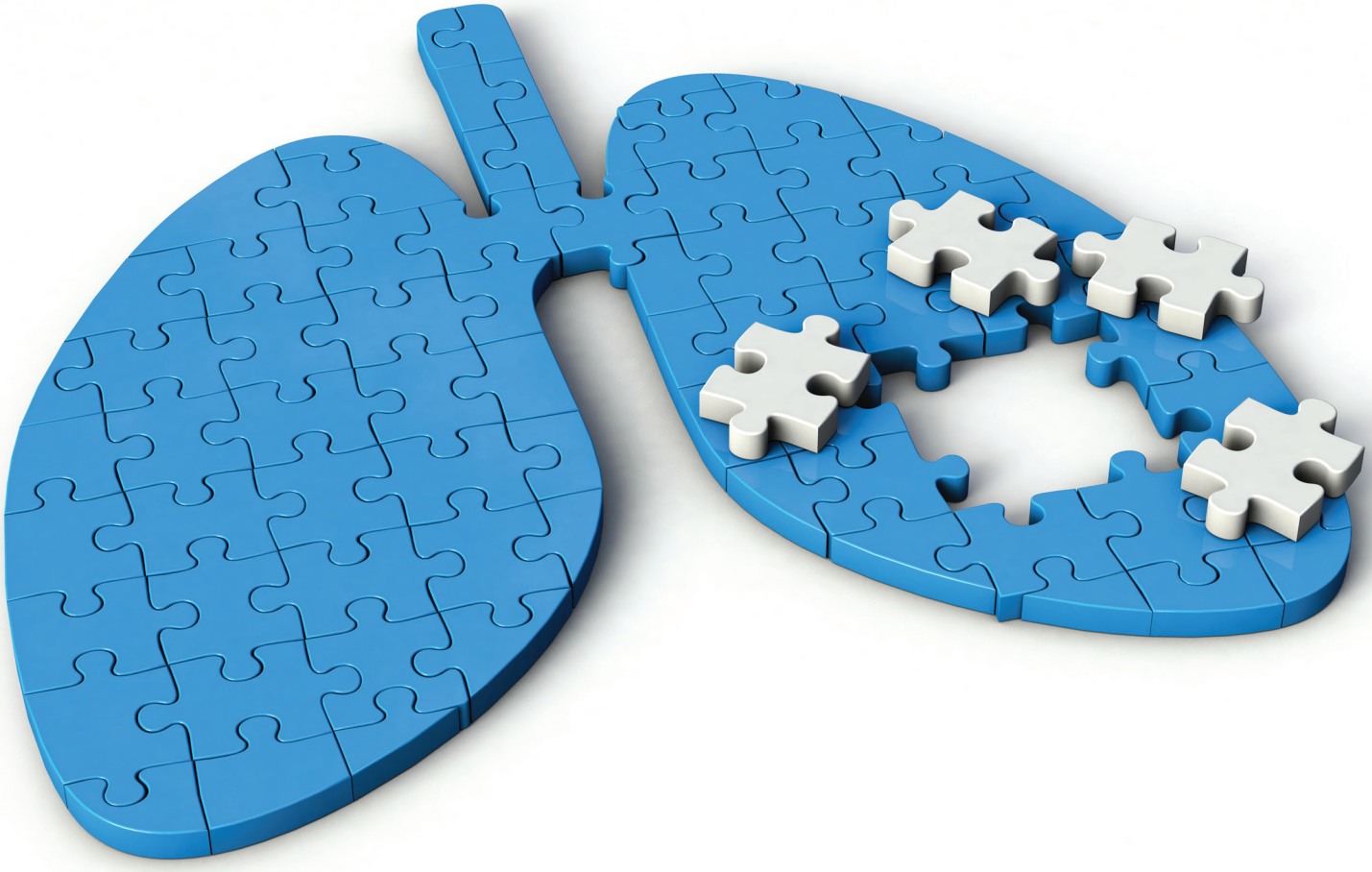
ONCOLOGY ISSUES

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

Vol. 36 | No. 2 | 2021

3D Lung Nodule Tool Fills a Gap in Patient Care

Reducing distress and improving shared decision-making



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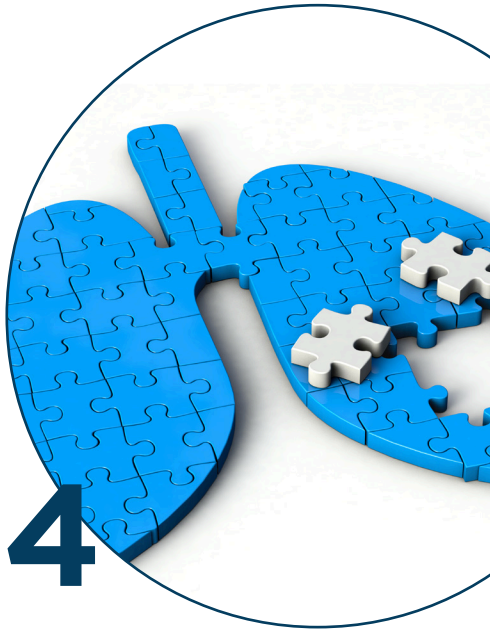
contents

Oncology Issues
Vol. 36 | No. 2 | 2021



14

A 3D Lung Nodule Tool Improves Patient Distress Following LDCT

Patients diagnosed with pulmonary nodules during their annual lung cancer screening experience high levels of distress due to limited understanding of lung nodules and misconceptions about cancer risks. To improve the care of these patients, MaineHealth, Maine Cancer Care Network designed a study to explore the use of a 3D lung nodule tool to help providers educate patients during shared decision-making consults.

by Theresa Roelke

DEPARTMENTS

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FROM THE EDITOR

Education on Demand

BY SIBEL BLAU, MD

As I write this column, I cannot help but reflect on the headline of the *New York Times* Jan. 10 Weekend Briefing, "A year ago this week, China first identified the coronavirus and House Democrats were preparing articles of impeachment. Here we are again." Three months into 2021 and the burdens on our healthcare delivery system and workers continue unabated.

Understanding the pressures that its member programs and practices continue to face, ACCC is actively looking at how it can support the membership, including providing on-demand education, training, and resources to fit into *your* schedule—at a time and place most convenient for you during this extended public health emergency.

For example, with the explosion of telehealth and virtual appointments, care coordination has never been more critical. In the first of a three-article series (page 30), Dr. Oyer and colleagues write about the design and development of An Optimal Care Coordination Model for Medicaid Patients with Lung Cancer, including how to use the model to assess high-impact areas such as physician engagement; financial, transportation, and housing needs; and management of comorbid conditions. Articles about beta-testing the model and practical implications of the model for clinical practice in the United States will follow in subsequent issues of this journal.

Then turn to page 36, to read about a multi-phase ACCC education initiative to improve care for patients diagnosed with advanced epithelial ovarian cancer. Cancer programs and practices will benefit from the learnings shared during the project's three quality improvement (QI) workshops and the curation of a comprehensive library on patient- and provider-specific ovarian cancer resources.

Finally, read about two ACCC Visiting Experts Programs that took place at six institutions on pages 50-72. These multidisciplinary educational opportunities brought together teams of physicians, nurses, pharmacists, pathologists, administrators, and others to develop QI initiatives that enhanced care for patients with multiple myeloma and patients with acute lymphocytic leukemia. The successes that these QI teams realized through their hard work and dedication while simultaneously having to pivot due to COVID-19 is inspiring. We can all learn from their example.

Meanwhile, education at our own programs and practices continues—both virtually and in person (at a safe social distance). My practice has embraced virtual learning for its staff and providers by incorporating webcasts and in-practice presentations from vetted organizations, including ACCC, the American Society of Clinical Oncology, the Community Oncology Alliance, our state oncology society, and many others. COVID-19 webinars were complemented by virtual drug education programs in the context of new drug approvals.

Though virtual meetings are more accessible to staff, this type of learning has a downside. A lack of human contact, busy schedules, and screen fatigue presented additional burdens for our staff. For our providers, the ability to join virtual tumor boards or multidisciplinary discussions remotely was offset by technology glitches.

As a member of the Quality Cancer Care Alliance (QCCA), my practice also participated in virtual opportunities to share experiences, policies, and processes to help each other navigate the many challenges associated with COVID-19. Specifically, QCCA members uploaded relevant policies in a SharePoint forum and created shared infographics and documents to educate patients, staff, and providers. QCCA also provided virtual education opportunities for providers and staff. Bi-annual summits recruited great speakers and attendance increased, facilitated by the ability to participate virtually. Research staff and investigators also participated in and benefited from virtual meetings.

Though overall satisfaction and scores for these virtual education opportunities are high, their growing numbers required significant coordination and prioritization, and my practice eventually assigned a dedicated employee to this task. Other practices may consider a similar move to help coordinate ongoing education and training. And, like many of you, I look forward to the day when in-person education and networking is once again safe for us all. OI

The Future is Bright

BY RANDALL A. OYER, MD

I'd like to start my last column by thanking ACCC, its board of trustees, and all of you for allowing me to serve as president of this collaborative, forward-thinking association. Assuming the ACCC presidency in March of 2020, just as the COVID-19 public health emergency went into effect, was certainly a dramatic way to enter office. That said, I am pleased with how much we have accomplished these last 12 months—despite the nationwide shutdown and ongoing pandemic.

As I end my tenure as ACCC president, I want to thank everyone for their dedication to the President's Theme "Community Oncology Can Close the Gap in Cancer Research." Those of us who work in oncology have long understood that clinical trials are the gold standard of treatment for patients with cancer. This year the entire world had first-row seats to the life-saving nature of clinical trials through the herculean efforts to develop and bring to market several COVID-19 vaccines.

These scientific and medical breakthroughs do not happen in a vacuum. They occur when key stakeholders come to the table with their combined expertise, knowledge, and resources to collaborate on a common goal. This happened for ACCC this year with its collaboration with ASCO (American Society of Clinical Oncology) to foster racial and ethnic minority participation in cancer treatment trials to better reflect the diversity of people at risk for or living with cancer. Stay tuned: Much more will be coming from this in 2021.

Until then, I ask you to join your fellow ACCC member programs and practices already participating in the ASCO Registry on COVID-19 and Cancer to gather evidence on the effect of COVID-19 on patients with cancer. Thanks to support from Conquer Cancer, the ASCO foundation, ASCO provides payments (both for start-up and for each patient entered) to help cover expenses involved in participating. As of February 1, there were 1,771 patients in the registry. The greater diversity and number of patients the registry represents, the more we can learn from this unique experience in cancer care. Register today at asco.org/asco-coronavirus-information/coronavirus-registry.

Based on the baseline and longitudinal data on patients with cancer and COVID-19 collected by the registry, ASCO plans to deliver periodic reports with key findings that will influence future care delivery. You can read an executive summary of the first of these reports, "Road to Recovery Report: Learning from the COVID-19 Experience to Improve Clinical Research and Cancer Care," online at http://bit.ly/ASCO-R2R. The report contains post-pandemic recommendations in key areas, such as these four telemedicine recommendations:

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

Though the last 12 months brought unprecedented change to oncology, healthcare, our country, and the world at large, it also brought us together to improve the future for our patients and their families. And the future is bright. We *can and will* improve our response to emergent diseases, like COVID-19. We *can and will* improve patient access to clinical trials. We *can and will* improve health equity overall. Personally, I can think of no one more capable or more prepared to lead us in these efforts than 2021-2022 ACCC President Krista Nelson, MSW, LCSW, OSW-C, BCD. As program manager of Quality and Research, Cancer Support Services and Compassion at Providence Cancer Institute, Krista can help us all improve our empathy, mindfulness, active listening, and many other skills that are necessary to make the improvements I just highlighted. Please join me in welcoming Krista. I know you will give her all the support, resources, and tools she will need to succeed. OI

Coming in Your 2021 *ONCOLOGY ISSUES*

- Transportation: A Holistic Approach to a Systemic Problem
- The Center for Indigenous Cancer Research at Roswell Park Comprehensive Cancer Center
- 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
- Reducing Readmissions After Chemotherapy with Predictive Modeling of Risk Factors
- Integration of Prehab, Rehab, and Prospective Surveillance into Interdisciplinary Teams
- A Nurse Navigator-Led Community-Based Cardio-oncology Clinic
- Shifting Chemo Administration from Inpatient to Outpatient Setting Improves Care and Reduces Costs
- Integrating Spiritual Care in the Outpatient Oncology Setting
- Use of Pharmacy Informatics to Standardize Pharmacist Review of Oral Oncolytic Medications for Hospitalized Patients
- Medication Transitions in Hematologic Malignancy Patients at a Safety Net Hospital
- Tailoring Distress Screening in Oncology Populations: Timing Distress Screening in Surgically Resectable Esophageal Cancer

more online @ accc-cancer.org

PODCAST | Psychosocial Oncology Services During COVID-19

Jeffrey Kendall, PsyD, LP, shares how patients with cancer are dealing with the "new normal," and how oncology social workers, psychologists, and psychiatrists are working to help them through this unprecedented time. Go to accc-cancer.org/COVID-19, then "Publications."

COMMUNITY | Join the COVID-19 Discussion Group

Participate in important peer-to-peer conversations on strategies to maintain safety, quality cancer care, and program operations during and after COVID-19. Share how your cancer program is staffing to meet flexing patient and operational needs; if your cancer program is seeing the expected increase in later-stage cancer patients; the long-term impact the pandemic has had on the financial performance of your practice, hospital, or health system; and much more. To access, go to accc-cancer.org/COVID-19 and then "Member Discussions." Having trouble joining the group? Email llucas@accc-cancer.org.

RESOURCE | COVID-19 Financial Advocacy Resources

Stay informed on rapidly changing updates to financial assistance programs and insurance coverage in response to the public health emergency. Information on manufacturer patient assistance programs, COVID-19 related funds and programs, patient resources, and more is updated weekly. accc-cancer.org/FAN-COVID19.

WEBCAST | Cancer Care in the COVID-19 Era

In a virtual session at the ACCC 47th Annual Meeting and Cancer Center Business Summit, a panel of healthcare professionals with diverse perspectives share real-world data and experiences about the impact of COVID-19 on cancer care delivery, from staffing for clinic vs. telehealth visits, ramping up outreach and screening efforts, strategies to protect and strengthen operational and financial performance, mentoring and support techniques to bolster an exhausted workforce, and more. accc-cancer.org/AMCCBS.

PODCAST | Supporting Caregivers During COVID-19

Friends, family, and loved ones are essential to a patient's support system, but COVID-19 has limited their access to the care process, appointment, and care providers. Lawrence D. Wagman, MD, discusses how the role of caregivers has changed during the pandemic and how the cancer care team can support these caregivers. Go to accc-cancer.org/COVID-19, then "Mini-Podcasts."

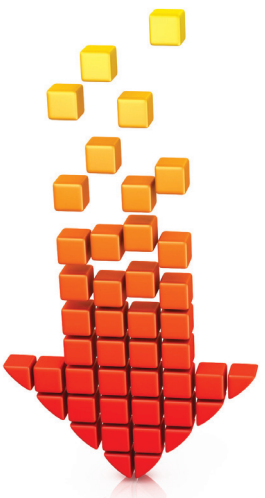
fast facts

COVID-19 Impact on U.S. Cancer Programs

- Clinic and support staff were furloughed and/or laid-off; some were forced to take salary cuts.
- Whenever possible, staff members transitioned to remote work during the worst of the pandemic.
- Telehealth and virtual visits were implemented virtually overnight.
- Social distancing required immediate policies to establish safe occupancy levels, to space patient appointments, and to ensure physical distance of patients and staff.

Source: ACCC COVID-19 Webcast 10: Optimizing Staffing Strategies Amid COVID-19. courses.accc-cancer.org/products/optimizing-staffing-strategies-amid-covid-19.

Precipitous Drop in Cancer Patient Visits in March and April 2020; Full Impact Not Yet Known



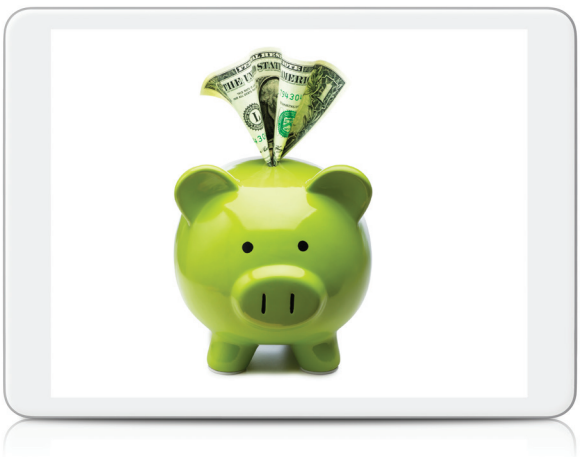
A comparison of Week 4, 2020 data to Week 18, 2020 from select oncology practices revealed that:

- New patient clinic consults fell **66%** at community oncology practices and **38%** at academic- or hospital-based cancer programs.
- Established patient clinic consults fell **51%** and **14%** respectively.
- Inpatient hospital consults fell **92%** and **7%** respectively.
- Radiation therapy visits fell **94%** and **8%** respectively.

Source. ACCC COVID-19 Webcast 15: Risk Stratification for Cancer Patients During COVID-19. courses.accc-cancer.org/products/risk-stratification-for-cancer-patients-during-covid-19.

How COVID-19 Changed Financial Navigation

- Access to financial navigators onsite at cancer programs was limited as most transitioned to remote work.
- In-person financial navigation consults dramatically decreased, with most patient contact taking place virtually—by phone or email.



- The number of patients with cancer needing these services increased due to job and/or insurance loss; requests for food and transportation also increased.
- The number of patients with cancer feeling depressed and/or suicidal increased.

Source. ACCC COVID-19 Webcast 5: Financial Assistance Amid COVID 19. courses.accc-cancer.org/products/financial-assistance-amid-covid-19.

Oncology's Top Medium- to Long-Term Concerns Related to COVID-19

1. Managing care for established patients that was delayed (**64%**).
2. Integrating telehealth into "normal" operations in a sustainable way (**53%**).
3. Increasing number of late-stage diagnoses and poor patient outcomes (**49%**)
4. Increasing staff and provider burnout (**47%**).

Source. The Advisory Board. From ACCC COVID-19 Webcast 10: Optimizing Staffing Strategies Amid COVID-19. courses.accc-cancer.org/products/optimizing-staffing-strategies-amid-covid-19.

COVID-19 Education Hits the Mark

In 2020 ACCC's COVID-19 Resource Center featured **16** mini-podcasts, **15** webcasts, and a dedicated online discussion group to facilitate peer-to-peer learning. Of the learners who accessed these resources:

- **90%** shared that resources had a positive impact on contributions to the team and patient outcomes.
- **82%** reported that resources improved knowledge, skills, or strategy.
- **74%** said resources improved their ability to provide better care.

Source. ACCC Community Cancer Care Delivery Amid COVID-19 Impact Report. For a copy of this report, email llucas@accc-cancer.org.

New Year, New Administration, New Health Policy Director

BY KRISTIN FERGUSON, DNP, RN, OCN

In my new role at ACCC as senior director, cancer care delivery and health policy, I am excited to take over writing this bimonthly column and communicating to our multidisciplinary membership about pertinent workforce, reimbursement, and cancer care delivery issues. Not only will I write about advocacy and policy issues that ACCC is working on, but I will dive deep on issues like the growing number of value-based care models, home infusion trends, strategies for improving clinical trial access, and how to maintain a resilient oncology workforce.

I am an oncology nurse with more than 11 years of experience in a variety of cancer care settings—both inpatient and outpatient—in direct care and leadership roles. Supporting patients and staff did not always allow me to keep up to date with health policy. I learned more about health policy and the importance of provider and patient advocacy by living near the White House, attending health policy events, and going to Capitol Hill to speak with congressional members and their staff about policy concerns, such as the Cancer Drug Parity Act, NIH (National Institutes of Health) and NINR (National Institute of Nursing Research) funding, and how to ensure that any new opioid policies do not create barriers for patients with cancer. Unfortunately, I also know intimately about being a family caregiver and advocating from that perspective because my mother was diagnosed with metastatic pancreatic cancer in September 2017. At that point, I had already worked as an oncology nurse for 8 years but quickly learned that being on the other side of cancer care has its own unique set of challenges and requires advocacy that many people without healthcare experience are not equipped for.

In my short time at ACCC, there have already been several policy changes that will impact oncology care moving forward. ACCC rang in the new year celebrating the inclusion of the CLINICAL TREATMENT Act in the large omnibus that was passed by Congress and signed into law. Previously, Medicaid beneficiaries were unable to have standard of care costs associated with clinical trial participation covered by their insurance. This prevented many from accessing clinical trials and likely increased health disparities. With this inclusion, ACCC is hopeful that there will be greater clinical trials participation from marginalized and underrepresented groups, which will improve data and allow them to be more reflective of the general population.

Another big update was the delay in the implementation of the Radiation Oncology Model from July 1, 2021, to Jan. 1, 2022. Many concerns were brought to light on the administrative burden this new model may cause programs and practices that are trying to maintain normal operations during and after the COVID-19 pandemic. This delay allows stakeholders to work with the Centers for Medicare & Medicaid Services to address concerns related to the proposed payment cuts and the potential impact these could have on patients and programs, especially in rural communities.

With the change of administration from Trump to Biden, it is hard to say what health policy changes will come in the next four years. As the COVID-19 pandemic continues and large-scale vaccination campaigns take place, more focus will likely be dedicated to public health services and the importance of value-based care models versus fee-for-service models, which were hit hard by decreased patient visits in 2020. Medicaid expansion in states that have not yet expanded under the Affordable Care Act will no doubt continue. Telehealth and not *whether* but *how* it will continue and under what provisions, reimbursement methodologies, and regulations is yet to be seen. How cancer care and the oncology delivery workforce will be impacted is uncertain, but all agree that rapid advances in biomarker testing and precision medicine require health policy and adequate reimbursement for services to continue to advance. As more oral drugs are developed, will we continue to see a shift in how and where patients are treated? How will technology play a role in where care is delivered and how patients are educated? What role will each member of the healthcare team play in our complex care delivery system?

As an oncology nurse, I advocated at the patient level: educating patients on new therapies, ensuring that patients were connected to community resources when they needed help with transportation or psychosocial care, and completing prior authorizations in a timely manner. As an oncology clinical operations manager, I advocated for multidisciplinary team members to have clinic support to provide quality care to patients, initiatives to prevent burnout, and education resources to improve overall knowledge. In my new role, I am looking forward to connecting with ACCC members, hearing your stories, and learning how ACCC can best advocate for policies that improve the quality of care we all strive to provide. I look forward to continuing the conversation through future meetings and policy initiatives as ACCC continues to grow. Please feel free to email me at KFerguson@accc-cancer.org about any workforce, reimbursement, or cancer care delivery trends you are seeing. I look forward to hearing your thoughts and learning more about how ACCC can help. OI

Kristin Ferguson, DNP, RN, OCN, is senior director, cancer care delivery and health policy, Association of Community Cancer Centers, Rockville, Md.

Change of Course for Some 2021 Payment Rates and Policies

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

One of the many lessons we learned in 2020 was that anything can happen and if it was related to regulatory changes, it was likely to change or be delayed, and 2021 has not disappointed. The end of December 2020 brought a flurry of activity for the Centers for Medicare & Medicaid Services (CMS), the Medicare Physician Fee Schedule (PFS), the Hospital Outpatient Prospective Payment System (OPPS), and ambulatory surgical centers (ASCs). Changes were also made to the Most Favored Nation (MFN) drug payment policy and the Radiation Oncology Model (RO Model), and the public health emergency (PHE) was extended yet again.

2021 PFS Updates

As previously reviewed in *Oncology Issues*,[1] a 14 percent increase to reimbursement for hematology/oncology and 5 percent decrease for RO under the PFS was anticipated for CY 2021. This was largely due to the dramatic changes to the evaluation and management coding and reimbursement for outpatient and office visit Current Procedural Terminology codes **99202-99215** for new and established patient visits. Many specialties were opposed to the reimbursement. After considerable pushback and lobbying by various specialty societies for Congress to change the finalized reimbursement values specific to the PFS, changes were made.

On Dec. 27, 2020, the Consolidated Appropriations Act, 2021, was signed into law by the president. The changes outlined in the Act, also referred to as the COVID relief package, adjusted the finalized 10.2 percent decrease to the PFS with an overall 3.3 percent increase. The changes in reimbursement values were not strictly applied to the conversion factor, which changed from the finalized $32.4085 to $34.8931 but also resulted in changes to the relative value units for physician work, practice expense, and malpractice of nearly every Current Procedural Terminology and Healthcare Common Procedure Coding System (HCPCS) service. In addition to the payment increase, the Act included several other provisions, including:

- A 3.75 percent increase in PFS payments for CY 2021.
- Suspension of the 2 percent payment adjustment (sequestration) through March 31, 2021.
- Reinstatement of the 1.0 floor on the work Geographic Practice Cost Index through CY 2023.
- Delayed implementation of the inherent complexity add-on code for evaluation and management services (**G2211**) until CY 2024.
- Delay of the RO Model to start no sooner than Jan. 1, 2022.

The increase in the conversion factor and changes to relative value units mean that instead of a 14 percent increase overall for hematology/oncology, the combined impact for 2021 is now a 13 percent increase. Instead of a 5 percent decrease, radiation oncology now has a combined impact of a 1 percent increase; this percentage still includes the decrease in stereotactic radiotherapy equipment valuation, which is being applied over a four-year phase-in period.

In response to what CMS believed was not an appropriate acknowledgment of the complexity of some evaluation and management services provided to patients by some specialties, the agency created **HCPCS G2211**: Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed healthcare services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established.) Because reimbursement of this code affected the overall negative impact to healthcare, CMS placed a moratorium on the code until 2024. In other words, though it was not deleted, it will not be recognized by Medicare or Medicare Administrative Contractors until 2024. As a G-code, commercial payers are not required to accept this code regardless of the moratorium. Review of payer policy is necessary in the interim.

The 2 percent sequestration payment adjustment was placed on hold due to the April 2020 PHE; it was supposed to end Dec. 31, 2020. The sequestration was adjusted to extend through March 31, 2021, but due to the ongoing and uncertainty of just how long the PHE will last, there is some discussion that the sequestration may be extended through the end of 2021.

One of the other big changes was the delay of the RO Model. In the Dec. 1, 2020, release of the PFS final rule, the RO Model was officially delayed until July 1, 2021, under an interim final rule. This would have created a 4.5-year RO Model payment policy and delay some of the quality reporting and payments until the first full 12-month performance year. The Act delayed the RO

Model, stating that it cannot start prior to Jan. 1, 2022. It is uncertain at this time whether the full length of the model will be increased from the now four-year model to at least five years, which was the initial intent. It is also uncertain whether the randomly selected core-based statistical areas will need to change. When the RO Model was delayed initially to July 1, 2021, CMS indicated that it was not necessary to select new participants due to the six-month delay. With the additional delay, attention will be focused on the participants and whether this means a new selection of core-based statistical areas.

2021 Hospital OPPS and ASC Updates

Following closely on the heels of the changes published to the PFS were payment updates under OPPS for outpatient hospital settings and ambulatory surgical centers. The reasoning behind the changes is not as dramatic, and as sometimes happens, there are errors in the reimbursement data published by CMS, so adjustments (correction notices) are published. Reimbursement changes under OPPS were primarily for HCPCS codes related to drugs and biologicals. Many included an increase from the final rule publication, whereas others saw no or minimal change. Reimbursement for ASCs included a decrease to nearly every code, surgical service, and ancillary service covered.

Public Health Emergency Extension

On Jan. 31, 2020, the first PHE due to COVID-19 was declared by Alex M. Azar II, secretary of Health and Human Services (HHS). It is important to note that when a public health emergency is declared it does extend for 90 days. Since that first declaration, the PHE was subsequently renewed on April 21, 2020; July 25, 2020; and Oct. 23, 2020. The latest PHE was scheduled to end on Jan. 21, 2021; however, on Jan. 7, 2021, it was renewed and is currently scheduled to end April 21, 2021. There is discussion that the PHE may also continue through the end of 2021 because of the uncertainty of COVID-19 and to provide some consistency to healthcare providers.

The continued PHE means that the extensions and waivers finalized in March and April 2020 will continue, including:

- The extension of services available as telehealth.
- The place of service for the patient and provider.
- Payment of telehealth services as if provided in-person.
- Changes in direct supervision for therapeutic services in the office setting.

Once the PHE does end, some services will discontinue immediately, and others will be phased out to ensure that patients and providers are confident and prepared to return to in-person visits. Continued access to telehealth services for all patients and providers, not just the providers or traditional telehealth services in place prior to the PHE, is expected, and there is work being done to push for this continuation.

MFN Drug Payment Policy Delay

On Nov. 20, 2020, CMS announced the MFN Model, a new Medicare payment model related to the reimbursement of Medicare Part B drugs. This model is in response to an executive order issued on Sept. 13, 2020, on lowering drug prices by putting America first. This model would test the method of lowering drug costs by paying no more than the lowest price drug manufacturers receive in other similar countries, specifically any country in the Organization for Economic Cooperation and Development that has a gross domestic product per capita that is at least 60 percent of the U.S. gross domestic product per capita.

The premise was to create a payment model based on the 50 most costly single-source drugs and biologics (including biosimilars) in the United States, excluding certain drugs based on various criteria, and pay for the drugs in some equivalency to what other countries pay for the same drug. The MFN Model would be in place for seven years and payments would be phased in over the first four years to reach the full model design. The impact of the model reimbursement would be most widely felt by providers who purchase the drugs and not the drug manufacturers themselves. Because the payment change was provided to the purchaser, it did not incentivize the seller to lower the drug rates in the United States. Due to the burden the MFN Model would create for providers and the fact the model was not put through an official rulemaking process, it has been delayed from the Jan. 1, 2021, start date.

On Feb. 8, 2021, CMS posted an update to the MFN Model regarding several court orders filed following the publication of the interim final rule. A temporary restraining order was filed by ACCC on Dec. 23, 2020, which temporarily restrained HHS from implementing the model. This restraining order expired on Jan. 20, 2021. On Dec. 28, 2020, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction in *Biotechnology Innovation Organization v. Azar*. This prohibited HHS from implementing the model as planned for Jan. 1, 2021. On Feb. 4, 2021, CMS stated, "Given this preliminary injunction, the MFN Model was not implemented on January 1, 2021 and will not be implemented without further rulemaking."[2]

At this time, until additional rulemaking is published with the ability for stakeholders to comment, it appears that the MFN is on hold. This is a theme with some of the last-minute policymaking changes pushed through at the end of 2020 and very beginning of 2021, prior to the switch to the new administration. It is possible that more changes or halts in policy will be made in 2021 to allow the usual chain in command the opportunity to vet and allow for stakeholder input prior to implementing new policies. Stay tuned: 2021 is proving to be another exciting year! OI

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

References

1. Bedard T. 2021 Coding update and the OPPS and PFS final rules. *Oncol Issues*. 2021;36(1):7-20.
2. Centers for Medicare & Medicaid Services. Most favored nation model. Available online at: innovation.cms.gov/innovation-models/most-favored-nation-model. Last accessed February 17, 2021.

tools

Approved Drugs

- On Feb. 5, 2021, the U.S. Food and Drug Administration (FDA) approved Bristol Myers Squibb's (bms.com) **Breyanzi® (lisocabtagene maraleucel)**, a CD19-directed chimeric antigen receptor T-cell therapy for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma not otherwise specified (including diffuse large B-cell lymphoma arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.
- On Jan. 15, 2021, the FDA granted accelerated approval to **Darzalex Faspro™ (daratumumab and hyaluronidase-fihj)** (The Janssen Pharmaceutical Companies of Johnson & Johnson, janssen.com) in combination with bortezomib, cyclophosphamide, and dexamethasone for newly diagnosed light chain amyloidosis.
- On Jan. 15, 2021, the FDA approved **Enhertu® (fam-trastuzumab deruxtecan-nxki)** (Daiichi Sankyo, daiichisankyo.com) for adult patients with locally advanced or metastatic human epidermal growth factor receptor 2 (HER2)-positive gastric or gastro-esophageal adenocarcinoma who have received a prior trastuzumab-based regimen.
- On Feb. 9, 2021, the FDA granted regular approval to Regeneron Pharmaceuticals' (regeneron.com) **Libtayo® (cemiplimab-rwlc)** for patients with locally advanced basal cell carcinoma previously treated with a hedgehog pathway inhibitor (HHI) or for whom an HHI is not appropriate and accelerated approval to Libtayo for patients with metastatic basal cell carcinoma previously treated with an HHI or for whom an HHI is not appropriate.
- On Dec. 16, 2020, the FDA approved **Margenza™ (margetuximab-cmkb)** (MacroGenics, macrogenics.com) in combination with chemotherapy for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.
- On Jan. 22, 2021, the FDA approved the combination of **Opdivo® (nivolumab)** (Bristol Myers Squibb, bms.com) and **Cabometyx® (cabozantinib)** (Exelixis, exelixis.com) as first-line treatment for patients with advanced renal cell carcinoma.
- On Dec. 18, 2020, the FDA approved the first oral gonadotropin-releasing hormone receptor antagonist **Orgovyx™ (relugolix)** (Myovant Sciences, Inc., myovant.com) for adult patients with advanced prostate cancer.
- On Dec. 17, 2020, the FDA approved **Riabni™ (rituximab-arrx)** (Amgen, amgen.com), a biosimilar to Rituxan® (rituximab), for the treatment of adult patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, granulomatosis with polyangiitis (Wegener's granulomatosis), and microscopic polyangiitis.
- On Dec. 18, 2020, the FDA approved **Tagrisso® (osimertinib)** (AstraZeneca, astrazeneca.com) for adjuvant therapy after tumor resection in patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
- On Feb. 3, 2021, the FDA granted accelerated approval to **Tepmetko® (tepotinib)** (EMD Serono, emdserono.com/us-en) for adult patients with metastatic NSCLC harboring mesenchymal-epithelial transition exon 14 skipping alterations.
- On Feb. 5, 2021, TG Therapeutics (tgtherapeutics.com) announced the FDA has approved **Ukoniq™ (umbralisib)** for the treatment of adult patients with relapsed or refractory marginal zone lymphoma who have received at least one prior anti-CD20 based regimen and adult patients with relapsed or refractory follicular lymphoma who have received at least three prior lines of systemic therapy.
- On Jan. 14, 2021, the FDA approved **Xalkori® (crizotinib)** (Pfizer, pfizer.com) for pediatric patients one year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma that is ALK-positive. The safety and efficacy of crizotinib have not been established in older adults with relapsed or refractory, systemic ALK-positive anaplastic large cell lymphoma.
- On Dec. 18, 2020, the FDA approved **Xpovio® (selinexor)** (Karyopharm Therapeutics Inc., karyopharm.com) in

combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

Drugs in the News

- Moleculin Biotech, Inc. (moleculin.com) announced that the FDA granted orphan drug designation to **annamycin** for the treatment of soft tissue sarcomas.
- Ambrx (ambrx.com) announced that the FDA granted **ARX788** fast track designation as monotherapy for the treatment of advanced or metastatic HER2-positive breast cancer for patients who have received one or more prior anti-HER2-based regimens in the metastatic setting.
- Bio-Thera Solutions (bio-thera.com/en) announced that the FDA has accepted its biologics license application (BLA) for **BAT1706**, a proposed biosimilar to Avastin® (bevacizumab).
- CNS Pharmaceuticals, Inc. (cnspharma.com) announced that the investigational new drug application (NDA) for **berubicin** for the treatment of glioblastoma multiforme is now approved and in effect as filed with the FDA.
- The Janssen Pharmaceutical Companies of Johnson & Johnson (janssen.com) announced the initiation of a rolling submission of its BLA to the FDA for **ciltacabtagene autoleucel (cilta-cel)** for the treatment of adults with relapsed and/or refractory multiple myeloma.
- Rafael Pharmaceuticals, Inc. (rafaelpharma.com) announced that the FDA has granted fast track designation to **CPI-613® (devimistat)** for the treatment of acute myeloid leukemia.
- Immunicum (immunicum.se) announced that it has received orphan drug designation from the FDA for **ilixadencel** for the treatment of soft tissue sarcoma.
- Takeda Pharmaceutical Company (takeda.com/en-us) announced that the FDA has approved the supplemental NDA for **Iclusig® (ponatinib)** for adult patients with chronic-phase chronic myeloid leukemia with resistance or intolerance to at least two prior kinase inhibitors.
- Jazz Pharmaceuticals (jazzpharma.com) announced that it has initiated the submission of a BLA to the FDA seeking marketing approval for **JZP-458** for use as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia or lymphoblastic lymphoma in adult and pediatric patients who have developed hypersensitivity or silent inactivation to *Escherichia coli*-derived asparaginase.
- Steba biotech (stebabiotech.com) announced that the FDA has granted fast track designation for **padeliporfin ImPACT (Immune Photo Activated Cancer Therapy)** for the treatment of adult patients with low-grade and unifocal high-grade upper tract urothelial cancer.
- Merck (merck.com) announced that the FDA has accepted and granted priority review for a new supplemental BLA for **Keytruda® (pembrolizumab)** in combination with platinum- and fluoropyrimidine-based chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the esophagus and gastroesophageal junction.
- Pfizer Inc. (pfizer.com) announced that the FDA has accepted for priority review the supplemental NDA for **Lorbrena® (lorlatinib)** as a first-line treatment for people with anaplastic lymphoma kinase-positive metastatic NSCLC.
- Bayer (bayer.com/en) announced that the FDA approved a supplemental NDA to add overall survival and other secondary endpoint data from the Phase III ARAMIS trial to the **Nubeqa® (darolutamide)** prescribing information.
- Bristol Myers Squibb (bms.com) announced that the FDA has accepted its supplemental BLA and granted priority review for **Opdivo® (nivolumab)** in combination with fluoropyrimidine- and platinum-containing chemotherapy for the treatment of patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma. The FDA also accepted the company's supplemental BLA and granted priority review for Opdivo for the treatment of patients with resected esophageal or gastroesophageal junction cancer in the adjuvant setting after neoadjuvant chemoradiation therapy.
- Avelas Biosciences, Inc. (avelasbio.com) announced that the company has received breakthrough therapy designation from the FDA for **pegloprastide (AVB-620)** for the intraoperative detection and visualization of positive margins during breast cancer surgery.
- Istari Oncology (istarioncology.com) announced that the FDA granted orphan drug designation for **PVSRIPO** for the treatment of advanced melanoma.
- Incyte (incyte.com) announced that the FDA has accepted for priority review its BLA for **retifanlimab** as a potential treatment for adult patients with locally advanced or metastatic squamous cell carcinoma of the anal canal who have progressed on, or who are intolerant of, platinum-based chemotherapy.
- Amgen (amgen.com) announced submission of an NDA to the FDA for **sotorasib** for the treatment of patients with KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test, following at least one prior systemic therapy.
- Roche (roche.com) announced that **tiragolumab** has been granted breakthrough therapy designation by the FDA in combination with Tecentriq® (atezolizumab) for the first-line treatment of people with metastatic NSCLC whose tumors have high PD-L1 expression with no EGFR or ALK genomic tumor aberrations.
- Junshi Biosciences (junshipharma.com/en/AboutUs.html) announced that FDA has granted **toripalimab** fast track designation for the first-line treatment of mucosal melanoma.
- Merus (merus.nl) announced that the FDA granted fast track designation to **zenocutuzumab (Zeno)** for the treatment of patients with metastatic solid tumors harboring NRG1 gene fusions that have progressed on standard of care therapy. OI

spotlight

St. Elizabeth Cancer Care
Edgewood, Kentucky

St. Elizabeth Cancer Care is an outpatient department of St. Elizabeth Healthcare, a large multi-hospital system. The cancer program treats approximately 300,000 patients annually across four hospital-based locations in rural and urban communities in northern Kentucky and southern Indiana.

St. Elizabeth Cancer Care opened the doors to St. Elizabeth Cancer Center—a new 250,000-ft^2 facility—in October 2020. "Patient survey after patient survey indicated that the community wanted to receive care in one building; to receive real multidisciplinary care; and to try and make sure that patients have one point of contact to help direct their care," explains Douglas Flora, MD, LSSBB, executive medical director of oncology at St. Elizabeth Healthcare. Through the three years of planning and development it took to launch the new facility, St. Elizabeth Cancer Care leadership sought the input of frontline staff—including oncology nurses, physicians, therapists, and front desk staff—to ensure that the new facility matched staff workflows to best facilitate patient care. The new facility is designed to reduce the risk of infections, including measures to reduce the spread of COVID-19 (e.g., touch-free doors, impermeable terrazzo floors that are easy to keep clean, and a built-in contact tracing and tracking software system). This new cancer center offers patients quality cancer care under one roof, including medical, radiation, and surgical oncology and a full complement of supportive care services.

St. Elizabeth Cancer Center is considered the hub of St. Elizabeth Cancer Care's four hospital-based locations: St. Elizabeth Cancer Center (Edgewood, Ky.), St. Elizabeth Cancer Care Grant (Williamstown, Ky.), St. Elizabeth Cancer Care Ft. Thomas (Ft. Thomas, Ky.), and St. Elizabeth Cancer Care Dearborn (Dearborn, Ind.). St. Elizabeth Cancer Center received the Outstanding Achievement Award by the American College of Surgeons' Commission on Cancer in 2010, 2013, 2016, and 2019 and was named a Care Continuum Center of Excellence by the GO2 Foundation for Lung Cancer in 2019.

A Staffing Model to Meet All Needs

Many of St. Elizabeth Cancer Care's oncologists are employed by St. Elizabeth Edgewood Hospital at St. Elizabeth Cancer Center, and they travel once or twice a week to treat patients at its remaining three locations. Oncologists who are not employed by St. Elizabeth Edgewood Hospital work for the St. Elizabeth Physician Group, and their services are leased by the cancer program through the hospital. All other staff are employed by St. Elizabeth Healthcare and are employees of the hospital-based location in which they work.

Because St. Elizabeth Cancer Care treats patients in two states, its oncologists must be licensed to practice in both Kentucky and Indiana. All other staffing is standardized across all four hospital-based locations. Each location employs hospital outpatient department clerical support and ambassa-

St. Elizabeth Cancer Center

Main lobby

Infusion pod

dors, registered nurses, advanced practice registered nurses, physicians, medical assistants, nurse navigators, infusion nurses, tumor registrars, an IT specialist, a process improvement specialist, quality data abstractors, social workers, financial navigators, and precertification staff. The only exception to this standardized staffing model is that a nurse practitioner travels between St. Elizabeth Cancer Care Grant and St. Elizabeth Cancer Center. A nurse practitioner is employed at each of the remaining two cancer care locations—St. Elizabeth Cancer Care Ft. Thomas and St. Elizabeth Cancer Care Dearborn. To provide patients specialized care, St. Elizabeth Cancer Care oncologists maintain relationships with the private practices in its community. These providers often collaborate with community physicians to offer surgery options not otherwise available. St. Elizabeth oncologists may also make referrals to community physicians and vice versa, so patients can receive the specific care and treatment they require.

A Suite of Multidisciplinary Services

St. Elizabeth Cancer Care offers medical oncology services at each of its four locations and radiation oncology services in two locations. Having multiple community locations enables St. Elizabeth Cancer Care to keep patients as close to home as possible during treatment. Medical oncology employs 12 medical oncologists, 9 advanced practice registered nurses, and clinic nursing staff. Oncology infusion services are offered at all four St. Elizabeth oncology locations. St. Elizabeth Cancer Center has a 58-chair infusion suite, and the remaining locations offer 12- to 15-chair infusion suites. St. Elizabeth Cancer Center's infusion bay is set up in pods of chairs and beds, with each section containing 12 chairs, and a dedicated infusion pharmacy is located at the center.

St. Elizabeth Cancer Center's infusion pharmacy is staffed by three clinical pharmacists, three compounding technicians, and two technicians who hand deliver infusion medications. The cancer center pharmacy functions as a touchpoint for all St. Elizabeth oncology pharmacy sites, with workspaces for infusion clinical and technician staff, an inpatient clinical pharmacist, an oncology postgraduate year two resident, and an investigational drug services pharmacist. Patients at St. Elizabeth Cancer Center also have access to a retail pharmacy where they can pick up their oncology and non-oncology prescriptions after an appointment. The remaining St. Elizabeth Cancer Care locations' infusion suites each have a dedicated oncology pharmacy staffed by a clinical infusion pharmacist and a compounding technician.

To further expand access to care, radiation oncology services are available at St. Elizabeth Cancer Center and St. Elizabeth Cancer Care Ft. Thomas. St. Elizabeth Cancer Care provides patients EBRT, SRS, SBRT, HDR brachytherapy, and Calypso radiotherapy through three state-of-the-art linear accelerators in its hub and one in its Ft. Thomas location. The radiation oncology department is staffed by four radiation oncologists, three therapists per treatment machine, a lead therapist, a computed tomography technologist, four certified medical dosimetrists, four contracted medical physicists, and reception and nursing staff, including nurse practitioners. To minimize travel burdens for patients living in more remote locations, treatment appointments are completed in the morning at St. Elizabeth Cancer Care Ft. Thomas, so consults and follow-up slots are available in the afternoon. Patients receiving radiation treatment at St. Elizabeth Cancer Center will soon have access to these services via a dedicated entrance and parking lot a short distance away once construction is completed in May.

St. Elizabeth Cancer Center also offers surgical oncology and specialty services. With 12 surgeons on staff, the cancer center provides surgical treatments for gynecologic, thoracic, and general oncology. The cancer center is currently looking to improve the available surgical oncology services by adding several dedicated surgical oncologists.

The cancer program prioritizes patients' psychosocial care through a variety of free supportive care services available to patients at St. Elizabeth Cancer Center's integrative oncology department. Located on first floor, the department offers yoga and meditation, art and music therapy, on-site counseling, social work services, financial navigation, acupuncture services, therapeutic massage, and disease-specific support groups. Patients may be referred to integrative oncology services by social workers after they complete an intake form or if a need arises during their treatment. A Panera-style cafeteria is also available to patients, which promotes healthy eating options for those in treatment.

Demonstration kitchen in Integrative Oncology

Retail pharmacy

A Determination to Reduce Barriers to Care

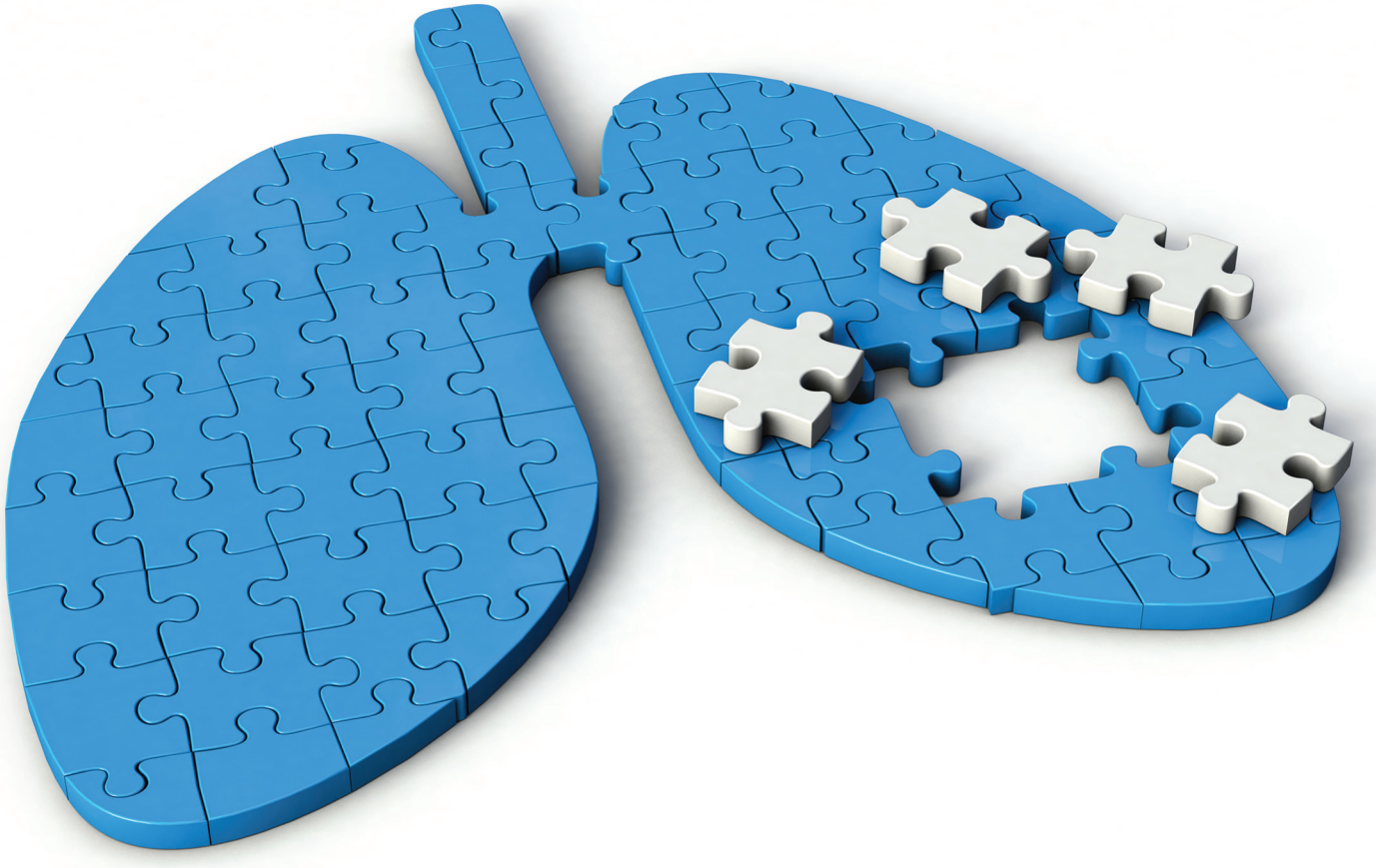
Each year, St. Elizabeth Cancer Care seeks out several diverse pockets of patient advocates, community representatives, civic leaders, and other local stakeholders to identify barriers to quality cancer care in its community. In 2020, health literacy and lung health were chosen as areas for improvement via a community health needs assessment and patient survey results. Because of poor health literacy in its service area, the cancer program has invested heavily in its community outreach efforts. For example, its integrative oncology team is developing a formal program to run demonstration teaching kitchens led by local chefs, oncology dietitians, and the St. Elizabeth Cancer Care integrative medical director, who is certified in lifestyle medicine to teach patients with cancer how to cook and eat safely to improve their quality of life. These classes are free to patients and are available at the St. Elizabeth Cancer Center. "We're teaching patients how to cook foods that they can still taste while on chemotherapy," explains Dr. Flora. "And teaching them diets or nutritional exercises that might help reduce their risk of breast cancer recurrence or colon cancer polyp development."

In response to a high incidence of lung cancer resulting from the region's high smoking rates, St. Elizabeth Cancer Care established a robust lung cancer screening program. The program is one of the largest lung cancer screening programs in the United States, says Dwinelva Zackery, director of integrative oncology at St. Elizabeth Healthcare. "Last year, we screened about 4,200 patients for lung cancer," she says. "We're finding lung cancer in about 1 in every 56 scans."

Two dedicated nurse navigators help patients navigate through St. Elizabeth Healthcare when they are referred to the program. A nodule review board made up of the two nurse navigators, medical oncology, radiology, pulmonology, thoracic surgery, and primary care meets weekly to review and discuss all lung screenings, including those with incidental findings or findings from patients' other computed tomography scans. Patients can be screened at all St. Elizabeth Cancer Care locations and are then referred to the lung cancer screening program. Once referred and treatment plans are made, patients receive care in the St. Elizabeth oncology location that is closest to their home.

As the development of the new cancer center and dedication to expanding its cancer services show, St. Elizabeth Cancer Care truly puts its patients' needs first. "This organization really puts the patient at the center," says Zackery. "There's been a lot of commitment from St. Elizabeth Healthcare to build in all of those supports that are so critical to a patient as they go through such a difficult time. I'm really proud of being able to be a part of building that for our patients, our families, and our community." OI

A 3D Lung Nodule Tool Improves Patient Distress Following LDCT



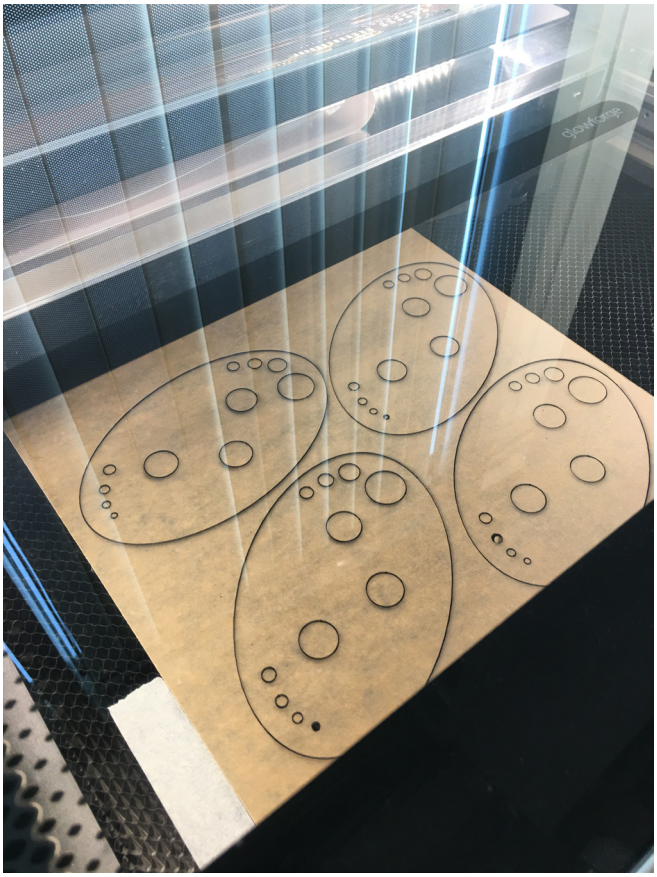
BY THERESA ROELKE, MSN, RN, AGNP-C

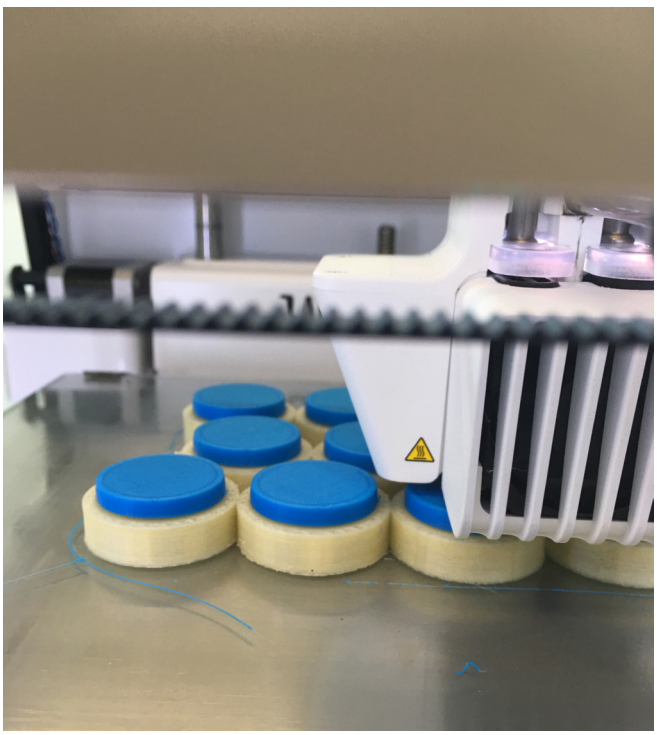
A 2017 study published in the journal *Heart, Lung and Circulation* showed that incidental nodules are seen in 13.9 percent of computed tomography (CT) angiograms performed across the country.[1] Today, thousands of Americans learn they have pulmonary nodules from low-dose computed tomography (LDCT) scans taken during annual lung cancer screenings. These patients experience high levels of distress owing to limited understanding of lung nodules and misconceptions about cancer risks. To improve the care of these patients, MaineHealth, Maine Cancer Care Network designed a study to explore the use of a 3D lung nodule tool to help providers educate patients during shared decision-making consults.

Across the United States, as well as within Maine, there is limited access to screening. Increased public awareness, patient education about screening, and state facilities that perform LDCT screening can improve patient outcomes and quality of life.[7]

A Brief History of LDCT Lung Cancer Screening

Every two and a half minutes someone in the United States is diagnosed with lung cancer, and an estimated 234,030 new cases in the U.S. were diagnosed in 2018.[2] The national five-year survival rate for lung cancer is 18.1 percent, which means that four out of five people diagnosed with lung cancer will not survive longer than five years.[3] In December 2013, the U.S. Preventative Services Task Force (USPSTF) issued its final recommendation on lung cancer screening. It states that annual lung cancer screening with LDCT is recommended for adults age 55 to 80 years who have a 30-pack a year smoking history and who currently smoke or have quit within the last 15 years.[4] As a result of the USPSTF recommendation, the Centers for Medicare & Medicaid Services agreed to cover LDCT lung cancer screening, with the stipulation that there must be a documented shared decision-making visit between the patient and the referring clinician. A shared decision-making consult educates patients about the risks and benefits of screening, including follow-up diagnostic testing, overdiagnosis, false positive rates, total radiation exposure, and the impact of comorbidities.[5] Currently, only 6 percent of the estimated seven





Top: Face plate laser cut from high gloss acrylic sheets. Bottom: Nodules being 3D printed with dissolvable PVA supports.

million adults who fall under USPSTF recommendations for lung cancer screening undergo LDCT screening.[6] Reasons behind this low patient volume include:

- Patients' lack of trust in the U.S. healthcare system
- Stigma and shame around smoking
- Limited patient education and knowledge
- Screening availability of providers and clinics
- The clinical nature of smoking addiction.

Across the U.S., as well as within Maine, there is limited access to high-quality lung cancer screening. Increased public awareness, patient education about screening, and state facilities that perform LDCT screening can improve patient outcomes and quality of life.[7] As these guidelines are widely implemented across the country and awareness and education on lung cancer screening increase, the number of people who undergo LDCT screening is expected to rise dramatically.

Pulmonary Nodules 101

A pulmonary nodule is defined as a single lesion in the lung that is surrounded by functional lung tissue and has a diameter less than 3 cm without associated pneumonia, atelectasis (complete or partial collapse of the lung), or lymphadenopathy. Pulmonary nodules are mostly benign growths caused by prior infection or areas of scarring on the lungs.[8] The vast majority of positive lung cancer screening results involve the detection of pulmonary nodules.[9] According to the National Cancer Institute's National Lung Screening Trial,[10] the rate of positive screening tests is 24.2 percent, of which 96.4 percent are false positives. To support clinicians who read and interpret LDCT findings, the American College of Radiology developed a standardized process called LungRADS,® which, based on the radiographic appearances of the lung nodules, assigs LDCT scans to one of five categories[11]:

- RADS 0: Insufficient data for interpretation
- RADS 1: A negative scan
- RADS 2: Nodules with benign appearance or behavior
- RADS 3: Nodules that are probably benign
- RADS 4A: Suspicious findings
- RADS 4B: Very suspicious findings.

The recommended follow-up (with CT, positron emission tomography [PET]/CT, or biopsy) depends on the nodule's malignant probability. Statistically, 90 percent of lung nodules are categorized as RADS 1 or RADS 2. These are nonexistent or very small, benign-appearing nodules (usually less than 6 mm) with less than 1 percent risk of becoming malignant. The recommended follow-up for these categories of nodules is to continue annual LDCT screening. Five percent of lung nodules are category RADS 3 and have a 1 to 2 percent risk of becoming malignant. In these cases, the recommended follow-up is LDCT screening in 6 months. Two percent of lung nodules are category RADS 4A and have a 5 percent to 15 percent risk of malignancy. A follow-up LDCT in three months or a PET/CT is recommended. Finally, 2 percent of lung nodules are category RADS 4B, which have more than a 15 percent risk of malignancy. Chest CT, with or without contrast; PET/CT; and/or sample biopsy is recommended for these cases.

LDCT Screening and Patient Distress

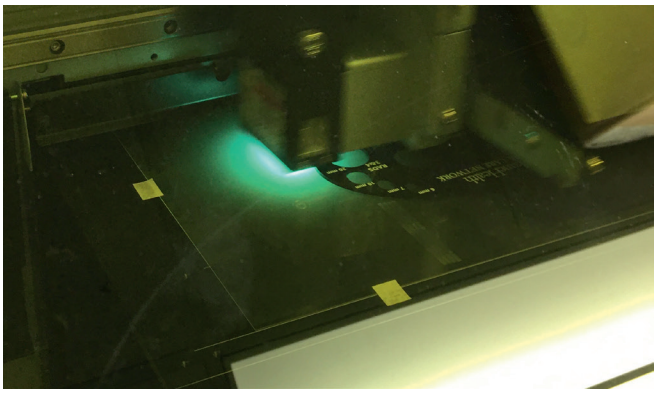
During the shared decision-making consult that accompanies LDCT lung cancer screening, clinicians educate patients about the low risk of malignancy stemming from a lung nodule finding. However, despite the overall low incidence of malignancy, several qualitative and survey studies indicate that lung nodule findings lead to clinically significant distress in as many as 25 percent of patients.[12,13] These patients tend to overestimate their risk of lung cancer. The distress from a lung nodule finding is unique in that patients' distress may persist for months to a year after their initial screening—the length of time before recommended follow-up with radiography. This finding contrasts sharply to patients who experience false-positive mammograms, where the uncertainty is addressed in a shorter window of time via a biopsy.[1,12] These data reveal a clinical unmet need for improved patient understanding of lung nodules, the risk they pose, and their short- and long-term management. Currently, visual lung nodule models are not used during the shared decision-making consult to support patient education. Incorporating a 3D educational tool as part of the shared decision-making process can enhance patient and provider communication, improve patient knowledge about malignancy risk, and reduce emotional distress, thereby improving patient quality of life.

The MaineHealth, Maine Cancer Care Network Experience

In 2018, MaineHealth, Maine Cancer Care Network developed and piloted the first such tool—a brainchild of experienced nurse navigator, Theresa Roelke, MSN, RN, AGNP-C.

After numerous LDCT shared decision-making consults with anxious and distressed patients, Roelke conceptualized the idea of a 3D tool that that could be used to better educate patients about their lung nodules and cancer risks. After developing the design on paper, Roelke reached out to the Maine College of Art in Portland to discuss partnership opportunities. The college connected Roelke to a student, William Kittredge, with expertise in 3D modeling and printing. Working together, Roelke and Kittredge created a nylon and resin prototype with lung nodules of different features and sizes. As a starting point, they used an existing tool of unknown origin and began a process of diagramming and prototyping iterations. The final prototype 3D lung nodule tool represented lung nodules of increasing diameter and with varying physical features.

In May 2018, Roelke piloted the 3D lung nodule tool during shared decision-making consults with patients to address the significance of nodule size, appearance, and malignancy risk. The tool's effectiveness was assessed using a five-question patient survey (four quantitative questions and one qualitative question). Thirty-one surveys were completed during the pilot. Preliminary data indicated that patients found the 3D lung nodule tool helpful, improving their understanding of lung nodules and the significance of nodule size and appearance. The average score for helpfulness (1 being *not helpful* and 10 being *extremely helpful*) was 9.4 out of 10 (see Figure 1, page 18). Preliminary data also showed that use of the 3D lung nodule tool decreased patient distress



Top: UV Printing text and graphics to the face plate. Bottom: 3D printing allows quick variance in color and materials.

Figure 1. Data from Patient Survey of Piloted 3D Lung Nodule Tool

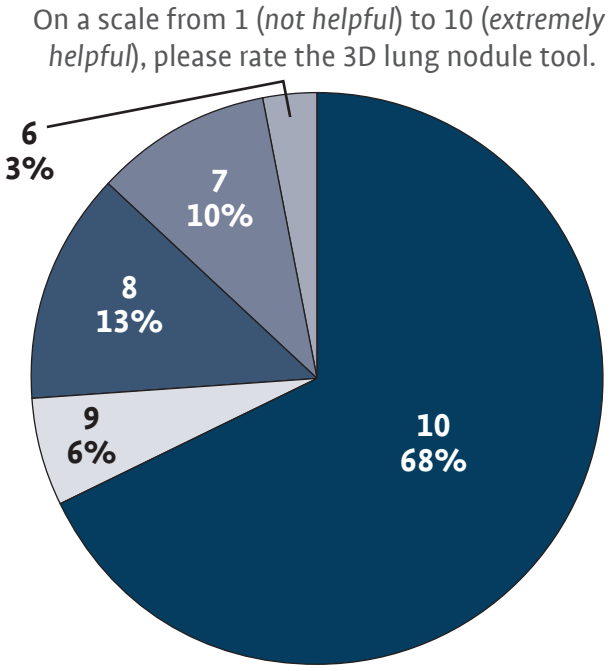


Table 1. Benefits of a 3D Lung Nodule Tool

This tool can be used in any setting where conversations with patients about lung cancer screening findings occur, including primary care practices, pulmonology clinics, emergency departments, hospital inpatient units, and cancer programs or practices to help:

- Create a paradigm shift in LDCT shared decision-making consults by engaging patients and providing them with greater meaning and context.
- Establish a personal connection with patients whether education is offered in person or virtually.
- Engage patients in an experiential learning experience.
- Provide a multi-sensory experience that can help improve patient recall of information and education.
- Improve patient understanding of lung nodules.
- Help patients better understand their imaging report.
- Reduce patient distress.
- Offer patients the opportunity to share education on nodules with family and friends.
- Improve understanding of metric measurements in patients unfamiliar with the measurement system.

LDCT = low-dose computed tomography.

during the shared decision-making consult. Other benefits to this patient education tool are listed in Table 1, below left.

Future Direction

At the height of the pandemic in 2020, collaboration began with the University of Southern Maine Maker Innovation Studio (MIST Lab) to refine the 3D lung nodule tool and print additional units for distribution across MaineHealth. MIST Lab's vision is to partner with healthcare, business, industry, and education to bring experiential learning to providers and patients. Figure 2, page 19, is the 3D lung nodule tool that has undergone refinement in preparation for large volume production. The tool includes nodule characteristics: lobulated shown in yellow, smooth in blue, and spiculated in red, as well as the LungRADS categories. LungRADS 1 and 2 nodule findings are positioned to the right with corresponding nodule sizing and LungRADS 3 and 4 nodule findings are positioned on the left.

In 2021 the team hopes to begin implementing use of the 3D lung nodule tool in lung screening sites across MaineHealth and the Northern New England Clinical and Translational Research Network. The MaineHealth Innovation Center is currently in conversations with a local manufacturer to mass produce the 3D lung nodule tool. The plan is to offer an option to custom print an organization's name on the tool itself. The team is looking to introduce the 3D lung nodule within the primary care setting where lung nodules are commonly discussed with patients.

The end goal is to disseminate the tool to lung screening programs and pulmonology clinics throughout New England and then across the country to improve patient education and shared decision-making around LDCT screening in both the inpatient and outpatient setting.

Another future goal is to develop additional tools to support patient education on nodules found within the context of lung screening and on diagnostic CT chest imaging, including thyroid and vocal cord nodules.

Additionally, there may be future opportunity to collaborate with the Research Bases of the National Cancer Institute Community Oncology Network, of which Maine Cancer Care Network is a member. This may provide a venue for a much larger confirmatory and national Cancer Care Delivery Research study.

Finally, Roelke and her colleagues plan to continue to introduce the 3D lung nodule tool and present future research findings at national and international lung cancer conferences to encourage further discussion around the use of 3D modeling to improve patient health literacy. By initiating these discussions, Roelke's team seeks to challenge lung screening programs across the country to consider more broadly the use of technology and innovation to support patient understanding of commonly found lung nodules, lung cancer, and preservation of lung health as it relates to quality of life. The goal is to collaborate with patients to educate them on a given diagnosis and to establish a plan of care, while also creating meaningful health goals that are uniquely appropriate to individual patients. In doing so, individual patients are empowered to assume health autonomy and health stewardship.

Figure 2. 3D Lung Nodule Tool for Large Volume Production

The end goal is to disseminate the tool to lung screening programs and pulmonology clinics throughout New England and then across the country to improve patient education and shared decision-making around LDCT screening in both the inpatient and outpatient setting.

Maine Medical Center Cancer Institute won a 2020 Association of Community Cancer Centers (ACCC) Innovator Award for its 3D lung nodule tool. Roelke and colleagues presented this innovation at the ACCC 37th [Virtual] National Oncology Conference. Listen to their on-demand session at courses.accc-cancer.org/p/ACCCNOC. OI

Theresa Roelke, MSN, RN, AGNP-C, is a geriatric nurse practitioner at Maine Medical Center Cancer Institute in Scarborough, Maine.

References

1. Slatore CG, Wiener RS. Pulmonary nodules: a small problem for many, severe distress for some, and how to communicate about it. *Chest*. 2018;153(4):1004-1015.

2. Dela Cruz CS, Tanoue LT, Matthay RA. Lung cancer: epidemiology, etiology, and prevention. *Clin Chest Med*. 2011;32:605-644.

3. Blackburn C. 2018 State of lung cancer report. Available online at: naaccr.org/2018-state-lung-cancer-report. Published March 13, 2018. Last accessed January 12, 2021.

4. Virginia MA. Screening for lung cancer: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2014;160(5):330-338.

5. Centers for Medicare & Medicaid Services. Decision memo for screening for lung cancer with low dose computed tomography (LDCT) (CAG-00439N). Available online at: cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274. Published October 21, 2016. Last accessed January 12, 2021.

6. National Cancer Institute. Cancer trends progress report. Available online at: progressreport.cancer.gov/detection/lung_cancer. Last accessed January 12, 2021.

7. Simon S. Lung cancer screening rates remain low. Available online at: cancer.org/latest-news/lung-cancer-screening-rates-remain-low.html. Published February 2, 2017. Last accessed January 12, 2021.

8. Perandini S, Soardi G, Motton M, et al. Distribution of solid solitary pulmonary nodules within the lungs on computed tomography: a review of 208 consecutive lesions of biopsy-proven nature. *Pol J Radiol*. 2016;81:146-151.

9. Aberle DR, Adams AM, Berg CD, et al. Reduced lung-cancer mortality with low-dose computed tomographic screening. *N Engl J Med*. 2011;365(5):395-409.

10. Kramer BS, Berg CD, Aberle, DR, Prorok PC. Lung cancer screening with low-dose helical CT: results from the National Lung Screening Trial (NLST). *J. Med. Screen*. 2011;18(3):109-111.

11. American College of Radiology. Lung CT Screening Reporting & Data System (Lung-RADS). Available online at: acr.org/Clinical-Resources/Reporting-and-Data-Systems/Lung-Rads. Last accessed January 12, 2021.

12. Slatore CG, Wiener RS, Golden SE, et al. Longitudinal assessment of distress among veterans with incidental pulmonary nodules. *Ann Am Thorac Soc*. 2016;13(11):1983-1991.

13. Freiman MR, Clark JA, Slatore CG, et al. Patients' knowledge, beliefs, and distress associated with detection and evaluation of incidental pulmonary nodules for cancer: results from a multicenter survey. *J Thorac Oncol*. 2016;11(5):700-708.

Implementing a Remote Work Program for Cancer Registrars

BY LAURA L. VONDENHUEVEL, BS, RHIT, CTR

Healthcare technology is ever-changing and—in a COVID-19 world—remote work options are now a necessity. Yet many cancer registries are still rooted in the physical spaces they occupy in clinics. Remote work options are a positive selling point for organizations in a competitive job market when it comes to attracting experienced certified tumor registrars (CTRs). The work of cancer registrars is conducive to remote work programs because much of their work is electronic and can be accessed virtually if the right systems and technology are in place.

Cancer Registry Work Today

The cancer registry work landscape looks very different from when I started in 2007. At that time many of us were still abstracting from paper medical records. A few of us had partial electronic sources for data, and sometimes the dictated notes, imaging results, and lab results were in a format that could be navigated electronically. Our casefinding sources were pages of small print reports from our coding or billing software or pathology reports off the printer. Now, we have file extracts that we can import into our cancer registry software that will flag patients who already exist for review and even add follow-up data. We have pathology reports that are put into a folder or even extracted for import into our software. With the innovation of electronic health records (EHRs) and the ability for many of these processes to be completed without a single printed page, if you are not already doing so due to COVID-19, now is the time to allow cancer registry staff to work remotely—either a few days a week or full time—depending on the needs of the facility.

When it comes down to it, a remote work program relies heavily on two key factors: the policy to guide the program and technical requirements from the health system's information technology team.

Remote Work Program at Kettering Health Network

When I started at Kettering Health Network in the spring of 2018 as the manager of the cancer registry, the organization already had a remote work program in place. Since 2014, eligible staff, once they obtained their CTR credential, were permitted to work from home two days per week. The team staggered days so that one day a week everyone was in the office and avoided having days when no CTR was in the office. On remote workdays, CTRs only abstracted and had to meet a productivity benchmark. When working in the office, CTRs worked on tasks that were still heavily reliant on paper, such as follow-up, physician quality assurance, or casefinding activities.

CTRs are expected to work during their regular hours on the days they work remotely, creating a culture that remote work is still work taking place during "office hours"—the office just happens to be a home office. Though there is a set schedule for days when CTRs are in the office or remote, the program allows the manager flexibility if there is a time when a CTR is otherwise unable to come into the office—winter weather is a good example in Ohio—and yet able to perform work remotely. The same applies to CTR work hours; if there is an issue or staff needs to flex some hours, they arrange this in advance with their manager.

When it comes down to it, a remote work program relies heavily on two key factors: the policy to guide the program and technical requirements from the health system's information technology (IT) team. A clear, standardized policy that is developed with input from staff, human resources, and payroll helps ensure that all know what is expected of them. Additionally, as our remote work program was getting started, early engagement with IT was important because there were many ways to "work remotely" but ultimately the solution that works for this department is what our IT team is able and willing to support long term.

Developing and Implementing the Remote Work Program

The CTR remote work policy consisted of several key sections:

- Qualifications for program participation
- Staff expectations in the remote setting
- Payroll considerations
- Productivity and quality standards.

When building the framework for the remote work program, the manager at the time reached out to other hospitals who had staff working remotely to see how their programs functioned. It was important for staff that this program was voluntary and no one would be forced to participate. Rather, participation was a benefit for those who had earned their CTR. Expectations were outlined in the policy that included:

- Suggestions for defining remote workspaces and creating focused work environments.
- The mandate that CTRs could not be a primary caregiver while they were working from their home office.
- A requirement and process for notifying the manager when there was a disruption to their workday. Specifically, CTRs were to notify the manager and report to the office to complete their day.
- Completion of remote worklogs.
- Eligibility criteria that had to be met and maintained for CTRs to continue in the program, including maintenance of their CTR credential, no formal discipline in the past six months, demonstration of ability to maintain their productivity and quality level, and factors in their most recent performance evaluation.

Payroll and human resources collaborated with the manager to include guidance for worker's compensation potential, pay status from a home office that might not be in the same municipality as the primary work site for tax withholding, and shift differential eligibility. After the remote work program was implemented, changes were made over time to these policies, but these core items have remained the same to this day.

To set the CTR team up for success, requirements are standardized for office and remote work. Staff are required to have a computer, dual monitors, a modem and/or router that is password protected, high-speed Internet, and a phone with the ability to leave messages. Second monitors are provided to those who need one, with the understanding that it will be returned if they leave the organization. However, CTRs are responsible for obtaining and/or using their own home computers. No network software applications are downloaded onto their home computer. Utilizing a virtual private network to gain access to the hospital's network and then logging directly into their office workstations in a virtual environment means that CTRs have access and the capability to run all of the software needed with minimal effort. Cancer registry software, an EHR, and shared network drives ensure that CTRs can see their abstracting lists, have access to the same resources—no matter where they are working—and communicate with one another via an instant messaging system. (Be aware that not all cancer registrars are as comfortable with technology outside of the EHR or cancer registry software, so it may take some training and patience as everyone gets set up.)

Staff Reflections

When developing the remote work program, it was helpful for CTRs to have a productivity standard in place and a goal to meet while working remotely. But be flexible. When our CTRs realized that the established goal was not realistic, as abstracting requirements changed and our network became more complex, the manager met with the team and they agreed on a new goal. CTRs reported that having this expectation and the ability to provide feedback was one of the top reasons they felt comfortable working remotely, because some were afraid their productivity would go down. The shared goal and the knowledge that the manager validates work logs and productivity data help keep everyone on task. Using abstracting initially as the primary goal of the remote work program set clear expectations about what tasks CTRs were to work on. For a team that always worked with paper in the office and with their teammates a desk away, it served as a tangible measure of the program's success. In fact, the manager at the time said that they found staff more productive at home when it came to abstract work because there were fewer distractions.

Another unexpected benefit of having the flexibility to work remotely was letting staff work when they otherwise might not be able to make it into the office. For example, if they did not feel well enough to work in the office, they would sometimes reach out to the manager to see if they could work from home that day and come in later in the week instead.

By its very nature, a cancer registry workflow allows more managerial flexibility and oversight because the work does not require in-office work or direct patient contact. With remote

work becoming more prevalent—and now mandatory in some regions due to the ongoing public health emergency—this flexibility is amplified even more, because managers can track progress and know that the work is being done correctly without needing to interface daily in an office.

There is often a perception that working remotely is not for everyone, especially when staff has worked in a facility for a long time. It is important to gain buy-in early in the process and communicate often as the remote work program moves forward. Our CTRs shared that it was important to stay motivated to work and not be distracted by household tasks, such as dirty laundry, neighbors, or other unplanned disruptions to the workday. CTRs were concerned that these might overtake the duties they needed to complete the work. In my experience, and for context, in the office you might be distracted by someone walking by and asking a question, chatting in the break room about weekend plans, or talking on the phone. In other words, both settings have distractions that staff must manage—they are just different.

Cancer Registry Remote Work Today and Beyond

When I came onboard in 2018 with Kettering Health Network, I had just come from working remotely for more than six years from my home office. Outsourcing and consulting cancer registry companies use their remote work programs to attract CTR candidates, so I was excited to see that this organization had already started offering this as a benefit for their staff. With a CTR shortage as our workforce starts to reach retirement, it is something that more organizations can leverage to help retain seasoned CTRs and attract new CTRs to the field.

Key to the success of all cancer registries is the importance of the "junk in, junk out" rule. In other words, high-quality data is the pillar of a good cancer registry database. So, when building your remote work program, quality and productivity are vital. One of the changes we made was to increase the frequency of quality assurance reviews. This helped create a feedback loop in real time, instead of the old process, which called for a single review annually. I meet with CTRs to review cases and answer any questions they might have. Sometimes we take questions from these reviews to our team meetings to make sure we are on the same page. In addition to quality reviews, I provide CTRs with individualized monthly reports from the cancer registry software that show how many cases they are doing per week, because we shifted our productivity goal to a weekly number instead of a daily number. This report accomplished two things: It helped improve our overall team productivity and it decreased CTR anxiety. CTRs can see how many cases they are doing and how that fits into the total cases the team did each month—CTRs see only their numbers and the team's total number of cases. This report also improved the types of conversations we have regarding productivity. We still talk about down weeks, but more often we talk about the weeks they were over goal and how that offsets a week that might be lower. Seeing the big picture puts this into perspective for management and staff.

Another shift made we made was to expand the types of work that could be done at home. Initially CTRs were abstracting only, but now they do casefinding, follow-up work, committee or conference activities, or other tasks for which a more focused, remote work environment is appropriate. Most of this work is now paperless and this additional flexibility has helped CTRs plan their time more efficiently. CTRs have certain tasks they are responsible for each month as part of the overall departmental workflow, so they can plan their own week knowing when things are due as a part of that big picture. It has also opened the possibility that in the future we can allow more days at home for individuals who would want that as an option or perk.

Remote Work and COVID-19

Looking back at the program we have here at Kettering Health Network and the impact the COVID-19 pandemic had here in Ohio in March 2021, I'm grateful we already had these policies in place. We were ordered to send all staff home to work if possible, so it made it easy to get the items in place to send our last person home. It was still a shock to some people to be at home all the time, so for the first few months we scheduled online lunch time, so everyone could connect with each other as they would in the office—no agenda and no work talk. We also increased our staff meetings to make sure all of us were on the same page as the situation evolved. I'm very proud of the team for leaning into the challenges so far.

Remote Work as a Viable Option in a Cancer Registry

As we strive to grow our profession in a time of shortage and enter the age of more widely accepted telecommuting and remote work, it is not a surprise that there is so much interest in setting up remote work options for cancer registry staff. One of the first questions many applicants ask me when filling a position at our organization is whether we offer the option to work from home—either part-time or full-time. It is a constant conversation starter on professional association discussion pages. My observation is that remote work is now expected as part of the normal operations of the cancer registry. With this shift also comes the expectation that cancer registrars be able to troubleshoot some low-level technical difficulties, such as how to reboot their modem and/or router, and some understanding at a high level about how they are connecting into the network, so they can determine whether they need to reboot their remote session or reboot both their remote session and their own personal computer. CTRs must stretch their comfort with technology outside of EHRs and cancer registry software to feel more confident working remotely. If a robust IT system is put in place to instruct CTRs on the ins and outs of remote work technology and a solid foundation is put in place for staff expectations, benchmarks, and human resources concerns, working from home is now a viable—if not preferred or mandatory—method of cancer registry work. Healthcare is an evolving field, and our systems and work options must mirror this. OI

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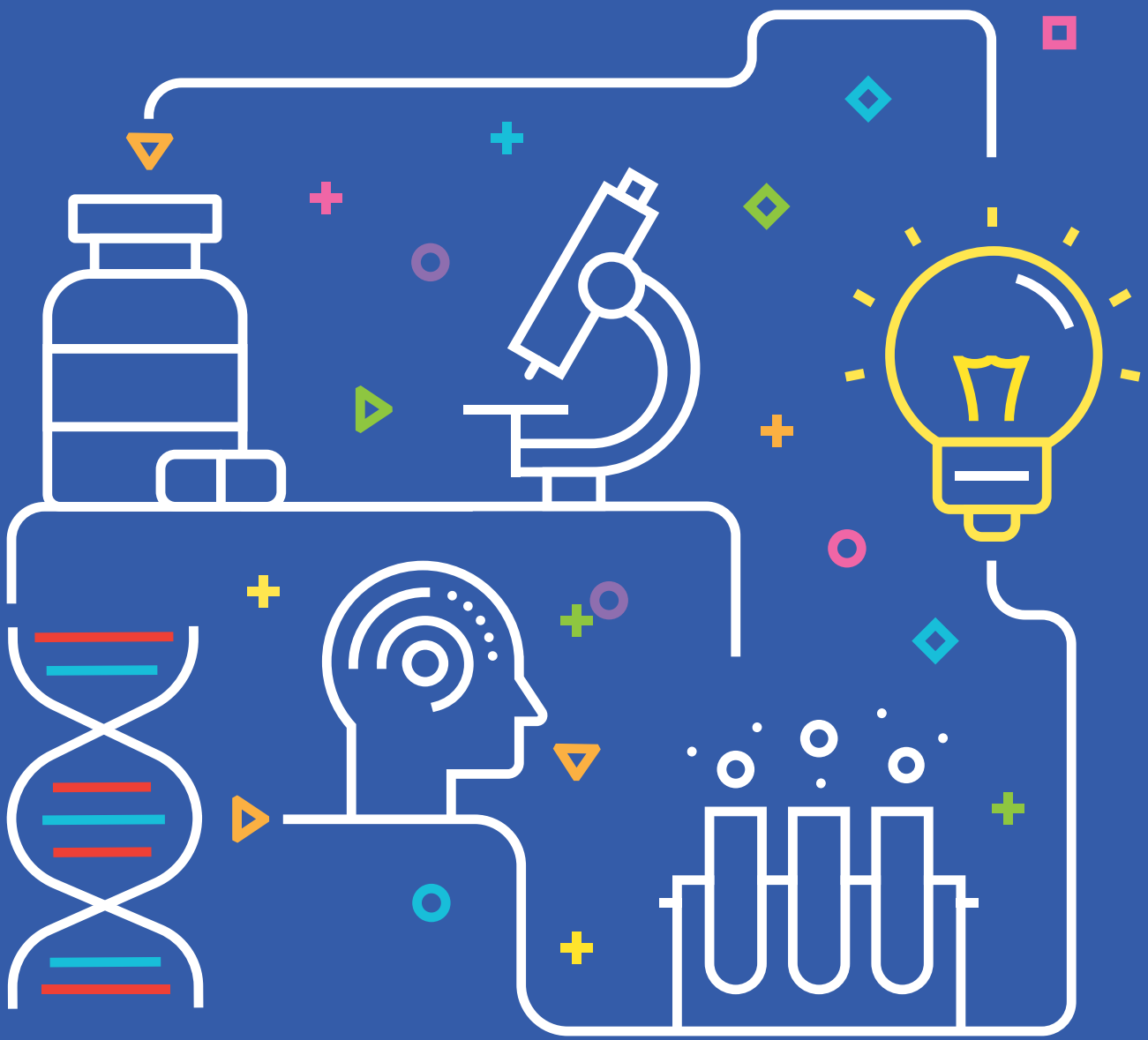
Maine Cancer Genomics Initiative

A Model for Translational Outreach



BY JENS RUETER, MD; JENNIFER BOURNE, MS; AND AMANDA PATTON, MA

The right treatment for the right patient at the right time is the aim of precision medicine. In oncology, identification of actionable biomarkers is increasing the paths to this goal in a growing number of disease subtypes. Advances in molecular biomarkers with U.S. Food and Drug Administration-approved targeted therapies and companion diagnostic tests, growth of treatment paradigm-changing immune checkpoint inhibitor therapies, and the emergence of chimeric antigen receptor T-cell therapy have highlighted the need for clinical, operational, and programmatic changes in cancer care delivery. New knowledge is accruing at warp speed, yet cancer care providers work in real time.

As researchers dive deeper into the nuanced biology of the diseases comprising cancer, the role of biomarkers in diagnosis and treatment expands and precision oncology continues to gain momentum. However, even in the instance of non-small cell lung cancer, which saw clinical guidelines for biomarker testing first issued in 2013 and then updated in 2018, standardizing implementation of these testing recommendations across all care settings is challenging. In a recent article, Pennell and colleagues describe the state-of-the-science and guidelines around biomarker testing for patients with advanced non-small cell lung cancer and the real-world difficulties clinicians face in bringing these into clinical practice.[1] The authors conclude that for the oncology community to more fully integrate these advances, there is a need for:

- Education on biomarkers and biomarker testing for providers, patients, administrators, payers, and policymakers.
- Provider education on how to understand and appropriately apply next-generation sequencing report information.
- Physician champions to spearhead integration of biomarker testing into practice.
- Communication across disciplines with agreed-upon common vocabulary and terminology.
- Access to tests and timely results so that this information can be incorporated into treatment planning.

In Maine, a program that addresses these issues has been underway for several years.

The Maine Cancer Genomics Initiative (MCGI), a collaboration between The Jackson Laboratory (JAX) and oncology care providers and patients across the state, may be an ideal incubator for a model that engages all oncology stakeholders as partners in advancing biomarker testing and application into practice...

A Community-Engaged Approach

The Maine Cancer Genomics Initiative (MCGI), a collaboration between The Jackson Laboratory (JAX) and oncology care providers and patients across the state, may be an ideal incubator for a model that engages all oncology stakeholders as partners in advancing biomarker testing and application into practice, increasing access to state-of-the-art genomic testing and to clinical trials.

According to the U.S. Census Bureau, Maine slightly edges out Vermont as the state with the highest proportion rural population (61.6 percent vs. 61.3 percent, respectively).[2] Although residents in some areas of Maine have convenient access to high-quality cancer care at academic medical centers and robust community practices, participation in clinical research is challenging not only due to the state's rural character but also because Maine, with a total population of 1.3 million, is so sparsely populated.[3] Oncology providers in the state already participate in important cancer collaborative research groups and clinical trials. However, JAX, an independent, nonprofit biomedical

Dr. Jens Rueter (L) with participating clinicians at an MCGI Genomic Tumor Board session.

research institution based in Bar Harbor, Maine, wanted to find a way "to harness the power of working in the community, to bring all oncology providers in the state together in collaboration with The Jackson Laboratory, to get more done for cancer care," said Jennifer Bourne, MS, program manager for the Maine Cancer Genomics Initiative.

The MCGI launched in 2016, with patient enrollment starting in July 2017. The first phase of the initiative focused on making genomic somatic cancer testing more accessible across the state. Leveraging the translational resources of the Jackson Laboratory for Genomic Medicine facility in Connecticut, JAX developed a cancer genomics panel. During the initiative's foundational phase (2016-2020), MCGI conducted a study that offered cancer somatic testing to clinicians for their patients at no cost and enrolled almost 1,650 patients. By surveying cancer clinicians and their patients, MCGI aimed to learn from their experience with integrating results of panel testing into practice. MCGI partnered with staff at the Maine Medical Center Research Institute and Center for Outcomes and Evaluation to design the survey instruments for the study and for data analysis.

Nearly all medical oncology practices in Maine—with the exception of the Veterans Administration—are participating in the MCGI. Early on, MCGI staff conducted extensive outreach to the community, traveling to practices and meeting with clinicians to explain the program's goals. Then, in August 2017, MCGI launched its first genomic tumor board program. Bourne credits these ongoing MCGI-hosted meetings with furthering clinician interest in the initiative. The genomic tumor board program is part of the interpretability education component of the MCGI, designed to expand clinician understanding of how the genetic panel test results are interpreted. Prior to the COVID-19 public health emergency, these conferences were held on-site at clinicians' practices. The JAX MCGI team would travel to the providers' site and "review any of the patient test results that the clinician wanted to review," Bourne said. From the start, the conferences included a virtual component and now—as a consequence of the COVID pandemic—are held exclusively via video conferencing.

Education around the evolving science and complexities of integrating genomic testing results into clinical practice is just one component of the MCGI. Operational support is another key piece of the initiative. Integration of rapidly changing clinical advances that necessitate cross-discipline specialists and application of new technologies can be impeded by multi-factorial operational and process-related challenges that impact all oncology stakeholders—patients, providers, payers, and policymakers.

"One of the interesting things about the MCGI study," said Bourne, "is that we have enabled practices in the state of Maine that have no research infrastructure to participate in a human subject protection program-compliant way in this study. What that means is we have a clinical research manager and clinical research associate in our offices who talk to the patients at rural practices who might want to participate in the MCGI study and enroll them on the study. In this way we provide support to enable the practice to be part of the research and ensure that interested participants are able to join the study."

In another example, an MCGI team member coordinates all genomic tumor board meetings. During a 60-minute session, four cases are usually discussed. MCGI staff coordinating the conference manage all of the logistics: scheduling the virtual tumor board, contacting participating practices for potential case submission, coordinating the cases to be discussed, and sending these to the prep team and expert advisers in advance of the conference. The conference coordinator also ensures that all of the technical components needed to run the session are in place and tracks provider attendance because continuing medical education is offered for participation. Typically, the discussion focuses on the results of the panel tests, so imaging is not required. "The exception to that is the neuro-oncology practice. They often send brain scans to incorporate into the discussion as well," Bourne said.

Each genomic tumor board conference includes a clinical trials expert who is prepared with information on any locally available studies for which the patient's genomic test results are a match. "In these sessions, we also have had national, and one international, medical experts in the translational medical oncology area, so treating clinicians are able to have peer consults with key opinion leaders in the field," which brings added value, notes Bourne. MCGI genomic tumor board case presentations are de-identified and any MCGI participating practice can call in to the conferences.

Though gaining buy-in "always takes a little bit of time," said Jens Rueter, MD, Jackson Laboratory Medical Director and Principal Investigator of MCGI, "… we made it very clear that we're doing this to help the clinicians and the patients overall in navigating through very complex genomic information. … I think people saw over time that what we are doing will provide them with value, and they were excited to participate as they recognized that the MCGI is what they want for their patients."

The MCGI was designed based on the needs of the Maine community. "The personalization that we were able to take to the practices by building this group, this alliance, and then getting their feedback about what's it like to integrate these things; I think that's made it exciting in a lot of ways," said Bourne.

MCGI offices are located in the community, in space leased from ACCC member MaineGeneral Harold Alfond Center for Cancer Care. When the COVID-19 virus spread escalated, an unanticipated opportunity for additional collaboration emerged. The Jackson Laboratory, which offers next-generation sequencing, expanded its capability to include COVID-19 testing. A number of the Maine institutions, including some hospitals participating in the MCGI, turned to the JAX for these tests, notes Dr. Rueter, including MaineGeneral. By providing access to COVID-19 testing, the Jackson Laboratory was able to support these programs as they moved to restore elective surgery procedures delayed by the pandemic.

A Model for Translational Outreach

JAX is one of only seven National Cancer Institute-designated cancer centers dedicated to basic and translational cancer research. Scientists at the JAX Cancer Center engage in laboratory research that combines advances in knowledge of human cancer genomics with mouse biology and genetics to ask clinically meaningful questions about cancers with a goal of finding precise genomic solutions for the disease. The JAX Cancer Center extends to two campuses that comprise approximately 50 members with multidisciplinary expertise focused on a single research goal: understanding and targeting the genomic complexity of cancer. MCGI connects to this goal as "a model of what we call translational outreach," said Dr. Rueter. "If you think about it this way—we need to more quickly apply the basic science findings to clinical problems and then take the clinical outcomes back to the bench. The JAX Cancer Center has its programs right at that interface—translational research."

Engaging with community providers is vital, Dr. Rueter believes, because the learning "goes both ways."

As an example, Dr. Rueter explains the JAX Cancer Center's long-standing participation in SWOG and a number of SWOG subcommittees. "In many of these committees, we are providing expertise in the mouse modeling of diseases. On the other hand, the MCGI is represented in SWOG within the Cancer Care Delivery Committee. We are contributing to discoveries at the last step in the translational process—implementation in the clinic."

"We don't have Phase I, II, and III clinical trials, but we have a strong foothold in the basic translational world, and we also have now a growing footprint in the ultimate translation, which is integration into practice," said Dr. Rueter. As a next step, the JAX Cancer Center is working on a study proposal that would "apply a rigorous clinical trial to an MCGI-type model. Within the SWOG framework, we want to use that approach toward really a rigorous evaluation of what actually works and what doesn't work so that we can bring that whole field of precision medicine forward."

Engaging with community providers is vital, Dr. Rueter believes, because the learning "goes both ways."

For translational research institutions "it's important to know what the clinical problems are that we are trying to address, and what we can do to impact those problems and what are the effects of that intervention? Just because we are providing [genomic] testing, for example, doesn't mean that it is ultimately positively impacting patient outcomes. We need the feedback from the community on what works and what doesn't work. At the same time, the clinical community also needs to know what are the newest trends in the discovery process? What are the new data that are coming out and how should I be re-thinking my practicing conventions, and how do I need to adapt to deliver the best possible care to my patients?"

As the field of precision oncology moves forward "to deliver the best care, all the components have to work hand-in-hand.

You need the right biomarker, you need the right drug, you need the right study design to understand the implications of both of them, and then apply it to practice."

With MCGI's genomic tumor boards, Dr. Rueter believes that JAX is on the right track "because we are trying to address a core issue that is not ours alone. Everyone is grappling with the question of how do you best present complex data, in a format [for clinicians]? How do you organize this so that people actually show up and can participate? And then, what are the outcomes and how do we address the remaining questions."

In October 2020 the MCGI team moved into the next phase of work with the Maine oncology community. The focus will be on accessibility of cancer genomic testing, supporting clinicians with interpretability of results and actionability in precision oncology. The MCGI team will expand efforts to make access to more treatments and clinical trials possible while continuing to facilitate regional access to cancer genomic testing. OI

Jens Rueter, MD, is medical director, The Jackson Laboratory, and principal investigator of MCGI. Jennifer Bourne, MS, is program manager for MCGI. Amanda Patton, MA, is a freelance healthcare writer.

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References

1. Pennell NA, Arcila ME, Gandara DR, West H. Biomarker testing for patients with advanced non-small cell lung cancer: real-world issues and tough choices. *Am Soc Clin Oncol Educ Book*. 2019;39:531-542.

2. U.S. Census Bureau. Geographic areas and rural data. Available online at: gis-portal.data.census.gov/arcgis/apps/MapSeries/index.html?appid=7a41374f6b03456e9d138cb014711e01. Last accessed October 21, 2020.

3. U.S. Census Bureau. Maine. Available online at: data.census.gov/cedsci/profile?g=0400000US23. Last accessed October 21, 2020.

MCGI Participating Oncology Programs & Practices in Maine [as of 12/2020]

- Harold Alfond Center for Cancer Care, Augusta*
- MDI Hospital Oncology and Infusion Therapy, Bar Harbor
- MaineHealth Waldo County General Hospital Oncology and Infusion Therapy, Belfast
- Northern Light Cancer Institute, Northern Light Eastern Maine Medical Center, Brewer*
- Cancer Care at Midcoast Hospital, Brunswick
- Pines Hematology/Oncology, Cary Medical Center, Caribou*
- Northern Light Cancer Care at Northern Light Maine Coast Hospital, Ellsworth
- New England Cancer Specialists, Kennebunk
- York Hospital Oncology & Infusion Care, Kittery
- Hematology-Oncology Associates at Central Maine Healthcare, Lewiston*
- St. Mary's Center for Cancer & Blood Disorders, Lewiston
- MaineHealth Stephens Memorial Oncology Clinic, Norway
- Northern Light Cancer Care at Northern Light Mercy Hospital, Portland
- Northern Light Cancer Care at Northern Light AR Gould Hospital, Presque'Isle
- MaineHealth Cancer Care Center York County, Sanford
- New England Cancer Specialists, Scarborough*
- Maine Medical Partners Medical Oncology, South Portland
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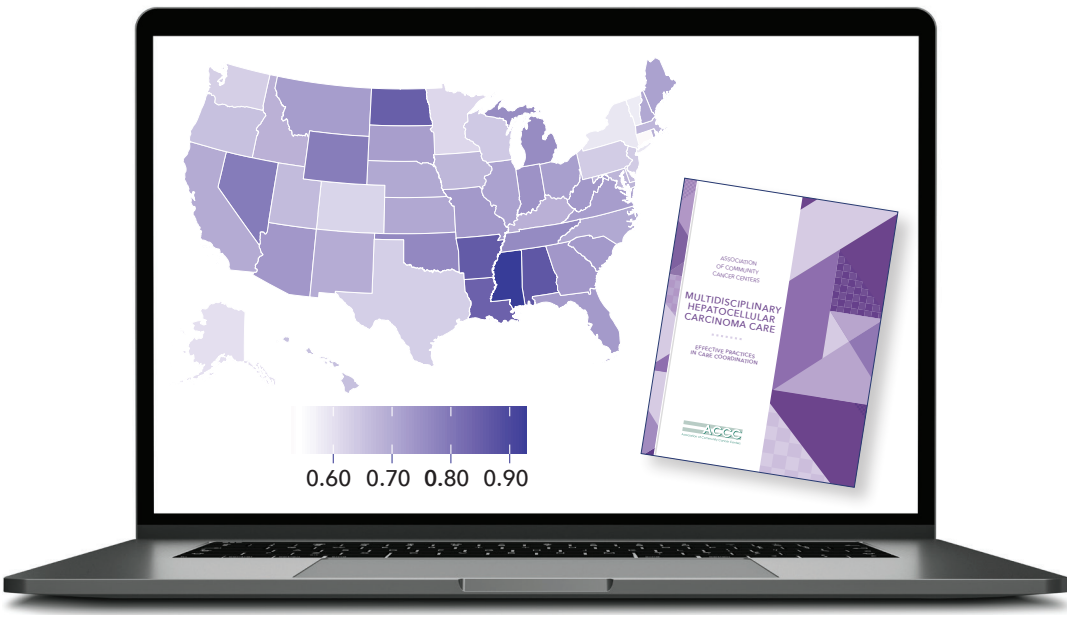

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An Optimal Care Coordination Model for Medicaid Patients with Lung Cancer:
Rationale, Development, and Design

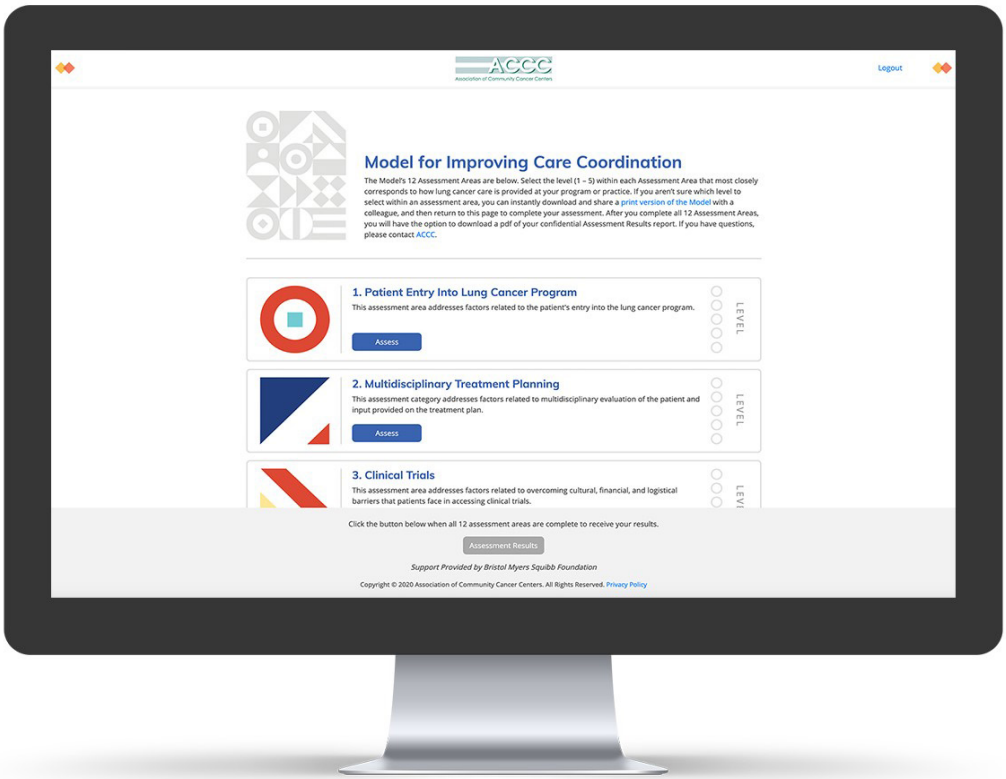
BY RANDALL A. OYER, MD; CHRISTOPHER S. LATHAN, MD, MS, MPH; THOMAS M. ASFELDT, MBA, RN, BAN; AMANDA KRAMAR; AND LEIGH M. BOEHMER, PHARMD, BCOP

Patient-centered care that is accessible, affordable, evidence based, and well coordinated is integral to high-quality cancer care delivery.[1] Medicaid and other socioeconomically disadvantaged patients may have disproportionately high-risk profiles (e.g., prevalence of adult cigarette smoking: 24.5 percent for Medicaid insurance [including dual coverage or other state-sponsored health plans] vs. 10.5 percent for private insurance).[2] Additional challenges include inconsistent coverage for lung cancer screening in state Medicaid programs[3] and burden from comorbidities.[4,5] Advanced-stage cancer diagnosis[4,6]; barriers related to travel distance and time, vehicular access, or other reliable options[7]; and treatment initiation delays[4,6] are other challenges. Cancer outcomes are also often worse among Medicaid patients compared to privately insured patients[4-6,8-10] (e.g., significantly lower median overall survival in stage I/II non-small cell lung cancer [3.42 years vs. 6.23 years, respectively; $p < 0.05$]).[5]

In 2016, the Association of Community Cancer Centers (ACCC) embarked on a three-year initiative to design, test, and refine an Optimal Care Coordination Model (OCCM) for Medicaid patients with lung cancer. This model aimed to assess and strengthen lung cancer care delivery systems across the United States that have the potential to improve outcomes for Medicaid patients by identifying disparities and inequities and facilitating access to and use of multidisciplinary coordinated care. The multidisciplinary aspect includes disciplines such as medical oncology, pathology, radiation oncology, thoracic surgery, oncology nursing, and patient navigation.[1] Case planning requires enhanced coordination from multidisciplinary teams for timely care and improved patient experience and clinical outcomes.[1]

Development of an Optimal Care Coordination Model for Medicaid Patients with Lung Cancer

As a leading United States education and advocacy organization comprising more than 28,000 multidisciplinary practitioners in 2,100 cancer programs and practices, ACCC is uniquely positioned to undertake this initiative.[11] A 13-member Advisory Committee was established in January 2016, with representation from physicians, an oncology nurse, a social worker, a patient navigator, cancer center executives, patient advocates, and researchers, with expertise spanning medical oncology, disparities research, and community outreach. The



list of members, including affiliations and expertise, is available at accc-cancer.org/projects/improving-care-coordination/leadership.[12] This Advisory Committee assessed institutional environments, patients' social determinants of health, social needs, and their consequences that lead to disparities in care to inform OCCM development. The environmental scan included a literature review of experiences and outcomes of Medicaid patients across the lung cancer care continuum, such as outcome disparities with non-Medicaid patients, treatment variations and delays, care coordination between primary care providers and oncology specialists, and supportive services to manage psychosocial needs. These documents are available on the ACCC website.[13] Key stakeholder interviews were conducted with Advisory Committee members, lung cancer survivors and patient advocates, and staff from ACCC Cancer Program Members between April and May 2016. Broad barriers to lung cancer care delivery for Medicaid patients were identified, including:[14]

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

Subsequently, a competitive application process open to all ACCC Cancer Program Members was established, and five Development Sites demonstrating best practices in care coordination for Medicaid patients with lung cancer were selected. The criteria to evaluate the sites included 1) volume of Medicaid patients with lung cancer; 2) diversity of the patient population; 3) breadth and depth of patient services; and 4) relationships with healthcare providers, Medicaid offices, and community partners. Site-specific perspectives of physicians, staff, and Medicaid patients on effective practices, challenges, and solutions for coordinating care delivery were documented during on-site visits between August and October 2016. Key stakeholder interviews encompassed screening, diagnosis, and treatment; problems in accessing timely, high-quality care; social supports; involvement in healthcare decision-making; and factors affecting treatment outcomes. After these interviews, an in-person meeting of the Advisory Committee was convened in November 2016. Development of the OCCM was undertaken by a Technical Expert Panel with guidance from the Advisory Committee, ACCC staff, and research consultants, as required. The list of members, including affiliations and expertise, is available at: accc-cancer.org/projects/improving-care-coordination/leadership.[12]

OCCM Design

Central to the design of the OCCM was the National Cancer Institute Community Cancer Centers Program's Multidisciplinary Care (MDC) assessment tool.[15] This tool was designed to enhance access to care and quality of care delivery in the community setting, where most patients with a cancer diagnosis receive care.[15] It measures implementation across key assessment areas, such as case planning, physician engagement, and coordination of care, on a scale of 1 (*evolving MDC program*) to 5 (*achieving MDC excellence*).[15] The OCCM has an architecture similar to the MDC assessment tool, with multiple assessment areas and aspirational levels of development.

The OCCM was designed to be a usable framework that offers lung cancer programs, regardless of setting, size, and resource level, and the flexibility to conduct continuous assessments of care coordination practices and measure strengths and opportunities in the pursuit of optimal patient outcomes. The OCCM framework was guided by two overarching principles: 1) a patient-centered focus, where patients' needs and preferences determine how the health system organizes and provides care, and 2) reliance on data and evidence for assessment areas to ensure the Model's responsiveness and relevance. The corresponding model, which builds on the MDC assessment tool, focused on 13 high-impact assessment areas across the lung cancer care continuum:

1. Patient access to care
2. Prospective multidisciplinary case planning
3. Financial, transportation, and housing needs
4. Management of comorbid conditions
5. Care coordination
6. Treatment team integration
7. Electronic health records and patient access to information
8. Survivorship care
9. Supportive care
10. Tobacco cessation, including evaluation of use
11. Clinical trials
12. Physician engagement
13. Quality measurement and improvement.

Details are provided in a companion manuscript by Smeltzer et al. to be published in *Oncology Issues*, Vol. 36, No. 3, 2021. An important principle of the OCCM is that it was not intended to be all-encompassing, resulting in a lengthy academic exercise, but rather a high impact, usable model that could be deployable in any setting.

Each OCCM assessment area has five levels, rated from 1 (indicative of *fragmented care with low focus placed on care coordination*) to 5 (indicative of *optimal care coordination with a patient-centered focus*). The assessment tool not only aids cancer programs in identifying the current level but is designed to determine an achievable or aspirational future target level and ultimately facilitate improvement to this level. Each program's starting point will be different, as will its target level for near- and long-term improvement. Depending on the assessment area, achieving a Level 5 will be attainable for some programs and may be aspirational for others. Though a program may choose to evaluate an assessment area in isolation, the OCCM framework relies on the interplay between assessment areas within a system and should, ideally, be evaluated in its entirety. For each assessment area, programs

should select at least one measurable parameter as an evidence-based, institution-specific benchmark to address patient experience, patient outcomes, and cost-effectiveness. These metrics should be continually monitored to inform future quality improvement plans. Congruent efforts in care coordination include the Commission on Cancer, which collects standardized data for monitoring of treatment patterns and outcomes[16]; the Quality Oncology Practice Initiative,[17] which collects evidence-based performance data to identify, develop, and implement quality improvement initiatives; and the Oncology Care Model, a specialty model from the Center for Medicare and Medicaid Innovation to address financial barriers.[18]

BETA OCCM and Beyond

Community-based cancer programs were selected for pilot testing via a competitive application process. These sites conducted self-assessments of lung cancer care delivery systems and promoted multidisciplinary coordinated care through quality improvement projects over 12 months. These results (Smeltzer et al., 2021) informed model refinements. Overall, the Technical Expert Panel met at least five times to review inputs from development and testing sites, then working with the Advisory Committee and the Lead Clinical Research Consultant on recommended changes to the model. The Technical Expert Panel focused its reviews on titles, definitions, and level elements of assessment areas to reflect direct learnings from the National Cancer Institute Community Cancer Centers Program project and daily experiences in the cancer center environment. A final manuscript by Oyer et al., describing the refinements, nationwide dissemination with online resources to enable expanded use, and implications for Medicaid policy and clinical practice is slated for publication in *Oncology Issues*, Vol. 36, No. 4, 2021.

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References

1. Institute of Medicine. *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*. Washington, DC: National Academies Press; 2013.

2. Wang TW, Asman K, Gentzke AS, Cullen KA. Tobacco product use among adults - United States, 2017. *MMWR Morb Mortal Wkly Rep*. 2018;67(44):1225-1232.

3. American Lung Association. Lung cancer screening coverage in state Medicaid programs. Available online at: lung.org/getmedia/cb086cfd-2fbb-4737-b518-e83cf1fcc411/lung-cancer-screening-1.pdf.pdf. Last accessed October 6, 2020.

4. Slatore CG, Au DH, Gould MK. An official American Thoracic Society systematic review: insurance status and disparities in lung cancer practices and outcomes. *Am J Respir Crit Care Med*. 2010;182(9):1195-1205.

5. Shi R, Diaz R, Shi Z, et al. The effect of payer status on survival of patients with stage I/II non-small cell lung cancer: NCDB 1998-2011. *Anticancer Res*. 2016;36(1):319-326.

6. Halpern MT, Ward EM, Pavluck AL, et al. Association of insurance status and ethnicity with cancer stage at diagnosis for 12 cancer sites: a retrospective analysis. *Lancet Oncol*. 2008;9(3):222-231.

7. Syed ST, Gerber BS, Sharp LK. Traveling towards disease: transportation barriers to health care access. *J Community Health*. 2013;38(5):976-993.

8. Niu X, Roche LM, Pawlish KS, Henry KA. Cancer survival disparities by health insurance status. *Cancer Med*. 2013;2(3):403-411.

9. Singh GK, Williams SD, Siahpush M, Mulhollen A. Socioeconomic, rural-urban, and racial inequalities in U.S. cancer mortality: part I-all cancers and lung cancer and part II-colorectal, prostate, breast, and cervical cancers. *J Cancer Epidemiol*. 2011;2011:107497.

10. Ward E, Halpern M, Schrag N, et al. Association of insurance with cancer care utilization and outcomes. *CA Cancer J Clin*. 2008;58(1):9-31.

11. Association of Community Cancer Centers. ACCC Overview. Available online at: accc-cancer.org/home/about. Last accessed October 6, 2020.

12. Association of Community Cancer Centers. Improving Care Coordination: project leadership. Available online at: accc-cancer.org/projects/improving-care-coordination/leadership. Last accessed October 6, 2020.

13. Association of Community Cancer Centers. Improving Care Coordination: project resources. Available online at: accc-cancer.org/projects/improving-care-coordination/project-resources. Last accessed October 6, 2020.

14. Association of Community Cancer Centers. Optimal Care Coordination Model for lung cancer patients on Medicaid: environmental scan. Available online at: accc-cancer.org/docs/projects/resources/pdf/accc-care-coord-environmentalscan-final.pdf?sfvrsn=721c4439_0. Last accessed October 6, 2020.

15. Swanson PL, Strusowski P, Asfeldt TM, et al. Expanding multidisciplinary care in community cancer centers. In: Marino M, Patton A, eds., *The NCCCP: Enhancing Access, Improving the Quality of Care, and Expanding Research in the Community Setting*. Rockville, Md.: Association of Community Cancer Centers, 2012:40-44.

16. American College of Surgeons. Commission on Cancer. Available online at: facs.org/quality-programs/cancer/coc. Last accessed October 6, 2020.

17. American Society of Clinical Oncology Practice Central. Quality oncology practice initiative. Available online at: practice.asco.org/quality-improvement/quality-programs/quality-oncology-practice-initiative. Last accessed October 6, 2020.

18. Centers for Medicare & Medicaid Services. Oncology care model. Available online at: innovation.cms.gov/initiatives/oncology-care/. Last accessed October 6, 2020.

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

ASSOCIATION OF COMMUNITY CANCER CENTERS

IMPROVING THE QUALITY OF CARE FOR PERSONS WITH ADVANCED EPITHELIAL OVARIAN CANCER

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More than 20,000 women are diagnosed with ovarian cancer each year in the United States, most with advanced stage disease.[1] With five-year cause-specific survival of 47 percent, ovarian cancer is the fifth leading cause of cancer death among women in the United States.[2,3] However, outcomes vary significantly by tumor stage, histologic type, and socio-demographic factors. Disparities in outcomes may be attributable to many factors, including sub-optimal quality of care.[4-6] In the United States, fewer than one third of patients with this disease currently receive guideline-concordant care.[7] Recent advancements in curative intent therapeutic options for patients with ovarian cancer put a renewed emphasis on the need for high-quality care delivery.[8,9]

Improvement in overall outcomes and eliminating disparities in outcomes require proactive delivery of quality care. This necessitates a firm definition of quality and effective strategies to deliver evidence-based care. The National Comprehensive Cancer Network clinical practice guidelines provide an evidence-based standard for care.[10] However, non-adherence to National Comprehensive Cancer Network guidelines is associated with disparities in outcomes for persons with ovarian cancer.[11] More resources are needed to guide the implementation of evidence-based standards and quality improvement (QI) initiatives in ovarian cancer.

To address these gaps, the Association of Community Cancer Centers (ACCC) launched a multi-phase initiative to improve care delivery for ovarian cancer in the United States in 2019. The project was guided by an expert multidisciplinary Steering Committee, which included gynecologic oncologists, pathologists, genetic counselors, nurse navigators, social workers, and cancer program administration. In this article, we describe the process and outcomes from this QI initiative.

Our Approach and Methodology

The education project had three primary components, including an application survey, recruitment and execution of three QI workshops, and the curation of a comprehensive resource library dedicated to patient- and provider-specific ovarian cancer educational resources.

The ovarian cancer workshop application was developed to survey a diverse group of ovarian cancer programs across the United States. The goals were two-fold: first, to ascertain areas of greatest need for QI initiatives and, second, to identify ACCC member programs for participation in the QI projects. After completion of the survey, the project Steering Committee and ACCC staff evaluated the results and identified areas to target and cancer programs to include in the QI projects.

Three cancer programs were selected based on the Steering Committee review of the workshop application results. The ACCC team conducted one-day on-site workshops with the care delivery teams at each cancer program. The workshops included guided discussion to identify challenges and specific barriers the teams

faced in optimal care delivery and develop a problem statement for the project. Based on the problem statements, QI interventions were determined and QI metrics were developed to quantify progress during the study period.

Application Survey

The QI workshop application survey was designed to collect clinical information about each cancer program and to provide information on the key challenges and opportunities for improving ovarian cancer care. The survey was designed with multi-stage input from the Steering Committee. The final version included 20 items and was administered online using the Qualtrics platform.[12] The survey was distributed to ACCC, Oncology State Societies at ACCC, and Society of Gynecologic Oncology members via email promotion and was open for participation for four weeks.

Steering Committee Guidance

The Steering Committee provided guidance on the scope of the project, including the content of the application survey, site selection, defining quality care, and development of each site's QI project. Interactions occurred via email, quarterly conference calls, two in-person meetings, and one follow-up web-based conference with the three cancer programs who participated in the QI workshops. Additionally, several subject-matter experts from the Steering Committee participated in the in-person site QI workshops. The Steering Committee created content for a didactic session in each workshop, covering multiple aspects of quality care for patients with ovarian cancer.

Through this comprehensive educational process, the Steering Committee developed an ovarian cancer quality care document. This document served to provide evidence-based guidance on best practice in ovarian cancer care by identifying quality-directed program components, implementation barriers, and recommendations. Upon finalization, the quality document will be widely disseminated as a resource to ovarian cancer programs across the cancer care continuum.

Workshop Methodology

After the application survey was closed for responses, sites for the QI projects were selected by a two-stage process. First, the Steering Committee independently ranked the applications and selected a group of finalists. The finalists were then stratified by geographic region and type of cancer program. The committee then convened to discuss the finalists, cancer programs were ranked, and the three participating cancer programs were selected based on committee consensus.

Each QI workshop was preceded by conference calls with the cancer program and ACCC teams, where the topic for the QI initiative was determined and key stakeholders were identified. On-site workshops were scheduled for a full day, with key stakeholders who represented the multidisciplinary care team from each cancer program scheduled to attend. In addition to project development, the workshops included didactic sections led by a content expert from the Steering Committee. The didactic sessions were customized to meet the needs and interests of each cancer program. QI workshops included robust discussion to obtain feedback on "pain points," challenges, and concerns from key stakeholder groups. Discussions were facilitated with custom discussion guides, created by the ACCC team, intended to employ a grounded theory approach. Development of each QI project utilized the Plan-Do-Study-Act (PDSA) methodology.[13,14]

After robust stakeholder discussion, development of a consensus problem statement from each cancer program was guided by BiteSize QI.[15] Stakeholders then worked together to build consensus around the changes that could be made that would address the identified problem, strategies to implement change, and potential barriers to success. A specific intervention(s) was selected and stakeholders defined metrics of success. Measures of improvement were delineated, which included both quantitative data benchmarks and qualitative process-level information.

Each project was given a six-month prospective timeline consisting of three PDSA cycles, each two months in length. Data were collected retrospectively to define the ovarian cancer population at the cancer program and to define the baseline data benchmarks for each study. Data were evaluated at baseline, two months, four months, and six months to measure the success of the project in improving quality benchmarks in alignment with the PDSA cycles.

Application Survey Summary

Application survey responses were received by 26 cancer programs. After exclusion of five responding cancer programs that were not current ACCC members, 21 were eligible for selection into the QI workshops. Respondents included diverse program types, including National Cancer Institute (NCI)-designated comprehensive cancer centers (five), comprehensive community cancer programs (six), academic comprehensive cancer programs (five), integrated network cancer programs (three), and a range of other categories. The 26 responding cancer programs had a median of 51 annual new ovarian cancer cases (range, 22-190). The average reported stage distribution for patients with ovarian cancer across cancer programs was 30 percent Stage I/II and 70 percent Stage III/IV. The average race distribution across cancer programs was 80 percent white, 10 percent black or African American, 3 percent Asian, and 7 percent other. Eighty-five percent of cancer programs reported having a multidisciplinary team for ovarian cancer care. Programs reported 80 percent germline multigene panel testing on average, and 75 percent provided genetic counseling.

Each cancer program identified key areas for QI via free-text response. Genetic testing and counseling were the most frequently mentioned topic (12 of 26 programs). The second and third most frequent topics included clinical trial enrollment and availability and multidisciplinary team care, respectively (see Figure 1 below). After the two-stage selection process, three cancer programs were chosen for the QI initiatives: the Willis-Knighton Cancer Center, the Blavatnik Family—Chelsea Medical Center at Mount Sinai, and Duke Cancer Center.

The Willis-Knighton Cancer Center Experience

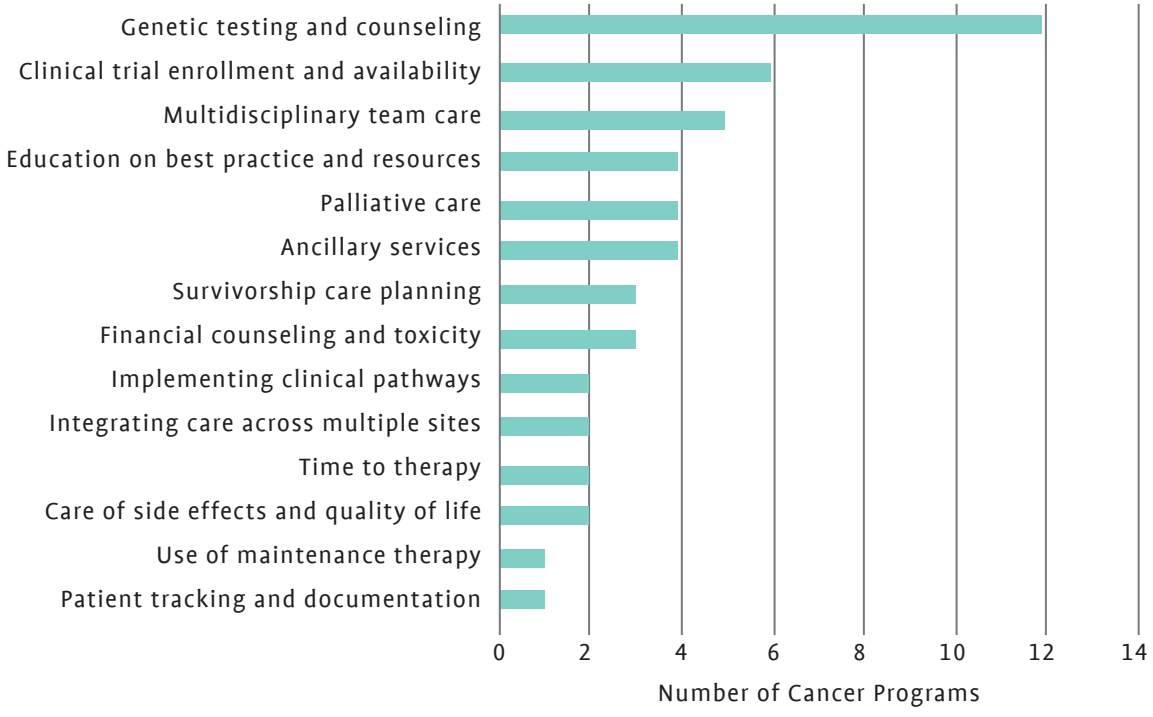
Willis-Knighton Cancer Center in Shreveport, La., is an ACCC member that serves as a site for the NCI Community Oncology Research Program and for Gynecologic Oncology Group clinical trials. The cancer center serves as a referral center for many rural communities and treats women diagnosed with ovarian cancer within a catchment area greater than 100 miles. For this project, the multidisciplinary ovarian cancer team decided to focus on improving genetic testing practices.

At the site visit, the ovarian cancer team self-assessed the strengths and weakness of its current program. Treatment of ovarian cancer at Willis-Knighton Cancer Center improved greatly over the past 20 years, with most improvement initiated 12 years ago when the first gynecologic oncologist joined the cancer center. High-quality surgical care was a self-identified strength of the program, as well as a strong group of medical oncologists and cancer-dedicated obstetrician-gynecologists who were invested in providing quality care within the ovarian cancer program. The team had strong support from cancer center administration and information technology (IT).

Many patients were referred from outside the Willis-Knighton Cancer Center system, at different stages of care and diagnosis. Patients may have received sub-optimal surgery or experience delays in care before they reach Willis-Knighton Cancer Center. The ovarian cancer team identified several areas for potential improvement:

- Provider communication
- Survivorship care
- Previvor (persons with a high-risk of developing ovarian cancer) care
- Genetic testing as areas for potential improvement.

Figure 1. Key Areas of QI in Ovarian Cancer Identified from the Application Survey



Process of Care

Referral patterns and processes of care provided some challenges at the Willis-Knighton Cancer Center; approximately 75 to 80 percent of patients with ovarian cancer treated at the cancer center lived outside the Shreveport area. The cancer center received 60 to 100 referrals (all cancer types) per month, and patients with ovarian cancer sometimes arrived months after the suspected diagnosis, resulting in delays in care. Sub-optimal surgical resection performed by general surgeons prior to referral to Willis-Knighton Cancer Center was a particular concern. Given the referral patterns and rural setting, transportation was also identified as an issue for many patients with ovarian cancer. The ovarian cancer team is exploring strategic partnership with rideshare companies (i.e., Uber, Lyft) to address this barrier.

During treatment, patients with ovarian cancer at Willis-Knighton Cancer Center may have been seen by a gynecologic oncologist, obstetrician-gynecologist, and medical oncologist. Currently, provider-to-provider communication is fragmented. Though the care teams worked together well, additional structure around communication could improve care processes. Two potential solutions for communication were discussed, a virtual tumor board and a new communication tool within the electronic health records (EHR) system. An additional solution identified was the development of podcasts to educate patients and persons about ovarian cancer, to aid with both community awareness and patient understanding of the care process. The ovarian cancer team decided the lead gynecologic oncologist would move forward with the development of these podcasts.

Genetic Testing

The rates of germline and somatic testing in patients with ovarian cancer at Willis-Knighton Cancer Center were unknown. Due to the recent evidence regarding upfront maintenance treatment options for patients with ovarian cancer based on molecular profiles, the team would like to develop a clinical pathway for germline and somatic testing for every patient at the time of their ovarian cancer diagnosis.[7] One barrier to reflex testing identified was the need for physician-specific order sign-off. It was determined that this barrier could be addressed by the cancer committee. Additional barriers to optimal testing included:

- Insurance reimbursement
- Referral timing
- Team communications as it pertains to current workflows and practice processes
- Patient logistics and transportation.

The ovarian cancer team at Willis-Knighton Cancer Center aimed to improve the rates and processes around genetic testing. The team also set goals to improve inter-team communications and enhance patient education through a provider generated podcast. The problem statement, aims statement, and proposed solutions evaluated in three PDSA cycles are described in Table 1, page 41. Key measurements included the proportion of patients with ovarian cancer who:

1. Received germline testing within 60 days of first clinic contact.
2. Had a positive germline test.
3. Received somatic testing within 60 days of first clinic contact.
4. Had a positive somatic test.

Findings from Willis-Knighton Cancer Center

The cancer center increased the proportion of patients with ovarian cancer who received genetic testing during this study. During the pre-study retrospective period, 31 percent of patients did not receive genetic testing. In the three consecutive two-month periods of this project, the percentage un-tested dropped to 8 percent, 8 percent, and 15 percent, respectively (Table 2, page 42). Per post-study feedback, the QI workshop boosted collaboration between key players in cancer care at Willis-Knighton Cancer Center. The ovarian cancer team used this project to improve the care coordination of its multidisciplinary team. As a result of the workshop, the IT department provided a new opportunity to improve care in other disease sites by establishing genetic testing reminders in the EHR. The team also worked with IT to create a Health Insurance Portability and Accountability Act-compliant platform to efficiently communicate among team members. The ovarian cancer team started working with the cancer committee at Willis-Knighton Cancer Center to raise the bar, implementing tumor molecular profiling in conjunction with germline genetic testing to care for other cancers at the center.

The COVID-19 pandemic created unexpected challenges and opportunities during this QI project. The pandemic decreased the number of patient visits and reduced the amount of face-to-face contact between the ovarian cancer team and patients. However, during this time, the team's genetic educator utilized Zoom technology to conduct virtual meetings with patients. She educated patients on the value of genetic testing and conducted 190 genetic tests for patients and family members across all cancer types via mail-out home test kits.

Several barriers to genetic testing were identified during the QI project. For somatic testing, the need to obtain pre-authorization before testing emerged as a barrier to optimal timing of testing. In addition, the need for supplemental patient education remained a barrier to germline testing. Through this project, Willis-Knighton Cancer Center identified a future opportunity to eliminate this barrier by producing a germline testing-specific video for patient education purposes. After completion of the project, Willis-Knighton Cancer Center began using a video

Table 1. Problems, Aims, and Approaches by Cancer Center

Willis-Knighton Cancer Center	The Blavatnik Family—Chelsea Medical Center at Mount Sinai	Duke Cancer Center
Problem Statement		
For the past five years, patients and their families at the Willis-Knighton Health System have not consistently received genetic testing and genetic counseling. This may have led to missed opportunities for appropriate therapies and potentially impacted care for their families.	Historically, newly diagnosed patients with ovarian cancer and family members at the Blavatnik Center have not had systematic genetic testing for somatic mutations or comprehensive genetic pre- and post-counseling. This could potentially impact their understanding of current or potential treatment plans and could have significant implications for their family members.	Historically, patients with ovarian cancer at Duke Cancer Center have been under-enrolled in clinical trials. This is preventing future advances and we are concerned about the diversity of our enrollment.
Aim Statement		
In the next six months, germline (and somatic if eligible) testing orders will be placed within 60 days of clinic encounter in the Willis Knighton Healthcare System, with the goal to achieve 100% for patients with a new diagnosis of ovarian cancer and a 15% improvement.	In the next six months pre- (video) and post-counseling efforts will be increased at the Blavatnik Center to ensure 100% of patients receive pre-counseling and 100% of all positive testing patients will receive post-counseling.	Within the next six months, enrollment of clinical trial candidates at Duke Cancer Center (both gynecologic oncology clinic locations) will improve by 20%. We expect that systematic identification of candidates will improve the overall diversity of enrolled subjects.
Solution		
We will utilize prospective tracking with data benchmarking, an EHR notification, and a backup verification of testing from gynecologic oncology associates at six- to eight-week follow-up.	The solutions identified include: • Creating SmartSet in the EHR • Offering educational video to patients prior to testing • Providing and documenting family member letter for cascade testing Additionally, the team will create a protocol for reflex somatic testing for all newly diagnosed patients with ovarian cancer.	• Create a smart phrase in the EHR to prompt physicians to screen patients • Utilize the smart phrase in the EHR • Generate a clinical trials screening report • Utilize a medical student to review the screening report for potentially eligible patients • Provide feedback on the smart phrase • Provide feedback on clinical trials enrollment
Plan-Do-Study-Act Approach		
Cycle 1: Prospectively track germline and somatic testing, record data.	Cycle 1: Prospectively track germline testing and genetic counseling pre-testing; document conversations about cascade testing.	Cycle 1: Develop the pre-screening process and add the smart phrase as a reminder for physicians to conduct their own screening.
Cycle 2: Utilize alert in the EHR to notify the provider that a patient with ovarian cancer needs genetic testing.	Cycle 2/3: Add "Smart Set" to EHR; implement genetic education video for pre-testing; utilize family member letter for cascade testing.	Cycle 2: Implement the new pre-screening system across the ovarian cancer program.
Cycle 3: Gynecological oncology associates will check each patient at six- to eight-week follow-up visit to ensure the genetic testing has been completed.		Cycle 3: Provide feedback to clinical trials team on pre-screening system and utilize the revised screening system. Provide additional feedback to providers on clinical trials screening and enrollment for patients with ovarian cancer.

Table 2. Willis-Knighton Cancer Center QI Metrics by Study Period

Retrospective data	Metric		Cycle 1		Cycle 2		Cycle 3	
	n	%	*n*	%	*n*	%	*n*	%
Testing to date	28		12		12		13	
Germline only	7	25	4	33	5	42	7	54
Somatic only	3	11	2	17	2	17	0	0
Both or optimal	12	43	5	42	4	33	4	31
Neither	6	21	1	8	1	8	2	15
Before or within 60 days of initial encounter	28		12		12		13	
Germline only	6	21	4	33	5	42	6	46
Somatic only	3	11	2	17	2	17	0	0
Both or optimal	10	36	4	33	4	33	4	31
No genetic testing	9	32	2	17	1	8	3	23

QI= quality improvement

tutorial on the risk and benefits of genetic testing and started providing additional virtual resources as needed.

Willis-Knighton Cancer Center identified several additional areas to target in future interventions. The most pressing areas included boosting patient access to clinical trials, expanded survivorship and previvor care, and patient transportation and logistics as a barrier to care, which could be addressed in a follow-up project similar to the current initiative. Additionally, Willis-Knighton Cancer Center would like to develop a gynecologic oncology fellowship in collaboration with Louisiana State University to train physicians in the area.

The Blavatnik Family—Chelsea Medical Center at Mount Sinai Experience

The Blavatnik Center is located in New York, N.Y., and is part of the Tisch Cancer Institute, an NCI-designated cancer center. It is part of a large referral system and provides cancer care to patients in and around New York City. The cancer program expressed interest in three target areas for the QI initiative:

1. Universal genetic evaluation for patients with ovarian cancer; determining best means of genetic/genomic triage
2. Developing a survivorship program
3. Improving patient access to interventional radiology for diagnostic confirmation and symptom management.

After pre-workshop planning meetings, the Blavatnik Center chose a QI project to address challenges around genetic testing and counseling in patients with ovarian cancer. The workshop's discussion focused on issues related to germline and somatic mutation testing, genetic counseling, and cascade testing of family members for patients treated for ovarian cancer at the Blavatnik Center. Based on this self-assessment, at baseline, germline testing was a standard of care for patients with ovarian cancer and testing rates were high. However, many (or most) patients with ovarian cancer were not receiving pre-test genetic counseling due to lack of availability of genetic counselors. Though the baseline practice of testing without pre-test counseling allowed for quicker return of genetic testing results, there was concern about adequacy of patient education and shared decision-making.

Based on the findings of the SOLO1,[8] PRIMA,[16] and PAOLA-1[17] trials, gynecologic oncologists and gynecologic pathologists at the Blavatnik Center discussed initiating reflex somatic testing for patients with ovarian cancer with negative germline testing. After workshop discussions, the physicians determined a protocol for reflex testing, setting a goal of 100 percent somatic testing for germline negative patients with ovarian cancer. Additionally, there are ongoing discussions about which somatic tests will be used.

The process for ordering additional pathology slides for somatic testing at the time of diagnosis was identified as a barrier to testing. Gynecologic oncology and gynecologic pathology physicians identified a solution and plan of action during the workshop.

Genetic Counseling

The ovarian cancer team discussed barriers to achieving 100 percent genetic counseling rates for patients with ovarian cancer at the Chelsea location. An important barrier cited was the lack of a dedicated genetic counselor for patients with ovarian cancer on-site at the Chelsea location. An additional barrier identified was the current process for tracking receipt of genetic counseling in the EHR. Gynecologic oncologists cannot consistently determine whether a patient received genetic counseling using the EHR, and the ovarian cancer team tracked this information in a separate list. Finally, although a genetic counseling video was available to help with pre-test genetic counseling, it was not utilized by every patient.

The ovarian cancer team also expressed a desire to improve family member education after a patient had a positive germline test result. The practice has been to educate patients about family implications at the initial genetic counseling appointment (if it occurs) or initial physician discussion. When a patient had a positive germline test, the clinical team urged them to encourage family members to get tested and get follow-up at subsequent visits.

The ovarian cancer team identified cascade testing of patients' family members after a positive germline mutation as a high priority. However, several implementation barriers were identified. The first barrier is that family members are not the patients of the ovarian cancer team; therefore, the team cannot contact these individuals directly. Health Insurance Portability and Accountability Act and additional legal restrictions provide clear limits. A second barrier is when patients have family members who live outside of the Blavatnik Center catchment area and cannot come to the center. A third barrier is some patients' unwillingness or inability to contact family members. Finally, the language spoken by the family member can also be a potential barrier.

Several potential solutions identified included the clinical care team tracking all post-test counseling, providing patients with a copy of test results, and a simplified letter for family members. The letter for family members would need to be available in at least three languages. There is also a need to provide resources for family members who are out of town to find genetic counseling resources in their area. Additionally, with improved EHR resources, automated patient lists could be generated and used to track pending and/or outstanding patients requiring genetic testing and counseling. Finally, the ovarian cancer team cited a desire to hire a new genetic counselor on-site, even though the genetic counseling services existed in other parts of the healthcare system.

Based on the workshop discussion, the Blavatnik Center decided to focus on confirming rates of germline testing and improving processes for somatic testing, cascade testing, and pre- and post-test counseling. The problem statement, aim statement, and proposed solutions for the Blavatnik Center project are presented in Table 1, page 41.

Findings from the Blavatnik Family—Chelsea Medical Center at Mount Sinai

QI metrics from the Blavatnik Center are shown in Table 3, page 44. Results from baseline data demonstrated that a high proportion of patients with ovarian cancer received genetic testing; however, the timeliness of testing and methods of obtaining testing varied widely. These data confirm assumptions from the workshop and justify the focus on universal testing, counseling, and cascade testing. Overall, the ovarian cancer team reported that the project improved the clinical workflow around genetic testing.

Data from the project follow-up demonstrate successful implementation of the educational videos on genetic testing. Patient feedback on this video was generally positive, but the Blavatnik Center plans to develop an in-house version of the video that is customizable to the site. They also plan to disseminate the video counseling method to the broader Mount Sinai network and to expand in additional languages (currently available in Spanish, Mandarin, and English). Additionally, the ovarian cancer team made progress with referrals for cascade testing and were able to pilot a program supplying notification via written letter for at-risk family members related to the patient's pathogenic test result. Future direction includes a scale-up of the counseling intervention to other sites within the healthcare system and development of a previvor clinic at the Blavatnik Center.

The Duke Cancer Center Experience

Duke Cancer Center is an NCI-designated comprehensive cancer center located in Raleigh-Durham, N.C. It is located in a region that is both urban and rural, serving as a referral center for a wide range of communities. The Duke Cancer Center QI project focused on improving clinical trial enrollment for patients with ovarian cancer.

Table 3. The Blavatnik Family—Chelsea Medical Center at Mount Sinai QI Metrics by Study Period

Measurements	Baseline	Prospective Study Period (Periods 1-3 combined)
Proportion of newly diagnosed patients with ovarian cancer who received germline testing.	27/27	14/14
Proportion of patients with ovarian cancer who are presented the educational videos on genetic testing.	N/A	14/14
Proportion of newly diagnosed patients with ovarian cancer who had a deleterious (positive) result from germline testing.	5/27	4/15
Proportion of newly diagnosed patients with ovarian cancer patients who had a VUS result from germline testing.	9/27	1/15
Proportion of newly diagnosed patients with ovarian cancer who received the family letter for cascade testing, of those who had a positive result from germline testing.	N/A	3/4

QI= quality improvement; VUS= variant of uncertain significance.

The focused discussion at the workshop self-assessed the current state of the clinical trials program for ovarian cancer. The Duke Cancer Center team expressed concern that enrollment in clinical trials by ovarian cancer patients was low and racial disparities may exist. Processes for screening potential clinical trial participants in ovarian cancer have been physician dependent and not fully standardized. The Duke Cancer Center team agreed that additional quantitative work could help solidify numbers of patients with ovarian cancer and ovarian cancer clinical trial enrollees by race and other demographic factors.

A potential solution identified was universal pre-screening of all patients for trial eligibility by the clinical trials team. The prospective screening team would notify physicians on a patient's potential eligibility for an open trial before each appointment. There was agreement on the merits of this solution, but current staffing was an obstacle. An additional barrier identified was inadequate lead time in identifying potential patients who were eligible for a trial prior to their appointments. Providers do not always have advanced notice when a new patient with ovarian cancer is scheduled, limiting screening capabilities. Additionally, the type of visit characterization may not be standard across Duke Cancer Center sites. Potential solutions utilizing the EHR were also identified, including the creation of an automated list of potentially eligible patients and adding an EHR smart phrase to remind physicians to discuss clinical trials with patients.

Based on the workshop discussion, the Duke Cancer Center team decided to implement the solution in stages. In a proof-of-principle stage, medical students will initiate the process improvement steps without hiring additional staff, thereby justifying the future addition of staffing should clinical trial enrollment increase.

An additional goal identified by the Duke Cancer Center cancer care team was to prospectively document pre-screening for clinical trials and establish benchmarks to track progress. The first phase sought to establish the benchmarks through a retrospective review of all new patients with ovarian cancer seen in the previous six months. Metrics identified included the number of new patients with ovarian cancer who were treated at the center, the percentage of those who were potentially eligible for an open clinical trial, the percentage who were offered a clinical trial, the percentage who enrolled in a clinical trial, the percentage who received germline genetic testing, and the percentage who received somatic mutation testing. The final two metrics related to genetic testing were included for planning a future QI project. These metrics may also help identify whether sub-optimal rates of genetic testing could be a barrier to clinical trial enrollment.

The solutions selected for the prospective QI project are as follows:

1. Create a smart phrase in the EHR to prompt physicians to screen patients for clinical trials.
2. Utilize the smart phrase in the EHR.
3. Generate a clinical trials screening report.
4. Utilize a medical student to review the screening report for trial eligible patients.
5. Provide feedback on the smart phrase.
6. Provide individual clinician feedback on clinical trial enrollment.

The problem statement, aim statement, and proposed solutions developed during the workshop at Duke Cancer Center are shown in Table 1, page 41.

Duke Cancer Center Findings

Baseline data were collected on a random selection of 400 patients treated for ovarian cancer at Duke Cancer Center from 2018 to 2019 (Table 4, page 46). Patients with ovarian cancer reported their race as white (71.5 percent), black/African American (11.5 percent), and other or not reported (17.0 percent). The stage distribution was 25.5 percent stage I, 12.5 percent stage II, 39.0 percent stage III, and 17.8 percent stage IV. Overall, there was documentation that 12.0 percent of patients discussed clinical trials with the provider. Thirty patients (7.5 percent) were documented to have consented or enrolled in a clinical trial.

Prospective data collection was planned for the time frame of the study. Due to unanticipated staffing delays and the COVID-19 pandemic, the two-month cycles could not be implemented as planned. However, three elements of the intervention were implemented, including creating a smart phrase in the EHR, utilizing the smart phrase in the EHR, and generating a clinical trials screening report. Prospective data from the study period are not currently available for this cancer program.

The Duke Cancer Center ovarian cancer team successfully implemented the smart phrase within the EHR to remind physicians to screen for trials. The retrospective data collection was completed and provided helpful information on the total number of patients enrolled and the numbers of patients eligible for each trial.

During this study, several barriers to patients with ovarian cancer clinical trial enrollment were identified, including both provider- and patient-based barriers. The Duke Cancer Center team was able to identify providers who were enrolling patients in clinical trials at the lowest rates and could thereby work to understand practice barriers and areas for improvement. From the patient perspective, a recurrent and major barrier to trial enrollment was transportation and travel time to Duke Cancer Center. It was determined that many patients decline enrollment because of lengthy travel times and a desire to avoid unnecessary clinic visits. Given the complex nature of many clinical trials, they are not typically available in rural communities and clinics, and this system-level factor was identified as a barrier to trial access across the Duke Cancer Center catchment area.

In addition to the interventions implemented in this QI initiative, two potential solutions were identified. First, the clinical trials director will start recognizing the provider with the highest enrollment in ovarian cancer trials each month to provide awareness and visibility to the program. Second, the Duke Cancer Center team is exploring innovative ways to integrate telemedicine into clinical trials. Overall, Duke Cancer Center found the project to be helpful and plan to continue this work, possibly expanding to address disparities in patients with uterine cancer.

> This project demonstrated that cancer programs of all types across the United States face similar challenges in providing quality care for women with ovarian cancer. Multiple stakeholders can contribute to QI solutions with a team approach and clear communication around quality gaps.

Discussion

Despite many advances in the treatment of ovarian cancer over the last two decades, the quality of care remains variable across geographic sites and hospital settings. The majority of women with this disease do not receive guideline-adherent care.[5,7,18,19] The reasons may include access to sites with gynecologic oncologists, as well as disease-site prioritization within cancer centers.[20,21] It has been recognized that thorough pathologic evaluation resulting in accurate diagnosis with histologic type and stage assignment is a mainstay of quality care programs.

The application survey was successful in identifying commonly cited areas of need for QI in ovarian cancer care. The most frequently identified areas were genetic testing and counseling, clinical trial enrollment and availability, and multidisciplinary team care. The three cancer programs selected for QI projects chose to focus on genetic testing and counseling (two cancer programs) and clinical trial enrollment and availability (one cancer program). Guidance and involvement from the expert Steering Committee informed application survey development and site

Table 4. Retrospective Data from Duke Cancer Center

N=400	*n*	%
Patient race		
Asian	7	1.8
Black/African American	46	11.5
Caucasian/white	286	71.5
Multiracial	1	0.3
Two or more races	6	1.5
Not reported/declined	53	13.3
Stage at diagnosis		
Missing	21	5.3
I	102	25.5
II	50	12.5
III	156	39.0
IV	71	17.8
Is there documentation that the trial was discussed by the provider seeing the patient?		
Missing	316	79.0
No	36	9.0
Yes	48	12.0
Is there trial documentation by study personnel?		
Missing	316	79.0
No	45	11.3
Yes	39	9.8
Did the patient consent or enroll for a clinical trial?		
Missing	316	79.0
No	54	13.5
Yes	30	7.5

selection and enriched the projects at each cancer program. The Steering Committee's development of the ovarian cancer quality document was a significant contribution that will have a lasting impact on ovarian cancer care.

Project workshops proved beneficial for identifying barriers to delivery of quality care in patients with ovarian cancer and finding meaningful solutions. Bringing multiple stakeholders together from across each institution with external facilitation allowed for structured discussion and focused time. Each cancer program developed a problem statement and a specific plan to address the need and measure progress throughout the six-month study period.

Cancer programs reported benefits from the QI workshops, improved care for patients in the areas of focus for the study, and plans for long-term sustainability of study initiatives. Challenges from the COVID-19 pandemic during the prospective study period limited the ability of some cancer programs to execute the studies as planned and also provided some opportunity to improve care through the expanded use of technology.

Overarching Impact

This multi-stage QI project had a substantial impact in several areas. The needs assessment from the application survey identified several priority areas for QI initiatives, including genetic testing and counseling, clinical trial enrollment, and multidisciplinary team care. These areas of needed improvement were identified consistently across a wide range of hospital types from community cancer programs to NCI-designated comprehensive cancer programs.

A Steering Committee of gynecologic oncology care experts guided this project. The ovarian cancer care quality document produced as part of this project will be disseminated broadly and could have a lasting impact on care delivery. The committee also guided project selection and development at each of the three testing sites. All three cancer programs reported a meaningful impact on quality and process of care from the project.

The successful implementation of three unique QI projects across three diverse institutions serves as a proof of principle for QI in ovarian cancer care. Addressing a specific issue in ovarian cancer is feasible in a focused one-day multi-stakeholder workshop and was implemented with success. All three cancer programs felt that the project served as a catalyst to influence change by providing the QI structure, eliciting broad stakeholder perspectives, and building consensus around the issue.

The use of technology proved critical to the QI solutions implemented at each cancer program. These included better utilization of the EHR, audiovisual tools for patient education, and telehealth solutions. The QI project demonstrated that IT professionals are important members of the multidisciplinary teams and can play a vital role in quality improvement. When invited to the table and elevated as key team members, IT professionals were willing to invest in the projects and provide sustainable solutions to improve care for persons with ovarian cancer.

This project demonstrated that cancer programs of all types across the United States face similar challenges in providing quality care for women with ovarian cancer. Multiple stakeholders can contribute to QI solutions with a team approach and clear communication around quality gaps. A focused approach to QI, in which consensus is built around a specific problem and solution, can address a specific problem in a relatively short period of time. The approach was successful across the three diverse cancer centers in this project and could be similarly applied in other settings and in the context of other cancer types.

Key Take-Aways from the ACCC Education Initiative

- Top priorities for QI in ovarian cancer include genetic testing and counseling, clinical trial enrollment, and multidisciplinary team care.
- A focused and structured QI approach, where consensus is built around a problem and solution, can address a specific quality issue in a relatively short time.
- Multiple stakeholders can contribute to QI solutions with a team approach and clear communication around quality gaps.

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References

1. Siegel RL, Miller KD, Jemal A. Cancer statistics, 2020. *CA Cancer J Clin.* 2020;70(1):7-30.

2. Torre LA, Trabert B, DeSantis CE, et al. Ovarian cancer statistics, 2018. *CA Cancer J Clin.* 2018;68(4):284-296.

3. American Cancer Society. *Cancer Facts & Figures 2020*. Atlanta, GA: American Cancer Society; 2020.

4. Collins Y, Holcomb K, Chapman-Davis E, Khabele D, Farley JH. Gynecologic cancer disparities: a report from the Health Disparities Taskforce of the Society of Gynecologic Oncology. *Gynecol Oncol.* 2014;133(2):353-361.

5. Bristow RE, Powell MA, Al-Hammadi N, et al. Disparities in ovarian cancer care quality and survival according to race and socioeconomic status. *J Natl Cancer Inst.* 2013;105(11):823-832.

6. Temkin SM, Rimel BJ, Bruegl AS, Gunderson CC, Beavis AL, Doll KM. A contemporary framework of health equity applied to gynecologic cancer care: a Society of Gynecologic Oncology evidenced-based review. *Gynecol Oncol.* 2018;149(1):70-77.

7. Bristow RE, Chang J, Ziogas A, Campos B, Chavez LR, Anton-Culver H. Sociodemographic disparities in advanced ovarian cancer survival and adherence to treatment guidelines. *Obstet Gynecol.* 2015;125:833-842.

8. Moore K, Colombo N, Scambia G, et al. Maintenance olaparib in patients with newly diagnosed advanced ovarian cancer. *N Engl J Med.* 2018;379:2495-2505.

9. Banerjee S, Moore KN, Colombo N, et al. Maintenance olaparib for patients (pts) with newly diagnosed, advanced ovarian cancer (OC) and a BRCA mutation (BRCAm): 5-year follow-up (f/u) from SOLO1. *Ann Oncol.* 2020;31(suppl 4):S613.

10. Armstrong DK, Alvarez RD, Bakkum-Gamez JN, et al. NCCN Guidelines insights: ovarian cancer, version 1.2019. *J Natl Compr Canc Netw.* 2019;17(8):896-909.

11. Chen F, Bailey CE, Alvarez RD, Shu XO, Zheng W. Adherence to treatment guidelines as a major determinant of survival disparities between black and white patients with ovarian cancer. *Gynecol Oncol.* 2021;160(1):10-15.

12. Qualtrix XM. Available online at: https://www.qualtrics.com. Last accessed December 18, 2020.

13. Cleghorn GD, Headrick LA. The PDSA cycle at the core of learning in health professions education. *Jt Comm J Qual Improv.* 1996;22(3):206-212.

14. *Key Driver 2: Implement a Data-Driven Quality Improvement Process to Integrate Evidence into Practice Procedures*. Rockville, MD: Agency for Healthcare Research and Quality. Available online at: https://www.ahrq.gov/evidencenow/tools/keydrivers/implement-qi.html.

15. BiteSize QI. Available online at: https://bitesizeqi.org. Last accessed December 18, 2020.

16. González-Martín A, Pothuri B, Vergote I, et al., and the PRIMA/ENGOT-OV26/GOG-3012 Investigators. Niraparib in patients with newly diagnosed advanced ovarian cancer. *N Engl J Med.* 2019;381(25):2391-2402.

17. Ray-Coquard I, Pautier P, Pignata S, et al., and the PAOLA-1 Investigators. Olaparib plus bevacizumab as first-line maintenance in ovarian cancer. *N Engl J Med.* 2019;381(25):2416-2428.

18. Bristow RE, Chang J, Ziogas A, Anton-Culver H. Adherence to treatment guidelines for ovarian cancer as a measure of quality care. *Obstet Gynecol.* 2013;121(6):1226-1234.

19. Villanueva C, Chang J, Ziogas A, Bristow RE, Vieira VM. Ovarian cancer in California: guideline adherence, survival, and the impact of geographic location, 1996-2014. *Cancer Epidemiol.* 2020;69:101825.

20. Villanueva C, Chang J, Bartell SM, Ziogas A, Bristow R, Vieira VM. Contribution of geographic location to disparities in ovarian cancer treatment. *J Natl Compr Canc Netw.* 2019;17(11):1318-132.

21. Temkin SM, Rubinsak L, Benoit MF, et al. Take me to your leader: reporting structures and equity in academic gynecologic oncology. *Gynecol Oncol.* 2020;157(3):759-764.

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MULTIDISCIPLINARY MULTIPLE MYELOMA CARE: MODELS OF QUALITY IMPROVEMENT

BY ALEXANDRA HOWSON, PHD

Quality improvement (QI) is increasingly important as healthcare organizations pursue greater efficiency and value in the services they provide. The Institute for Healthcare Improvement views QI as a rapid-cycle test of a new process that is designed to improve quality, safety, and value in healthcare. Using Plan-Do-Study-Act methodology, the rapid-cycle approach identifies a need for improvement, determines the necessary steps to implement change, establishes metrics to measure progress, and immediately implements small tests of the changes needed for improvement (see Figure 1, right, page 53).

The Association of Community Cancer Centers (ACCC) has supported QI initiatives for many years through its Visiting Experts Program. In 2020 ACCC offered QI programs designed to optimize care for patients with multiple myeloma (MM). Via custom workshops, multidisciplinary team members from three cancer programs appraised their own challenges and opportunities to improve care and developed QI plans that were specific, measurable, and actionable over a six-month time frame. The QI time frame included workshop participation, baseline data reporting, progress calls with ACCC, and outcomes evaluation.

Multiple Myeloma

MM is the second most common hematologic cancer in adults and is characterized by the multiplication of monoclonal plasma cells in bone marrow.[1,2] Osteolytic bone disease is a dominant feature of MM that often results in skeletal-related events, such as osteopenia or pathologic fracture; contributes to considerable morbidity; and can reduce quality of life. There is no cure for MM and most patients relapse following initial therapy, although treatment options for newly diagnosed and relapsed or refractory MM have expanded rapidly in the last two decades. In addition to autologous hematopoietic cell transplantation and radiation, immune-modulating drugs, proteasome inhibitors, and monoclonal antibodies (e.g., daratumumab, elotuzumab) have been introduced that invoke deeper responses and have improved survival. However, disease management can be complex, especially because 35 to 40 percent of patients are older than 75 years.[3] Immunotherapies for MM continue to evolve. Checkpoint inhibitors, chimeric antigen receptor T-cell therapies that target B-cell maturation antigens, bispecific antibodies (e.g., blinatumomab), and antibody drug conjugates are all currently under investigation for patients with relapsed and refractory MM.[4]

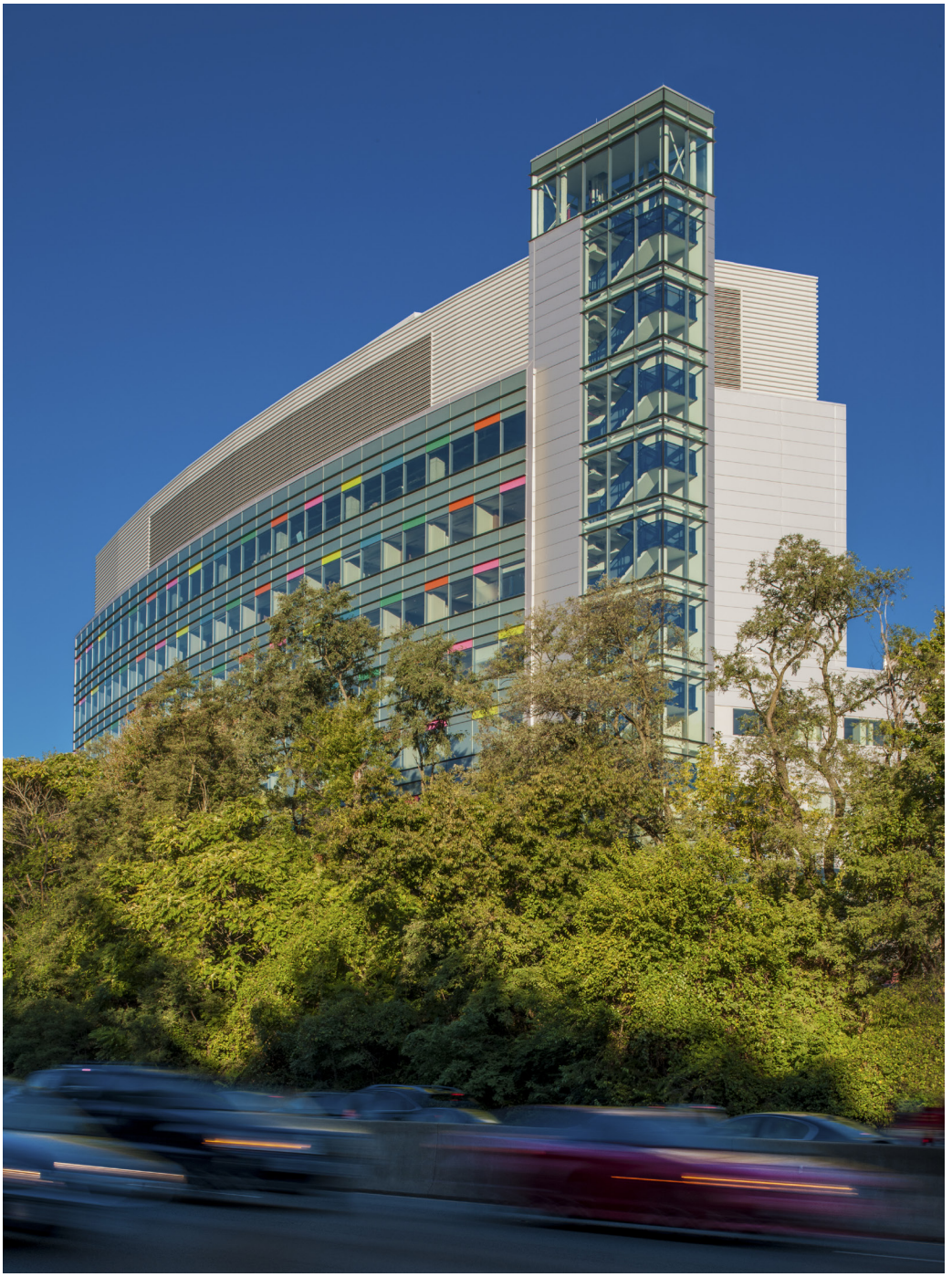
MM Visiting Experts Program

ACCC conducted three visiting experts workshops focused on care for patients with multiple myeloma. The four six-hour workshops were held live at Holy Cross Hospital in Silver Spring, Md., and CalvertHealth Medical Center in Prince Frederick, Md., and online at Central Care Cancer Center in Bolivar, Mo. Each cancer program received content presentations from visiting expert faculty and participated in extensive, facilitated discussions to develop a QI intervention. In the ACCC process, these discussions allow team members to review and prioritize potential challenges they can reasonably address within a six-month period and evaluate the likely impact and feasibility of each challenge. When attendees have established consensus about which challenge to tackle, they identify a clear aim, document steps to achieve the aim within the timeline, and describe measures for tracking progress. Table 1, page 54, provides an overview of the MM Visiting Experts Program.

The Holy Cross Health Experience

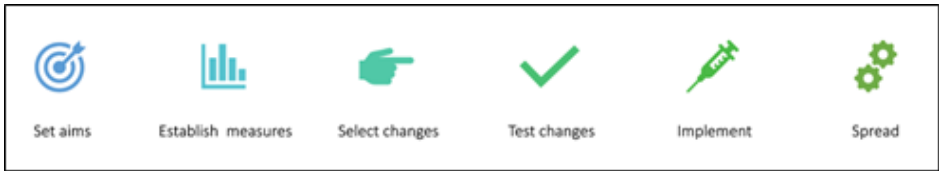
Holy Cross Health, a member of Trinity Health and located in Maryland, has multiple primary care sites and two hospitals in Montgomery County. Serving the nearly two million residents of Montgomery and Prince George's counties, this Catholic, not-for-profit health system is dedicated to caring for a diverse population with special consideration for the most vulnerable and underserved. Holy Cross Health's cancer program, located within a 449-bed hospital in Silver Spring, Md., is an American College of Surgeons Commission on Cancer accredited Comprehensive Community Cancer Program. The annual volume of myeloma patients is relatively low (approximately 14) because affiliated community physicians diagnose and treat most myeloma patients outside of the hospital setting. Transplant candidates and relapsed patients are referred to tertiary academic centers for care.

In February 2020, 19 participants from pharmacy, nursing, medical oncology, research, social work, and administration



Holy Cross Hospital

Figure 1. Institute for Healthcare Improvement: Six Steps in Rapid Cycle Improvement



attended the Visiting Experts Workshop at Holy Cross Hospital. The team quickly reached consensus on their QI priority. Many of the patients whom Holy Cross Hospital serves are undocumented immigrants who are often under- or uninsured. As a result, these patients have limited access to a full spectrum of myeloma therapies. Oncologists also reported difficulty in identifying referral centers willing to accept under- or uninsured patients when transplant is indicated. Currently, social workers help this high-need population apply for prescription assistance programs or enroll them in state insurance programs if they are eligible. When patients find insurance coverage, they typically return to community providers for their care, occasionally without the hospital's knowledge, which results in patient no-shows at the hospital. Despite effective communication between pharmacists and oncologists about treatment for patients with MM, the QI team agreed that lack of navigation capacity in community clinics caused delays in the diagnosis, treatment initiation, and referral to tertiary care.

Building Navigation Capacity

The goal of the QI intervention was to utilize hospital social work or nurse navigation to coordinate care for 75 percent of under- and uninsured patients with MM referred by community partners. To this end, the QI team proposed to review charity care data for MM ICD (*International Classification of Diseases*) codes to determine the caseload requiring navigation and develop a protocol for navigation referrals. By the one-month check-in with ACCC, it was clear that charity data were less accessible than anticipated, so the QI team regrouped to define the target population more clearly as (1) uninsured patients and (2) underinsured patients or patients with a high co-pay or deductible who cannot afford treatment. Using this definition, baseline review of electronic health record (EHR) data showed that 10 patients with MM were seen at Holy Cross Hospital between January and September 2019 and 5 were within the QI target population. The team resolved to reduce the average time from chemotherapy order to first infusion from seven to four days.

Between months one and three, the QI team also met frequently with the financial navigation team to understand the insurance verification process and formalize a protocol to ensure earlier treatment initiation. This collaboration with the financial navigator and inpatient case manager/social worker led to a new internal communication process to initiate financial assistance paperwork more quickly for this target population and a process to track and monitor patients with MM treated at the infusion center. The QI team also operationalized its navigation intervention by outlining the roles and duties of key staff and hospital units (see Figure 2, page 55).

Process, Process, Process

Holy Cross Hospital and affiliated community oncology providers experienced a significant decrease in patient volume because of the COVID-19 pandemic. Thus, the QI team was unable to test its new workflow or collect outcomes data. Nonetheless, team members saw communication and operational improvements, in part because they implemented the initiative with existing resources and focused their efforts on learning from colleagues in other departments. The outpatient infusion center health unit coordinator noted, "In the past, maybe we wouldn't have reached out to certain departments and said, 'Well, how are you handling this? How does this work?' So it gave us an opportunity to talk with each other and come up with solutions for how to navigate the system or help the patient navigate the system."

As a result, communication with the insurance verifier is now more effective for uninsured patients with other types of cancer, leading to improved care coordination and timeliness of care. Prior to the QI project, it was not routine practice for case managers to alert the outpatient infusion center about under- or uninsured patients pending discharge. The new protocol gave the QI team the opportunity to enhance its existing verification

Table 1. Overview of the Multiple Myeloma Visiting Experts Program
Program Goals
Educate attendees on effective practices for supporting, treating, and managing patients with multiple myeloma.
Facilitate development of a tailored QI intervention focused on optimizing care for patients with multiple myeloma.
Follow cancer program implementation progress for six months.
Visiting Expert Faculty
Maria Chaudhry, MD, assistant professor of medicine, Division of Hematology, The Ohio State University—James Cancer Hospital and Solove Research Institute
David H. Vesole, MD, PhD, FACP, co-division chief, director of research, Multiple Myeloma Division, John Theurer Cancer Center, Hackensack University Medical Center; director, Myeloma Program, professor of medicine, Georgetown University
Srinivas Devarakonda, MD, assistant professor of internal medicine, Division of Hematology, The Ohio State University—James Cancer Hospital and Solove Research Institute
Ashley Rosko, MD, associate professor, Division of Hematology, The Ohio State University—James Cancer Hospital and Solove Research Institute
Jennifer Bires, LICSW, OSW-C, executive director, Life with Cancer and Patient Experience, Inova Schar Cancer Institute
Adriana Rossi, MD, associate director, Myeloma Center and assistant professor of medicine, Division of Hematology and Medical Oncology, Weill Cornell Medicine
Content Presentations
An Overview of Multiple Myeloma
What is New in Relapsed and Refractory Myeloma?
Multiple Myeloma in Aging Adults
Psychosocial Impact of Multiple Myeloma
Renal Disease in Multiple Myeloma
Quality Improvement Process
Development of QI Intervention in Multiple Myeloma Visiting Experts Workshop
QI Intervention Launch and Identification of Baseline Data
Progress Check-In Calls with ACCC at 1, 3, and 6 Months
Team Evaluation Interviews and Final Data Collection
Completion of Final Project Summary Report

Figure 2. Roles and Responsibilities of Holy Cross Health Staff and Units

Physicians	• Physicians learn of services available and become aware of referral process. • Physician's office is re-educated on calling outpatient infusion center to make appointment.
Insurance Verification Department	• Insurance verification department calls patient regarding co-pay or security deposit; if patient is not able to afford payment due, patient is given the option to apply for financial assistance or meet with patient advocate (Holy Cross Health term for financial navigator). • Patient advocate meets with patient to assess for financial assistance/charity.
Inpatient Unit	• Case management on the unit learn of process change. • As soon as the decision to discharge a patient has been made, inpatient case manager alerts outpatient infusion center and connects patient with the financial assistance department to start clearance process for outpatient service.
Outpatient Infusion Center	• Insurance verification representative communicates patient insurance status to the outpatient infusion center coordinator. • When patient is uninsured, insurance verification department provides phone number to financial assistance department. • Outpatient infusion center coordinator notifies oncology social worker with the oncology patients who still need to be cleared by the financial assistance department.
Oncology Social Worker	• Oncology social worker uses HealthQuest for financial assistance process. • Oncology social worker reminds patient to contact the financial assistance department if documents are still pending before visit.

process. The process entails outpatient infusion center staff contacting the insurance verifier, printing patient eligibility paperwork, and faxing information to the insurance verifier for entry in the patient records. The outpatient infusion center coordinator reviews the registration list in advance of treatment initiation to identify any patients with outstanding financial clearance issues. If a patient has not been approved for charity care, central scheduling alerts the outpatient infusion center and proactively routes them to the oncology social worker. Through HealthQuest, the oncology social worker identifies missing documents and reminds the outpatient infusion center staff to prompt the patient to complete paperwork.

The QI team has shared information about the process enhancements at the weekly tumor board. A kickoff meeting was held with the community medical oncologists to make them aware that under- and uninsured patients can begin treatment more quickly at Holy Cross Hospital through this new protocol. The QI team plans additional outreach efforts to enable referring physicians to identify eligible patients who could benefit from financial assistance and educate the Holy Cross Hospital oncology team about the new process. The teams also plan to document the new inpatient to outpatient transition process to ensure that eligible patients can be referred more quickly when volume returns to pre-pandemic levels.

The CalvertHealth Medical Center Experience

CalvertHealth Medical Center in Prince Frederick, Md., is a not-for-profit health system with a mission to promote wellness and provide health care to approximately 125,000 residents of southern Maryland. CalvertHealth is the only medical facility in Calvert County and offers an array of services across the health continuum for this predominantly rural community. The cancer program at CalvertHealth is accredited by the Commission on Cancer as a community cancer program and in the last 12 months has treated 58 patients with MM, including patients for whom care is shared at tertiary academic care centers.

Developing a Protocol to Review and Assess the Use of Bone-Modifying Agents

Twenty-eight participants from pharmacy, nursing, medical oncology, palliative care, radiation oncology, navigation, social work, quality improvement, and administration attended the February 2020 Visiting Experts Workshop at CalvertHealth. Delays in bone marrow biopsy scheduling emerged in discussion as the highest priority challenge for QI, but participants recognized that this challenge would be complex to address within the time frame. The absence of a systematic process for documenting the administration of bone-modifying agents and monitoring toxicity emerged as an additional area in need of improvement. Osteoclast inhibitors (i.e., bisphosphonates such as zoledronic acid, denosumab) inhibit bone resorption and are used in the management of MM to reduce the risk for skeletal-related events. Recent updates to National Comprehensive Cancer Network guidelines recommend that patients have a dental examination and preventive dentistry before treatment is initiated with bone modifying agents to reduce the potential for oral infection and osteonecrosis of the jaw.[5] However, many patients in the community that CalvertHealth serves lack access to dental care due to low levels of dental insurance and a shortage of dental providers. These factors pose significant barriers to the baseline dental clearance that National Comprehensive Cancer Network guidelines recommend prior to treatment initiation in myeloma. Therefore, the QI team focused the intervention on improving the following areas of myeloma management:

- Review and assessment of bone-modifying agents used to reduce the risk for skeletal-related events.
- Screening for individuals at risk for bone-modifying agent-related complications.
- Strategies to monitor and minimize dental complications.

The QI goals were to proactively assess the use of bone-modifying agents in 75 percent of patients with MM and to conduct dental assessment during clinic for 25 percent of patients.

The team developed the following components of the intervention that were internally approved for use:

- Dental consult form to be completed by the dentist at the baseline examination.
- Dental screening form to be completed by a nurse or medical assistant in the physician's office.
- Standing orders for initiating denosumab and zoledronic acid.
- Dental folder to upload all forms for each patient with MM in the EHR.

Dental consult forms were provided to patients for completion by a dentist. A nurse or medical assistant in the physician's office used dental screening forms during patient visits. Infusion and office nurses were subsequently educated about both the importance of dental screening and the workflow process for completing and uploading forms. Infusion nurses were to alert the physician's office if patient dental forms were not on file.

Improving Bone Modifying Agent and Dental Screening Outcomes

At baseline, consecutive chart review from the two EHR systems (NextGen and Meditech) between January and December 2019 identified 58 patients with a diagnosis of MM (patients who had not achieved remission or who were in remission or relapse). Nine patients were excluded because they did not receive care at CalvertHealth. None of the remaining 49 patients had completed a dental screening form prior to treatment, and of the patients who received bone modifying agents (n = 25), only 20 percent had evidence of a dental consult documented within their medical records. None of the patients had a dental folder present in their record. The clinical team began using the approved protocol on June 1, 2020, and the standing orders in August 2020.

A review of patient data after implementation of the approved protocol and standing orders identified advances to improve the bone modifying agent and dental screening outcomes for 37 patients with MM (Figure 3, page 58). Fifty-one percent of the 37 patients (n = 19) received a bone-modifying agent as part of their therapeutic regimen. Patients did not receive a bone-modifying agent likely because of observation status, co-morbid medical conditions that preclude use (e.g., renal insufficiency, dental abnormalities, electrolyte abnormalities), patient preference, or provider oversight. At this time, the medical records do not have clear explanations documented.

Fifty-eight percent of patients (n = 11) underwent dental screening, and one patient underwent a comprehensive dental consultation. Patients did not undergo a dental screening and/or comprehensive dental consultation likely because of team oversight, competing responsibilities, unavailability of forms, lack of staff training, or poor documentation in the medical record. In terms of documentation, 58 percent (n = 11) of the 19 patients who received a bone-modifying agent had a dental screening form included within their EHR. Fifty-nine percent of all 37 patients (n = 22) had a dental folder within their medical records.

CalvertHealth Medical Center

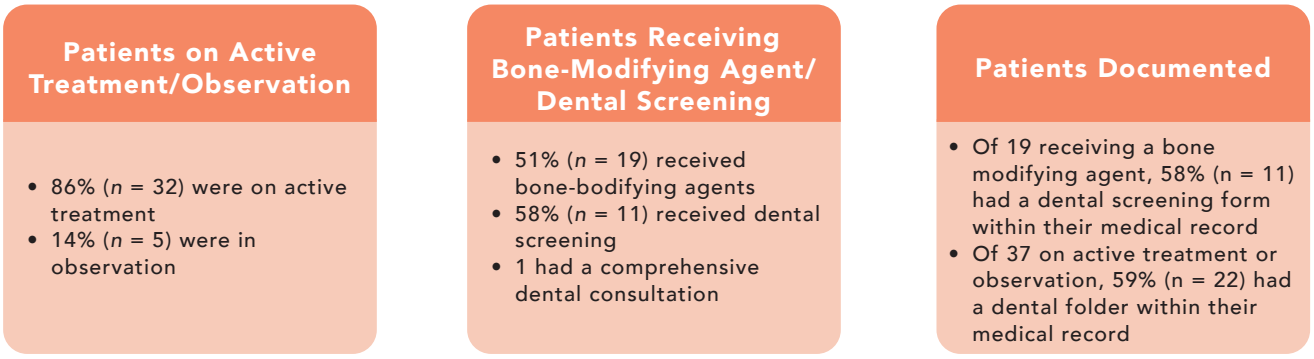
Going forward, CalvertHealth will continue its efforts to adhere to the most current national guidelines for evaluation and treatment of patients with multiple myeloma. The medical team will use multidisciplinary tumor boards to review and implement these guidelines for treatment and toxicity monitoring. CalvertHealth's six-month goal is to achieve 100 percent adherence to guidelines for administration of bone-modifying agents and to have clear documentation to explain lack of administration. Its second six-month goal is for 100 percent of patients to receive a bone-modifying agent, screening with a dental questionnaire, and laboratory testing to assess for toxicity risk.

Unanticipated Payoffs

The CalvertHealth QI team was able to make tremendous strides toward achieving its goals. Christine Shipley, clinical director of Oncology Services, pointed to several factors that contributed to success. First, Shipley and the QI team had protected time to work on the intervention, which gave the team space to carefully compile data points, establish data collection methods, and define the workflow. Second, education for infusion nurses was instrumental in raising awareness about screening and the need for dental standing orders. Shipley noted that a payoff for this education was "… better communication amongst the team. We're physically separated, so it kind of pulls us closer together and brings that continuum of care and that consistency—regardless of whether you're in the doctor's office or the infusion center."

There were other unanticipated payoffs, too. Although Shipley and her colleagues assumed that they would be starting at a zero baseline for dental screening, they were pleasantly surprised to find that a small percentage of patients with MM had been screened prior to the intervention. Additionally, QI team members appreciated how the intervention increased their awareness of patients' concerns about dental issues and how patients have become more receptive to being screened. Medical assistant Teresa

Figure 3. Patients with Multiple Myeloma Seen at CalvertHealth June to August 2020.



Sculley said, "It's just amazing how many people are afraid to talk about their dental issues, thinking it's going to hurt them or something. Our patients were a little skeptical at first, but when you explain to them why, they're all for it. Now they just come in, and I go over the same questions. 'Do you have any bleeding gums, any loose teeth, anything bothering you recently, any sores in your mouth that we need to be concerned about?' They don't mind answering those questions now. I think they know that we're looking out for them in any way we can to help them with what they're going through."

The Central Care Cancer Center Experience

Central Care Cancer Center, Salina, Kan., operates 11 comprehensive cancer treatment centers across Kansas and Missouri and is certified through the Association of Clinical Oncology Quality Oncology Practice Initiative. Most patients are currently seen at locations in Bolivar, Mo., and western Kansas, although the cancer center is currently preparing to open a new clinical site in Kansas City. The Bolivar site has one full-time hematologist/oncologist who sees mostly Caucasian patients insured through Medicare (70 percent). Approximately 10 to 15 percent are enrolled in Medicaid and 15 to 20 percent are privately insured. Although most clinical trials are run at larger academic medical centers, patients seen at Central Care Cancer Center, including approximately 70 per year with MM, have access to some clinical trials through community partnerships.

Improving Patient Adherence to Oral Chemotherapy Regimens

In May 2020, 14 participants from pharmacy, nursing, medical oncology, radiation oncology, clinical research, financial counseling, and administration attended the QI workshop at the Bolivar, Mo., site. The team identified low adherence to oral chemotherapy medications as the top challenge associated with managing patients with multiple myeloma. Oral chemotherapy regimens in MM can be confusing for older patients to follow and their complexity potentially limits shared decision-making, medication adherence, and adequate management of treatment side effects. The agreed-on QI aim was to improve oral chemotherapy adherence, tolerability, and outcomes for new patients with MM 65 years or older by streamlining initial medication review, patient education, and geriatric assessment. To this end, the QI team developed an EHR template for the pharmacist to document the results of medication review for providers. The team mapped out the medication and supplement review process to ensure that all team members understood their roles and the steps in the process (Figure 4, page 60).

At the three-month check-in, the QI team also distilled the three metrics to use to evaluate improvement in adherence and changes due to the QI intervention:

1. Delays between planned treatment cycles.
2. Reduction in total chemotherapy doses.
3. Discontinuation of initial treatment regimen.

Lastly, the QI team finalized a three-part geriatric assessment protocol based on sample assessments that one of the visiting experts provided. This protocol included a brief questionnaire, a hand grip strength test, and an ambulation assessment. The QI team codified the geriatric assessment workflow to clarify how to conduct the assessment, which staff would conduct and document the assessment, and how the assessment would be used to tailor treatment (Figure 5, page 60).

Central Care Cancer Center

Improving Patient Assessment, Managing Process Challenges

This low-cost intervention improved patient assessment. The Bolivar site saw 76 patients with MM between January and July 2020. By the six-month check-in, clinicians had completed eight geriatric assessments and 29 medication reviews. Treatment changed from baseline for 10 patients, although—because of process challenges and barriers to patient-pharmacist interaction—the medication reviews and geriatric assessments did not actually inform these decisions. For instance, the pharmacist explained that patients had little opportunity to build a relationship with him because he worked mainly onsite at the Kansas City location. As a result, patients did not always recognize his area code when he called and even when he was able to connect with them by telephone to offer the medication review, nearly all patients initially declined the service.

To address this communication challenge, the Bolivar site nurses used the COVID-19 screening calls prior to appointments to ask patients to bring a medication list or a bag with all their medication bottles to review at their next visit. The pharmacist was subsequently able to flag potential medication adherence

Figure 4. Central Care Cancer Center's Medication and Supplement Review Process

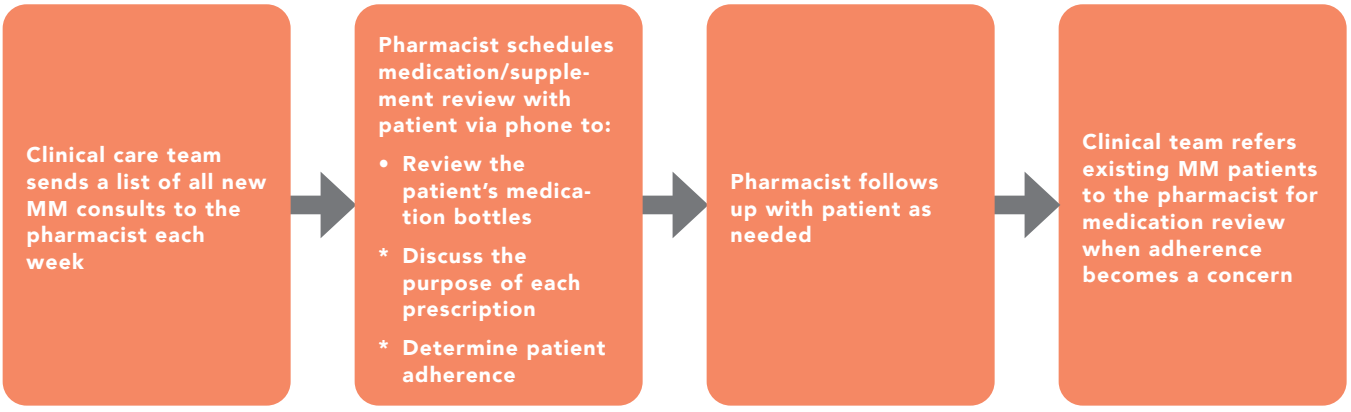


Figure 5. Central Care Cancer Center's Geriatric Assessment Workflow

issues to the oncologist. However, information gleaned through this process was insufficient for treatment decision-making. Other challenges concerned the reluctance of some patients to come into the clinic during the pandemic, be in physical proximity with others, and use hand grip strength assessors during the geriatric assessment. Patients with ambulation problems were also hesitant to agree to geriatric assessment, which, though endorsed enthusiastically by staff, took 20 to 30 minutes to complete and exacerbated existing staffing shortages. Additionally, there was some overlap between the geriatric assessment questions and questions from the existing review of systems form.

Opportunities to Streamline Protocols

In response to these challenges, the QI team has identified opportunities to streamline protocols. First, the medication and supplement review process may benefit by identifying established patients who are likely to benefit from intervention versus mandating medication review for all new consults. Second, determining the specific personnel who will tell patients to expect a call from the pharmacist and where this communication is likely to occur in the workflow could make patients more comfortable with the medication review process. Lastly, the QI team has already integrated some of the geriatric assessment questions in the standard review of systems form to reduce assessment redundancy.

Closing Thoughts

The success of QI interventions relies on an amalgam of external and internal factors. Despite limited resources, staff shortages, and reduced patient volume due to COVID-19, the three participating cancer programs addressed communication and operational improvements. Holy Cross Hospital enhanced its navigation capacity for routing under- and uninsured patients to financial assistance, CalvertHealth Medical Center increased its dental screening and review of bone-modifying agents, and Central Care Cancer Center streamlined its process for medication review and geriatric assessment to improve adherence to oral chemotherapy regimens. Internal factors contributing to the cancer programs' successes included leadership commitment, staff enthusiasm, protected time to work on the intervention, and staff education. As a result of participating in the ACCC Visiting Experts Program, the cancer programs also improved staff communication and accountability. This multidisciplinary cooperation helped the cancer programs enhance existing service lines and create a foundation for consistency and collaboration to improve patient care.

Alexandra Howson, PhD, is an experienced medical writer, researcher, and educator with a strong background in principles of adult learning combined with clinical practice as a registered nurse. Based in Seattle, Howson trained in Scotland as a registered general nurse and has a doctorate in sociology.

ACCC thanks the staff at Holy Cross Hospital, CalvertHealth Medical Center, and Central Care Cancer Center for engaging in this multiple myeloma QI initiative and sharing their experiences. Additional resources about multiple myeloma are available at accc-cancer.org/multiple-myeloma.

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References

1. Siegel RL, Miller KD, Jemal A. Cancer statistics, 2020. *CA Cancer J Clin*. 2020;70(1):7-30.

2. Palumbo A, Anderson K. Multiple myeloma. *New Engl J Med*. 2011;364(11):1046-1060.

3. Palumbo A, Bringhen S, Ludwig H, et al. Personalized therapy in multiple myeloma according to patient age and vulnerability: a report of the European Myeloma Network (EMN). *Blood. 2011; 118(17): 4519-4529*.

4. Shah UA, Mailankody S. Emerging immunotherapies in multiple myeloma. *BMJ*. 2020;370.

5. Kumar SJ, Callander NS, Adekole A, Anderson L, et at. Multiple Myeloma, Version 3.2021, NCCN Clinical Practice Guidelines in Oncology. JNCCN. 2020;18(12). doi.org/10.6004/jnccn.2020.0057.

ASSOCIATION OF COMMUNITY CANCER CENTERS

MULTIDISCIPLINARY ACUTE LYMPHOCYTIC LEUKEMIA CARE: MODELS OF QUALITY IMPROVEMENT

BY ALEXANDRA HOWSON, PHD

Quality improvement (QI) is increasingly important as healthcare organizations pursue greater efficiency and value in the services they provide. The Institute for Healthcare Improvement views QI as a rapid-cycle test of a new process that is designed to improve quality, safety, and value in healthcare. Using Plan-Do-Study-Act methodology, the rapid-cycle approach identifies a need for improvement, determines the necessary steps to implement change, establishes metrics to measure progress, and immediately implements small tests of the changes needed for improvement (see Figure 1, right, page 65).

The Association of Community Cancer Centers (ACCC) has supported QI initiatives for many years through its Visiting Experts Program. In 2020 ACCC offered QI programs designed to optimize care for patients with acute lymphocytic leukemia (ALL). Via custom workshops, multidisciplinary team members from three cancer programs appraised their own challenges and opportunities to improve care and developed QI plans that were specific, measurable, and actionable over a six-month time frame. The QI time frame included workshop participation, baseline data reporting, progress calls with ACCC, and outcomes evaluation.

Acute Lymphocytic Leukemia

ALL is an uncommon cancer that accounts for less than 1 percent of all cancers in the United States.[1] This heterogenous hematologic malignancy involves the proliferation of immature lymphoid cells in peripheral blood, bone marrow, and other organs. The risk for developing ALL is highest for children, decreases in a person's mid-20s, and rises after the age of 50 years. About 27 percent of patients with ALL are diagnosed at age 45 years or older.[2] For many patients, the diagnostic journey begins in the emergency room, where clinical presentation and peripheral blood parameters prompt bone marrow biopsy. Biopsy findings are central to diagnosis, and prognostic factors include white blood cell count at diagnosis, disease subtype, time to achieve complete remission, and quantification of measurable residual disease, which also supports risk stratification and therapeutic decisions. National Comprehensive Cancer Network guidelines recommend clinical trial participation or chemotherapy for induction therapy for all patients whenever possible. Allogenic hematopoietic cell transplant for eligible patients or multi-agent chemotherapy are recommended as consolidation therapies, depending on risk. Five-year survival for adults 40 to 59 years is 24 percent and for adults 60 to 69 years it is 17.7 percent.[2] More than 80 percent of adults diagnosed with ALL achieve complete remission, although relapse is likely for 30 to 50 percent of these patients.[3-5] Outcomes for patients who relapse are poor, with an estimated survival of approximately 10 percent.[3-5] Immunotherapy with blinatumomab, inotuzumab ozogamicin, or tisagenlecleucel are recommended as remission induction approaches for patients with relapsed or refractory ALL.[2] These agents need to be administered in cancer programs with expertise in immunotherapy administration and management of toxicities, which can be potentially life-threatening.

ALL Visiting Experts Program

ACCC conducted three visiting experts workshops focused on care for patients with ALL. The six-hour workshops were held live at Inova Schar Cancer Institute in Fairfax, Va., and online at Altru Cancer Center in Grand Forks, N.D., and Vanderbilt University Medical Center in Nashville, Tenn. Each cancer program received content presentations from visiting expert faculty and participated in extensive, facilitated discussions to develop a QI intervention. In the ACCC process, these discussions allow team members to review and prioritize potential challenges they can reasonably address within a six-month period and evaluate the likely impact and feasibility of each challenge. When attendees have established consensus about which challenge to tackle, they identify a clear aim, document steps to achieve the aim within the timeline, and describe measures for tracking progress. Table 1, page 65, provides an overview of the ALL Visiting Experts Program.

The Inova Schar Cancer Institute Experience

Inova Schar Cancer Institute in Fairfax, Va., is part of the Inova Health System and provides oncology care via a dedicated inpatient unit that is supported by four hematologists/oncologists on rotation, advanced practice providers (APPs), pharmacists, nurse navigators, and social workers. At diagnosis, patients with ALL

Inova Schar Cancer Institute

are transferred to the oncology inpatient unit and connected with an inpatient program (Life with Cancer) to address psychosocial concerns, fertility preservation, and insurance-related issues. After the inpatient stay, patients transition to the outpatient clinic with the support of a nurse navigator.

Increasing Clinical Confidence via Nurse/Pharmacist Visits

In March 2020, 12 workshop participants representing pharmacy, nursing, medical oncology, pathology, social work, and QI identified outpatient capabilities as a key area in need of QI. Although the outpatient physician clinic sees patients with a wide variety of hematologic malignancies every day, outpatient nurses were less comfortable caring for patients with ALL than for patients with other hematologic malignancies due to lack of opportunities for building skills in interpreting lab results, managing complex treatment regimens, coordinating procedures (e.g., lumbar punctures and intrathecal chemotherapy), and monitoring treatment-related adverse effects. At the same time, the transition to outpatient care can be anxiety-provoking for patients because they have less frequent contact with their providers when they move to the outpatient setting. Participants agreed that an intervention designed to increase the frequency of nurse/pharmacist visits by 25 percent for patients with ALL in the outpatient setting and provide education about ALL to outpatient clinic and infusion nurses would improve patient care and enhance nurse confidence when caring for this patient population (see Table 2, page 66).

Repurposing Existing Tools

One month into the QI initiative, the team repurposed an existing scheduling option in their clinical management system to establish a schedule for nurse/pharmacist visits for patients with ALL. Halfway through the QI time frame, the team had delivered education to 60 percent ($n = 30$) of infusion nurses on ALL causes, symptoms, diagnostic testing, treatment, and survivorship and conducted a pre- and post-test, which demonstrated discernible

Figure 1. Institute for Healthcare Improvement: Six Steps in Rapid Cycle Improvement

Table 1. Overview of the ALL Visiting Experts Program

Program Goals
Educate attendees on effective practices for supporting, treating, and managing patients with ALL.
Facilitate development of a tailored QI intervention focused on optimizing care for patients with ALL.
Follow cancer program implementation progress for six months.
Visiting Expert Faculty
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Rima Koka, MD, PhD, assistant professor, associate residency program director, Department of Pathology, associate director, Section of Hematology, Department of Pathology, University of Maryland School of Medicine
Jeff Klaus, PharmD, BCPS, clinical pharmacy specialist, Hematologic Malignancies/Hematopoietic Cell Transplantation, Barnes Jewish Hospital
Meredith Barnhart, PhD, LCSW-R, OSW-C, director, Information Resource Center, The Leukemia & Lymphoma Society
Content Presentations
An Overview of ALL and Measurable Residual Disease Testing
Management of BCR-ABL Tyrosine Kinase Inhibitors and ALL Immunotherapy Reactions
The Leukemia & Lymphoma Society Education and Services
QI Process
Development of QI Intervention in ALL Visiting Experts Workshop
QI Intervention Launch and Identification of Baseline Data
Progress Check-In Calls with ACCC at 1, 3, and 6 Months
Team Evaluation Interviews and Final Data Collection
Completion of Final Project Summary Report

learning gains. The team had also developed a rubric to structure the nurse/pharmacist visits (Table 3, right).

Inova Schar Cancer Institute saw four patients with newly diagnosed ALL between March and June and the QI team anticipated that they would initiate the nurse/pharmacist visit with these new patients. Given the low volume for patients with ALL (n = 19 in 2019), the team also expanded catchment to include patients with other hematologic malignancies to allow for more effective evaluation of the feasibility and acceptability of the nurse/pharmacist visit.

Pivot Required: Tracking Patient-Provider Interaction Frequency

Staffing redeployment to meet COVID-19 requirements, high clinic nurse caseload, and a surge of oncology patients with complex needs in June thwarted team attempts to implement the nurse/pharmacist visits. Undeterred, the QI team developed a template to track visits of new patients with ALL seen in the QI period (n = 8). Jillian Powers, BSN, RN, OCN, the oncology nurse navigator, explained that this tool enabled nurses to track patients who visited the outpatient setting for lab work, transfusion support, and chemotherapy. Powers shared, "I was able to track the frequency of how often they were seen by one of our providers, either a nurse practitioner or a physician. And then, I was also able to track when they had communication with the clinic nurse, whether it was in person or by MyChart message, or a telephone call regarding their care or questions they had. So, we were able to track the frequency of how often they were seen by providers rather than the nurse visits that we had intended to do."

The tracking tool now provides a structure for both the inpatient and outpatient care teams that helps to streamline communication and identify future opportunities to integrate nurse/pharmacist visits with other clinical visits. The QI team plans to use this tracking tool as a model for other cancer types in both inpatient and outpatient settings.

Table 2. Inova Schar Cancer Institute: Overview of QI Activities and Measures of Success

Activity	Measure of Success
1. Create schedule in Epic for lab check and nurse/pharmacist visit	Schedule in Epic
2. Develop a process for what is covered with patients during nurse/pharmacist visit	Rubric for nurses/pharmacists to follow
3. Implement nurse/pharmacist visit	• Track number of patients seen • Track number of questions raised by patients during visit • Track percentage of nurses/pharmacists who follow rubric during visit
4. Create a process for outpatient clinic nurses to shadow during nurse/pharmacist visit	• Track number of nurses who shadow visits • Measure percentage increase in outpatient nurse confidence from pre to post
5. Implement lunch-and-learns or other educational series for outpatient nursing staff	• 50 nurses participate in educational sessions • Measure percentage increase in outpatient nurse confidence from pre to post

Refocusing on the Big Picture

Although the nurse/pharmacist visits could not be implemented as intended, attention to process steps and thoughtful planning allowed the team to pivot and create a surrogate tool that supplied invaluable data about patient transitions from inpatient care to the outpatient setting. Allison Anderson, BSN, RN, the outpatient clinic nurse working with the QI team, emphasized, "We were able to very easily identify things that needed to be tracked and monitored. And we were able to find opportunities to capture the patient and their needs, to make sure that nothing falls through the cracks, and to ensure that there is consistency with our care. It was more difficult to put it into action, but it was an excellent opportunity to identify those factors. The project really helped us refocus on the big picture." There were discernible gains for clinic staff. For instance, they were able to develop a more comprehensive picture of patients' lab results, which in turn helped them to anticipate patient symptoms and side effects. Anderson stressed that, overall, participating in the planning process increased communication between her, other team members, and patients and helped the team identify barriers that they needed to address and resources they need to marshal to ensure continuity of care.

A new outpatient nurse practitioner started in October 2020 and Jillian Powers, the nurse navigator, felt that the new tracking process would help orient her to the management of patients with ALL. Additionally, QI team members view their endeavor as a first step toward raising wider awareness among Inova Schar Cancer Institute staff and leadership about how hematology care

Table 3. Nurse/Pharmacist Visit Rubric

Topic to be Addressed	Action Items
Registered Nurse	
Lab results	• Review available lab results.
Disease symptoms/ treatment side effects	• Inquire about any symptoms/side effects patient is currently having. • Provide education on self-care management. Report uncontrolled or severe issues to MD. • Establish follow-up plan to re-evaluate.
Home medications	• Ensure patient has adequate supply of all necessary home medications. – Send refills to pharmacy if necessary. • If patient on specialty drug, confirm patient has been in touch with pharmacy for timely refills/delivery. • Refer to clinical pharmacist for monthly medication review visit and as needed for questions/education related to current/new medications.
Psychosocial needs	• Inquire about any current psychosocial issues the patient may have. • Refer to *Life with Cancer* therapists/services as needed. • Refer to Inova Schar Cancer Institute case management as needed.
Appointments	• Confirm and review upcoming infusion/admission/APP/physician/nurse visits and provide printed schedule.
Clinical Pharmacist	
Home medications	• Ensure patient is taking all home medications as prescribed. • Ensure patient is taking all prescribed PRN (as needed) home medications appropriately for symptom management.
Current treatment regimen	• Ensure patient is aware/has good understanding of current treatment regimen schedule and reportable side effects of drugs in regimen. • Provide education/treatment calendar as needed.
Clinical pharmacist recommendations	• Consult with attending oncology physician for any recommendations for drug discontinuation, dose adjustments, or additions.

differs from solid tumors, especially how patients with ALL require intensive monitoring, labs, tracking, and transfusion support. Contingent on staffing, the QI team anticipates growing their nurse/pharmacist visits beyond ALL disease management to become standard of care for all patients with cancer. For now, Powers is hopeful that the project is sustainable and will strengthen relationships between patients and providers, help patients better manage side effects, and reduce patient anxiety as they transition from inpatient to outpatient care.

The Altru Cancer Center Experience

The Altru Cancer Center in Grand Forks, N.D. is part of the Altru Health System, which serves northeast North Dakota and northwest Minnesota. Altru Cancer Center has seven outreach clinics across its service area and is accredited by the American College of Surgeons' Commission on Cancer. Recently, in response to costs and the changing medical landscape, cancer care at Altru Cancer Center was consolidated to provide diagnosis and treatment for many cancer types in an inpatient multi-specialty unit (MSU). Specialist care, including ALL evaluation, is provided through the Mayo Clinic Care Network, an approximately six-hour drive from Grand Forks.

Building Clinical Competency in ALL Therapy

Provider capacity is limited in this North Dakota community—many providers leave the area and recruitment to the area is challenging, especially in oncology. As a result of this recruitment challenge, many MSU nurses lack training in blood counts, are unfamiliar with approaches to oncologic emergency, and feel underprepared to manage patients with ALL. The low annual

Altru Cancer Center

volume of patients with ALL at Altru Cancer Center (n = 6 from 2018 to 2020) compounds this collective sense of unfamiliarity with management considerations specific to ALL and presents few opportunities for nurses to build competency in managing patients with this disease. To build clinical competency, the seven participants who attended the workshop in March, including nurses, the chaplain, a clinical nurse educator, a family nurse practitioner, and the director of cancer services, agreed to focus their QI intervention on supporting nurses to meet Oncology Nursing Society (ONS) standards for performing ALL induction, consolidation, and salvage treatment.

The team decided on a combination of didactic and practicum learning tactics to improve clinical competency among MSU nurses. The goal was to increase competency by 50 percent as measured by the ability of staff to achieve the following:

- Earn an ONS provider card for chemotherapy and immunotherapy (previously chemotherapy and biotherapy)
- Participate in an education activity to improve patient outcomes
- Pass a 25-question ALL-specific written test
- Participate in a practicum learning experience.

Participants in the QI initiative would also be able to accrue points on the Nursing Clinical Ladder, which is a program designed to reward professional development for nurses.

In May, one month into the initiative, two of the four core QI team members were reassigned to focus on efforts related to the COVID-19 pandemic. Despite their departure, the QI team implemented a competence procedure to identify nurses eligible for ONS chemotherapy/immunotherapy certification (Table 4, right).

Earning the ONS Provider Card

Six of ten inpatient nurses had already received their ONS provider cards for chemotherapy and immunotherapy by the first QI milestone and the ALL-specific online test was anticipated to launch in June. However, by July, Altru Health System had undergone significant restructuring. The director of Cancer

Table 4. Inpatient Chemotherapy/ Immunotherapy Competence Procedure

Purpose: Organize information on chemotherapy/ immunotherapy certification and enhance administration capacity in the inpatient setting.

1. Manager or Supervisor will recognize nurses with strong skill and knowledge to prepare for certification. Minimum of 6 months of independent nursing care is preferred.
2. Nurse agrees to undertake this responsibility.
3. Nurse will go online to the Oncology Nursing Society webpage and sign up to take the course: Fundamentals of Chemotherapy Immunotherapy Administration Certification Course.
    a. A copy of certificate will be kept on file in NetLearning.
4. Nurse will complete Employee Health form.
5. Nurse will complete Hazardous Drug Risk Acknowledgement form.
6. Nurse will spend time at the Cancer Center administering agents with the following time frame and objectives:
    a. Nurse will use proper technique while accessing port.
    b. Nurse will learn and use proper technique and utilization of the CSTD (closed system transfer device) to priming chemotherapy.
    c. Nurse will use proper technique and safety precautions while hanging chemotherapy.
    d. Nurse will be introduced to Epic Beacon.
7. Nurse will schedule time with inpatient validator to review inpatient Epic Beacon for releasing orders. The inpatient validator will then sign off validation in NetLearning.
8. The certification class is renewed every other year. On the year in between, nurse will need to take class offered by the Cancer Center to maintain validation.

Services had departed, and more than 170 employees were unexpectedly laid off. Those remaining had adopted additional roles and responsibilities.

Though this organizational restructuring undoubtedly slowed implementation of the intervention, by the end of the QI time frame the overall number of inpatient MSU nurses with ONS provider cards increased by 125 percent (Figure 2, page 70). The team expects a total of 11 certified nurses by the end of 2020.

Moreover, an unanticipated outcome from the QI intervention was a 42 percent increase in the number of port-validated nurses from 12 to 17. Prior to the intervention, there was no full coverage by port-validated staff on the inpatient unit, leading to occasional treatment delays for patients with cancer.

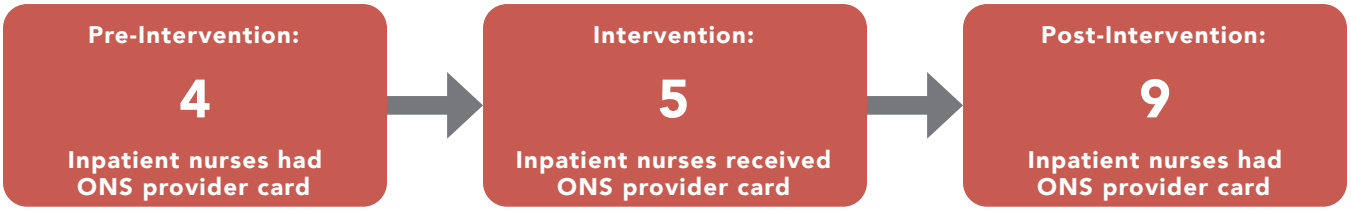
Clinical Education and Practicum

By the end of the intervention period the ALL test had been finalized, although not yet released. The original 25-question test was reduced to 11 multiple-choice and open-ended questions that focused on the clinical presentation, diagnosis, and treatment of patients with ALL, as well as on chemotherapy management considerations. To prepare for the ALL test—which Katie Richardson, MSN, RN, practice manager for Cancer Services and Palliative Care, anticipated would be delivered in late 2020 or early 2021—learners will be provided with a blood cancers 101 video and ONS articles and resources. After learners complete the test, Richardson will review results and invite learners to participate in additional educational activities to address persistent knowledge gaps. In terms of the practicum experience, the QI team was able to provide it to those with newly acquired ONS provider cards. Additionally, nurses who received their ONS provider cards shadowed nurses in the outpatient chemotherapy clinic to increase their knowledge and comfort level in caring for patients with cancer.

Poised for Success

This QI project served as Altru Cancer Center's 2020 Cancer Services Quality Improvement Project and therefore garnered a strong commitment from participants to ensure success. Despite the unanticipated restructuring and layoffs that occurred during the intervention period, the QI team improved clinical competency for managing patients with ALL in the MSU by increasing the number of nurses with ONS provider cards for chemotherapy/ immunotherapy and the number of nurses equipped to manage chemotherapy portacaths. As a result of building competence through this ALL-specific clinical education, inpatient nurses now feel poised to manage patients with ALL. There is a more clearly defined process for chemotherapy delivery and Altru Cancer Center now provides full chemotherapy coverage in the MSU. Moving forward, ONS certification in chemotherapy/immunotherapy is likely to become an expectation for charge nurses in

Figure 2. Number of Inpatient Nurses with an ONS Provider Card



the MSU, and the QI initiative will be incorporated into the Clinical Ladder points system in 2021.

The Vanderbilt University Medical Center Experience

Vanderbilt University Medical Center annually serves approximately 2 million people and is one of the largest academic medical centers in the Southeast region. Adult patients with ALL (approximately 130 per year, including those currently undergoing treatment and in various stages of follow-up) are seen in the Department of Hematology/Oncology, which is served by a long-term follow-up care clinic, and staff liaise with the Department of Pediatrics to determine care for adolescents diagnosed with ALL.

Assessing Need, Developing Tools, Coordinating Care

The nine participants of the May 2020 visiting experts workshop included administrators, nurses, and medical oncologists. The group highlighted the lack of centralized electronic health record (EHR) tools that the entire care team can access to coordinate care for patients with ALL. For instance, at the time of the workshop, patients received a handwritten calendar of appointment times for treatment, procedures, and associated workups. Participants felt that this calendar could be optimized to better support both internal and patient-provider communication with, for instance, reminders to acquire laboratory results from local providers; resources for patients concerning housing, emotional, or financial assistance; and automatic adjustments to a patient's monitoring schedule should treatment be delayed.

The four core QI team members, including a hematologist/oncologist, two managers (of patient care and quality and accreditation), and the hematology clinic nurse, planned to conduct a needs assessment and identify resources to support coordination of care as a platform for developing and piloting an Epic tool prototype for patients with ALL. Conversations with stakeholders outside the QI team revealed wider interest for an EHR-based care coordination tool for ALL and throughout Vanderbilt University Medical Center. Unfortunately, however, an Epic design freeze was instated due to a system-wide upgrade. In response, the team explored existing tools in Epic that would not require additional programming and decided to create an EHR-based calendar that would help move patients with ALL through the care continuum and notify patients and providers about changes in the schedule.

At the end of the QI period, the QI team had begun using this Epic reminder tool to coordinate patient care. For instance, when one patient with ALL needed surgery (unrelated to ALL treatment), the patient's ALL treatment schedule had to be shifted by three weeks. The reminder tool was used to notify all care team members that imaging, labs, and other treatment-related components would need to be rescheduled. A reminder was also sent seven days prior to the resumption of ALL therapy to allow time for the care team to evaluate the patient's health status and readiness for treatment. Though the patient did not have access to a visual calendar, the clinic nurse was able to provide information about schedule changes and updates.

Determining Meaningful Measures of Success

Although Vanderbilt University Medical Center was unable to implement its original intervention as planned, the opportunity for QI combined with the addition of a new nurse to support Olalekan Oluwole, MD, the hematologist/oncologist, allowed the QI team to review clinic processes, workflow, and team communication. Amelia Taggart, RN, the hematology clinic nurse, noted that due to this review, QI team members realized that they were not aware of all the functions that Epic offers and are now being trained on other existing Epic tools that are available to

Vanderbilt University Medical Center

streamline patient care. In addition, Caroline Cavanaugh, RN, staff nurse at the hematology clinic, found that using the reminder tool strengthened communication between her and Dr. Oluwole, with whom she now has regularly scheduled meetings to review cases and answer questions. As Cavanaugh explained, this fortified communication has enabled her to offer greater clarity to patients with ALL regarding next steps in their treatment. "I didn't work with Epic before I came to Vanderbilt University Medical Center. I have used [the reminder tool] a lot to try and help remind me to talk to the doctor or remind both of us," shared Cavanaugh. "And if we need to adjust [a care plan], having me in the loop helps me follow up when things need to be rescheduled or adjusted." Since beginning to use the Epic tools, Cavanaugh has also noticed a reduction in messages from patients with ALL and other tumor types inquiring about results or treatment-related issues.

On Nov. 1, 2020, the team introduced a new process to support communication and maintain continuity of care by assigning APPs to specific physicians. The team now plans to determine metrics, such as "missed appointments," that will meaningfully measure the effectiveness of both the calendar tool and tighter coordination between APPs and physicians in improving patient-provider and provider-provider communication. A future goal that has emerged from participation in the QI project involves converting paper-based care pathways into EHR-based documentation that any nurse can access to support patient care.

Closing Thoughts

QI is a form of experiential learning that involves hypothesis testing and performance improvement, but QI interventions do not always run to plan. Organizational and personnel changes are common obstacles in these initiatives and, thus, planning and implementation needs to be responsive and flexible. In addition to the hurdles that might usually be expected as part of QI, the staff involved in the interventions described were tested by the COVID-19 pandemic in unimaginable ways. Yet these committed healthcare professionals embraced their challenges and persisted with improvement in ways that speak to robust organizational commitment to QI, strong local leadership, and personal fortitude. The success of these initiatives demonstrated careful upfront cataloguing of challenges that were real, the ability of participants to adapt, and creative repurposing of existing EHR-based tools. These factors point to improvement in the management of patients with ALL with the potential for sustainability well beyond the intervention period.

Alexandra Howson, PhD, is an experienced medical writer, researcher, and educator with a strong background in principles of adult learning combined with clinical practice as a registered nurse. Based in Seattle, Howson trained in Scotland as a registered general nurse and has a doctorate in sociology.

ACCC thanks the staff at the Inova Schar Cancer Institute, Altru Cancer Center, and Vanderbilt University Medical Center for engaging in this acute lymphocytic leukemia QI initiative and sharing their experiences. Additional resources about acute lymphocytic leukemia are available at accc-cancer.org/all-care.

ACCC acknowledges Allison Harvey, MPH, CHES®, and Aubrey Villalobos, DrPH, MEd, of Rhizome, LLC, for their contributions to this article and consultation throughout the Acute Lymphocytic Leukemia Visiting Experts Program.

References

1. Siegel RL, Miller KD, Jemal A. Cancer statistics, 2020. *CA Cancer J Clin.* 2020;70(1):7-30.

2. National Comprehensive Cancer Network: NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia (Adult and AYA). Version 2.2020.

3. Hoelzer D. Monitoring and managing minimal residual disease in acute lymphoblastic leukemia. *Am Soc Clin Oncol Educ Book.* 2013;33:290-293.

4. Jain N, et al. Acute lymphoblastic leukemia in adults. In: Hoffman R, et al., eds. *Hematology: Basic Principles and Practice*. 6th ed. Philadelphia, PA: Saunders-Elsevier; 2013:960-980.

5. Fielding AK, Richards SM, Chopra C, et al. Outcome of 609 adults after relapse of acute lymphoblastic leukemia (ALL); an MRC UKALL12/ECOG 2993 study. *Blood.* 2007;109:944-950.

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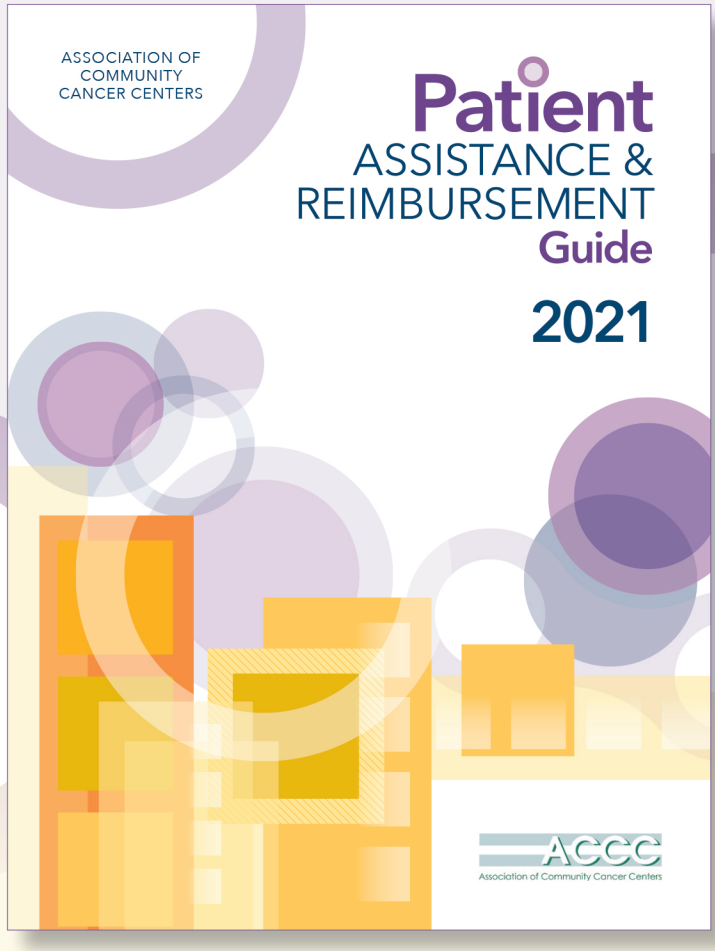

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THE EVOLVING IMMUNOTHERAPEUTIC LANDSCAPE IN RENAL CELL CARCINOMA

A Q&A with Robert A. Figlin, MD, FACP; Jocelyn Mohs, PharmD, BCOP; and Laura S. Wood, RN, MSN, OCN

As the role of immunotherapies for treating patients with renal cell carcinoma (RCC) grows, keeping up with the pace of emerging data on combination therapy regimens, effective practices for monitoring and managing immune-related adverse events (irAEs), and educating patients to empower informed decision-making can be challenging. In 2019 the Association of Community Cancer Centers developed an education program to provide all members of the multidisciplinary care team knowledge and resources to help successfully integrate immunotherapies into the treatment of patients with RCC. The program was offered in two formats: a live, on-site learning workshop and an audio-guided online course. Three cancer programs hosted half-day workshops onsite at their institutions:

- The Cancer Center at Christus St. Michael Health System, Texarkana, Texas. Live workshop held Dec. 11, 2019.
- OSF HealthCare Saint Anthony Medical Center, Patricia D. Pepe Center for Cancer Care, Rockford, Ill. Live workshop held Jan. 15, 2020.
- Hawaii Pacific Health, Honolulu, Hawaii. Live workshop canceled due to COVID-19. Virtual workshop held Sept. 29, 2020.

At these workshops, a three-member multidisciplinary expert faculty panel provided both didactic presentations and collaborative open discussion with members of the multidisciplinary care teams. Topics covered included, but were not limited to, a review of the rationale for using immunotherapies and immunotherapy combinations, optimal sequencing of therapies, patient selection criteria, and monitoring and managing irAEs in patients with metastatic RCC. Collateral issues discussed included coordination and communication within the multidisciplinary care team, coverage and reimbursement, and improving patient education and engagement. Table 1, page 76, highlights the quality improvement action plans developed by the three participating sites at these workshops.

Table 1. Action Plans Developed at the RCC Workshops

OSF Healthcare
Develop a tool to assess the knowledge level of mission partners caring for patients with RCC on immunotherapy
Survey and identify knowledge gaps of mission partners on immunotherapy
Develop and implement immunotherapy education plan for all front-line caregivers
Develop and implement patient education, tools, and resources specific to immunotherapy
Develop and implement new triage tools and resources for immunotherapies
Develop and implement immunotherapy survivorship care plan
CHRISTUS St. Michael Health System
Initiate a multidisciplinary tumor board focused on management of irAEs and include sub-specialists who can offer guidance on management of irAEs
Hawaii Pacific Health
Develop uniform staff education (system) for the management and identification of immunotherapy side effects and/or irAEs, including uniform algorithms for symptom-based immunotherapy calls
Engage pharmacy in patient education
Manage prior authorization for chemotherapeutics, biologics, immunotherapies, and oral agents
Assemble working group that could include pharmacy, registered nurse, navigation, advance practice providers, and oncology program liaison to develop patient education on symptom management for cancer oral therapies based on site-specific agents
Assemble immunotherapy working group for interdepartmental referrals and access: oncology, dermatology, rheumatology, endocrinology, pulmonary, and gastrointestinal

Oncology Issues interviewed the expert faculty panel from the live workshops. Below they share key insights on immunotherapy and patients with renal cell carcinoma.

OI. What are some of the challenges that community practitioners face when choosing an immunotherapy-inclusive regimen for their patients with RCC?

Dr. Figlin. The biggest challenge for practicing physicians is the absence of comparative effectiveness research. Physicians have multiple options for patients with RCC in the frontline setting, but they have no data with which to choose one over the other as they [treatments] were never compared. So that's the first challenge. The second challenge is recognizing that these are new classes of drugs—immunotherapy or immunotherapy combined with a target agent. Immune-related adverse events are not typical for patients with kidney cancer, and physicians must learn how to effectively manage them. The third challenge is to recognize that kidney cancer management is really what I call "a team sport," meaning that it takes a group of clinicians—physicians, nurses, subspecialists—to care for these patients because one can never know when a potentially life-threatening irAE might occur.

Dr. Mohs. It is very challenging to stay current on the new indications for immunotherapy agents and then appropriately apply their role as monotherapy or in combination with chemotherapy or oral targeted therapies. As use of immunotherapy agents expands, it is challenging to optimally sequence treatment options in each tumor type. Community practitioners must stay alert to the potential development of common and rare immune-related adverse events and not be lulled into thinking these agents are always well tolerated. It is important to become familiar with guideline-based management of less common irAEs and how

toxicities can overlap in presentation. We also need to educate patients on the signs and symptoms and typical onset of rare immune-related adverse events.

With pharmacists integrated into many multidisciplinary care teams across internal medicine and all specialties [i.e., critical care, emergency department, neurology, etc.], our program has utilized its oncology pharmacy residents to educate all pharmacy staff on irAEs through grand rounds presentations. This education helps health system pharmacists bring awareness of recognition, mitigation, and management of irAEs back to their teams as a part of patient care.

Wood. Being a member of the Oncology Nursing Society and the American Society of Clinical Oncology provides me timely updates regarding current data and safety information on immunotherapy regimens. Best practices are shared through journal club meetings, disease team meetings, and nursing meetings. Our EHR [electronic health record] provides an avenue of communication with other providers, including primary care physicians and multidisciplinary providers involved in the daily care and management of irAEs. That said, busy community practitioners who may not have ready access to all these resources may encounter issues such as:

- Lack of knowledge of, and availability to, companion diagnostics and/or diagnostic or prognostic biomarker tests for eligibility and response assessment of select immunotherapy agents.
- Care coordination challenges, including EHR limitations; for example, multiple practices and private subspecialty groups that lack a common or access to a common EHR.
- Lack of standardized local payer formularies, making immunotherapy selection difficult and/or pharmacy formularies challenging to manage.

OI. On the topic of coverage and reimbursement of immunotherapies, did RCC workshop attendees share specific challenges; for example, issues obtaining pre-certifications and/or prior authorizations? Any solutions to share with our readers?

Dr. Figlin. The biggest challenge they [workshop participants] shared is one we all face: Immunotherapy drugs and treatments are hugely expensive, and they're being scrutinized heavily by payers. Oftentimes there is an unfortunate delay in therapy between the time that the patient and the physician agree on a treatment plan and when payers finally agree to cover that treatment. When a patient with RCC is being treated with immunotherapy, those delays are not in the best interest of the patient. [These types of payer challenges] were articulated by the RCC workshop participants. So, the biggest barrier is access to care for these expensive, potentially effective therapies.

Dr. Mohs. Having a vigorous prior authorization process on the front end of starting immunotherapy treatment can prevent many reimbursement issues. Staff dedicated to completing all pre-certifications or prior authorizations can be very efficient, especially if they have a background in coding and reimbursement. Pharmacists or even experienced pharmacy technicians can help lead the prior authorization process, as well as assist with submitting denial appeals on behalf of providers. One challenge in the realm of prior authorization and reimbursement is the lag in payer coverage for immunotherapy agents with new data showing positive outcomes in a unique treatment setting.

Wood. Our cancer program has reimbursement specialists who complete the prior authorization for all oncolytics prior to initiation of treatment. These reimbursement specialists received additional training on the immunotherapy medications, indications, and combination regimens. Oral oncolytics are sent to our specialty pharmacy, which completes the prior authorization and any patient assistance applications.

OI. At the Hawaii workshop, attendees shared that many patients with RCC must travel to other islands to receive treatment.

Dr. Figlin. Hawaii is a unique state in that the islands are separated by water, but certainly across the United States many patients with RCC must travel long distances to receive immunotherapy treatment. These are complicated therapies with potential serious side effects that need be managed by an experienced care team. Excessive travel presents challenges and risks, and clinicians must be mindful of those.

OI. In terms of the actual administration and monitoring for irAEs and having experienced staff available to do both, do you see any specific challenges?

Dr. Figlin. Oncology staff are very familiar with intravenous transfusions and starting people on oral medications, so the administration of immunotherapy agents is not the challenge. The challenge is that irAEs can occur at any time and how are they going to be managed? If a patient with RCC who is being treated with immunotherapy presents at the emergency department [ED], are the ED clinicians aware of the toxicities associated with these treatments? Is somebody available 24/7 to make sure that if something occurs in the middle of the night, the patient doesn't have to wait until the next day to have their issues resolved? So, the challenge and the barriers to care are really education and access. From workshop discussions, it's clear that practicing oncologists are so busy they have little time to educate their colleagues about irAEs. That must be something we improve and potentially a future education program: practical strategies to help oncologists educate their community colleagues on immunotherapy and, specifically, irAEs.

Wood. In addition to renal cell carcinoma, immunotherapy is now used to treat multiple malignancies, so training of staff has become much more comprehensive. Telling patients and caregivers to communicate to their primary care provider and emergency department staff that the patient is being treated with immunotherapy—not chemotherapy—continues to be a major component of patient education. At our cancer program, patients on immunotherapy clinical trials are given an additional copy of the informed consent to take with them to every medical visit. All patients are also given copies of the immunotherapy education sheet and the NCCN [National Comprehensive Cancer Network] irAE infographic to take to provider appointments.

Challenges experienced by some community oncology programs or those in rural locations include:

- The need for specialty trained staff to provide comprehensive immunotherapy patient education.
- Patients who must travel long distances to receive treatment.
- Availability of emergency services.
- Lack of familiarity with guideline-based management of irAEs, including standardized, early toxicity intervention.
- Administration of routine lab testing and standard monitoring of organ function (i.e., thyroid, skin) and staff trained and/or available to conduct these assessments (e.g., APPs [advanced practice providers], nurses, pharmacists).
- Radiologists and other imaging specialists with a sufficient level of experience to interpret inter-treatment scans; for example, pseudo-progression.

OI. Dr. Figlin called the care of patients with RCC being treated with immunotherapy "a team sport." From what you heard from your colleagues at the workshops, do you see any kind of care coordination challenges between oncology and the other sub-specialties?

Dr. Figlin. I think that all community practitioners are on the learning curve with regards to immunotherapy and RCC. Often, the oncologist is more knowledgeable about the treatment regimens and the subspecialists—endocrinologists, gastroenterologists, and pulmonary physicians—are less familiar with this class of drugs. I think it will take some time before they fully understand the complexities of the immunotherapy treatments we [oncology] give.

Wood. [On the topic of care coordination] our cancer program collaborates directly with a team of multidisciplinary providers. We host an irAE tumor board that many of our collaborating specialists participate in. Standardized testing and treatment algorithms were developed during the irAE tumor board meetings and are shared at staff meetings, grand rounds, and ED and hospitalist meetings.

Robert A. Figlin, MD, FACP, is Steven Spielberg Family Chair in Hematology Oncology; professor of medicine and biomedical sciences; director, Division of Hematology Oncology; deputy director, Integrated Oncology Service Line; deputy director, Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center, New York, N.Y. Jocelyn Mohs, PharmD, BCOP, is pharmacy supervisor, Infusion Clinic Pharmacy, Sanford Roger Maris Cancer Center, Fargo, N.D. Laura S. Wood, RN, MSN, OCN, is renal cancer research coordinator, Cleveland Clinic Taussig Cancer Institute, Cleveland, Ohio.

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6 STEPS
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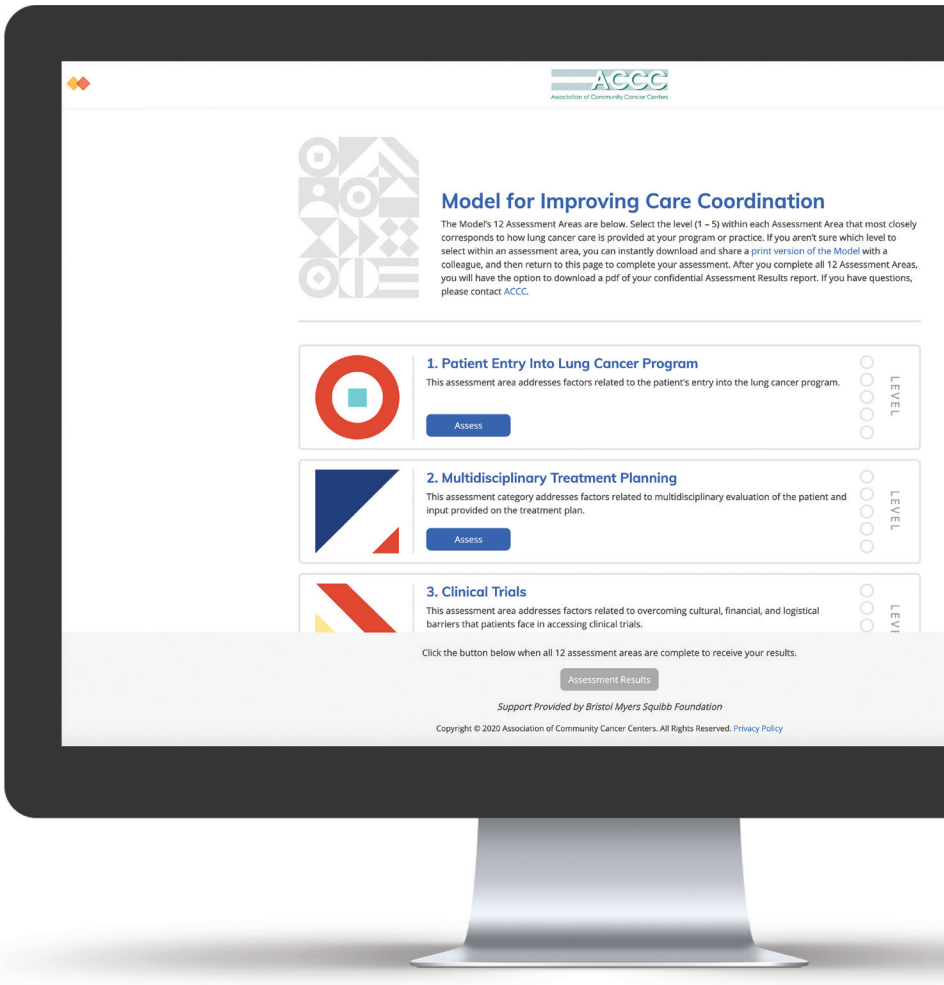
for Lung Cancer Patients on Medicaid



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Delegate Rep: Richard Ballard, BS, MS
Website: weknowcancer.org

Valley View Hospital
Calaway Young Cancer Center
Glenwood Springs, Colo.
Delegate Rep: Hans Lindbloom, BSN
Website: vvcancercenter.org

University of Wisconsin Carbone Cancer Center
Hematology, Medical Oncology & Palliative Care Division
Madison, Wisc.
Delegate Rep: Julene Gaspard, MBA
Website: uwhealth.org/uw-carbone-cancer-center/cancer/10252

Mercy Medical Center
Mercy Cancer Center Canton
Canton, Ohio
Delegate Rep: Nicole Haines, RN, BSN, OCN
Website: cantonmercy.org/cancer/

CANCER BUZZ Podcasts Explore Health Equity

On the mini-podcast *Cultural Humility & Sensitivity*, Christopher Lathan, MD, MS, MPH, medical director, Dana-Farber Cancer Institute at St. Elizabeth's Medical Center, and associate medical director, Dana-Farber Cancer Institute Network, discusses how the legacy of racism in American healthcare continues to affect research and explores strategies for cancer programs to better communicate with minority groups and other underrepresented populations.

In healthcare, implicit and unconscious bias manifests in many ways. On the mini-podcast, *Building Trust with Marginalized Groups*, Nadine Barrett, PhD, MA, MS, director, Office of Health Equity and Disparities, Duke Cancer Institute, and director, Duke Community Connections Core, Duke Clinical and Translational Science Institute, shares steps that cancer programs can take to build trust with patients from marginalized and underrepresented groups and ensure a more equitable and accessible healthcare environment.

Rosemary Thomas, MPH, CHES, director of operations, Penn Medicine Center for Health Equity, and associate director, Penn Med Program for LGBTQ Health, guests on the mini-podcast, *LGBTQ+ Patients with Cancer*, where she explores the barriers and challenges that LGBTQ patients with cancer face and how cancer programs can make their care more inclusive.

ICYMI: Webcast on *Integrating the Community Voice to Advance Cancer Research*

Optimal cancer care delivery changes from place to place—what works best for one location and patient population may not be ideal for another. The same reasoning also applies to cancer research. Understanding the needs of your patient population is critical to trial design and implementation. But how can you proactively involve your community in cancer research? In the ACCC webcast, *Integrating the Community Voice to Advance Cancer Research*, guests Carla Strom, MLA, assistant director for operations, Office of Cancer Health Equity, Wake Forest Baptist Comprehensive Cancer Center, and Kathryn Weaver, PhD, MPH, associate professor of public health services, Department of Social Sciences and Health Policy, Wake Forest School of Medicine:

- Discuss strategies to incorporate your community's needs and perspective into your research program.
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Mentoring Those New to Oncology

BY KERRI MICHALIK, MHA, BSN

Oncology is often viewed as a challenging field, but those who work in oncology find many small and large rewards that make the daily challenges worth the effort. Unfortunately, these challenges are exacerbated in programs experiencing a shortage of clinical care staff (i.e., oncologists, registered nurses, and advanced practice providers), often resulting in increased burnout and turnover rates among staff. More, oncology providers and professionals gain opportunities to grow in their career and often move on to different care settings along their career trajectory. In my breakout session at the 37th ACCC [Virtual] National Oncology Conference, held Sept. 14-18, 2020, I shared that mentorship is often the missing link to facing these staffing challenges.

Getting Started

Building a mentorship program in your cancer program or practice helps staff feel more connected to the work that they do and to the organization they work in, while also improving staff retention and decreasing turnover rates. The shortage of healthcare workers in the United States has only worsened since the pandemic. It's a buyer's market and staff can go wherever they want. If they express an interest in oncology, it's our responsibility to make them feel at home in that setting and to keep them anchored.

The key to maintaining staff is investing in them through education, growth opportunities, and/or promotion. Through mentorship, cancer programs and practices better understand their own staff, so nurses, oncologists, advanced practice providers, front desk staff, and even management can build on their weaknesses, celebrate their strengths, and grow within their organization.

Flexibility is the key to effective mentorship. If you are just getting started developing a mentorship program or are looking to revitalize an existing one, follow these five simple steps:

1. Use mentors who *want* to mentor.
2. Ensure that the mentor and mentee share a *genuine* connection.
3. Understand that mentoring requires a *commitment* of time and effort.
4. Consider starting with a 360-degree feedback *assessment* and/or a DiSC assessment. (The DiSC model describes four main styles: D is for Dominance, i is for Influence, S is for Steadiness, and C is for Conscientiousness. Learn more at discprofile.com).
5. Set both short- and long-term *goals*.

Assessments serve as a foundational base of a mentorship program, providing both parties (mentor and mentee) with a profile of the mentee's strengths, weaknesses, and opportunities for improvement. Assessments like DiSC also help mentees better understand themselves; that is, their personality and how they work. From the mentor perspective, a 360-degree assessment can identify a specific weakness and bolster your efforts to bring that person out of their shell and work on that weakness together and in a respectful way.

How to Mentor Well

The mentor-mentee relationship is vital to building what should be a long-lasting relationship. If either party feels pressured to participate, no one will benefit. In this situation, mentors and mentees simply skip meetings.

So, the first step to building an effective mentorship program is finding mentors who truly want to help those new to oncology and who are open to sharing experiences together. If, for whatever reason, the relationship between the mentor and mentee fails, build a safe environment where either party can request a new partner. The pairing of mentors and mentees is a flexible and adaptable process. The end goal is to foster a strong relationship that benefits both participants.

Mentors should provide their mentees honest feedback in a respectful manner to help them grow. Mentors should also feel comfortable opening up to their mentees so that they may learn from their mentor's experiences. A mentor is responsible for helping the mentee grow. This means sharing their own pitfalls and mistakes and being as candid as possible. Mentoring and being mentored are both a commitment. Both individuals need to want to put in the time and effort. In some instances, mentors and mentees choose to meet outside normal work hours—sometimes over a shared meal. It's most beneficial when the mentors and mentees designate a time to meet based on their own schedules, rather than having a set time assigned by another individual or the cancer program.

(continued on page 84)

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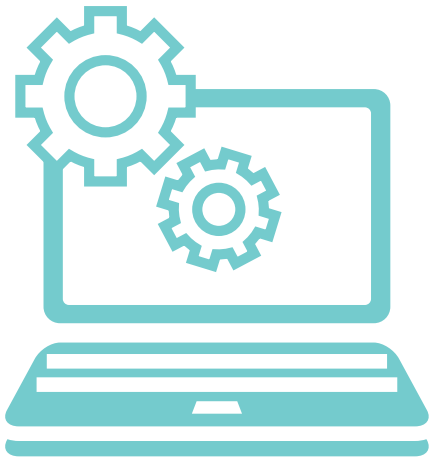

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(continued from page 82)

One of the largest benefits of mentorship for those new to oncology is the connection to a person they trust and can learn from. The mentor becomes their go-to person when the mentee is having a rough day or has made a mistake and needs guidance. In most cases, the mentor should not be the mentee's direct manager or even a close colleague; sometimes a mentor can come from outside the organization itself as long as the expertise is there. Don't burn bridges when people move on in their career. Stay connected with colleagues and others who offer valuable experience and knowledge. You may onboard someone who would be a great fit with a mentor who just left your program or practice and with whom you still share a relationship.

Lastly, sharing valuable resources is often overlooked when mentoring. These resources could be professional organizations like ACCC or ONS (the Oncology Nursing Society), where individuals find a community to help them grow. Mentors should also share any books, podcasts, and lecture series they like to help their mentees with continuing education. Experienced mentors share resources so their mentees can continue to learn and grow on their own time and at their own pace.

Challenges Faced

Setting up a mentorship program in a large cancer program or practice spread out across multiple clinic locations is not an easy task.

In one such situation, a participant at my breakout session shared that their cancer program did not pair its expert staff with new staff in a traditional mentor and mentee relationship, mostly due to the availability and ratio of experts to new staff. Instead, the cancer program hosted central calls where experts across the organization were available to teach and answer attendee questions. This structure was thought to be an underlying reason behind the low attendance. To improve attendance, the cancer program incorporated these town hall-style meetings into the internal certification program that all staff must complete to maintain their education and position in the cancer program. Interestingly, this new structure brought only slight improvements in attendance.

At Geisinger Cancer Institute, we developed a similar town hall approach in response to the COVID-19 pandemic and the increased need for psychosocial services our staff was experiencing. These town halls connected staff with psychologists—regardless of whether there was a mentor relationship or not—to talk about their challenges. Our staff could participate in these town halls at a time that was most convenient for them, and it was something staff felt like they *wanted* to do versus something they *had* to do.

Another attendee of my breakout session shared how it can be challenging to differentiate between preceptorship and mentorship—especially with nursing. Unlike the preceptorship process that pairs senior nursing staff with new nurses, this cancer program found that the same group of nurses on the floor would mentor nurses seeking guidance and that the nurses doing the mentoring were advanced in their role or in a leadership position. In other words, individuals who wanted to mentor would naturally do so and would do so on their own time.

This experience was similar to another one shared during my breakout session. Instead of setting up a robust mentorship program in this small community program, nursing leadership noticed that new nurses generally found their niche during the onboarding process and would then assign these nurses to the area they gravitated toward. Mentoring occurred naturally as new nurses were welcomed and included by senior nursing staff in the area that best fit their personalities. Unfortunately, this type of organic mentorship is difficult to create in larger programs, especially in cancer programs or practices with multiple locations, which is why a formal mentoring program can help.

Building Community

One of the best rewards you can gain from mentoring (whether you are the mentor or the mentee) is a greater sense of inclusion and community within your organization. This sense of community will in turn help your cancer program or practice decrease turnover rates and build staff satisfaction.

In another example shared during my breakout session, one ACCC member program sought to build a close-knit community between staff by making sure that infusion nurses and staff are part of the small celebrations and everyday rewards that oncology often brings. For example, this cancer program includes its nursing staff in its survivorship days. Nurses are taken off the floor (even just for an hour) so they can see and visit with patients who were once part of their daily routine but who are now in survivorship care. Often infusion staff are not able to participate in these types of celebrations because they are needed to treat current patients. But when this cancer program arranges scheduling so that staff members can participate in celebrations, staff feel connected, silos are broken down, and everyone is reminded of the key part they play in the cancer program and patients' lives. OI

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