines and specialties to share information, collaborate on getting the job done, and support each other through thick and thin. Think about all that we have accomplished in the past few months! We have learned very quickly about a new disease and how to care for its victims. We have learned how to keep our patients and staff safe in a very risky environment. And we have rapidly integrated new tools into our daily workflow.

I think going forward that there will be some good that comes of everything that we have been through together. I, for one, am going to remember how ACCC was able to quickly pivot and became a trusted source of COVID-19 resources and beacon to my program and to may others as we navigated the unchartered territory of this global pandemic together.

Thank you for being our ACCC colleague and member. Please continue to care for one another and for yourselves OI

## Coming in Your 2020 *ONCOLOGY ISSUES*

- Developing a Model of Risk Modification for Breast Cancer Using Integrative Oncology
- Optimizing Provider Access in the Rural Healthcare Setting by Utilizing a Physician-Advanced Practice Provider Model
- Built to Care: Cancer Centers for the Future
- The Role of Nurse Practitioners in Clinical Research
- Cybersecurity in Oncology Practices
- Management of Hospital Admissions for Checkpoint Inhibitor Immune-Related Adverse Events at a Regional Cancer Center
- Medication Transitions in Hematologic Malignancy Patients at a Safety Net Hospital
- An Investigation of Self-Determined Work Motivation Among Young Adult Central Nervous System Cancer Survivors
- Leveraging a 3D Lung Nodule Educational Tool to Reduce Patient Distress
- Utilizing Technology to Identify Patient Co-morbidities and Reduce Hospital and ED Admissions
- Onboarding Experienced Non-oncology Nurses to Address Staffing Shortages: Miami Cancer Institute's Oncology Training Academy
- Improve Oral Oncolytic Workflow and Reduce Treatment Delays with a Pharmacist Collaborative Practice Agreement

# more online @ accc-cancer.org

### BLOGS | COVID-19 & Cancer Patient Registry: Your Voice Matters

ACCC President Randall Oyer, MD, shares why your program should participate in the new ASCO Survey on COVID-19 in Oncology Registry (ASCO Registry), which seeks to collect information about patterns of symptoms and severity of COVID-19 infection, how COVID-19 influences the delivery of cancer care, and how patient cancer and COVID-19 outcomes are affected. Learn more at accc-cancer.org/covid19-cancer-registry.

### SURVEY | Resources to Strengthen Your Research Program

Interested in a series of webcasts on topics like "Research Engagement and the Importance of Identifying a Physician Champion" and "Diversifying Clinical Trial Investigators to Include NPs, PAs, and PharmDs." Need information about clinical trials in member-identified areas of interest like geriatric oncology, biomarker testing and precision medicine, and tissue acquisition and biorepositories? Want to participate in developing a library of resources to help identify and then solve challenges facing community-based clinical research programs? Then take this short 10-question survey: surveymonkey.com/r/R9G7ZGM.

### PODCAST | Financial Health Literacy

On this episode of CANCER BUZZ, Sarah Hudson-DiSalle, PharmD, RPh, Oncology Pharmacy Manager, Medication Assistance Program and Reimbursement Services, The James Cancer Hospital and Wexner Medical Center, Ohio State University Department of Pharmacy and Lori Schneider, Operations Manager, Green Bay Oncology, discuss the importance of financial health literacy for patients with cancer, how cancer team members can better help patients and caregivers avoid financial toxicity, and how financial navigation delivers value to both patients and cancer programs. Listen to the full episode at accc-cancer.org/podcast.

### WEBCAST | ACCC COVID-19 Webcasts

In "Developing a COVID-19 Recovery Plan," Jennie R. Crews, MD, MMM, FACP, Medical Director, Research Integration and SCCA Network, Seattle Cancer Care Alliance offers tips to safely and efficiently resume pre-COVID level patient visits and procedures and guidance on operational and technological issues. In "Implementing Virtual Tumor Boards Amid COVID-19," Shelli Laux, MBA, RHIA, CTR, CCRP, Administrative Director of Oncology Service Line, WellSpan Health, shares effective practices for virtual tumor boards, methods for ensuring attendance and participation, and insights into post-pandemic sustainability.

# fast

## Study Finds Malnutrition, Physical Inactivity Negatively Affect Cancer Care and Outcomes

- Many patients involved in clinical trials for cancer drugs may be malnourished and sedentary, a factor that may result in inaccurate results for the trials, according to a 2019 study.
- The study finds that malnourished patients had higher rates of side effects from therapy, hospitalizations, lower response rates, and a shortened survival.
- Specifically, **39%** of patients enrollied in a Phase I or II clinical trial were severely malnourished at the time of study initiation; **52%** of patients were sedentary, with minimal physical activity.
- There was about a two-fold increased risk of hospitalizations and severe side effects in malnourished patients, and these patients were only able to stay on the clinical trial study for half as long.

Source. Jain R, et al. Impact of baseline nutrition and exercise status on toxicity and outcomes in Phase I and II oncology clinical trial participants. Oncologist. 2019 Nov 20. doi: 10.1634/theoncologist.2019-0289.

## Top 5 Contributors to Physician Burnout

**55%** Too many bureaucratic tasks (e.g., charting, paperwork)

**33%** Spending too many hours at work

**32%** Lack of respect from administrators, employers, colleagues, or staff

**30%** Increasing computerization of practice (EHRs)

**29%** Insufficient compensation, reimbursement

Source. Medscape National Physician Burnout & Suicide Report 2020. medscape.com/slideshow/2020-lifestyle-burnout-6012460?faf=1#1.

# facts

## COVID-19's Impact on Hospitals

America's hospitals suffered significant financial damage as a result of the COVID-19 pandemic response. Data from more than 800 U.S. hospitals showed that volume and revenue declines, along with flat to rising expenses, resulted in a dramatic fall in margins within a matter of weeks in March 2020, plunging not-for-profit hospitals, which historically operate on thin margins, deep into the red. Specifically data revealed:

- Operating margins dropped **150%** year-over-year and **170%** below budget for the month of March
- Operating room minutes were down **20%** year-over-year
- Emergency department visits dropped **15%** year-over-year
- Median hospital occupancy rate was **53%** for the month
- Budgeted inpatient revenue was down **13%** in March
- Budgeted outpatient revenue was down **17%** in March
- Bad debt and charity care rose **13%** year-over-year

Source. National Hospital Flash Report. Flashreports.kaufmanhall.com/national-hospital-report-april-2020.

## COVID-19's Impact on Patients

In April 2020 a national survey found that:

- **66%** of Americans (10 million people) postponed or cancelled healthcare visits due to COVID-19, including appointments for chronic health conditions such as cancer, diabetes, heart attack, and stroke.
- **6%** postponed cancer screenings.
- **10%** postponed specialist care for existing conditions, including cancer.
- Two-thirds of those patients (**67%**) hoped to reschedule care within a month of COVID-19 restrictions being relaxed.

Source. The Harris Poll COVID-19 Tracker. Theharrispoll.com/the-harris-poll-covid19-tracker.

## COVID-19's Impact on Physicians

In April 2020 a national survey of physicians found:

- Close to half of all physicians (**48%**) are treating patients through telemedicine, up from **18%** in 2018.
- **21%** of physicians were furloughed or experienced a pay cut during the pandemic.
- **14%** of physicians plan to change practice settings as a result of COVID-19.
- **18%** of physicians plan to retire, temporarily close their practices, or opt out of patient care.

Source. The Physicians Foundation. 2018 Survey of America's Physicians: Practice Patterns & Perspectives. Physiciansfoundation.org/wp-content/uploads/2018/09/physicians-survey-results-final-2018.pdf.

# Leadership Panel Addresses Top Issues in Oncology Care

BY CHRISTIAN G. DOWNS, JD, MHA

In April, at the virtual 2020 Community Oncology Alliance Annual Conference, leaders across the cancer care community gathered online for a panel discussion of current events and policy priorities in oncology care. COVID-19 and its fallout on community cancer centers dominated the discussion, which was moderated by Ted Okon, MBA, executive director of the Community Oncology Alliance.

Okon opened the discussion by asking panel members to identify the biggest issues facing community cancer care today. Replies included financial instability, declining clinic volumes, and a rise in unemployed patients in the wake of the COVID-19 pandemic. "We are seeing a surge in the number of patients needing financial counseling," said Christian Downs, executive director of the Association of Community Cancer Centers. "These are formerly insured patients who have now lost their jobs and who have never needed this type of support. Oncology is seeing now and potentially well into the future an acute need for financial counseling."

Okon asked participants for their predictions about the future of telehealth as a viable, reimbursable model for delivery of healthcare services. Brad Tallamy, senior director of government affairs at AmerisourceBergen, said telehealth can play an important role in oncology care delivery. "We need to keep the virtual health revolution going," said Tallamy. "This is especially important for immunocompromised individuals like cancer patients. More patients will expect these services after the pandemic is over."

Ben Jones, vice president of government relations at The US Oncology Network, agreed. "This has been one of the rare bright spots in this crisis," said Jones. "We have the ability to speak with one voice, break down barriers, and push for rapid deployment of telehealth. There will be enormous patient demand for telehealth going forward."

Downs noted that concerns about patients feeling uncomfortable with online physician visits has proven unwarranted with the recent patient enthusiasm for virtual care. "We have seen over the last several months of COVID-19 that patients are comfortable with these types of services," affirmed Downs. "What's important now is to make sure that payments [to healthcare providers] come through. We've already heard from providers that reimbursement is on the decline."

In response to Okon's question about potential downsides to telehealth, Deborah Kamin, RN, PhD, vice president of policy and advocacy at the American Society of Clinical Oncology, replied that, in addition to concerns about the potential loss of the human interaction that takes place during face-to-face visits, she worries about logistics and reimbursement. "We're concerned about the infrastructure needed for successful telehealth," explained Dr. Kamin. "Not all providers and patients have the same resources. While telehealth can improve access to rural and underserved patients, the technology, staffing, and reimbursement structure need to be in place."

Upon the panel's conclusion, Okon asked the participants to identify issues of concern that they see on the horizon after the worst of the pandemic passes.

"White bagging is going to be the biggest issue facing oncology," affirmed Tallamy. He added that an interesting corollary to this is the unintended consequence that COVID-19 has had on the drug industry. "There has been a complete reversal on the issue of drug pricing reform," said Tallamy. "The biopharmaceutical industry has never been in a stronger position because it is their innovation that is going to win the COVID-19 pandemic."

Dr. Kamin said that patient access to cancer care during a time of massive unemployment is a growing concern. "These people will still need cancer treatment, so how do we ensure access?" she asked. Another troubling issue, said Dr. Kamin, is home infusions. "We do not think that home infusion is a safe alternative," she affirmed. "Yes, it is a challenge to identify what patients can be delayed and which treatments can be adjusted, but home infusion is not the solution. Unfortunately, we are already seeing a push from payers and PBMs to expand home infusions."

Downs concluded the panel by expressing concern about long-term reimbursement trends once the current injection of money into the economy comes to an end. "[The government] has dumped a tremendous amount of money into the country," remarked Downs. "My concern is which happens when the 'bill comes due?' Will oncology have to play defense to make sure that we don't get hit with huge reimbursement cuts?" OI

*Christian G. Downs, JD, MHA, is executive director, Association of Community Cancer Centers, Rockville, Md.*

# The Role of Medicare Administrative Contractors and Updates to Coding Policy

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

Medicare Administrative Contractors (MACs) act on behalf of the Centers for Medicare & Medicaid Services (CMS) as a direct point of contact for claims submission and payment, policy establishment, and special pricing of services. Other services by MACs, per CMS, include enrollment of providers under Medicare's fee-for-service program, responses to provider inquiries, and education about Medicare fee-for-service billing requirements. MACs replaced Medicare Fiscal Intermediaries and Carriers, so that MACs are now a central point of contact. (Historically, Fiscal Intermediaries covered those paid under the Hospital Outpatient Prospective Payment System and Carriers covered those paid under the Medicare Physician Fee Schedule).

MACs cover assigned designated jurisdictions, which are split by CMS to encompass the United States and its territories. MAC contracts are awarded through an application process once every 10 years. As part of the Medicare Access and CHIP Reauthorization Act enacted on April 16, 2015, contract terms were extended from the previous 5-year agreement to 10 years. It is possible for a jurisdiction to be awarded to a different contractor as part of the rebidding process, and MACs may be awarded more than one jurisdiction. Some of the recent changes made in September 2017 include the states of Alabama, Georgia, and Tennessee, which were awarded to Palmetto GBA after Cahaba GBA, LLC, lost the rebid. In September 2019, Wisconsin Physician Services was again awarded Jurisdiction 5, and the contract for Jurisdiction E (currently run by Noridian Healthcare Solutions) is up for rebid, which should be announced by October 2020. Table 1, page 8, identifies the current MAC awards for each jurisdiction along with the covered states and links to the home page of each MAC.

MACs are responsible for creating and maintaining Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs). LCDs and LCAs contain information, such as what diagnoses are considered medically necessary, specific documentation requirements for a given modality, and how to bill for services. Since October 2018, LCDs have undergone process and content changes for all MACs. Some changes include more transparency to the process, as well as public and stakeholder input—providers can participate in discussions about and submit requests for new ideas and revisions to LCDs. Additionally, the LCD itself will now only have initial information related to the modality or service, whereas the LCAs attached to the LCD contain the billing and coding guidelines, as well as codes covered in the *International Classification of Diseases*, 10th revision. Not all MACs will have LCDs or LCAs related to oncology services, but there are several that do or have created resources on their websites. It is important to sign up for email alerts from your respective MAC to ensure receipt of alerts regarding coverage and coding changes, including opportunities for educational webinars and resources for providers.

Over the last several years, many of the MACs have implemented changes that may only pertain to their jurisdiction. Therefore, it is important to remember that when discussing scenarios with other providers, the context and application of coding guidelines may not apply to everyone. The following are some examples of recent MAC updates that are impactful to oncology services and may not apply to everyone nationwide but are important to be aware of.

## Local Coverage Article A56141

In a recent update impacting medical oncology providers, Palmetto GBA (Jurisdictions J and M) revised their LCA: "Billing and Coding: Chemotherapy (A56141)," effective April 30, 2020. Palmetto GBA is now requiring the use of **modifier KX** for the drugs listed in the policy that are used off label, along with additional coding edits. In addition, several of the drugs outlined in LCA A56141 require medical record documentation to support certain drug combinations, other failed therapies, previous drugs, etc. It is important to note that other MACs do not have the same billing requirements as part of their LCDs or LCAs.

LCA A56141 went into effect November 1, 2018, and Palmetto GBA indicated that it feels that this is an appropriate time for providers to comply with the coverage requirements listed in the article. Therefore, Palmetto GBA is implementing diagnosis edits for HCPCS codes and will continue to provide notification on effective dates of any edits implemented. All coverage require-

(continued on page 9)

**Table 1. Medicare Administrative Contractors Awarded as of September 2019**

| JURISDICTION | MAC | WEBSITE | STATES COVERED |
|---|---|---|---|
| J15 | Celerian Group Company (CGS) | cgsmedicare.com | Kentucky, Ohio |
| JN | First Coast Service Options | medicare.fcso.com | Florida, Puerto Rico, Virgin Islands |
| J6 | National Government Services (NGS) | ngsmedicare.com | Illinois, Minnesota, Wisconsin |
| JK | National Government Services (NGS) | ngsmedicare.com | Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, Vermont |
| JE | Noridian Healthcare Solutions | noridianmedicare.com | American Samoa, California, Guam, Hawaii, Nevada, Northern Marianas Islands |
| JF | Noridian Healthcare Solutions | noridianmedicare.com | Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming |
| JH | Novitas Solutions | novitas-solutions.com | Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, Texas |
| JL | Novitas Solutions | novitas-solutions.com | Delaware, Washington, D.C., Maryland, New Jersey, Pennsylvania, Virginia (counties of Arlington, Fairfax; City of Alexandria) |
| JJ | Palmetto GBA | palmettogba.com | Alabama, Georgia, Tennessee |
| JM | Palmetto GBA | palmettogba.com | North Carolina, South Carolina, Virginia (except areas noted as Novitas), West Virginia |
| J5 | Wisconsin Physician Services (WPS) | wpsgha.com | Indiana, Iowa, Kansas, Nebraska |
| J8 | Wisconsin Physician Services (WPS) | wpsgha.com | Michigan, Missouri |

(continued from page 7)

ments in the coverage article continue to remain in effect. In the email notification by Palmetto GBA about the updates to LCA A56141 it stated, "Providers should pay specific attention to the coverage article as it relates to billing off label use and the HCPCS **modifier KX** for any drug or biological outlined in the article."

The following language is located within LCA A56141, specifically about **modifier KX**.

*"Palmetto GBA expects that providers identify off-label uses by the use of the 'KX' modifier appended to the CPT/HCPCS code for the drug. These off-label uses must be supported by clinical research under the conditions identified in this section. Peer-reviewed medical literature may appear in scientific, medical, and pharmaceutical publications in which original manuscripts are published, only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication. In-house publications of entities whose business relates to the manufacture, sale, or distribution of pharmaceutical products are excluded from consideration. Abstracts (including meeting abstracts) are excluded from consideration. Such usages will be subject to review at the discretion of Palmetto GBA. For review of medications under these considerations, please submit full articles, not abstracts, for consideration."*

LCA A56141 can be found by visiting the Palmetto GBA website and selecting the respective jurisdiction and medical policies, palmettogba.com.

## Radiation Oncology-Specific LCDs and Coverage Articles

A few MACs have radiation oncology-specific LCDs and LCAs related to intensity-modulated radiation therapy and stereotactic radiotherapy services—stereotactic radiosurgery (SRS) and stereotactic body radiotherapy. However, over the last several years, many MACs have retired LCDs specific to radiation oncology services. When a MAC retires an LCD, the LCD is still applicable for billing and coding guidelines, audits, medical necessity, and Advanced Beneficiary Notices. For example, Novitas Solutions indicates in its retired LCD Radiation Therapy Services (L27515) that only one immobilization device can be billed per volume of interest. If a head and neck patient had a mask, bite block, and custom head cushion, only one device is billable for any provider under Novitas Solutions. The rest of the MACs do not have this same limitation; for those outside of the Novitas Solutions jurisdictions, three different immobilization devices could be billed.

In other radiation oncology LCDs, MACs have various statements about the necessary participation of the radiation oncologist and neurosurgeon when providing stereotactic radiotherapy services. Currently, Noridian Healthcare Solutions states within LCA A57461, "No one physician may bill both the neurosurgical codes 61781-83, 61796-61800, 63620 or 63621 and the radiation oncology 77xxx codes. The physician(s) billing these codes must be physically present during the entire process of defining the target volume and structures at risk. If either the radiation oncologist or the neurosurgeon does not fully participate in the patient's care, that physician must take care to indicate this change by using the appropriate -54 modifier (followed by any appropriate -55 modifier) on the global procedure(s) submitted. As the services are collegial in nature with different specialties providing individual components of the treatment, surgical assistants will not be reimbursed."

First Coast Service Options also addresses the available codes for radiation oncologists and neurosurgeons in LCA A57275 but does not state that the neurosurgeon must be physically present for the entire process. First Coast Service Options states, "Usually, a radiation oncologist will work with a neurosurgeon to perform SRS. Radiation oncologists and neurosurgeons have separate CPT codes for SRS. CPT codes 61796-61800 are reported for the work attributed to the neurosurgeon. These codes are mutually exclusive with the radiation oncology CPT codes 77432 and 77435; therefore, the same physician should not bill for both these codes."

Lastly, National Government Services also has an LCA for stereotactic radiotherapy, but it does not address the billing codes or participation by any of the providers within the LCD or LCA.

Due to the variances in policy by MACs and the potential for updates to policies throughout the year, it is important that providers are familiar with their MAC and how to access its information. The LCDs and LCAs can be used as educational tools with staff and providers to understand the expectations of the payer, coverage limitations, and documentation requirements. In addition, in the absence of other payer policy or in discussions with private payers, they may aid in supporting departmental processes to align with Medicare expectations. OI

*Teri Bedard, BA, RT(R)(T), CPC, is director, Client Services, Revenue Cycle Coding Strategies, LLC, Des Moines, Iowa.*

# tools

## Approved Drugs

- On May 22, the U.S. Food and Drug Administration (FDA) approved **Alunbrig® (brigatinib)** (Takeda Pharmaceutical Company Limited, takeda.com/en-us/) for adult patients with anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer as detected by an FDA-approved test.
- On April 8, the FDA approved **Braftovi® (encorafenib)** (Pfizer.com, pfizer.com) in combination with **Erbitux® (cetuximab)** (Bristol Myers Squibb, bms.com) for the treatment of adult patients with metastatic colorectal cancer with a BRAFV600E mutation, as detected by an FDA-approved test, after prior therapy.
- On May 29, Eli Lilly and Company (lilly.com) announced that the FDA has approved **Cyramza® (ramucirumab)**, in combination with erlotinib, for the first-line treatment of people with metastatic non-small cell lung cancer with epidermal growth factor receptor exon 19 deletions or exon 21 mutations.
- On May 1, the FDA approved **Darzalex Faspro™ (daratumumab and hyaluronidase-fihj)** (Janssen Biotech, Inc., janssen.com) for adult patients with newly diagnosed or relapsed/refractory multiple myeloma.
- On April 21, the FDA expanded the indication of **Imbruvica® (ibrutinib)** (Pharmacyclics LLC, pharmacyclics.com) to include its combination with rituximab for the initial treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma.
- On April 15, UroGen Pharma Ltd. (urogen.com) announced that the FDA granted expedited approval for **Jelmyto™ (mitomycin)** for pyelocalyceal solution, a first-in-class treatment indicated for adults with low-grade upper tract urothelial cancer.
- Merck (merck.com) announced that the FDA has approved an additional recommended dosage of 400 mg every six weeks for **Keytruda® (pembrolizumab)**, Merck's anti-PD-1 therapy, across all adult indications, including monotherapy and combination therapy.
- On April 10, the FDA approved **Koselugo® (selumetinib)** (AstraZeneca, astrazeneca.com) for pediatric patients, two years of age and older, with neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas.
- On May 8, AstraZeneca (astrazeneca.com) and Merck (merck.com) announced that **Lynparza® (olaparib)** in combination with bevacizumab has been approved in the United States for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA mutation and/or genomic instability. Patients will be selected for therapy based on an FDA-approved companion diagnostic test.
- On May 19, the FDA approved **Lynparza® (olaparib)** (AstraZeneca and Merck, astrazeneca.com and merck.com) for adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer who have progressed following prior treatment with enzalutamide or abiraterone.
- On May 15, the FDA approved the combination of **Opdivo® (nivolumab)** plus **Yervoy® (ipilimumab)** (Bristol Myers Squibb, bms.com) as first-line treatment for patients with metastatic non-small cell lung cancer whose tumors express PD-L1 (≥1%), as determined by an FDA-approved test, with no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations.
- On May 26, the FDA approved the combination of **Opdivo® (nivolumab)** plus **Yervoy® (ipilimumab)** (Bristol Myers Squibb, bms.com) and two cycles of platinum-doublet chemotherapy as first-line treatment for patients with metastatic or recurrent non-small cell lung cancer with no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations.
- On April 20, the FDA granted accelerated approval to **Pemazyre™ (pemigatinib)** (Incyte Corporation, incyte.com) for the treatment of 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.

- On May 15, the FDA expanded the indication of **Pomalyst® (pomalidomide)** (Celgene Corporation, celegene.com) to include treating adult patients with AIDS-related Kaposi's sarcoma after failure of highly active antiretroviral therapy and Kaposi's sarcoma in adult patients who are HIV negative.
- On May 15, the FDA approved **Qinlock™ (ripretinib)** (Deciphera Pharmaceuticals, LLC, deciphera.com), for adult patients with advanced gastrointestinal stromal tumor who have received prior treatment with three or more kinase inhibitors, including imatinib.
- On April 3, the FDA approved **Reblozyl® (luspatercept-aamt)** (Bristol Meyers Squibb, bms.com) for the treatment of anemia failing an erythropoiesis stimulating agent and requiring two or more red blood cell units over eight weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis.
- On May 8, the FDA granted accelerated approval to **Retevmo™ (selpercatinib)** (Eli Lilly and Company, lilly.com) for the following indications: adult patients with metastatic RET fusion-positive non-small cell lung cancer; adult and pediatric patients greater than 12 years of age with advanced or metastatic RET-mutant medullary thyroid cancer who require systemic therapy; and adult and pediatric patients greater than 12 years of age with advanced or metastatic ZET fusion-positive thyroid cancer who require systemic therapy and who are refractory to radioactive iodine (if radioactive iodine is appropriate).
- On May 15, the FDA granted accelerated approval to **Rubraca® (rucaparib)** (Clovis Oncology, Inc., clovisoncology.com) for patients with deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.
- On May 6, the FDA granted accelerated approval to **Tabrecta™ (capmatinib)** (Novartis, novartis.com) for adult patients with metastatic non-small cell lung cancer whose tumors have a mutation that leads to mesenchymal-epithelial transition exon 14 skipping as detected by an FDA-approved test.
- On May 18, the FDA approved **Tecentriq® (atezolizumab)** (Genentech Inc., gene.com) for the first-line treatment of adult patients with metastatic non-small cell lung cancer whose tumors have high PD-L1 expression (PD-L1 stained ≥50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells covering ≥10% of the tumor area [IC ≥ 10%]), with no EGFR or ALK genomic tumor aberrations.
- On May 29, the FDA approved **Tecentriq® (atezolizumab)** in combination with **Avastin® (bevacizumab)** to treat people with the most common form of liver cancer.
- On April 22, the FDA granted accelerated approval to **Trodelvy™ (sacituzumab govitecan-hziy)** (Immunomedics, Inc., immunomedics.com) for adult patients with metastatic triple-negative breast cancer who have received at least two prior therapies for metastatic disease.
- On April 17, the FDA approved **Tukysa™ (tucatinib)** (Seattle Genetics, seattlegenetics.com) in combination with trastuzumab and capecitabine for adult patients with advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.
- On April 29, the FDA approved **Zejula® (niraparib)** (GlaxoSmithKline, us.gsk.com/en-us) for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

## Drugs in the News

- Agenus Inc. (agenusbio.com) announced that the FDA has granted Agenus fast track designation for investigation of **balstilimab (anti-PD-1)** for the treatment of cervical cancer.
- EMD Serono (emdserono.com) and Pfizer Inc. (pfizer.com) announced the submission of a supplemental biologics license application (BLA) to the FDA and breakthrough therapy designation for **Bavencio® (avelumab)** for first-line maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma.
- Bristol Myers Squibb (bms.com) announced that the FDA has accepted its new drug application (NDA) for **CC-486**, an investigational oral hypomethylating agent, for the maintenance treatment of adult patients with acute myeloid leukemia who achieved complete remission or complete remission with incomplete blood count recovery, following induction therapy with or without consolidation treatment, and who are not candidates for, or who choose not to proceed to, hematopoietic stem cell transplantation.
- Cellectar Biosciences, Inc. (cellectar.com) that the FDA has granted fast track designation for **CLR 131** in lymphoplasmacytic lymphoma/Waldenstrom's macroglobulinemia in patients who have received two or more prior treatment regimens.
- AstraZeneca (astrazeneca.com) and Daiichi Sankyo's (daiichisankyo.com) **Enhertu® (fam-trastuzumab deruxtecan-nxki)** has been granted FDA breakthrough therapy designation for the treatment of patients with HER2-positive unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma who have received two or more prior regimens including trastuzumab and orphan drug designation for the treatment of patients with gastric cancer, including gastroesophageal junction cancer.
- AVEO Oncology (aveooncology.com) announced that it has submitted an NDA to the FDA for **Fotivda® (tivozanib)**, the company's vascular endothelial growth factor receptor tyrosine kinase inhibitor, as a treatment for relapsed or refractory renal cell carcinoma.
- Bristol Myers Squibb (bms.com) and Bluebird Bio, Inc. (bluebirdbio.com) announced the submission of a BLA to the FDA for **idecabtagene vicleucel (ide-cel; bb2121)** for the treatment of adult patients with multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody.

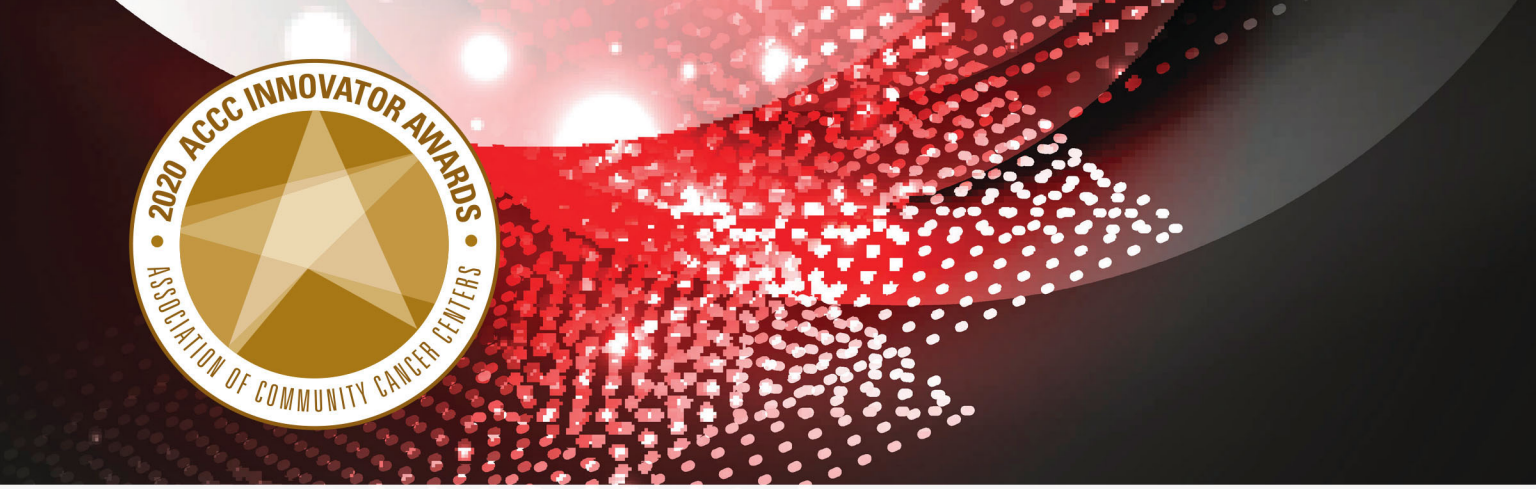
- Merck (merck.com) announced that the FDA has accepted and granted priority review for a new supplemental BLA for **Keytruda® (pembrolizumab)** for the treatment of adult and pediatric patients with unresectable or metastatic solid tumors with tissue tumor mutational burden-high mutations/megabase, as determined by an FDA-approved test, who have progressed following prior treatment and who have no satisfactory alternative treatment options.
- Novartis (novartis.com) announced that the FDA granted regenerative medicine advanced therapy designation to **Kymriah® (tisagenlecleucel)** for an investigational new indication to treat patients with relapsed or refractory follicular lymphoma.
- Merck (merck.com) announced the U.S. launch of **Ontruzant® (trastuzumab-dttb)**, as a biosimilar of the reference biologic medicine Herceptin® (trastuzumab).
- Medivir AB (medivir.com) announced that the FDA has granted orphan drug designation to **MIV-818** for the treatment of patients with hepatocellular carcinoma, the most common type of primary liver cancer.
- Marker Therapeutics, Inc. (markertherapeutics.com) announced that the FDA granted orphan drug designation to **MT-401**, a multi-tumor-associated antigen-specific T-cell product for the treatment of patients with acute myeloid leukemia, following allogeneic stem cell transplant.
- Cardiff Oncology, Inc. (cardiffoncology.com) announced that the FDA granted fast track designation to **onvansertib**, its oral and highly selective polo-like kinase 1 inhibitor, for the second-line treatment of patients with KRAS-mutated metastatic colorectal cancer.
- Precigen, Inc. (precigen.com) announced that the FDA has cleared the investigational NDA to initiate a Phase I/II trial for Precigen's **PRGN-2009**, an investigational immunotherapy utilizing the AdenoVerse™ platform designed to activate the immune system to recognize and target HPV+ solid tumors.
- Hutchison China MediTech Limited (chi-med.com) announced that the FDA has granted two fast track designations for the development of **surufatinib** for the treatment of both advanced and progressive pancreatic neuroendocrine tumors and extra-pancreatic (non-pancreatic) neuroendocrine tumors in patients who are not amenable for surgery.
- Karyopharm Therapeutics (karyopharm.com) has submitted a supplemental NDA to the FDA seeking approval for **Xpovio® (selinexor)**, its first-in-class, oral selective inhibitor of nuclear export compound, as a new treatment for patients with previously treated multiple myeloma.

## Approved Genetic Tests and Assays

- Caris Life Sciences® (carislifesciences.com) announced the submission of two pre-market approval applications for **MI Exome™ CDx** and **MI Transcriptome™ CDx** to the FDA. MI Exome™ CDx, whole exome sequencing (DNA), and MI Transcriptome™ CDx, whole transcriptome sequencing (RNA), are precision medicine assays that include key companion diagnostic biomarkers with therapy claims and detect all classes of alterations, including genomic signatures for microsatellite instability, tumor mutation burden, and loss of heterozygosity.
- Myriad Genetics, Inc. (myriad.com) announced that the FDA approved the **myChoice CDx®** test for use as a companion diagnostic by healthcare professionals to identify patients with advanced ovarian cancer with positive homologous recombination deficiency status who are eligible or may become eligible for first-line maintenance treatment with Lynparza® (olaparib) in combination with bevacizumab.
- Roche (roche.com) announced FDA approval for the **cobas® HPV test** for use on the fully automated, high-throughput cobas 6800/8800 Systems. The cobas HPV test identifies women at risk for cervical cancer by detecting the presence of high-risk human papillomavirus DNA in cervical samples.
- Personal Genome Diagnostics, Inc. (personalgenome.com) received FDA clearance for **PGDx elio™** tissue complete, the first genomic profiling diagnostic kit for oncology.
- Sectra (sectra.com) has received a 510(k) clearance by the FDA for **Sectra Digital Pathology Module** when used together with Leica Biosystems' scanner AT2 DX. This enables healthcare providers to use Sectra's digital pathology solution for primary diagnostics.
- Qiagen (qiagen.com) announced launch of its novel **therascreen® BRAF V600E RGQ PCR Kit (therascreen BRAF V600E Kit)** following FDA approval as a companion diagnostic to the BRAF inhibitor Braftovi® (encorafenib), which the FDA has approved for use in combination with cetuximab for the treatment of adult patients with metastatic colorectal cancer with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy. OI

## RxVantage Virtual Meetings

This digital solution helps providers reconnect with life science experts and resources that have been severely disrupted by COVID-19-related social distancing. Seamlessly integrated into the RxVantage platform, with one click practices can turn any in-person appointment into a secure virtual meeting, equipped with two-way high-definition video, audio, and screen sharing. Virtual meetings can also be started instantly with more than 60,000 product experts, nurse educators, reimbursement specialists, or medical science liaisons who are members of the RxVantage expert community. Free for all healthcare providers. Learn more at rxvantage.com.




# CONGRATULATIONS

## 2020 ACCC INNOVATOR AWARD RECIPIENTS

ACCC is proud to recognize these Cancer Program Members for their significant achievements in enhancing oncology care.

**Beaumont Health System, Beaumont Cancer Institute**
*Royal Oak, MI*
Integration of Prehab, Rehab, and Prospective Surveillance into Interdisciplinary Teams

**Franciscan Health Cancer Center Indianapolis**
*Indianapolis, IN*
A Nurse Navigator-Led Community-Based Cardio-Oncology Clinic

**Maine Medical Center Cancer Institute**
*Scarborough, ME*
Leveraging a 3D Lung Nodule Educational Tool to Reduce Patient Distress

**Mercy Cancer Care**
*St. Louis, MO*
Reducing ED Visits and Hospital Admissions after Chemotherapy with Predictive Modeling of Risk Factors

**Miami Cancer Institute**
*Miami, FL*
Onboarding Experienced Non-Oncology Nurses to Address Staffing Shortages: Development of a Transitional Oncology Training Academy

**St. Luke's Cancer Institute**
*Boise, ID*
Improve Oral Oncolytic Workflow and Reduce Treatment Delays with a Pharmacist Collaborative Practice Agreement

**Tennessee Oncology**
*Nashville, TN*
Utilizing Technology to Identify Patient Co-Morbidities and Reduce Hospital and ED Admissions

**University of Arizona Cancer Center, Banner University Medical Center Tucson**
*Tucson, AZ*
Shifting Chemo Administration from Inpatient to Outpatient Setting Improves Care and Reduces Costs

Looking for Inspiration? Hear directly from the 2020 Innovator Award winners this fall during the ACCC 37th National Oncology Conference.

**INNOVATE.**
**ACHIEVE.**
**INSPIRE.**

**For more details—and to register—please visit accc-cancer.org/NOC**

ACCC
Association of Community Cancer Centers

# spotlight

## Benefis Sletten Cancer Institute
### Great Falls, Montana

Located in central Montana, Benefis Sletten Cancer Institute provides multidisciplinary cancer care to a vast 13-county region bordering the Rocky Mountains. This catchment area is larger than the states of Connecticut, Delaware, New Hampshire, New Jersey, and Vermont combined and is home to a rural population of about 164,000 people. Benefis Sletten Cancer Institute is an oncology specialty within the not-for-profit Benefis Health System and operates as an outpatient department in a separate facility on the health system's largest medical campus in Great Falls, Mont.

Oncology services and supportive care are housed under one roof, which allows patients in central Montana to receive multidisciplinary cancer care at one location. Benefis Sletten Cancer Institute is staffed by two radiation oncologists, three medical oncologists, and two advanced practice providers in medical oncology, who are employed by Benefis Health System. The cancer institute recently upgraded its radiation oncology equipment to provide patients stereotactic radio surgery and external beam radio therapy, via a state-of-the-art Varian Edge. The health system works closely with its general surgeons and contracts with independent practitioners in Great Falls who provide surgical oncology services. Benefis Sletten Cancer Institute is certified by the American Society of Clinical Oncology Quality Oncology Practice Initiative for its medical oncology services and is the only cancer program in central Montana to be accredited by the Commission on Cancer. Patients are referred to Benefis Sletten Cancer Institute by primary care providers or upon diagnosis from the main hospital. A nurse navigator and lay navigator work the front line by helping with referrals as they come in. These navigators are dedicated to working with providers and the cancer care team by screening all new patients to identify their needs up front, which streamlines patient care and triage. A social worker then sits with patients for a small orientation-style meeting during which patients can ask questions. Once a patient's needs are established, the providers, nursing staff, and allied members of the cancer care team work together to deliver seamless patient care. This includes coordinating same-day, back-to-back appointments for tests, consults, and treatment. If needed, nutrition or genetics consults are arranged during patient infusions for patient convenience.

### Patient-Centered Care

The Benefis Sletten Cancer Institute was designed to make patients feel comfortable and welcome. A large fireplace and leather furniture help to create a warm waiting area, and throughout the center patients are greeted with soft cream tones and accent walls in earthy tones of green, blue, and purple. The 20-chair infusion suite sits at the east-facing, back end of the building. The nurses' station spans one side of the infusion suite, facing the patients, and is staffed by five full-time oncology-certified nurses who are chemotherapy certified. A dedicated infusion pharmacy is adjacent to the suite and is staffed by a board-certified oncology pharmacist and two pharmacy technicians. Patients can receive treatment in several areas of the infusion suite and can take advantage of the many supportive areas available. These include areas within the infusion suite that are dedicated to patients' various needs, like a section where they can have small family gatherings, do puzzles, read in a nook, or view a 50-gallon colorful aquarium. In a large solarium located at the back of the suite, patients can experience the benefits of plants, natural light, and the majestic views of Montana's big sky in four infusion chairs. Patients who prefer privacy can receive infusions in curtained-off areas within the suite. The infusion suite is designed to meet many different patient needs, explains Betsy Smith, MS, CGC, a certified genetic counselor at Benefis Sletten Cancer Institute.

In its effort to provide dynamic patient-centered care, Benefis Sletten Cancer Institute ensures that its patients have access to technology. Computers are available in the Resource Center at the front of the building so that patients can email and research their disease. The infusion suite also has iPads for patients to use while receiving treatment. For those who prefer print material, the Resource Center has books and brochures available.

Benefis Sletten Cancer Institute provides its patients a variety of supportive care options. Next to the Resource Center is the Medspa, staffed part-time by a cosmetologist who helps patients with skin care, head shaves, and wig and prosthetic fitting. Patients can also access numerous support services, including social work, genetic counseling and testing, financial navigation, and other services specific to patients'

cultural needs. Within Benefis Sletten Cancer Institute's service area are three American Indian reservations and one federally recognized landless tribe. The Native American population makes up about 7 percent of the institute's patient population. To meet these patients' cultural needs, the health system built a Native American Welcoming Center located near the front entrance of the main hospital, just two blocks from the cancer institute. This unique space is available to Native American patients and their families, a place where they can gather together and participate in various cultural practices, such as a smudging ceremony, where a cleaning smoke bath is created and used to purify the body, aura, and energy. "It's great to have a room dedicated to our Native American population where we can provide that support to their loved ones," explains Smith.

## Meeting the Needs of Rural Patients

The cancer institute treats a rural patient population that faces significant financial and travel burdens, often separating patients from their homes and support networks during treatment. Approximately one-fifth of its total patient population must travel more than 100 miles to see their provider and receive treatment, which is often impacted by snowy weather. Many of the cancer institute's patients are also of low socioeconomic status and/or are covered under a form of government insurance, including TriCare, Indian Health Services, Veterans Affairs, Medicare, or Medicaid. To care for patients as close to home as possible, Benefis Sletten Cancer Institute established a joint venture with the Northern Montana Hospital in Havre, Mont. The hospital employs a medical oncologist, and Benefis Sletten Cancer Institute provides radiation oncology services. A radiation oncologist from the institute travels 112 miles at least once a month to see 6 to 12 patients on average for new patient consults and follow-ups. The institute's radiation oncology team works with the cancer care team at Northern Montana Hospital daily and oversees all of its radiation oncology treatments. The institute's radiation oncologists use telemedicine for weekly management visits for patients receiving radiation treatment when they are not on-site and are also available for follow-ups and consults via telemedicine as needed.

For those patients who must travel to the institute for treatment, Benefis Health System provides the opportunity to stay in two housing facilities. These Gift of Life Housing facilities are on the Benefis Health System campus—one adjacent to the cancer institute and the other next to the main hospital. Patients with short-term stays can take advantage of hotel-style rooms, and those who have longer stays can occupy apartment-style units or use a fully equipped RV hookup outside the facilities. Taking into account both housing facilities and 11 RV hookup sites, all of which are free of charge, a total of 22 rooms are available. Benefis Health System supports the Gift of Life Housing through donations from its foundation and philanthropy by former patients, family members, and the community. "This housing option has actually made treatment possible for a large number of our patients, who otherwise may not have been able to get the care they need," explains Smith.


## Technology and Research

Furthering access to quality care in a rural setting, the Benefis Sletten Cancer Institute takes pride in its capacity to make clinical trials and specialized care available to patients. A gynecologic oncologist from the University of Utah visits Benefis Sletten Cancer Institute twice a month to provide consultations and specialized cancer surgeries to patients locally. He also works closely with Benefis Health System's gynecologists and oncologists in ongoing patient care. This partnership was established by a Benefis Health System physician who had prior ties and fellowship experience at the university. Over time the physicians developed a collaborative, informal relationship, which resulted in the ability to provide patients in central Montana access to specialized care. In turn, Benefis Sletten Cancer Institute refers patients to tertiary centers, including the Huntsman Cancer Institute at the University of Utah.

To establish access to clinical trials, a clinical trial team was formed, which consists of a clinical regulatory research coordinator, a clinical research registered nurse, and a part-time clinical research nurse. The team screens all new patient referrals and those whose cancers recur for potential clinical trial options. The clinical trial team meets with physicians regularly to help identify eligible patients who can be offered participation in trials. The team also participates in tumor boards to educate physicians on new trial options and changes in protocol that might impact patients. Finally, Benefis Sletten Institute works with the Montana Cancer Consortium to give patients access to a broad range of national clinical trials. About 4 percent of the institute's patients are enrolled in clinical trials annually, and the program has between 80 and 120 trials open for enrollment, which are either nationally sponsored or offered by industry. "What has impressed me the most about the institute is its ongoing commitment to meet and exceed the needs of our patients," explains Smith. OI

# Multidisciplinary Conference Case Planning in the Virtual Space

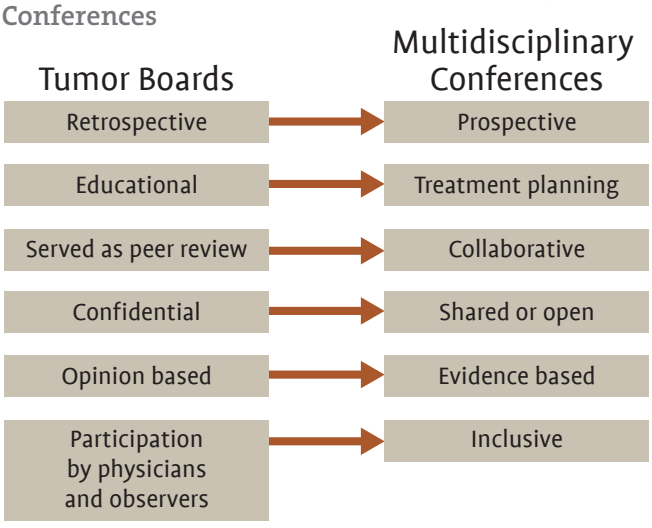
BY JONATHAN TREISMAN, MD, FACP; SHERRI COSTA, MS, RN, AOCNS;
CATHERINE SCHOTT, BSN, RN; AND JEANETTE FRAWLEY, MSW, CISW


The care of patients with cancer is multifaceted, and the tools for diagnosing, staging, and treating patients continue to increase in complexity. Consultations about individual patient cases have traditionally taken the form of tumor boards—the standard for communication among the multiple specialists involved in the care of a patient. A tumor board generally is held as a scheduled meeting (typically over lunch) in which participants gather and present a patient's currently available data. Because patient cases are presented only once during a prescheduled meeting, discussions about individual cases may be retrospective or lack complete patient information, limiting meaningful input. Presentation of new patient data—or the results of additional tests that may have been recommended during the first presentation—typically do not occur during subsequent tumor boards. Additional limitations to this model include increasing and competing demands on providers and a lack of evidence that tumor boards benefit patient outcomes. Although tumor boards may be effective as a teaching tool, their benefit to patient care remains uncertain.

Though tumor boards continue to be the standard for multidisciplinary conferences in most cancer programs, the evolving nature of medicine and the merging of individual provider organizations into large healthcare institutions have made this process impractical. Increasingly, traditional tumor boards are giving way to prospective multidisciplinary conferences that allow ongoing evaluation of a patient and patient participation in the discussion, improving shared decision making. Ideally, these prospective conferences serve as quality improvement tools that incorporate peer review, appraisal of the care process, and adherence to guidelines and pathways. (Figure 1, page 18, highlights the main differences between tumor boards and prospective multidisciplinary conferences.) This new prospective conference approach has been advanced by video technology, which allows individuals to participate from remote locations. One obstacle to accommodating the participation of all potential providers remains: time.

> The virtual online multidisciplinary conference would take the place of our traditional tumor board and allow for asynchronous, ongoing dialogue about patient evaluation and care.

Figure 1. Tumor Boards vs. Multidisciplinary Conferences




Source. Katterhagen and Wishart.[1]

## A Model for Optimizing Care Coordination

Ascension is a massive healthcare system with a presence in 21 states and the District of Columbia. In Wisconsin alone, Ascension operates 24 hospitals and 111 clinics and employs more than 900 physicians. In the Milwaukee metro area, Ascension provides community-based cancer care services across multiple locations spanning the city and its surrounding suburbs. For Ascension, the geographic spread of its many clinics and the competing time constraints of its providers have made it difficult to bring together multidisciplinary team members and relevant specialists for in-person tumor boards.

In 2017 Ascension SE Wisconsin Hospital in Milwaukee had the opportunity to serve as one of the seven Association of Community Cancer Centers (ACCC) member cancer programs selected to test the care coordination model developed through the ACCC Optimal Care Coordination Model project. This initiative, now named Improving Care Coordination: A Model for Lung Cancer, was recently featured in the March/April 2020 *Oncology Issues*. The final phase of the Improving Care Coordination project focused on testing the beta care-coordination model. All seven testing sites implemented 12-month quality improvement projects using the model, to ensure its practicality in helping cancer programs improve care for their patients. As part of Ascension's quality improvement projects for the Improving Care Coordination project, Ascension SE Wisconsin Hospital retrospectively audited its patient charts, which revealed several specific areas for improvement, including:

- Late-stage presentation
- Low LDCT screening rates
- Delays in time to first treatment
- Gaps in navigation services
- Limited lung cases presented at tumor boards
- Gaps in resources, such as having a dedicated thoracic surgeon and optimal equipment.

In response, the ACCC model was used to create two quality improvement projects to focus our efforts: develop a lung cancer clinical pathway and create a virtual tumor board. Before we began the latter project, our hospital's tumor board took the form of regularly scheduled meetings in which members of a multidisciplinary team gathered for discussion either in person or via phone. Individual patient cases were often discussed at only one point in time, meaning that cases were frequently retrospective. There was also considerable difficulty in bringing together all participants at the same time and place. This generally meant that our tumor boards were local events, which limited them to the expertise of local clinicians.

Prior to engaging in the ACCC Improving Care Coordination project, our tumor boards began with participants receiving an email with a meeting agenda listing the patient cases to be discussed. A team member provided significant administrative support, including creating and emailing the agenda, maintaining a calendar of meeting dates, ordering food, tracking attendance, ensuring that equipment was functional, troubleshooting any technology difficulties, and other tasks required to meet accreditation requirements.

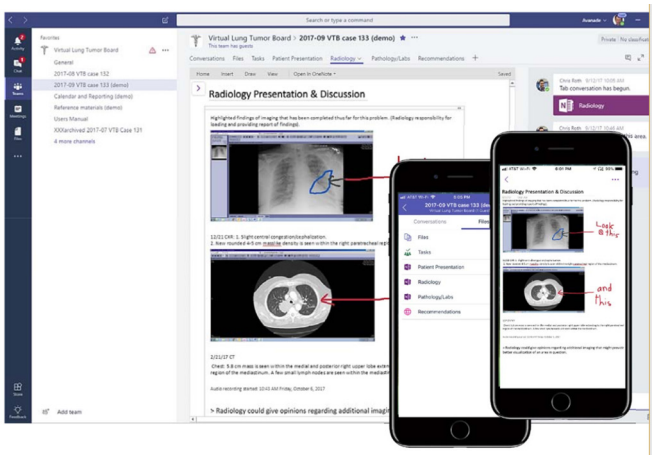
As part of its work as a testing site for the Improving Care Coordination Model, Ascension SE Wisconsin Hospital developed and piloted an alternative method for conducting tumor boards that did not require participants to meet at a specific time and place. The virtual online multidisciplinary conference would take the place of our traditional tumor board and allow for asynchronous, ongoing dialogue about patient evaluation and care. Our virtual tumor board used Microsoft Teams to create a Health Insurance Portability and Accountability Act (HIPAA)-compliant platform, which enabled multiple participants to safely access the platform when and where they chose.

## Implementing the Virtual Tumor Board

Our virtual tumor board required a robust platform that can securely combine multiple applications that allow for not only discussing patient cases but also sharing patient data, including diagnostic studies and images. Our platform also needed to incorporate a mechanism for tracking the activities of the invited participants and notifying them of new posts. We found Microsoft (MS) 365—which includes MS Teams, One Note, Power BI, and other integrated applications—to be appropriate for our needs.

Ascension SE Wisconsin Hospital began by first determining the specific needs of our tumor board (see Table 1, page 19). Next, a team of providers, including physicians, administrators, navigators, and quality representatives, visited the Microsoft Innovation Center in Chicago, during which we conducted a day-long whiteboard discussion. We shared our vision of what we wanted our tumor board to be able to do, defined key elements of the tumor board process, and provided the information that led to the conceptual design of our virtual tumor board. In the end, the virtual tumor board was a collaborative effort between our multidisciplinary team, Avanade (an IT consulting group),

| Table 1. Specific Needs of Our Virtual Tumor Board |
|---|
| HIPAA compliance: to protect patient's medical information. |
| Accessible: to allow prospective and ongoing discussion and collaboration. |
| Prospective: to encourage and improve multidisciplinary decision making. |
| Collaborative: to allow outside expert participation by individuals from remote sites to ensure multidisciplinary team involvement. |
| Increased case presentation: to ensure that all patient cases are presented to the multidisciplinary team. |
| Case planning: to facilitate integration of care pathway(s) into the conference. |
| Documentation: to provide a summary of recommendations. |
| Reporting functions: to ensure compliance with CoC requirements. |

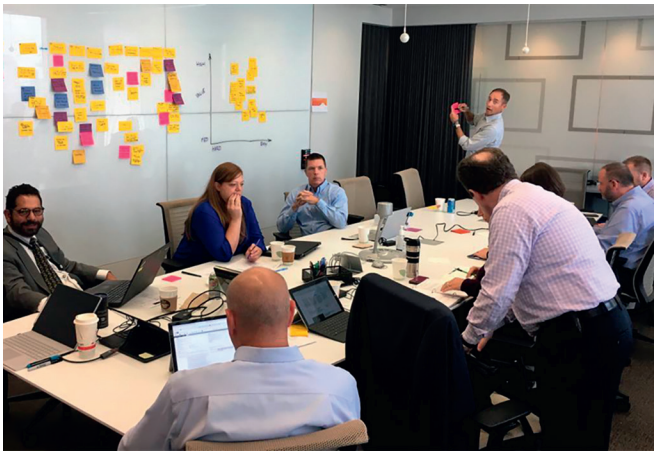



Phone App Improves Participation in the Virtual Tumor Board.

Virtual tumor boards improve access by eliminating time and space constraints, unifying fragmented healthcare systems, and introducing a new potential education platform.

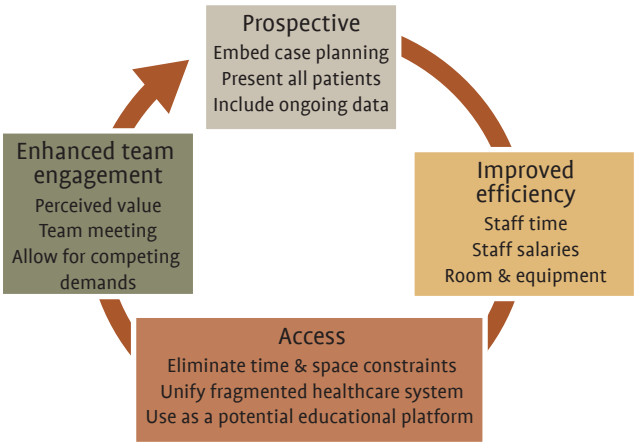
Microsoft, and Ascension SE Wisconsin Hospital's IT department. It was conceptualized by Dr. Jonathan Treisman and operationalized with modifications using the hospital's available infrastructure and existing computer platform. Key considerations in the design process included:

- The virtual tumor board must be secure and HIPAA compliant to protect sensitive patient information. This process involved discussions with our healthcare system's IT members, compliance officers, and legal counsel. We also discussed secure practices and the potential liability involved in posting identifiable patient information that could leave a historical record. This led us to develop a disclaimer and use de-identified patient information for the purposes of the pilot.
- Technology and consultants. We chose to use Microsoft Teams for our virtual tumor board rather than incurring the cost and time of developing a completely new program. Microsoft Teams is a widely available platform that was readily accessible to our providers and had advanced security features. We collaborated with Microsoft and used ACCC grant money to contract consultation services from Avanade to adapt MS Teams for our use and provide training.
- The need to ensure buy-in of key participants. Participation is fundamental to the effectiveness of a tumor board and necessary to provide optimal patient care, as defined by the Commission on Cancer's (CoC) participation requirements. Key participants included pulmonology, thoracic surgery, medical and radiation oncology, pathology, radiology, and supportive care staff. Virtual tumor boards offer an alternative venue that is more accessible and time flexible and can help improve provider participation and enhanced discussion by the multidisciplinary team.
- Access and training. (As stated above, Avanade provided staff training on the virtual tumor board.)
- Outcomes. Specifically, we wanted to improve the number of case presentations, attendance, and prospective nature of cases, as well as decrease time to first treatment, with the ultimate outcome of improved patient care.
- Tumor board elements. The program allowed for presentation of history, imaging, and pathology, which are key elements for the tumor board discussion, with a place for comment and questions.



Whiteboard discussion at Microsoft Innovation Center.

Figure 2. Benefits to Virtual Tumor Boards




Pilot participants used Office 365—which includes Microsoft Teams—to test the virtual tumor board. A navigator was appointed to assemble case presentations, monitor group discussions, assist with notifications, and create summaries. Key participants included the provider team identified above; physician champions ensured that the multiple disciplines involved in the virtual tumor board were represented in discussions. We also created a process for tracking attendance and recorded the elements required by the CoC accreditation standard for tumor boards.

The pilot program took the place of Ascension SE Wisconsin Hospital's in-person thoracic tumor board conference from October 2017 to September 2018. All patients presented at the virtual tumor board had a suspicion or confirmed diagnosis of lung cancer.

## Our Results

Ascension SE Wisconsin Hospital realized several benefits from the virtual tumor board format:

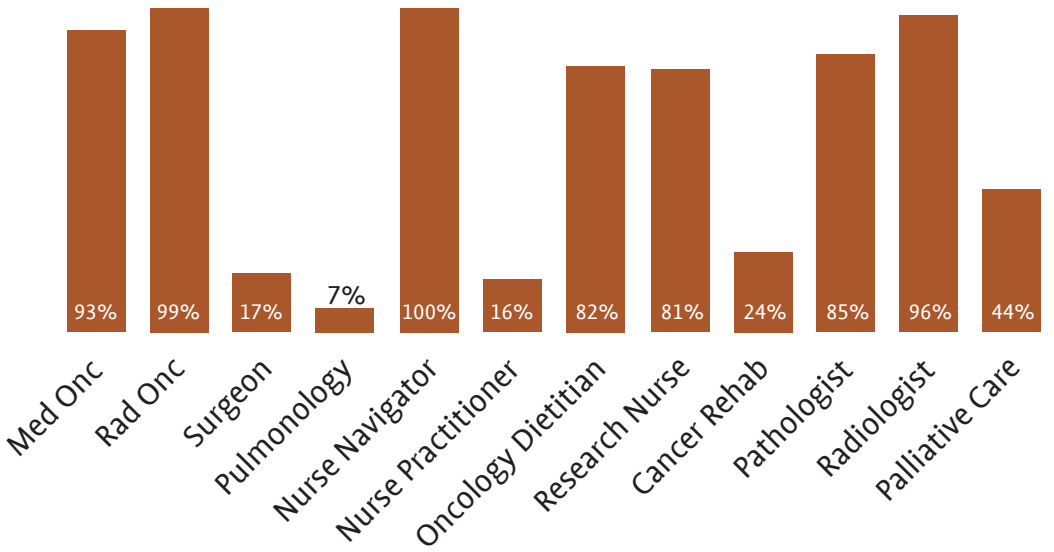
- Virtual tumor boards are prospective—not retrospective—allowing providers to embed case planning, present on all patients, and account for ongoing data and testing.
- Virtual tumor boards are more efficient than traditional tumor boards. They require less staff time and resources (room and equipment).
- Virtual tumor boards improve access by eliminating time and space constraints, unifying fragmented healthcare systems, and introducing a new potential education platform.
- Virtual tumor boards can improve team engagement because they are perceived by providers as having more value than traditional tumor boards, they can more easily bring together a larger team of providers, and they allow providers to meet competing demands.

Figure 2, above, highlights some of the key benefits to virtual tumor board implementation.

Virtual tumor board participants also realized several benefits when compared to in-person tumor boards. For example, providers were able to participate in discussions by texting their questions, opinions, and recommendations at the time of their choosing, allowing clinicians from remote locations to join the discussion. With more clinicians able to lend their input, case discussions were enhanced by a higher level of multidisciplinary expertise (see Figure 3, right). The ability to embed the case planning process into a virtual environment also meant that participants were able to follow up on the results of any diagnostic tests recommended in previous discussions. To enable these interactions, we used Microsoft Teams to create individual channels representing each patient's profile. Within these channels were tabs that allowed access to case presentations, pathology reports and images, radiology reports and images, and other pertinent patient data. Participant dialogue took placed in conversation tabs; conversations could also occur within the individual patient tabs, which were then incorporated into the multidisciplinary team conversation. Team members were notified of new information or additional comments when they were individually tagged (via "@mentioned") about specific questions, enabling ongoing dialogue. Virtual tumor board participants found that this environment allowed for a dynamic discussion platform insulated from the restraints of time and place.

During the 12-month pilot, virtual tumor board participants discussed 108 patient cases. Comparatively, 27 patients had been presented to the tumor board the previous year. Most participants said that they spent 5 to 15 minutes on each case presented in the virtual tumor board. Seventy-five of the 108 patients reviewed were included in REDCap data that tracked the patients evaluated during the pilot. (REDCap is browser-based, metadata-driven electronic data capture software and workflow methodology for designing clinical and translational research databases.) Sixty-seven percent of the patients presented during the pilot were discussed

Figure 3. Virtual Tumor Board Participation*




*Note: Since the time of the pilot, Ascension SE Wisconsin Hospital has hired two dedicated thoracic surgeons, which has greatly improved surgeon participation.

prior to receiving any treatment. Virtual tumor board participants surveyed after the pilot identified these top three benefits:

1. The ability to participate when the provider chose
2. Elimination of travel to attend the virtual tumor board
3. Broader specialty participation.

The participant survey indicated several additional perceived benefits, including:

- 56 percent "strongly agree the virtual tumor board is a good use of time" versus 11 percent who said the same of the traditional tumor board.
- 50 percent believed the virtual tumor board "served as pre-treatment planning" versus 15 percent who said the same of the traditional tumor board.
- 78 percent reported that "patient management was facilitated due to virtual tumor board discussion."

Participants said the virtual tumor board format allowed them to have ongoing dialogue about individual patients as more data was gathered and that providers could easily re-open or re-discuss cases and review archived discussions. Participants also agreed that the virtual tumor board provided clear and rapid communication of the information affecting a patient's diagnosis to all of the providers involved in the care of that patient, increasing the coordination of referrals and specialists and promoting continuity of care between primary care and the oncology team.

## Lessons Learned

Our use of a virtual tumor board resulted in a significant increase in the number of patients presented compared to the standard tumor board. For cancer programs looking to implement a similar virtual tumor board, our team saw this increase as a result of the virtual platform aided by the program's navigator, who assisted with presenting and tracking input from the pilot participants.

Like most cancer programs, our providers are faced with multiple competing priorities that hinder their ability to participate in meetings at a set time and place. The asynchronous nature of the virtual tumor board allowed participants to access the tumor board whenever convenient and with their preferred device (laptop, phone, tablet). This format can also remove the presence of distractions that can occur when a participant is attempting to multitask during a scheduled meeting.

Because virtual tumor boards transcend geography, they can include specialists not routinely involved in a patient's care, making this technology especially beneficial to rural clinics. Virtual tumor boards can also be an effective tool for gathering individual specialists to discuss relatively uncommon diagnoses. Finally, because the virtual tumor board has the benefit of tracking responses and evaluating them in the context of patient outcomes, they can help improve patient care. OI

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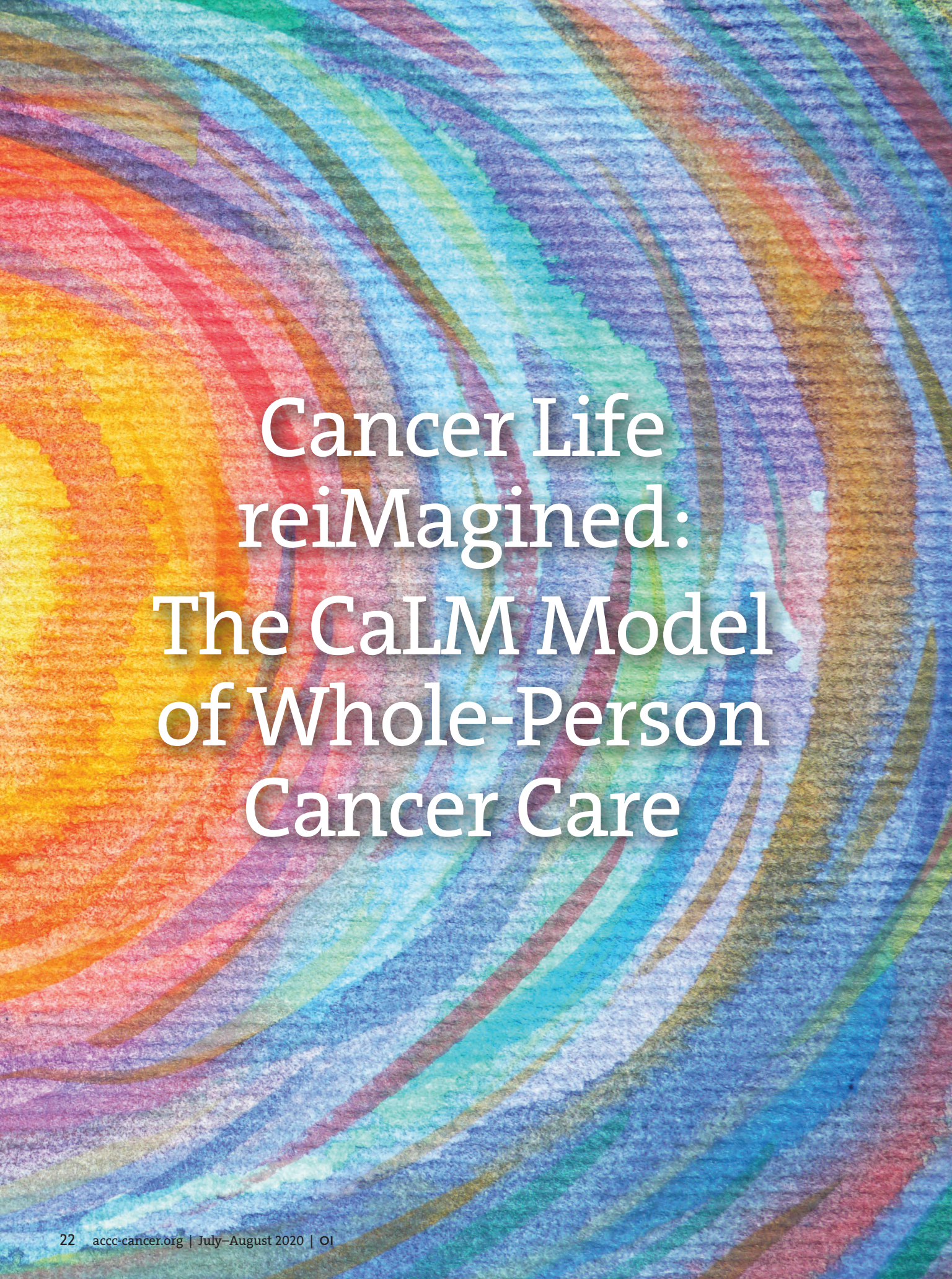


# Cancer Life reiMagined: The CaLM Model of Whole-Person Cancer Care

BY REBEKKAH M. SCHEAR; S. GAIL ECKHARDT, MD; ROBIN RICHARDSON; BARBARA JONES, PHD; AND ELIZABETH KVALE, MD


# *Co-designing a model with patients, survivors, and the community*

Christina is 35 years old and has been living with metastatic colorectal cancer for the last several years. She is bright, vivacious, and has an edgy honesty about her. Our team first met Christina in 2017 when she responded to an opportunity to be part of an "experience group"—a type of focus group convened by the Value Institute for Health and Care at the Dell Medical School—that allowed us to learn in depth what life is like for patients living with certain medical conditions or disease. At the time, our team was in the process of building a new model of cancer care. Christina had already undergone five surgeries, four rounds of chemotherapy, and three rounds of radiation. She was receiving treatment and care at a cancer center in Houston, Tex.; but, with a young daughter, a husband, and a full life in Austin, Tex., traveling for treatment on top of coordinating care with multiple specialists was disruptive and stressful for Christina and her family. In discussion, she spoke with transparency and clarity about her cancer journey; the experience of coping with cancer in her 30s; and, most important, her thoughts on re-designing the cancer care system to better serve people dealing with cancer in the midst of life's complexities. In March 2018,

The CaLM model is designed to deliver cutting-edge cancer therapies in coordination with psychosocial and palliative care. This interdisciplinary, team-based approach to care prioritizes survival and supports everyone's capability, comfort, and calm as they fight cancer.

Christina became the first member of the Patient and Family Advisory Board we developed to guide the design of a new model of cancer care. In spring 2019, she transferred her care to the Livestrong® Cancer Institutes at UT Health Austin, becoming one of our earliest gastrointestinal oncology patients.

## Keep CaLM and Transform Care

In our current healthcare system, cancer care delivery is often fragmented. Patients and caregivers face many challenges, including providers who do not communicate effectively; disjointed, uncoordinated services that do not address all of their issues; and fragmented, costly systems of care.

In the traditional model of cancer care, providers prioritize the delivery of medical services and disease treatment, with the social, emotional, spiritual, cultural, and financial aspects of care often considered ancillary. In fact, many patients are referred to external community resources to receive these comprehensive care services, with scheduling and coordinating appointments falling on the patient and/or caregiver. When these services are not provided in coordination and communication with the patient's medical treatment team, care can become further fragmented. Patients often have limited familiarity with supportive care services, and the goals for care within each specialty may not align, which can result in conflicting guidance and/or treatment for patients. Bottom line: Navigating a cancer diagnosis can be the equivalent of a full-time job. It can bring chaos to patients' daily lives, which can make working, social activity, and daily activities difficult to manage.

Further, for many patients today, cancer is becoming a chronic disease. This is very good news. At the same time, too often cancer care delivery is focused on high-acuity medical decision making. Patients can feel as though they are "living from scan to scan," relying heavily on oncologists to drive their care. However, oncologists are often unequipped to address emotional, social, and practical issues. This care model does not optimize an individual's ability to live a resilient life.

The mission of the Livestrong Cancer Institutes—a collaboration between the Dell Medical School at the University of Texas at Austin and the Livestrong Foundation founded in 2014—is to radically improve the individual's cancer experience and quality of life, revolutionize cancer treatment, and re-invent the way patients are cared for. Central to our approach is the creation and operationalization of the CaLM Model of Whole-Person Cancer Care™. Cancer Life Reimagined (CaLM) is a comprehensive, clinical, and supportive ambulatory care model that provides "wraparound" care for patients and caregivers in all phases of the cancer continuum.

Livestrong Cancer Institutes set out to build a model that treats the mind, body, and heart, as one entity. The CaLM model is designed to deliver cutting-edge cancer therapies in coordination with psychosocial and palliative care. This interdisciplinary, team-based approach to care prioritizes survival and supports everyone's capability, comfort, and calm as they fight cancer.

## Building the Foundations of CaLM

The Livestrong Cancer Institutes use the National Academies of Science, Engineering, and Medicine's definition of patient-centered care, which is "respectful of and responsive to individual patient preferences, needs and values, and ensures that patient values guide all clinical decisions."[1] The CaLM concept draws from decades of research and advances in the fields of psychosocial oncology, palliative care, integrative oncology, and cancer survivorship. In essence, CaLM is an oncology medical home approach that integrates high-acuity, sub-specialty clinical cancer care with comprehensive, ongoing supportive care. Patients receive best-in-class cancer treatment that encompasses a suite of coordinated supportive services to care for the whole person and their loved ones. CaLM is designed to:

- Optimize the patient experience and outcomes
- Address the unsustainable financial future of cancer care
- Create a scalable strategy to use providers efficiently
- (Ultimately) attain cost savings for the patient, the payer, and the system.

The CaLM model values emotional, social, financial, and practical care equally with clinical services delivered to treat the disease.

In developing the model, we leveraged the work of leading oncology organizations, including the American Society of Clinical Oncology, the American College of Surgeons Commission on Cancer, the National Cancer Institute, the American Cancer Society, the Cancer Support Community, and Livestrong Foundation—all of which have paved the path in improving cancer care. The CaLM model is heavily influenced by the work that our philanthropic partner, the Livestrong Foundation, executed in determining the essential elements of survivorship care,[2] particularly its 23 elements of patient-centered cancer care.[3] The CaLM model builds on these elements through the implementation of strategies, programs, and interventions that operationalize each element in the clinical setting (see Figure 1, right). The CaLM model is also anchored in several evidence-based models of care:

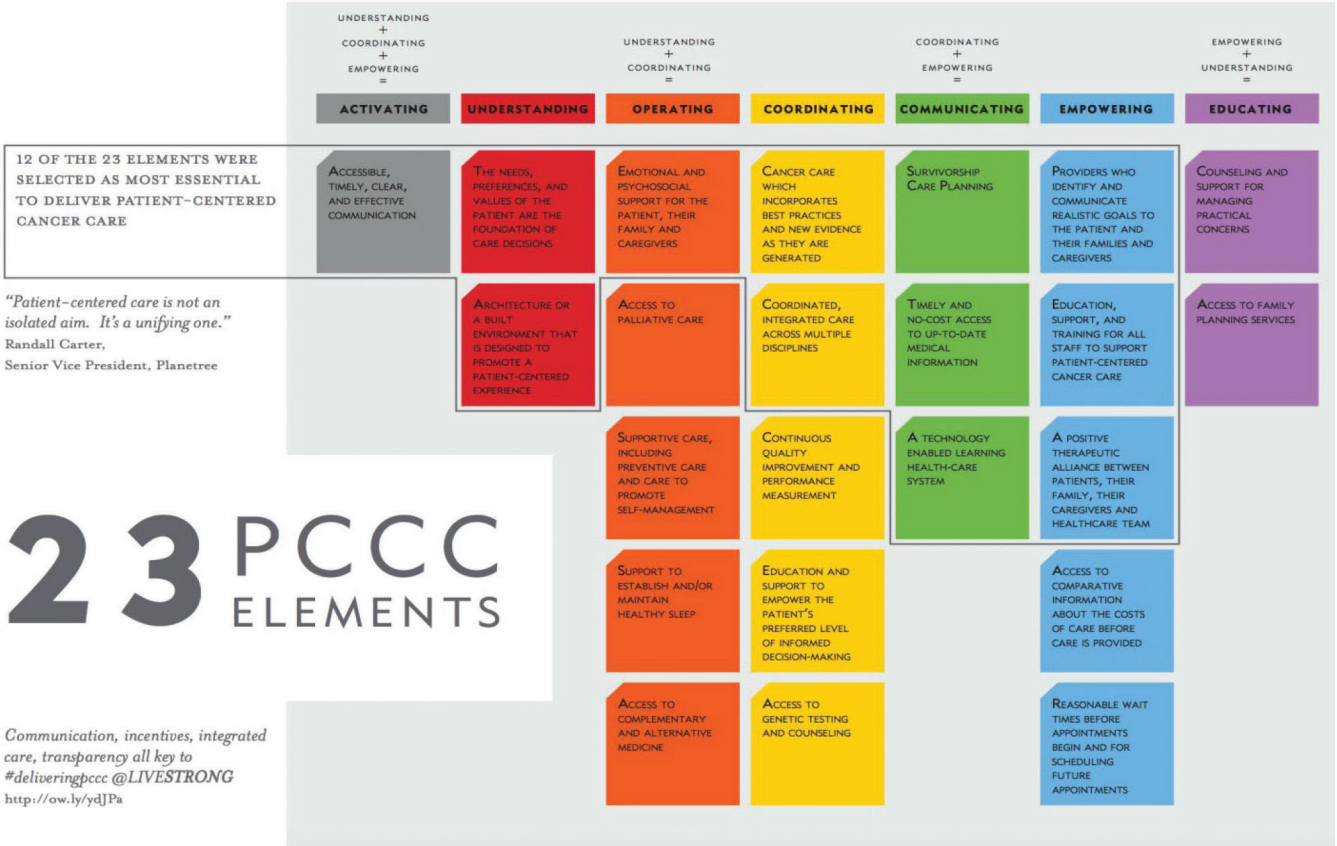
- The National Academy of Medicine's 2013 report *Delivering High Quality Cancer Care: Charting a New Course for a System in Crisis*[1]
- The work of the Agency for Healthcare Research and Quality and John Sprandio, MD, on the oncology patient-centered care medical home model[4]
- The collaborative care model, developed jointly by the American Psychiatric Association and the Academy of Psychosomatic Medicine[5]
- The Robert Wood Johnson Foundation and MacColl Center for Healthcare Innovation chronic care model.[6]

## Co-Designing the Model

To kick off the design process, in 2017 we established several cross-functional community work groups at the Livestrong Cancer Institutes, including one group focused solely on patient-centered support. Composed of administrators and clinicians from other cancer programs in the Austin area, leaders from local and national non-profit cancer patient support organizations, researchers from the University of Texas, and patients and survivors from the central Texas community, these groups met quarterly for one year. Participants collaborated to identify the ideal components of patient-centered cancer care and discuss what an optimal care delivery process would look like.

During this same time frame, we also embarked on a local and national "listening tour," visiting more than 35 cancer programs, meeting with social workers, oncologists, and palliative care teams to:

Figure 1. The Essential Elements of Patient-Centered Cancer Care

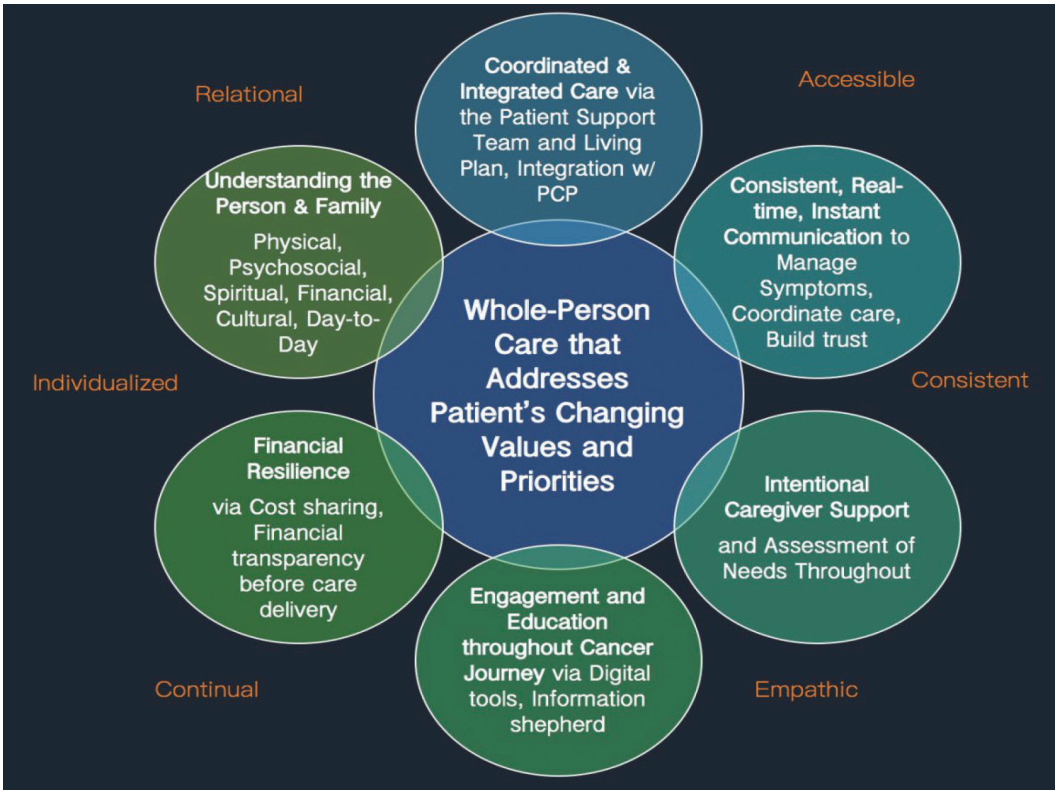



1. Understand existing resources that we could leverage.
2. Identify perceived service gaps in patient-centered care.
3. Build partnerships for our referral network.

In May 2017 we convened a half-day town hall attended by 80 representatives from local cancer support organizations. We led participants (many of whom had never worked together before) through a series of interactive discussions to help identify service gaps and brainstorm solutions. These conversations not only validated some of our team's ideas but also helped us define what the CaLM model needed to do differently. For example, though some clinics were using interdisciplinary care teams, patient care was still primarily directed by a physician. We wanted to create a model that gave equal weight to the voices of all those involved in the patient's cancer journey, including patients and caregivers. What emerged was a framework for the CaLM model that focused on delivering care and building services where there were clear gaps (see Figure 2, page 26). The CaLM framework includes the following key components:

- ***Understanding the whole person.*** CaLM incorporates all aspects of well-being into a holistic care experience by learning about the psychological, emotional, physical, social, cultural, practical, and spiritual needs and preferences of patients and their loved ones. CaLM uses this knowledge to support them.
- ***Relational, empathic care.*** The model provides a single point of contact for care coordination. CaLM provides relational care by nurturing strong, trusting, and consistent relationships between patients, families, and our providers. Empathy is the guiding principle—how providers act, treat patients, and treat one another.
- ***Coordination and integration.*** The model connects providers to the patient by bridging gaps in data, knowledge, communication, and information and overcoming system fragmentation.
- ***A home across the continuum.*** Survivorship is a cornerstone of the CaLM model, which is tailored to patients' cancer journeys. Whether patients have advanced disease, are on a curable trajectory, or are living with cancer as a chronic condition, CaLM is a touchstone of love and support during and after active treatment.
- ***Dimensionally accessible care.*** Livestrong Cancer Institutes is committed to delivering affordable, high-quality care that is geographically located where patients have reasonable transportation and that delivers the breadth of services needed.

Figure 2. Framework for the CaLM Model




- ***Education for shared decision making.*** The CaLM model prepares healthcare providers, patients, and families by breaking down clinical terminology to better discuss difficult topics, address gaps in health literacy, and empower patients to make decisions that reflect their preferences and values. CaLM shifts the care away from a traditional, patriarchal healthcare delivery system in which the physician drives care without assessing patient preferences.
- ***Personalized and individualized care.*** Treatment and care planning are tailored to the unique needs and values of the individual. CaLM respects the preferences of patients and their loved ones, supporting their participation in care in a way that is culturally respectful, valuable, and meaningful.

We recognized that building a successful model of patient-centered cancer care went beyond seeking a stamp of approval from patients and survivors to engaging them to help co-design the model from the inside out. In March 2018 we brought together a diverse group of 29 individuals to form a Patient and Survivor Advisory Board. The advisory board worked closely with our team to determine how to operationalize CaLM, keeping patients' needs and values as our North Star. (Of note: The Patient and Survivor Advisory Board helped develop a young adult oncology program due to a significant care gap for this patient population in Austin.) Over 18 months, the patients, survivors, and caregivers on the board worked side by side with our leadership team to design each service line. Specifically, the Patient and Advisory Board:

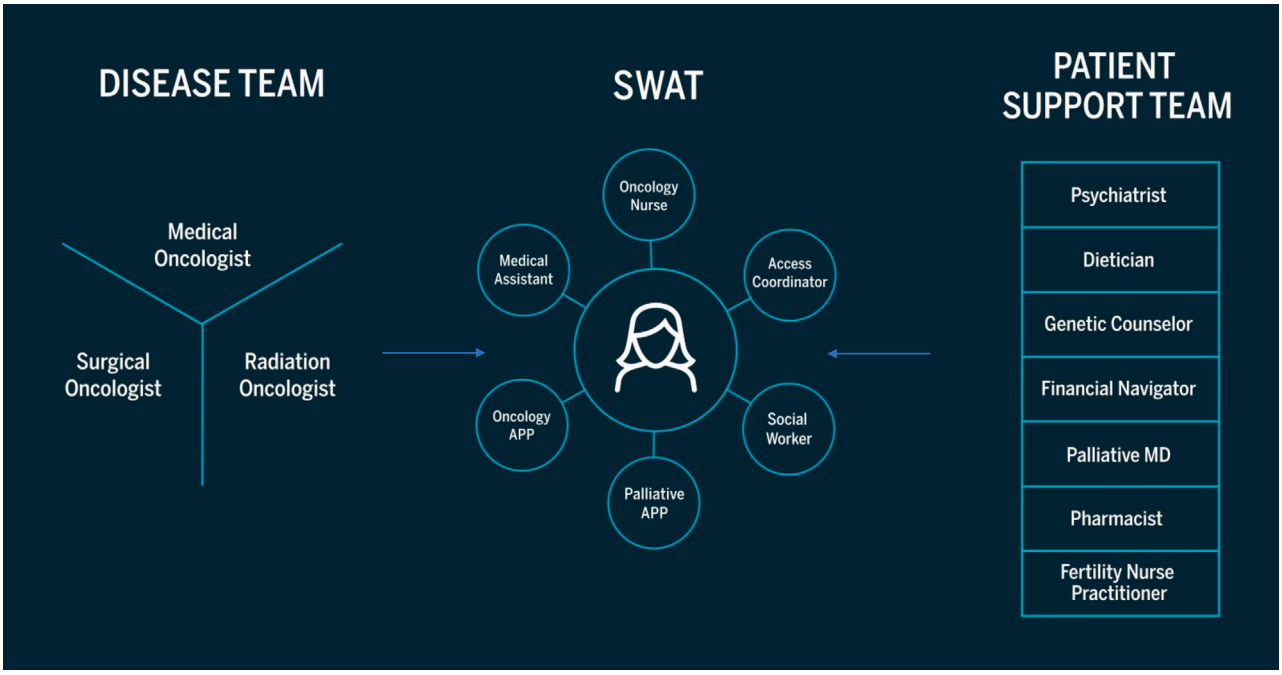
- Provided strategic advice
- Devised criteria for hiring an ideal clinical team
- Participated in job interviews with potential clinical candidates
- Joined in mock operational exercises as we prepared to go live with the model
- Reviewed patient-facing materials
- Advised on resources
- Guided our clinical trial and translational research strategy.

In March 2019, after the clinic opened, the board evolved to include more patients and survivors of different ages, socioeconomic status, and geographic locations. Clinical team hires met with the Patient and Survivor Advisory Board to optimize the new working oncology program. It is our vision to anchor the CaLM model in the lived experiences of those affected by cancer, moving away from bringing the "work to the patients" to a place where we "bring the patients to the work" in order to further integrate our patient advisors in the planning and operations of our model.

## Implementing an Interdisciplinary Care Team Approach

The CaLM model's infrastructure is built on a foundation of collaborative, interdisciplinary providers called the patient support team. This team consists of supportive care experts who collaboratively manage patients' care by assessing and addressing

Figure 3. CaLM Staffing Model




patients' needs and values. At the heart of the patient support team is the SWAT team, which is composed of an oncology advanced practice provider, palliative advanced practice provider, supportive care and survivorship doctor, oncology social worker, nurse navigator, medical assistant, and community navigator. This team triages patients, manages symptoms, provides education and clinical navigation, and conducts a whole-person assessment to proactively manage the patient's treatment and care. Medical, surgical, and radiation oncologists comprise the disease team that drives the treatment planning process; they plug in to the SWAT team but, unlike a traditional model of cancer care, they do not need to see the patient at each visit. The CaLM staffing model (Figure 3, above) encourages oncologists to focus on treatment planning and decision making, while reducing patient reliance on them for services outside their scope of practice. This methodology of staffing results in:

1. Payer cost savings due to maximizing oncologists' scope of practice and increasing patient volume.
2. Patients' immediate access to subspecialists to manage their specific needs.
3. A single point of contact for patients when coordinating care.
4. Clinical providers work at the top of their license.

After completing patient-reported outcomes (PROs) and intake forms, patients meet with the SWAT team for a whole-person assessment throughout the first several visits. Patients first see a disease-specific advanced practice provider. Depending on patients' priorities, symptoms, and immediate needs, the palliative advanced practice provider or social worker may meet with patients and their families to share the types of integrated services that CaLM provides (and patients may schedule separate visits later). Patients may also need to meet with one or more members of the patient support team. During this same initial visit, some domains may be assessed to help the care team get to know the patient and their values (see Figure 4, page 28). Many of these domains are assessed over time as the team builds a strong and trusting relationship with the patient. The clinical team uses the electronic health record (EHR) and/or a document called "Whole Person Assessment" to track these domains. Providers share this information so that all members of the care team have access to the data. Over several months in 2019, the Livestrong Cancer Institutes developed the whole-person assessment process to use components of medical oncology intake forms, psychosocial distress screens and intakes, psychiatric intakes, integrative oncology intakes, and palliative care intakes.

Simultaneous with a patient's initial visit, his or her case is reviewed during multidisciplinary tumor boards. Once the disease team determines the best treatment options, the oncologist(s) reconnect with the SWAT team and review the treatment options and any patient concerns that may have surfaced in their initial assessment. Afterwards, the disease team meets with the patient to discuss treatment protocols and options, including any clinical trials.

In May 2019 we piloted a weekly interdisciplinary case review for an hour each with the SWAT, disease, and patient support teams to:

- Discuss the patient's immediate clinical, practical, and psychosocial needs, so that the teams can prioritize services.
- Discuss the patient's whole-person assessment.
- Develop a comprehensive care plan.
- Coordinate clinical care.

Figure 4. Domains for Assessing the Whole Person

**SEXUAL**
Fertility
Body image
Sexual needs and issues
Couple communication and needs

**CULTURAL**
Language
Immigration status
Meaning of pain, illness, death, suffering
Rituals
Health-related preferences based upon culture
Cultural traditions and beliefs

**VALUES AND PREFERENCES**
Treatment goals
Life goals
Communication preferences

**PHYSICAL**
Medical history (including family history)
Physical symptoms, chief complaint/issue
Pain analysis (location, cause), discomfort, meaning, history

**EMOTIONAL**
History of grief, loss, and illness
Coping and strengths
Stress relief
Disease understanding and prognostic awareness
Demographics: race, ethnicity, gender identity, sexual orientation, age, marital status, kids, employment, living situation, religion, spirituality, language, health literacy, immigration status, socioeconomic status, family structure, etc.
Personal trauma
Sources of support
Communication preferences
Cultural/ethnic, spiritual, and familial needs

**SOCIAL AND PRACTICAL**
Social history and development life history
Social determinants of health
Financial issues
Cancer, jobs, education
Social community and support system; family system and impact on family (including children in family)
Education level
Sleep
Exercise
Spiritual or meaning making practices

Each expert weighs in on the patient's major challenges to ensure coordinated and streamlined care. This case review process is critical in helping the team map a complete picture of the whole person and his or her family and life context. By asking, "What's important to you, today?" and building trusting relationships with patients and caregivers, we know our patients and the challenges they face outside the clinical setting and keep a pulse on patients' priorities. Over the patient's next visits, the SWAT, patient support, and disease teams work with patients to develop a care plan that includes cancer treatment, symptom management, emotional support, nutritional support, and any other components that patients need (see Figure 5, right). Most critical resources and services are delivered internally. CaLM service lines (in-house programs) include:

- Nutritional support
- Palliative care and symptom management
- Psychosocial and emotional support
- Genetic counseling
- Financial counseling
- Care coordination (navigation)
- Fertility preservation.

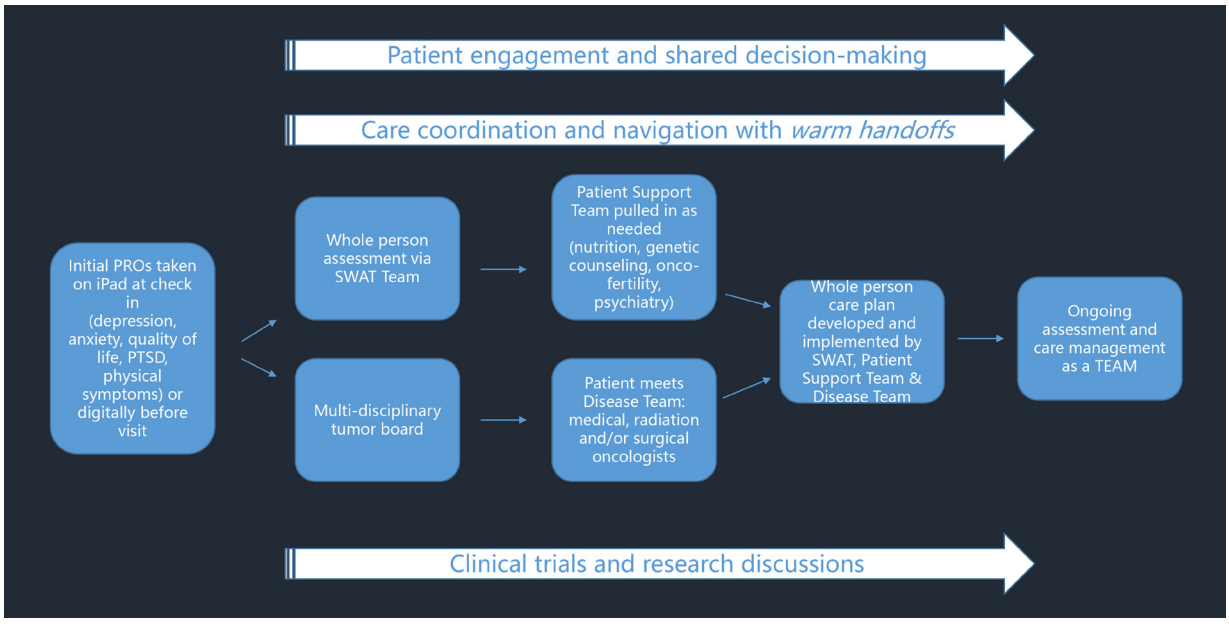
Livestrong Cancer Institutes also make referrals out to the local community for physical therapy (prehabilitation/rehabilitation), spiritual care, career and legal support, wellness/fitness/yoga programming, and integrative oncology (see Table 1, page 30). We plan to launch some of these service lines in-house in the near future.

## Effective Teamwork Requires Specific Training

As more cancer programs move toward a team-based approach to care, clinicians can struggle with working functionally in their teams. Cancer care is complex and requires healthcare providers across disciplines to collaborate to learn, assess, problem solve, and deliver coordinated care,[7] but seasoned clinicians may not have had the interprofessional training to equip them with the skills and tools to collaborate successfully. Our team recognizes that we cannot simply put hired clinicians together and expect them to work as a team. We need to train and teach clinicians how to be most effective in these teams. Accordingly, Livestrong Cancer Institutes is working with Dell Medical School, Center for Health Interprofessional Practice and Education to deliver training that will develop clinician proficiency in the following competencies:

- Work with other clinical experts to maintain mutual respect, understanding, and shared values.
- Use clinical experts' full scope of knowledge, skills, and abilities to provide care that is safe, timely, efficient, effective, and equitable.
- Communicate with team members to clarify their responsibilities in executing a treatment plan or public health intervention.
- Recognize how each individual contributes uniquely (i.e., experience level, expertise, culture, power, and hierarchy within the team) to effective communication, conflict resolution, and positive interprofessional working relationships.

Figure 5. CaLM Care Pathway




- Engage with the team to constructively manage disagreements regarding the values, roles, goals, and actions that may arise among professionals and with patients, patients' families, and community members.
- Plan, deliver, and evaluate care by applying relationship-building values and team principles.

Training is delivered through a series of sessions led by a team—including a physician, nurse, social worker, and pharmacist—that can model effective interprofessional practices. The competencies listed above will be used as a benchmark to assess improvement in desired areas.

## Measuring What Matters to Patients

Data show that assessing symptom-related, patient-reported outcomes may actually increase cancer patient survival.[8] The U.S. Food and Drug Administration defines patient-reported outcomes as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else."[9] The goals of our overarching patient-reported outcomes strategy include:

1. Managing patient symptoms and side effects and screening for issues (in real time when possible).
2. Assessing whether treatments and interventions are effective (and creating adherence to interventions).
3. Assessing patient experience with CaLM services and facilitating patient-centered cancer care.
4. Assessing and managing emotional, social, cultural, physical, financial, spiritual, and practical issues and needs of patients and caregivers over time.
5. Providing a common frame for the CaLM interdisciplinary team to use when discussing and/or implementing whole-person care.
6. Engaging patients in their healthcare journey and managing their health.

In 2018 the Livestrong Cancer Institutes implemented a vigorous process (see box on page 31) to select appropriate patient-reported outcomes to test in the CaLM model, utilizing the "capability, comfort, calm"[10] framework of Elizabeth Teisberg, PhD, and Scott Wallace, JD, MBA, of the Dell Medical School, Value Institute for Health and Care. Their research findings identify three outcomes that matter most to patients' healthcare experience:[11]

- ***Capability.*** Frequency or degree to which patients can do what matters to them.
- ***Comfort.*** Freedom from physical and/or emotional pain and/or suffering.
- ***Calm.*** Patients' abilities to live their lives as they pursue care (free from the chaos of the healthcare experience).

In the CaLM model, patients receive five short digital assessments (in English or Spanish) either 24 hours before their appointment via email or SMS, or on an iPad at check-in. These include the Generalized Anxiety Disorder assessment (GAD 2/7) to gauge anxiety, the Patient Health Questionnaire (PHQ 2/9) to measure depression and suicidality, the Functional Assessment of Cancer Therapy (FACT G) to assess quality of life, the MD Anderson Symptom Inventory to assess physical symptoms, and a modified version of the Primary Care Post-Traumatic Stress Disorder

**Table 1. CaLM Community Partners**

| Organization | Program/Service |
|---|---|
| Wonders & Worries | Counseling and support programs for children with a parent dealing with cancer |
| Regarding: Cancer | Peer matching for cancer patients and caregivers |
| CANLAW | Access to free professional legal services for cancer patients and their loved ones |
| American Cancer Society | Navigation support to local and national resources; cancer information |
| Cancer Rehab and Integrative Medicine | Acupuncture, oncology massage, physical therapy, lymphedema therapy |
| Cancer and Careers | Online resources and support for employment issues when coping with cancer |
| HorseLink | Equine therapy and daylong retreats for patients and loved ones |
| Flatwater Foundation | Financial coverage and access to one-on-one therapy or counseling with licensed professionals for longer term emotional support for patients or loved ones |
| Livestrong at the YMCA | Free/low cost exercise and wellness 12-week program for cancer patients and survivors |
| Yoga 4 Cancer | Free or low-cost group yoga classes geared toward patients and survivors at any phase of treatment or in post-treatment survivorship |
| Livestrong Fertility | Access to free fertility preservation stimulation medication (women) and discounted services (extraction, freezing) for men and women |

Assessment to measure any post-traumatic stress disorder (PTSD) from traumatic life events (e.g., a cancer diagnosis or previous cancer-related experience). Each assessment is conducted at the patient's first visit and every medical oncology and/or SWAT visit that follows. We track patients' symptoms, side effects, and emotional issues over time, so that we can address them immediately. Table 2, right, shows the validated patient-related outcome tools in use, the subdomain that each measures, and the cadence of assessment.

## Interconnection with Local Cancer Care Delivery System

To deliver high-quality, person-centered cancer care, we need to work in tandem with the local cancer care delivery system. Central Texas has more than 45 non-profits, cancer organizations, and institutions that provide cancer-related services or programs to patients and their families, and numerous other organizations provide access to needed social services for indigent and vulnerable patients. To leverage these existing resources, the Livestrong Cancer Institutes partnered with these organizations and built referral pathways in our navigation strategy. Our team reaches out on behalf of the patient to community resources to minimize the barriers that patients face when seeking referrals.

Table 1, above, lists some of the organizations with whom we have built robust partnerships and direct referral pathways. The vetting process before initiating memorandums of understanding with each organization includes holding initial discussions, streamlining referral pathways, and making site visits to understand the nuances of their service, ensure alignment with our navigation methodology, and develop ease of access for patients.

## Is the CaLM Model Working?

Our team has built a robust evaluation strategy to assess the impact of the CaLM model. In addition to tracking traditional clinical measures, we plan to measure:

- Whether patient goals are defined and met through care coordination, quality of care, and symptom management.
- Patient access to treatment and care.
- Provider burnout rates.
- Patient ease of referral and communication with community partners.

**Table 2. Patient-Reported Outcome Measures Used in the CaLM Model**

| | Domain | Sub-domain | Cadence |
|---|---|---|---|
| Generalized Anxiety Disorder Screen (GAD 2) | Comfort, calm | Anxiety | First visit and every visit |
| Patient Health Questionnaire (PHQ 2/9) | Comfort | Depression | First visit and every visit |
| Functional Assessment of Cancer Therapy (FACT-G) | Capability, comfort | Quality of life: physical, social, emotional, and functional well-being | First visit; then every 3-6 months as needed |
| MD Anderson Symptom Inventory | Comfort, capability | Physical symptoms: pain, fatigue, nausea, disturbed sleep, distress and/or feeling upset, shortness of breath, difficulty remembering, lack of appetite, drowsiness, dry mouth, sadness, vomiting, numbness, and tingling | First visit and every visit |
| Primary Care Post-Traumatic Stress Disorder Assessment | Comfort | Trauma, post-traumatic stress disorder | First visit; then every 3-6 months as needed |

Currently, EHR limitations prohibit us from collecting these data, but we are preparing to switch to a more functional and appropriate EHR built for oncology settings. However, based on early data collected via patient-related outcomes, we are seeing trends that the CaLM model is improving patient quality of life and reducing severity of physical and psycho-social symptoms. Figures 6-7, pages 32-33, show baseline and follow-up anxiety scores for a small population of patients from June to August of 2019. The data in Figure 7 illustrates a decrease of mild-to-moderate and severe anxiety from 41 percent to 28 percent of patients. As our clinic continues to grow in patient volume, we expect the data to continue to trend in the same direction with an increase in patients with no to low anxiety and a decrease in severity of anxiety.

More recent data show that the CaLM Model also improves physical symptoms (Figure 8, page 34). Data are from the MD Anderson Symptom Inventory baseline results (initial visit) and endline results (most recent visit previous to March 1, 2020). Trends show a reduction of moderate and severe pain (a decrease from 40 percent to 33 percent combined); by their most recent visit, nearly two thirds of patients rated their pain as mild. The data also illustrate a decrease in severe fatigue of 11 percent, from 34 percent to 23 percent, and a decrease in moderate and severe symptom interference in mobility by 16 percent.

## Two Qualitative Examples of Success

### *Patient A*

A gastrointestinal oncology patient first came to the Livestrong Cancer Institutes at UT Health Austin after receiving treatment

### Selecting Our Patient-Reported Outcomes

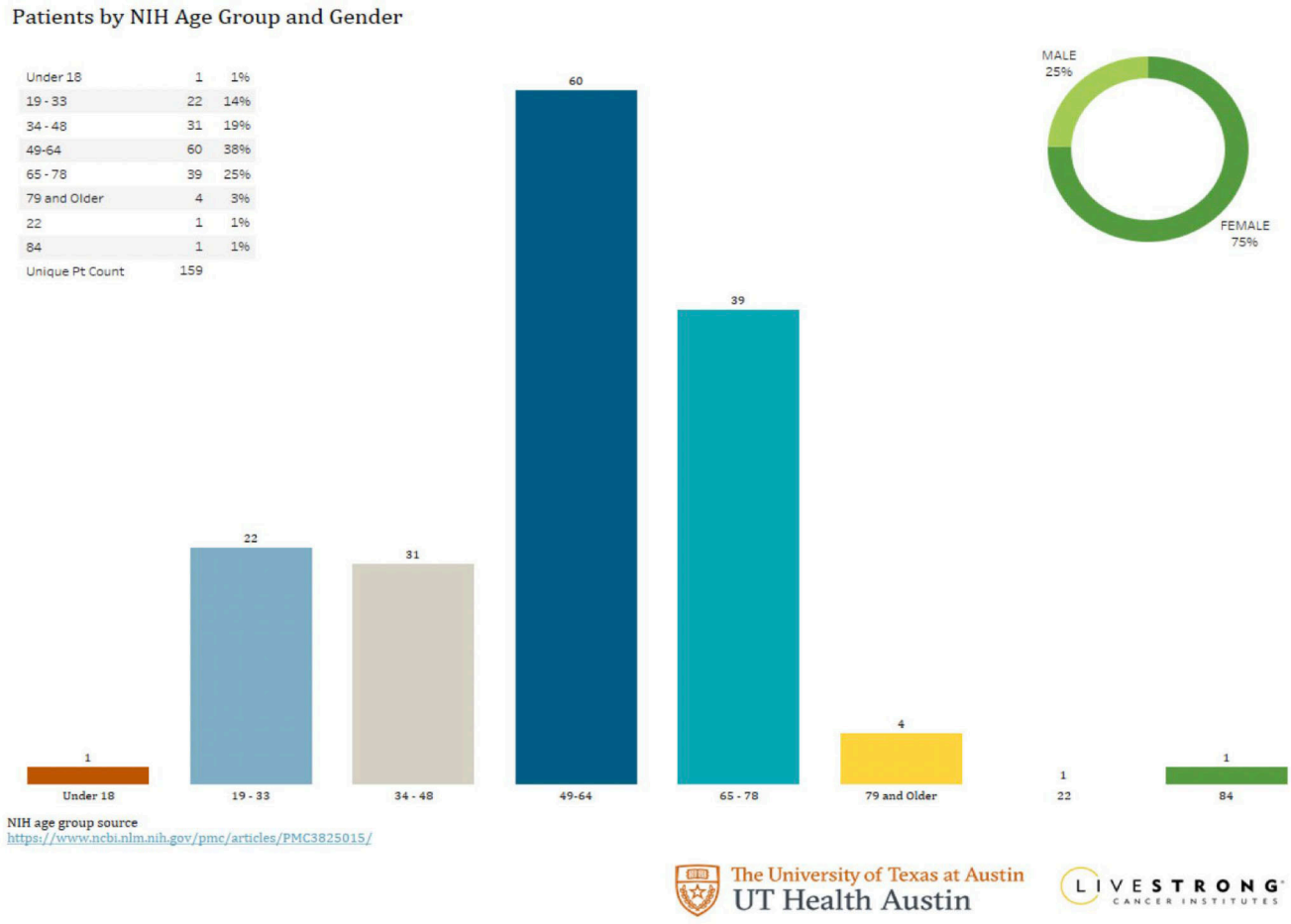
Our team piloted a PRO baseline research study in the Seton Infusion Center with nearly 150 patients and caregivers. We collected data at two time points and used several measures, including the FACT-G with Palliative Module (to measure quality of life); PROMIS-Cancer Specific Measures (to measure function, anxiety, depression, fatigue, and pain); COST tool (to measure financial toxicity); CAHPS survey (to gather data on the cancer care experience); and the BASC tool (to gather data on the caregiver experience). The overall model for factors impacting quality of life showed that depression and pain significantly decreased quality of life, and for every one unit increase in the COST score, we get one unit increase in quality of life. The CaLM model controls for cancer stage, type, race, and age.

In May 2018, a large cross-functional team of providers, social workers, researchers, nurses, and experts from across the Value Institute, Oncology Department, palliative care, psychiatry, and the cancer community (Livestrong, Seton) gathered to hold a deep-dive discussion about our PRO strategy.

In July 2018, the Cancer Institutes' Patient Advisory Board held a mirroring discussion to provide their input, and the participating patients and caregivers expressed strong approval for the list of PROs and domains, validating and adding to it.

In August 2018, our PhD researcher compared the list of PRO domains to peer-reviewed literature to map it against best practices and identify validated tools for each domain where possible.

Figure 6. CaLM Patient Demographics for GAD Data



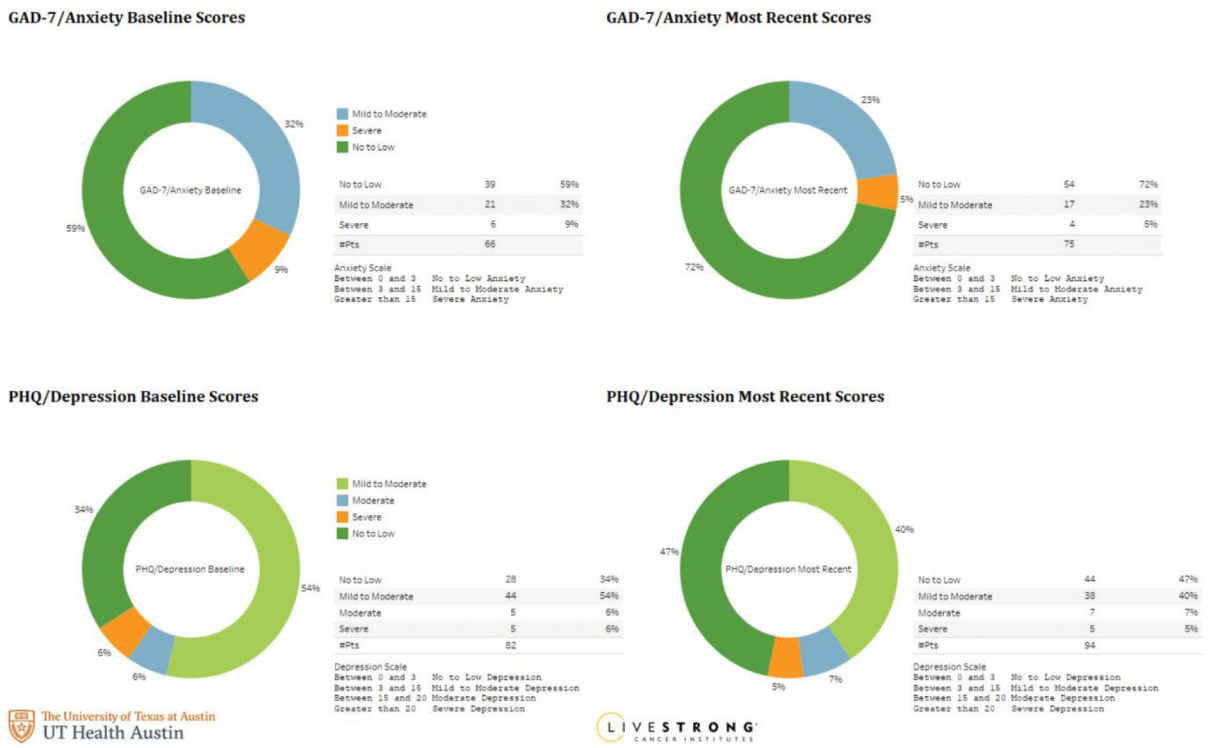

at another well-known local cancer center. The patient presented stable disease but was not satisfied with treatment for his anxiety and physical symptoms. He had been given referrals for emotional support without direction on how to select a psychosocial provider, which was extremely confusing to him. He self-referred to us after reading about our program on our website. At his first visit, he filled out the patient-related outcome assessments, which demonstrated severe anxiety and depression. As the team reviewed his results and spoke with him about his immediate concerns, it became clear that the primary issues requiring triage were his mental health and palliation of gastrointestinal symptoms. Because his disease was stable and he was on maintenance chemotherapy, the team facilitated a shorter "meet and greet" with his gastrointestinal oncologist and opted for a more robust assessment and treatment with the clinical social worker, oncology psychiatrist, and palliative care advanced practice provider. As a result, the team was able to stabilize the immediate issues that had been causing him high distress. The patient now has regularly scheduled visits with an oncology psychiatrist and the palliative care team, and his psychosocial issues are under control. His colorectal cancer is periodically co-managed by Livestrong Cancer Institutes at UT Health Austin and MD Anderson Cancer Center.

### *Patient B*

An oncology patient initially refused treatment because she preferred alternative treatment options. She had specific nutritional needs and preferences that she wanted honored. After her first visit, the SWAT team better understood the context of her life and her values and preferences. The whole-person assessment identified that her religious beliefs conflicted with the treatment regimen she was offered and her deep-rooted fear and mistrust of the healthcare system. An oncology dietitian worked with the patient to develop a highly personalized nutrition plan that met the patient's nutritional restrictions and guidelines. Over time, our team continued to provide supportive care without treatment and, while consistently respecting the patient's values and preferences, the team was able to build trust. The patient soon opted into clinical treatment for her disease.

As these patient stories show, the CaLM model is a closely coordinated approach and a change in clinical care culture that results in a connection between providers and patients. Because

Figure 7. Baseline and Endline Anxiety Scores (General Anxiety Disorder Scale)



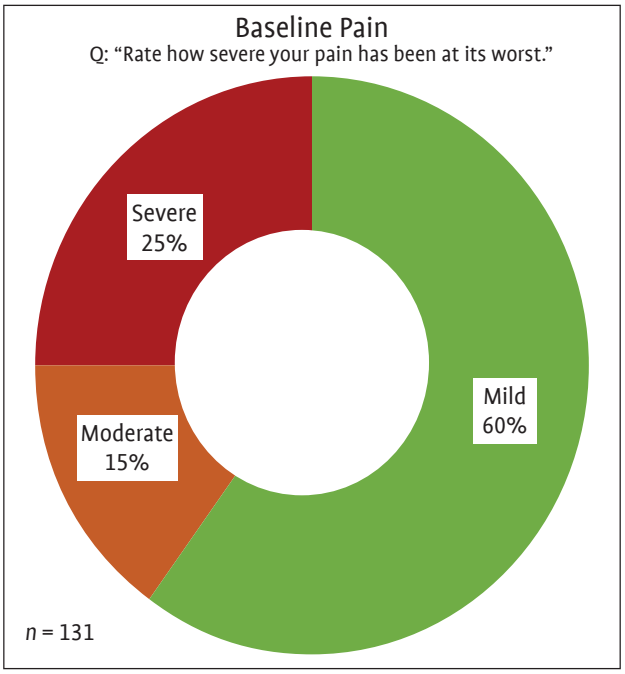

referrals outside of the CaLM team are limited, all team members are present for daily huddles and conversations and are kept current as patient treatment and/or care evolves. Clinical treatment alone does not encompass whole-person care. These examples illustrate that to improve patient quality of life, the needs of the mind, body, and spirit must be addressed. Lastly, a relational, empathic approach requires building trust over time in small transactions with patients and caregivers. Because patients see the same empathic providers at every visit, the CaLM model forges therapeutic, trusting relationships between patients and their care team; providers receive honest information to truly meet patients where they are.

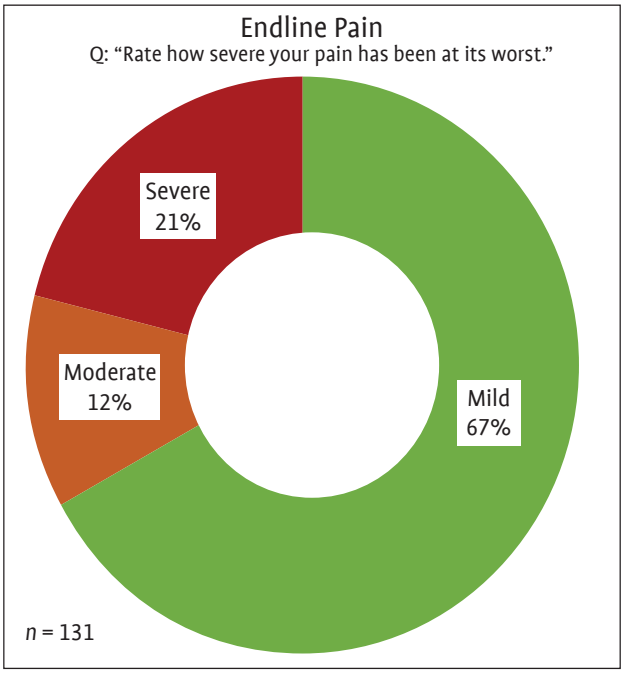
## Lessons Learned

Figure 9, page 35, offers a brief timeline of program development and implementation of the CaLM model. Below are key lessons learned during the program's first year of operation:

- ***Teams have baggage.*** Although many believe in the power of interdisciplinary care teams, few healthcare professionals are trained in effective teamwork, and even fewer have experience with this approach to care. We opened our clinic expecting providers to have bought in to this idea, without any training or clearly defined roles and responsibilities. We assessed for resilience and adaptability in interviews, but that did not always translate into the start-up environment. Encouraging providers to put the patient first and to have an "all hands-on deck" approach without training and support will not lead to desired outcomes. Providers bring components of their previous institutions' culture, even if only subconsciously. To address this, our team is working with the Center for Interprofessional Practice and Education (healthipe.utexas.edu) to train the team in this emerging field.
- ***Everyone will tell you "No."*** Change is not easy, especially in healthcare. Just because a team wants to innovate, disrupt, and rethink healthcare does not mean that it understands the high level of detailed work, flexibility, and perseverance that change takes. Building a new clinic from scratch is never easy. Leadership may accuse you of being inefficient; referral partners may think you are naïve; and you may have to defend every decision you make. The care team may even question all of the non-clinical work it takes to effect change, but if you stay the course, listen, and are willing to iterate, it will not happen overnight but you may get there.
- ***Patients may not trust you.*** Patients—especially patients with cancer—are not always treated well. They may experience poking or prodding without understanding why. They may feel identified as if they are their disease rather than a person. Patients have an expertise that few practicing oncologists have: what daily life is like with cancer. When developing patient advisory boards or other patient engagement efforts, trust, consistency, and respect must be earned. One of the first members of our Patient and Family Advisory Board was hesitant

Figure 8. Results are illustrated for all patients seeking active or survivorship care for cancer at some point between December 2018-February 2020, excluding patients seeking solely a second opinion consult. MD Anderson Symptom Inventory asked patients to rate symptom severity and symptom interference at their worst, within the last 24 hours. Ratings were aggregated as follows for analysis: 0-3: Mild Severity or Interference; 4-6: Moderate Severity or Interference; 7-10: Severe Severity or Interference.



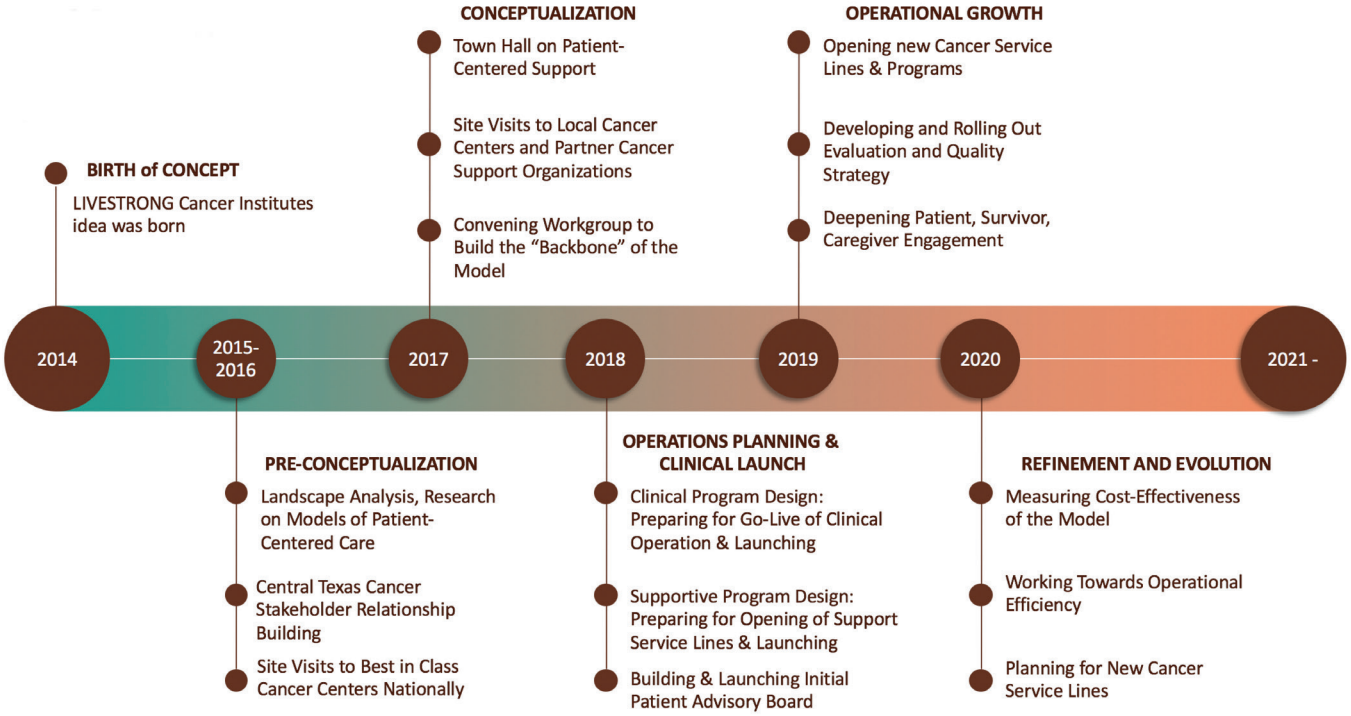

to work with us. He is the father of a post-treatment cancer survivor who was diagnosed at eight months old and told us that he would not be our "yes man." He recognized that some patient boards may simply rubberstamp ideas intended to serve the healthcare system so that they are "approved" by patients and caregivers. After learning about the CaLM model—our intentions to co-design with patients and family and recognize patients and loved ones' unique expertise—he finally joined. Over the past year, our team has come to know the father and his family by staying consistent with our messaging, accountable to the board, and respectful of how members want to drive the work. This work takes time and does not always fit into project plans and set timelines, but you have to meet patients where they are, listen to what they are saying (not what you want or expect them to say), and push past those who are reluctant to include patients. Patients participated in mock clinical operations in the hallway after our compliance officer told us that we could not have them in the clinic prior to opening. When our leadership discouraged us from involving survivors in clinic launch preparations, we brought our patient advisors to meetings so that our leadership could speak directly to them. Asking for forgiveness, rather than permission, may be a necessary approach for any innovator.

## Vision for the Future

Our hope is to continue to illustrate the efficacy of the CaLM model and gather data (particularly cost-benefit analysis data) that proves that reshaping care to an interdisciplinary, whole-person focus will lower costs for the patient, system, and payer, while improving patient outcomes. Our ultimate goal is to find unique ways to scale and replicate the CaLM model and share it with institutions that want to be forward-facing. We want to share how to bring patients to the work (rather than the work to patients) and how to offer patient-centered care in which patients are at the center of all aspects of care—from design and implementation, to directing and evaluating. Because no program, service, or material is introduced in our clinic without our patient advisors helping to design the effort, we will let Christina have the final word on what we offer.

"I know some things about my future: that it will involve more treatment and that I am likely to die far sooner than I hoped. I know to keep holding on to that small flame of initial confidence because while treatment keeps me stable, medicine will keep advancing. I know my care at the CaLM clinic is going to allow me to enjoy my life outside of cancer. I will get to laugh at my daughter's stories and share intimate moments with my husband. I know I want to keep using my voice to tell people about my life and my experience. It makes me feel strong, and I hope it can help someone else—be it getting tested themselves or just learning how to better support a friend going through it. Knowledge is power, and I am happy to share mine." OI

Figure 9. CaLM Timeline Roadmap

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# Improving Cancer Care by Addressing Food Insecurity

BY TRACEY F. WEISBERG, MD


Food insecurity has become an increasing concern for Americans that healthcare providers can often overlook. It is not associated with any one demographic group; anyone can become food insecure at any point in their life. The U.S. Department of Agriculture defines food insecurity as the "limited or uncertain availability of nutritionally adequate and safe foods or limited or uncertain ability to acquire acceptable foods in socially acceptable ways."[1] In 2017 food insecurity affected 12.7 percent of the U.S. population; 15.8 percent of Maine's residents experienced food insecurity that same year.[2]

Several factors contribute to Maine's high rate of food insecurity. For example, only two-thirds of workers in Maine earn a living wage, and constraints on state benefits (e.g., the Supplemental Nutrition Assistance Program, or SNAP) prevent many people from qualifying for them.[2] Figure 1, page 38, demonstrates the average prevalence of food insecurity by state from 2016 to 2018.[3]

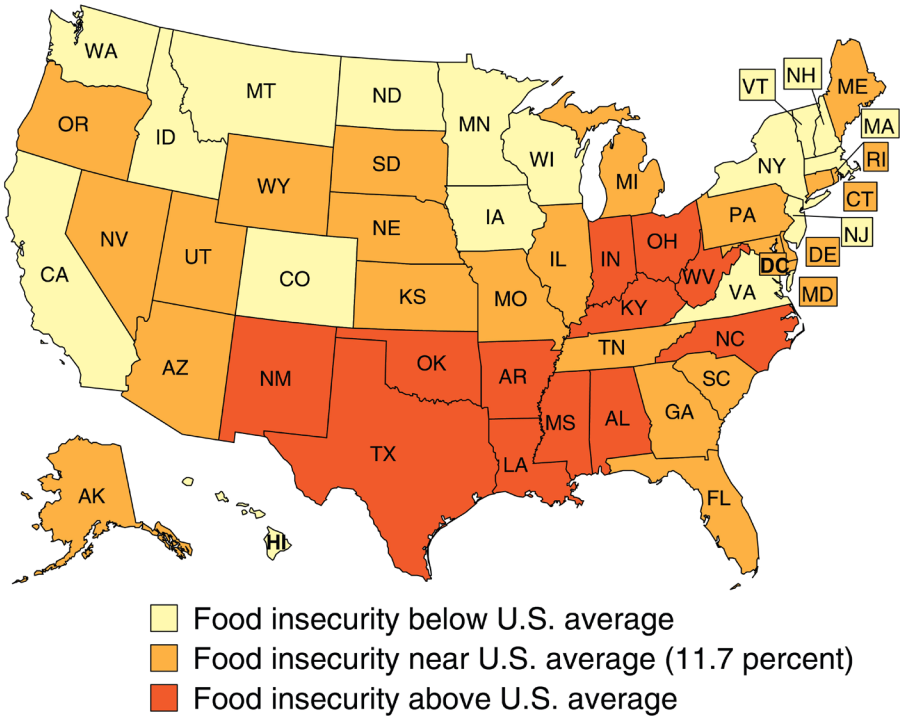
The terms *food insecurity* and *hunger* are often used interchangeably in everyday vernacular, but it is important to note that measuring food insecurity is not the same thing as measuring hunger. Rather, hunger is a potential consequence of food insecurity.[1] Food insecure patients can become sicker and struggle more to afford their medications. A study on food insecure patients in Kentucky found that 55 percent did not take their medication because they could not afford to do so, compared to 12 percent of their food secure peers.[4] The study also found that food insecurity is associated with a lower quality of life in the areas of physical, emotional, and functional well-being.[4]

> Our data revealed that 61 percent of our male patients and 39 percent of our female patients were food insecure. Our results also revealed that food insecurity impacted the entire age range of the patients we serve, although the highest percentage of food insecure patients are were 50 to 59.

## Do We Have a Problem?

New England Cancer Specialists sought to create a way to help our food insecure patients improve their health and quality of life. To do so, in 2017 we set out to determine the demographics of our patients and find out how many were food insecure. We

Figure 1. Prevalence of Food Insecurity, Average 2016-18.




Source: USDA, Economic Research Service using Current Population Survey Food Security Supplement data, U.S. Census Bureau.

received funding for our study from our state oncology society, and with the help of two students at our practice, we gathered the basic demographics of our patient population. Both students were college juniors with medical school aspirations. The students developed a patient-reported outcomes (PROs) survey for all patients that asked them to answer questions about potential food insecurity as well as several symptoms (including difficulty sleeping, fatigue, pain, mood, and appetite) based on Common Terminology Criteria for Adverse Events 4.0 guidelines.[5] We identified patients as food insecure based on their selection of either the second or third option in the survey:

1. In the last year, I have never worried about running out food.
2. I was worried about running out of food and not being able to buy more.
3. I ran out of food and was not able to buy more.

We recorded results from the PROs survey to establish the prevalence of food insecurity in our practice. We also assessed whether food insecure patients had more symptoms of distress compared to food secure patients. In addition, we evaluated adherence to adjuvant therapy for patients with early stage breast cancer based upon their food insecurity.

## Demographics of Food Insecurity

Our data revealed that 61 percent of our male patients and 39 percent of our female patients were food insecure. Our results also revealed that food insecurity impacted the entire age range of the patients we serve, although the highest percentage of food insecure patients were 50 to 59. We found this surprising, because we expected that our young patients and patients on Medicare without supplemental insurance would be the most food insecure. Our data showed that 94 percent of our food insecure patients have a primary care physician, and many of them reported that they had not been asked about food security before. Almost all of our patients (97 percent) have healthcare insurance.

Although we thought that our under- or uninsured patient populations would most often screen positive for food insecurity, our data show that food insecurity can affect anyone. Our data revealed that 17 percent of our patients who screened positive for food insecurity at some point in their treatment are covered under Maine Care, 39 percent have Medicare with supplemental coverage, 6 percent have Medicare only, and 34 percent have private insurance.

We wondered why this specific population (patients with healthcare insurance) were screening positive for food insecurity. Was it the big co-pays and/or deductibles, or was it caused by other issues?

## Distress and Food Insecurity

We found that patients who indicated that they were food insecure reported, on average, more symptoms (difficulty sleeping, fatigue, pain, and mood) compared to their case-control matches. This finding was consistent across the board, with highly significant *t* values (see Table 1, below). Our data also show through a correlated *t* test that the difference in these scores (0-3 scale for difficulty sleeping, fatigue, and pain and a 0-4 scale for mood and appetite) was significant, with a 99 percent power for each symptom except appetite, which had an 85 percent power.

One factor to note with this study is that there are patients who are food insecure but do not screen positive for food insecurity. Patients do not admit to being food insecure for many reasons. They may fail to answer this question correctly because they fear getting social workers involved. Or they may fear that their children could be taken from them if they cannot demonstrate that they can adequately provide for them. Also, not all patients who screen positive for high levels of distress or difficulty sleeping screen positive for food insecurity. But having data on these self-reported items can give our providers an opportunity to initiate conversations with patients who may be vulnerable.

## Food Insecurity and Treatment Adherence

We next sought to determine whether providing food assistance to food insecure patients with early stage breast cancer would improve their adherence to adjuvant therapy. The study took place from January 2017 to June 2019. During this time, our practice saw 42 patients who met our study criteria. We collected data from our patient-reported symptoms survey and collected information from our financial advocates regarding how many of these patients had received food assistance. We matched food secure case-controls for disease, stage, gender, and age. We then quantified adherence to adjuvant therapy by the number of months these patients received treatment.

Our results indicated that food insecure patients tended to complete fewer months of treatment than their food secure counterparts. Food insecure patients who refused assistance had the lowest number of months of completed treatment; most food insecure patients who received assistance completed more of their treatment.

It is important to recognize that we are a small practice; therefore, our sample size is small, so the statistical significance is not yet relevant. Though we concluded that receiving food assistance likely increases the likelihood of food insecure patients completing their therapy, we also recognize that socioeconomic factors can also contribute to why patients do not complete their adjuvant treatment.

## Our Screening Process

We found that addressing food insecurity in our patient population is relatively simple and does not require much money. In refining our patient screening tool (Figure 2, page 40), we studied food insecurity screening tools that were already validated in the healthcare setting. We found that the "two-item hunger score" (also called the "vital signs score") that was published in 2010 and 2015 has the highest sensitivity and specificity for identifying food insecure patients.[6,7] (A one-item screening tool yields less patient sensitivity and specificity.) The tool we now use has two questions, and either one of them would yield acceptable results.[6,7] We ask our patients to answer yes or no to the following:

1. Within the past 12 months, we were worried whether our food would run out before we got money to buy more: often true, sometimes true, or never true.

**Table 1. Data from Food Insecurity Screening**

| PRO Symptom | Food Insecurity | Food Security | *t*-values* |
|---|---|---|---|
| Difficulty sleeping | 0.954 | 0.497 | 4.249 |
| Fatigue | 1.369 | 0.799 | 8.6 |
| Pain | 1.04 | 0.586 | 4.399 |
| Mood | 1.078 | 0.49 | 4.929 |
| Appetite | 0.556 | 0.323 | 2.708 |

*value greater than 2.358 is significant.

Figure 2. Patient Screening Tool

NEW ENGLAND
Cancer Specialists

Name_____ Date_____

Please circle all symptoms /side effects that apply since your last visit.

| **Do you have any of the following?** | Living Will Yes No | Durable Power of Attorney Yes No | Do Not Resuscitate order (DNR) Yes No | | |
|---|---|---|---|---|---|
| **Pain Choose number** | None 0 1 | Mild 2 3 | Moderate 4 5 | Severe 6 7 | Very Severe 8 9 | Unbearable 10 |
| **Fever/Chills** | None | Mild sensation of cold | Moderate: shaking, chills | Severe and prolonged | |
| **Fatigue Choose number** | None 0 1 | A little: relieved by rest 2 3 4 | Quite a bit: limits activity 5 6 7 8 | Very much: limits self care 9 10 | |
| **Nausea/Vomiting/ Food Intake** | None | 1-2 episodes/day-less than normal intake | 3-5 episodes/day-occasional intake | 6-10 episodes/day-no intake | 11 or more episodes/day - no intake |
| **Diarrhea** | None | 2-3 loose stools/day some cramps | 4-6 loose stools/day moderate cramps | 7-9 loose stools/ day severe cramps | 10 or more loose stools/day, bloody stools |
| **Constipation** | None | 1 stool every 2-3 days | 1 stool per week | No stool for more than 1 week | No stool & severe abdominal pain |
| **Mouth sores** | None | Mild mouth soreness | Painful ulcers but can eat | Painful ulcers, cannot eat | Need to be fed by a tube |
| **Hot flashes** | None | Occasional | Mild – 1 per day | Moderate – up to 10 times per day | Severe – more than 10 per day |
| **Numbness/ Tingling** | None | Mild | Moderate | Severe | Loss of use of extremity |
| **Shortness of breath** | None | With moderate activity | With minimal activity | Shortness of breath at rest | |
| **Irregular heartbeat** | None | Occasional | Several times per week | Daily | Requiring medical attention |
| **Skin rash** | None | Minimal – no itching | Moderate – some itching | Extensive – severe | Skin blistering or loss of skin |
| **Urinary symptoms** | None | Frequency/urgency | Mild pain or difficulty voiding | Moderate pain or difficulty voiding | Extreme pain or cannot void |

Please check one of the three **Food Security** questions listed below that applies to you or your family:

___ Within the last 12 months, I have had no concerns about having enough food.

___ Within the last 12 months, I have worried about whether our food would run out before we could get money to buy more.

___ Within the last 12 months, the food we bought didn't last and we did not have money to buy more.

| | | |
|---|---|---|
| Do you need any **medication refills** today? | Yes | No |
| Have you been **admitted to the hospital or seen in the Emergency Department** since your last visit? | Yes | No |

2. Within the past 12 months, the food that we bought just did not last and we did not have enough money to get more: often true, sometimes true, or never true.

At each office visit, our patients are given the paper patient screening tool to fill out while in the waiting room. (Our goal is to ultimately have patients take the survey on iPads.) By now, our patients are familiar with our survey process. The food insecurity questions are located at the bottom of the form, and there is nothing about our screening process that singles anyone out. After patients complete the form, they are greeted and brought into an exam room by the medical assistant, who then manually enters patients' responses into our electronic health record. This is done in the exam room, so the information remains private. If a patient screens positive for food insecurity, the medical assistant will alert the physician or nurse navigator, who will ask one of our financial advocates to begin assisting the patient.

## Leveraging Community Resources

Our financial advocates first help patients determine whether they are eligible for the SNAP program. This federal program gives monthly benefits to those who are eligible, enabling them to purchase food at grocery stores, farmers' markets, and retail outlets. The benefits are loaded onto debit-like card that recipients can use when shopping. Unfortunately, SNAP does not provide much money. According to 2015 data, SNAP covered on average $1.86 per meal in the United States, whereas an average meal costs $2.36.[8]

Fortunately, the University of Southern Maine, just six miles from our Scarborough location, has a phenomenal program called "SNAP-Ed." It is a nutritional education program for anyone; participants do not have to be enrolled in the SNAP program. The program teaches participants how to make shopping lists, how to buy food on a limited budget, how to determine what is healthy food, and how to best prepare good meals. Our practice found this information to be invaluable, so we created a handout for our patients based on the program called "Finding Savings in Every Grocery Aisle" (see Figure 3, page 42).

The handout gives patients helpful quick tips for eating better, even on a budget. We have found that the combination of the SNAP and SNAP-Ed program can help people who are food insecure put food on the dinner table while also making healthy nutritional choices.

Our practice understands that food insecurity can impact the entire family, including children. If the parent does not qualify for a federal program, there may be other programs his or her children can receive help from. This can then help alleviate some of the food security issues for the entire family.

## How Our Practice Helps

Though this country spends a lot of money on complex medical treatments, very few resources are dedicated to helping people maintain adequate nutrition. Our practice has taken the initiative to help our patients by providing relief bags full of food to those who need them. These are meant to provide temporary, 24-hour relief to patients in emergency situations. The bags are filled with nonperishable items that are not meant to meet a patient's entire nutritional needs but rather to help if their cupboard is temporarily empty. Originally, our practice provided this assistance in brown paper bags (like the food assistance programs in many grocery stores), but we switched to using bags with the practice's logo to enhance patient privacy. Because every patient treated in our practice receives one of our bags, there is no distinguishable difference between the bags that contain food. For patients who need additional resources, our financial advocates help connect them to local food banks.

Our practice understands that food insecurity can impact the entire family, including children. If the parent does not qualify for a federal program, there may be other programs his or her children can receive help from. This can then help alleviate some of the food security issues for the entire family.

To fund this program, our practice has implemented a "jeans day" every Friday. Staff who want to wear jeans donate $2 to our food security program. To date, our staff has collected over $5,000 through this activity—all of which has gone to buy food cards so that patients can buy groceries.

Our most recent initiative is the "Give and Take Table" set up in our waiting room, where people can leave and take healthy food items as needed. (Our financial advocates put together a list of acceptable items to leave on the table, such as non-perishable items and healthy options.) Patients can choose to take food regardless of their income level and without judgment. This has helped us create a space to help reduce food insecurity and promote healthy eating habits. This initiative led our practice to also offer healthy snacks in the treatment room for our patients, including yogurt, fruit, and string cheese. These are projects that most practices can fund, and though they may not address everyone who is food insecure, they have helped and are most appreciated by our patients.

To help on a larger scale, our practice has created two foundations: the Snell Foundation and the Dean Snell Cancer Foundation. Our financial advocates help patients apply to these foundations for assistance with food insecurity and other needs, such as financial assistance with mortgages, rent, utilities, or medical services on an as-needed basis.

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Figure 3. Finding Savings in Every Grocery Aisle

## Beverages

- Tap water is free. Don't bother to buy bottled water. Be sure your tap water is safe—get your free water testing kit here: wellwater.maine.gov.
- Don't own a water bottle? Many organizations give out free water bottles at local fairs and events.
- Choose low-fat or fat-free dairy options. For dairy alternatives, be sure to pick a variety that does not have added sugar or is labeled "unsweetened."
- Skip the sugar-sweetened beverages (soda, juice drinks, energy drinks, sports drinks). They offer you and your family nothing for nutrition that cannot be found in more healthful options.
- Coffee and teas can be a source of added sugars. Skip the pre-made drinks and brew your own at home. It is cheaper and you can control how much creamer and sweetener you put in.
- Do you have a beverage habit? Try to cut by using this tip: Mix half your regular beverage option such as soda or juice with seltzer, club soda, or plain water. Over time, mix less soda and more seltzer/water into your beverages.

## Bread

- Choose breads that are made with 100 percent whole grains or 100 percent whole wheat.
- Brown and multi-grain breads don't necessarily contain whole grains.
- Switching to whole-grain breads can be difficult. Help your family make the switch by choosing bread options that are made with "whole-grain white flour."

## Cereal

- Choose cereals made with whole grains, such as whole wheat or whole oats (should be the first ingredient listed).
- Check the serving size—is ¾ cup really how much you would eat?
- Look for cereals with less than 7 grams of sugar per serving, 3 or more grams of fiber.
- Great options include oatmeal, bran flakes, and corn flakes (unfrosted).
- Remember, you can always add sweetener, such as a tablespoon of dried fruit or a teaspoon of honey or maple syrup drizzled over the cereal.
- If you are having a hard time switching to a whole-grain cereal, make a mixture. Start by adding a small amount of whole-grain cereal and add more as the week goes on.

## Produce

- Buy what is in season. Not sure? Check out this great chart for Maine: getrealmaine.com.
- Looking for the freshest? Check out your local farmers' markets: mainefarmersmarkets.org/market; check to see if your farmers' markets accept EBT (electronic benefit transfer).
- Don't be afraid to break up the bunch. Just because bananas come attached together doesn't mean you have to buy the whole bunch. Only buy what you need. If you are buying grapes or cherries, don't be shy; only take what you want rather than the whole pre-packaged bag.

## Canned Fruits

- Choose fruits that are packed in water or 100 percent fruit juice. Be sure to drain the fruit well and discard the liquid.

## Canned Vegetables

- Choose low-sodium or "no-salt added" canned vegetables when available. Drain and rinse well.
- Add flavor by using herbs and spices. Look for low-cost herbs and spices at discount dollar stores.

## Canned Beans

- Canned beans are a great option to keep on hand for a quick way to add protein.
- Choose low-sodium or "no-salt added" canned beans when available. Drain and rinse well.

## Milk

- Choose low-fat (1%) or skim milk.
- Looking for ways to switch to low-fat milk? Try this schedule:
  - Week #1: Mix whole milk with 1% milk
  - Week #2: Mix whole milk with skim milk
  - Week #3: Buy only 1% milk
  - Week #4: Mix 1% with skim milk
  - Week #5: Buy only skim milk

## Yogurt

- Choose low-fat or fat-free yogurt with no added sugars (check the ingredient list).
- Tip: Pick up plain yogurt and add your own toppings like a teaspoon of your favorite jam, a drizzle of honey, or some frozen fruit!
- Tip: Buy a large container of yogurt and make your own single serving. It is cheaper! Skip the smaller packaged yogurts and opt for the large container. It only takes a few seconds to scoop out a serving of yogurt, and you'll save money too! Figure 4, page 44, is an illustration of a unit price comparison.

## Cheese and Other Dairy Products

- Choose low-fat cheese or use half as much regular cheese in recipes.
- When buying sour cream or cream cheese, look for low-fat or fat-free options.
- Dry milk is great because you don't need to refrigerate it. Keep it on hand for when you run out of milk for cereal; add it to hot cereal or smoothies for added protein. It can be expensive because you must buy so much all at once. One box has 32 servings in it, for roughly $0.30 per serving. You can split a box with a friend and split the cost. This is also an alternative to stopping at the local convenience store to purchase milk where you might pay up to $1 more per gallon than at the grocery store.

## Frozen Produce

- Buy the biggest container of frozen whole fruit with no added sugar or toppings and frozen vegetables with no added sauces. This will be your cheapest option because frozen produce lasts up to six months.

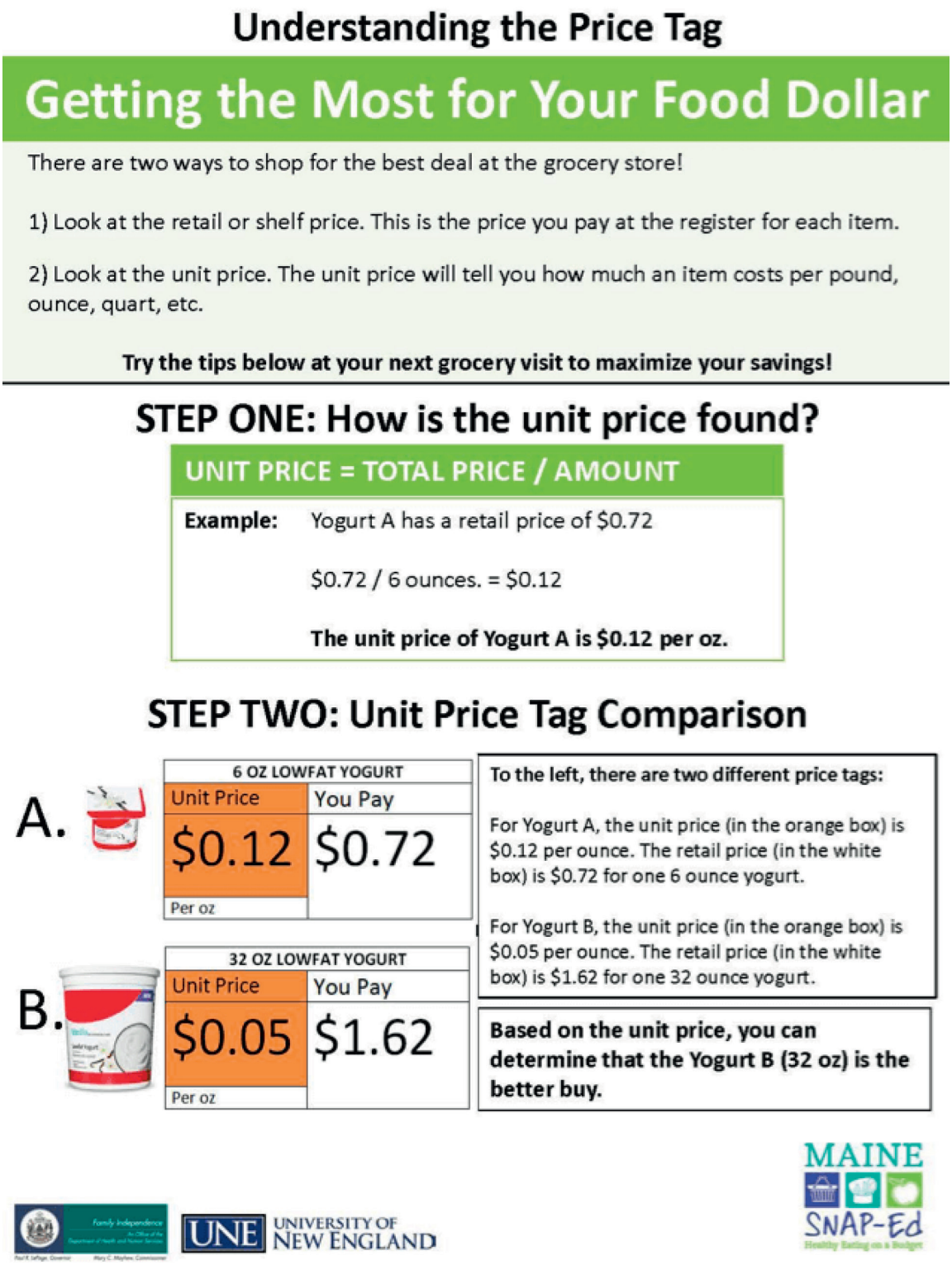
## Meat- and Seafood-Based Proteins

- Choose lower fat red meat options like 93 percent ground beef or cuts called "loin" or "round."
- Cut back on portion sizes. Remember, a serving size of meat is only the size of a deck of cards. Eating less meat will save you more money.
- Skip the prepackaged lunch meat. You might have to wait in line at the deli, but you'll skip the cost of the pre-package convenience and only be buying what you need.

## Plant-Based Proteins

- Lentils. There are so many varieties of lentils, but the most common are green and red lentils. Lentils are great because they will last a long time in your pantry—just don't forget about them. You can find lentils in the same aisle as dried and canned beans. A serving of beef can be as much as $1.49, whereas a serving of lentils is $0.10.
- Beans. If you're looking for a way to stretch your budget and improve your family's nutrition, consider adding more beans to your menu. They're convenient and versatile and lend themselves to many tasty dishes. Beans are a rich source of protein, fiber, vitamins, and minerals. Beans can be added to casseroles or soups to add flavor, texture, and more nutrients.

Figure 4. A Unit Price Comparison



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## Takeaways

It takes a community to identify food insecurity and come up with effective strategies to help. For cancer practices or programs interested in implementing a similar food assistance program, we offer these takeaways:

- Understand why food security is important and how it affects your patients and their families.
- Educate and train your physician leaders and key staff about food insecurity.
- Understand why it is important to do universal screening for food insecurity and identify the best way to screen in your setting. This should be incorporated into your institutional workflow so that it is sustainable and confidential.
- Show sensitivity when screening for food insecurity; inform patients that your practice is screening all patients. Normalize the screening procedure so that patients do not feel singled out.
- Research federal, state, and local resources available to help with people experiencing food insecurity.

A food insecure patient is not always the one you would expect. He or she may come from a middle-class family or have private insurance. Understand that if patients cannot maintain proper nourishment, they will likely be unable to battle cancer and manage treatment toxicities. OI

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## Patient Case Study

A 28-year-old self-employed male has a history of defuse large cell lymphoma and is being treated with CHOP chemotherapy. In the middle of his treatment, his advanced practice provider starts to notice that the patient is losing weight. The physician recognizes that weight loss is not common for patients receiving CHOP treatment. When researching the issue, we noted that this patient had not otherwise been ill. But he reported some fatigue and said he was not eating well. We discovered through our screening process that the patient did not have enough money to buy groceries for himself and his family. He fed his kids and wife but was not getting adequate food himself. At this time, the family had lost their insurance and could now qualify for state assistance. We immediately got our financial advocates involved. They were able to help the patient obtain a leukemia and lymphoma grant, which allowed for enough funds to supplement his income and establish food security for the family. Our practice also helped the patient during his treatment by providing multiple grocery cards out of our own funds. In the end, the patient completed his treatment, and now he is in remission, back to work, and no longer food insecure.

# Developing and Implementing a Radiation Oncology App to Improve the Patient Experience


WellSpan Health is an integrated health system that serves the communities of central Pennsylvania and northern Maryland. The organization is comprised of eight hospitals, more than 19,000 employees, and more than 170 patient care locations. WellSpan is a charitable, mission-driven organization, committed to exceptional care for all, lifelong wellness, and healthy communities. WellSpan has experienced rapid growth in recent years and currently provides care at six community-based cancer centers in South Central Pennsylvania.

In 2018 the Oncology Service Line recognized the potential to improve the patient experience with the development and implementation of a mobile radiation oncology application (app). This app supports the healthcare organization's goal to deliver a patient experience that is simpler, builds loyalty, and reduces patient anxiety.

Patient education is a central feature of the app. A multidisciplinary team of physicians, nurses, and radiation therapists helped to develop standardized, comprehensive, disease-site specific patient education on various radiation therapy treatment modalities and their side effects.

## An Idea is Born

The inspiration for a mobile app started during a 2018 system-wide re-evaluation of patient education materials at each of the six radiation oncology centers. The service line and radiation oncologists quickly realized that radiation therapy materials and resources varied significantly between clinic locations. In the process of implementing standardized patient education, the idea of providing consistent and targeted educational resources to patients in the form of a mobile app was proposed to WellSpan IT developers. This plan to improve and standardize patient education received early support from all clinic locations and the treating physicians.

At the time, several WellSpan service lines were exploring apps and other digital technology options, with some identifying commercially available applications that met their needs. However, given the unique needs of radiation oncology patients and the complex nature of radiation therapy treatments, Cancer Service Line leadership decided the best option was to develop an in-house app that would enable greater customization, as well as the ability to update information and patient education as needed.

## Technology and Features

Radiation Oncology collaborated with IT to design and create the app, leveraging several technologies. For example, Native iOS and Android applications were developed using Swift and Kotlin, respectively. To support the mobile app, a custom Representational State Transfer (REST) Application Programming Interface (API) was developed using Microsoft's ASP.NET Core platform. This API connects to WellSpan's Epic Instance using Epic's web services. Epic web services are used to provide authentication based on a patient's MyChart credentials and to retrieve upcoming appointments.

Patient treatment appointments are easily accessible in the app. The app interfaces with Epic, so the schedules are taken directly from WellSpan's electronic health record. Changes made in the electronic health record scheduling system automatically appear in the app. To date, this feature is the one most utilized by patients. Having the ability to see schedule changes and upcoming appointment times helps reduce patient anxiety and improves coordination of care with other specialties during treatment.

One of the most important aspects of cancer care is patient-provider communication. The app allows patients to play a more active role in communicating with their care team, as well as improved and increased communication—additional touchpoints—between treatment teams and patients.


ACCC 36th National Oncology Conference. (L to R) ACCC Executive Director Christian G. Downs, JD, MHA; ACCC Past-President Ali McBride, PharmD, MS, BCOP; Bryan Schmalhofer, MBA, RT(R)(T); and ACCC President Randall A. Oyer, MD.

Patient education is a central feature of the app. A multidisciplinary team of physicians, nurses, and radiation therapists helped to develop standardized, comprehensive, disease-site specific patient education on various radiation therapy treatment modalities and their side effects. With online educational material available on the radiation oncology app, patients and families benefited from on-demand access to treatment- and disease-specific education. (This information is not meant to replace the traditional education given to patients during treatment appointments—rather, the mobile app supplements face-to-face education and written education and is easily accessible in between appointments or when questions arise.) Providing multiple sources and platforms of information gives our patients options on how they self-educate and greater control of the role they play in their care. With a system-wide approach and standardized education, we are also more likely to direct patients toward quality and up-to-date information. Finally, patients and family members can go back and review information in the app at their own pace and when questions arise, reducing the need for patients and family members to turn to the Internet for non-vetted information.

In addition to standardization of patient education materials, Press Ganey data identified an opportunity to improve education about the management of radiation oncology treatment-related side effects. To meet this need, WellSpan partnered with ASTRO to embed its digital education platform, "RT Answers," which directs patients to relevant education based on disease site and symptoms, into the app. The app also provides vetted education videos and disease-specific "frequently asked questions" that patients can discuss with physicians and other providers before, during, and after treatment.

The app allows patients to monitor and report symptoms to their care team. Figure 1, right, illustrates the steps in patient symptom reporting. The app lets the patient select a specific symptom and rate it on a severity scale. The goal is to have patients play a more active role in their treatment and side effect management. By increasing patient awareness of common symptoms—and tracking them in the app—more effective management of symptoms and the necessary interventions are more likely to occur during treatment visits. Figure 2, right, shows sample data for a patient's average symptom ratings over time.

One of the most important aspects of cancer care is patient-provider communication. The app allows patients to play a more active role in communicating with their care team, as well as improved and increased communication—additional touchpoints—between treatment teams and patients. Building relationships with our patients and getting to know them is a fundamental WellSpan principle; gaining the trust of our patients is key, and the app allows our patients to learn more about their care teams through short biographies that providers can tailor as they see

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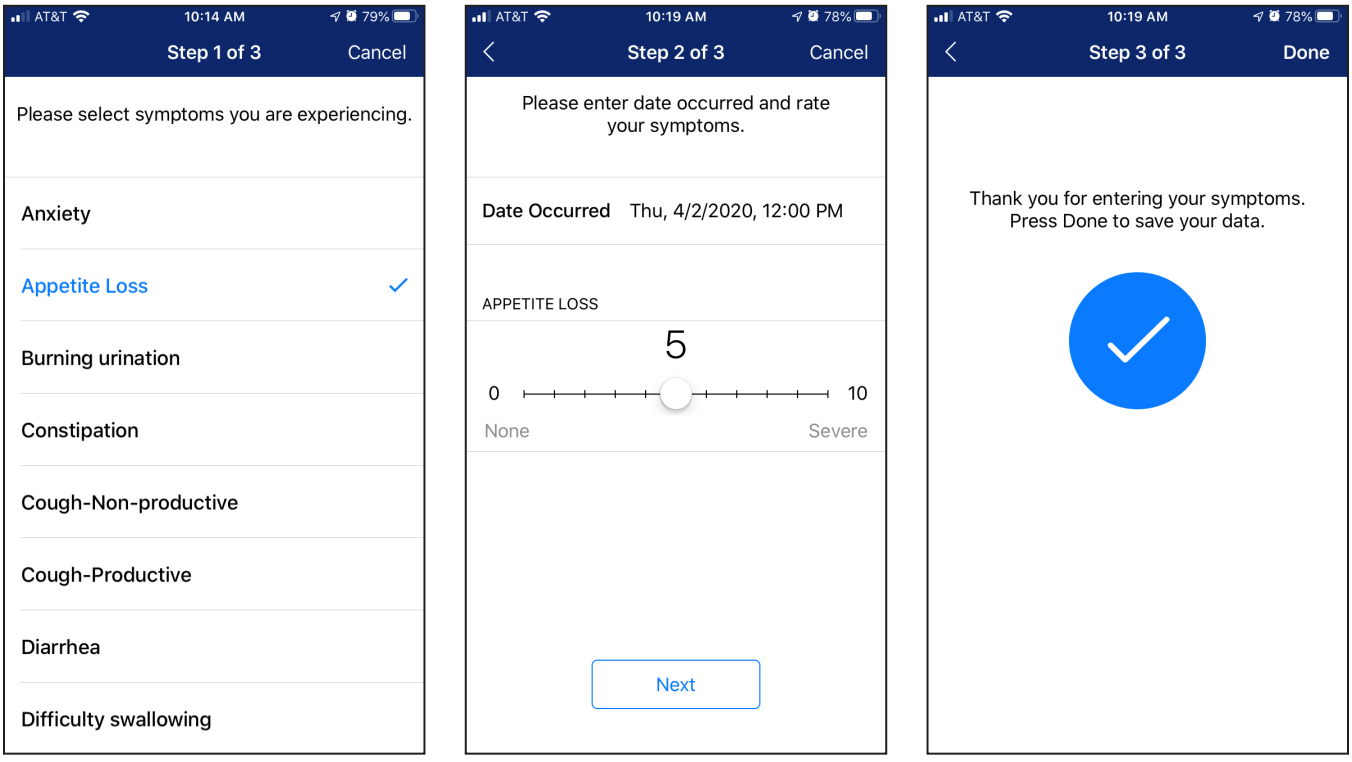
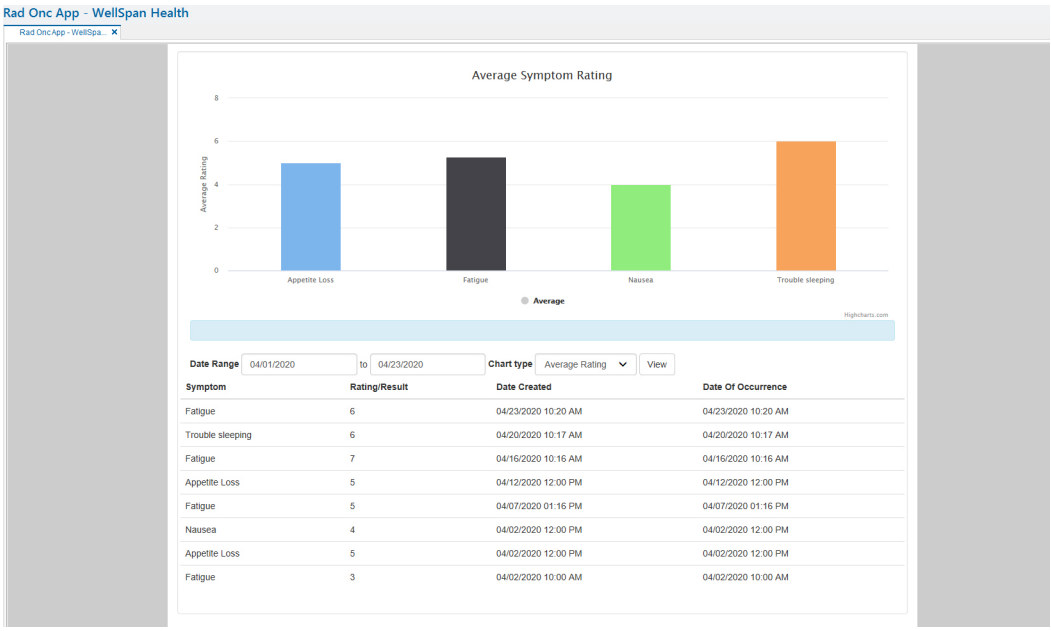
## Figure 1. Patient Symptom Reporting




## Figure 2. Sample Data of Average Symptom Ratings Reported over Time



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fit. This access to the care team adds a personal touch to the care we provide and creates connections outside of the disease and treatment.

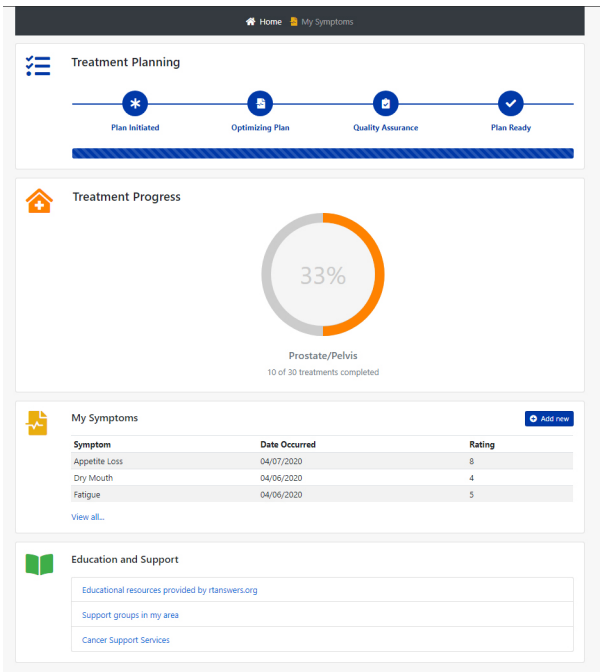
Finally, the app also includes information on available support services. All WellSpan support groups and services specific to the patients' geographical location and/or the cancer center where they receive treatment is easily accessible on the app, including links to phone numbers and websites.

## Next Steps

WellSpan has several initiatives in progress to improve the digital services we offer our patients. For example, we are currently in the process of transitioning from a standalone mobile app. The shift will include the app's functionality in MyWellSpan, WellSpan Health's implementation of Epic's MyChart platform. This platform offers patients personalized and secure access to portions of their medical records and enables secure management of information on any device—mobile, tablet, or PC. Key considerations for transitioning from a standalone mobile app to MyWellSpan are:

- An integrated online patient experience.
- Easier communication using secure messaging.
- Proxy access for family and caregivers.
- Improved awareness and access to other WellSpan services and benefits.
- Support of multiple devices.

Figure 3. Treatment Plan and Treatment Progress Indicator




Bringing the mobile app, and the work already completed, onto this system-wide platform allows us to leverage other online WellSpan initiatives, while providing a more seamless patient experience, because most of our patients are already using MyWellSpan prior to a cancer diagnosis. With the great work already happening throughout the organization to increase MyWellSpan usage, oncology service line leadership anticipates a synergistic effect, streamlining and removing barriers to patient adoption.

Another exciting development is the future integration of our Dosimetry Dashboard. Dosimetry Dashboard is a custom web app used to coordinate the treatment planning workflow. The data captured by the Dosimetry Dashboard will allow patients to monitor the progress and status of their treatment plan during this phase of care. Providing this additional information aims to reduce the anxiety experienced by many patients as they await the start of treatment. Lastly, we are evaluating the development of a treatment progress indicator that would display the remaining fractions in the current course of treatment. Figure 3, left, shows a prototype of the redesigned app as a responsive website. Giving patients visual progress indicators seeks to empower them with information and, for some, provide light at the end of the tunnel.

## Final Thoughts

A great deal of innovation and progress has happened since setting an initial goal of standardizing patient educational material. WellSpan has learned many lessons implementing its mobile app and made some thoughtful pivots along the way. With any digital strategy it is important to have a roll-out plan in place early in the process. Key considerations when implementing a new technology should include plans to enroll patients and educate staff. Gaining buy-in from all stakeholders is critical to success.

Our patients expect and deserve convenience, which can have different meanings to different people. We must remain nimble and continue to adapt to the unique needs of our patients with cancer. This objective requires our organization to continually evaluate and improve its technology. Throughout all of the changes and new developments, one constant remains: WellSpan's unwavering commitment to improving the care and experience we provide our cancer patients. Developing and implementing a mobile app has taught us to always keep the patients and their needs at the forefront of any new digital initiative. If we do so, we will successfully navigate any twists and turns along the way and continue to head in the right direction. OI

WellSpan acknowledges the efforts of Bryan Schmalhofer, MBA, RT(R)(T), former radiation oncology operations manager for the WellSpan Oncology Service Line, who was instrumental in the development and implementation of the app and who presented this 2019 ACCC Award-Winning technology at the ACCC 36th National Oncology Conference in Orlando.

# J9358

ENHERTU®
fam-trastuzumab deruxtecan-nxki
20 mg/mL INJECTION FOR INTRAVENOUS USE

4U

# Effective July 1, 2020:
# ENHERTU J-Code is available[1]

| Code | Description | Vial Size | Billing Units | NDC |
|---|---|---|---|---|
| **J9358** | Injection, fam-trastuzumab deruxtecan-nxki, 1 mg | 100 mg | 100 units | 65597-406-01 |

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**For questions or assistance, please call ENHERTU4U, Monday through Friday, 8 AM - 8 PM ET**

**1-833-ENHERTU**
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**www.ENHERTU4U.com**

## IMPORTANT SAFETY INFORMATION

### Indication

ENHERTU is a HER2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

**WARNING: INTERSTITIAL LUNG DISEASE and EMBRYO-FETAL TOXICITY**

- **Interstitial lung disease (ILD) and pneumonitis, including fatal cases, have been reported with ENHERTU. Monitor for and promptly investigate signs and symptoms including cough, dyspnea, fever, and other new or worsening respiratory symptoms. Permanently discontinue ENHERTU in all patients with Grade 2 or higher ILD/pneumonitis. Advise patients of the risk and to immediately report symptoms.**
- **Exposure to ENHERTU during pregnancy can cause embryo-fetal harm. Advise patients of these risks and the need for effective contraception.**

**Please see additional Important Safety Information and a Brief Summary of full Prescribing Information on following pages.**

# Important Safety Information

ENHERTU® 4U
fam-trastuzumab deruxtecan-nxki
20 mg/mL INJECTION FOR INTRAVENOUS USE

## WARNINGS AND PRECAUTIONS

### Interstitial Lung Disease / Pneumonitis

Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with ENHERTU. In clinical studies, of the 234 patients with unresectable or metastatic HER2-positive breast cancer treated with ENHERTU, ILD occurred in 9% of patients. Fatal outcomes due to ILD and/or pneumonitis occurred in 2.6% of patients treated with ENHERTU. Median time to first onset was 4.1 months (range: 1.2 to 8.3).

Advise patients to immediately report cough, dyspnea, fever, and/or any new or worsening respiratory symptoms. Monitor patients for signs and symptoms of ILD. Promptly investigate evidence of ILD. Evaluate patients with suspected ILD by radiographic imaging. Consider consultation with a pulmonologist. For asymptomatic ILD/pneumonitis (Grade 1), interrupt ENHERTU until resolved to Grade 0, then if resolved in ≤28 days from date of onset, maintain dose. If resolved in >28 days from date of onset, reduce dose one level. Consider corticosteroid treatment as soon as ILD/pneumonitis is suspected (e.g., ≥0.5 mg/kg prednisolone or equivalent). For symptomatic ILD/pneumonitis (Grade 2 or greater), permanently discontinue ENHERTU. Promptly initiate corticosteroid treatment as soon as ILD/pneumonitis is suspected (e.g., ≥1 mg/kg prednisolone or equivalent). Upon improvement, follow by gradual taper (e.g., 4 weeks).

### Neutropenia

Severe neutropenia, including febrile neutropenia, can occur in patients treated with ENHERTU. Of the 234 patients with unresectable or metastatic HER2-positive breast cancer who received ENHERTU, a decrease in neutrophil count was reported in 30% of patients and 16% had Grade 3 or 4 events. Median time to first onset was 1.4 months (range: 0.3 to 18.2). Febrile neutropenia was reported in 1.7% of patients.

Monitor complete blood counts prior to initiation of ENHERTU and prior to each dose, and as clinically indicated. Based on the severity of neutropenia, ENHERTU may require dose interruption or reduction. For Grade 3 neutropenia (Absolute Neutrophil Count [ANC] <1.0 to 0.5 x $10^9$/L) interrupt ENHERTU until resolved to Grade 2 or less, then maintain dose. For Grade 4 neutropenia (ANC <0.5 x $10^9$/L) interrupt ENHERTU until resolved to Grade 2 or less. Reduce dose by one level. For febrile neutropenia (ANC <1.0 x $10^9$/L and temperature >38.3°C or a sustained temperature of ≥38°C for more than 1 hour), interrupt ENHERTU until resolved. Reduce dose by one level.

### Left Ventricular Dysfunction

Patients treated with ENHERTU may be at increased risk of developing left ventricular dysfunction. Left ventricular ejection fraction (LVEF) decrease has been observed with anti-HER2 therapies, including ENHERTU. In the 234 patients with unresectable or metastatic HER2-positive breast cancer who received ENHERTU, two cases (0.9%) of asymptomatic LVEF decrease were reported. Treatment with ENHERTU has not been studied in patients with a history of clinically significant cardiac disease or LVEF <50% prior to initiation of treatment.

Assess LVEF prior to initiation of ENHERTU and at regular intervals during treatment as clinically indicated. Manage LVEF decrease through treatment interruption. Permanently discontinue ENHERTU if LVEF of <40% or absolute decrease from baseline of >20% is confirmed. When LVEF is >45% and absolute decrease from baseline is 10-20%, continue treatment with ENHERTU. When LVEF is 40-45% and absolute decrease from baseline is <10%, continue treatment with ENHERTU and repeat LVEF assessment within 3 weeks. When LVEF is 40-45% and absolute decrease from baseline is 10-20%, interrupt ENHERTU and repeat LVEF assessment within 3 weeks. If LVEF has not recovered to within 10% from baseline, permanently discontinue ENHERTU. If LVEF recovers to within 10% from baseline, resume treatment with ENHERTU at the same dose. When LVEF is <40% or absolute decrease from baseline is >20%, interrupt ENHERTU and repeat LVEF assessment within 3 weeks. If LVEF of <40% or absolute decrease from baseline of >20% is confirmed, permanently discontinue ENHERTU. Permanently discontinue ENHERTU in patients with symptomatic congestive heart failure.

### Embryo-Fetal Toxicity

ENHERTU can cause fetal harm when administered to a pregnant woman. Advise patients of the potential risks to a fetus. Verify the pregnancy status of females of reproductive potential prior to the initiation of ENHERTU. Advise females of reproductive potential to use effective contraception during treatment and for at least 7 months following the last dose of ENHERTU.

Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 4 months after the last dose of ENHERTU.

## Adverse Reactions

The safety of ENHERTU was evaluated in a pooled analysis of 234 patients with unresectable or metastatic HER2-positive breast cancer who received at least one dose of ENHERTU 5.4 mg/kg in DESTINY-Breast01 and Study DS8201-A-J101. ENHERTU was administered by intravenous infusion once every three weeks. The median duration of treatment was 7 months (range: 0.7 to 31).

Serious adverse reactions occurred in 20% of patients receiving ENHERTU. Serious adverse reactions in >1% of patients who received ENHERTU were interstitial lung disease, pneumonia, vomiting, nausea, cellulitis, hypokalemia, and intestinal obstruction. Fatalities due to adverse reactions occurred in 4.3% of patients including interstitial lung disease (2.6%), and the following events occurred in one patient each (0.4%): acute hepatic failure/acute kidney injury, general physical health deterioration, pneumonia, and hemorrhagic shock.

ENHERTU was permanently discontinued in 9% of patients, of which ILD accounted for 6%. Dose interruptions due to adverse reactions occurred in 33% of patients treated with ENHERTU. The most frequent adverse reactions (>2%) associated with dose interruption were neutropenia, anemia, thrombocytopenia, leukopenia, upper respiratory tract infection, fatigue, nausea, and ILD. Dose reductions occurred in 18% of patients treated with ENHERTU. The most frequent adverse reactions (>2%) associated with dose reduction were fatigue, nausea, and neutropenia.

The most common adverse reactions (frequency ≥20%) were nausea (79%), fatigue (59%), vomiting (47%), alopecia (46%), constipation (35%), decreased appetite (32%), anemia (31%), neutropenia (29%), diarrhea (29%), leukopenia (22%), cough (20%), and thrombocytopenia (20%).

## Use in Specific Populations

- **Pregnancy:** ENHERTU can cause fetal harm when administered to a pregnant woman. Advise patients of the potential risks to a fetus. There are clinical considerations if ENHERTU is used in pregnant women, or if a patient becomes pregnant within 7 months following the last dose of ENHERTU.
- **Lactation:** There are no data regarding the presence of ENHERTU in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with ENHERTU and for 7 months after the last dose.
- **Females and Males of Reproductive Potential:** Pregnancy testing: Verify pregnancy status of females of reproductive potential prior to initiation of ENHERTU. Contraception: *Females*: ENHERTU can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 7 months following the last dose. *Males*: Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 4 months following the last dose. Infertility: ENHERTU may impair male reproductive function and fertility.
- **Pediatric Use:** Safety and effectiveness of ENHERTU have not been established in pediatric patients.
- **Geriatric Use:** Of the 234 patients with HER2-positive breast cancer treated with ENHERTU 5.4 mg/kg, 26% were ≥65 years and 5% were ≥75 years. No overall differences in efficacy were observed between patients ≥65 years of age compared to younger patients. There was a higher incidence of Grade 3-4 adverse reactions observed in patients aged ≥65 years (53%) as compared to younger patients (42%).
- **Hepatic Impairment:** In patients with moderate hepatic impairment, due to potentially increased exposure, closely monitor for increased toxicities related to the topoisomerase inhibitor.

**To report SUSPECTED ADVERSE REACTIONS, contact Daiichi Sankyo, Inc, at 1-877-437-7763 or FDA at 1-800-FDA-1088 or fda.gov/medwatch.**

**Please see a Brief Summary of full Prescribing Information on following pages.**

**Reference: 1.** Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions. https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-1-2020-drugs-and-biologicals.pdf. Accessed April 6, 2020.

ENHERTU4U provides patients and their providers access and reimbursement support for ENHERTU. Reimbursement is not guaranteed.



Daiichi-Sankyo | AstraZeneca

**ENHERTU® (fam-trastuzumab deruxtecan-nxki) for injection, for intravenous use**
**Initial U.S. Approval: 2019**

**BRIEF SUMMARY: See package insert for full prescribing information.**

**WARNING: INTERSTITIAL LUNG DISEASE and EMBRYO-FETAL TOXICITY**

- **Interstitial Lung Disease (ILD) and pneumonitis, including fatal cases, have been reported with ENHERTU. Monitor for and promptly investigate signs and symptoms including cough, dyspnea, fever, and other new or worsening respiratory symptoms. Permanently discontinue ENHERTU in all patients with Grade 2 or higher ILD/pneumonitis. Advise patients of the risk and the need to immediately report symptoms *[see Dosage and Administration (2.2) in the full prescribing information, Warnings and Precautions (5.1)]*.**
- **Embryo-Fetal Toxicity: Exposure to ENHERTU during pregnancy can cause embryo-fetal harm. Advise patients of these risks and the need for effective contraception *[see Warnings and Precautions (5.4), Use in Specific Populations (8.1, 8.3)]*.**

## 1 INDICATIONS AND USAGE

ENHERTU is indicated for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

This indication is approved under accelerated approval based on tumor response rate and duration of response *[see Clinical Studies (14.1) in the full prescribing information]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

## 4 CONTRAINDICATIONS

None.

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Interstitial Lung Disease/Pneumonitis

Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with ENHERTU *[see Adverse Reactions (6.1)]*. In clinical studies, of the 234 patients with unresectable or metastatic HER2-positive breast cancer treated with ENHERTU, ILD occurred in 9% of patients. Fatal outcomes due to ILD and/or pneumonitis occurred in 2.6% of patients treated with ENHERTU. Median time to first onset was 4.1 months (range: 1.2 to 8.3).

Advise patients to immediately report cough, dyspnea, fever, and/or any new or worsening respiratory symptoms. Monitor patients for signs and symptoms of ILD. Promptly investigate evidence of ILD. Evaluate patients with suspected ILD by radiographic imaging. Consider consultation with a pulmonologist. For asymptomatic (Grade 1) ILD, consider corticosteroid treatment (e.g., ≥0.5 mg/kg prednisolone or equivalent). Withhold ENHERTU until recovery *[see Dosage and Administration (2.2) in the full prescribing information]*. In cases of symptomatic ILD (Grade 2 or greater), promptly initiate corticosteroid treatment (e.g., ≥1 mg/kg prednisolone or equivalent). Upon improvement, follow by gradual taper (e.g., 4 weeks). Permanently discontinue ENHERTU in patients who are diagnosed with any symptomatic (Grade 2 or greater) ILD *[see Dosage and Administration (2.2) in the full prescribing information]*.

### 5.2 Neutropenia

Severe neutropenia, including febrile neutropenia, can occur in patients treated with ENHERTU. Of the 234 patients with unresectable or metastatic HER2-positive breast cancer who received ENHERTU, a decrease in neutrophil count was reported in 30% of patients and 16% had Grade 3 or 4 events. Median time to first onset was 1.4 months (range: 0.3 to 18.2). Febrile neutropenia was reported in 1.7% of patients.

Monitor complete blood counts prior to initiation of ENHERTU and prior to each dose, and as clinically indicated. Based on the severity of neutropenia, ENHERTU may require dose interruption or reduction *[see Dosage and Administration (2.2) in the full prescribing information]*.

### 5.3 Left Ventricular Dysfunction

Patients treated with ENHERTU may be at increased risk of developing left ventricular dysfunction. Left ventricular ejection fraction (LVEF) decrease has been observed with anti-HER2 therapies, including ENHERTU. In the 234 patients with unresectable or metastatic HER2-positive breast cancer who received ENHERTU, two cases (0.9%) of asymptomatic LVEF decrease were reported. Treatment with ENHERTU has not been studied in patients with a history of clinically significant cardiac disease or LVEF less than 50% prior to initiation of treatment.

Assess LVEF prior to initiation of ENHERTU and at regular intervals during treatment as clinically indicated. Manage LVEF decrease through treatment interruption. Permanently discontinue ENHERTU if LVEF of less than 40% or absolute decrease from baseline of greater than 20% is confirmed. Permanently discontinue ENHERTU in patients with symptomatic congestive heart failure (CHF) *[see Dosage and Administration (2.2) in the full prescribing information]*.

### 5.4 Embryo-Fetal Toxicity

Based on its mechanism of action, ENHERTU can cause fetal harm when administered to a pregnant woman. In postmarketing reports, use of a HER2-directed antibody during pregnancy resulted in cases of oligohydramnios manifesting as fatal pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Based on its mechanism of action, the topoisomerase inhibitor component of ENHERTU, DXd, can also cause embryo-fetal harm when administered to a pregnant woman because it is genotoxic and targets actively dividing cells *[see Use in Specific Populations (8.1), Clinical Pharmacology (12.1), Nonclinical Toxicology (13.1) in the full prescribing information]*. Advise patients of the potential risks to a fetus.

Verify the pregnancy status of females of reproductive potential prior to the initiation of ENHERTU. Advise females of reproductive potential to use effective contraception during treatment and for at least 7 months following the last dose of ENHERTU. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 4 months after the last dose of ENHERTU *[see Use in Specific Populations (8.1, 8.3)]*.

## 6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Interstitial Lung Disease / Pneumonitis *[see Warnings and Precautions (5.1)]*
- Neutropenia *[see Warnings and Precautions (5.2)]*
- Left Ventricular Dysfunction *[see Warnings and Precautions (5.3)]*

### 6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of ENHERTU was evaluated in a pooled analysis of 234 patients with unresectable or metastatic HER2-positive breast cancer who received at least one dose of ENHERTU 5.4 mg/kg in DESTINY-Breast01 and Study DS8201-A-J101 (NCT02564900). ENHERTU was administered by intravenous infusion once every three weeks. The median duration of treatment was 7 months (range: 0.7 to 31).

In the pooled 234 patients, the median age was 56 years (range: 28-96), 74% of patients were <65 years, 99.6% of patients were female, and the majority were White (51%) or Asian (42%). Patients had an ECOG performance status of 0 (58%) or 1 (42%) at baseline. Ninety-four percent had visceral disease, 31% had bone metastases, and 13% had brain metastases.

Serious adverse reactions occurred in 20% of patients receiving ENHERTU. Serious adverse reactions in >1% of patients who received ENHERTU were interstitial lung disease, pneumonia, vomiting, nausea, cellulitis, hypokalemia, and intestinal obstruction. Fatalities due to adverse reactions occurred in 4.3% of patients including interstitial lung disease (2.6%), and the following events occurred in one patient each (0.4%): acute hepatic failure/acute kidney injury, general physical health deterioration, pneumonia, and hemorrhagic shock.

ENHERTU was permanently discontinued in 9% of patients, of which ILD accounted for 6%. Dose interruptions due to adverse reactions occurred in 33% of patients treated with ENHERTU. The most frequent adverse reactions (>2%) associated with dose interruption were neutropenia, anemia, thrombocytopenia, leukopenia, upper respiratory tract infection, fatigue, nausea, and ILD. Dose reductions occurred in 18% of patients treated with ENHERTU. The most frequent adverse reactions (>2%) associated with dose reduction were fatigue, nausea, and neutropenia.

The most common adverse reactions (frequency ≥20%) were nausea, fatigue, vomiting, alopecia, constipation, decreased appetite, anemia, neutropenia, diarrhea, leukopenia, cough, and thrombocytopenia.

Tables 3 and 4 summarize common adverse reactions and laboratory abnormalities observed in ENHERTU-treated patients.

**Table 3: Common Adverse Reactions (≥10% All Grades or ≥2% Grades 3 or 4) in Patients in DESTINY-Breast01 and Study DS8201-A-J101**

| Adverse Reactions | ENHERTU 5.4 mg/kg N=234 | |
|---|---|---|
| | All Grades % | Grades 3 or 4 % |
| **Gastrointestinal Disorders** | | |
| Nausea | 79 | 7 |
| Vomiting | 47 | 3.8 |
| Constipation | 35 | 0.9 |
| Diarrhea | 29 | 1.7 |
| Abdominal pain[a] | 19 | 1.3 |
| Stomatitis[b] | 14 | 0.9 |
| Dyspepsia | 12 | 0 |
| **General Disorders and Administration Site Conditions** | | |
| Fatigue[c] | 59 | 6 |
| **Skin and Subcutaneous Tissue Disorders** | | |
| Alopecia | 46 | 0.4[d] |
| Rash[e] | 10 | 0 |

(continued)

**Table 3: Common Adverse Reactions (≥10% All Grades or ≥2% Grades 3 or 4) in Patients in DESTINY-Breast01 and Study DS8201-A-J101**

| Adverse Reactions | ENHERTU 5.4 mg/kg N=234 | |
|---|---|---|
| | All Grades % | Grades 3 or 4 % |
| **Metabolism and Nutrition Disorders** | | |
| Decreased appetite | 32 | 1.3 |
| Hypokalemia | 12 | 3.4 |
| **Blood and Lymphatic System Disorders** | | |
| Anemia[f] | 31 | 7 |
| Neutropenia[g] | 29 | 16 |
| Leukopenia[h] | 22 | 6 |
| Thrombocytopenia[i] | 20 | 3.4 |
| **Respiratory, Thoracic and Mediastinal Disorders** | | |
| Cough | 20 | 0 |
| Dyspnea | 13 | 1.3 |
| Epistaxis | 13 | 0 |
| Interstitial lung disease[j] | 9 | 2.6[k] |
| **Nervous System Disorders** | | |
| Headache[l] | 19 | 0 |
| Dizziness | 10 | 0 |
| **Infections and Infestation** | | |
| Upper respiratory tract infection[m] | 15 | 0 |
| **Investigations** | | |
| Aspartate aminotransferase increased | 14 | 0.9 |
| Alanine aminotransferase increased | 10 | 0.9 |
| **Eye Disorders** | | |
| Dry eye | 11 | 0.4[n] |

Events were graded using NCI-CTCAE version 4.03. N=number of patients exposed;
PT = preferred term.
Percentages were calculated using the number of patients in the Safety Analysis Set as the denominator.

a Grouped term of abdominal pain includes PTs of abdominal discomfort, gastrointestinal pain, abdominal pain, abdominal pain lower, and abdominal pain upper.
b Grouped term of stomatitis includes PTs of stomatitis, aphthous ulcer, mouth ulceration, oral mucosa erosion, and oral mucosa blistering. One Grade 1 event of aphthous ulcer was not included in the summary of grouped term stomatitis (from DESTINY-Breast01).
c Grouped term of fatigue includes PTs of fatigue and asthenia.
d This Grade 3 event was reported by the investigator. Per NCI-CTCAE v.4.03, the highest NCI-CTCAE grade for alopecia is Grade 2.
e Grouped term of rash includes PTs of rash, rash pustular, rash maculo-papular.
f Grouped term of anemia includes PTs of anemia, hemoglobin decreased, hematocrit decreased, and red blood cell count decreased.
g Grouped term of neutropenia includes PTs of neutropenia and neutrophil count decreased.
h Grouped term of leukopenia includes PTs of leukopenia, lymphopenia, and white blood cell count decreased.
i Grouped term of thrombocytopenia includes PTs of thrombocytopenia and platelet count decreased.
j Interstitial lung disease includes events that were adjudicated as ILD: pneumonitis, interstitial lung disease, respiratory failure, organizing pneumonia, acute respiratory failure, lung infiltration, lymphangitis, alveolitis.
k All events had fatal outcomes (n=6).
l Grouped term of headache includes PTs headache, sinus headache, and migraine.
m Grouped term of upper respiratory tract infection includes PTs influenza, influenza like illness, upper respiratory tract infection.
n This Grade 4 event was reported by the investigator. Per NCI-CTCAE v.4.03, the highest NCI-CTCAE grade for dry eye is Grade 3.

Other clinically relevant adverse reactions reported in less than 10% of patients were:

- *Injury, Poisoning and Procedural Complications*: infusion-related reactions (2.6%)
- *Blood and Lymphatic System Disorders*: febrile neutropenia (1.7%)

**Table 4: Selected Laboratory Abnormalities in Patients with Unresectable or Metastatic HER2-positive Breast Cancer Treated with ENHERTU**

| Laboratory Parameter | ENHERTU 5.4 mg/kg N = 234 | |
|---|---|---|
| | All Grades % | Grades 3 or 4 % |
| **Hematology** | | |
| White blood cell count decreased | 70 | 7 |
| Hemoglobin decreased | 70 | 7 |
| Neutrophil count decreased | 62 | 16 |
| Platelet count decreased | 37 | 3.4 |

(continued)

**Table 4: Selected Laboratory Abnormalities in Patients with Unresectable or Metastatic HER2-positive Breast Cancer Treated with ENHERTU**

| Laboratory Parameter | ENHERTU 5.4 mg/kg N = 234 | |
|---|---|---|
| | All Grades % | Grades 3 or 4 % |
| **Chemistry** | | |
| Aspartate aminotransferase increased | 41 | 0.9 |
| Alanine aminotransferase increased | 38 | 0.4 |
| Hypokalemia | 26 | 3.0 |

Percentages were calculated using patients with worsening laboratory values from baseline and the number of patients with both baseline and post-treatment measurements as the denominator. Frequencies were based on NCI-CTCAE v.4.03 grade-derived laboratory abnormalities.

### 6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparisons of the incidence of antibodies to ENHERTU in the studies described below with the incidence of antibodies in other studies or to other products may be misleading.

Treatment-induced anti-fam-trastuzumab deruxtecan-nxki antibodies (ADA) developed in 0.6% (4/640) patients who received ENHERTU across all doses. Due to the limited number of patients who tested positive for ADA, no conclusions can be drawn concerning a potential effect of immunogenicity on efficacy or safety. In addition, neutralizing activity of anti-ENHERTU antibodies has not been assessed.

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

Risk Summary

Based on its mechanism of action, ENHERTU can cause fetal harm when administered to a pregnant woman. There are no available data on the use of ENHERTU in pregnant women. In postmarketing reports, use of a HER2-directed antibody during pregnancy resulted in cases of oligohydramnios manifesting as fatal pulmonary hypoplasia, skeletal abnormalities, and neonatal death *[see Data]*. Based on its mechanism of action, the topoisomerase inhibitor component of ENHERTU, DXd, can also cause embryo-fetal harm when administered to a pregnant woman because it is genotoxic and targets actively dividing cells *[see Clinical Pharmacology (12.1), Nonclinical Toxicology (13.1) in the full prescribing information]*. Advise patients of the potential risks to a fetus.

There are clinical considerations if ENHERTU is used in pregnant women, or if a patient becomes pregnant within 7 months following the last dose of ENHERTU *[see Clinical Considerations]*.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Clinical Considerations

*Fetal/Neonatal Adverse Reactions*

Monitor women who received ENHERTU during pregnancy or within 7 months prior to conception for oligohydramnios. If oligohydramnios occurs, perform fetal testing that is appropriate for gestational age and consistent with community standards of care.

Data

*Human Data*

There are no available data on the use of ENHERTU in pregnant women. In postmarketing reports in pregnant women receiving a HER2-directed antibody, cases of oligohydramnios manifesting as fatal pulmonary hypoplasia, skeletal abnormalities, and neonatal death have been reported. These case reports described oligohydramnios in pregnant women who received a HER2-directed antibody either alone or in combination with chemotherapy. In some case reports, amniotic fluid index increased after use of a HER2-directed antibody was stopped.

*Animal Data*

There were no animal reproductive or developmental toxicity studies conducted with fam-trastuzumab deruxtecan-nxki.

### 8.2 Lactation

Risk Summary

There is no data regarding the presence of fam-trastuzumab deruxtecan-nxki in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with ENHERTU and for 7 months after the last dose.

**8.3 Females and Males of Reproductive Potential**

Pregnancy Testing

Verify pregnancy status of females of reproductive potential prior to initiation of ENHERTU.

Contraception

*Females*

ENHERTU can cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1)]*. Advise females of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 7 months following the last dose.

*Males*

Because of the potential for genotoxicity, advise male patients with female partners of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 4 months following the last dose *[see Nonclinical Toxicology (13.1) in the full prescribing information]*.

Infertility

Based on findings in animal toxicity studies, ENHERTU may impair male reproductive function and fertility *[see Nonclinical Toxicology (13.1) in the full prescribing information]*.

**8.4 Pediatric Use**

Safety and effectiveness of ENHERTU have not been established in pediatric patients.

**8.5 Geriatric Use**

Of the 234 patients with HER2-positive breast cancer treated with ENHERTU 5.4 mg/kg, 26% were 65 years or older and 5% were 75 years or older. No overall differences in efficacy were observed between patients ≥65 years of age compared to younger patients. There was a higher incidence of Grade 3-4 adverse reactions observed in patients aged 65 years or older (53%) as compared to younger patients (42%).

**8.6 Renal Impairment**

No dose adjustment of ENHERTU is required in patients with mild (creatinine clearance (CLcr) ≥60 and <90 mL/min) or moderate (CLcr ≥30 and <60 mL/min) renal impairment *[see Clinical Pharmacology (12.3) in the full prescribing information]*. No data are available in patients with severe renal impairment.

**8.7 Hepatic Impairment**

No dose adjustment of ENHERTU is required in patients with mild (total bilirubin ≤ULN and any AST >ULN or total bilirubin >1 to 1.5 times ULN and any AST) or moderate (total bilirubin >1.5 to 3 times ULN and any AST) hepatic impairment. In patients with moderate hepatic impairment, due to potentially increased exposure, closely monitor for increased toxicities related to the topoisomerase inhibitor, DXd *[see Dosage and Administration (2.2) in the full prescribing information]*. No data are available in patients with severe (total bilirubin >3 to 10 times ULN and any AST) hepatic impairment *[see Clinical Pharmacology (12.3) in the full prescribing information]*.

**17 PATIENT COUNSELING INFORMATION**

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Interstitial Lung Disease

- Inform patients of the risks of severe or fatal ILD. Advise patients to contact their healthcare provider immediately for any of the following: cough, shortness of breath, fever, or other new or worsening respiratory symptoms *[see Warnings and Precautions (5.1)]*.

Neutropenia

- Advise patients of the possibility of developing neutropenia and to immediately contact their healthcare provider should they develop a fever, particularly in association with any signs of infection *[see Warnings and Precautions (5.2)]*.

Left Ventricular Dysfunction

- Advise patients to contact their healthcare provider immediately for any of the following: new onset or worsening shortness of breath, cough, fatigue, swelling of ankles/legs, palpitations, sudden weight gain, dizziness, loss of consciousness *[see Warnings and Precautions (5.3)]*.

Embryo-Fetal Toxicity

- Inform female patients of the potential risk to a fetus. Advise female patients to contact their healthcare provider of a known or suspected pregnancy *[see Warnings and Precautions (5.4), Use in Specific Populations (8.1)]*.
- Advise females of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 7 months after the last dose *[see Use in Specific Populations (8.3)]*.
- Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 4 months after the last dose *[see Use in Specific Populations (8.3)]*.

Lactation

- Advise women not to breastfeed during treatment and for 7 months after the last dose of ENHERTU *[see Use in Specific Populations (8.2)]*.

Infertility

- Advise males of reproductive potential that ENHERTU may impair fertility *[see Use in Specific Populations (8.3)]*.

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USPI-ENH-C1-1219-r001-B

BY ERICA MARTINEZ, RN, CHPN, OCN


# Genetic Cancer Screening and Testing in a Medically Underserved Community

Genetic screening and testing are paving the way for improved patient care and outcomes on a broad scale that encompasses both cancer treatment and prevention. Access to this testing is key to identifying and thereby reducing disease burden, suffering, and cost. Being able to offer patients genetic screening and testing services also helps cancer programs provide the highest level of care. For medically underserved and rural regions, multiple barriers can limit access to these services, including cost and cultural and geographic challenges. This article describes how a community cancer center in rural Arizona overcame these obstacles so that patients receive genetic testing and counseling at no cost.

## The Partnership

Prior to September 2018, Yuma Regional Medical Center Cancer Center in Yuma, Ariz., had limited access to genetic testing services. There are no genetic counselors in Yuma, a geographically expansive, medically underserved city of 200,000. Before 2018, if patients wanted to receive genetic counseling services, they often had to travel more than 180 miles to do so. This was not a feasible option for most cancer patients.

> In the first four months of the program's implementation, Yuma Cancer Center achieved a four-fold increase in genetic testing.

Yuma Cancer Center's patient population is largely Hispanic and elderly. Many patients are uninsured, underinsured, or low-income. To break down these barriers to care, the cancer center sought a way to provide free genetic screening and access to genetic counseling and testing to all its patients. Accordingly, in September 2018, Yuma Cancer Center entered into a collaborative partnership with Myriad Genetics—a molecular diagnostic company based in Salt Lake City, Utah. It was an easy decision to make, because Myriad permitted the cancer center to use its tele-education and genetic counseling services at zero cost to the facility and its patients. (Yuma Regional Medical Center is not

obligated to use Myriad Genetics testing services; patients can request that tests be sent to a preferred laboratory.)

In the eight months preceding the launch of the partnership with Myriad Genetics, only 24 patients at Yuma Cancer Center were referred for genetic testing. In the first four months of the new program, 54 out of the 222 patients the cancer center screened underwent genetic testing.

## The Process

The collaboration required participation from the cancer center's registration team, medical assistants, oncology nurse navigators, and medical oncologists, who together designed and implemented the new program. The interdisciplinary team incorporated genetic screening into the cancer center's workflow for registering new patients. When new patients check in, registration staff help them complete a hereditary cancer quiz. This simple screening tool is used to flag patients who may need to be evaluated by a genetic counselor. The quizzes are forwarded to Myriad Genetics, where a determination is made on whether the patient needs further assessment. If a patient is determined not to require assessment, a white laminated card is placed in the patient's chart indicating that no further action is necessary. The process ends for these patients.

If the hereditary cancer quiz shows that a patient needs further assessment by a genetic counselor, a blue laminated card is placed in the patient's chart. This alerts providers that a genetic consult and testing appointment should be ordered. Providers indicate at check-out that a tele-education visit with one of Myriad's genetic counselors is necessary and the visit is scheduled. (Figure 1, right, illustrates this workflow.)

## Tele-Education Visits

When patients arrive for their tele-education visits with a genetic counselor, the medical assistant escorts them to a designated room that is set up with a telephone and tablet provided by Myriad Genetics. At the start of the appointment, patients watch a short video on genetics and hereditary cancer screening.

After watching the video, patients place a call to the Myriad Genetics tele-education line, and they undergo a comprehensive hereditary risk assessment on the phone with a genetic counselor. On average, the tele-education appointment lasts between 30 to 40 minutes. Spanish-speaking genetic counselors are available for Spanish-speaking patients. After the assessment, the genetic counselor immediately emails a copy of the patient's assessment to the medical assistant and oncology nurse navigator at Yuma.

Patients who meet National Comprehensive Cancer Network guidelines for genetic testing complete the necessary paperwork (a test requisition and an application for financial assistance if needed) with help from their provider and the medical assistant. Patients are then escorted to the laboratory draw station where the patient's blood specimen is collected and sent to Myriad Genetics. Patients receive the results at their next follow-up appointment at the cancer center, typically within two weeks.

For patients who test positive, Myriad Genetics provides additional information for them to share with their family members and other medical providers. Yuma Regional Medical Center's oncology nurse navigators are available to meet with family members to educate and support them.

## Billing and Reimbursement

Myriad Genetics provides the tele-education components of the program—including the hereditary cancer quiz, educational video, and comprehensive education and assessment—free of charge to patients at the Yuma Cancer Center. The genetic test itself is a separate component that Myriad bills through the patients' insurance. These tests are treated like any other bill-for-service a patient receives. If a payer requires prior authorization before the test can be ordered, nurse navigators obtain the necessary documentation. For patients who do not have insurance or cannot afford genetic testing, Myriad Genetics has financial assistance options available. Oncology nurse navigators at the cancer center also work with patients to identify financial resources to pay for testing.

## Program Results

In the first four months of the program's implementation, Yuma Cancer Center achieved a four-fold increase in genetic testing. During that time, 222 patients at Yuma Cancer Center completed the hereditary cancer quiz. Of those 222 patients, 108 were flagged to proceed with tele-education and assessment. Of those 108 patients, 54 followed through with genetic testing.

Seven months post-implementation, 76 genetic tests were ordered. Sixty-seven of those tests were completed. Of the 67 completed tests, 6 resulted in gene-positive results, and another 10 returned with high-risk negative results. In total, about 24 percent of patients who received genetic testing saw a change in their clinical management.

## Key Takeaways

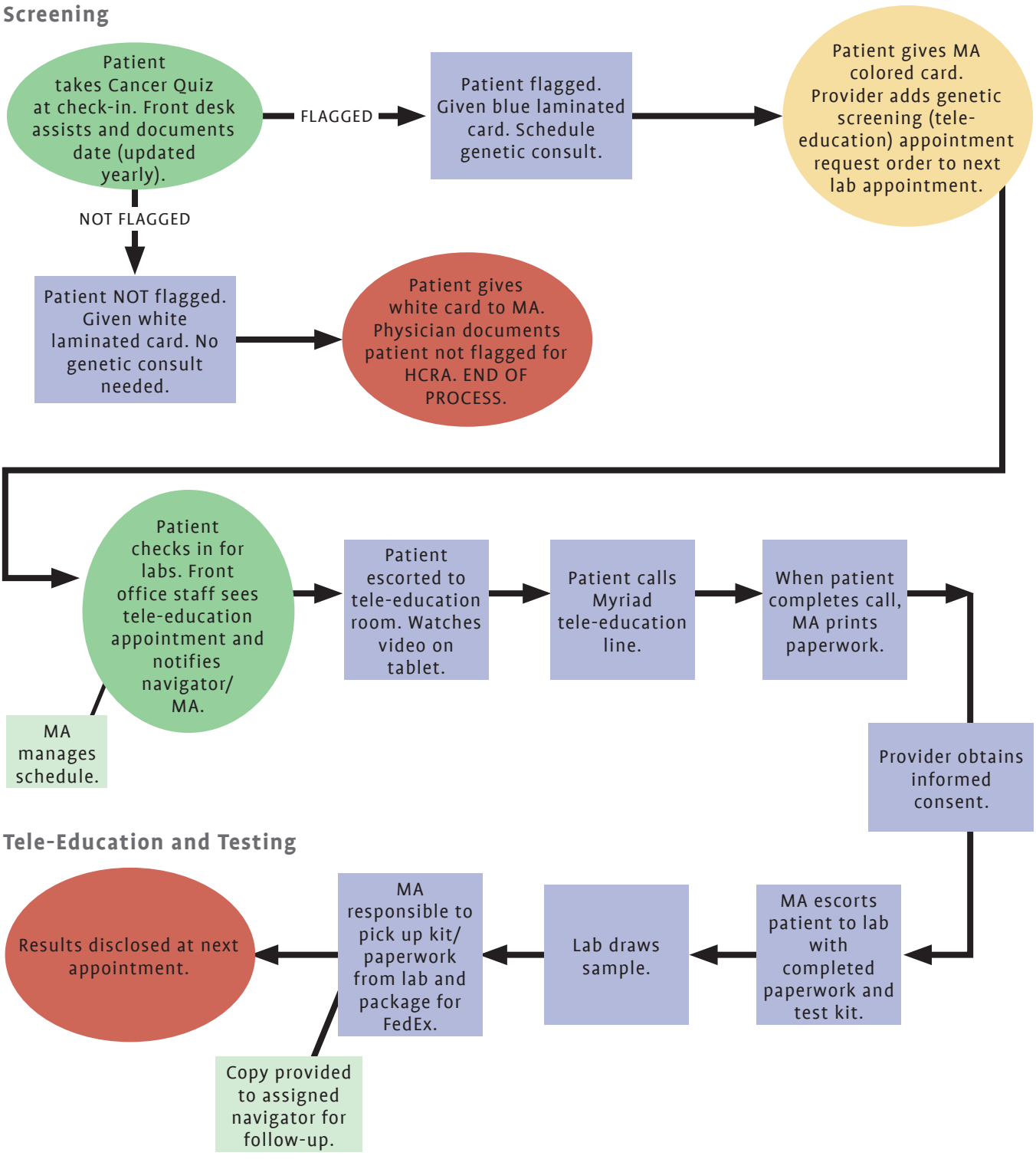
Yuma Cancer Center's genetic screening and education is the fruit of a successful collaboration between a community cancer center and a genetic testing company. It is important to note that no additional full-time equivalents were needed to develop and implement this program.

If done correctly, this model can be replicated by other cancer programs—whether they are hospital-based or freestanding practices—and in disciplines other than oncology. A similar program at Yuma Regional Medical Center's woman's health clinic was launched after the successful implementation of the genetic screening program at Yuma's Cancer Center. Yuma is also looking to implement genetic screening and tele-education at its breast imaging center and family medicine clinics.

Currently, genetic screening and testing at Yuma's Cancer Center is limited to patients with known cancer diagnoses. Yuma Regional Medical Center would like to expand this service to all patients consulted at the cancer center. We are also exploring ways to provide testing to family members of those patients who test positive. OI

*Erica Martinez, RN, CHPN, OCN, is an oncology nurse navigator with Yuma Regional Medical Center Cancer Center in Yuma, Ariz.*

Figure 1. Yuma Cancer Center Tele-Education Workflow




*Note:* MA = medical assistant; HCRA = hereditary cancer risk assessment.

# action

## ACCC Welcomes Its Newest Members

**CHI Saint Joseph Lexington Cancer Center**
Lexington, Kentucky
Delegate Rep: Greg Bodager, MSN
Website: chisaintjosephhealth.org/lexington-cancer-care

**Fort Wayne Medical Oncology and Hematology, Inc.**
Fort Wayne, Ind.
Delegate Rep: Carrie Asher
Website: fwmoh.com

**Scotland Memorial Hospital**
**Scotland Cancer Treatment Center**
Laurinburg, N.C.
Delegate Rep: Paula Love, RN, BSN, CLNC
Website: scotlandhealth.org/medical-services/cancer-center-duke-health-affiliate

**Utah Cancer Specialists**
Salt Lake City, Utah
Delegate Rep: Amy Pasmann, MS, RN
Website: utahcancer.com

## ACCC Launches a New Membership Platform!

On May 20 ACCC launched its new online features, making your online experience more seamless, intuitive, and engaging. Here's what you can expect:

- You will be able to sign into our website, eLearning platform, and ACCCeXchange with the same login information.
- ACCCeXchange (the listserv) has a new look, which will make asking questions and sharing information with your peers even easier.
- A revitalized ACCCeLearning experience will make professional development more streamlined than ever before. With a cleaner look and a growing catalog of online education, ACCC will offer more virtual content for the multidisciplinary team.

**How to Update Your Information**

1. Go to accc-cancer.org and click "Log in" at the top of the page.
2. Create a password.
3. Once your password is created, you will be linked to your "My Profile" page, where you can view and update your information. Click "Change" on the right side of the screen to make any changes.
4. Please take a moment to indicate your areas of concentration from the drop-down menu. This is a new feature that will allow us to provide you with relevant resources, better understand your needs, and effectively communicate about our education programs. Select as many as apply.

For answers to any questions you may have and for a deeper dive into these updates, visit the ACCC FAQ page at accc-cancer.org/home/connect/accc-faq.

## Featured Clinical Research Trial:
### The ASCO Survey on COVID-19 in Oncology (ASCO) Registry

ACCC is partnering with ASCO on this important registry trial that looks to close the COVID-19 and cancer data gap. And we strongly urge ACCC members to help take something positive away from this national medical emergency by helping ASCO, ACCC, and the greater oncology community gather, capture, and analyze critical data on clinical care to help:

- Analyze distribution of symptoms and severity of COVID-19 among people with cancer.
- Examine the impact of COVID-19 on cancer treatment and outcomes.
- Document how cancer care delivery has been affected by the pandemic. For example, what steps and processes did cancer programs take to protect patients and staff?

The registry is collecting both patient and practice data. Patient data includes the number of patients with a confirmed COVID-19 diagnosis AND 1) initiating treatment for new diagnosis, OR 2) with clinically evident cancer receiving anti-cancer treatment, OR 3) with clinically evident cancer receiving supportive care only, OR 4) disease-free but receiving adjuvant therapy within 1 year after surgical resection. Practice data includes:

- Number of confirmed COVID-19 cases
- Use of telemedicine
- Modifications of infusions and other treatments
- Screening and triaging processes
- Physical changes to clinic workflows
- Drug and PPE shortages
- Staffing changes.

Participation is easy. First, execute a research participation and data use agreement with ASCO. Second, submit your data to ASCO via web-based REDCap forms (ASCO will de-identify and provide data back for your own use) OR collect data locally using a "cloned" REDCap project and upload data to ASCO monthly. Keep in mind: the ASCO Registry qualifies as a High-Weighted Practice Improvement Activity under the Merit-based Incentive Payment System (MIPS). Interested programs and practices can find agreement and data capture forms online at asco.org/asco-coronavirus-information/coronavirus-registry.

# A New ACCC Online Experience!

## Your accc-cancer.org experience is now more seamless, intuitive, and engaging!

You can now sign into our website, eLearning platform, and register for meetings with the same login information. Go to https://accc.force.com/login to start. Click on "Reset Password" to activate your account, then go to your "My Profile" page to update your personal information and indicate your Areas of Concentration. If your institution has strict firewalls, please provide your personal email address.

ACCCeXchange

YOUR COMMUNITY FOR IDEAS & INSIGHT

ACCCeXchange now has a new look! While things may feel a little different, we are pleased to continue to offer a virtual community for ACCC members to share knowledge, address tough questions, and get real-time feedback and solutions from colleagues. When logged in, navigate to "Groups" in the top right-hand corner of the page, then click on ACCCeXchange to share a post or ask a question.

ACCCeLearning

MULTIDISCIPLINARY EDUCATION + PROFESSIONAL DEVELOPMENT

Access multidisciplinary education and resources that support the delivery of quality cancer care. With a variety of flexible online formats that fit individual learning preferences, you can take your professional development to the next level through in-depth courses or gain quick knowledge in shorter learning formats. Get started at http://courses.accc-cancer.org/.

## If you have any questions or feedback, please reach out to ACCC at membership@accc-cancer.org.

views

# Registry Staff Without Borders

BY LINDA M. KENYON, MS, CTR

I was surprised to receive an email from ACCC asking whether I had a certified tumor registrar (CTR) who was working remotely in Africa and whether I would be willing to write about this experience. Honestly, it took a few moments to sink in because the professional relationship between Caroline Chevallier Hackney as part of the registry staff at CHI St. Joseph Health in Bryan, Tex., has just become matter of fact. I had to remind myself of how this all started, two years ago, before she moved to Mozambique in southeast Africa.

## Setting the Stage

My name is Linda Kenyon, and I am a CTR in Bryan, Tex. I am also an adjunct professor in the Cancer Data Management program at San Jacinto Community College, a program approved by the National Cancer Registrars Association (NCRA). Most of my students at San Jacinto and most likely many of the CTRs reading this article are abstractors, like myself. I went to the University of Texas at Austin and received a bachelor's degree in sociology and a master's degree in community regional planning, graduating in 1977 with an area of specialty in education and social welfare.

I worked in a variety of social service positions for 21 years, until 2000, when I decided I did not want to be a supervisor anymore. I wanted a new profession. I knew nothing about abstracting when human resources for the State of Arkansas suggested this career path to me. My first interview showed me that the process of data collecting and coding, called cancer abstracting, required intellect, thoroughness, and organizational skills. I was intrigued!

In 2000, I started working at the Arkansas Central Cancer Registry in Little Rock, Ark., and then three years later for Methodist Health in San Antonio, Tex. I started working as a traveling or on-site registrar in 2005. The following year, as a traveling consultant for Himagine Solutions, I arrived at CHI St. Joseph Health and transitioned to a full-time position in early 2008.

## Cancer Data Management

In 2014 I had plans to slow down and shift to part-time employment working three days a week. A short while later at the Texas Cancer Registrars Association annual conference, the director of the Cancer Data Management (CDM) program at San Jacinto Community College approached me about an adjunct position to teach abstracting skills. I applied and started teaching in 2015.

The CDM program has a selective admission process, which occurs after every new certificate cycle. Candidates for the program must submit an application, transcript, and position paper on why they want to be a registrar to the program director. My first introduction to Caroline Chevallier Hackney was when I reviewed her candidate application, which revealed education well above the required associate of arts degree and years of experience working in a hospital pathology department as a manager of the lab. She was accepted into the CDM program in fall 2018.

## An Advocate for the CDM Program

As the director of the Health Information Management program at San Jacinto Community College, North Campus, in Houston, Tex., Carla Ruffins is not a CTR but is a strong advocate for San Jacinto Community College's CDM program. There are only six CDM programs approved by NCRA nationally, and Ruffins believes that it is an honor to have one of them in Texas. In her role as Health Information Management director, Ruffins looked to further improve the CDM program by creating an advisory board to make the program's practicum curriculum more robust. Ruffins also wanted the CDM program to work more closely with the hospitals where students would be assigned to for their practicum experience. She worked diligently to find an appropriate hospital placement for each student during their first semester of the program. Caroline Hackney asked whether CHI St. Joseph Health would host her and we accepted. After completing two semesters of the CDM program, Caroline arrived at CHI St. Joseph Health to begin the 160-hour on-site clinical program required of all CTR examination applicants. The required hours include demonstration of all registry-related skills, such as case finding, follow-up, oncology staging and coding, attendance at a hospital-based cancer conference, and a cancer committee meeting of leadership at a local hospital's cancer program.

Now, I will step up on my "soapbox" and urge hospitals nationwide to strongly consider making your facility a practicum location. The CDM program practicums require only 160 hours, not all of which must be completed on the grounds of a hospital. Each hosting facility must plan "in-house" coverage annually to help students meet their practicum requirement, which is only a semester per student. Students who do not complete this requirement cannot sit for the CTR exam.

(continued on page 64

ASSOCIATION OF COMMUNITY CANCER CENTERS

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### Who Should Enroll?

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### Cost

**FREE** to ACCC and Oncology State Society at ACCC members, and $155 for non-members. Join ACCC as an Individual Member ($155) to access this resource—and others—for free.

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The **Association of Community Cancer Centers (ACCC)** is the leading education and advocacy organization for the cancer care community. Founded in 1974, ACCC is a powerful network of 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, Instagram, and LinkedIn; read our blog, ACCCBuzz; and tune in to our podcast, CANCER BUZZ.

The **ACCC Financial Advocacy Network** is the leader in providing professional development training, tools, and resources that will empower providers to proactively integrate financial health into the cancer care continuum and help patients gain access to high quality care for a better quality of life.

Association of Community Cancer Centers

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## Off to Africa

During her final semester of classes prior to the practicum, Caroline's husband received a research grant that required a move to Mozambique. Caroline, determined to see her certificate program through, continued the San Jacinto Community College coursework online while living abroad. With her coursework completed, Caroline returned to the United States for her practicum. She graduated in August 2019 and returned to Africa. She traveled to the United States for the CTR exam in October, passed, and earned her CTR credential. As it happened, at that same time, CHI St. Joseph Health needed a part-time abstractor, and we asked Caroline whether she would consider working remotely from Africa.

## CTR Without Borders

So, what does it take to set up a registry position for an individual living more than 8,000 miles away? Not much, it turns out. And now—because of COVID-19—many of us have had a crash course on how to set up remote workers on the fly. In our situation, CHI St. Joseph Health was able to put all the necessities in place, including:

- A virtual private network to provide access to the hospital database using her laptop
- Access to the registry software
- Access to ancillary databases
- Benchmarks for workload and productivity
- Access to a secure web email account.

Caroline was provided access to the cancer program's shared drive and a personal folder was created within the drive. This folder allowed me to post lists that she could work from. In return, Caroline built spreadsheets for cases, made a file for each week, and would post these in her personal folder. If she had problems or questions about a case, she would enter them on the shared drive, and I would answer without having to use email. Likewise, I was able to review each case saved on the shared drive and entered my initials when a case was ready for submission.

During Caroline's first year as a remote CTR, I reviewed every abstract and gave constructive and corrective criticism to build her skills. Once a month we had a conversation over the phone to discuss the tricky points of an abstract or to plan strategies for accomplishing a registry caseload. We chose Viber, a free mobile application, to host a secure telephone call. This eliminated any additional costs to the hospital.

Caroline was always an email away. We used spreadsheets to document her progress, productivity, and accuracy. She was also included in the management decisions concerning the hospital's registry workload. For example, when CHI St. Joseph Health acquired a hospital that was not accredited by the Commission on Cancer, Hackney was asked to be the abstractor. This meant that she needed to be trained by the Texas State Central Cancer Registry to complete state software abstracts. From Mozambique, Caroline completed the Texas State Registry training for WebPlus and all of the required user approval paperwork for Texas. After her training was complete, staff at CHI St. Joseph College Station established virtual private network access to the hospital's electronic health record. Caroline now completes CHI St. Joseph College Station's required abstracts by using WebPlus, a free software made available through the National Program of Cancer Registries (NPCR), a division of the Centers for Disease Control and Prevention.

As all CTRs are aware, our license hinges on adequate and appropriate education. CHI St. Joseph Health is one of the regional hubs of Texas Central Registry training for the state. Several area hospitals take advantage of CHI St. Joseph Health for both the North American Association of Central Cancer Registries and NCRA training, which is free thanks to NPCR grants to the Texas Central Cancer Registry. Once recordings of live trainings are complete, I send Caroline a link so that she can access them, keep her skills up to date, and maintain her license while in Africa.

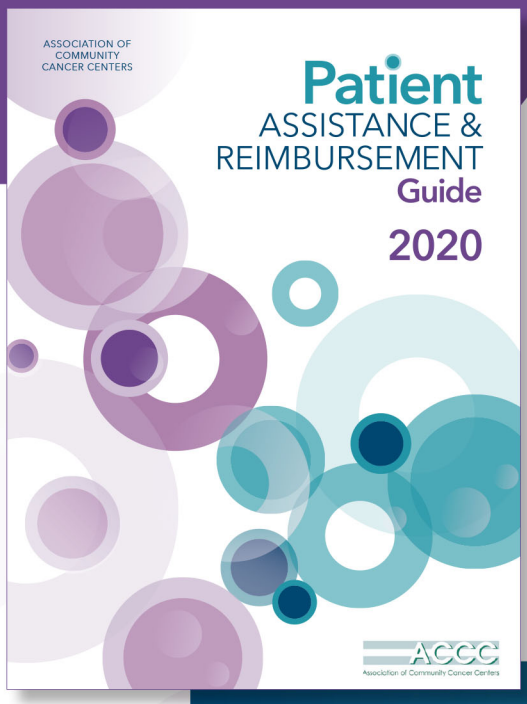
## Lessons Learned

Although we likely would not have set out to hire someone living outside the country to work for our registry, this experience has proven to be a good one. Our facility was able to "test drive" a potential new hire during her practicum and could decide whether this individual was a fit for the organization. During this time, we discovered different skills that the potential new hire possessed and were able to use these skills for projects other than abstracting. Hackney had about 20 years of administrative experience, as well as years of computer experience. In 2018 five reference manuals were updated and revised. Caroline was able to translate these changes and edit registry policies and procedures to ensure that the registry was compliant with these manual changes. She also offered to draft our 2019 annual report. While in Mozambique, the College of American Pathologists updated its cancer guidelines, and Caroline was again able to change our templates to reflect the guideline revisions. She created spreadsheets in our shared computer drive to track her weekly productivity, including columns for my feedback and space for her replies. This is a demonstration of Caroline's desire to improve her skill level.

Knowing the potential new hire well made it easier to create plans for good communication and security, both important factors for the accrediting agencies and hospitals. With pre-planning and constant diligence to ensure that all systems are working and secure, it is not difficult to have a remote employee on board. A good manager should provide enough positive feedback so that the employee will be efficient, effective, and happy in his or her role working with you wherever he or she may live. With COVID-19 and other possible pandemics, this type of remote work is likely here to stay.

*Linda M. Kenyon, MS, CTR, is cancer data manager at CHI St. Joseph Health in Bryan, Tex., and adjunct professor at San Jacinto Community College, San Jacinto, Houston, Tex.*

# Help patients find the financial assistance they need.




Find the latest patient assistance information, including the addition of a table of contents that organizes medications by their administration type and an encompassing list of all oncology-related medications.

**Download the most up-to-date version at accc-cancer.org/PatientAssistanceGuide**

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. Join our social media communities; read our blog, ACCCBuzz; and tune in to our podcast, CANCER BUZZ.

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- **AUGUST 14**
  Ensuring a Sustainable Radiation Oncology Service Line in an Uncertain Future
- **OCTOBER 23**
  Take Your Financial Navigation Services to the Next Level and Help Your Patients and Program
- **DECEMBER 11**
  The 2021 PFS and OPPS Final Rules: What You Need to Know

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