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ONCOLOGY ISSUES

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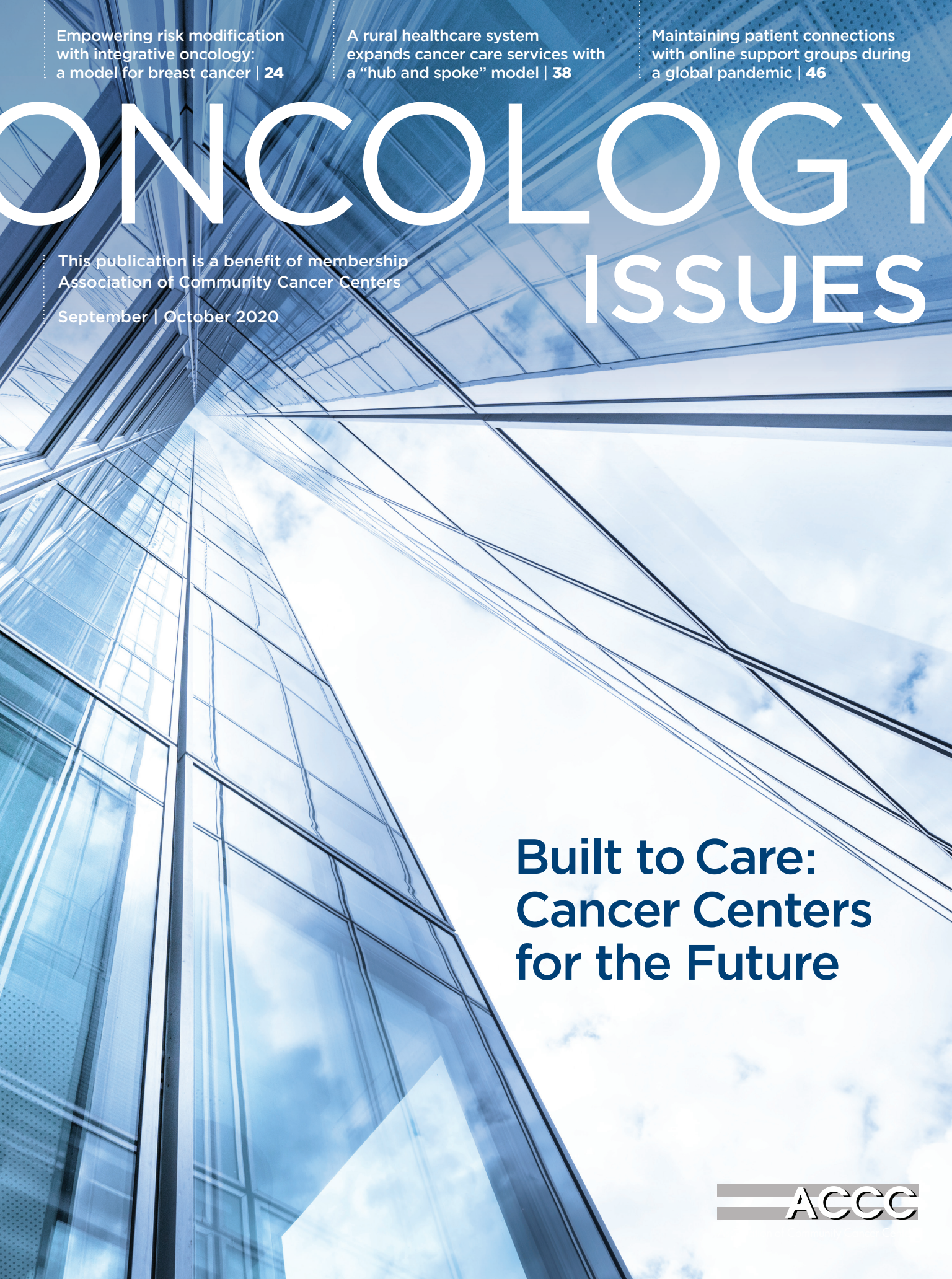
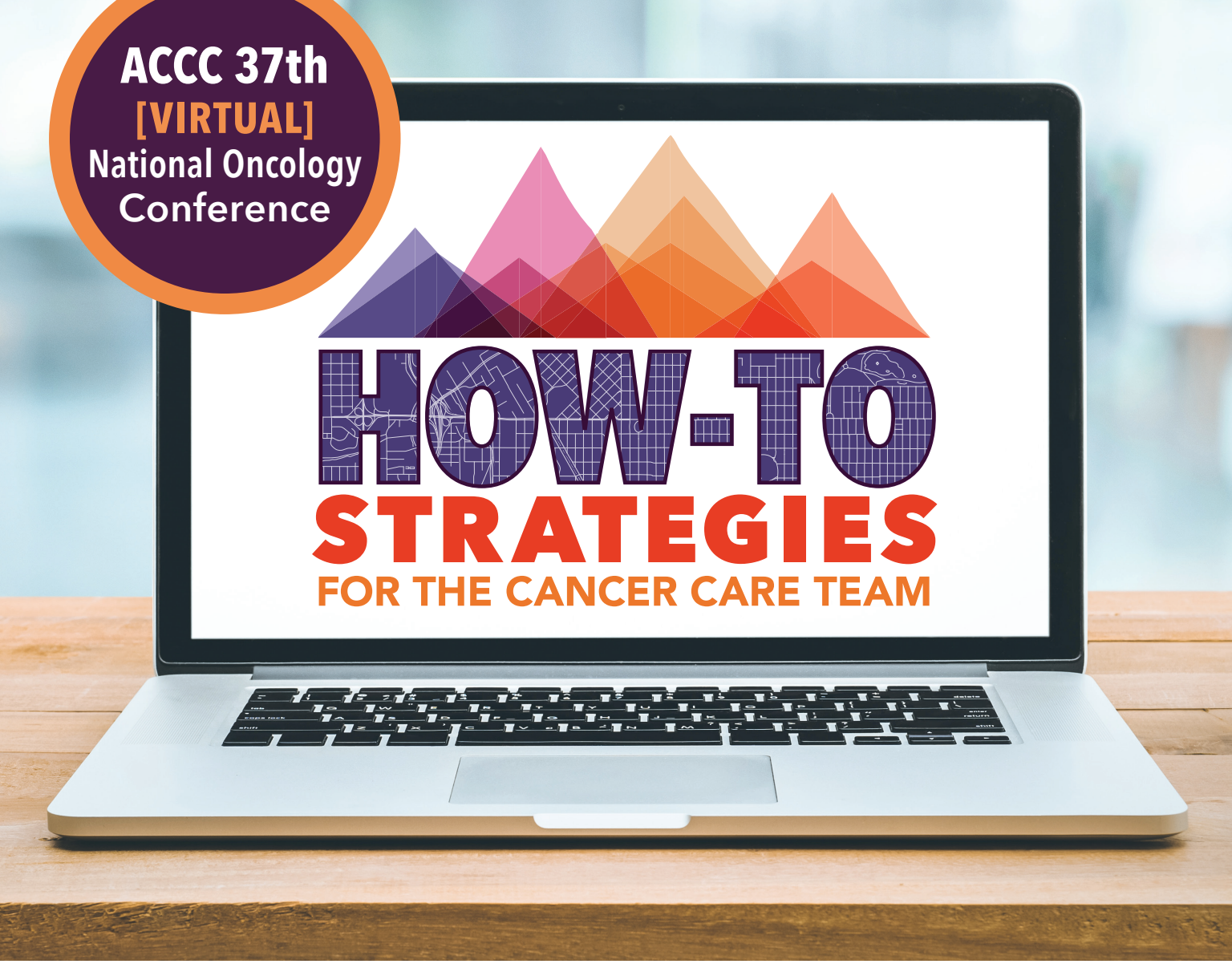
Association of Community Cancer Centers

September | October 2020



Built to Care: Cancer Centers for the Future

ACCC



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FROM THE EDITOR

Addressing Racism and Disparities in Oncology

BY JENNIE R. CREWS, MD, MMM, FACP, AND NADINE BARRETT, PHD, MA, MS

I am privileged to share this column with Dr. Nadine Barrett, an ACCC board member and director, Community Engagement and Stakeholder Strategy, Duke Cancer Institute and Duke Clinical Translational Science Institute, and assistant professor, family medicine and community health.

Our country is experiencing an unprecedented and long overdue focus on disparities, inequities, and structural and institutional racism fueled by the deaths of George Floyd, Breonna Taylor, Ahmaud Arbery, and many others who have recently lost their lives due to racism. This, coupled with longstanding health system challenges and barriers that have been brought to light by the disproportionate burden of COVID-19 incidence and mortality on people of color and marginalized populations, is leading to intentional focus on institutional racism in healthcare systems and facilities.

Now is a critical time to call out where racism and disparities exist in oncology and to examine our personal and professional roles and responsibilities to enact change. Not only is there a moral and ethical imperative to do so, but there is the opportunity for us to enhance and accelerate the impact of our organizations through the strength, perspective, and expertise that a diverse workforce and equitable analyses of our patient services and programs can provide. Looking at cancer care delivery through the lens of equity, diversity, and inclusion will allow us to better understand and authentically value the diverse perspectives of our patients and the communities we serve, tailoring care to better meet the needs and remove the barriers that lead to gaps in outcomes.

This work can feel overwhelming, and it can be difficult to know where to concentrate our efforts. Here are some ideas to consider and customize to your own cancer program and community's needs:

- Practice self-reflection and self-education to understand the current climate and how it impacts our work.
- Promote and enable dialogue about racism and disparities within your program.
- Establish a diversity, equity, and inclusion council. Look for participants who bring a diversity of skills and backgrounds as well as gender, race, and sexual orientation. Empower the council to share recommendations and have access to senior leadership.
- Ensure that members of your patient advisory council reflect your patient population and the communities you serve.
- Evaluate policies and procedures for implicit and unconscious bias.
- Examine disparity in the context of quality improvement initiatives. Quality improvement must be framed from an equity perspective to have the greatest impact.
- Identify community partners and opportunities to collaborate to improve cancer awareness, education, access to screening, treatment, and clinical research and trials.
- Make intentional and focused efforts to increase participation of racial and ethnic minorities and underserved patient populations, including the elderly, in clinical research and trials.
- Start mentoring programs and evaluate how you employ, promote, and integrate diverse individuals in all levels of your organization, including senior leadership.
- Identify and disseminate resources to support this important work, such as Project Implicit (implicit.harvard.edu), anti-racism calendars like the one developed by the Duke Office of Diversity and Inclusion (drive.google.com/file/d/1fUoJWdabhCulMR-AksHjCOSawYaQRn1T/view), *How to Be an Antiracist* by Ibram X. Kendi, and *White Fragility* by Robin DiAngelo.

Most important, we should focus not on fixing individuals but rather on fixing programs, structures, and practices within our health systems to effectively address racism and equity and improve outcomes for all of our patients with cancer. OI

ACCC PRESIDENT'S MESSAGE

ACCC, With an Assist

BY RANDALL A. OYER, MD

From the COVID-19 pandemic, which exposed systemic gaps and disparities in care, to the egregious acts of racism we continue to see in our country, I think that everyone—both inside and outside of our specialty—would agree that 2020 has been a challenging year for cancer patients and cancer programs. Fortunately, oncology has always faced challenges, and cancer care teams are ever ready to change course and do what needs to be done to care for our patients and their families. But we do not have to do this alone. ACCC stands ready to assist by:

- **Sharing lessons learned from COVID-19.** During this pandemic, our healthcare teams rapidly deployed digital health resources, including telemedicine, to the great benefit of our patients and staff. We must continue to work together in teams, identify and adopt best practices, and learn from each other. You can start by listening to ACCC's series of COVID-19 webcasts and podcasts at accc-cancer.org/COVID-19. Still, for all the lessons the pandemic has brought over the past months, we must be transparent and humble and recognize that there is much we do not yet know about this disease. To accelerate understanding and answer pressing questions, the oncology community is working quickly to gather needed data. Please help by enrolling today in the ASCO Survey on COVID-19 in Oncology (ASCO) Registry at asco.org/asco-coronavirus-information/coronavirus-registry.
- **Bringing to light critical needs, problems, and unknowns.** Our country has critical unmet needs in comprehensive vaccination, serology testing, available treatment options, and public health practice. Telemedicine and other digital health tools are in their infancy in terms of technology integration, workflow, best practices, and reimbursement. There are large populations who have unmet needs in cancer prevention, diagnosis, treatment, and care coordination due to socio-economic disparities; bias, including racism; and structural barriers. Further, bias due to under-representation on clinical trials is a critical threat to the validity of cancer research that exacerbates existing health disparities.
- **Developing solutions and resources to meet these needs, solve these problems, and bring clarity to these unknowns.** This past summer ACCC partnered with the American Society of Clinical Oncology (ASCO) on a request for information to identify and implement novel strategies and practical solutions to increase clinical trial participation by racial and ethnic minority populations. (More to come on this exciting initiative.) For cancer programs experiencing challenges with telehealth implementation and reimbursement, ACCC has an on-demand webcast that covers changes to telehealth services, supervision, provider-based designations, coding for services, and more. Listen today at courses.accc-cancer.org/telehealth-reimbursement-update. Or maybe you are seeking clarification on how changes that the Centers for Medicare & Medicaid Services has put forth in the proposed CY 2021 Outpatient Prospective Payment System and Physician Fee Schedule rules will affect your cancer program or practice? ACCC's on-demand webcast on the proposed rules can put the agency's proposals in perspective. Listen today at: courses.accc-cancer.org courses.accc-cancer.org/2021-OPPS-PFS-Proposed-Rules. Solutions and resources exist, and I strongly urge you to spend time exploring ACCC's robust education portfolio of webcasts and podcasts, blogs, online courses, educational supplements, and more.

I end this column with specific suggestions for how *you* can help. First, join the ASCO COVID-19 in Cancer Registry so that your cases are counted. (Remember: it is an acceptable clinical trial registry for the MIPS [Merit-based Incentive Payment System] COVID-19 Clinical Trials Improvement Activity.) Second, check back regularly for updates on promising ideas put forward from the joint ASCO-ACCC request for information. Third, plan for diversity, equity, and inclusion training for yourselves, your colleagues, and your staff. Finally, have and welcome frank conversations on racism. Only by working together can we make the necessary changes at our cancer programs and in our communities. OI

Coming in Your 2020 *ONCOLOGY ISSUES*

- Transitioning a Comprehensive Psychosocial Program to a Virtual Format: Telehealth at Its Best
- After the Outbreak: Preparing for the Return of Cancer Cases
- The Role of Nurse Practitioners in Clinical Research
- Confronting Cyber Threats to Your Oncology Practice: How to Prepare for (and Respond to) the Potentially Inevitable
- All It Takes Is One: How to Secure Your Practice Against Cybercriminals
- Avoidable and Unavoidable ER Utilization by Cancer Patients on Systemic Therapy
- Remote Work Program for Hospital-Based Cancer Registrars
- Use of Pharmacy Informatics to Standardize Pharmacist Review of Oral Oncolytic Medications for Hospitalized Patients
- Management of Hospital Admissions for Checkpoint Inhibitor Immune-Related Adverse Events at a Regional Cancer Center
- Medication Transitions in Hematologic Malignancy Patients at a Safety Net Hospital
- An Investigation of Self-Determined Work Motivation Among Young Adult Central Nervous System Cancer Survivors
- Expanding Cancer Care Access to Meet Growing Need: Survey Shows a Range of New Initiatives

more online @ accc-cancer.org

BLOG

3D Model Helps Ease Patient Distress

When people receive news of a lung nodule after screening, they are often distressed. To help improve patient understanding, Maine Medical Center partnered with an art student from a local university to design and implement a 3D model that can be used in many healthcare settings—including primary care, emergency departments, inpatient settings, and pulmonology offices—to help give patients the necessary education to make informed healthcare decisions with their physicians. Read more at accc-cancer.org/2020-ACCC-Innovator-Awards-Blog. Then register for the ACCC 37th [Virtual] National Oncology Conference, September 14-18, to learn more about this innovation, and the other seven 2020 ACCC Innovator winners at accc-cancer.org/NOC.

WEBCAST

Risk Stratification for Cancer Patients During COVID-19

New patient levels for cancer programs are starting to increase after a significant drop, but their needs may be changing—and they may return at a volume that programs are not prepared for. Join Charles Saunders, MD, Chief Executive Officer, and Jennifer Webster, MS, Vice President of Analytics, IntegraConnect, as they present an overview of the current landscape of patient levels and services at cancer programs. Learn how to effectively manage oncology business during and after the pandemic while maintaining a quality patient experience. Hear how predictive analytics can show the impact COVID-19 may have on value-based care in the future. Listen at accc-cancer.org/risk-stratification-webcast.

E-NEWS

Inaugural Issue of the ACCC Research Review

This eNewsletter is a key component of the 2020-2021 ACCC president's theme: *Community Oncology Can Close the Gap in Cancer Research: Here's How*. The inaugural issue offers information about the ASCO Survey on COVID-19 in Oncology (ASCO) Registry and how to enroll patients; five key takeaways for eliminating the systemic inequities that minority and underserved patients face from an FDA Oncology Center of Excellence webcast; two practice-impactful precision medicine clinical trials; and more. Available online at accc-cancer.org/research-newsletter-july-2020.

PODCAST

Clinical Trials During COVD-19

On this episode of CANCER BUZZ, Joanne Riemer, RN, BSN, Research Oncology Nurse, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins Hospital, shares how immunotherapy clinical trials have been affected by the pandemic and what cancer programs can do to safely and effectively administer clinical trials. Learn more at accc-cancer.org.

fast

Healthcare Survey Says...

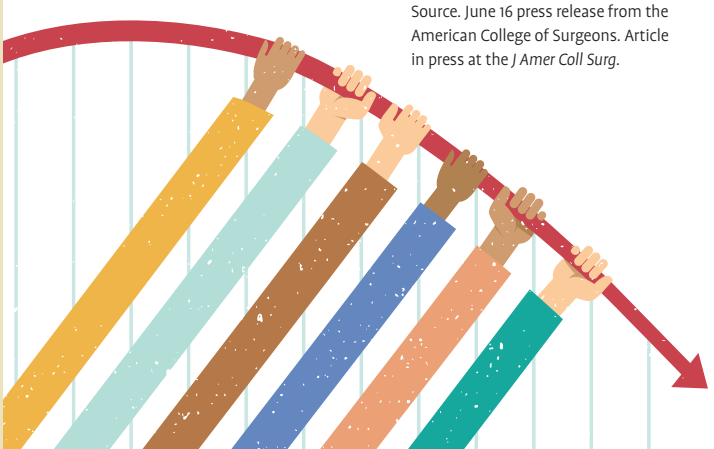
- **98%** of respondents agree that care and cost variations exist across locations, health systems, and even among departments in the same hospital.
- **63%** don't believe they would pay an identical amount for the same treatment or condition regardless of where they are treated; physicians were more aware than hospital executives of cost and care differences.
- **73%** said healthcare would be a main issue in the upcoming election.
- Nearly **90%** said the healthcare system needs a complete overhaul.
- **40%** of consumers say that in the future, hospitals should consider the high cost of medicines, while only **13%** of executives surveyed think the same.

Source. Mending Healthcare in America 2020: Consumers + Costs. go.wolterskluwer.com/Mending-Healthcare-2020.html.

5 Key Factors That Helped Washington State "Flatten the Curve" for COVID-19

1. Early communication and coordination among stakeholders
2. Regional coordination and situational awareness of the healthcare system
3. Rapid development and access to testing
4. Proactive management of long-term care facilities and vulnerable populations
5. Effective physical distancing in the community

Source. June 16 press release from the American College of Surgeons. Article in press at the *J Amer Coll Surg*.



facts

Using AI to Predict Risk of Thyroid Cancer on Ultrasound

After algorithm training, researchers at Thomas Jefferson University found that:

- Their algorithm performed with **97%** specificity and **90%** predictive positive value, meaning that **97%** of patients with benign nodules will have their ultrasound read as "benign" by the algorithm, and **90%** of malignant or "positive" nodules are truly positive as classified by the algorithm.
- The high specificity is indicative of a low rate of false positives—if the algorithm reads a nodule as "malignant," it is very likely to be malignant.
- The overall accuracy of the algorithm was **77%**.

Source. Daniels K, et al. Machine-learning for the genetic risk stratification of thyroid nodules by ultrasound. *JAMA Otolaryngol Head Neck Surg.* DOI:10.1001/jamaoto.2019.3073, 2019.

Are We Meeting Our Patients' Needs?

- A recent ASTRO survey found that **1 in 3** patients need more information on cancer treatment side effects.
- Information gaps were related to how severe patients considered their treatment-related side effects to be. Patients who reported severe side effects were more likely to say they did not know enough about them. More than a third of patients (**38%**) who reported having severe side effects also said they felt uninformed, compared to **4%** of those who reported having minimal side effects.
- Patients treated with radiation therapy wanted more information on skin irritation, GI symptoms, and fatigue.
- Patients treated with chemotherapy wanted more information on nerve damage, GI symptoms, and fatigue.
- Patients treated with surgery wanted more information on pain, nerve damage, and numbness.

Source. Shaverdian N, et al. Nationwide survey of patients' perspectives regarding their radiation and multidisciplinary treatment experiences. *J Oncol Pract.* 2019 Nov 20. doi.org/10.1200/JOP.19.00376.

Parents Get Sun Smart

- **74%** of parents say they worry about sun protection more with their children than their parents did with them.
- **90%** of parents believe it's important to teach their children healthy habits now, so they will keep them when they are adults.

Source. June 16 press release about a study by the American Academy of Dermatology. Aad.org.

Physician Assistant Compensation

- Total compensation: **$118,000**
- Base compensation: **$113,000**
- Productivity or incentive pay (**27%** of PAs receive it): **$14,000**
- Annual bonus (50% of PAs get one): **$4,000**
- Overtime (35% of PAs receive it): **$4,000**
- Hourly PA pay rate for men: **$68**
- Hourly PA pay rate for women: **$63**

Source. Becker's ASC Review. beckersasc.com/benchmarking/15-statistics-on-physician-assistant-pay-in-2020.html.

CMS's Proposed Payment Rules for 2021: What You Need to Know

BY CHRISTIAN G. DOWNS, JD, MHA

On Aug. 4, the Centers for Medicare & Medicaid Services (CMS) released its 2021 Hospital Outpatient Prospective Payment System (OPPS) and Medicare Physician Fee Schedule (PFS) proposed rules. The agency also released an accompanying executive order proposing increased flexibility for telehealth and rural healthcare in light of the COVID-19 pandemic.

CMS is waiving the 60-day publication requirement for the final rule and replacing it with a 30-day notification. The final rule will become effective Jan. 1, 2021, although it may not be published until Dec. 1, 2020. Comments on the proposed rule are due Oct. 5, 2020.

OPPS Highlights

The OPPS proposed rule would continue many of the controversial policies that CMS has implemented in recent years that have been upheld by the courts. These include the payment reduction for clinic visits at excepted (grandfathered) off-campus departments and the reduction in payment for drugs purchased under the 340B program. Overall, hospitals would see a 2.6 percent increase in payments under the proposed OPPS rule. This update is based on the projected hospital market basket increase of 3.0 percent minus a 0.4 percent adjustment for multi-factor productivity.

340B Program

CMS proposes increasing the 340B payment cut to Average Sales Price (ASP)-28.7 percent from ASP-22.5 percent. The agency arrived at this number after concluding that survey data found an average acquisition cost of ASP-34.7 percent. CMS proposes to use ASP-34.7 percent as acquisition cost and add 6 percent of ASP for overhead and handling costs. CMS seeks comments on whether it should continue to pay for these drugs at ASP-22.5 percent. This policy has been the subject of ongoing litigation, and it was most recently upheld by the D.C. Circuit Court in July 2020.

CMS proposes continuing to reimburse drugs not purchased under the 340B program at ASP+6 percent if they have pass-through status or qualify for separate payment. The packaging threshold would remain at $130 for drugs without pass-through status.

Scope of Practice

CMS proposes to make permanent a policy finalized under the May 1 COVID-19 interim final rule that allows nurse practitioners, clinical nurse specialists, physician assistants, and certified nurse midwives to supervise the performance of non-surgical extended duration therapy services (e.g., lengthy drug administration). Under current rules, these services require direct supervision (supervising practitioner is in the building and immediately available to assist) during the initiation of the service and general supervision for the rest of the service.

Multianalyte Assays with Algorithmic Analyses

CMS proposes excluding certain cancer-related, protein-based multianalyte assays with algorithmic analyses from the OPPS packaging policy and the date of service rule (14-day rule). This would allow these tests to be separately reimbursed under the Clinical Laboratory Fee Schedule.

PFS Highlights

Since the COVID-19 public health emergency (PHE) was declared earlier this year, CMS has issued waivers to increase flexibility and reduce regulatory burdens. In the PFS proposed rule, CMS proposes to make permanent, extend, or transition out of these new rules. The American Society of Clinical Oncology notes that CMS estimates a +14 percent overall impact for hematology/oncology and a −6 percent impact for radiation oncology in 2021.[1] The proposed CY 2021 PFS conversion factor is $32.26, a decrease of $3.83 from the CY 2020 Medicare PFS conversion factor of $36.09.

Evaluation and Management Visits

Per the CY 2020 Medicare PFS final rule, beginning in 2021, CMS will largely align its evaluation and management (E&M) visit coding and documentation policies with changes enacted by the CPT® Editorial Panel for office/outpatient E&M visits. CMS proposes to clarify the times for which prolonged office/outpatient E&M visits can be reported and proposes revising the times used for rate setting for this code set.

Quality Payment Program

Due to the COVID-19 pandemic, CMS will not introduce any Merit-based Incentive Payment System (MIPS) Value Pathways for the 2021 performance period. CMS proposes a new alternative payment model performance pathway reporting option in 2021 to align

with the MIPS Value Pathways framework. As part of the introduction of the performance pathway, CMS will sunset the CMS Web Interface as a collection type beginning in the 2021 performance period. CMS will continue to allow clinicians eligible for MIPS to participate in the program either as individuals or as part of a group or virtual group. CMS is expanding the use of the alternative payment model entity submitter types to allow the use of all MIPS submission mechanisms. CMS proposes using performance period (rather than historical) benchmarks to score quality measures in 2021. The agency is concerned that it may not have a representative sample of historic data for 2019 (due to the pandemic), which would impact 2020 data submission, skewing benchmarking results.

Telehealth/Virtual Care

CMS proposes: (1) adding services to the Medicare telehealth list on a Category 1 basis and (2) creating a third temporary category of criteria for services added to the Medicare telehealth list. "Category 3" will describe services added to the Medicare telehealth list during the COVID-19 PHE that will remain on the list through the calendar year in which the PHE ends.

In March 2020, CMS established separate payments for audio-only telephone E&M services. Although the agency is proposing to not continue to recognize these codes after the PHE ends, the agency states that it recognizes that "the need for audio-only interactions could remain as beneficiaries continue to try to avoid sources of potential infection, such as a doctor's office." Therefore, the agency is seeking comment on whether it should develop coding and payment for a service like the virtual check-in but for a longer unit of time and subsequently with a higher value. CMS is seeking comment on whether this service should be made permanent.

For the duration of the COVID-19 PHE, CMS has adopted an interim final policy revising the definition of direct supervision to include the virtual presence of the supervising practitioner using interactive audio/video real-time communications technology. CMS proposes continuing this policy through Dec. 31, 2021.

New Telehealth Codes Proposed

For CY 2021, CMS is proposing to add the following list of services to the Medicare telehealth list on a Category 1 basis. Services added to the Medicare telehealth list on a Category 1 basis are similar to services already on the telehealth list.

- HCOPS Code GPC1X: Visit Complexity Associated with Certain Office/Outpatient E/Ms
- HCOPS Code 99XXX: Prolonged Services
- HCOPS Code 90853: Group Psychotherapy
- HCOPS Code 96121: Neurobehavioral Status Exam
- HCOPS Code 99483: Care Planning for Patients with Cognitive Impairment
- HCOPS Codes 99334-99335: Domiciliary, Rest Home, or Custodial Care Services
- HCOPS Codes 99347-99348: Home Visits.

Additional Resources

ACCC is reviewing these proposed rules and will provide comments by the Oct. 5 due date. To obtain further guidance from health policy experts about how these proposed rules may affect oncology practices, listen to our archived Aug. 14 webcast, "The 2021 Proposed PFS and OPPS Rules: Practical Implications and Considerations," at courses.accc-cancer.org/2021-OPPS-PFS-Proposed-Rules. OI

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

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1. ASCO. Medicare Provider and Hospital Outpatient Reimbursement Proposals Set Stage for 2021 and Post-Pandemic Landscape; Accompanying Executive Order Focused on Telehealth, Rural Care. Available online at: asco.org/practice-policy/policy-issues-statements/asco-in-action/medicare-provider-and-hospital-outpatient. Last accessed August 21, 2020.

The Role of Nonphysician Practitioners in Oncology

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

The scope of work provided by nonphysician practitioners (NPPs) has evolved and changed significantly. When the Medicare program was signed into law in 1965, nurses predominantly assisted physicians. Now, it is common to see NPPs, such as nurse practitioners and physician assistants, provide more of that care and, where allowed, on their own.

NPPs are professionals licensed by a state for respective health programs related to their training. Medicare requires any services provided by NPPs to be medically necessary and within the scope of practice in the state in which the NPPs practice, regardless of whether they received training in another state. Medicare also requires an NPP to have an active and valid Medicare and/or Medicaid provider number, whether their services are under their name or provided incident to a supervising physician.

In the oncology setting, the role of NPPs can vary, which depends on factors such as a hospital's granted privileges, whether the NPP's training covers specific education related to chemotherapy and radiation treatment delivery, and the NPP's state scope of practice.

In May 2015 the *CPT® Assistant*—from the American Medical Association (AMA)—outlined the requirements needed to identify the relationship between NPPs and the physician(s) they work under. When there are no state laws governing the collaboration between an NPP and the physician(s) under whose supervision and medical direction he or she is working, the AMA indicates that there must be a written agreement between the NPP and any collaborating physicians. The written agreement defines the collaboration within the NPP's state scope of practice and his or her relationship to the physician(s) to work through any potential issues outside of the NPP's state scope of practice. Any services that are not defined by the written agreement cannot be billed to Medicare. It is worth noting that in some states an NPP cannot provide any medical services until the written collaboration agreement is appropriately filed with the state in which the NPP and physician(s) are working.

Billing for Services

When NPPs are employed by a cancer program/practice and if the previously mentioned guidelines allow for them to provide services, services are either billed when provided incident to and under the physician's National Provider Identifier (NPI) or independent of the physician and under the NPPs NPI.

Incident to is specific to Medicare, and MedLearn Matters (MLN) SE0441 offers this definition for the term: "'Incident to' services are defined as those services that are furnished incident to physician professional services in the physician's office (whether located in a separate office suite or within an institution) or in a patient's home."[1] If the services are not provided incident to, the services are billed under the NPP's NPI, and Medicare reimburses those services at 85 percent of the Physician Fee Schedule rate.

For services to qualify as incident to, specific criteria must be met. According to the Centers for Medicare & Medicaid Services, any services must be part of the patient's normal course of treatment in which the physician "personally performed an initial service and remains actively involved in the course of treatment."[1] The physician must also provide direct supervision of the services provided incident to and the medical record must reflect that the requirements were met.

MLN SE0441, more specifically, states that these services must also be:[1]

- An integral part of the patient's treatment course
- Commonly rendered without charge (included in the physician's bills)
- Of a type commonly furnished in a physician's office or clinic (not in an institutional setting); and
- An expense to the physician.

Incident to only applies to services that qualify to be provided by an NPP under the direct supervision and a direct financial expense to the physician. For example, the employee (NPP) working incident to the physician is employed by the physician, a leased employee, or an independent contractor. Incident to does not apply to the hospital or skilled nursing facility settings. Any professional services provided by an NPP in the hospital must be billed under the NPP's NPI.

If an oncology practice decides to employ an NPP, the question then becomes what services can be provided by that NPP? After the course or plan of care is established by the medical or radiation oncologist, an NPP can see the patient in follow-up, if there are

no changes in the patient's plan of care. For these follow-up visits, NPPs should bill to the established outpatient visit codes **99212-99215**. If during the visit a new problem is identified, the physician must then be involved in the visit. In other words, NPPs cannot see patients for new problems, and these services must be performed by the physician. An NPP-provided service should be billed under the physician's name and NPI, if performed incident to, or under the NPP's NPI (if accepted and recognized by the payer) at a reduced reimbursement rate.

Radiation Oncology Considerations

There are some additional considerations for NPP services provided to radiation oncology patients. Because many of the services provided in radiation oncology are not just consultative and require supervision of staff and clinical skills, NPPs may not be qualified to provide specific supervision and/or work. For example, patients receiving radiation therapy can be evaluated to treat side effects; however, when the patient is seen once every five fractions for treatment management, this visit (code **77427**) must be provided by the radiation oncologist. The guidelines within the AMA CPT® manual and the American Society for Radiation Oncology *Safety is No Accident* comprehensive reference guide support this practice.[2,3] The American Society for Radiation Oncology further clarifies that every aspect of care for radiation oncology needs to be managed by a board-certified radiation oncologist.

"Each aspect within the process of care requires knowledge and training in cancer biology, certain benign disease processes, radiobiology, medical physics, and radiation safety that can only be demonstrated by board certification in radiation oncology to synthesize and integrate the necessary knowledge base to safely render complete care. In addition to knowledge and technical skills, clinical staff must function as a cohesive team by communicating and interacting effectively with colleagues and patients."[3]

Going Forward

It is important that oncology programs and practices—whether they already employ NPPs or are looking to hire an NPP—review the published scope of practice information for their state. This review is necessary to understand (and comply with) NPP services that can be performed or supervised to avoid sanctions, license revocation, or suspension.

During the public health emergency (PHE) response to COVID-19, the Centers for Medicare & Medicaid Services has issued some waivers to expand access to care. For example, NPPs can provide telehealth visits. Billing for telehealth services was expanded to include those who are eligible to bill Medicare for their professional services. If the work of seeing the patient and the services provided are within the NPP's state scope of practice, hospital granted privileges, and training, then they can provide services to oncology patients during the PHE.

However, it is uncertain how long these expanded waivers will remain in place. In addition, it is uncertain what changes may be extended or in place as we continue to move toward CY 2021. Many believe that healthcare changes made during the PHE will follow us into the near future. It is best practice to stay informed because these changes may impact the role and services provided by NPPs in the oncology setting. OI

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

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tools

Approved Drugs

- On Aug. 5, the U.S. Food and Drug Administration (FDA) approved **Blenrep (belantamab mafodotin-blmf)** (GlaxoSmithKline, gsk.com) for adult patients with relapsed or refractory multiple myeloma who have received at least four prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.
- On May 29, the FDA approved **Cyramza® (ramucirumab)** (Eli Lilly and Company, lilly.com) in combination with erlotinib for first-line treatment of metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) mutations.
- On June 12, Merck (merck.com) announced that the FDA has approved an expanded indication for **Gardasil®9 (Human Papillomavirus 9-valent Vaccine, Recombinant)** for the prevention of oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58.
- On July 7, the FDA approved **Inqovi® (decitabine and cedazuridine)** (Astex Pharmaceuticals, Inc., astx.com) for adult patients with myelodysplastic syndromes, including the following: (1) previously treated and untreated, *de novo* and secondary myelodysplastic syndromes with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia) and (2) intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.
- On June 16, the FDA granted accelerated approval to **Keytruda® (pembrolizumab)** (Merck, merck.com) for the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (≥10 mutations/megabase [mut/Mb]) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options. On June 24, the FDA approved Keytruda for patients with recurrent or metastatic cutaneous squamous cell carcinoma that is not curable by surgery or radiation. On June 29, the FDA approved Keytruda for the first-line treatment of patients with unresectable or metastatic microsatellite instability-high or mismatch repair deficient colorectal cancer.
- On July 31, the FDA granted accelerated approval to **Monjuvi® (tafasitamab-cxix)** (MorphoSys US Inc., morphosys.com and Incyte, incyte.com), a CD19-directed cytolytic antibody, indicated in combination with lenalidomide for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant.
- On June 16, the FDA extended the indication of **Mylotarg™ (gemtuzumab ozogamicin)** (Pfizer Inc., Pfizer.com) for newly diagnosed CD33-positive acute myeloid leukemia to include pediatric patients one month and older.
- On June 11, Pfizer Inc. (pfizer.com) announced that the FDA has approved **Nyvepria™ (pegfilgrastim-apgf)**, a biosimilar to Neulasta® (pegfilgrastim).
- On June 10, the FDA approved **Opdivo® (nivolumab)** (Bristol Myers Squibb Co., bms.com) for patients with unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based chemotherapy.
- On June 29, the FDA approved **Phesgo™ (pertuzumab, trastuzumab, and hyaluronidase-zzxf)** (Genentech, Inc., gene.com) for subcutaneous injection for the following indications. The first is use of the agent in combination with chemotherapy as: (1) neoadjuvant treatment of patients with human epidermal growth factor receptor 2 (HER2)-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer and (2) adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence. The second is use of the agent in combination with docetaxel for treatment of patients with HER2-positive

metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

- On June 22, the FDA granted accelerated approval to **Xpovio® (selinexor)** (Karyopharm Therapeutics, karyopharm.com) for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least two lines of systemic therapy.
- On June 18, the FDA granted accelerated approval to **Tazverik™ (tazemetostat)** (Epizyme, Inc., epizyme.com), an enhancer of zeste homolog 2 (EZH2) inhibitor, for adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least two prior systemic therapies and for adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options.
- On July 24, the FDA granted accelerated approval to **Tecartus™ (brexucabtagene autoleucel)** (Kite Pharma, kitepharma.com), a CD19-directed genetically modified autologous T-cell immunotherapy, for the treatment of adult patients with relapsed or refractory mantle cell lymphoma.
- On July 31, Roche (roche.com) announced that the FDA approved **Tecentriq® (atezolizumab) plus Cotellic® (cobimetinib) and Zelboraf® (vemurafenib)** for the treatment of BRAF V600 mutation-positive advanced melanoma patients.
- On June 15, Jazz Pharmaceuticals plc (jazzpharma.com) and its partner PharmaMar (pharmamar.com) announced that the FDA approved **Zepzelca™ (lurbinectedin)** for the treatment of adult patients with metastatic small cell lung cancer with disease progression on or after platinum-based chemotherapy.

Drugs in the News

- EMD Serono (emdserono.com/us-en) announced that the FDA has approved the supplemental biologics license application (BLA) for **Bavencio® (avelumab)** for the maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma that has not progressed with first-line platinum-containing chemotherapy.
- Black Diamond Therapeutics, Inc. (blackdiamondtherapeutics.com) announced that the FDA granted fast track designation to **BDTX-189** for the treatment of adult patients with solid tumors harboring an allosteric HER2 mutation or an EGFR or HER2 Exon 20 insertion mutation who have progressed following prior treatment and who have no satisfactory treatment options.
- CNS Pharmaceuticals, Inc. (cnspharma.com) announced that the FDA has granted orphan drug designation for its lead product **Berubicin** for the treatment of malignant gliomas.
- Checkmate Pharmaceuticals, Inc. (checkmatepharma.com) announced that the FDA granted fast track designation to its product candidate, **CMP-001**, in combination with a programmed cell death receptor 1 (PD-1) blocking antibody (nivolumab or pembrolizumab) for two development programs, including initial treatment of patients with unresectable Stage III or Stage IV melanoma to prolong the time to disease progression and treatment of patients with unresectable or metastatic melanoma refractory to prior anti-PD-1 blockade to improve the overall tumor response rate.
- Celyad Oncology SA (celyad.com) announced that the company's investigational new drug application (NDA) for **CYAD-211**, a short hairpin RNA (shRNA)-based allogeneic chimeric antigen receptor T candidate and second non-gene edited off-the-shelf program, is in effect with the FDA.
- Y-mAbs Therapeutics, Inc. (ymabs.com) announced that the BLA for **Danyelza™ (naxitamab)** for the treatment of patients with relapsed/refractory high-risk neuroblastoma has been accepted for priority review by the FDA.
- Leap Therapeutics, Inc. (leaptx.com) announced that the FDA has granted orphan drug designation for **DKN-01** for the treatment of gastric and gastro-esophageal junction cancer.
- AVEO Oncology (aveooncology.com) announced that the FDA accepted for filing its NDA seeking approval for **Fotivda® (tivozanib)**, a vascular endothelial growth factor receptor tyrosine kinase inhibitor as a treatment for relapsed or refractory renal cell carcinoma.
- Hutchison China MediTech Limited (chi-med.com) announced that the FDA has granted fast track designation for the development of **fruquintinib** for the treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; an anti-vascular endothelial growth factor biological therapy; and, if RAS wild type, an anti-EGFR therapy.
- Bristol Myers Squibb (bms.com) and bluebird bio, Inc. (bluebirdbio.com) announced the submission of their BLA to the FDA for **idecabtagene vicleucel (ide-cel; bb2121)**, the companies' investigational B-cell maturation antigen-directed chimeric antigen receptor T-cell immunotherapy, for the treatment of adult patients with relapsed and refractory multiple myeloma.
- Merck (merck.com) announced that the FDA accepted and granted priority review for a new supplemental BLA for **Keytruda® (pembrolizumab)** as monotherapy for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma. The company also announced that the FDA has accepted and granted priority review for a new supplemental BLA seeking accelerated

approval for Keytruda in combination with chemotherapy for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer whose tumors express PD-L1 (combined positive score ≥10), based on the Phase 3 KEYNOTE-355 trial.

- Oncopeptides AB (oncopeptides.se/en/) announced the submission of an NDA to the FDA for accelerated approval of **melflufen (melphalan flufenamide)** in combination with dexamethasone for the treatment of adult patients with multiple myeloma whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD38 monoclonal antibody.
- Merck (merck.com) announced that the FDA has granted breakthrough therapy designation to the hypoxia-inducible factor-2 alpha inhibitor **MK-6482** for the treatment of patients with von Hippel-Lindau disease-associated renal cell carcinoma with nonmetastatic renal cell carcinoma tumors less than 3 cm in size, unless immediate surgery is required.
- Ipsen (ipsen.com) announced that the FDA has granted fast track designation for the investigational use of **Onivyde® (liposomal irinotecan)** in combination with 5-fluorouracil/leucovorin and oxaliplatin together, known as NALIRIFOX, for patients with previously untreated, unresectable, locally advanced, and metastatic pancreatic ductal adenocarcinoma.
- Blueprint Medicines Corporation (blueprintmedicines.com) announced the submission of an NDA to the FDA for **pralsetinib** for the treatment of patients with advanced or metastatic RET mutant medullary thyroid cancer and RET fusion-positive thyroid cancers.
- Myovant Sciences (myovant.com) announced that its NDA for once-daily, oral **relugolix** (120 mg) for the treatment of men with advanced prostate cancer has been accepted for priority review by the FDA.
- AstraZeneca (astrazeneca.com) announced that **Tagrisso® (osimertinib)** has been granted breakthrough therapy designation for the adjuvant treatment of patients with early-stage (IB, II and IIIA) EGFR-mutated NSCLC after complete tumor resection with curative intent.
- Karyopharm Therapeutics Inc. (karyopharm.com) announced that the FDA has accepted for filing its supplemental NDA seeking approval for **Xpovio® (selinexor)** as a new treatment for patients with multiple myeloma after at least one prior line of therapy.
- Merus N.V. (merus.nl/) announced that the FDA has granted orphan drug designation to **Zenocutuzumab (Zeno)** for the treatment of patients with pancreatic cancer.

Approved Genetic Tests and Assays

- Adaptive Biotechnologies (adaptivebiotech.com) received clearance from the FDA for its **clonoSEQ® Assay** to detect and monitor minimal residual disease in blood or bone marrow from patients with chronic lymphocytic leukemia.
- Roche (roche.com) announced FDA approval of the **cobas® EZH2 Mutation Test** as a companion diagnostic for Tazverik™ (tazemetostat) (Epizyme, Inc., epizyme.com). This molecular test detects abnormalities in the EZH2 gene in patients with follicular lymphoma, a type of non-Hodgkin lymphoma, who may be eligible for treatment with Tazverik, a cancer drug that acts as a selective EZH2 gene inhibitor.
- Zebra Medical Vision (zebra-med.com) said it received FDA clearance from the FDA for its **mammography technology** that uses artificial intelligence to prioritize and identify suspicious mammograms.
- Roche (roche.com) announced FDA approval of new **Ventana HER2 Dual ISH DNA Probe Cocktail** assay for the detection of the HER2 biomarker in breast cancer and as a companion diagnostic for Herceptin® (trastuzumab) therapy.
- The FDA has approved the **Guardant360 CDx assay** (Guardant Health), a liquid biopsy companion diagnostic that also uses next-generation sequencing technology to identify patients with specific types of mutations of the EGFR gene in metastatic NSCLC. Though the Guardant360CDx assay can provide information on multiple solid tumor biomarkers, today's approval is specific to its use in identifying EGFR mutations in patients who will benefit from treatment with Tagrisso® (osimertinib), an FDA-approved therapy for metastatic NSCLC. OI

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spotlight

St. Charles Cancer Center
Bend, Oregon

Bend, Ore., is a famous destination for lovers of adventure and the outdoors. Through days full of sunshine and mountainous views, St. Charles Cancer Center provides comprehensive cancer care to patients in central and eastern Oregon, a service area of 32,000 square miles. Located on the west side of the St. Charles Hospital campus, the cancer center operates as an outpatient department of the St. Charles Health System, a four-hospital system with locations in Bend, Redmond, Prineville, and Madras, Ore.

St. Charles Cancer Center provides multidisciplinary oncology and hematology services. The leading sites treated at St. Charles Cancer Center include breast, colon, lung, and prostate cancers. The cancer program is accredited by the American College of Surgeons Commission on Cancer and the National Accreditation Program for Breast Centers. It is also one of 24 cancer centers in the United States to receive the 2018 Commission on Cancer Outstanding Achievement Award. In prioritizing multidisciplinary care, St. Charles Cancer Center provides services to its community that compete with large academic cancer programs.

A Spirit of Teamwork

The cancer center houses medical and radiation oncology services, an infusion center, a dedicated infusion pharmacy, and supportive cancer care services. Surgical oncology services are provided as part of the cancer program within the main hospital and in outpatient surgery centers. The cancer center provides specialty surgeries through a dedicated lung cancer surgeon, fellowship-trained colorectal surgeon, and fellowship-trained breast surgeon. All physicians and staff of St. Charles Cancer Center are employed by St. Charles Health System.

The cancer center's medical oncology services provide patient care through a dynamic system of teamwork built around its physicians, rather than the popular nurse-run triage model. Eight physicians provide medical oncology services through teams that are made up of two physicians, each with a dedicated nurse and medical assistants; a scheduler who is shared; a scribe; and a physician assistant with two dedicated medical assistants. Four radiation oncologists make up the radiation oncology team. All schedulers, registration clerks, and financial navigators provide services to patients across all modalities of treatment.

Comprehensive Care

St. Charles Cancer Center provides various modalities of radiation treatment via two LINAC machines and a computed tomography simulator, including IMRT, IGRT, and SBRT. A 22-chair infusion suite with a private room is located on the second floor of the cancer center and is staffed with up to 10 chemotherapy- and biotherapy-certified nurses. Chairs are placed around the suite so patients can view the Cascade Mountain range through spacious windows that provide plenty of natural light. Scribes are available in the clinic areas to help streamline patients' appointments, so patients can check out and schedule their next appointment at once. Scribes will also capture the necessary documentation so that physicians' notes are completed in a timely manner, including any assessments and plans of care.

The USP-800-compliant infusion pharmacy is adjacent to the infusion suite in which the cancer center can compound chemotherapy on-site. Three oncology pharmacists and four pharmacy technicians make up the pharmacy staff. The pharmacy does not dispense its own oral oncolytics but receives these medications through specialty pharmacies. Pharmacy staff are dedicated to helping patients find financial support through its oral chemotherapy support program and providing education to patients on both oral and/or infused therapies.

"We help patients navigate through chemotherapy and financial assistance, so that cost is not a barrier to starting therapy," explains Sarah Hawkins, PharmD, BCPS, BCOP, pharmacy manager at St. Charles Cancer Center.

The cancer center offers patients access to a variety of supportive care services free of charge. Speech pathology, oncology rehabilitation, palliative care, social work, nurse navigators, along with complementary services such as Reiki and acupuncture are available. The cancer center recently implemented a survivorship program for patients who have finished active treatment and are transitioning back into healthy self-care. This program runs in coordination with supportive services, such as rehabilitation and nutrition, and educates patients on exercise, activity, movement, diet, and mental health while they are in survivorship care. By engaging the community, the cancer center is also able to provide food directly to patients in need through its Harvest for Hope

program, which also provides snacks for patients in the infusion suite. To learn about and gain access to these services, all patients have an initial meeting with a social worker to assess needs via a distress thermometer. Staff at St. Charles Cancer Center are proud to provide a vast array of supportive services to treat patients' psychosocial needs.

Close to Home Care

To bring care close to home and ensure treatment adherence, St. Charles Cancer Center has a satellite clinic in Redmond, Ore., 25 miles north of the main cancer center and a remote clinic in Burns, Ore., that is more than 100 miles away.

"Because we are so spread out, some of our patients have to travel great distances to get to us, which can be a limiting factor," explains radiation oncologist Linyee Chang, MD. Each clinic follows the same staffing model the main cancer center follows. Medical oncology's physician teams travel to each location together to provide care at the clinics, and each team visits a clinic about once a month.

The Redmond location has a medical oncology clinic with a dedicated pharmacy, staffed by an oncology pharmacist, that was recently upgraded to be USP-800 compliant. The Redmond clinic's infusion suite is staffed full-time with chemotherapy- and biotherapy-certified nurses and schedulers who rotate between its two clinic locations. The Redmond clinic provides chemotherapy and follow-up visits to patients. To further serve patients in the rural setting, plans are in place to include radiation oncology services in Redmond and expand its infusion services to include a total of 15 chairs and one private room.

The Burns clinic provides infusion services and follow-up visits only, because all surgical and radiation treatments for these patients must be done at St. Charles Cancer Center. On average staff will see about 60 patients per month at the Bend location and 16 patients per day at each satellite clinic.

Protecting the Community

St. Charles Cancer Center prioritizes risk reduction and preventive services through its high-risk clinics. The high-risk breast clinic applies "smarter screening" by giving women who are identified as higher risk for breast cancer more intensive screening, explains Dr. Chang. Women receive genetic testing, imaging, and education about possible risk reductions. St. Charles Cancer Center refers to and partners with Central Oregon Radiology to perform this screening. Patients' information is collected in a database so that their primary care physicians have access to consult reports from the cancer center. The database will then alert providers when a patient's next imaging is due and coordinate care between the cancer center and the patient's primary care physician. St. Charles Cancer Center is expanding its high-risk clinics to include a pulmonary nodule clinic to identify lung cancers at an earlier stage and a high-risk colorectal clinic that will be managed by its colorectal surgeon and genetic specialists.

Central Oregon also sees more sun daily than many states and sits at a higher altitude, giving the area the nickname of the "high desert" of Oregon. Due to these factors, St. Charles Cancer Center sees more visitors in the summer and a higher incidence rate of skin cancers compared to the other states. The cancer center provides extensive education on its website on how to best protect the skin while outside and how to spot a potentially cancerous mole from sunburns.

Providers and staff at St. Charles Cancer Center are dedicated to delivering strategic preventative and comprehensive cancer care to its community. "We are really focused on how we treat people. We treat our patients in a way that we would want to be treated, and I think that really shows in our care," says Tom Schumacher, BSN, MHA, director of St. Charles Cancer Center. OI

BY MATT STURM, MBA; MEAGAN O'NEILL, MPH; AND LILI HAY, MBA, MSIS

Built to Care:
Cancer Centers for the Future

Despite the recent national pandemic that has swept across the United States and the negative financial impact it has had on our healthcare system, the confluence of a rapidly aging population, a growing rate of cancer incidence, and aging and undersized facilities underscore the need for development or growth of new cancer programs. Taking into account the impact of numerous challenges in our dynamic healthcare industry—for example, changing treatment patterns, emerging and costly therapies, and an often turbulent reimbursement landscape—it is more important than ever to apply a rigorous planning process to the design of any new facility. If not, errors such as oversizing, undersizing, or not allowing for sufficient flexibility can have significant adverse implications for years or even decades. But for healthcare systems and integrated networks that take the time to conduct due diligence and thoroughly analyze and understand their market, a properly designed and constructed cancer center can be the catalyst for an exceptional new chapter in the organization's history.

> Many cancer centers were not designed to be adaptable, which creates barriers to incorporating new technologies and/or approaches to care. As cancer services continue to evolve with new treatments and equipment, it is key to create a physical space that is flexible and able to accommodate both medical and technical advances.

Most cancer care is provided in the outpatient setting, and most organizations will focus their cancer centers on providing these types of ambulatory services. In recent years, the ambulatory care center market segment has seen significant growth. According to a CBRE analysis of the most recent U.S. Census Bureau data, the number of outpatient centers in the United States increased 51 percent from 26,900 in 2005 to 40,600 in 2016; the growth in the outpatient space continued through 2019, with more than 2.1 million square feet of new space being completed in the fourth quarter.[1,2] Cancer centers are a significant contributor to this exponential growth. This is not surprising, because healthcare providers are working to aggregate cancer services into a single space, facilitate seamless patient care across the continuum, and create a financially viable model to accommodate current and

future patient volumes. At the same time, patients are becoming actively involved in the selection of their healthcare team. A key consideration for many patients is the availability of comprehensive services in one accessible location and in the community where they live. In addition, the rise in the number and effectiveness of multidisciplinary clinics necessitates expanded and flexible cancer center designs.

Below we discuss other factors that are driving healthcare providers to consider building a new cancer center.

In an era of infinite challenges and finite resources, health systems must employ a very rigorous approach to strategic planning to ensure that financial resources are optimally deployed. Many organizations find value in bringing structure to their planning process by adopting a planning rubric.

Need for Additional Capacity

Cancer disproportionally impacts the elderly population. Given the aging demographics of the United States, the number of new cancer patients is projected to continue to grow for years to come. Centers for Disease Control and Prevention data indicate that new cancer cases have increased approximately 20 percent for each of the last two decades, a trend that is anticipated to continue beyond 2020.[3] The growth in patient volumes is straining many cancer programs, particularly those that were built five or more years ago. Cancer centers with spatial limitations face throughput issues and may experience longer wait times for first available appointments. In addition, cancer centers with limited space often rely on outside labs, pharmacies, and support services, creating additional bottlenecks in the system that extend patient wait times at each step of their treatment.

Patient Centricity

Patients expect the highest quality healthcare experience at the most accessible and affordable location possible. Moreover, cancer treatment presents unique facility challenges to accommodate both the clinical (e.g., immunocompromised) and psychological (e.g., healing environment) needs of patients. Contemporary cancer centers are specifically designed to meet these challenges and offer patients a holistic care environment.

Aging Environments

Many cancer centers were not designed to be adaptable, which creates barriers to incorporating new technologies and/or approaches to care. As cancer services continue to evolve with new treatments and equipment, it is key to create a physical space that is flexible and able to accommodate both medical and technical advances.

To effectively address each driving factor described above, hospitals, health system leaders, and integrated networks must first explore the four main phases of new cancer center planning and understand the dependencies between each phase. The remainder of this article details these phases and explains the complexities that must be considered when pursuing a cancer center facility project.

Phase One: Strategic Planning

Cancer care is perhaps the most dynamic field of medicine. Clinical innovation and rapidly changing treatment protocols require program flexibility, and reimbursement restraints and expectations for improved clinical outcomes and enhanced access to care require continual quality improvement.

These and other transformational pressures on the cancer care delivery system not only heighten the importance of strategic planning (so that organizations are well prepared to respond to these changes) but also increase the complexity of planning. In a recent planning guide, ECG shed light on the potential strategies that organizations may pursue in response to these specific challenges.[4] Notably, responding to many of the forces transforming the cancer marketplace will require facility solutions; therefore, it is critical to address these requirements throughout the strategic planning process.

Only a few years ago, health systems defined long-range planning to encompass a 10 or 15 year time frame. Today, most organizations consider 3 to 5 years to be long-term planning, given the pace of change in the industry and the level of disruption. Therefore, organizations that have not developed or refreshed their cancer program's strategic plan in the last three years should do so.

Strategic Framework

As Michael Porter wrote, "The essence of strategy is choosing what *not* to do."[5] In an era of infinite challenges and finite resources, health systems must employ a very rigorous approach to strategic planning to ensure that financial resources are optimally deployed. Many organizations find value in bringing structure to their planning process by adopting a planning rubric. Commonly, entities use a four-part planning framework that progresses from defining the organization's purpose to identifying supporting goals and strategies and finally to articulating specific tactics (see Figure 1, right).

The first phase of the planning process involves defining key foundational elements unique to the organization and its aspirations. The mission and vision play an important role in charting a long-term course for the organization and provide a foundation upon which all future decisions will be made.

Following the development of foundational elements, the framework focuses on directional elements: goals and strategies. These elements provide increasing levels of granularity to the strategic plan and begin to shape the organization's roadmap. The goals articulate what the organization will achieve to realize

Figure 1. Strategic Planning Framework

its vision, and the strategies describe how it will pursue these goals.

The implementation stage involves determining specific tactics to execute the strategies; these should be precisely defined actions. For example, a tactic to enable development of the requisite research support infrastructure is to hire a research coordinator during the next fiscal year.

Key Strategic Factors for Oncology Programs

When developing an oncology strategic plan for an organization, there are many topical areas or cancer program capabilities to assess, including:

- Physician and administrative leadership and expertise
- Screening, education, and prevention
- Diagnostic capabilities
- Treatment resources
- Facilities and technology
- Supportive care resources
- Research efforts
- Quality improvement.

These areas should be developed at the cancer site-specific program level, with the organization first determining the appropriate sequence of planning efforts (e.g., which tumor sites to begin with). For each of the topical areas noted above, cancer program leadership should consider current program capabilities and marketplace competition and how they impact strategy and tactic development. These eight topical areas, including detailed components, are presented in Figure 2, page 20.

Growth Strategies

Realizing larger strategic aspirations requires program growth—whether it is achieving scale or generating financial performance to support key investments. Most related initiatives are organized into one of two categories: growth in place and regional expansion.

Growth in place focuses on increasing market share within an established service area. As previously noted, detailed plans (strategies and tactics) should be developed for site-specific programs. For the facility, specific investments may be necessary to modernize the program (to keep up with community standards) or to differentiate it from competitors (from either a clinical or aesthetic perspective). In other cases, additional capacity to accommodate growth is warranted.

Alternatively, regional expansion moves beyond growth in place, focusing on expansion of the geographic area served. Regional expansion is typically considered once an organization has attained high levels of performance in its existing service area and clinical portfolio. When contemplating regional expansion, three factors must be addressed: deciding where to expand, establishing the number of new sites desired, and defining a development strategy (i.e., build versus buy).

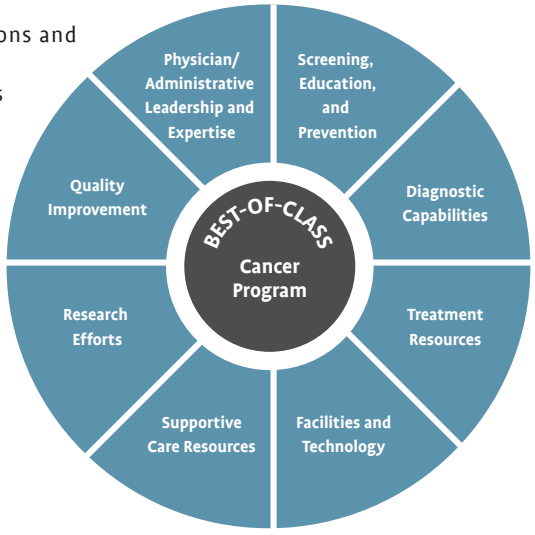
Figure 2. Cancer Program Capabilities

Physician/Administrative Leadership and Expertise
- Cancer leadership (clinical and administrative dyad)
- Dedicated and subspecialized surgeons and oncologists for tumor sites
- Physician champions for tumor sites

Quality Improvement
- Cancer site-specific reporting
- Real-time data that actively informs program (re)design
- National quality initiative participation
- Preparation for value-based care

Research Efforts
- "Critical mass" of research studies, scientists, and grants
- Dedicated research staff
- Collaboration with other entities

Supportive Care Resources
- Dedicated navigators
- Social work, psychosocial, nutritional and financial counseling, etc.
- Integrated palliative care
- Seamless transition to survivorship



Screening, Education, and Prevention
- Adherence to national guidelines
- Genetic counseling services
- Formalized community outreach
- Integration with primary care and other specialties

Diagnostic Capabilities
- Seamless evaluation
- Imaging expertise
- Access to advanced diagnostics

Treatment Resources
- Multidisciplinary care teams
- Prospective tumor boards
- Clinical pathways utilized in 90% of applicable cases

Facilities and Technology
- Electromagnetic technology
- Interventional oncology
- Pharmacogenetics
- Dedicated and updated space

If the organization opts for regional expansion, new facilities may be needed. Part of strategic planning includes determining whether there are existing clinical resources in the area to acquire or whether new services need to be developed. Outreach via telemedicine or telehealth must also be taken into consideration. This analysis will inform the scope of facility renovation or construction required to support the new locations and the new remote and/or virtual services.

Phase Two: Business Planning

Business planning is a critical element that may be completed prior to or in coordination with the next phase, which is facility planning. The business plan objectively quantifies the need for and financial viability of the construction project. This plan typically consists of three elements:
- Volume projections
- Preliminary facility sizing
- Financial feasibility.

First, clinical volumes, at both service and modality levels, must be modeled. The volume projections will be based on the goals and aspirations articulated in the strategic plan, combined with underlying assumptions. These assumptions correlate with planning strategies and include percentage growth or market capture, volumes at the service level (e.g., surgery, imaging, radiation, and medical oncology), and assumed service utilization rates (e.g., the number of treatments per patient). Volume modeling is an iterative process; it is critical that the projections are as accurate as possible, because they serve as the basis for all subsequent analyses. Given the importance of these values, it is also imperative to ensure that key organizational stakeholders agree with the underlying assumptions used to create the projections, as well as with the projected numbers.

After calculating the clinical volumes anticipated for the new cancer center, these values are translated into projected estimates for facility requirements. Typically, at this stage, preliminary sizing estimates focus on total square footage requirements to support the various clinical departments and attendant clinical volumes. A precise calculation is not needed at this point, and there will be no architectural renderings or block diagrams. Rather, the intent is to estimate total square footage so that initial project costs may be calculated.

Next, financial projections are developed for the cancer program based on all historical information that is available (e.g., revenue and expenses per unit of service) and that will consider the projected new volumes. The analysis will factor in the contemplated financial investments, including facility construction and equipment, to develop a holistic perspective. The result from this analysis is typically expressed on a net present value basis, where multiple years of future returns are compared to near-term

financial investments. Any project with a positive net present value is considered financially viable.

Phase Three: Facility Planning

Having established a strategic direction for the cancer program and qualitatively defined facility needs (e.g., space for expansion, capacity for new technology, and new outreach locations), the next step is to translate the plans into quantitative measures used to define the details of the project and allow for a financial viability assessment.

First, the volume projections are translated into objective values that include the number of exam rooms, square footage requirements, and capital asset requirements. The analysis is based on plans to develop clinical services, offer innovative technologies, and account for anticipated demographic changes. This assessment should project both near-term (e.g., 3 years) and long-term (e.g., 10 years) facility requirements. As a part of this process, the organization should take a close look at its current operational performance compared to industry benchmarks. The development of a new or expanded facility often presents key opportunities to improve workflows, enhance the use of human resources, and better serve patient needs. The organization should take advantage of this effort to drive operational change in a way that improves levels of service, efficiency, quality, and satisfaction.

It is important to validate the calculated resource requirements (e.g., room totals) by running the projected volumes through a stress test, created by using a throughput and utilization model. Some levers in the model, such as cancer center hours of operation, will be predetermined by the project leaders. Other variables layered into the analysis include expected exam and treatment minutes per case, room turnaround times, and utilization percentage factor by room type. These analyses prevent facility under-sizing by accounting for periods of inefficiency.

Before completing the sizing analysis, it is also key to evaluate the impact of other strategic and industry factors not addressed during prior phases. These may include local building regulations, innovations regarding the built environment (e.g., patient-centered design, green design, Planetree, and sustainability/LEED), and different technologies. By taking these factors into consideration, the organization is better prepared to plan a facility that will meet longer-term needs. In addition, it is important to create a space that is adaptable to ever-evolving clinical care and technology trends. Design flexibility must be tempered to avoid building unnecessary space.

The financial capabilities supporting the built environment should also be accounted for beginning with the facility cost. There is a fine balance between determining what is needed and planning for the unexpected (e.g., scale and types of equipment and the space or rooms to accommodate them).

At this planning phase, the budget is directional and is used to assist the decision-making process. The final budget is based on full schematic design floor plans developed by the design team. If the final design aligns with the agreed-upon program, estimates should be within 8 percent to 10 percent of the final project budget. These budget variances usually correlate with the addition of higher-quality finishes, public amenities, and equipment. The cost model should consider multiple factors, including:

- The sum of all department gross square feet
- General circulation and other remaining building department gross square feet
- Major medical equipment needed for treatment and clinical support areas
- Project fees (e.g., site development and permits)
- Additional capital fees (e.g., minor movable equipment, IT, and contingency fees)
- Inflation.

> It is critical to develop an oversight planning team to serve as the central communication group, facilitate information exchange, and be the decision-making authority for various project work streams. This team will also regulate change management and establish structures and tools needed (i.e., dashboards, issues trackers, budgets, and a master schedule) for the cancer center project to be successful.

The desired level of IT and medical equipment innovation must also be determined in the facility planning stage. In cancer care, new and improved technologies and medical solutions are introduced at an exponential rate; therefore, organizations should include a contingency amount when designing a new cancer facility. Acknowledging that patients desire the latest technologies and services as essential to their treatment plans, how forward thinking and state of the art do you want your cancer center to be? How much can you afford? What is on the horizon for cancer care that is critical to include in the scope and practice of your new facility? These questions should be asked as part of the final step in facility planning.

Phase Four: Activation and Transition Planning

For patients, their family members, physicians, and staff, opening a new cancer center provides the organization with the opportunity to expand and establish world-class levels of service, efficiency, quality, and satisfaction. For success, the health system must prepare staff to provide patient care in the new facility and prepare the new facility for staff to provide patient care. This entails a resource-intensive, transformative process focused on converting design plans and a construction site into an operational healing environment that is integrated with the rest of the health system.

Figure 3. Readiness Categories

It is critical to develop inter- and intra-departmental workflows, refine inter-building relationships, and cultivate an exceptional patient and family experience in the new environment. Though it is often challenging to fully comprehend these changes, especially for operational staff who have never been through such a project, activation and transition planning is one of the most important and exciting phases of the facility development process.

This phase is generally organized in six readiness categories, as shown in Figure 3, above.

Organizational Readiness

It is critical to develop an oversight planning team to serve as the central communication group, facilitate information exchange, and be the decision-making authority for various project work streams. This team will also regulate change management and establish structures and tools needed (i.e., dashboards, issues trackers, budgets, and a master schedule) for the cancer center project to be successful. This type of team is typically composed of health system operations, administration, and nursing leadership and cancer center physicians. The importance of physician membership on this oversight team cannot be overstated, because active stakeholder involvement is critical to the success of the project. The ultimate deliverables are a workforce and a building that are in sync and well prepared to provide safe and quality care.

Operational Readiness

The health system and cancer center oversight team must establish a collective understanding of the care delivery model in the new cancer center. Building upon where the architects, designers, and planners left off, operational readiness is the time during which floor plans are reviewed, operational workflows are customized and optimized for the new space, and consensus is built on inter- and intra-departmental processes. Form work groups for each area within the cancer center that will encompass direct patient care or be directly affected by changes in the patient care process.

Examples of work groups within the operational readiness category include the following:

- Medical oncology/hematology
- Radiation oncology
- Surgical oncology
- Infusion
- Pharmacy
- Lab
- Registration
- Care coordination
- Case management/social work
- Financial navigation
- Materials management
- Environmental services.

The work groups will meet to develop operation manuals that define the high-level scope of services within each department; key rooms and spaces; staffing and volumes; performance metrics; operational workflows; and departmental routes for patients and their families and for staff.

People Readiness

Opening a new cancer center poses unique challenges—most notable, preparing clinicians and staff to deliver high-quality care in new ways in a new environment. Once processes are established by the operational readiness work groups, it is critical to train to any new standards through multiple methods of education. Staff must be oriented to the new building, department space, and workflows within the cancer center. Training can be conducted through in-person walk-throughs, as well as via online learning modules. In addition, it is key during this readiness phase to communicate with the staff and the community as often as possible to keep them informed of progress and expectations. Newsletters, newspaper articles, blog posts, and town hall meetings are suggested to convey transparent and up-to-date messages.

Technology Readiness

Many organizations are installing state-of-the-art technology (e.g., magnetic resonance imaging guided linear accelerators and proton therapy) to attract patients who are seeking the latest treatment innovations. However, the new equipment and treatment modalities present challenges to staff who may be unfamiliar with them or have been trained to use other devices. Therefore, a plan must be in place to procure and install the equipment, as well as train staff on its uses.

Facility Readiness

New cancer center activation is highly dependent on the successful completion of construction and facility handover, which must be thoroughly planned and aligned to minimize risk. Significant IT, medical equipment, furniture, casework, and fixtures must be installed; building systems must be tested; and security plans for the building must be implemented. This process involves multiple stakeholders throughout the organization, including facilities, biomed, engineering, security, supply chain, and environmental services, to ensure that the building is compliant to code and regulatory standards.

Opening Readiness

Finally, to prepare for a safe and timely opening that is aligned with the strategic plan and organizational goals, it is critical to focus on planning for the opening day. There are various exercises that can be done with the cancer center leadership team to determine how to best transition into the new space, while assuring patients that they will receive high-quality care during the move. Because most cancer centers are ambulatory in nature, planning is significantly less intense than for a hospital setting, where patients must be physically transferred to a new space during their inpatient stay. Scenario planning can be conducted for all details of the transition process, including time and day of the week, equipment move scheduling, opening sequence of departments, and notification to the community of the official closing of the old space. If necessary, a command center can be implemented to ensure that any real-time issues are escalated quickly and addressed immediately to eliminate any impact to patient care.

Closing Thoughts

Any major construction project has the potential to create a lot of energy and excitement for an organization or program. This is especially true for cancer centers, where patients and donors have emotional attachments to the center and often participate in some of the planning efforts. A well-organized and well-planned cancer center project can pay dividends for years to come through improved patient satisfaction, increased employee engagement, better care coordination, and potentially improved clinical outcomes. With one chance to "get it right," organizations should be certain to take the necessary time for thorough due diligence and strategic planning to make certain that the facility is appropriately designed and sized to meet its aspirations. OI

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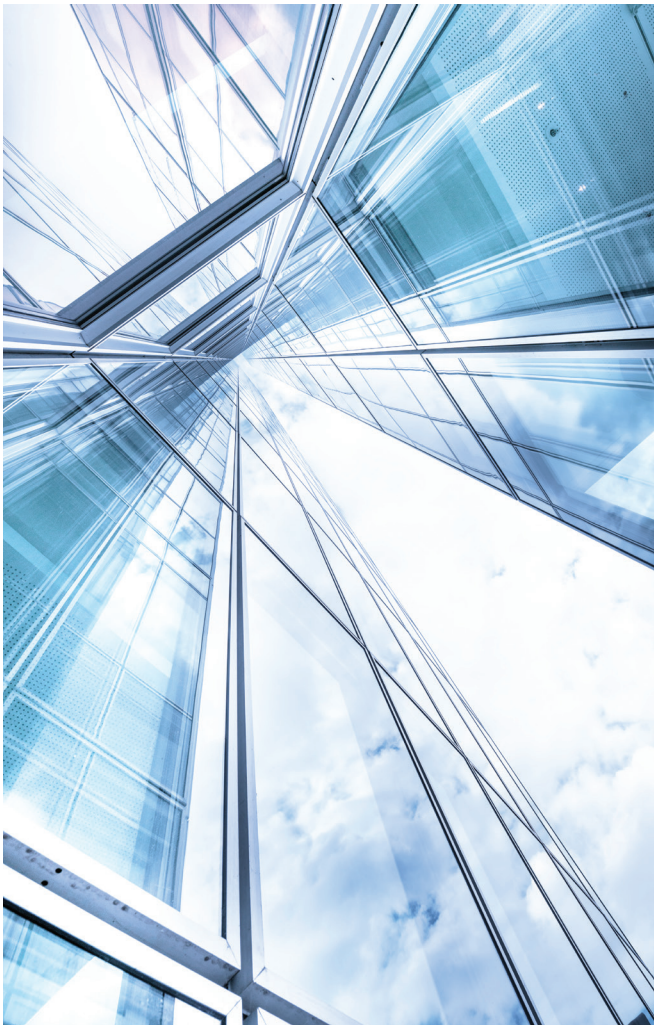


Empowering Cancer Patients Using Integrative Medicine:

A Novel Model for Breast Cancer Risk Modification

BY CHRISTINA M. BOWEN, MD; ROBIN HEARNE, MS, RN;
CAROLINE DIXON; AND CHARLES H. SHELTON, MD

The Outer Banks Hospital (TOBH) is a small critical access hospital with a two-time commendation level Commission on Cancer (CoC)-accredited program in Nags Head, N.C. The town of Nags Head is located on the Outer Banks, a series of barrier islands off the shore of North Carolina. A popular beach vacation destination, the Outer Banks sees seasonal shifts in its population. During the off-season, the hospital primarily serves a demographic that often reflects common rural disparities, such as disproportionately high percentages of advanced stages of cancer presentation and patients with complex socioeconomic needs. As a CoC-accredited critical access hospital—one of only about a dozen nationwide—TOBH has developed a quality program with a focus on removing rurally linked barriers to care.

Breast cancer is the most common cancer in eastern North Carolina, as well as nationally. Because it is so common, our team repeatedly looks at ways to create innovative approaches to improve breast care locally and favorably impact community outcomes. The hospital's quality improvement (QI) models are simple, and other community hospitals can easily replicate them.

In 2018, TOBH completed an analysis of the many known risk factors for breast cancer within its rural population to see if an opportunity existed to remove disparity as part of a QI project. The analysis was conducted with acknowledgment that some risk factors for cancer are inherently biological, genetically determined, and difficult to change and that many risk factors are biological, environmentally influenced, and *sometimes modifiable*. Examples of the former include family history, ethnic ancestry, breast density, age of menarche, height, and age of menopause. Examples of the latter include BMI (body mass index), exercise, diet, stress and anxiety, use of and timing of hormone replacement therapy, alcohol consumption, and smoking. Our study examined existing patients with breast cancer for most known common biological risk factors, and we used this information to create a two-step process to:

> All patients with newly diagnosed breast cancer are now evaluated prospectively for genetic counseling and testing locally at our hospital based on national guidelines for hereditary breast cancer.[1]

Although the underlying mechanisms of the cancers may be different—mostly hormone related in post-menopausal women and inflammatory mediated in pre-menopausal women—they potentially provide a common denominator for customized intervention through a risk modification model.

1. Model the management of all breast care within the region through risk stratification.
2. Help create care pathways to mitigate the risks wherever possible.

This article summarizes how this rural hospital leveraged integrative medicine with oncology to develop a risk assessment and risk modification model and highlights its early outcomes to mitigate some of the rurally linked disparities in cancer as they pertain to breast care.

Our Quantitative Risk Factor Analysis

To satisfy CoC Standard 4.7, TOBH conducted a multi-year quality study that looked at collective risk factors for breast cancer occurrence based on some unusual observed patterns in local demographics. Our radiation oncologist and Cancer Committee chairman observed a seemingly higher-than-expected prevalence of familial clustering of breast (and linked ovarian and pancreatic) cancers regionally, higher local obesity rates, and an excess of other cumulative above-average risks for breast cancer within our rural population, at least within the existing population of locally treated breast cancer patients. These observations suggested a need to further examine these risk factors and identify any other risks collectively. The hope was that an extensive analysis of known risk factors in existing patients with cancer would reveal patterns that would allow customization of treatments through risk reduction and possibly allow broader modeling of this rural risk in the larger cancer-free population as prevention.

Indeed, further data analysis revealed a remarkably high clustering of breast cancers within families in our demographic area. This finding suggested a need to consider more proactive genetics evaluation, which we incorporated into our cancer program. All patients with newly diagnosed breast cancer are now evaluated prospectively for genetic counseling and testing locally at our hospital based on national guidelines for hereditary breast cancer.[1] Four years of data analysis reveal that 55 percent of patients presenting with breast cancer to our hospital have positive family histories that reveal close (first- or second-degree) relatives with breast or ovarian cancer. Many of these families include at least one first-degree relative, and often at early ages (<50), and 6 percent of patient families report more than one first-degree relative with breast or ovarian cancer. These numbers are roughly four times the comparable percentages seen in large population studies where the majority (75 to 85 percent) of patients with breast cancer studied in larger populations nationally have *no* family history of breast cancer.[2] These flipped familial clustering patterns observed within our region versus elsewhere might suggest a high rural prevalence AND:

- Known inheritable genetic mutations (e.g., BRCA1 or 2) for which patients can be tested OR
- As-yet undiscovered genetic mutations, which likely are not very penetrant in a population and therefore perhaps not as relevant OR
- Shared environmental risk factors clustering within families (e.g., poor diet, common environmental exposures).

Results from our quality study also confirmed high rates of obesity within our rural population of breast cancer patients (~38 percent are obese; 32 percent are overweight, 70 percent have BMI > 25). High rates of obesity (BMI > 30), especially in post-menopausal women, have been shown to consistently increase breast cancer rates due to excess estrogens.[3] It is no surprise that the median age of women with breast cancer at TOBH is 63 (same as nationally), and 87 percent of breast cancers in our community are hormone receptor (ER) positive. Obesity may also be a shared environmental risk factor linked to rural socioeconomics. Additionally, obesity in premenopausal women may correlate with the genesis of triple-negative breast cancers.[4] Although the underlying mechanisms of the cancers may be different—mostly hormone related in post-menopausal women and inflammatory mediated in pre-menopausal women—they potentially provide a common denominator for customized intervention through a risk modification model.

As mentioned previously, due to the observed high rates of familial clustering of breast cancer (55 percent of patients have known family history of same cancers), our hospital cancer program has become very proactive in testing for genetic mutations. We currently test 100 percent of consenting patients ourselves using a genetics extender model. Yet, our three-year broad-panel gene testing results indicate that only 6 percent of patients with breast cancer have true identifiable pathogenic mutations linked directly to their breast cancer (including BRCA, PTEN, CHEK2, CDH1, ATM, RAD51C, etc.).[5] These data suggest that the majority (>90 percent) of familial clustering within the rural area we serve may be due to other low-risk, yet to be identified genetic (polygenic) mutations or, more likely, represent epigenetic-linked somatic events that led to genomic instability in the cells. Examples of such precipitating events include potential carcinogens in the diet or environment, previous radiation exposures, alcohol and tobacco use, or lifestyle (and health) modifiers of our epigenome. Examples of the latter include obesity, type II diabetes mellitus and circulating high levels of insulin, lack of exercise, poor diet, inferior cardiovascular disease, stress, and sleep patterns.

Regardless of the underlying mechanisms, TOBH's cancer patient data indicated a high-risk population rurally with clearly identifiable risk factors and an opportunity for novel intervention by our cancer program.

Our Nature+Nurture QI Approach

Robin Hearne, RN, MS, director of Cancer Services for TOBH, first suggested a novel blended approach to address the care of the whole patient with cancer. With experience in quality care and research, Hearne brings a combined interest in both conventional therapy as a nurse and integrative approaches to cancer care. She completed an integrative medicine leadership program at Duke University and plays a pivotal role in our risk modification project. She envisioned a truly innovative quality improvement approach that considers the role of *nature and nurture* by merging integrative medicine with our traditional oncology team in the overarching goal of care for the whole cancer patient.

Our oncology team, led by Charles Shelton, MD, focused on the conventional "nature" (familial and genetic) contributions to cancer risk in our breast cancer patients. Dr. Shelton heads our breast tumor board, which meets twice per month, where we discuss all new cases prospectively as a multidisciplinary team, including integrative medicine, and we test all patients for inheritable germline mutations based on recommended guidelines.[1] Though germline mutations are not modifiable in the conventional sense (you cannot change your family of origin), preventive strategies currently include prophylactic surgery (if deemed very high risk; e.g., BRCA mutation) and chemoprevention as potential interventions in very high-risk patients who are found to be carriers or who are otherwise very high risk (30+ percent lifetime risk of breast cancer). TOBH created a separate high-risk breast clinic based on this project and we follow all patients closely with pathogenic variants in their DNA and offer risk reduction based on National Comprehensive Cancer Network (NCCN) guidelines.[6]

The integrative medicine team focused on the complementary "nurture" (environment and lifestyle) component and how environmental modifications and lifestyle changes can help reduce recurrences in patients with cancer and even help to prevent cancer in non-cancer patients. Examples of these modifications include:

- Foods and supplements that diminish inflammation, including acetylsalicylic acid and nonsteroidal anti-inflammatory drugs
- Regular exercise
- A reduction in alcohol consumption
- Tobacco cessation
- Lower body fat and weight management
- Better sleep habits
- Stress reduction
- Access to spirituality and social support
- Similar whole-patient health approaches that promote stability in the genome.

If we could identify these risks clinically in patients already diagnosed with breast cancer, we believed that our team could identify and customize interventions relevant to our demographics to mitigate a patient's risks for future cancers. Further, we hypothesized that we could employ an appropriate model to change the lifestyle in the at-risk population by identifying women who would benefit most from risk-reduction strategies using available risk stratification such as the Gail model[7] or Tyrer-Cuzick tool.[8]

> From our pilot study, we identified an individual's modifiable and unmodifiable risks and developed customizable risk assessment tools appropriate for our general population based on these relevant data.

TOBH's cancer program began this holistic model of *nature + nurture* for breast care primarily as a pilot study in 2018 to examine collective risk factors for all of its patients with breast cancer living locally (i.e., not seasonal, vacationing patients). The model was then expanded in 2019 to include the at-risk unaffected population (without cancer) to better understand which factors might be modifiable in both patient groups. Stating this differently, the primary focus was therefore on developing a model program to help reduce cancer risk in patients with known breast cancer (e.g., current active patients). A secondary focus was the general population at risk that shares similar risk factors but in whom cancer has not been detected (e.g., screening population) where prevention was a long-term goal. This novel risk identification (using existing risk stratification tools) and customizable risk modification model, therefore, has a potential preventative application for both patient demographics: those with a personal history of breast cancer and those without it.

Our Study Methods

For the first part of our project, we performed an in-depth specific risk analysis of all patients with breast cancer treated at our small community critical access hospital population over three years (2016, 2017, and 2018). We later updated it with four-year data.[5] This analysis included a retrospective review of electronic health records (EHRs) for 165 patients, the majority of whom (>90 percent) Dr. Shelton evaluated and/or treated. Risk factors for breast cancer are well described in the literature. Therefore, we selected the majority of the known risk factors, tabulated these risks, and quantitated them within our known breast cancer population to see whether any results were outliers with respect to a reference population. To align data with our project goal, we separated the risks into two broad categories and tabulated each as "modifiable" and "not modifiable" (see Table 1, page 28). We queried the patient records for 46 risks, having identified 14 as "modifiable" risks and 32 as "not modifiable" risks. These were analyzed for each patient based on information in the patient's EHR. If information was lacking, it was scored as

Table 1. Risk Factors for Breast Cancer

Modifiable Risks	Not Modifiable
BMI	Gender
Exercise	Age
Diet	Ethnicity
Alcohol	T size (≤2cm, 2.1-5.0cm, >5.1cm)
Tobacco	Stage
Aspirin/nonsteroidal anti-inflammatory drugs	Receptors
Vitamin D	Family history first-degree breast cancer
Stress	Family history second-degree breast cancer
Sleep	Family history more than one first degree
Spiritual	Genetics
Support	Density on mammography
Night shift work	Menarche
Completed intended therapy	Parity
On aromatase inhibitor or tamoxifen if ER+	Age at birth of first child
	Breastfed
	Age at menopause
	Surgical oophorectomy
	Post-menopause hormone replacement therapy
	Oral contraceptive use
	Previous biopsy breast
	Personal history of breast cancer
	Previous ionizing radiation

unavailable. In earlier years, the patient EHRs had less information, particularly in the area of modifiable risks, which may skew the study results by presenting a lower number of modifiable risks. In other words, if providers had solicited more information, the average number of modifiable risks could potentially have been higher than our results show. Also of note, patients seen by oncologists often had better available information (e.g., family history, age of menarche, etc.) for all of these metrics than what was already in electronic records before a diagnosis of cancer was made, highlighting how the information available in mining data can vary greatly based on the historian (often primary care physicians [PCPs], who usually do not have time to complete full family history questionnaires).

It is possible to make an argument that several of the not modifiable risks identified in Table 1 are, in theory, modifiable. For example, if several decades ago a woman knew that she could lower her risk of breast cancer by planning the birth of her first-born child at an earlier age, she could have modified her risk. Similarly, a postmenopausal woman may choose not to take estrogen replacement therapy. However, for the purposes of the study analysis, we assumed—given that the median age of women in our study population was 63 years—that women were not then aware that having a first child at an older age was a risk factor for breast cancer, so we considered that metric unmodifiable. In our at-risk population (younger age, no cancer), these could, of course, be considered modifiable through timely education.

As hypothesized, our analysis of patient records revealed many cumulative risk factors for breast cancer, because the analyzed population already had breast cancer. Though we acknowledge that this biases the study results, we were unable to simultaneously perform a control arm study of the normal non-cancer population to see whether rural risk is inherently high due to Health Insurance Portability and Accountability Act concerns in accessing women's records without informed consent. We are currently performing a parallel study on the patient population without cancer as part of an institutional review board-approved study based on these same pilot data. Preliminary results from that study confirm the same findings of higher-than-expected familial clustering and other associated high risks in the at-risk rural population as well (e.g., high BMI and high alcohol use, poor diet and exercise, and high familial risks). In the unaffected population, for example, familial cancer is also high: 41 percent of women screened report strong family histories of breast cancer; 8 percent have ovarian cancer; and 5.3 percent have pancreatic cancer in their families. Overall, 21 percent of all screened patients without breast cancer at the time of mammography meet NCCN guidelines for genetic testing for hereditary breast and ovarian and pancreatic cancer.[9] This means that one in five patients in our screened population should be considered for genetic testing for hereditary breast and ovarian and pancreatic cancer. Additionally, in high-risk patients identified by our current risk assessment tool (Tyrer-Cuzick), most women share the same modifiable risks of higher-than-normal body weight, poor diet, and inconsistent exercise, and they could benefit from this approach of modifying their risks through lifestyle changes as well.

From our pilot study, we identified an individual's modifiable and unmodifiable risks and developed customizable risk assessment tools appropriate for our general population based on these relevant data. Though it may seem strange at first to examine the collective risk factors in a patient who has cancer, we were using our findings to identify risks that are modifiable versus those that are not and then offer customized interventions. Again, we acknowledge that some of the known risks cannot be changed (gender, age, menopause age, age of menarche, height, ethnics, family history), but our hope was to identify those that are modifiable, study them in the context of a model providing holistic interventions through integrative medicine approaches, and extend our model to other programs seeking to lower the future risks of secondary cancers and/or proactively prevent primary cancers. Accordingly, we have now integrated the same model into our risk reduction model for unaffected women as a primary form of cancer prevention.

Results from Our Breast Cancer Risk Analysis Quality Study

We discovered several interesting outcomes from this quality study: First, we found that most patients with breast cancer had many known collective high risks for breast cancer, many of which are modifiable given appropriate education and patient motivation. The median number of modifiable risks per patient was 4, with a range of 0 to 14. The median number of not modifiable risks was 10, with a range of 0 to 32. The typical person with breast cancer in our study collectively had 14 of 46 total potential screened risks, one-third of which are modifiable.

Second, we found that the most prevalent and significant risk factors in our population rurally were a positive family history of breast cancer (or ovarian cancer) in more than 55 percent and an elevated BMI in 70 percent. High breast density was also remarkably common on imaging (40 to 50 percent had heterogeneously or very dense breasts on imaging, both of which can increase the risk of breast cancer by a factor of 2 or more compared to fatty breasts).[10] These are clearly not all modifiable risks, but they can be modeled and used for targeted interventions. Because we have many families with first-degree and second-degree relatives affected by similar cancers and disproportionately high percentages of people with high BMI, we chose the Tyrer-Cuzick tool, which accounts for these risks and, in the recent 2019 version of the tool, for breast density. Accordingly, based on our demographics, our team adopted the Tyrer-Cuzick model v8[11] to stratify these risks and better identify at-risk women for referral to a high-risk breast clinic, which was our initial vision with this plan. We implemented our high-risk breast clinic in July 2019 in our screening (unaffected) population as a direct result of this breast cancer risk analysis study, and we now refer all patients with an absolute lifetime breast cancer risk of 20 percent or higher to that specific clinic and simultaneously to the risk modification program as appropriate. To date, using this model in 4,500 women screened annually in our rural population, 7.5 percent of unaffected women (N = 337 estimated by July 2020) have lifetime breast cancer risks greater than 20 percent. We offer each woman participation in this program, as well as following them in a high-risk breast clinic, which includes additional imaging, risk modification through our integrative medicine team, chemoprevention when indicated, and genetic testing when appropriate. See Figure 1, page 30.

Third, we discovered that the majority of patients had several modifiable risks where intervention was indeed possible. Most commonly, these were elevated BMI (weight), poor diet, excess alcohol consumption, poor exercise habits, and smoking. The median number of modifiable risks (per patient) in our population of breast cancer patients was 4/14; several patients had 8/14 modifiable risks (the maximum identified in any study patient). No patient had every risk (14/14). These data suggested a potential to greatly impact our patient population's risk for second breast cancer or risk for recurrence through holistic interventions and perhaps extending this model to individuals in the at-risk population who do not currently have cancer but who likely share the same biological and environmental risks. Only 3/165 patients in our analysis had no identifiable modifiable risks, but that could be explained easily by poor documentation early on in our records. Stated another way: Analyzing three years of data from our resident population of patients with breast cancer, we found that 98 percent had some modifiable risks where intervention could be potentially effective in future cancer prevention. Figure 2, page 30, lists the top five modifiable risks.

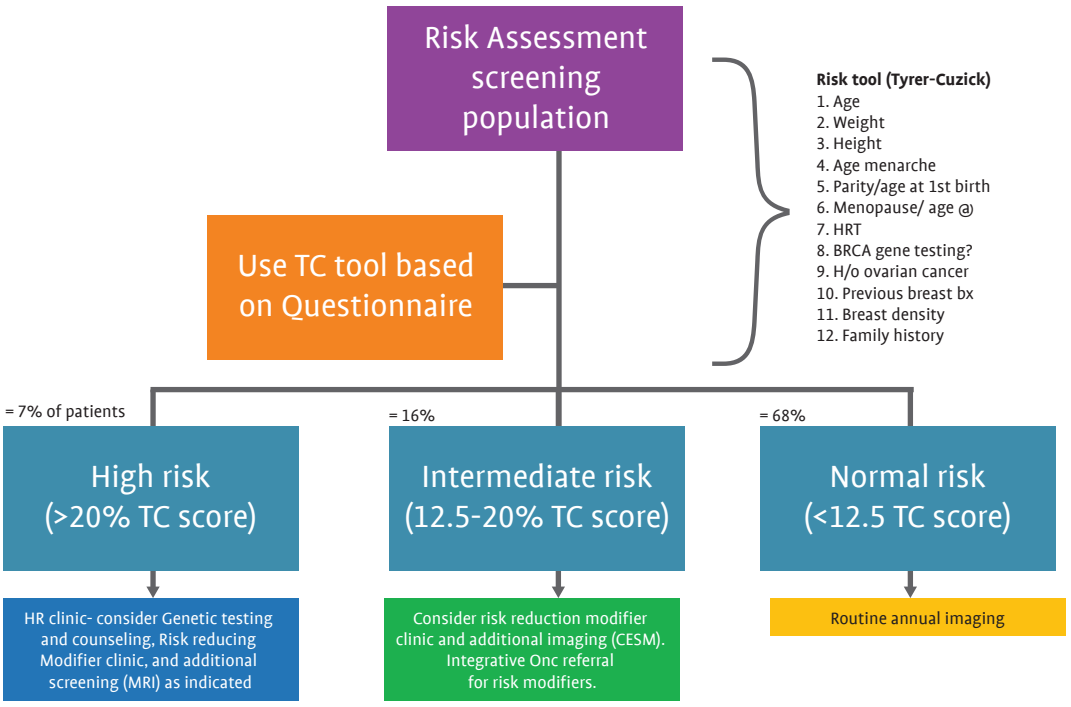
The Role of Integrative Medicine

The literature has shown that adding an integrative medicine program to a traditional oncology program can improve the care of oncology patients. As such, ASCO (the Association of Clinical Oncology), the Society of Integrative Oncology, and the National Cancer Institute now include integrative oncology as category 1 and 2 evidence-based approaches to integrative cancer care.[12,13] We found that our patient population has embraced the model in which we combine conventional care and complementary therapies. It is the perfect blend of nature and nurture.

As a small community cancer program, we are fortunate to have a physician who is board certified in integrative medicine, and since early 2017 we have added this clinician prospectively to all case discussions at every tumor board. Now, three years later, we continue to use and expand on these services. In 2018, the authors of this article presented TOBH's use of integrative medicine at the meeting of the Society of Integrative Oncology as a best practice model on how integrative techniques can complement and enhance patient care.[14] Our team believes that every patient benefits from integrative medicine. When modifiable lifestyle risk factors for cancer occurrence or recurrence are a focus, the benefit of integrative medicine becomes even more evident.

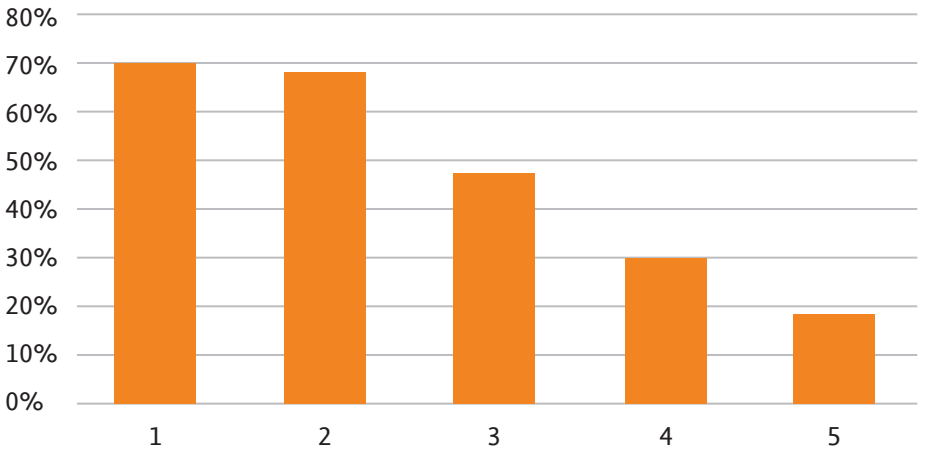
An integrative medicine physician has not only helped us manage patients during active therapy by mitigating nausea and neuropathy and other chemotherapy, hormone therapy, and radiation treatment-related side effects through various complementary approaches but has also enhanced the overall care of our patients. With a holistic focus, the integrative care continuum

Figure 1. The Outer Banks Hospital Risk Assessment Model*



*This model is used to assess risk in the general population for breast cancer given high familial clustering in first- and second-degree relatives, high BMI rates, and high breast density, as well as other risks we examined. We have found the Tyrer-Cuzick model best suited for these metrics. CESM = contrast enhanced screening mammogram.

Figure 2. Top 5 Modifiable Risks by Rank



Poor diet (#1) in 70% of all patients

Elevated BMI (#2) in 68% of all patients

A sedentary lifestyle (#3) in 48% of all patients

Alcohol use (>1 per day) (#4) in 31% of all patients

Current tobacco (#5) in 18% of all patients

n = 161

can encompass a discussion of life stressors, social and family support, spirituality, mindfulness and stress adaptation/reduction techniques, diet quality and supplements, exercise specifics and frequency, sleep patterns, tools to achieve healthy outcomes, and more.

As we move into the next phase of our risk modification model, which focuses on how best to customize and integrate interventions targeted to modifiable lifestyle factors into long-term care, our patients with breast cancer will benefit from integrative oncology care as part of their overall survivorship care.

With the quantitative risk factor analysis of our patients with breast cancer completed in 2018, we hypothesized that our patients with breast cancer could benefit from several risk modification strategies led by the integrative medicine physician as part of our Integrative Oncology Program. Our integrative medicine physician customizes interventions throughout a patient's entire course of therapy, including lifestyle, eating habits and alcohol consumption, sleep, and stress reduction. Because a large portion of our integrative program is focused on mindfulness, stress reduction, and quality of life, we engaged our breast care team to discuss risk modifiers with their patients with breast cancer and help patients set their own goals for change. With the addition of these integrative services, our breast care program has evolved into truly customized precision care.

Using evidence-based literature, we share the relative risks (hazard ratios and each risk factor's potential impact on their outcomes) of each modifiable factor with our patients, empowering patients with information so that they can make their own modification goals. Although lifestyle recommendations from the American Cancer Society[15] and ASCO[16] include similar risk reduction guidance, we have found that patients are not aware of how—when taken together—taking proactive steps can help reduce their risk of second cancers. We give them data to show them how much it can add to their outcomes as it becomes part of a proactive survivorship plan.

It is our opinion that integrative medicine and traditional oncology care as a blended model can synergistically lower the chances of recurrence of cancer in existing patients with cancer as much as traditional therapies, such as anti-estrogens in ER+ breast cancer, which is our most common occurrence. Most people are simply not aware of integrative medicine options. Our physician champion is ideal for offering this education, and our Cancer Committee fully embraces this model. Additionally, we believe that most traditionally trained physicians are reluctant to attempt lifestyle modifications in their patients, because they can be truly hard to change, but TOBH has embraced integrative medicine as a critical component of our cancer services. Moreover, we are not alone in our efforts. Others in the academic cancer community also consider these metrics important; for example, the recent Breast Cancer Weight Loss Study randomized study, which is looking at body weight reduction, along with exercise, will have data forthcoming in the next few years.[17]

Early data from randomized trials now show that active exercise lowers the risk of recurrence of cancers in comparison to sedentary lifestyles. Similarly, other modifiers, which we also believe act as epigenetic modifiers, can reduce the risk of recurrence of the same cancer or a possible second cancer, particularly in breast cancer, where the majority of second cancers occur many years and/or decades later and are often estrogen mediated. Many of our modifiable factors lower estrogen; for example, weight loss, BMI reduction, alcohol minimization, and improved diet. Our study revealed even more concentration of these modifiable risks in those women with second cancers (on average 20 years later), with 90 percent of second cancers in our women occurring in those with BMI > 25, suggesting that lifestyle and obesity greatly contributed and therefore these women could potentially benefit even more from adopting changes for these modifiable risks. Because these are clearly risks that we can change though programmatic efforts, TOBH has incorporated this information into this wellness approach to all patients with breast cancer.

Educating Our Providers and Patients

Despite mounting evidence that lifestyle choices (tobacco cessation, exercise, healthy diet, stress reduction) play a role in helping to prevent cancer, often these components of whole-patient wellness are not emphasized or even discussed by oncologists. Further, a 2008 study showed that patient adherence is poor, with only 5 percent of cancer survivors meeting all of a set of three basic recommendations (diet, physical activity, and smoking cessation), and taken alone, compliance in each area was poor.[18]

Very few physicians or providers take the time (or have the time) to explain to patients what their risks are and how they can reduce them. In our limited experience, all patients are interested in this information, but it is hard to find anyone willing to sit down with patients to help share its relevance. A study of childhood cancer survivors support this, where less than one-fifth of patients (18 percent) had visits with their providers in follow-up to discuss risks of future cancer and ways to screen for or reduce the risks of second cancers and other poor outcomes.[19]

Prior to the addition of our integrative medicine program, TOBH did a poor job of sharing this information and educating its patients, which may have influenced the recurrence rates noted in our quality study. In that analysis, second cancers in patients with previous breast cancers accounted for 15 percent of our total breast cancer cases. Among those patients, the analysis showed an even higher concentration of elevated BMI (90 percent of patients with second cancers had high BMI and were post-menopausal) and familial histories of cancer (100 percent of second cancer patients had a family history of breast cancer in addition to their own previous breast cancer). Our study revealed that prior to 2018, very few EHRs showed any discussions about lifestyle considerations or any mention of modifiable risks other than what we included in survivorship plans, which was very generic. With the addition of an integrative medicine physician to our team, this became a focus for our cancer program and is now part of ongoing active survivorship. Patients are seen at intervals during and after therapy regularly as part of routine care. In addition, in 2018, to help improve patient education about these risk factors, we shared data on the various risk factors and their relative effects on cancer occurrence and potential

Dr. Christina Bowen consulting with a local cancer survivor.

recurrence with our oncologists and our PCPs (see Table 2, page 33).

To show the potential benefits of modifying these risk factors, we proactively engaged our local breast cancer patient population, discussing their individual risks and explaining how these may potentially correlate with recurrence and/or new cancers. Since 2018, all patients with breast cancer now see our integrative medicine physician for an initial risk-reduction consultation. Patients learn which modifiable risk factors apply to them and the potential benefits from taking action to modify these customized risks. We provide patients with evidence-based information and review the anticipated benefits of various risk reduction strategies, including the estimated relative benefits of each, and let them choose, for example:

- Exercising regularly can lower risk of breast cancer by up to 20 percent
- Weight loss/BMI reduction can reduce risk by 10 percent per 5 BMI points
- Improved diet can reduce risk by 11 to 15 percent
- Moderating alcohol can reduce risk by 67 percent
- Quitting tobacco can reduce risk by 15 percent
- Supplementing with vitamin D if patients are deficient (or maintaining normal levels) can also reduce risk.

We highlight the risk factors that patients can control and modify and the ones they cannot. This is similar to a model in childhood cancers that highlights the relevant idea that the risk and severity of outcomes (vis-à-vis complications, or second cancers) are potentially modifiable by preventive strategies that encourage healthy lifestyle behaviors, specialized surveillance and screening, and risk management.[18]

We share these data proactively with our patients by introducing the idea early in their cancer journey and then again throughout their various treatments. We reinforced the idea at multiple touch points with various providers. Near the end of their primary therapy (typically, radiation therapy is last), we then encourage patients to choose their own personal goals from among these modifiable risks. Once the patient's goals are identified, we provide resources to meet these objectives through our Wellness Center, which includes our integrative medicine physician, a nutritionist, and a health coach, among others. Patients define their own goals based on their unique situations, finalize these goals in our "modifiable risk" clinic, and are then held accountable on all subsequent follow-up visits as goals are shared with their primary care providers as well as all oncology team members. Patients are supported both by their PCP and by the oncology team to improve their overall health in ways that we know will improve not only disease-specific survival but also overall survival due to the potential to affect other chronic diseases. Metrics are tracked and reviewed with patients at follow-up visits with support provided by our integrative oncology team. Because the median number of modifiable risks is four in most patients, we ask that patients usually work on three to four goals in their first year. Each goal is customized to their unique needs.

We believe that this risk modification model serves as a great liaison between our chronic disease team and our oncology providers and promotes not only self-empowerment but also better communication between PCPs and oncologists. These goals (often BMI reduction, minimizing alcohol intake, exercising more) often benefit patients in other ways, so our PCPs embrace the risk modification model. We believe that this innovative approach results in better care coordination and broader patient engagement. Furthermore, we have found that 98 percent of our patients have at least one modifiable risk that they are willing to try to improve. Several patient case studies follow.

(continued on page 34)

Table 2. Risk Factors and Relative Risk of Cancer Occurrence and Recurrence

Factor	Relative Risk
	Very High/Effect
Ionizing radiation <30 years of age	22-40×
Personal history of LC15	8-10×
BRCA1/BRCA2 mutations	3-7×
Other genetics: TP53, ATM, CDH1	4.0-8.0×
CHEK2, PTEN mutations	2.1-4×
<50-year-old woman with first DR breast cancer (1-3)	2.0-12.0×
≥50-year-old woman with first DR breast cancer (1-3)	1.6-2.6×
Age (70-74 vs. 30-34)	18×
Age >65	4×
Age at first birth (>30 vs. <20)	1.9-3.5×
Bone density (highest quartile vs. lowest)	2.7-3.5×
Breast density on mammography (dense vs. fatty)	1.8-6.0×
History previous breast biopsy benign	1.7×
History ADH on biopsy	3.7×
Personal history of breast cancer <40	>2×
Ashkenazi heritage	3-5×
	Moderate Risk/Effect
Alcohol use	1-2×
Early menarche (<12-13)	1-2×
Height	1-2×
BMI > 25	1.25-1.32×
High socioeconomic status	1.1-2×
Oral contraceptive use (past use/current vs. never)	1.07-1.2×
Post-menopause hormone replacement therapy (current vs. never)	1.2x
Dense breast (25%-50% vs. fatty)	1.1-2×
Personal history of breast cancer before age 40	1.1-2×
Late menopause (>55)	1.1-2×
Diabetes mellitus type II	1.1-2×
Tobacco use	1.1×
Night shift work	
Not completed intended treatment	?
Breastfed (>16 weeks vs. less/none)	0.73×
Party (>5 vs. none)	0.71×
Recreational exercise	0.70×
Post-menopause BMI <25	0.63×
Oophorectomy by 30 years old	0.30×
Aspirin/nonsteroidal anti-inflammatory drugs	0.79×

Notes: DH = degree relative; ADH = Atypical Ductal Hyperplasia.

(continued from page 32)

Case Study One

A 65-year-old post-menopausal female with stage IA ductal carcinoma with estrogen and progesterone receptor positive (ER+ PR+) markers and a history of elevated BMI at baseline with plans to start aromatase inhibitors or tamoxifen was offered weight reduction and/or weight stability via exercise and diet as way to further minimize the risk of breast cancer recurrence. She was encouraged to pick three metrics (weight loss to help BMI, diet changes, regular exercise five days a week) among others unique to her risks as potentially modifiable goals at the time of her risk reduction consult, which is typically at one month following the last treatment. Over the first year, we followed up on these measures at subsequent visits, usually at three months, six months, and annually. Because most of our patients (87 percent) have hormone receptor-positive breast cancers, where these risk factors more tightly correlate with cancer-specific recurrence, we think that this program will magnify favorable outcomes.

Case Study Two

A 42-year-old female with breast cancer at presentation had a borderline high BMI (26), a poor diet, and inconsistent exercise regimens; she also wanted to reduce her stress during and after her treatments. She drank more than seven glasses of wine a week and embraced a model in which these risks could be explained to help her modify her lifestyle. She was found to be BRCA positive, as well, and had further risk reduction surgeries, including oophorectomy and bilateral nipple-sparing mastectomies. Though her risk reduction is less likely to be mitigated by her lifestyle than by her surgeries, her recurrence rates and her overall health clearly benefit from the changes we implemented. Her weight is ideal now (BMI < 25), her alcohol consumption is three glasses per week, and her exercise is regular now. She remains recurrence free.

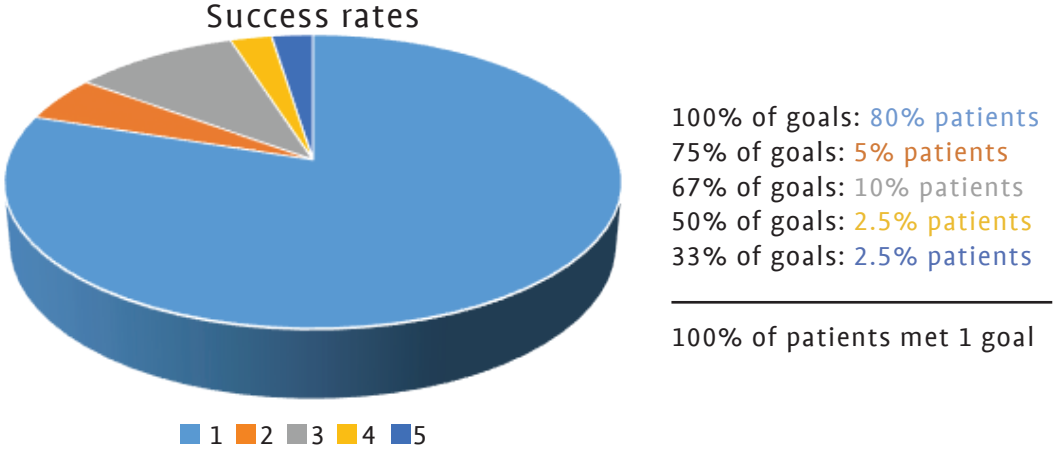
Case Study Three

A 53-year-old female with ER+ breast cancer has a strong family history of breast cancer but negative genetics and had a high BMI at baseline and is a smoker. She chose weight reduction, especially knowing that she may gain weight on aromatase inhibitors, taking weekly yoga and Pilates classes. This patient also chose smoking cessation as her second custom risk modifier. We connected the patient to a smoking cessation clinic that we offer and followed up with the patient at our Wellness Center. She achieved all of her goals.

Looking Ahead

Since starting this risk modification model, TOBH has found that its patients are enthusiastic and willing to embrace the factors they can control themselves. We have strong buy-in from our oncologists, who now consistently refer patients to our Wellness Center, headed by Dr. Bowen. To date every patient referred for this model of risk modification has bought in to the program, and we are tracking data as a part of a follow-up QI project. Thus far, 64 patients with breast cancer have been enrolled in this integrative model and 100 percent have achieved at least one goal of risk modification (e.g., improved diet), and 80 percent of patients have achieved every goal (most commonly increased exercise, weight management, and improved diet). See Figure 3, below. Contrast this success to the 5 percent results cited earlier in a 2008 study.[18] It is interesting to anecdotally note that when patients are empowered to make their own goals and choices rather than providers telling them what they "should" do, there is considerably more success. We have also found that this model excites PCPs because these cancer-specific goals are mostly free of cost, and the same lifestyle goals often help with other chronic diseases (e.g., hypertension, type II diabetes, hyperlipidemia, coronary artery disease, vascular disease, etc.).

Figure 3. Results—Early* Success



* Average f/u is 10 months, range 4-28

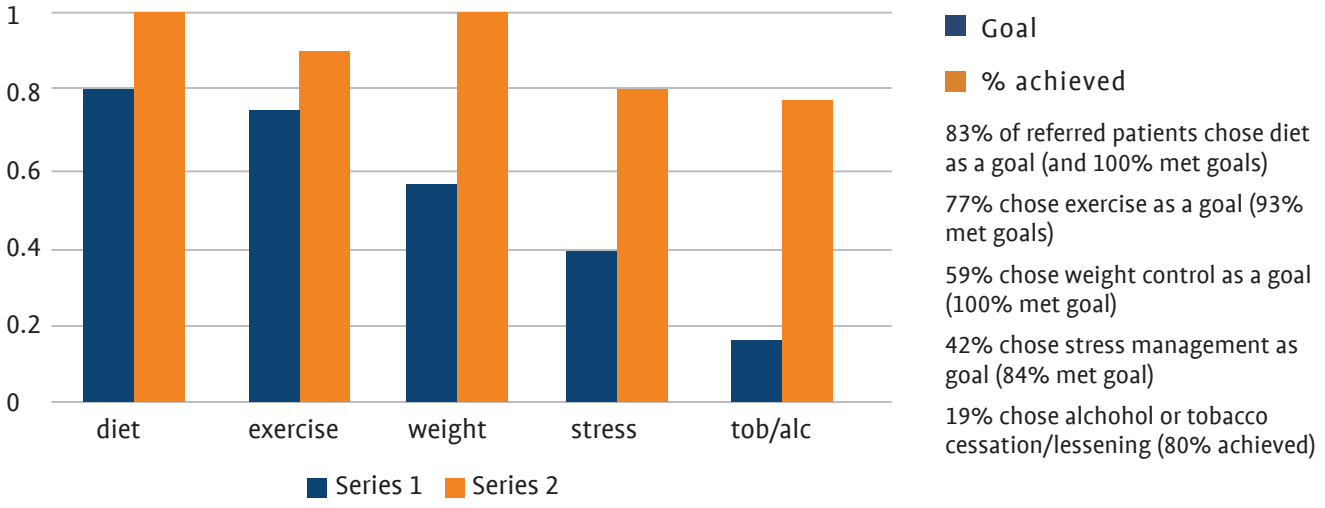
One other surprising outcome from this QI project was the amount of non-compliance we found in women with breast cancer in regards to hormone therapy; 13 percent of patients with ER-positive breast cancer were discovered to be not compliant with hormone therapy (anti-estrogen therapy in ER-positive cancers) in this study due to side effects most often (and therefore discontinued use) and a general lack of an understanding of the continued need for maintenance. This rate of 87 percent compliance is below the CoC reference standard of 90 percent,[20] which is a national target in quality programs, again highlighting how disparity can easily creep into rural areas. Most women, and even some PCPs we found, did not realize that it lowers the relative risk of recurrence by 50 percent, and many PCPs assume that oncologists are following all of these patients when in fact rurally they may not be. We have since added this metric to our risk modifier checklist (even making it a goal to minimize side effects from hormone therapy) and now rely on our integrative medicine team as a tool to help mitigate the negative effects of hormone therapy (especially weight gain and vasomotor symptoms) and thereby increase compliance rates with hormone therapy for breast cancer patients. Anti-estrogen therapy is pharmacologically the greatest modifier of recurrence/occurrence, and we have already seen an improvement in compliance with hormone therapy in our patient population accordingly (we are consistently >90 percent). If no other measures of success emanate from this risk modification program, our process has already succeeded in improving these statistics by this measure alone.

To date, we have referred all interested newly diagnosed patients with breast cancer who have at least one modifiable risk (98 percent of our analyzed patients) who we believe can benefit from this process of education and personalized goal setting and then measured accountability by the oncology team. Figure 4, below, shows the outcomes from this approach since we started. The majority of patients referred to our Wellness Center hit every metric and maintained their goals over time. The average weight loss in patients choosing that specific goal was 13 pounds, and 100 percent of patients with weight management as a main goal achieved their goal. We have also seen our second cancer rates decline in these patients, but this metric will need 10 to 15 years of follow-up to be considered real.

By innovatively empowering our patients to become their own risk-modifying tool, we engage more patients and potentially lower the risk of recurrence of future cancers. Furthermore, an added benefit to their health from these improved self-selected lifestyle choices is that they help in chronic disease management (e.g., diabetes, cardiac disease, etc.). By engaging patients, setting goals with them, showing them the potential magnitude of those changes, and then holding them accountable to themselves and to us, we are improving overall health and quality of life of our breast cancer patients. We plan a follow-up analysis of these benefits in future projects.

Plans include expanding this holistic model to other cancer sites with similarly modifiable risk factors and into other at-risk populations before cancer is even diagnosed. For example, as stated earlier, by analyzing these data we discovered that based on familial history, dense breasts, and high BMI, we have a high-risk population in which mathematical modeling helps to stratify risk for better targeted screening in breast care. For this reason, we now use the Tyrer-Cuzick model (v8)[11] to calculate lifetime risks for breast cancer in our screening population in order to appropriately offer genetic testing to identify unmodifiable risks (family history and heritage), as well as to assign patients to low-, intermediate-, and high-risk groups for various risk reduction strategies and alternative secondary screening. Since implementing

Figure 4. Success by Goal



this strategy, based on NCCN guidelines, we have discovered that 7.5 percent of our population at any given time are high risk, defined as lifetime risk of breast cancer greater than 20 percent, 16 percent are at moderate risk (defined as 12.5 to 20 percent), and 76.5 percent are low risk (defined as <12.5 percent lifetime risk of breast cancer). From the perspective of risk modeling, 23.5 percent of our patients carry the majority of high and moderately high risks collectively. We currently contact all high-risk patients we have screened and see them in consultation to discuss this model and enroll them into our high-risk (unaffected) breast clinic. Our plan is to expand this model to include both the high- and moderate-risk groups that could each benefit the most from this approach of risk reduction via our integrative medicine team (see Figure 1, page 30). Plans include duplicating this model for other cancer types where we identify modifiable risks.

Our integrative medicine and wellness team is a valuable part of this risk model by offering lifestyle choices, which we believe can be as preventative as other modalities, and it is affordable and certainly less invasive. By offering risk reduction through education about BMI, exercise, diet, stress reduction, alcohol moderation, and smoking cessation, among others, we feel that we can lower the chances of developing cancer as much via alternative and complementary approaches as we can through traditional medicines. In other words, we believe that the effects of these modifiers can be as powerful in relative risk reduction, especially if patients are empowered with this information.

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BY KATHLEEN LARAIA, MS, AND KENDRA G. WORDEN MSN, FNP-C, AOCNP

A Rural Healthcare System Expands Cancer Care with a "Hub and Spoke" Model

According to the American Society of Clinical Oncology (ASCO), the number of practicing oncologists has not kept pace with the growing demand for cancer treatment as baby boomers continue to age, resulting in a shortage of qualified oncology providers in many parts of the country.[1] This physician shortage—and other obstacles to care—is especially prevalent in rural settings.

The seven Munson Healthcare hospitals in northern Michigan are designated by the Centers for Medicare & Medicaid Services as either sole community hospitals or critical access hospitals. Among other factors, these designations indicate a degree of inaccessibility to local hospitals due to regional topography (there are many large lakes in this region, some with drawbridges) or the presence of prolonged, severe weather conditions (Grand Traverse County in Michigan averages 118 inches of snow per year). Munson Healthcare hospitals are located an average of 35 miles apart, and driving conditions make travel time between them at least 45 minutes.

In rural communities such as ours, geographic distances and economic factors often have a negative effect on patient access to specialized providers and timely treatment. Munson Healthcare's oncology service line serves patients in 27 counties located in the lower northern region of Michigan and in the eastern upper peninsula. Many of our patients travel more than 50 miles to receive oncology care.

When an area is medically under-resourced, it can have a negative effect on care coordination, leading to delays in advanced imaging, diagnostic procedures, and surgical interventions. Advanced practice providers (APPs)—which our system defines as both nurse practitioners and physician assistants—can help improve access to quality care in the rural setting.

In many rural areas, a lack of primary care and regular screening result in cancer being detected in emergency departments at advanced stages. Such cases require intense intervention and result in lower success rates than cancers discovered earlier through primary care management and regular screening.

Recruiting providers into rural areas is challenging. Providers in sparsely developed regions earn less than their urban counterparts and must treat populations strewn over hundreds of miles. There are other impediments as well. Spouses may be unable to find work in rural regions, and compensation is comparatively low. Employers in Traverse City, Mich., are said to advise potential employees that they will earn "a view of the bay, for half the pay." Subsequently, physicians and physician specialists in urban areas far outnumber those in rural communities (Table 1, below).

When an area is medically under-resourced, it can have a negative effect on care coordination, leading to delays in advanced imaging, diagnostic procedures, and surgical interventions. Advanced practice providers (APPs)—which our system defines as both nurse practitioners and physician assistants—can help improve access to quality care in the rural setting. To better leverage APPs, improve APP/physician partnerships, and ease transportation challenges for our rural patients, Munson Healthcare's oncology service line implemented a physician/APP "Hub and Spoke Model of Care" (see Figure 1, right).

Hub and Spoke Model

Munson Healthcare's hub and spoke model of its oncology service line was developed over a period of four years from 2016 to 2020 (Figure 2, page 42). The "hub" is Cowell Family Cancer Center, located in Traverse City on the campus of the Munson Medical Center (MMC). It is a 400-bed tertiary care hospital that houses most of the health system's major oncology services, including radiation oncology, gynecologic oncology, cardiothoracic surgery, neurosurgery, and urologic and colorectal surgery, as well as advanced diagnostic services, a compounding pharmacy, and inpatient care. The "spokes" consist of five sole community and/or critical access hospitals that offer medical oncology clinics and infusion services and two outpatient health centers that host therapeutic infusion services. These regional cancer clinics provide medical oncology consultation and follow-up, chemotherapy, therapeutic infusion services, and survivorship care.

We implemented a physician/APP model at each of our regional clinics. Under this model, Munson's eight medical oncologists practice at the Cowell Family Cancer Center and travel to the regional clinics to conduct weekly clinics. They work in tandem with APPs who provide daily oversight of the operations, management, and provision of care at these regional clinics.

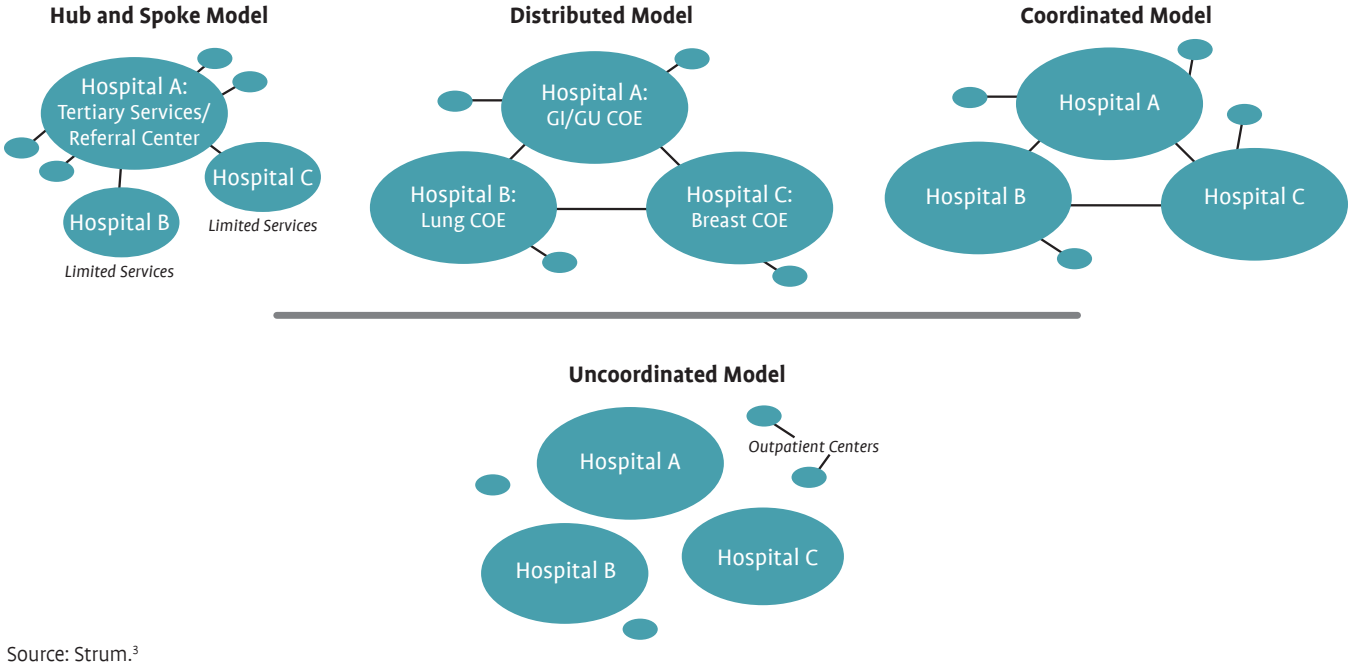
In an effort to treat patients in the communities where they live, new patients can access our service line via an initial consult

Table 1. National Rural Health Snapshot

	Rural Setting	Urban Setting
Percentage of population	19.3%	80.7%
Number of physicians per 10,000 people	13.1	31.2
Number of specialists per 100,000 people	30	263
Population aged 65 and older	18%	12%
Average per capita income	$45,482	$53,657
Non-Hispanic white population	69-82%	45%
Adults who describe health status as fair/poor	19.5%	15.6%
Adolescents who smoke	11%	5%
Male life expectancy (in years)	76.2	74.1
Female life expectancy (in years)	81.3	79.7
Percentage of dual-eligible Medicare beneficiaries	30%	70%
Medicare beneficiaries without drug coverage	43%	27%
Percentage covered by Medicaid	16%	13%

Source: Reproduced with permission from the National Rural Health Association[2]

Figure 1. Regionalization Framework: Regional Service Line Models



Source: Strum.[3]

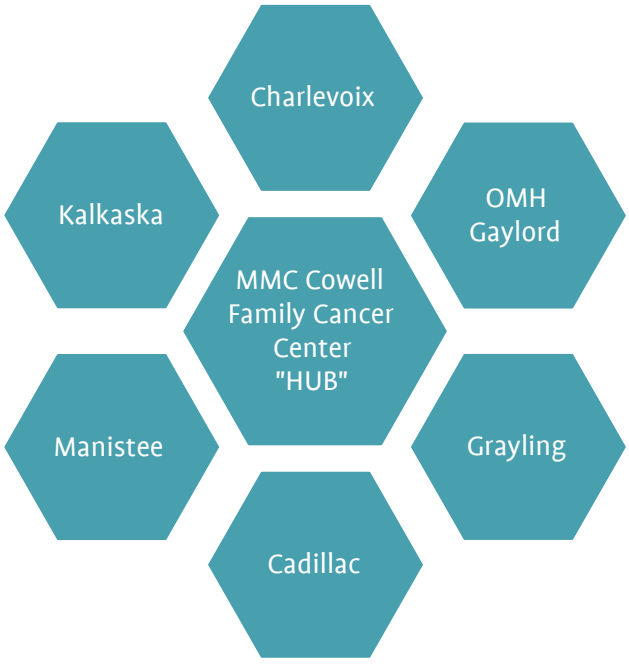
at Cowell Family Cancer Center or at any of these regional clinic locations, where APPs initiate care coordination with patients' primary care physicians, specialists, and necessary diagnosticians. Advanced diagnostics and surgical interventions are typically performed at Cowell Family Cancer Center, with follow-up care and chemotherapy delivered at the regional clinics. For patients who must travel to Cowell Family Cancer Center to receive care, Munson Medical Center provides housing at a nominal cost at its 30-bed manor, in addition to two RV hook ups for those with mobile housing.

Four outpatient APPs and three inpatient APPs located at Cowell Family Cancer Center collaborate closely with and support our medical and gynecologic oncologists. Cowell Family Cancer Center's medical oncology outpatient APP team is responsible for:

- Triaging symptoms
- Administering same-day visits for acute symptom management
- Providing guidance to infusion suite nurses
- Conducting patient survivorship visits and chemotherapy education
- Making appropriate outbound referrals
- Performing bone marrow biopsies
- Seeing patients for on-site treatment office visits and routine follow-up care.

We now offer same-day appointments with APPs, which has increased the number of patients evaluated and managed in outpatient settings, thereby decreasing emergency department visits and maintaining continuity with known providers.

Figure 2. Munson Healthcare's Hub and Spoke Model of Care Delivery



A gynecologic oncology APP offers both inpatient and outpatient care. This provider is responsible for admitting patients, monitoring patients during a hospital stay, and discharging patients from the hospital. This APP also sees patients in the outpatient setting, coordinating chemotherapy care at the regional clinics, overseeing patient care during chemotherapy treatment, managing patient side effects, and providing survivorship visits.

Most patients alternate their visits between an APP and a physician throughout the course of treatment. Munson's hub and spoke model has streamlined our clinic schedules, allowing our physicians to see more new patients sooner after their referrals. Adding APPs to the provider mix has also allowed patients to be seen on schedule and at appropriate intervals throughout the course of their treatment. We now offer same-day appointments with APPs, which has increased the number of patients evaluated and managed in outpatient settings, thereby decreasing emergency department visits and maintaining continuity with known providers.

This collaborative approach to cancer care has significantly increased provider availability at Cowell Family Cancer Center. The hub and spoke model of care has also improved patient satisfaction, increased the availability of physician providers at the regional clinics, and improved access to oncology care for northern Michigan's rural populations.

Inpatient Services

The provision of specialty care at a community hospital located in a rural healthcare system poses unique staffing challenges that an academic medical center or urban hospital may not experience. Though some consider it advantageous to have only attending physicians care for patients in this setting, a lack of medical students, residents, interns, and fellows creates a staffing shortage when the number of physicians is inadequate. By expanding our provider pool to include APPs in the inpatient setting, we have been able to close this physician gap and streamline the care of oncology patients in our hospitals.

Inpatient care is delivered at the Cowell Family Cancer Center via a coordinated transfer process. Having inpatient APPs provide this care allows patients to receive more timely consultations, procedures, admissions, and/or discharges. Inpatient APPs communicate directly with physicians who both direct inpatient care and conduct outpatient clinics at the Cowell Family Cancer Center or at one of the regional clinics. A physician does inpatient rounds either after clinic hours or prior to the start of the next day. This schedule improves care coordination in both the inpatient and outpatient settings, allowing treatment to continue without delay, and results in fewer physician interruptions during busy clinic days.

Multidisciplinary Care

In fall 2014, Munson's oncology service line launched its first multidisciplinary clinic—the Multidisciplinary Thoracic Oncology Program—an APP-led clinic that cares for newly diagnosed thoracic oncology patients. Individuals with cancers of the mid/distal esophagus, lung, or thymus are referred to the clinic by their treating provider (often their primary care provider, pulmonologist, or gastroenterologist). An APP screens all referrals for appropriateness, triages patients based on clinical need, and orders any necessary diagnostic tests to ensure that patients are completely staged by the time of their first thoracic oncology clinic visit. As directed by the APP, thoracic oncology staff facilitate any necessary staging studies, which are coordinated by a nurse navigator.

Once patients are prepared for their first visit, thoracic oncology staff initiate contact with patients, provide an overview of the clinic's services, and schedule patients for a day of coordinated multidisciplinary visits. On the day of their visit, patients are met by an APP, radiation oncologist, medical oncologist, and cardiothoracic surgeon. Patients are seen, examined, and interviewed by each of the providers during their program day, and their staging studies, diagnosis, prognosis, and potential treatment options are explained by the multidisciplinary team. This weekly clinic also includes a tumor board, in which a radiologist reviews all pertinent imaging, pathology presents tissue pictures and an overview of the pathological nature of the malignancy, and physicians present a treatment plan for each patient.

APPs summarize and present final recommendations to patients and then answer any questions. Patients also meet with other ancillary service providers during this visit, including a nurse navigator, palliative care provider, dietitian, social worker, financial navigator, and cancer researcher, as appropriate. Thoracic oncol-

Cowell Family Cancer Center - Munson Medical Center, Traverse City, Mich.

ogy patients leave their clinic day with a complete itinerary of the next steps in their treatment plan.

Throughout a patient's treatment journey, an APP acts as a liaison between the patient, referring provider, and all ancillary services. APPs and the thoracic oncology clinic team collaborate closely with medical oncology, radiation oncology, and cardiothoracic surgery providers to ensure good communication within the patient's team. The APP-led thoracic oncology clinic has expedited the workup of newly diagnosed patients, many of whom travel great distances for their care, improving the timeliness of initiating treatment after a new diagnosis.

Also part of an APP's responsibilities in the thoracic oncology clinic is oversight of our Lung Screening Program in collaboration with community primary care physicians. Smoking creates one of the top health disparities within northern Michigan's rural regions, which led Munson to offer low-dose computed tomography screening. Within the Munson Healthcare system, 4,813 lung cancer screening tests were performed from September 2015 through September 2019. These screenings identified 54 lung cancer cases, of which 47 were non-small cell lung cancers. Coordination, counseling, and follow-up for these patients is a collaborative effort among oncology APPs, the radiology team, and community primary care physicians. Our oncology service line has also created the Tobacco-Free Coalition of Northern Michigan to develop smoking cessation strategies in concert with our community partners.

Practice Economics

In 2018, an ASCO survey on the state of oncology practice in America found that the main sources of strain for oncologists are

payers, staffing, prior authorization pressure, and electronic health record burdens.[4] These pressures coupled with a volatile and uncertain reimbursement climate have resulted in many oncology practices consolidating or affiliating with larger health systems. The oncology specialists that are affiliated with Munson Healthcare have done so through professional services agreements (PSAs). Physician reimbursement in many PSAs is based on a dollar rate per worked relative value unit, which can discourage the use of APPs.

When physician reimbursement is based on specific, direct interactions with patients, there exists a monetary motivation for physicians to assume most patient care themselves rather than delegate aspects of care to APPs. Because physicians have only so much time in their schedules to see patients, patients must therefore wait for appointments, decreasing their access to care. To enable APPs to see patients directly and pick up that slack, Munson Healthcare has created a PSA compensation model that encourages the use of APPs within the outpatient setting. This model projects an expected full-time equivalent utilization model that defines compensation for physician supervision of APPs.

As Munson Healthcare integrates its APPs into the PSA model, we are looking for opportunities to shift appropriate responsibilities to APPs, thus creating more efficiencies and greater patient access to care. Munson Healthcare APPs contribute significantly to the care and management of oncology patients within our vast catchment area. The primary responsibilities for APPs now include:

- Transition of care from primary care physicians (suspected or new cancer diagnosis)
- Chemotherapy education and management
- Symptom management
- Mentorship and onboarding of other APPs and continued competency through ongoing professional practice evaluation/focused professional practice evaluation
- Bone marrow biopsy procedures
- Inpatient care management
- Peer-to-peer prior authorization with payers
- Palliative care
- Survivorship care.

The aging population in northern Michigan is increasing at a greater rate than the state's overall population, resulting in an increase in new and recurring cancer rates in the area. At the same time, the number of oncology specialists in rural areas is declining or becoming stagnant. According to ASCO's 2018 report, The State of Oncology Practice in America, more than 90 percent of oncologists practice in non-rural areas.[5] A study commissioned by ASCO in 2014 predicted a shortage of oncologists in the United States by 2025 due to an aging workforce as well as increased numbers of cancer survivors.[5] Munson's hub and spoke physician/APP model looks to address both increased patient demand and challenges related to adequate provider staffing, retention, and compensation. Bottom line: Our concerted effort to recruit, implement, and utilize advanced practice providers allows us to deliver accessible, coordinated, and efficient care for all of our oncology patients. OI

Munson Healthcare Oncology Service Line at a Glance

Oncology providers

- 8 hematology oncologists
- 5 radiation oncologists
- 1 gynecologic oncologist
- 15 APPs (13 nurse practitioners, 2 physician assistants)

Locations

- 7 clinic locations
- 94 infusion chairs

Patients

- 3,600 new patient visits annually
- 2,200 analytic cases annually
- 94,375 patient visits

Patient experience

- Overall Press Ganey top box score improved 4 percentage points

Kathleen LaRaia, MS, is executive director and Kendra G. Worden, MSN, FNP-C, AOCNP, is a nurse practitioner at Oncology Services, Multidisciplinary Thoracic Oncology Program and Patient Navigation, at Munson Medical Center in Traverse City, Mich.

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Additional Resources

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NPAF National Patient Advocate Foundation

The American Society of Breast Surgeons

AOSW Association of Oncology Social Work Excellence in Psychosocial Oncology

APSHO Advanced Practitioner Society for Hematology and Oncology

Metastatic Breast Cancer MBCalliance together we are stronger than the disease

NCCS National Coalition for Cancer Survivorship

CancerCare

ACCC Association of Community Cancer Centers

The **Association of Community Cancer Centers (ACCC)** is the leading education and advocacy organization for the cancer care community. Founded in 1974, ACCC is a powerful network of 25,000 multidisciplinary practitioners from 2,100 cancer programs and practices nationwide. As advances in cancer screening and diagnosis, treatment options, and care delivery models continue to evolve–so has ACCC–adapting its resources to meet the changing needs of the entire oncology care team. For more information, visit accc-cancer.org or call 301.984.9496. Follow us on Facebook, LinkedIn, Twitter, and Instagram; read our blog, ACCCBuzz; and tune in to our podcast, CANCER BUZZ.

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Maintaining Patient Connections with Online Support Groups

COVID-19 has brought change for all of us, but for cancer patients and survivors that change has been particularly profound. Whether they are in active treatment or survivorship, people living with cancer often experience significant physical limitations, and this pandemic has put considerable restraints on aspects of all of our lives.

The accompanying loneliness that this isolation can bring has no easy remedy. Before COVID-19, many patients, survivors, and caregivers had the option of attending support groups that brought them into the company of other people also living with cancer. The effect that such groups can have on the lives of patients and their loved ones is often significant. Being able to communicate with others experiencing common challenges is a powerful coping tool.

Part of the hardship of COVID-19 is that the imperative to stay well by sheltering in place eliminates the option for group gatherings and other much-needed sources of peer support. As the pandemic swept the nation earlier this year, and as healthcare facilities subsequently closed their doors, support groups and services were among the first casualties. Patients accustomed to regularly coming together to share their challenges and triumphs were suddenly confined to their homes.

As with many other groups and organizations, some cancer programs and practices have reached out to their patients virtually to provide the encouragement they once enjoyed in face-to-face support groups. Since March 2020, Elizabeth Bornstein, MSSA, LCSW, OSW-C, APHSW-C, an oncology clinical counselor at the Sarasota Memorial Cancer Institute in Florida, has helped the patients she once counseled in person transition to virtual sessions.

"My mission has been to meet and help people where they are," says Bornstein. "Since March, Florida residents have had to hunker down at home, and that includes our cancer patients and their loved ones. So for them to be able to step out of their isolation, even for just a little bit each week, and to feel a sense of connection to others going through similar situations, is so important."

> Our groups are facilitated by a range of professionals: nurse navigators for networking and education groups, licensed mental health professionals for weekly support groups, and certified practitioners and instructors for the other groups.

Bornstein spoke to *Oncology Issues* about how she was able to keep the lines of communication among patients open after her clinic's doors closed.

Q. Tell us about Sarasota Memorial Cancer Institute.

A. Sarasota Memorial Health Care System is located in Sarasota, Fla. Founded in 1925, this 839-bed regional medical center is one of the largest public community health systems in the state. It has a comprehensive range of services, with specialized expertise in heart, vascular, cancer, orthopedic, and neuroscience services, as well as a network of outpatient centers. We also have urgent care centers, laboratories, diagnostic imaging, physician practices, skilled nursing, and rehabilitation programs. It is the only hospital in Sarasota County that provides obstetrical services, pediatrics, Level III neonatal intensive care, psychiatric services, and a Level II trauma center.

When it is completed in 2021, the Sarasota Memorial Cancer Institute oncology tower will serve as the heart of Sarasota Memorial Health Care's evolving cancer program. From the ground up, the oncology tower is designed to provide a patient-centered environment for services that cover the entire continuum of cancer care---from prevention, screening, and diagnosis to treatment, clinical trials, follow-up, survivorship care, and support.

In 2019 the Cancer Institute began a major expansion of its services with the groundbreaking of an oncology tower on the main campus and a radiation oncology center at a satellite campus. When all phases of the expansion are complete, the Cancer Institute will provide the full spectrum of patient-centered cancer services.

Q. What support groups do you provide?

A. About two years ago, we took responsibility for a range of cancer support and wellness programs that we had previously collaborated on in our community. We became responsible for 20 groups with 75 meetings happening each month. All groups are under the umbrella of our integrative cancer support and wellness services known as the Thrive Program.

All of these groups were ongoing prior to COVID-19. They are all outpatient and meet at different locations in our community. People with cancer and their loved ones could attend based on what was most interesting, helpful, and convenient for them location-wise, and they had free access to all of them.

Q. What were your groups like before the coronavirus struck?

A. Of the 20 groups, some are cancer-specific monthly, weekly, and bi-weekly gatherings, and they include networking and education groups, support groups, arts-based groups, and others, such as meditation, yoga, tai chi, and qigong. They were happening at different locations until March, when we put the Thrive Program on hold because of COVID-19. We serve a community with a predominantly senior population and our groups are open to adults of all ages.

Our groups are facilitated by a range of professionals: nurse navigators for networking and education groups, licensed mental

Sarasota Memorial's Radiation Oncology Center is a 17,000-square-foot facility that offers two state-of-the-art linear accelerators for external beam radiation and an array of integrative care services to support holistic patient care.

health professionals for weekly support groups, and certified practitioners and instructors for the other groups. I facilitate a weekly patient support group and a weekly patient and caregiver support group with a nurse navigator, and a colleague facilitates a weekly caregiver support group. Our goal has been to provide these groups in person for our local community members who can benefit from these connections with one another close to their homes.

Q. What happened to your groups once social distancing became necessary?

A. Out of an abundance of caution and due to social distancing guidelines, we put our groups on hold in the beginning of March at the direction of our leadership. Knowing how important these groups are for connection and support, I was very concerned about abruptly ending them. I reached out to each of the group members by phone, just checking in on how they were doing in the midst of COVID-19 and asking how they were going about their day-to-day lives.

My colleague who facilitates the caregiver group was doing the same. In conversations with our Thrive coordinator, I expressed concerns about the level of isolation our patients and their loved ones were experiencing with their groups being on hold. I offered to pilot the virtual groups, and the decision was made to move forward. We knew it was the right thing to do.

Since we already knew the people coming to the groups every week and we had already completed their registration forms, we felt comfortable moving ahead. We consulted with our legal department and were told our existing registration forms were sufficient. We decided we would wait before adding additional group members until we had a comfort level with the virtual process. We informed our group participants about our move to virtual groups and gave them instructions and practice options. I began conducting support groups virtually in the last week of March, and my colleague began her group in the beginning of April.

The lobby of Sarasota Memorial's Radiation Oncology Center.

Q. Which platform do you use to host your virtual groups?

A. Our health system had already started using a Cisco platform called the Meeting App. It is simple and easy to use and had already been implemented in multiple areas of our health system, including Outpatient Behavioral Health and Oncology Counseling programs. It made logical sense to use a platform that was already proving successful in other areas. We were given training and written guidelines on how to arrange groups and invite participants to them. I learned to manage access to the groups, and I created a participant user guide to share with our group members.

Q. Did you encounter any technology or learning roadblocks?

A. The biggest challenge was that many participants had never used video conferencing like this before, so they didn't really know the etiquette or what steps to take to join.

I shared with participants the instructions that we created, and I offered initial and ongoing support as needed, including practice time to master the process of logging on. I gave participants a backup plan if something went awry with their video, so they could always call in on the phone. In one of our weekly groups, the majority of people were not initially comfortable with using the video, so we opted to use audio only for that group.

We decided to use the call-in option as a backup, as with technology connectivity can always go awry. There is a high level of uncertainty with COVID-19, so we didn't want the technology to cause undue stress for our participants. We provided reassurance and reminded the participants that the goal is to stick together no matter what challenges come our way.

Q. Is it more challenging serving patients in this space?

A. Access to and understanding of technology is a barrier for groups like ours and for people in general who want to stay connected with their family and loved ones during this time. It can be overwhelming and anxiety-provoking for people not accustomed to using this technology.

I wish there were an easier way for the mostly senior elders and people who are underserved in our community to access this technology. When people don't have access to tools to connect with one another, it is so isolating. When people do have the right tools and assistance, they are able to access the technology and join groups. Family members have come through in getting participants computers or tablets, so they can get involved in the video component of the groups. Even if we are only able to have participants join groups by audio, it is quite meaningful.

In our groups, we celebrate when we are able to connect and maintain our connections in any way possible. Whether via audio or video, we have proven that our patients can stay connected to one another. It is working so well, we've decided to add new participants as they express interest. We are completing the registration forms with them ahead of time by email or postal service and then training these new participants on how to join the groups when they meet.

As we well know, cancer doesn't go away because of a pandemic. Our group participants have still had to undergo tests, procedures, and treatments, as well as make difficult decisions, for example, about end of life. COVID-19 has certainly made living with cancer more challenging. Virtually, we've shared our sorrows and grief and have still managed to find a way for warmth, compassion, and connection to shine through.

Q. Do you have concerns about patient privacy?

A. Privacy is definitely a concern. That's one reason we were reluctant to explore any kind of virtual group previously. We can't really know who is in each person's home space. We can't control who is listening. We established ground rules and review them as part of our weekly support groups. We emphasize that privacy is of the utmost importance, and what is shared in the group stays in the group. We also remind participants each week that even though we're sitting in our offices, or our living rooms, or our kitchens, these are still support groups. This is an opportunity for each person to share openly, and our privacy depends on an honor code. We emphasize that to make sure people really understand.

Our health system selected the Cisco application in part because it is HIPAA compliant. Even though regulations are being relaxed right now during COVID-19, we really wanted to start this online effort on the right footing and have everything that we need in place for the long term. So we picked that platform intentionally. We're also using the existing registration form for entrance into our Thrive Program that is required for anyone participating in any of our groups.

Q. What do you think the future holds for your program's support groups?

A. If we had a magic wand, we would go back to the way it was before COVID-19. We hope the future can bring some level of normalcy soon. Originally, when we put our groups on hold, we anticipated that they would continue online until mid-April, when we would return to the office, but things have changed quite a bit since then. There's a lot of uncertainty we hadn't anticipated, so we're taking things as we go.

Q. Do you plan to expand these groups beyond their current membership?

A. Yes. We are in the process of bringing four of our monthly networking and education groups online. One is currently happening. We've also had interest in creating new weekly support groups, although we haven't embarked on that yet.

Virtual groups offer advantages particularly for people who are reluctant to leave their homes or who aren't feeling well enough to travel. Now that we've been offering our support groups online, I've heard interest from people all over our service area, some of whom have not previously attended in-person groups. Before, there was not enough participation to justify starting disease-specific weekly support groups, but now it seems there may be enough interest, particularly since people will not need to travel to their groups. Our Thrive Program is considering the potential options.

Q. Are there any lessons learned from your transition to virtual support groups that others may benefit from?

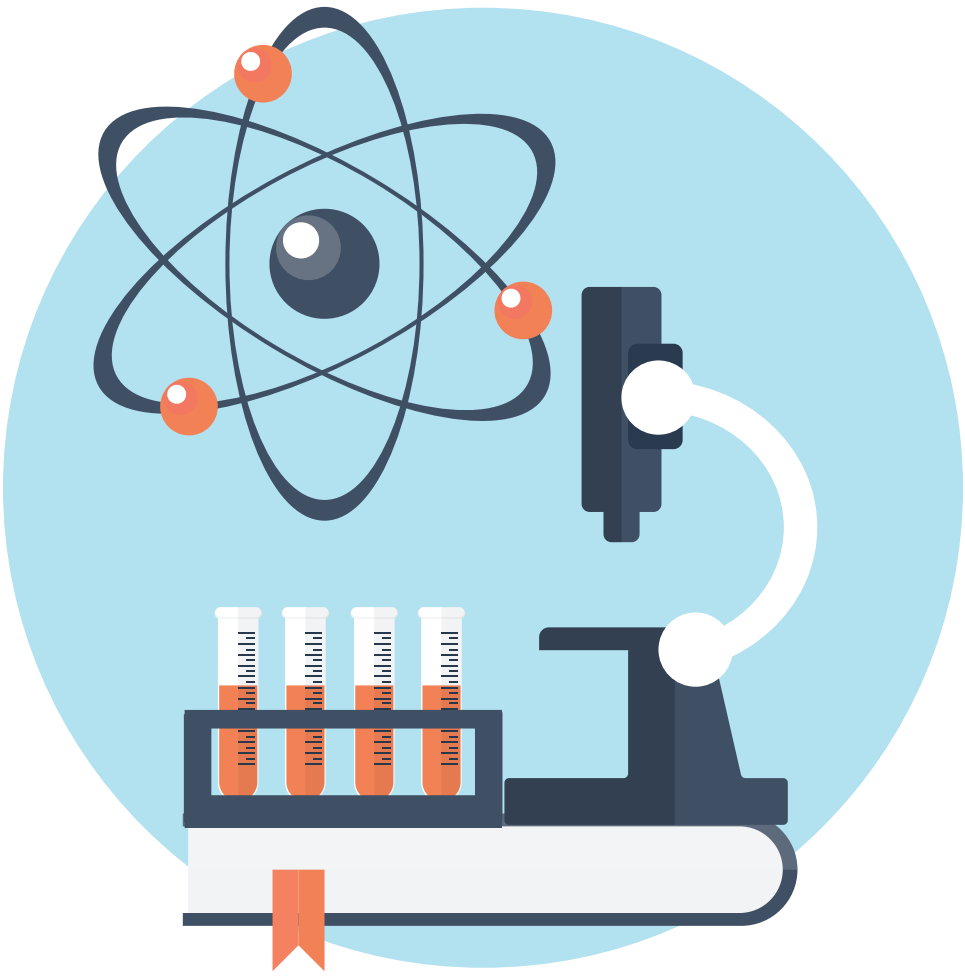
A. There are challenges with moving in-person groups to virtual groups in the way of completing screenings and registrations, maintaining privacy, addressing compliance concerns, and helping participants adjust to the necessary technology. Yet the benefits certainly outweigh the challenges, and it is well worth the effort. Virtual groups clearly foster and sustain human connection. As the uncertainty of the pandemic continues, our participants say that their virtual groups have been a lifeline, and they are grateful for them. We are committed to caring for our patients and their loved ones and continuing to make the groups happen.

Q. Any parting thoughts?

A. For cancer programs around the country considering moving their support groups online, I would say even with the unknowns and figuring it out as you go, in light of the times, it is critical to be able to offer support virtually. We've kept it simple, and we've found it's doable. Make it manageable by starting out small with a group or two. You can always expand once your comfort level grows.

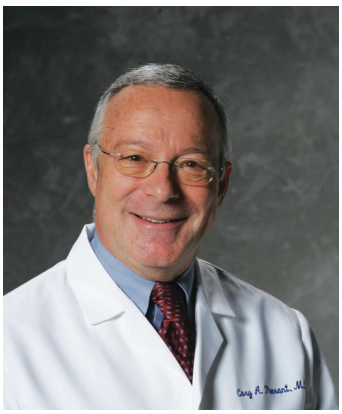
I encourage people to open their minds, find the resources, and make the time to figure out how best to offer something that will truly reach people in need. There are a lot of people with cancer in need of support and connection, especially now. COVID-19 isn't going away any time soon. Our patients and loved ones are depending on us to help them face the uncertainty of their cancer in the midst of this pandemic. Doing so together is the antidote for the understandable feeling of isolation while hunkering down at home. OI

Elizabeth Bornstein, MSSA, LCSW, OSW-C, APHSW-C, is an oncology clinical counselor at the Sarasota Memorial Cancer Institute, Sarasota, Fla.



Highlights from a Virtual ASCO 2020

BY CARY A. PRESANT, MD, FACP, FASCO



How does oncology survive the cataclysmic events of 2020? Once the national emergency of COVID-19 shut down all non-essential services and meetings, researchers and clinicians wondered how the American Society of Clinical Oncology (ASCO) was going to deal with the long-awaited presentations of data necessary to improve the care of cancer patients. Once the face-to-face meeting was canceled and replaced by a virtual event, oncologists had to reset their processes of understanding the importance of new scientific discoveries without the Chicago-based meeting.

As it turned out, ASCO staff and leadership held a sensational virtual meeting that streamed on small, personal screens throughout the world. It was attended by the largest number of participants in ASCO history, up to 43,000 individuals. The presentations were impressive. Listed below are my highlights of the ASCO 2020 abstracts, which were chosen if they were a practice-changing study or trial with important new advances.

COVID-19 and Cancer Patients

- In ***Abstract LBA110***, J. Warner et al. presented the outcomes of 1,035 patients proven to have COVID-19. Of the patients, 82% had solid tumors and 22% had hematologic malignancies (some had both). The hospitalization rate was 50%, 13% of patients died, and 14% were admitted to the ICU. Among patients with progressing cancer, mortality was 25%. Among those over the age of 75, mortality was 25%. The mortality rate among patients who received hydroxychloroquine was 2.6 times higher than among patients who did not receive hydroxychloroquine (patients were not randomized in this observational study).
- In ***Abstract LBA111***, L. Horn et al. presented the TERAVOLT study of 295 lung cancer patients with COVID-19 (82% NSCLC). Of the patients, 78% were hospitalized, and mortality was 36%. HR was 1.7 for patients over 65, 1.7 for patients receiving chemotherapy, and 1.04 for patients on IO drugs.

Breast Cancer

Localized disease

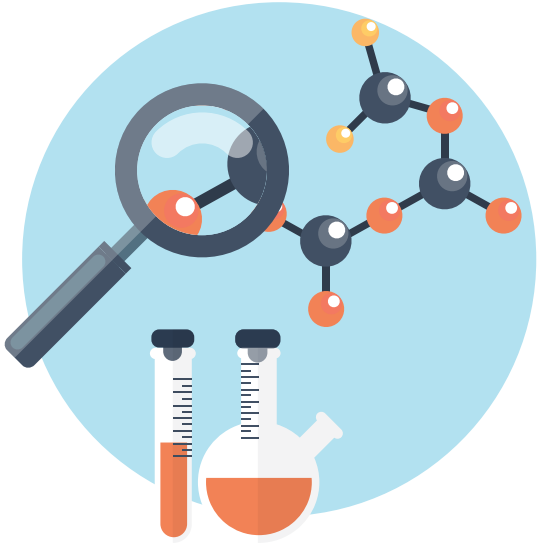
- In ***Abstract 500***, N. Harbeck et al. presented the KATLIN trial. Patients who had completed adjuvant doxorubicin plus cyclophosphamide were randomized to receive either trastuzumab plus pertuzumab plus a taxane (THP) or trastuzumab emtansine plus pertuzumab (KP). The invasive DFS was not different. However, the quality of life was inferior on THP, HR 0.71. Twenty-seven percent of patients on KP discontinued the treatment for toxicity. Cardiac toxicity occurred in 2.9% of patients with THP vs. 0.9% with KP. THP appears to remain the standard of care but with KP as an alternative for some patients.

ACRONYM LEGEND

ACP: Advanced care plans
AML: Acute myelocytic leukemia
APP: Advanced practice provider
CPS: Combined positive score
CR: Complete response
CRC: Colorectal cancer
DFS: Disease-free survival
EGFR: Epidermal growth factor receptor
EHR: Electronic health record
ELT: Early locoregional therapy
GA: Geriatric assessment
GIST: Gastrointestinal stromal tumor
HER2: Human epidermal growth factor receptor 2
HR: Hazard ratio
ICU: Intensive care unit
IO: Immuno-oncology
IS: Immediate surgery
ISCM: integrated supportive care model
MSI: Microsatellite instability
NN: nurse navigator
n.s.: Not significant
NSCLC: Non-small cell lung cancer
OS: Overall survival
PARP: Poly ADP (adenosine diphosphate)-ribose polymerase
PC: Palliative care
PD-L1: Programmed death-ligand 1
Pembro: Pembrolizumab
PFS: Progression-free survival
PR: Partial response
PTSD: Posttraumatic stress disorder
QOL: Quality of life
RCC: Renal cell cancer
RR: Response rate (CR+PR)
SOC: Standard of care
TKI: Tyrosine kinase inhibitor
TNBC: Triple-negative breast cancer
TP53: Tumor protein p53
VGPR: Very good partial response

Advanced disease

- In ***Abstract 1000***, J. Cortes et al. presented the results of Keynote 355. Patients with TNBC who were PD-L1-positive received chemotherapy (a taxane or gemcitabine plus carboplatin) with or without pembrolizumab. For all patients, PFS was 7.5 months with pembro vs. 5.6 months with placebo. For patients with higher PD-L1 (CPS >10), PFS was 9.7 months on pembro vs. 5.6 months on placebo, $p = 0.004$.
- In ***Abstract 1007***, A. Llombart-Cussac et al. presented the results of PARSIFAL. Patients received either letrozole plus palbociclib (PL) or fulvestrant plus palbociclib (PF). PFS was not different overall, but in patients who had previously failed an aromatase inhibitor, PFS was longer with PF, 27.5 months, compared to PL at 19.3 months, HR 0.86, n.s. Also, if patients had an ESR1 mutation after therapy, PFS was longer on PF, 27 months, compared to PL at 11 months, HR 2.3, $p = 0.001$.
- In ***Abstract 1005***, N. Lin et al. showed results of HER2CLIMB in patients with HER2-positive advanced disease. Adding tucatinib to trastuzumab plus capecitabine improved 12 month OS from 47% up to 71%, HR 0.58, $p = 0.005$.
- In ***Abstract LBA2***, S. Khan et al. evaluated patients with TNBC and compared ELT after 4 to 8 months of systemic therapy for metastatic disease vs. no ELT. Three-year OS was not different. Three-year locoregional recurrence was higher in patients without ELT, 25.6% vs. only 0.2% in patients with ELT, HR 0.37, $p = 0.003$. However, QOL at 18 months was worse with ELT than without ELT, $p = 0.01$, but QOL was not different at 30 months.



Cancer Prevention, Risk Reduction, and Genetics

- In ***Abstract 1500***, Z. Stadler et al. presented MSK-IMPACT. Of the 11,974 patients seen over 5 years who had an 88-gene test for germline mutations, 17.1% had pathogenic germline mutations and 7.1% had a targetable germline mutation. In BRCA1 or 2 mutation carriers, 44% received a PARP inhibitor. Of patients with Lynch syndrome and MSI-high, 66% received an IO drug.
- In ***Abstract 1506***, E. Swisher et al. presented results of MAGENTA. All patients at risk of hereditary breast-ovarian cancer watched an educational video before germline genetic testing. The authors compared actual genetic counseling pre-test vs. only post-test counseling vs. counseling pre-test and post-test. Distress at 3 months was 19% and non-inferior in all arms. Completion rate for genetic testing was higher with no pre-test counseling (88%) vs. with pre-test counseling (80%). Counseling can be reserved for patients with positive germline genetic tests.

- In ***Abstract 1507***, H. Rana et al. compared live genetic counseling with video education in patients with prostate cancer. There was no difference between live counseling vs. virtual education in receipt of testing (88% vs. 93%, respectively) and no difference in satisfaction or intent to disclose information to the family. Thirteen percent had pathogenic mutations.
- In ***Abstract 1514***, J. Weitzel et al. identified a method for avoiding false-positive tests for TP53 mutations due to aberrant clonal expression, important in properly identifying patients with Li-Fraumeni syndrome.

Cancer Care Delivery

- In ***Abstract 2000***, O. Mir et al. compared use of an NN who held weekly calls for 1 month and then every other week using a mobile application vs. SOC in patients receiving oral chemotherapy. Dose intensity was 0.93 with NN vs. 0.89 with SOC, $p = 0.04$. Hospitalization was 23% for NN patients vs. 32% for SOC, $p = 0.02$. NN showed high-value outcomes.
- In ***Abstract 2002***, L. Calvetti et al. compared home management with nurse telephone triage vs. historical controls. Hospitalization was reduced from 14.7% to 10.1%, $p = 0.002$.
- In ***Abstract 2003***, A. Lee et al. compared care before 1999 and after the Affordable Care Act of 2017 in states that expanded Medicaid (EXP) vs. states that did not. Mortality per 100,000 people was reduced more in states with EXP (65.1 down to 46.3) compared to no EXP (69.5 down to 52.3). There was less difference in African American patients compared to a greater difference in Hispanic patients.
- In ***Abstract 2006***, K. Vokinger et al. compared drug prices at drug launch in the United States vs. Europe (Germany, Switzerland, and England). Launch prices in the United States were 186% to 215% higher than in Europe. After launch, prices decreased in 86% to 90% of drugs in Europe, compared to decreases in only 19% of drugs in the United States.
- In ***Abstract 2024***, J. Kaltman et al. showed shorter median hospital length of stay (2 days) in patients with hematological malignancies or solid tumors if they had pre-hospital ISCM (including palliative care, psychiatry, psychology, interventional pain consult, social work, child life care, and distress screening) compared to having ISCM only after admission (length of stay 6 days), $p = 0.001$.

Colorectal Cancer

- In ***Abstract LBA4***, T. Andre et al. presented findings from Keynote 177 in patients with untreated metastatic CRC and MSI-high. Patients received either pembro or FOLFOX or FOLFIRI (control). PFS at 24 months was 48% for pembro vs. 19% for control, HR 0.6, $p = 0.0002$. Duration of response over 24 months was 83% with pembro vs. 35% with control.
- In ***Abstract 4000***, S. Siena et al. presented findings from the Destiny CRC01 trial. Patients with HER2-positive CRC received trastuzumab emtansine. RR was 45.3% and PFS was 6.9 months (compared to historical controls with regorafenib

(1% RR and 1.9 months PFS) or TAS102 (1.6% RR and 2.0 months PFS).

- In ***Abstract 4001***, S. Kopetz et al. presented results from BEACON CRC. Patients after one to two prior lines of treatment with a BRAF V600E mutation received triplet (encorafenib plus binimetinib plus cetuximab) vs. doublet (no binimetinib) vs. control FOLFIRI plus cetuximab (or irinotecan plus cetuximab). Median OS was 9.3 months on triplet, 9.3 months on doublet, and 5.9 months on control. HR was 0.60 vs. control.
- In ***Abstract 4002***, S. Lonardi et al. presented findings from PANDA in RAS/RAF wild-type patients over 70. PFS was similar in patients who received FOLFOX plus panitumumab (9.6 months) compared to 5FU plus panitumumab (9.1 months). Toxicity was higher with FOLFOX for neurotoxicity (3% vs. 0%), stomatitis (9.8% vs. 4.4%), and diarrhea (16.3% vs. 1.1%).
- In ***Abstract 4005***, Y. Kanemitsu et al. presented results of JCOG 0603. Patients after attempted curative resection of liver metastases from CRC received adjuvant mFOLFOX6 for 12 cycles or no therapy. Five-year DFS was 50% for FOLFOX vs. 37% for no therapy, HR 0.6, $p = 0.002$, but OS was not different.
- In ***Abstract 4018***, M. Fakih et al. presented findings from CodeBreak 100. Patients with KRAS G12C mutation were treated with the inhibitor sotorasib (AMG 510). All patients had received prior standard therapy, and 45% had received four or more prior therapies. PR was 7.1% but disease control was 76%. PFS was 4.0 months.
- In ***Abstract 4020***, A. Marabelle et al. studied patients with anal squamous cell cancer who received pembro. Seventy-three percent of patients were PD-L1-positive and 14% had CR or PR. Patients who were PDL1-negative had 3.3.% CR or PR. Duration of response was more than 24 months in 84.6%.

Gastrointestinal, Non-colorectal, and Pancreatic Cancer

- In ***Abstract 4504***, D. Sohal et al. compared patients with pancreatic cancer treated with neoadjuvant mFOLFIRINOX for six cycles vs. neoadjuvant gemcitabine plus nab-paclitaxel (GP) for nine doses. In all patients, neoadjuvant chemotherapy was followed by surgery and then post-op chemotherapy. Two-year OS was 43% for mFOLFIRINOX vs. 47% for GP. At surgery, pathologic CR or major response was seen in 25% for mFOLFIRINOX vs. 42% for GP.
- In ***Abstract 4505***, P. Ghaneh et al. compared IS for pancreatic cancer vs. neoadjuvant gemcitabine plus capecitabine followed by surgery (GC) vs. neoadjuvant FOLFIRINOX followed by surgery vs. neoadjuvant combined chemotherapy plus radiation therapy followed by surgery (CRT). Twelve-month OS was 42% for IS, 79% for GC, 84% for FOLFIRINOX, and 64% for CRT. Neoadjuvant therapy was superior to IS, HR 0.27, $p = 0.001$.

Genitourinary Cancer

Prostate cancer

- In ***Abstract 5602***, N. Shore et al. presented results from the HERO study. Patients with androgen-sensitive metastatic prostate cancer received the oral GnRH antagonist relugolix (R) or leuprolide acetate (L). Sustained castration rate was 97% for R vs. 89% for L, $p = 0.0001$. Prostate specific antigen (PSA) response at day 15 was 79% with R vs. 20% with L, $p = 0.0001$. Recovery of testosterone to over 50 mg/ml was seen in 30 days for R vs. only after 90 days for L. Major cardiac events were seen in 3.9% with R vs. 7.1% with L.

Non-prostate, renal cell cancer

- In ***Abstract 5001***, E. Plimack et al. reported data from Keynote 426. Patients with first-line advanced RCC received either pembro plus axitinib (PA) vs. sunitinib (S). Twenty-four month OS was 38.5% for PA vs. 27% for S, HR 0.68.
- In ***Abstract 5013***, S. Pal et al. reported on the combination of atezolizumab plus cabozantinib. RR was 27%, disease control was 64%, and PFS was 5.4 months.
- In ***Abstract LBA1***, T. Powles et al. reported on JAVAELIN Bladder 100 in bladder cancer patients without progression after four to six cycles of gemcitabine plus a platinum drug. OS was 24 months with maintenance avelumab vs. 14.3 months with best supportive care, HR 0.69, $p = 0.001$. In PD-L1-positive patients, 18-month survival was 70% for avelumab vs. 48% for best supportive care.
- In ***Abstract 5078***, N. Dizman et al. showed that taking probiotics before TKI therapy of RCC changed gut microbiome favorably. Patients with favorable microbiome had 92% clinical benefit vs. 50% in patients without favorable microbiome, $p = 0.036$.

Gynecologic Cancer

- In ***Abstract 6000***, A. Du Bois et al. presented data from DESKTOP1111. Patients with ovarian cancer at first relapse and eligible for disease-reducing surgery received IS and then chemotherapy or chemotherapy immediately. OS was 53.7 months for IS vs. 46.0 months for no IS, HR 0.75, $p = 0.02$.
- In ***Abstract 6002***, A. Poveda et al. presented findings from SOLO2. Patients with platinum-sensitive relapse who had responded to recent platinum therapy and who had BRCA mutation received either olaparib (O) or placebo (P). OS was 51.7 months for maintenance O vs. 38.8 months for P, HR 0.74, $p = 0.05$. At 60 months, survival was 42% for O vs. 33% for P.

Head/Neck Cancer

- In ***Abstract 6502***, N. Kiyota et al. studied patients with stage III and IV cancers with positive margins or extranodal extension after surgery. Patients receiving weekly cisplatin plus radiation therapy (Q1W) were compared to patients receiving cisplatin every 3 weeks plus radiation therapy (Q3W). Three-year OS was 72% with Q1W vs. only 59% for Q3W, HR 0.69, $p = 0.003$.

Hematologic Malignancy

Acute myelocytic leukemia

- In ***Abstract 7501***, C. Dinardo et al. compared primary therapy in patients with IDH2 mutation using enasidinib plus azacytidine (EA) vs. azacytidine alone (A). CR was achieved in 71% with EA compared to 42% with A. Event-free survival was 17.2 months with EA compared to 10.8 months with A.

Waldenstrom's macroglobulinemia

- In ***Abstract 8007***, C. Tam et al. compared zanabrutinib (Z) and ibrutinib (I) in the ASPEN trial. CR+VGPR rate was 28% for Z and 10% for I, $p = 0.09$. Atrial fibrillation occurred in only 2% on Z vs. 14% on I. Hypertension was 11% on Z vs. 16% on I. There were less pneumonia and less discontinuation on Z.

Hodgkin's disease

- In ***Abstract 8005***, J. Kuruvilla et al. presented data from Keynote 024. In patients with relapsed/refractory classic Hodgkin's disease, PFS in patients receiving pembro was 13.2 months vs. 8.3 months with brentuximab vedotin, $p = 0.003$.

Myeloma

- In ***Abstract 8506***, P. Hari et al. presented findings from the BMT CTN 0702 (STaMINA) trial. Patients who were in remission after autologous transplant (one or two transplants) with or without lenalidomide (L) plus bortezomib plus dexamethasone were randomized at 38 months to continued maintenance L or no continued L. Five-year PFS was 86% on continued L, compared to 67% without L. OS was equal.
- In ***Abstract 8501***, M. Dimopoulos et al. presented findings from the BOSTON study. Patients after one to three prior lines of therapy received bortezomib plus dexamethasone with selexinor (VDS) or without selexinor (VD). Time to next treatment was 16.1 months for VDS and only 10.8 months with VD, HR 0.66, $p = 0.001$.

Peripheral cutaneous T-cell lymphoma

- In ***Abstract 8018***, L. Li et al. reported on patients with peripheral cutaneous T-cell lymphoma treated with either gemcitabine, cisplatin, prednisone, and thalidomide (GCPT) or cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP). CR on GCPT was 42.9% vs. 27.6% on CHOP, $p = 0.049$. Four-year OS was 66.8% on GCPT vs. 53.6% on CHOP, $p = 0.039$.

Lung Cancer

Non-small cell, locoregional

- In ***Abstract LBA5***, R. Herbst et al. reported on data from the ADAURA trial. Patients with an EGFR mutation with stages IB to IIIA NSCLC after complete resection received either osimertinib (O) or placebo (P). In all patients, DFS at 36 months was 79% with O and 41% with P, HR 0.21, $p = 0.0001$. For patients with stage II or IIIA, DFS at 36 months was 80% with O and 28% for P, HR 0.17, $p = 0.0001$. OS was immature at 24 months and was 100% with O and 93% with P, but HR 0.4, n.s.

Non-small cell, metastatic

- In ***Abstract 9500***, E. Smit et al. presented results from DESTINY-Lung01. In patients with HER2 mutation or HER2 over-expression, trastuzumab deruxtecan achieved an RR of 62% and PFS of 14 months.
- In ***Abstract 9501***, M. Reck et al. presented findings from the Checkmate trial 9LA. In first-line therapy, patients received nivolumab and ipilimumab and chemotherapy (NIC), or chemotherapy alone (C). OS was 15.6 months on NIC vs. 10.9 months on C, HR 0.66.
- In ***Abstract 9507***, J. Rotow et al. presented results of combination osimertinib plus gefitinib as first-line therapy. The PR rate was 89.9%. PFS was more than 14.8 months.
- In ***Abstract 9508***, X. Wang et al. presented data from the SINDAS study. Patients with EGFR mutation and five or fewer metastases received either a tyrosine kinase inhibitor (TKI control) or the TKI plus stereotactic radiation therapy. PFS was 12.5 months for TKI vs. 20.2 months for TKI plus radiation, HR 0.62, $p = 0.001$. OS was 17.4 months for TKI and 25.5 months for TKI plus radiation, HR 0.68, $p = 0.001$.

Small cell

- In ***Abstract 9007***, B. Gronberg et al. studied patients who received chemotherapy plus radiation therapy. Patients randomized to daily radiation had an OS of 22.9 months, but patients receiving twice-daily radiation had an OS of 41.6 months, $p = 0.031$.

Mesothelioma

- In ***Abstract 9004***, M. Pagano et al. presented data from the RAMES study. In patients receiving second-line therapy, PFS was 6.2 months after gemcitabine (G) plus ramucirumab (R) vs. 3.3 months for G, HR 0.26. OS was 13.8 months with GR and 7.5 months with G, HR 0.71, p = 0.057.

Melanoma

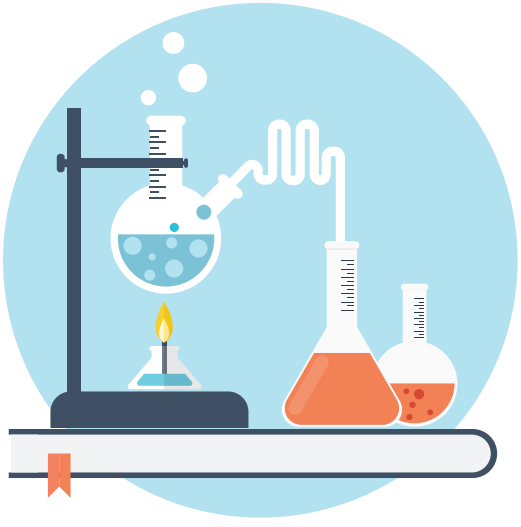
- In ***Abstract 10000***, A. Eggermont et al. presented findings from Keynote 054. Patients with stage III melanoma received either pembro or nothing. Three-year DFS was 64% on pembro vs. 44% on control, HR 0.56.
- In ***Abstract 10001***, A. Hauschild et al. studied patients with stage III melanoma who had a BRAF V600 E/K mutation. Patients receiving adjuvant dabrafenib plus trametinib had a 5-year relapse free survival of 52% vs. patents receiving placebo 38%, HR 0.51.
- In ***Abstract 10004***, D. Olson et al. studied patients failing a prior PD-L1 inhibitor but no prior CTLA4 inhibitor. They received pembro plus ipilimumab. RR was 27%, and duration of response was 18.5 months.

Sarcoma

- In ***Abstract 11503***, H. Joensuu et al. presented the long-term follow-up of the SSGXVIII/AIO trial in patients with resected GIST treated with adjuvant imatinib for 1 or 3 years. The 10-year OS was 79% with 3 years of therapy vs. 65% with 1 year of therapy, HR 0.55, $p = 0.004$.
- In ***Abstract 11508***, P. Chi et al. presented a phase II trial of binimetinib plus imatinib in patients with unresectable GIST receiving first-line therapy. PR was 68%, and eight out of nine patients became resectable.

Patient Symptoms and Survivor Care

- In ***Abstract 12000***, A. El-Jawahri et al. evaluated patients with relapsed/refractory AML. Patients received two PC evaluations per week or SOC therapy. There was less chemotherapy administered during the last 30 days of life with PC (66% vs. 35% with SOC), $p = 0.008$. There was also less anxiety, depression, and PTSD with PC, $p = 0.04$.
- In ***Abstract 12001***, T. Smith et al. evaluated patients on Phase I trials. Patients received two visits by the nurse and one visit by a physician or APP or SOC. Patients on PC had increased function ($p = 0.003$), fewer emotional problems ($p = 0.04$), and less general distress ($p = 0.01$). However, this study was performed at two sites, and the FACT-G was improved at site #1 ($p = 0.0001$) but not at site #2 ($p = 0.3$).
- In ***Abstract 12002***, C. Manz et al. studied an EHR automatic "Nudge" if patients had high predicted mortality or no APC. There were three to four times increased conversations about serious illness with physicians and two to three times increased APC after the Nudge.
- In ***Abstract 12009***, S. Mohile et al. looked at GA in patients over 70. In patients whose physician was given the results of the GA report, grade 3 to 5 toxicity was 50%, compared to 71% if physicians were not given the GA report. OS was equal.



- In ***Abstract 12010***, D. Li et al. studied GA in patients over 65. Patients who received SOC plus a GA and intervention by an APP had grade 3 to 5 toxicity in 51%, compared to 60% if patients received only SOC, $p = 0.02$. There was no difference in hospitalizations.
- In ***Abstract 12008***, P. Grimison et al. studied patients who had emesis despite SOC antiemetics following emetogenic chemotherapy. Patients who received tetrahydrocannabinol and/or cannabidiol (THC/CBD) had no further emesis (69% vs. only 57% in patients who received placebo (P)). Twenty-eight of patients after THC/CBD did not need (or were not given) rescue medications vs. only 15% of P patients who did not need rescue medications, $p = 0.03$.

How Can You Apply This Information in Your Program or Practice?

First, review all of the abstracts and published manuscripts of these studies; some are already available in the *New England Journal of Medicine*, the *Journal of the American Medical Association*, the *Journal of Clinical Oncology*, or *Lancet Oncology*. You also can search by abstract number online at meetinglibrary.asco.org. This will bring up the published abstracts with more details than this summary article. As always, remember to use your best clinical judgment, discuss these practice-changing data with colleagues, and attend virtual presentations (and in-person meetings when they resume) to help you decide which findings—when taken into consideration with individual challenges and preferences—will improve treatment for each of your patients.

Closing Thoughts

The ASCO annual meeting remains the singular most important event to learn the outcomes of the most noteworthy clinicals trials to guide cancer treatment decisions over the ensuing 12 months. Although the reports on these clinical trials are published in the *ASCO Post* or other journals, attending an annual, in-person meeting provides access to authors, discussants, critical comments, and informal chat impressions, as well as the opportunity to talk to poster authors. Attending a face-to-face meeting enhances scientific knowledge and increases professional satisfaction but at the cost of travel, time away from home and clinic, and the frustrations of navigating a meeting with more than 40,000 of your colleagues. Personally, I valued the virtual meeting of ASCO 2020 but missed the excitement and challenges of the in-person, Chicago-based meeting. So, in 2021, if the environment is safe for travel and for large, in-person meetings, I will be in Chicago along with the clinician and scientist crowds, looking for practice-changing study results and valuable conversations. But if COVID-19 remains a threat, the quality of science presented in 2020 lets me conclude that I will definitely attend the meeting's virtual counterpart. OI

Cary A. Presant, MD, FACP, FASCO, is a clinical professor at City of Hope Medical Center; chairman of the board emeritus at the Medical Oncology Association of Southern California; and past president of the Association of Community Cancer Centers.

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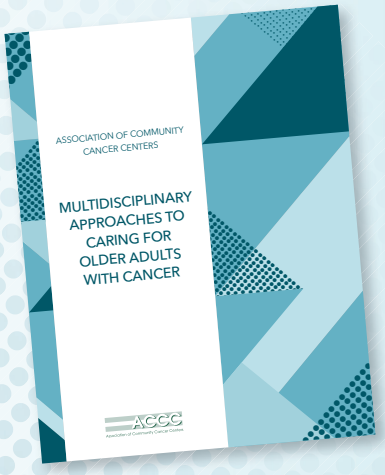

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The **Association of Community Cancer Centers (ACCC)** is the leading education and advocacy organization for the cancer care community. Founded in 1974, ACCC is a powerful network of 25,000 multidisciplinary practitioners from 2,100 hospitals and practices nationwide. As advances in cancer screening and diagnosis, treatment options, and care delivery models continue to evolve–so has ACCC–adapting its resources to meet the changing needs of the entire oncology care team. For more information, visit accc-cancer.org or call 301.984.9496. Follow us on Facebook, Twitter, and LinkedIn; read our blog, ACCCBuzz; and tune in to our podcast, CANCER BUZZ.

Financial support for this educational initiative was provided by Pfizer Oncology.

Advocating Amid a Crisis

The expanding role of financial advocates in the age of COVID-19

As consumers are expected to assume an increasing percentage of their healthcare costs, and as co-pays, coinsurance, and deductibles continue to rise, demand for the services of financial advocates is outpacing supply. Given that the COVID-19 pandemic has left millions of people unemployed and without the insurance benefits they once possessed, the need for financial advocacy in healthcare is reaching new heights.

Evidence of that need is increasingly apparent. In a survey of more than 1,200 cancer patients and survivors conducted between March 25 and April 8, 2020 by the American Cancer Society Cancer Action Network (ACS CAN), 38% of respondents report that COVID-19 has had a notable impact on their financial situation that affects their ability to pay for healthcare.[1] Forty-six percent of respondents whose annual household income is $30,000 or less say they are worried that the financial impact of the pandemic will make it difficult for them to afford their healthcare. Forty-three percent of respondents who reported that they or a family member living with them has recently lost a job say that person had employer-sponsored health insurance.

Although it is too early to accurately gauge the long-term impact on healthcare of the massive unemployment that has accompanied COVID-19, it is helpful to understand the state of financial advocacy before the pandemic hit. In late 2019, the Association of Community Cancer Centers (ACCC) asked its member institutions to answer survey questions about their financial advocacy services. In response, 292 people from 153 unique cancer programs shared information about their concerns, challenges, workload, training, resources, and technology regarding their financial advocacy services.

Workload

Most of the cancer centers represented in the survey (60%) employ one to three dedicated financial advocates. Ten percent employ four to five advocates, 13% employ six or more, and 10% employ none. One-third of respondents say they provide financial advocacy services to more than 20 patients per week. Asked if they have enough FTEs to meet their demand for financial advocacy services, 36% of respondents said they do not, and 34% replied "not always."

Rifeta Kajdic, the oncology program manager at St. Luke's Cancer Institute in Boise, Idaho, and a member of the ACCC Financial Advocacy Network Advisory Committee, says she is unsurprised by these numbers. "The cost of treatment is only increasing," says Kajdic. "In the past, financial navigation roles focused on high-risk patients, which were mainly those who were uninsured or underinsured. Now even patients with insurance need our help. With rising copays, coinsurance, and expensive drugs, just because you have insurance doesn't mean you won't be financially impacted."

In her capacity, Kajdic supports oncology patient financial advocates across five sites operated by St. Luke's in Idaho. She says St. Luke's employs 18 financial advocates dedicated to oncology across those sites. "At all sites combined, we might see about 400 new patients a month," says Kajdic. "We meet with an average of 70 patients per week. Demand for our services is only increasing as the pandemic puts so many people out of work."

In June 2020, the U.S. unemployment rate was 11.1%.[2] By July 2020, nearly 50 million people had filed for first-time unemployment benefits since the start of the pandemic.[3] In May, the

Kaiser Family Foundation estimated that nearly 27 million people in the U.S. may have lost employer-sponsored insurance due to massive layoffs.[4]

Distress Screening

An essential element of financial advocacy services is accurately identifying the patients who most need assistance. The National Comprehensive Cancer Network (NCCN) recommends that cancer programs conduct financial distress screenings for incoming patients and at regular intervals throughout treatment—particularly when there is a change in disease status—to determine their risk of being unable to afford their care. Forty-one percent of ACCC survey respondents say they always use distress screening tools, while 32% say they sometimes use such tools. Respondents cite multiple methods for assessing financial hardship, including using the NCCN's Distress Thermometer and other standardized assessments; assessing individual patients' insurance benefits; and interviewing patients.

Kajdic says it is important to be able to identify patients who may have a need for financial advocacy services as early as possible. "Some patients may not know they need help immediately," she explains, "but long-term they will likely need some assistance, so we want to make contact early on. Identifying patients and letting them know the resources they have is crucial to helping them have a successful patient journey."

Kajdic says that St. Luke's screens each incoming patient, and those evaluations are entered into the cancer institute's EHR (electronic health record). As soon as a patient referral is received, St. Luke's financial advocates review the patient's health insurance benefits and calculate deductibles, copays, and other patient responsibilities. Financial advocates then make appointments with the patients they deem at risk to explain to them their benefits and the potential availability of additional resources. "Patients look to financial advocates as an expert source to locate the resources they need," says Kajdic, "and the number of people who need financial advocacy services is only growing."

Organizational Challenges

To get a better handle on the roadblocks that most hinder the ability of financial advocates to help as many patients as possible, ACCC asked survey respondents to identify their biggest organizational challenges. Thirty-two percent cite "difficulty finding funding and/or resources for patients," 24% cite "ineffective organizational structure and/or processes," 16% cite "limited staff and increasing demand," and 11% cite "patient education needs/low financial health literacy."

Kajdic says these frustrations are common, given that the many recent clinical advances in oncology and subsequent new therapies have come with high price tags. "There are promising new treatments out there now," says Kajdic, "but reimbursement complexities associated with these treatments can result in heavier financial burden on the patient. Our goal is to help patients get the treatments they need without putting them at financial risk."

Because an increasing number of people are requiring assistance to afford new therapies, Kajdic says there are less resources to go around. "More people are tapping into assistance avenues to pay for treatment," she explains. "It's difficult finding resources now because more people need them. The resources that are available are being pulled in all directions."

Indeed, 50% of respondents say that lack of resources is their top concern in providing financial navigation services, followed by navigating a highly complex, changing landscape (37%), and patient education needs/low financial health literacy (31%). "Not being able to devote enough time to each patient to help as much as they need is the most challenging," said one respondent. "There is not enough of me."

Often these problems are exacerbated by issues that may not immediately come to mind, such as a patient's citizenship status. Another survey respondent remarked that "not having any resources for patients who do not have a social security number" is a big problem.

These challenges create roadblocks to treatment that can have a very real impact on patient outcomes. Eighty percent of survey respondents estimate that 1 to 10 patients they saw in the past month declined treatment due to financial concerns. Twenty percent of respondents say more than 11 patients a month decline treatment for this reason.

Navigation Know-How

Knowing how to navigate the labyrinth of funding resources for patients in need is a cultivated skill that most financial advocates

learn on the job and through relationship-building. Foundations, nonprofits, charity programs, manufacturer discounts, and other funding outlets often lack a steady funding stream, and each have variable (and often changing) qualifications. Being able to identify a patient's most promising options and see applications through to completion requires staying on top of a steady stream of continually changing resources.

Survey respondents say they are most confident navigating manufacturer and advocacy patient assistance programs, although they say they need additional help sorting through the wide variety of resources available. Seventy-six percent of respondents say they need additional help navigating Medicare and/or Medicaid options, 73% say they need help identifying private insurance options, and 53% say they need more assistance navigating manufacturer and/or advocacy patient assistance programs.

"As healthcare reimbursement, insurance, and funding grows more and more complex, financial advocate roles will grow in demand," says Kajdic. "There is an increased need for the skills and understanding that financial advocates possess, and they need to be able to tap resources to help them better understand insurance navigation, medical necessity, prior authorization, and all of the complex elements of healthcare funding."

Training and Resources

Currently, training for financial advocates is little more than a passing on of accumulated knowledge from one advocate to the next. Seventy percent of survey respondents say they have received no formal professional training in financial navigation.

"We need continuing education that allows financial advocates to be up to date in their area of expertise," says Kajdic. She points out that, as financial advocates bring more and more specialized knowledge to the multidisciplinary patient care team, they are being invited to participate in clinical care discussions. As they assume more prominent roles in patient care, says Kajdic, there is a growing need to standardize and pass on their collective knowledge.

"That's where tools like ACCC's Financial Advocacy Boot Camp and Patient Assistance Guide come in," says Kajdic. "These resources allow us to pass down crucial information that all financial advocates can benefit from. There has to be a sharing of information and tools and tricks and tips," she adds. "It's up to us to come up with these resources, or our knowledge is in danger of being lost."

Of those survey respondents who say they have received formal training in financial advocacy, 60% say it was through the ACCC Financial Advocacy Boot Camp. The Boot Camp provides new and veteran financial advocates training in conducting distress screening, maximizing insurance coverage and patient assistance, promoting cost-related health literacy, and other topics crucial to a successful financial navigation program. Thus far, more than 1,000 individuals have graduated from the ACCC Financial Advocacy Boot Camp.

Kajdic says a best practice for sustaining any financial advocacy program is to document and pass on advocates' cumulative expertise. "That's how most of us have learned," she says, "and now it's up to us to pass down our learning to others." In this spirit, ACCC continues working with financial advocates across the multidisciplinary cancer care team to harness their collected knowledge and formalize it into training and resources for members.

Measuring Impact

Many financial advocates will tell you that the ability to demonstrate the economic impact of their work plays a large role in their profession. "Gauging your impact allows you to take any abstract idea of what you do and turn it into valuable information," says Kajdic. "It's an important part of sustaining and growing future financial advocacy roles. Tracking the value of financial advocacy work illustrates its benefit to patients and to a cancer program's bottom line. Financial advocates really do help ensure the financial security of cancer programs."

However, only 45% of financial advocacy programs track their impact. When asked how they measure their financial success, 23% of survey respondents say they do not track their return on investment (ROI). Thirty-two percent say they are in the process of developing metrics or a tracking system to document the impact of their work. The programs that do track their impact use a variety of metrics, the most common of which include measuring overall reduction in institutional debt and calculating the number of patients who gained access to treatments through the intervention of financial advocates.

The ACCC Financial Advocacy Boot Camp and the ACCC Financial Advocacy Toolkit provide training, resources, and case studies that help financial navigation programs demonstrate the economic impact of their work on both patients and the cancer program.

Looking Forward

Looking ahead, we can see that the effects of the COVID-19 pandemic on healthcare delivery will continue to ripple through our entire healthcare system in ways we may not yet be able to imagine. This will make the work of financial advocates more important than ever.

Millions of people who were insured before the pandemic have lost their insurance due to cutbacks, layoffs, and shuttered businesses. "We anticipate a surge of patients who need serious assistance," says Kajdic. "There will be a higher demand for financial advocates to find resources. At the same time, resources will likely be more limited due to the economic fallout from the pandemic."

Kajdic says she trusts that financial advocates will rise to the occasion, as they always do when confronted by significant odds. "We're going to need to get creative," affirms Kajdic. "The people who come into these roles are first of all people who just want to help. We're going to have to pool our resources with other specialties, train people fast, find patients in the most need, and prioritize them."

Kajdic says she believes this profession is up to the task: "Financial advocates are very savvy. They feel a need to help their patients, and they will dig and dig until they find an answer." ●

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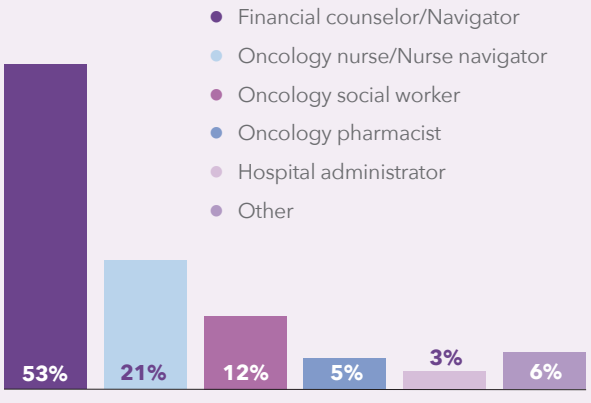
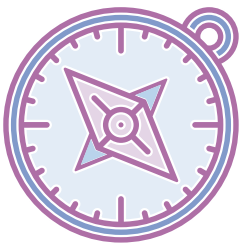
2019–2020 ACCC Financial Advocacy Network Census Survey

292 survey respondents from 153 unique cancer programs and practices

Who Took Our Survey n=292



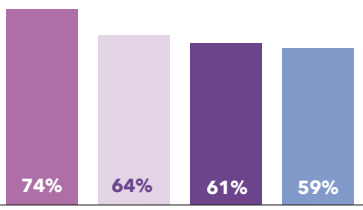
Years of Experience Providing Financial Navigation Services n=270



- **48%** Less than 5 years
- **23%** 5-10 years
- **22%** 11-20 years
- **7%** 20+ years

Roles and Responsibilities n=192

- Work directly with patients to address financial concerns
- Screen patients for their risk of financial toxicity and/or distress
- Identify and enroll patients in manufacturer financial assistance
- Identify and enroll patients in free-drug programs

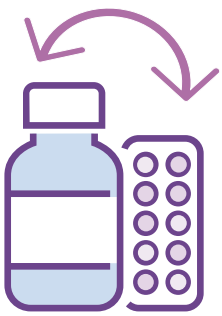


What's a Co-Pay Accumulator?

A co-pay accumulator—or accumulator adjustment program—is a strategy used by payers and pharmacy benefit managers (PBMs) that stop manufacturer co-pay assistance coupons from counting towards the deductible and the maximum out-of-pocket spending. When the co-pay card or coupon is exhausted, beneficiaries must pay the entire amount of their deductible before their plan benefits kick in.

A majority (**71%**) of respondents are unaware of co-pay accumulators. n=197

89% indicated they need better understanding and resources to feel adequately prepared to explain and assist patients in navigating these new rules. n=84

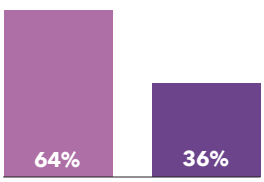


What's Non-Medical Switching?

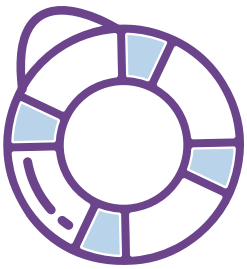
Non-medical switching is when a payer changes a patient's treatment regimen for reasons other than efficacy, side effects, or adherence. It is a drug formulary tactic used by payers to reduce drug costs.

64% of respondents are unaware of non-medical switching.

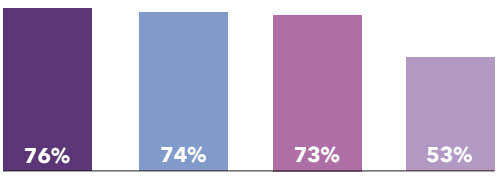
Of the **36%** that are aware of this trend, **81%** say "it always or sometimes impacts patient care." n=190



Help Needed Stat! n=197

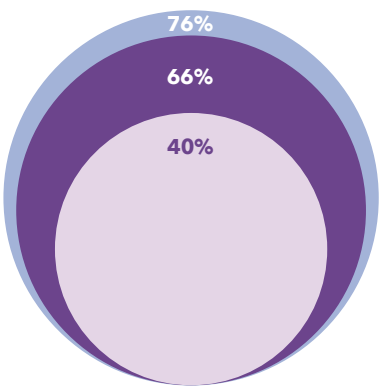


- Need help optimizing Medicare and/or Medicaid options
- Need training and materials on cost-related health literacy education
- Need help optimizing private insurance options
- Need help navigating manufacturer and/or advocacy patient assistance programs



What Can ACCC Do? n=174

- Create videos and webinars on select topics
- Provide customizable tools to support program implementation
- Provide more peer-to-peer learning opportunities



The ACCC Financial Advocacy Network is supported by Pfizer, Janssen, Johnson & Johnson, and Pharmacyclics

Cornerstone Partner: Pfizer Oncology Silver Partners: janssen Johnson & Johnson pharmacyclics

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

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

ACCC
Association of Community Cancer Centers

action

ACCC Welcomes Its Newest Members

Baptist Health System
Louisville, Ky.
Delegate Rep: Amanda Henson, MSHA, MBA, FACHE
Website: baptisthealth.com

Baptist Health Paducah
Paducah, Ky.
Delegate Rep: Michael Tutor, MBA
Website: baptisthealth.com/Paducah

System Membership
Munson Healthcare
Traverse City, Mich.
Delegate Rep: Kathleen LaRaia, MS
Website: munsonhealthcare.org/cancer

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

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

A Reminder from ACCC's Bylaws Committee

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

ACCC Research Review

This monthly e-newsletter is part of the 2020-2021 ACCC President's Theme, "Community Oncology Can Close the Gap in Cancer Research." In addition to updates from the President's task force, each issue will focus on:

- Clinical trials of interest to ACCC members, such as the recent Ochsner Health study published in the *New England Journal of Medicine* titled "Hospitalization and Mortality Among Black Patients and White Patients with Covid-19"
- Feature articles like "All Power to the Patient: Achieving Cancer Health Equity" with five key takeaway messages from this U.S. Food and Drug Administration Oncology Center of Excellence webinar
- Key insights from ACCC members in specific areas of research like precision medicine and oncogeriatrics.

If you missed this new e-newsletter, start with the inaugural issue at accc-cancer.org/research-newsletter-july-2020 and then catch up. Do you know someone in your research department who should be getting this important resource? Sign them up to receive this e-newsletter and other research-related updates at the link above.

ACCC Releases New IO Resources

Recent advances in immuno-oncology (IO) therapies have been rewarded by rapid, durable responses for subsets of patients in many cancers that have been resistant to conventional treatments. Just as with developments with chemotherapy and targeted therapies, increasing numbers of IO patients with metastatic disease are transitioning into post-treatment survivorship. However, these patients may experience late physical and psychosocial effects of cancer and its treatment (e.g., depression, pain, fatigue), which can negatively impact quality of life.

In this ACCC video series, expert panels discuss the unique survivorship needs of IO patients, including improving care coordination and communication within the multidisciplinary team and how to meet patients' psychosocial and physical well-being needs. These discussions identify actionable steps for cancer care providers and allied healthcare professionals to address the survivorship needs of this patient population. Watch today at accc-cancer.org/io-survivorship-webinars.

New Collaboration Seeks to Increase Clinical Trial Participation of Racial and Ethnic Minority Populations

In July ACCC and the American Society of Clinical Oncology (ASCO) announced a new collaboration to foster participation in cancer treatment trials to better reflect the diversity of people at risk for or living with cancer.

"We recognize that there are complex forces and systems that have created disparities in cancer research and that solving these problems will take a multi-faceted integrated approach reflecting the best current thinking and expertise from the entire cancer community," said ACCC President Randall A. Oyer, MD, co-chair of the new ASCO-ACCC steering group overseeing this initiative.

That same month, the two organizations released the ASCO-ACCC Request for Ideas, which closed at the end of August, seeking novel strategies and practical solutions to increase participation of under-represented racial and ethnic populations in cancer treatment trials. Request for Ideas' areas of focus included:

- Provider bias
- Challenges with access, insurance coverage, and cost of care
- Lack of awareness about trials
- Mistrust in the healthcare system and/or clinical research
- Linguistic, cultural, or literacy-related issues
- Study design barriers
- Barriers to family and community engagement.

The ASCO-ACCC steering group will review and select ideas that may be modified, combined, implemented, and evaluated by the two organizations. Submitted ideas may be implemented and evaluated through the ASCO Targeted Agent and Profiling Utilization Registry Study, for example.

Criteria used to review and prioritize proposed ideas will include the potential to address racial and ethnic disparities in cancer treatment trials, replicability of the strategy, and indications that the submitter has demonstrated a commitment to equitable cancer care, among others. Individuals who submit ideas will be given an opportunity to work on the idea implementation, if interested.

Celebrating Life Through City of Hope's Bone Marrow Transplant Program

BY STEPHEN J. FORMAN, MD

City of Hope's bone marrow transplant (BMT) program has performed more than 16,000 transplants and continues to be one of the largest and most successful programs in the nation.

But how did we get there?

Forty-three years ago, a young college student from Indiana became the hospital's first successful BMT patient. In October of that year, the 27-year-old received news from his physician that he had acute myeloid leukemia. In those days, an acute myeloid leukemia diagnosis was grim—most would say hopeless. Bone marrow transplantation as a cancer treatment was primitive at the time and not widely practiced. City of Hope was one of only six medical centers in the United States that offered the procedure.

The student's doctor advised him to get his affairs in order and he broke the devastating news to his family. His cousin, a doctor in Los Angeles, Calif., said she knew of a cancer treatment center in nearby Duarte, Calif., that had launched a BMT program.

A Historic First

Trusting his cousin's advice, the young man came to City of Hope for a BMT and his eldest brother was his match. He underwent a BMT as a patient of Karl Blume, MD, who established the BMT program at City of Hope in 1975 with Ernest Beutler, MD. Back then, the standard protocol for bone marrow transplantation required that the young man endure very high doses of chemotherapy followed by a three-hour treatment of total body radiation. Following the transplant, the student spent a month in isolation.

With his cancer in remission, the young man returned to school to complete a degree in computer science. He was one of City of Hope's longest-surviving BMT patients—35 years. He would remain in remission for the rest of his life, passing away in 2011.

Since that first patient, City of Hope's laboratory and clinical researchers have led the way for more effective and safer transplants with fewer side effects. Having performed more than 15,000 transplants—6 in 1976 and more than 800 in 2019—our program is now one of the largest and most successful in the world. Today, City of Hope performs, on average, 720 transplants each year.

In 1978, I joined City of Hope to work with Dr. Blume to help grow the new BMT program. I had the privilege of leading our Department of Hematology & Hematopoietic Cell Transplantation for more than 30 years, and Dr. Eileen Smith recently became the new chair in November of 2019.

Refining the Technique

The advent of bone marrow transplantation marked an important step forward in the battle against leukemia, lymphoma, and other diseases of the blood and immune system. City of Hope has played a crucial role in the advancement of these procedures. In early procedures, stem cells were collected exclusively from a matched family donor's bone marrow. As medicine advanced, two different sources for stem cells were discovered: peripheral blood (from the bloodstream) and umbilical cord blood. An autologous transplant uses stem cells from the patient's own blood.

With the advent of non-related and partially matched donors, BMT is saving more lives than ever before. One of the biggest innovations derived from research is the ability now to do transplants from half-matched family donors. This development has greatly expanded the pool of people who are eligible to receive BMTs.

When our program started, because of the physically challenging nature of the procedure, transplants were rarely performed in patients over the age of 30. Now, with refinement of the technique, age is no longer a barrier.

City of Hope was also one of the first institutions to do BMTs in patients over the age of 50 and now many patients over the age of 70 are undergoing successful transplants to cure their disease. We did this by approaching the procedure based on the idea of a reduced intensity, or "mini" transplant. This breakthrough method relies less on heavy doses of chemotherapy and radiation and more on the antitumor effects of the graft (called the graft-versus-tumor effect).

Patients ranging in age from 4 months to more than 80 years old have received BMTs at City of Hope.

In addition, City of Hope was one of the first hospitals to prove that BMTs can be done safely in patients with HIV. We performed the first transplant for AIDS-related lymphoma in 1998. Today, BMT is also used to treat numerous nonmalignant diseases, including sickle cell disease and autoimmune diseases.

Based on analysis by the Center for International Blood and Marrow Transplant Research, City of Hope's bone marrow

transplantation program is the only one in the nation that has had one-year survival above the expected rate of 15 consecutive years.

Looking forward, our program is focused on minimizing the side effects of the procedure, increasing its effectiveness, and expanding its reach. An outgrowth of the success of our BMT program has been the development and growth of our immunotherapy program. Chimeric antigen receptor T-cell therapy is a gene therapy that trains a patient's immune system to fight cancer. City of Hope has treated more than 500 patients with these therapies, and that number will keep growing.

City of Hope has also developed a vaccine, and tested it in clinical trials, for cytomegalovirus, a common and potentially deadly infection following transplant. Even before current vaccine trials, City of Hope's program was one of the first to develop a treatment for prevention of cytomegalovirus infection after transplant, which has nearly eliminated this threat.

"What has really differentiated our program is that all of this is wedded to a deeply humanistic vision of delivering care to the patient," says my colleague Joseph Alvarnas, MD, associate clinical professor in the Department of Hematology and Hematopoietic Cell Transplantation. He notes that we have a system in which we not only have hematologists caring for patients, but they also partner with members of supportive care medicine, from palliative care physicians to social workers to psychologists. All of these services create a much more grounded, human-centered vision of care delivery.

Celebration of Life

In 1998, City of Hope established a formal long-term follow-up program to maintain communication between patients, families, and physicians and to track outcomes so that the cancer center is aware of any problems, both physical and psychological, that patients may have following their transplant.

In addition, the "Celebration of Life" BMT reunion is an annual highlight at City of Hope, bringing together more than 4,000 attendees each spring. The reunion is a joyous day for everyone in attendance—physicians, nurses, and former patients and their families—as we celebrate the victories attained in fighting cancer. This tradition is in its fourth decade and one that our very first BMT patient (the young student) attended regularly.

Each year, City of Hope selects two patients who can celebrate life because an unrelated donor selflessly donated their stem cells or bone marrow. Those donors often come from across the nation and around the world to meet the patient whose life they helped save. For patients and donors who meet for the first time at City of Hope's BMT reunion, and kick off a day of festive activities, it is a moment they will never forget and one that often leads to lifelong and close friendships. Hugs, tears, and many heartfelt "thank yous" are exchanged as television cameras capture the reunions and those in the audience wipe away tears. After that first meeting, patients, donors and their families eagerly ask each other questions about the transplant and donation process and share details about their lives. After those patients and donors meet, City of Hope hosts a festive picnic and entertainment for thousands of patients who have had BMTs, their donors, and family members. Patients wear buttons that proudly display how long it's been since their transplant, or second birthday, took place. We've had Los Angeles Dodgers players and a manager, as well as Los Angeles Lakers players and cheerleaders, come out to meet our patients and pose for photos. At the end of the day, a massive group photo is taken, one that we are proud to say keeps growing year after year.

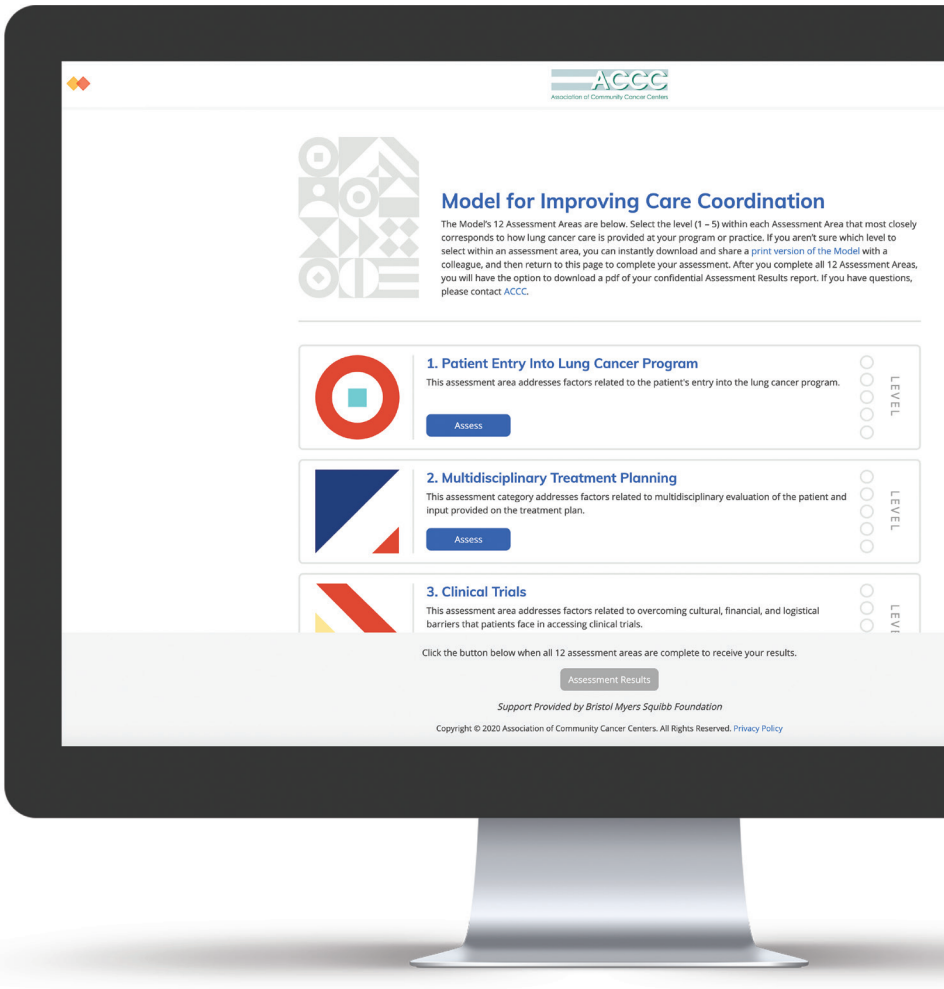
The annual reunion also enables physicians and researchers to further advance the science of stem cell transplantation through the sharing of the findings and advances at the Karl G. Blume-Gerhard Schmidt Memorial Lecture, which is held in conjunction with the event.

It can be somewhat overwhelming if you think about it: more than 16,000 transplants! I only stop and think about that number when someone asks me about it, because our focus is on saving one life at a time. I often forget how long it has been and how much we have accomplished.

My focus continues to be the same as it was in those early days of our BMT program: What does this patient need today, and how can our research help them achieve cure of their disease and return to life? There is a thrill when you see the possibilities of what you can do for someone that you could not do before. It is what we all believe here at City of Hope.

Stephen J. Forman, MD, is the director of City of Hope's Hematologic Malignancies Research Institute and director of its T Cell Therapeutics Research Laboratory, Duarte, Calif.

6 STEPS
to IMPROVE CARE COORDINATION
for Lung Cancer Patients on Medicaid



1. **Take the FREE, online assessment** (the Model) to identify 12 areas in which your program can improve care coordination and quality for patients with lung cancer.

2. See how your program measures up. **Download a customized PDF report** with your results embedded in each assessment area and a crosswalk to more than 100 quality measures.

3. **Discuss the results with your care team** and cancer program leadership to identify quality improvement (QI) opportunities.

4. **Access ACCC-curated resources** to help make the case for developing and implementing a QI project in one or more assessment areas, such as patient access, navigation, supportive care, multidisciplinary treatment planning, and more.

5. **Gain more team training** on the building blocks of successful QI project development and implementation. Available to a select number of ACCC Cancer Program Members.

6. **Share how your program is utilizing the Model's framework** to improve care coordination and by applying for an ACCC Innovator Award, submitting an article to *Oncology Issues*, or applying to present at an upcoming meeting.

Access the online tool, full Model & quality measures report, and testimonials from ACCC members who have used their assessment for quality improvement initiatives.

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