ONCOLOGY ISSUES

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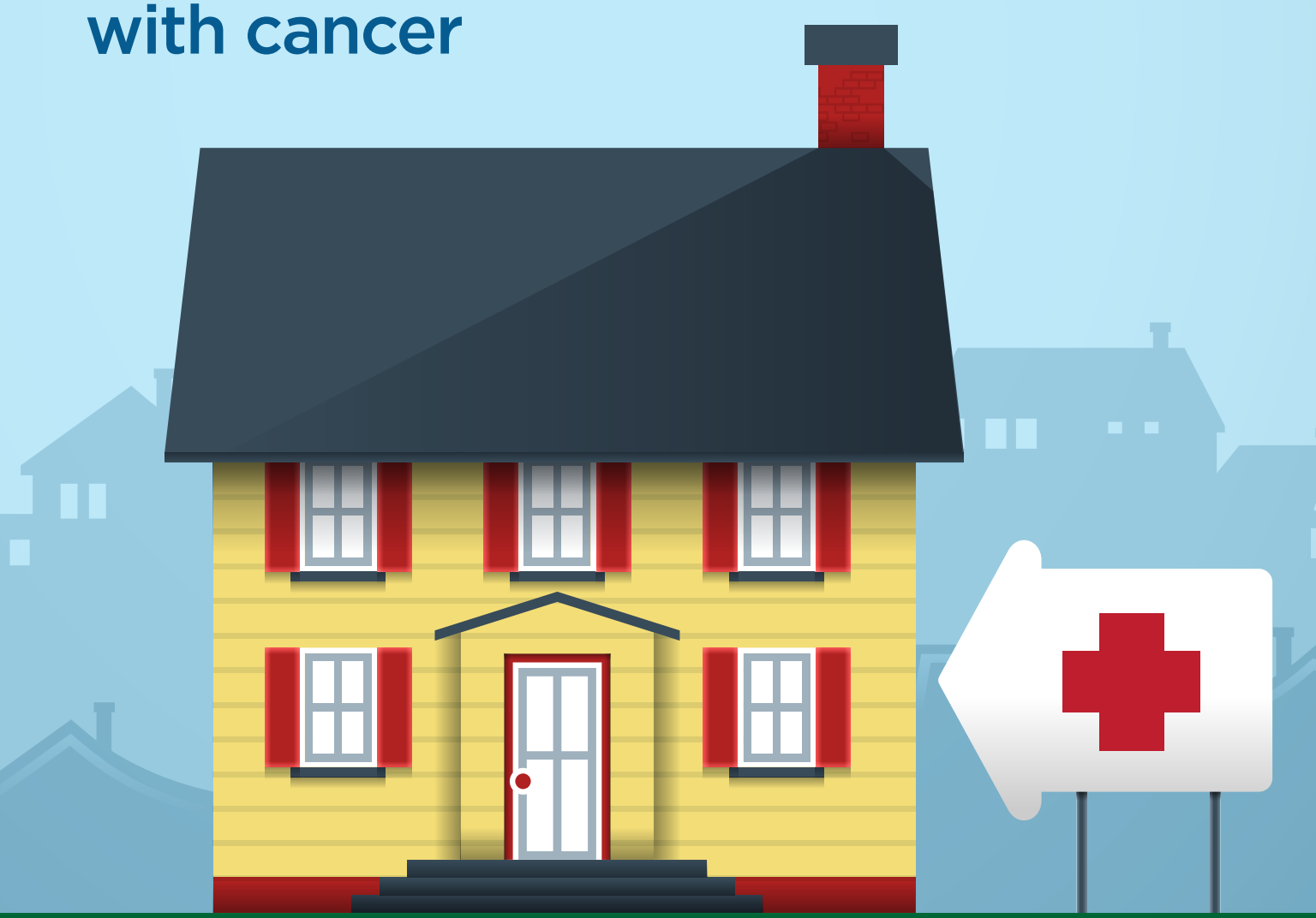
Home as a site of care for patients with cancer



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In this interview, Kathi Mooney, PhD, RN, FAAN, investigator and co-leader of the Cancer Control and Population Sciences Program at the NCI-designated Huntsman Cancer Institute talks about the development and implementation of the Huntsman at Home™ model, including its expansion to three rural locations.
by Amanda Patton

DEPARTMENTS

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FROM THE EDITOR

Reflections on the EOM

BY SIBEL BLAU, MD

The Center for Medicare & Medicaid Innovation (the Innovation Center) June 27, 2022, announcement of the Enhancing Oncology Model (EOM), successor to the recently completed Oncology Care Model (OCM), was much anticipated. The EOM is a five-year voluntary payment model set to begin on July 1, 2023. Under the EOM, participating oncology practices will take on financial and performance accountability for the total cost of episodes of care for chemotherapy to patients with seven common cancer types; two-sided financial risk arrangements are mandatory. (For an EOM-OCM comparison, turn to page 6.)

The Quality Cancer Care Alliance Network (QCCA) is a clinically integrated network of independent community oncology practices. Many QCCA members were highly successful OCM participants, and the program's Monthly Enhanced Oncology Services (MEOS) payments supported practice transformation, the use of shared data analytic tools, best practices, and the development of value-based care pathways. The yearlong interruption between the end of the OCM and the start of the EOM is disappointing to many oncology practices that committed to establishing infrastructure and staffing to support value-based care; many are now financially challenged to continue this support.

QCCA members and the newly formed Exigent Research, a coalition of QCCA practices and practices participating in the National Cancer Care Alliance, met in sunny Seattle in August 2022 for a comprehensive EOM session with subject matter experts, including Alex Chong, PhD, MA, a health insurance specialist for the Innovation Center. Following this session, member practices attended a closed-door meeting to discuss the model. Although practices were excited that value-based care is here to stay, reception of the OEM was "lukewarm." Here are some of our concerns.

The MEOS payments are much lower, and it will be challenging for many practices to support and grow the robust structure necessary to be successful under the EOM.

Two-sided risk from the onset of the EOM is unsettling. At the August meeting, experts and practice leaders discussed the term "risk." Oncology providers are moving toward precision medicine much faster than payers, and pricing a disease might be difficult due to heterogeneity within the same type of cancer. Take, for example, triple-negative breast cancer where treatment may vary from low-dose, short-course chemotherapy to multi-targeted chemo-immunotherapy with high toxicities. Determining the correct target price will be challenging.

Benchmarking is another concern. Some practices with historically well-run, value-based care programs did not perform well in the OCM simply because their benchmark was too low from the start. Practices that improved and did well in the OCM may encounter a similar issue under the EOM.

To succeed under the EOM, practices will need to be proactive. Implementation of technology like ePROs (electronic patient-reported outcomes) will help reduce emergency department admissions and improve patient care, yet technology solutions come with costs that may not be recouped with the lower MEOS payments.

Biosimilars will also play a role in savings like they did in the OCM. An active drug utilization program is a must and should be started now in any practice that has yet to do so.

Developing new processes in care management will also need to start early. OCM practices will need to teach non-OCM practices. QCCA practices shared analytic data during the OCM that tremendously helped others understand their weaknesses and make corrections in a timely manner.

Physician, nursing, administration, and social work leadership will be key. QCCA practices will start a taskforce of these leaders to analyze practice data and assess the viability of the EOM.

Though almost all QCCA practices plan to apply for the EOM, most are unsure whether they will follow through. Before practices can make that decision, we need more data analysis, and we must continue to proactively improve without disrupting our clinic flow and patient care. OI

The Home as a New Site of Cancer Care

BY DAVID R. PENBERTHY, MD, MBA

Though the home as a site of care is not a new concept, the COVID-19 pandemic brought renewed attention to this care setting. The goal of the hospital-at-home model is simple: to extend the walls of a hospital to include a patient's home—a pivot the U.S. healthcare system made overnight when the country shut down in March 2020. Flash forward two-plus years, as ACCCBuzz explored this topic in a four-part blog series at accc-cancer.org/hahmodel.

Bruce A. Leff, MD, professor of medicine and director of the Center for Transformative Geriatric Research at Johns Hopkins University School of Medicine and a leading proponent of the hospital-at-home model, recently keynoted a Modern Healthcare virtual briefing on "Transforming Care Delivery with Hospital at Home." I was struck by his vision for the future of hospitals, calling them, "a big ER, ORs, and ICUs. I think all other services will move into the home." His words stayed with me, and I used them to open the ACCC July 11 Tech Talk on "The Home as a New Site of Cancer Care."

About 40 engaged ACCC members joined this informal discussion. Some shared practical strategies for caring for patients in their homes; others simply listened. When asked where on the trajectory their cancer program or practice was in implementing the home as a new site of cancer care, answers from 44 registered participants ranged from "We do not offer any services to patients in their home" (25 percent) to "We have developed a formal program to provide services and a process to identify patients with cancer who can safely receive treatment in their homes" (7 percent). Most fell somewhere in between: "We are exploring the idea of offering some services to patients in their home" (32 percent) or "We offer select services to patients in their home" (27 percent).

For those cancer programs and practices looking to explore new ideas and begin offering care to patients in their homes, the Tech Talk offered several tips to support planning efforts:

- Understand how remote patient monitoring fits within a hospital-at-home program. Identify patients who can benefit from remote monitoring and providers who support this type of care. Consider focusing on patients recently discharged who can walk out of the hospital with the technology tools in hand.
- Start with your lower acuity patients first. Those who are taking up space in your infusion rooms and clinics for hydration, anti-emetics, and wellness checks—all services that can be provided safely in the home.
- When you are ready to administer chemotherapy in the home setting, focus on patients coming into the clinic multiple times a week or multiple times a month and then identify those medications and regimens that can be provided safely in the home.

ACCC Tech Talk participants acknowledged barriers to adoption and expansion of the hospital-at-home model include staffing and reimbursement. Though participants noted that personalized care in the home care is widely embraced by patients and providers, there are challenges with staffing efficiency. Remote patient monitoring helps, yet challenges persist. Although some private payers are supporting—and in some cases mandating—certain services being delivered to patients in their homes or in lower cost settings like home healthcare infusion clinics, the Centers for Medicare & Medicaid Services must change its reimbursement methodology to include telehealth, virtual care, and the hospital-at-home model before there will be widespread adoption by healthcare providers.

On July 18 the Biden administration extended the COVID-19 public health emergency through mid-October 2022. Once the public health emergency ends, telehealth will be available under Medicare for five additional months, and ACCC is supporting efforts to make these changes permanent. For example, the Telehealth Modernization Act—a key ask at the ACCC 2022 Virtual Hill Day—would recognize the home as a new site of care and reimburse telehealth services on a permanent basis.

To get involved and have a voice in shaping the future of cancer care delivery, reach out to Matt Devino, ACCC's director of Cancer Care Delivery and Health Policy, at mdevino@accc-cancer.org. The oncology care community benefits when we have diversity of experience, ideas, and input. We welcome your participation! OI

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- A Comprehensive Oncology Program for Elders (COPE)
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- Establishing Best Practice Care Coordination for Breast Screening, Cancer Detection, and Diagnosis
- Digital Reasoning: An Innovative Lung Nodule Program
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- Simulate and Educate: A Nurse-Led Pilot to Enhance Patient Education and Experience
- Changing the Tune for CAR-T: A Music City Experience in Remote Monitoring
- Genetic Navigation: Improving Patient Outcomes and Identification for Hereditary Cancers
- Improving Care Coordination of Patients with Pre- and Post-treatment Visits
- Population Health Navigation: An Innovative Approach for Addressing Cancer Health Disparities
- Addressing Social Determinants of Health through a Medical-Legal Partnership
- Chemotherapy Care Companion: A Remote Patient Monitoring Program

more online @ accc-cancer.org

BLOG

An Innovative Medical-Legal Partnership

Read how this 2022 ACCC Innovator Award winner assists patients with estate planning like bedside wills, powers of attorney, and advance directives, as well as issues related to insurance, employment, housing, family, immigration, education, and more: accc-cancer.org/vcu-partnership. Then attend the ACCC 39th National Oncology Conference, Oct. 12-14, to learn how to develop and implement a similar program at your institution: accc-cancer.org/NOC.

TOOL

Quality Improvement Tool

This ASCO-ACCC Research Site Self-Assessment helps clinical trial sites and research teams identify opportunities to improve equity, diversity, and inclusion in clinical trials while doing an internal review of existing policies, programs, and procedures that offer evidence-based strategies to improve the diversity of trial participants. redcap.asco.org/surveys/?s=MNXW38WFA3.

RESOURCE

Online Implicit Bias Training Program

Just ASK™ educates learners about the broader context of structural and systemic racism and the role of implicit bias in clinical trial selection, offering vignettes with real-world examples of implicit bias and guidance for mitigating disparities in cancer research settings. Take it today at: accc-cancer.org/just-ask-course.

PODCAST

Digital Literacy in Older Adults with Cancer

While telehealth has expanded the delivery of healthcare services, many populations—including older adults with cancer—lack the know-how to use technology to their advantage during their cancer journey. Lower levels of digital literacy impede patients from accessing timely information, feeling empowered to ask questions, and seeking the best treatment for their diagnosis. To help older patients become digitally literate, the Patient Empowerment Network offers a free program that teaches older adults with cancer valuable technology skills. Listen at: accc-cancer.org/digital-literacy-podcast.

WEBINAR

Using Telemedicine to Assess Psychological Health

Telehealth has forever changed the way cancer care team members interact with patients. A panel of supportive care specialists share practical tips on the use of psychosocial screening tools and how to effectively integrate them into practice, including the order, timing, and adaptation of various tools. A case study highlights the journey of a patient with metastatic breast cancer, then panelists discuss ways to efficiently capture what matters most to patients when communicating in a virtual care environment. Learn more at: accc-cancer.org/using-telemedicine-webinar.

fast

Physicians Share Top Strategies for Addressing Their Patients' Social Drivers of Health

- Investing in community capacity to address patients' social drivers of health.
- Investing in technological and human capacity to connect patients with community resources they need to be healthy.
- Screening patients to identify social needs.
- Significantly reducing existing payer reporting requirements and other administrative burdens to provide the necessary time to address social drivers of health.
- Creating financial incentives for physician-directed efforts to address social drivers of health.
- Including social drivers of health in risk scoring.

Source. The Physicians Foundation. 2022 Survey of America's Physicians. physiciansfoundation.org/physician-and-patient-surveys/the-physicians-foundation-2022-physician-survey-part-1.

Patients Believe Their Personal Health Data Could Help Cure Cancer

- Almost all survey respondents—nearly **90%**—support all patients with cancer sharing their health data anonymously to advance treatment research and discovery.
- **87%** indicated that they would not care if their data have already been anonymously shared.
- **86%** believe oncologists should be actively discussing the value of sharing patient data with researchers as part of patient-provider interactions.
- **85%** would agree to share their anonymous data if asked by their doctor.
- **53%** of respondents believe that a cure for cancer would already be available if all patient data were collected and combined.

Source. June 2021 survey by COTA, Inc., conducted by independent research firm PureSpectrum. cotahealthcare.com.

facts

5 Benefits of Identifying Patient Care Gaps

1. **Saving Time.** Consistently maximizing the number of patients seen and treated will increase practice revenue. For patients, a faster timeline supports early intervention and improved pain management. Instant access to patient data can result in faster diagnoses and treatment plans.
2. **Better Patient Care.** Work with primary care provider to note gaps and more closely coordinate treatment plans. Involve patients more actively in their own care to reduce office visits, lower costs, and improve outcomes.
3. **Improved Population Health.** Use data to identify patients who fall into a healthcare gap. For example, generate a list of patients who need immunizations, lab tests, or preventive screenings, and work to schedule them appointments. This generates a constant flow of revenue, but also ensures that patients are taking all necessary proactive health measures.
4. **Faster Reimbursement.** Payers demand different information and reject claims due to a lack of information. Using a digital program to gather and provide quality metrics makes it easier to communicate with public and private payers.

Source. 5 Ways Identifying Patient Care Gaps Will Benefit Your Independent Medical Practice. Amazing Charts: A Harris Healthcare Company. amazingcharts.com.

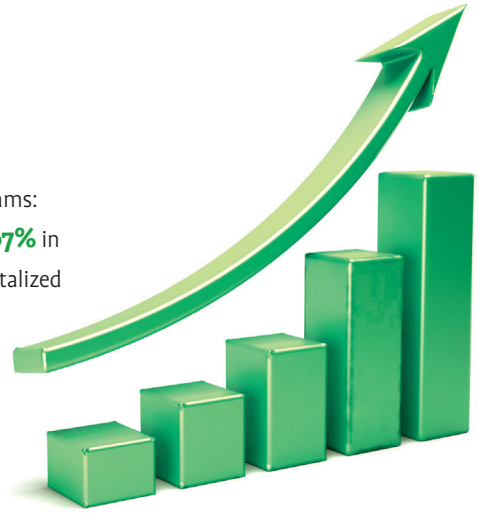
4 Best Practices for Handling Prior Authorizations

1. **Keep lists and references handy.** Keep payer requirements, state law, and common "trigger" medication information on hand and update often, so physicians and staff know what to include in requests. Focus on your major payers.
2. **Assign 1 (or 2) payers per staff member.** Each staff member should be familiar with their assigned payer's processes, including preferred methods of communication (fax, phone, or electronic), and serve as a "go-to" for questions about that payer.
3. **Encourage nurses and staff to keep physicians informed.** That way when prior authorization issues arise, physicians are not blindsided with extra administrative work and can prepare secondary plans for care if needed.
4. **Put a system in place to follow prior authorization requests to completion.** Regularly track your denials, research the reasons behind these denials, and apply those learnings to fix processes.

Source. Prior authorizations: relieving the burden. Athenahealth, Inc. athenahealth.com.

Report Card Shows Access to Palliative Care Continues to Increase

The U.S. shows continued growth in the overall number of hospital palliative care teams: **72%** of U.S. hospitals with **50** or more beds report a palliative care team—up from **67%** in 2015, **53%** in 2008, and **7%** in 2001. These hospitals currently serve **87%** of all hospitalized patients in the U.S.



Source. America's Care of Serious Illness: 2019 State-by-State Report Card on Access to Palliative Care in Our Nation's Hospitals. reportcard.capc.org/wp-content/uploads/2020/05/CAPC_State-by-State-Report-Card_051120.pdf.

An EOM and OCM Comparison

BY MATT DEVINO, MPH

On June 27, the Centers for Medicare & Medicaid Services (CMS) announced the long-awaited successor to the Oncology Care Model (OCM). The new Enhancing Oncology Model (EOM) is in many ways a very similar model to its predecessor, whose final participation period ended on June 30. Like OCM, EOM is a voluntary, multi-payer model, meaning that commercial payers, Medicare Advantage plans, and state Medicaid agencies are also eligible to apply to align their payment methodologies with EOM. Also like OCM, EOM participants will be responsible for the total cost of care during a six-month episode triggered by the receipt of an initiating cancer therapy for an included cancer type.

Many other OCM elements will remain the same in the EOM, including drug payments counting toward the total cost of care responsibility and all of the OCM's participant redesign activities—with the addition of two new requirements to implement a social needs screening tool and electronic patient-reported outcomes. However, interested applicants should consider several key differences between the OCM and the EOM before agreeing to participate in the new program.

Required Downside Risk from the Start

The OCM was largely a upside-only risk model, where participants were able to earn performance-based payments if they generated savings when compared to the model's risk-adjusted historical benchmarks. In the OCM, only participants that had not earned a performance-based payment by the initial reconciliation of performance period 4 were required to accept downside risk beginning in the eighth performance period or be terminated from the model. Any participants that had generated sufficient savings by that point in the model had the option to remain in the one-sided risk track for the remainder of the OCM.

In the EOM, on the other hand, all participating practices will be required to select one of two risk arrangements, including downside risk from the model's start. In the less aggressive risk arrangement, the upside risk will be 4 percent of the benchmark amount and downside risk will be 2 percent of the benchmark amount. In the more aggressive risk arrangement, the upside risk will be 12 percent of the benchmark amount and the downside risk will be 6 percent of the benchmark amount. In both risk arrangements, if a participant's performance period episode expenditures are greater than 98 percent of the benchmark, the participant will owe a performance-based recoupment. If their expenditures are less than the target amount, participants may still earn a performance-based payment.

Ultimately, this requirement to take downside risk from the start of the model may prove to be a significant disincentive for many practices interested in participating, particularly if they do not have prior experience in the OCM or another two-sided risk model. Even those with prior experience will be paying close attention to the specifics of the pricing methodology and price prediction models in analyzing whether it will be possible to achieve savings and avoid owing a performance-based recoupment under this new model.

Reduced Payments for Enhanced Oncology Services

One important financial element of the OCM was the ability for participants to submit claims for a per beneficiary per month payment amount for "enhanced services" called the Monthly Enhanced Oncology Services (MEOS) payment. These enhanced services included 24/7 access to a clinician, patient navigation services, the documentation of a care plan, and treatment consistent with nationally recognized clinical guidelines. In the OCM, the MEOS payment amount was $160 per beneficiary per month, all of which was included in the participant's total cost of care responsibility. Under the EOM, CMS reduced the MEOS payment by more than half to $70 per beneficiary per month. However, for dual-eligible beneficiaries, participants can bill for an additional payment of $30 (for a total of $100 per beneficiary per month), and the additional $30 will not be included in the total cost of care responsibility.

The significant reduction in MEOS payments is another point of concern for cancer programs and practices considering participation in the EOM, given that those payments were necessary to subsidize required practice transformation activities in the OCM. Though the additional MEOS payment for dual-eligible beneficiaries is a nice incentive to encourage participation from practices who treat underserved communities, it is yet to be seen whether that incentive will outweigh concerns around the potential for losses due to required downside risk.

Fewer Included Cancer Types

Nearly all cancer types were included in the OCM, including beneficiaries receiving hormone-only therapies for lower-complexity cancers. In designing the EOM, CMS made the decision to remove beneficiaries receiving exclusively hormonal therapies and limit the scope of the model to systemic chemotherapy treatment for just seven cancer types: breast cancer, chronic leukemia, small intestine/colorectal cancer, lung cancer, lymphoma, multiple myeloma, and prostate cancer. As CMS indicated in the EOM Request

for Applications, "These cancer types were selected because they are all prevalent cancer types treated in the United States and all have sufficient Medicare claims data for CMS to calculate benchmark prices for episodes among the Medicare [fee-for-service] population for purposes of EOM."[1]

The reduction in cancer types included in the EOM is beneficial in that it will allow CMS to create separate price prediction models, trend factors, and novel therapy adjustments specific to each cancer type. This lack of specificity in the OCM payment methodology resulted in negative experiences for practices treating more high-cost cancers and unequal opportunities for savings for programs treating lower-acuity patients. However, this narrowing of the model also represents a shrinking of the risk pool, and as one practice put it, "Smaller risk pools under full-risk scenarios is always concerning."

New Focus on Health Equity

Finally, the EOM seeks to address health equity in a way its predecessor did not—at least not explicitly. Model participants will be required to screen beneficiaries for health-related social needs, collect and submit beneficiary sociodemographic data, and develop health equity plans to show how the cancer program or practice will address disparities and promote equity within their patient population. CMS indicated that it may use reported sociodemographic data to share "certain aggregate, de-identified data… stratified by sociodemographic metrics (e.g., dual status, [low-income subsidy] eligibility, and race and ethnicity)" and for other monitoring and evaluation purposes. This focus on health equity is intended to align the model with the agency's strategic refresh and President Biden's relaunched Cancer Moonshot, both of which prioritize the advancement of health equity.

Cancer practices and programs are largely supportive of this new model element, given that social needs play a significant role in clinical outcomes. Though many past OCM participants are already screening for health-related social needs and collecting sociodemographic data of their patients, the reporting of these data allows for standardization and the opportunity for participants—and the broader healthcare community—to begin to address disparities in cancer treatment and outcomes in a concerted and meaningful way.

Application and Implementation Timeline

The first EOM performance period is set to begin on July 1, 2023. Physician group practices interested in participating must complete an application through the EOM Application Portal by 11:59 pm EST on Sept. 30, 2022. Notably, applications are non-binding, and the submission of an application is *not* an obligation to participate in the model. Approved applicants will receive a participation agreement, which will need to be signed in early 2023, formally confirming the practice's participation in the EOM. Additional information on the model and application process can be found online in the EOM Request for Applications: innovation.cms.gov/media/document/eom-rfa.

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

References

1. CMS. The Enhancing Oncology Model (EOM) Request for Applications. Published June 27, 2022. Accessed Aug. 26, 2022. innovation.cms.gov/media/document/eom-rfa

Highlights from the CY 2023 MPFS and HOPPS Proposed Rules

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

It's that time of year again, digesting the thousands of pages produced by the Centers for Medicare & Medicaid Services (CMS) to share the agency's vision of healthcare spending for physicians, hospitals, ambulatory surgical centers, and office settings for the coming year. This year, the proposed rules were released separately: the Medicare Physician Fee Schedule (MPFS)[1] on July 8, 2022, and the Hospital Outpatient Prospective Payment System (HOPPS)[2] on July 15, 2022. Both rules outline how CMS is planning to transition from the public health emergency (PHE) and the provisions and waivers in response to the COVID-19 pandemic to more of "how it used to be" mixed in with a "new normal."

Below are several of the proposed key items that relate or impact oncology programs and providers. Note: Some payment impacts are outside CMS's authority to change. This includes the 2 percent sequestration reduction that was fully reimplemented on July 1, 2022, after suspension due to the PHE and the 4 percent reduction in payments due to the pay-as-you-go rule that is expected to begin Jan. 1, 2023. The pay-as-you-go decrease is due to the economic relief provided as part of the COVID-19 response and a way for the federal government to earn back monies. These reductions (−6 percent) apply to Medicare payments for each code and are added to the payment policies proposed by CMS for calendar year (CY) 2023.

Medicare Physician Fee Schedule

The MPFS provides the regulatory information and payment rates for all physicians across all practice settings. Stakeholders had 60 days from July 8, 2022, to submit comments to CMS on the proposed changes for CY 2023.

The conversion factor is the value multiplied to the assigned relative value units (RVUs) of physician work, practice expense, and malpractice of each code to determine the dollar amount of each code's payment. CMS proposed a conversion factor of $33.0775—a decrease of 4.5 percent from the CY 2022 conversion factor of $34.6062. In Table 1, right, CMS provided a breakdown of the proposed payment impacts to oncology specialties. This breakdown only reflects the impact to the estimated RVUs and does not reflect other changes, such as the 4.5 percent decrease to the conversion factor.

CMS proposed updates to the malpractice RVUs for next year; these were last updated in CY 2020 and are required to be updated every three years. Based on the malpractice or practice liability insurance data collected from all 50 states, CMS proposed changes to the risk index values that are used to calculate the malpractice RVUs at the code level. Malpractice RVUs reflect the risk of the primary specialty assigned to the service that performs the service. For CY 2023, the risk index value for hematology/oncology is proposed to decrease from 0.765 to 0.741 for years 2023 to 2025 and, for radiation oncology, CMS proposed an increase from 0.840 to 0.905 for years 2023 to 2025.

Evaluation and Management Codes

Effective Jan. 1, 2023, there will be updates to the next set of evaluation and management (E/M) codes. These codes are the "Other E/M" visits (inpatient and observation visits, emergency department visits, nursing facility visits, domiciliary or rest home visits, home visits, and cognitive impairment assessments). These codes exclude critical care services, yet they match the framework (e.g., medical decision making or time-based) of the outpatient and office E/M visits that changed in 2021. CMS proposed to accept and move forward with the American Medical Association (AMA) Current Procedural Terminology (CPT®) Editorial Panel changes, with a few minor exceptions. Changes to the "Other E/M" visit codes made by the AMA were released in early July 2022 and can be found online at ama-assn.org/system/files/2023-e-m-descriptors-guidelines.pdf.

CMS clarified its proposal to slightly amend the definitions of "initial" and "subsequent" in relation to E/M visits for inpatient services. The agency does not recognize subspecialties, as is outlined in the CPT manual, so it proposed the following language:[1]

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

CMS also proposed three new Healthcare Common Procedure Coding System (HCPCS) codes to be used in place of the AMA created CPT code **993X0** for prolonged services. One code would be for hospital inpatient or observation care, one for nursing facilities, and one for home or residence. Starting in 2023, providers should use the below code to bill prolonged services for inpatient time-based visits with their Medicare beneficiaries:

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

SPECIALTY	TOTAL NON-FACILITY /FACILITY	ALLOWED CHARGES (MILLIONS)	COMBINED IMPACT
Hematology/oncology	Total	$1707	−1%
	Non-facility	$1130	−2%
	Facility	$577	1%
Radiation oncology and radiation therapy centers	Total	$1609	−1%
	Non-facility	$1540	−1%
	Facility	$69	−1%

- **GXXX1**. Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes **99223**, **99233**, and **99236** for hospital inpatient or observation care evaluation and management services). Do *not* report **GXXX1** on the same date of service as any other prolonged service for evaluation and management (**99358**, **99359**, **993X0**). Do *not* report **GXXX1** for any time unit less than 15 minutes.

These new HCPCS codes would replace the existing CPT codes for inpatient prolonged services:

- **99356**. Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour. (List separately in addition to the code for inpatient or observation E/M service.)
- **99357**. Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; each additional 30 minutes. (List separately in addition to code for prolonged service.)

As with outpatient prolonged services, CMS did not agree with the AMA on how it counted time to meet the threshold for billing new codes. In addition, the prolonged service code **GXXX1** can only be used with the highest-level hospital inpatient or observation care visit codes (**99223**, **99233**, and **99236**) when the time-based method is used.

CMS proposed that the prolonged service period described by **GXXX1** begins 15 minutes after the total times (as established in the physician time file) for codes **99223**, **99233**, and **99236** have been met. Additionally, CMS proposed that the **GXXX1** prolonged code would be for a 15-minute increment, and the entire 15-minute increment must be completed to bill the code.

CMS also proposed that **GXXX1** would apply to face-to-face and non-face-to-face time spent on patient care within the survey time frame. For codes **99223** and **99233**, this would be time spent on the date of the patient encounter. For code **99236**, this would be time spent within three calendar days of the patient encounter.

CMS proposed to fully integrate E/M split (or shared) visits for new and established patients in 2024 (a one-year delay) to allow full acquaintance and implementation of the other E/M visit changes for healthcare providers.

Telehealth Post-PHE

The provisions and waivers that were implemented in response to the COVID-19 pandemic will continue for 151 days after the end of the PHE. As of the time of this writing, the PHE is scheduled to end on October 13, 2022. CMS reiterated that if any codes are not included in the telehealth list of services that are identified as continuing permanently or temporarily, as a category 3 telehealth service, they will end on day 152 after the PHE's end date. Specific to oncology, services to be removed include:

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

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

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

Manufacturer Refunds for Discarded Single-Use Vial Amounts

Drugs and biological "drugs" are administered to patients in varying amounts; often, the amount administered is less than the total amount available in the drug's vial or package. Some of these drugs are only available in single-dose vials or single-dose packages. The U.S. Food and Drug Administration (FDA)-approved labeling for a drug packaged in a single-dose container typically states that any extra amount of the drug remaining after a dose is administered must be discarded. Based on this language, under Part B, Medicare established that any unused

and/or discarded amounts from a single-dose vial or single-dose package would be paid when reported on the claim with use of **modifier JW**. Note: **modifier JW** cannot be used with drugs that are not separately paid, such as drugs packaged into outpatient hospital services or other designated settings.

Section 90004 of the Infrastructure Investment and Jobs Act[3] requires manufacturers to provide a refund to CMS for certain discarded amounts of a refundable single-dose container or single-use package drug. The refund amount is the amount of the discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of the total charges for the drug in a given calendar quarter. CMS clarified that refundable single-dose vials or single-dose packages do not include radiopharmaceuticals, imaging agents, certain drugs requiring filtration, and certain new drugs. To accomplish the requirements of the Act, CMS proposed the following:[3]

- Use **modifier JW** (or if another modifier is used or added in the future for the same data) to identify discarded billing units of a billing and payment code to calculate the refund amount.
- For dates of service on or after Jan. 1, 2023, **modifier JW** will be required on claims for all single-dose container or single-use drugs when any amount is discarded, as part of CMS' current policy.
- Use **modifier JZ** on billing claims to attest there was no discarded amount from the single-dose vial or single-use package that is normally paid under Part B with **modifier JW**.
- The definition for refundable single-dose container or single-use package drug would apply "to drugs paid under Medicare Part B (that is, under any payment methodology) that are described as being supplied in a 'single-dose' container or 'single-use' package based on FDA-approved labeling or product information. This definition also includes drugs described in FDA-approved labeling as a 'kit' that is intended for a single dose or single use."[3]
- Excluded drugs would be radiopharmaceuticals, imaging agents, drugs requiring filtration during the preparation process, and drugs approved on or after the Act's date of enactment (Nov. 15, 2021), for which payment under Part B has been made for fewer than 18 months.
- Exclusion of drugs requiring filtration during their preparation process specifically pertains to those in which the dosing and administration instructions that are included in the labeling require filtration during the drug preparation process, prior to dilution and administration, and that require any unused portion be discarded after the filtration process be discarded.
- Annual reports would be sent to drug manufacturers no later than Oct. 1 of each year that include data from second, third, and fourth quarters of the previous year and the first quarter of the current year.
- Refunds by drug manufacturers would be due no later than Dec. 31 of the year in which the annual report was delivered.
- Establishment of a dispute resolution process, civil monetary penalties, and periodic review of Part B medication claims to ensure **modifier JW**, **modifier JZ** (if finalized), and discarded drug amounts are billed appropriately as part of the already developed claims audit policy and process.

Hospital Outpatient Prospective Payment System

The HOPPS provides the regulatory information and payment rates for facility-based settings, outpatient hospitals, and ambulatory surgical centers. Stakeholders had 60 days from July 15, 2022, to submit comments to CMS on the proposed changes for CY 2023.

CMS proposed a 2.7 percent increase to the Outpatient Department fee schedule. The agency estimates that total payments to HOPPS from providers will be approximately $86.2 billion, an increase of approximately $6.2 billion when compared to CY 2022 HOPPS payments. However, due to a June 15, 2022, U.S. Supreme Court ruling related to the 340B Drug Discount Program, CMS provided an alternate payment file for CY 2023 HOPPS rates, which takes into account the shift from average sales price (ASP) −22.5 percent to ASP +6 percent.

Procedures Assigned to New Technology APC Groups for CY 2023

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

For example, scalp cooling is a new technology that became effective July 1, 2021, and is used to describe initial measurement and calibration of a scalp cooling device for patients' use during chemotherapy administration to prevent hair loss. The scalp cooling device is included in Medicare's national coverage determination (NCD) policy, specifically, **NCD 110.6** (scalp hypothermia during chemotherapy to prevent hair loss). The scalp cooling cap is classified as a supply and is not paid separately under HOPPS. CMS has received comments that indicate that there are substantial resource costs ($1,900 to $2,400) for cap calibration and fitting. The Category 3 code **0662T** is billable once per chemotherapy session, which CMS interprets to be once per course of chemotherapy. Scalp cooling was new under the CY2022 HOPPS, so there are no claims data yet for this technology. As such, CMS proposed to continue assigning scalp cooling to a New Technology APC for CY 2023.

Payments of Drugs, Biologicals and Radiopharmaceuticals

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

- Packaging of drugs and biologicals estimated at a per day administration cost less than or equal to $135. (Note: In CY 2022, this amount was set at less than or equal to $130.)
- Continuing to separate payment for items with an estimated per day cost greater than $135 except for diagnostic radiopharmaceuticals; contrast agents; anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies or devices when used in a surgical procedure.

- Continuing the policy of making packaging determinations on a drug-specific basis rather than by HCPCS code for those codes that describe the same drug or biological in different dosages.
- Continuing the policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product approved for a reference product.
- Continuing to provide payment for diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on ASP methodology, because CMS considers these to be drugs under HOPPS.

340B Drug Discount Program

In the CY 2018 HOPPS final rule, CMS finalized the policy to pay for drugs purchased under the 340B Drug Discount Program at ASP −22.5 percent. (Note: This payment policy did *not* include drugs with pass-through payment status or vaccines.) This rate was significantly different than the previous rate of ASP +6 percent. Since this payment policy was updated in CY 2018, there has been significant litigation that has resulted in varying decisions, some which favored the plaintiff and some which favored the defendant (CMS). In response to these rulings, the payment policy for the 340B Drug Discount Program has had some back-and-forth adjustments between the ASP +6 percent and ASP −22.5 percent rates.

On June 15, 2022, the U.S. Supreme Court filed a decision in the *American Hospital Association v. Becerra*, No. 20-1114, 2022 WL 2135490 case.[4] The court reversed the decision of the U.S. Court of Appeals for the District of Columbia Circuit, citing that Health and Human Services secretary may *not* vary payment rates for drugs and biologicals among groups of hospitals in the absence of having conducted a survey of hospitals' acquisition costs. Though the court's decision concerned CY 2018 and CY 2019 payments, the decision has implications for CY 2023.

Utilizing the separately paid line items with modifier **JG** (the modifier used to identify drugs purchased under the 340B Drug Discount Program) in the CY 2021 claims data available for HOPPS rate-setting, the estimated payment differential would be an increase of approximately $1.96 billion in HOPPS drug payments. To ensure budget neutrality, CMS would apply this offset and decrease HOPPS payments by factoring in a 0.9596 adjustment for a revised CY 2023 conversion factor of $83.279. In comparison, CMS originally proposed the CY 2023 conversion factor, with payments for 340B drugs at ASP −22.5 percent, as $86.785. CMS provided 340B alternate payment files for CY 2023, which reflect a decrease in values; the files do not reflect how payments would be adjusted for CYs 2018 to 2022, which must also be paid back to hospitals. CMS is seeking comments on how to incorporate these additional adjustments for the aforementioned years.

The following is provided directly from a section of the CY 2023 HOPPS proposed rule titled *Summary of Major Provisions*, in which CMS summarizes the issue and request for comments:[2]

"For CY 2023, we formally propose at this time to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs and biologicals, including when furnished in nonexcepted off-campus PBDs [provider-based departments] paid under the [M]PFS. This proposal is in accordance with the policy choices and calculations that CMS made in the months leading up to publication of this proposed rule before the [U.S.] Supreme Court issued its decision in American Hospital Association v. Becerra (Docket 20-1114). However, we note that, in light of the Supreme Court's recent decision in American Hospital Association v. Becerra, we fully anticipate applying a rate of ASP + 6 percent to such drugs and biologicals in the final rule for CY 2023 and making a corresponding decrease to the conversion factor consistent with the [H]OPPS statute and our longstanding policy that this adjustment is made in a budget neutral manner. We are still evaluating how to apply the Supreme Court's recent decision to prior calendar years. In that decision, the Court summarized the parties' arguments regarding budget neutrality and stated that, '[a]t this stage, we need not address potential remedies.' We are interested in public comments on the best way to craft any potential remedies affecting cost years 2018 [to] 2022 given that the Court did not resolve that issue."

The CY 2023 final rules are expected to be released on or before Nov. 1, 2022. This is when we will find out whether the various payment policies and regulatory updates were finalized as proposed or something different. Outside of CMS's rulemaking, it is expected there may be some changes of other payment decreases, which the agency does not have the authority to change. It is quite possible the provider community may not know for certain until the end of December what reimbursement rates will be in place starting Jan. 1, 2023.

Lastly, as of the writing of this article, there is still no word on the status of the Radiation Oncology Model; we are still awaiting the outcome of the proposal due to a delay. OI

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spotlight

Coastal Cancer Center, Myrtle Beach, South Carolina

Coastal Cancer Center is a private oncology practice with four locations across South Carolina's Grand Strand, bordering the Atlantic Ocean. Established in 1982, Coastal Cancer Center has been a pillar in its community for decades. In 2010, it was the first practice in the state to become Quality Oncology Practice Initiative certified.

The cancer center has a unique patient demographic in that Myrtle Beach is one of the top 25 retirement destinations in the United States, creating a growing and diverse patient population. When describing patient demographics, Emily Touloukian, DO, medical oncologist and hematologist and president of Coastal Cancer Center, said, "We have a lot of snowbirds and people who retire in the area." A quarter of its patients are over the age of 65, and many of them have multiple healthcare providers—increasing the difficulty of maintaining a comprehensive record of each patient's care. "When you share your patients with another doctor, it is important to keep the lines of communication open," Dr. Touloukian explained. "We make it a priority to work well with all of the patient's physicians."

Coastal Cancer Center's patient-centered ethos is characterized by flexibility, convenience, and geographic location. The largest of the cancer center's four offices is in Myrtle Beach, which is open seven days a week with office visits and infusion services available on Saturdays and Sundays. "It seems like everything happens at five o'clock in the afternoon on Friday, so we want our patients to know that we are always here for them," Dr. Touloukian said.

Community-Based Care

The medical oncology clinic at Coastal Cancer Center is structured in pods. Each pod has a room where oncologists chart with their respective medical assistants, and each medical oncologist is responsible for three exam rooms. Oncologists, nurse practitioners, and physician assistants rotate through Coastal Cancer Center's four South Carolina clinic locations—in Myrtle Beach, Conway, Loris, and Murrells Inlet.

The Myrtle Beach infusion suite has 20 infusion chairs and a full-service pharmacy. Located along the main hallway of the clinic, the pharmacy is only a few steps from the front desk and infusion suite. A pharmacist, two pharmacy technicians, and four mixing technicians support the pharmacy and fill prescriptions on-site.

The Conway clinic is Coastal Cancer Center's second-largest facility. It has 12 infusion chairs and is open five days a week. Computed tomography and positron emission tomography scans are available at the Myrtle Beach and Conway clinic locations, making them a one-stop shop for those presenting to the cancer center.

The Loris and Murrells Inlet infusion suites have seven and eight infusion chairs, respectively, and are both open three days a week. "Having multiple locations is really convenient for our patients because we are close to them, no matter where they live," Dr. Touloukian said.

All Coastal Cancer Center infusion suites are staffed with oncology-certified registered

nurses. These nurses are positioned with a vantage point that provides a clear view of every patient—a necessary precaution in case patients experience a reaction to their treatment. Patients also have access to a television and/or a garden view during their treatment to support their comfort.

The oncologists, medical assistants, and nurses at Coastal Cancer Center are assigned to regular locations on specific days. "We want to be consistent for our patients," Dr. Touloukian said. Because the Myrtle Beach location is the only clinic open seven days a week, patients who frequent any of the other three centers can be seen at the Myrtle Beach clinic if they require care during the weekend.

Coastal Cancer Center works directly with other cancer care teams throughout the area to treat patients requiring radiation or surgical treatment.

Patient Support Services

A new patient coordinator receives all referrals and inquiries directly from patients who request an appointment. These new patient coordinators are responsible for contacting patients and scheduling them for a consultation within one week. During their first appointment, patients meet with the oncologist responsible for their care and discuss their treatment plan. Nurse practitioners and physician assistants then conduct a chemotherapy teaching session with patients to lay out their plan of care, discuss expectations, and ensure that the patient and their family are ready to start the treatment process.

Before beginning treatment, a patient representative meets with each patient to assist with any questions regarding their insurance coverage and treatment costs. If a patient needs financial assistance, the patient representative can help them apply for grants or navigate the Marketplace. Patients can also apply for funding from Coastal Cancer Center's non-profit organization, the Carolina Cancer Foundation, to cover their treatment-related costs. Patient representatives are available to help patients at any point during their cancer journey. "Cancer treatments are very expensive and can be a terrible financial burden," Dr. Touloukian said. "We always try to help our patients navigate that part of treatment and ease what burdens we can."

Coastal Cancer Center has a survivorship program to help patients transition back to their everyday routine after treatment. A few weeks following the completion of their treatment, patients return to the cancer center for a survivorship appointment at any of Coastal Cancer Center's four clinic locations. A nurse practitioner or physician assistant sits down with the patient to help them create a transition plan as they resume their day-to-day lives after cancer. During this visit, patients and providers will discuss the frequency of check-ups and screenings going forward, as well as any changes that patients may experience in their life post-treatment.

Delivering Care During the Pandemic

Coastal Cancer Center remained open throughout the COVID-19 pandemic. "We did not close our doors for a single day," Dr. Touloukian said. The pharmacy, lab, and imaging services it has available helped reduce the exposure risks their patients incurred during treatment throughout the pandemic because patients could receive their medication and complete any blood work and scans in one location.

Though COVID-19 was challenging for providers, patients, and staff to navigate, the pandemic also brought new ideas. "It showed us how innovative we can be," Dr. Touloukian said. Telehealth services were an innovation inspired by the pandemic that cancer center staff continue to use regularly. These services have improved the quality of care provided to older adults, who may also receive care outside South Carolina. "One of the ways I use telehealth now is to bring families into the exam room," Dr. Touloukian said. "Loved ones who are out of state or may not be able to make it to the office can now attend visits with their family members." OI

tools

Approved Drugs

- On June 24 the U.S. Food and Drug Administration (FDA) approved **Breyanzi® (lisocabtagene maraleucel)** (Bristol Myers Squibb, bms.com) for adult patients with large B-cell lymphoma who have refractory disease to first-line chemo-immunotherapy or relapse within 12 months of first-line chemo-immunotherapy or who have refractory disease to first-line chemo-immunotherapy or relapse after first-line chemo-immunotherapy and are not eligible for hematopoietic stem cell transplantation due to comorbidities or age. It is not indicated for the treatment of patients with primary central nervous system lymphoma.
- On Aug. 5 the FDA approved the new tablet formulation of **Calquence® (acalabrutinib)** (AstraZeneca, astrazeneca.com) for all current indications, including chronic lymphocytic leukemia, small lymphocytic lymphoma, and relapsed or refractory mantle cell lymphoma.
- On Aug. 5 the FDA approved **Enhertu® (fam-trastuzumab deruxtecan-nxki)** (AstraZeneca and Daiichi Sankyo, Inc., astrazeneca.com and daiichisankyo.com) for adult patients with unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-low (IHC 1+ or IHC 2+/ISH–) breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within six months of completing adjuvant chemotherapy. Enhertu was also approved by the FDA on Aug. 12 for the treatment of adult patients with unresectable or metastatic non-small cell lung cancer whose tumors have activating HER2 (ERBB2) mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy.
- On Aug. 5 the FDA approved **Nubeqa® (darolutamide)** (Bayer HealthCare Pharmaceuticals Inc., bayer.com) **in combination with docetaxel** for adult patients with metastatic hormone-sensitive prostate cancer.
- On Aug. 10, the FDA granted regular approval to **Tabrecta® (capmatinib)** (Novartis Pharmaceutical Corporation, novratis.com) for adult patients with metastatic non-small cell lung cancer whose tumors have a mutation leading to mesenchymal-epithelial transition exon 14 skipping, as detected by an FDA-approved test.
- On June 22 the FDA granted accelerated approval to **Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib)** (Novartis Pharmaceutical Corporation, novratis.com) for the treatment of adult and pediatric patients six years and older with unresectable or metastatic solid tumors with BRAF V600E mutation, who have progressed following prior treatment and have no satisfactory alternative treatment options.
- On July 14 the FDA approved **Xalkori® (crizotinib)** (Pfizer Inc., pfizer.com) for adult and pediatric patients one year of age and older with unresectable, recurrent, or refractory inflammatory anaplastic lymphoma kinase-positive myofibroblastic tumors.

Drugs in the News

- Genmab (genmab.com) announced its intent to submit a biologics license application (BLA) to the FDA for **DuoBody®-CD3xCD20 (epcoritamab)**, an investigational bispecific antibody for the treatment of patients with relapsed/refractory large B-cell lymphoma.
- The Menarini Group (menarini.com/en-us) and Stemline Therapeutics (stemline.com) announced that the FDA accepted and granted priority review to the new drug application (NDA) for **elacestrant** to treat patients with ER+/HER2– advanced or metastatic breast cancer.
- AstraZeneca (astrazeneca.com) and Daiichi Sankyo (daiichisankyo.com) have received notification of acceptance from the FDA and for its supplemental BLA, which was granted priority review, for **Enhertu® (trastuzumab deruxtecan)** for the treatment of adult patients unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-negative) breast cancer who have received a prior therapy in the metastatic setting.
- Roche (roche.com) announced that the FDA accepted and granted priority review to its BLA for **Lunsumio® (mosunetuzumab)** for the treatment of adults with relapsed or refractory follicular lymphoma who have received at least two prior systemic therapies.
- Mustang Bio, Inc. (mustangbio.com) announced that the FDA granted orphan drug designation to **MB-106**, an autologous chimeric antigen receptor

T-cell therapy for the treatment of Waldenström macroglobulinemia.

- Sierra Oncology, Inc. (sierraoncology.com) announced the submission of an NDA to the FDA for **momelotinib**, an ACVR1/ALK2, JAK1, and JAK2 inhibitor in development for the treatment of myelofibrosis.
- Immunity Bio, Inc. (immunitybio.com) announced that the FDA accepted for review the BLA for **N-803** for the treatment of patients with BCG-unresponsive non-muscle-invasive bladder cancer carcinoma *in situ* with or without Ta or T1 disease.
- Gamida Cell Ltd. (gamida-cell.com) announced that the FDA accepted for filling the company's BLA for **omidubicel** for the treatment of patients with blood cancers in need of an allogenic hematopoietic stem cell transplant.
- Kazia Therapeutics, Ltd. (kaziatherapeutics.com) announced that the FDA has awarded orphan drug designation to **paxalisib** for the treatment of atypical rhabdoid and teratoid tumors.
- Janssen (janssen.com) announced that the FDA has granted breakthrough therapy designation to **talquetamab** for the treatment of adult patients with relapsed or refractory multiple myeloma who have previously received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody.
- Coherus BioSciences, Inc. (coherus.com) and Shanghai Junshi Biosciences Co., Ltd. (junshipharma.com/en/Index.html) announced that the FDA accepted for review the BLA resubmission for **toripalimab in combination with gemcitabine and cisplatin** as first-line treatment for patients with advanced recurrent or metastatic nasopharyngeal carcinoma and for **toripalimab monotherapy** for the second-line or later treatment of recurrent or metastatic nasopharyngeal carcinoma after platinum-containing chemotherapy.
- TG Therapeutics, Inc. (tgtherapeutics.com) announced their voluntary withdrawal of the pending BLA/supplemental NDA for the combination of **ublituximab and Ukoniq®** (**umbralisib**) for the treatment of adult patients with chronic lymphocytic leukemia and small lymphocytic lymphoma.
- Wugen, Inc. (wugen.com) announced that the FDA granted fast track designation and rare pediatric disease designation to **WU-CART-007** for the treatment of relapsed or refractory T-cell acute lymphoblastic leukemia/lymphoblastic lymphoma.
- VBI Vaccines Inc. (vbivaccines.com) announced that the FDA granted orphan drug designation to **VBI-1901** for the treatment of glioblastoma.
- Byondis (byondis.com) announced that the FDA accepted the company's BLA submission for **[vic-] trastuzumab duocarmazine (SYD985)** for patients with HER2-positive unresectable locally advanced or metastatic breast cancer.

Devices and Assays in the News

- Adaptive Biotechnologies (adaptivebiotech.com) announced that Palmetto GBA, a Medicare administrative contractor, has expanded coverage for the **clonoSEQ® Assay** to include monitoring minimal residual disease in Medicare beneficiaries with diffuse large B-cell lymphoma.
- Guardant Health, Inc. (guardanthealth.com) announced that the FDA approved the **Guardant360® CDx** as a companion diagnostic to select patients with unresectable or metastatic HER2-mutant non-small cell lung cancer whose tumors have activating ERBB2 mutations for treatment with Enhertu.
- Berry Oncology (en.berryoncology.com/index.html) announced the launch of its innovative, one-time precision product **HIFI Pan-Cancer Screening**, which is an early multi-cancer screening product developed based on the company's proprietary HIFI technology platform.
- Pillar Biosciences (pillarbiosci.com) announced that the FDA accepted for review the company's premarket approval supplement application to expand the label/indication of **oncoReveal™ Dx Lung & Colon Cancer Assay** to include actionable targets for eight additional cancer types.
- Roche (roche.com) announced that the FDA approved its VENTANA MMR RxDx Panel label expansion to aid in identifying patients whose solid tumors are deficient in DNA mismatch repair and who may be eligible for Keytruda® (pembrolizumab) (Merck, merck.com).

FDA Guidance on Inclusion of Patients with Incurable Cancers in Clinical Trials

On July 29 the FDA issued finalized guidance on the inclusion of patients with incurable cancers in clinical trials for investigational therapies. The agency recommends that sponsors include patients with incurable cancer—defined as unresectable, locally advanced, or metastatic disease in solid tumors and/or hematologic malignancies with unfavorable long-term overall survival—in oncology clinical trials even if patients met criteria that would otherwise exclude them, such as in situations where a patient had previously received an available therapy in a non-curative setting. The recommendation by the FDA emphasizes that sponsors still need to follow regulations around informed consent before enrolling patients with incurable cancers in clinical trials. OI

Home as a Site of Care for Acutely Ill Patients with Cancer

BY AMANDA PATTON, MA

A conversation with Kathi Mooney, PhD, RN, FAAN

Dr. Kathi Mooney is a distinguished professor at the University of Utah College of Nursing and holds the Louis S. Peery and Janet B. Peery Presidential Endowed Chair in Nursing. An investigator and co-leader of the Cancer Control and Population Sciences Program at the National Cancer Institute-designated Huntsman Cancer Institute, Dr. Mooney leads research programs in patient remote symptom monitoring and management, technology-aided interventions, cancer family and caregivers, outcomes improvement for patients with cancer in rural and frontier communities, and innovative cancer care delivery model testing.

OI. Would you share a little about your career path and the development of the Huntsman at Home model for patients with cancer?

My background is as a nurse and, for more than 20 years, I have been in the academic setting, involved in research through the University of Utah College of Nursing and the Huntsman Cancer Institute. My research has always grown out of a very strong interest in improving approaches to symptom management that lead to better quality of life for patients with cancer and their families.

A lot of early cancer symptom management research focused on studying a single symptom, looking at the symptom, its frequency and pattern during treatment, and then developing interventions for the symptom. Most patients who are being treated for cancer have multiple symptoms, and I decided to take a different approach in that I wanted to know if we could deliver comprehensive symptom care in a better way than current approaches.

Unfortunately, the history of cancer care is that most acute symptom care occurs in the ED, and, more than half the time, patients are then admitted to the hospital to treat these acute episodes.

What I saw was that the standard of care was to give patients education prior to the start of treatment, hold chemo classes, provide a notebook with symptom care tips for patients, and tell patients to call the oncology team if they had a problem.

What I learned in my research is that patients were not using those materials, and they rarely called their oncology team about their poorly controlled symptoms. As a result, poorly controlled symptoms escalated to acute levels and patients ended up in the emergency department [ED]. Unfortunately, the history of cancer care is that most acute symptom care occurs in the ED, and, more than half the time, patients are then admitted to the hospital to treat these acute episodes.

It seemed to me that we should be more proactive around symptom management. When I considered how we might do this—well, treatment is given on an outpatient basis and patients spend most of their time at home. So how do we proactively know how patients are doing? Instead of waiting and expecting patients to contact us, how can we intervene before symptoms get out of hand and monitor patients at home?

Kathi Mooney, PhD, RN, FAAN

Based on that idea, a colleague and I developed an automated remote monitoring platform, Symptom Care at Home, that patients could proactively call on a daily basis and report their symptoms.[1] Or, if patients had not called in, the system would call them. The platform provided a daily check on patients' symptoms that were occurring and their severity level. Then, through a triage system, patients could receive automated coaching using the same content covered in the patient notebooks but tailored exactly to the symptoms and severity level reported that day. Symptoms that were worsening or out of control—moderate and higher levels—would trigger an alert to the oncology care team. In my studies, nurse practitioners [NPs] conducted the call backs to patients with poorly controlled symptoms, and we found NPs to be highly skilled in providing virtual symptom care.

Our studies demonstrated that, in fact, symptom reporting and proactive intervention are very effective in reducing symptom burden and decreasing ED utilization for care.

The remote symptom monitoring and care worked well to decrease symptom burden, but there were still times when acute symptom episodes resulted in unplanned healthcare utilization.

I was a part of a University of Utah health system committee looking at ways to decrease unplanned hospitalizations. And I was intrigued by the hospital-at-home model that is a common acute, home-based care model in single-payer countries but not in the United States. I found it interesting that this model had not been used in cancer. Mainly, hospital-at-home programs are geriatric focused or aimed at management of other acute, short-term conditions. But I thought that hospital-level care at home and acute oncology care could go together. Perhaps a focus on the home as a site of care—especially for the management of symptoms before they get out of control and to treat acute episodes that would otherwise require ED care or hospitalization—would offer a new way to improve care. Fortunately, there was a group of us at Huntsman Cancer Institute who were also interested in studying this model for oncology, and we were propelled forward through this interest and generous philanthropy, which was necessary to mount a demonstration project.

We started Huntsman at Home™ in 2018 before COVID-19, but as it turned out with the COVID-19 pandemic, keeping patients out of the ED and hospital became a high priority. CMS [the Centers for Medicare & Medicaid Services] provided a Medicare waiver for reimbursement of hospital-level acute care in the home during the pandemic.[2,3] This [reimbursement] allowed many healthcare systems to consider their own hospital-at-home programs even if they did not have philanthropy or other financial backing to begin.

However, I think there is still hesitancy on the part of health systems and oncology practices to jump into the hospital-at-home space until there is an assurance that there is going to be a permanent payment model for this setting. So payment, moving forward, is the uncertainty. From the research that we published in the *Journal of Clinical Oncology* in 2021, we have demonstrated that the oncology hospital-at-home model has value in terms of decreasing unplanned healthcare use and even the potential for substantial cost savings.[4] [For more, turn to "Delivering Hospital-Level Acute Care at Home: Learning from Huntsman at Home" on page 22.]

OI. Were you able to expand the model to three rural communities, as planned, despite the pandemic?

Yes, we have done that. Our timetable was delayed a bit because of the pandemic, but we began in August 2021. We've served about 80 patients in the three communities of Emery County, Carbon County, and Grand County in southeastern Utah—a two- to five-hour one-way drive from Huntsman Cancer Institute.

OI. Can you say more about those rural communities? Is the in-home acute care like the care provided in the local Salt Lake City program? Is the rural program structured with an NP lead?

We adapted the Huntsman at Home program for delivery in our rural communities, primarily to address the added coordination needs between local healthcare resources and Huntsman. The

rural program does have the same structure, with an NP lead, and we work with local home health agencies for the registered nurse care. When we started, we had an NP from our Salt Lake City program go out into the community for three days each week and conduct telehealth visits the other days. More recently, we have hired an NP who lives in the community. He serves as the primary NP for the three counties being served with telehealth support from our Salt Lake City program.

One component we adopted in our rural program that we did not do in the Salt Lake City program is the addition of a nurse navigator care manager who lives in the community. We found her knowledge of the people who live in her community to be incredibly important because of the social determinants of health that are impacting these patients. For example, travel to Huntsman Cancer Institute can be barrier to care—these communities are a two- to five-hour drive away, one way. We found that the coordination of care between the Huntsman at Home team, local home health agency, local safety-net hospitals, and patients' oncology team required someone who could effectively manage care across all those care settings. We found that it is important to determine which visits require travel to Huntsman Cancer Institute and which visits can be facilitated through telehealth. That level of scheduling—the discernment about when you need to see the patient in person and when a high-quality visit via telehealth is appropriate—is a huge benefit in terms of decreasing some of the transportation demands on patients and family caregivers, while still providing high-quality access to care paired with the ability to stay home. The nurse navigator care manager has been vital to effective care coordination and close monitoring of patient status.

In addition, we took a different approach to how patients are admitted to the rural program. In the Salt Lake City program, patients are primarily referred for admission. In the rural locations, we look at which patients are on active treatment or having active appointments at Huntsman for continuing care. We look at the frequency of patients' cancer care visits. Patients who have been to the ED and patients experiencing a range of escalating care needs, we directly contact to assess their needs and whether they would benefit from the program. So identification of patients who could benefit from acute or subacute services is more proactive for patients in the rural communities.

OI. Is the nurse navigator care manager also an NP or is that individual an advanced nursing provider who has had experience as a navigator?

She is actually a nurse in our Doctor of Nursing Practice [DNP] program, so she's on her way to becoming an NP. She has a very well-rounded skillset that includes case management and home health experience. Plus, she is a member of the community where she practices, and that really makes a difference.

OI. Have there been staffing challenges? Challenges in finding enough qualified nursing professionals in that area to work with the NP?

We do provide additional education to all the home health nurses because the home health support we need requires a knowledgeable background in oncology and an understanding of acute changes.

There is turnover among the home health agency nurses, but I don't know that their shortage is any worse than what is being experienced across all nursing right now.

We do provide additional education to all the home health nurses because the home health support we need requires a knowledgeable background in oncology and an understanding of acute changes. The assessment and understanding of the disease process and cancer symptom management is not a regular component of home health care. So, when there is turnover, it puts the onus on us to continually develop the home health nursing staff.

OI. Is the Huntsman at Home training for NPs and home health nurses in person? Online?

The training is hybrid. For NPs, some training modules are accessed online, such as the palliative care courses. Then, NPs spend about six weeks at Huntsman Cancer Institute, with time in the Supportive Oncology Clinic, rotations with the hospitalists taking care of acute inpatients, and going out on home visits with NPs in the Salt Lake City program. So there is a very systematic in-person training program, plus online education. For the home health agency RNs, the lead NP primarily does the education, plus some online courses, and that works quite well. They have in-person sessions, which allows the NP to identify patients the RNs have taken care of and to discuss current patients to develop their skillset.

OI. During a recent Modern Healthcare virtual briefing on hospital-at-home models, several presenters talked about hospitalist-led programs (these were not oncology-specific models). The Huntsman model is NP-led. ACCC is an advocate for oncology advanced practice providers (APPs) working at the top of their licensure. Why do you believe NPs are well-suited for this lead role in the cancer-care-at-home model?

I would certainly agree that we want NPs to work at the top of their license, and the Huntsman at Home program is a good demonstration of that. I don't think there are any studies comparing hospitalists and NP care outcomes. We could answer that question by doing a study. We have found an NP model to be a safe, effective, and economical model. We do have an excellent medical director who has been key in training and providing backup for the NPs. The NPs also work closely with the patient's oncologist.

NPs are now well integrated in oncology. They work in oncology ICUs [intensive care units] and with hospitalists on inpatient units. NPs run the day-to-day care of patients in the inpatient unit. The fact that NPs would take that approach into the home makes a lot of sense. I think it is important to have a physician as a consultant for patients who are not responding as you would expect to first-line approaches to their medical care, but the NPs are very experienced at caring for this patient population. Our medical director, who is both an oncologist and a palliative care physician, is very much involved as an active consultant and support resource to the NPs when needed.

Our Huntsman at Home NPs are experienced in symptom management and primarily work with the patient's oncologist. Some of the symptoms that we are trying to get ahead of—like dehydration from nausea and vomiting due to chemotherapy—NPs can address. But many of the issues we see relate to disease progression. As symptoms develop, there is always the question of whether it is an acute episode related to treatment or whether it is something related to disease progression. In these instances, the NP will reach out to the patient's oncologist to discuss imaging, treatment planning, and so forth. We find that the NPs work closely with the patient's oncologist, and this collaborative partnership seems to be important and useful in terms of proceeding with treatment and connecting back to the oncologist for treatment decision making. Our model is a hybrid of both acute, short-term problems related to side effects of treatment and also addressing disease progression as it occurs. An oncology NP can walk in both these worlds and make sure that physician involvement is incorporated for what is happening with the patient.

OI. Thinking about the role of technology in the delivery of care in the home, is there any specific technology used by Huntsman at Home that allows the program to go forward; for example, electronic patient-reported outcomes (ePROs)?

Although I'm not a techie myself, to provide care to patients at home and in the home, it is important to use technology. I think *how you use* the technology is more important.

Consider ePROs, increasingly recognized as an important tool to improve monitoring and responding to patient-reported symptoms at home. Technology does enable innovative solutions to support both early intervention and greater patient engagement in their care. As I mentioned earlier, over the past 20 years a colleague and I have developed an automated remote monitoring platform, Symptom Care at Home, that empowers patients to call in proactively and report symptoms they are experiencing.

This approach fits beautifully for patients in the subacute component of Huntsman at Home who are not getting daily visits but still experience symptom flare-up. The clinical team monitors the daily reports and steps up care when symptoms warrant it. The Symptom Care at home platform is an example of a technology-enabled system that makes outreach and monitoring of patients at home feasible and efficient.

When you talk about technology, everyone assumes you're talking about internet-based technology and telehealth, but—as we know—not everyone has access to the internet or a smartphone. Our Symptom Care at Home platform is an IVR [interactive voice recording] system that sends data over telephone lines. All you need is a telephone—it does not have to be a smartphone. We added web and app access for patients who prefer engaging with those systems and have the technology. So there is a range of technology now that can be used to remotely monitor and capture patients' experience and their reports. It is important to engage patients as they prefer and have ways for patients to report symptoms that are available to everyone.

One way to think about it is that the technology enables the reporting. But the quality of the symptom care is the key. If the symptom care isn't good, it doesn't matter whether it's delivered by whiz-bang technology or not.

In terms of hospital-at-home for acute episode care—for example, the patient is dehydrated, needs fluids, needs electrolyte replacement, and so forth—you need a nurse in the home to manage that care. So that is a high-touch situation. The patient may have some instability in their vital signs, and so you may also use remote vital signs monitoring to continue monitoring once the nurse has left the home. We do not use remote patient monitoring with all our oncology patients; we use it for some patients who have issues around blood pressure, heart rate, or oxygenation that we are concerned about. So we may include acute episode monitoring technology, plus the nurse in the home, and telehealth linkage with the NP. It is a combination of resources.

After an acute episode in oncology, I think it is important to have continuing subacute care as follow-up for, perhaps, 30 days. We know in oncology that many symptoms tend to reoccur—especially pain and some of the others, such as nausea and vomiting. These are the patients who end up going to the ED several times a month. If you can monitor and manage those patients at home proactively, you may stop symptoms from escalating. Continued automated symptom monitoring can detect early symptom recurrence as it develops. I think technology is important in providing care at home. It is a partner.

OI. Is there research around the oncology patient experience of hospital-at-home care? The caregiver experience?

We're currently doing a study to address that. I hope to close data collection within the next few months. Besides the patient experience, it is also looking at family caregiver burden. I think it's legitimate to ask, if you kept the patient in the hospital, would it be less burdensome to the family? But with COVID-19, families were not allowed to go into the hospital, and this added a great deal of stress for both the patient and their family, who would have preferred to be at home. And when visitation is allowed, is it really less burdensome for a family member to visit and support the person in the hospital, while they're trying to run their household, care for their children, and work? Hopefully, this study will shed some light on the family caregiver perspective and the patient.

In the general hospital-at-home literature, the studies usually report high patient satisfaction, but the caregiver perspective is often not described.

OI. Barriers standing in the way of this model's advancement seem to be reimbursement, patient selection, staffing, and resource capacity and availability. Do you see these as the main challenges?

The big one is reimbursement. I think more programs will develop once clear reimbursement models for acute and subacute levels of cancer care at home are established. The hesitancy to adopt this as a model is based around reimbursement and the investment needed to deliver these types of services. To date, cancer care has not involved the home—other than hospice care. We've always brought patients to us. To stand up a model that is home-based requires a huge amount of infrastructure and resources because you're including a whole new site of care. It [hospital-at-home care] really is a disruptive change in that it requires coordination and communication among systems—for example, our EHR [electronic health record] system doesn't work with the home health system's EHR and billing system. And how will pharmacy dispense drugs for care delivered in the hospital-at-home setting when they only have an inpatient model for dispensing these types of drugs and infusions? Much of the U.S. healthcare system infrastructure and regulations are not set up to embrace the home as a site of care. Health systems are not going to set up totally new infrastructure only to have payers say they are not going to reimburse the cost. So I think the reimbursement issue is the primary challenge that must be overcome for this model to be widely adopted in the United States.

In oncology, I don't think it is a really difficult question on who to admit to a hospital-at-home care model. Certainly, there are enough of the acute side effects of dehydration, constipation and bowel obstruction, nausea and vomiting, and infection that land people in the hospital—symptoms that we have demonstrated can be safely managed with the hospital-at-home model. Could hospital-at-home be beneficial for treatments like CAR T-cell therapy or bone marrow transplant or early surgery discharge? These are areas for us to branch out to and study. I think we've demonstrated the basic kinds of challenges that happen to patients with cancer that end up as hospital admissions who can be safely cared for at home. I see reimbursement and, therefore, how you stand up a [hospital-at-home] program as the challenge. The need, safety, acceptability, and positive outcomes are clearly established.

OI. Some cancer programs and practices have implemented components of at-home care for their patients, so at present there appear to be different models underway.

Besides those which came out of an academic setting, such as our cancer-specific Huntsman at Home, and those that came out of a health system that provide care for a number of conditions, there are start-up companies that are looking at how to help scale this for health systems or community practices where it is less efficient for the health system or community practice to develop by themselves. It is a new opportunity to examine how we provide care and where we provide care. With these new models, we have an opportunity to achieve real progress in improving quality of life and decreasing the morbidity of cancer and its treatment by more responsive monitoring and prompt treatment of adverse side effects and symptoms as they emerge. OI

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Delivering Hospital-Level Acute Care at Home:

Learning from Huntsman at Home

BY AMANDA PATTON, MA

Monies spent for acute care services, including unplanned hospitalizations and emergency department (ED) visits, are responsible for nearly half (48 percent) of U.S. cancer spending.[1] As value-based payment models look to improve quality and decrease costs, outcome metrics incentivize care transformation aimed at decreasing ED utilization and unplanned hospitalization rates. In recent years, cancer programs and practices have implemented innovative strategies to reduce ED visits and unplanned hospital admissions, including extended and weekend clinic hours, 24/7 oncology-specific urgent care clinics, supportive care clinics, algorithms to risk-stratify patients, and more.

Since 2018, Kathi Mooney, PhD, RN, FAAN, and her colleagues at Huntsman Cancer Institute at the University of Utah have piloted a different approach: Delivery of hospital-at-home care for acutely ill adult patients with cancer through the Huntsman at Home™ model.

The program "features ongoing monitoring and rapid response for patients with unstable, acute illness."[2] Intensive hospital-level care is delivered to eligible patients in their own homes by a care team that includes oncology nurse practitioners (NPs), home health registered nurses, and allied healthcare staff. Besides planned visits, patients can access services within two hours of coming home from the hospital and in response to urgent needs.

The Huntsman at Home model uses a team of specially trained home health nurses to help acutely ill patients with cancer proactively manage emerging treatment-related symptoms, such as pain, nausea, vomiting, febrile neutropenia, and infections. Overseeing the team and patients' care are Huntsman at Home experienced oncology NPs. The program's NPs directly communicate and collaborate with Huntsman Cancer Institute's medical director, a physician who is board certified in oncology and palliative care, and patients' primary oncology team. Bringing hospital-level care into the home reduces patients' travel and wait time for care burdens, improving the patient experience and quality of life by decreasing hours spent in the hospital or clinic setting.

Bringing hospital-level care into the home reduces patients' travel and wait time for care burdens, improving the patient experience and quality of life by decreasing hours spent in the hospital or clinic setting.

Services provided depend on patients' condition but may include "acute symptom management; clinical monitoring of cardiovascular parameters and oxygen therapy; laboratory value monitoring and replacement; medication titration," as well as administration of intravenous (IV) fluids, antibiotics, and other IV medications.[3] Chemotherapy or other anti-cancer infusions are not provided.

In 2021, Dr. Mooney and colleagues published "Evaluation of Oncology Hospital at Home: Unplanned Health Care Utilization and Costs in the Huntsman at Home Real-World Trial" in the *Journal of Clinical Oncology*.[3] The article presented results from a prospective, non-randomized study of 367 hospitalized patients with cancer. Study participants were identified at hospital discharge, with 169 patients admitted to the Huntsman at Home program and 198 patients receiving usual clinic-based care. All patients met the criteria for admission to the hospital-at-home program, and those in the usual care group lived outside the service area for the hospital-at-home program (i.e., more than 20 miles outside of Huntsman Cancer Institute's hospital on the University of Utah campus). The average age of patients in the study was 62 years, 85 percent of patients were White, and 77 percent had Stage IV cancer.

Members of the Huntsman at Home team include clinical care professionals from Huntsman Cancer Institute and Community Nursing Services.

Patients admitted to the hospital-at-home program either needed "continued acute-level medical care after hospitalization" or "had continuing unstable symptoms related to treatment or disease progression that would either require ED evaluation or further hospitalization."[3] The study looked at the period of 30 days after enrollment with Huntsman at Home or the usual care comparison group.

Study results indicated that the odds of unplanned hospitalizations were 55 percent lower in the hospital-at-home group and healthcare costs were reduced by 47 percent in comparison to the usual care group.[3] The hospital-at-home group also had fewer hospital stay days and saw a 45 percent reduction in ED visits, compared to the usual care group.[3]

Study authors reported that next steps for the Huntsman at Home model would be expansion of the program to accept admissions directly from a patient ED visit (rather than by referral) and extension of the model to three rural "geographically distant, under-resourced communities in the southeastern part of Utah."[2] The hospital-at-home care in these communities, located two to four hours from Huntsman Cancer Institute, would be delivered using a combination of telehealth, remote technologies, and in-person care.

In a poster session at the American Society of Clinical Oncology Annual Meeting in June 2022, "Oncology Hospital at Home in Rural Communities: The Huntsman at Home Rural Experience,"[4] Dr. Mooney presented an update on the model's implementation in three rural Utah communities—Emery County, Carbon County, and Grand County.

During the first six months of the expanded Huntsman at Home program, 47 patients were enrolled from these rural areas.[4] Of these, 7 patients experienced 9 acute illness episodes; the average length of the acute episodes of care was 6.1 days. During these acute episodes, treatment was delivered for the following: infection, respiratory distress/hypoxia, cardiac instability (hypotension, tachycardia), dehydration/electrolyte imbalance, and uncontrolled vomiting.[4]

The remaining 40 patients received subacute care aimed to prevent acute episodes and further escalation, requiring a visit to the ED or hospitalization. These patients were on the subacute service for an average of 15.8 days.[4] During the study period, researchers noted that the cancer burden for rural patients was exacerbated by geographic and social determinants of health. For nearly half (44.7 percent), transportation was a barrier to care access, 14.9 percent experienced food insecurity that affected their nutritional status, and 29.8 percent endured financial toxicity due to lost wages, co-pays, and/or out-of-pockets costs. For 48.9 percent of patients, low health literacy affected their ability to navigate their healthcare and to self-manage their care at home.[4]

The Huntsman at Home research presented in the American Society of Clinical Oncology 2022 poster session supports the feasibility of deploying hospital-at-home models to close gaps in access to "acute and subacute care" in rural communities, with the caveat that such models must include "adaptation to rural needs and culture, coordinated escalation procedures and a focus on addressing geographic and social determinants of health that impact cancer burden."[4]

Amanda Patton is a freelance writer in Richmond, Va. She served as associate editor of Oncology Issues *for 17 years.*

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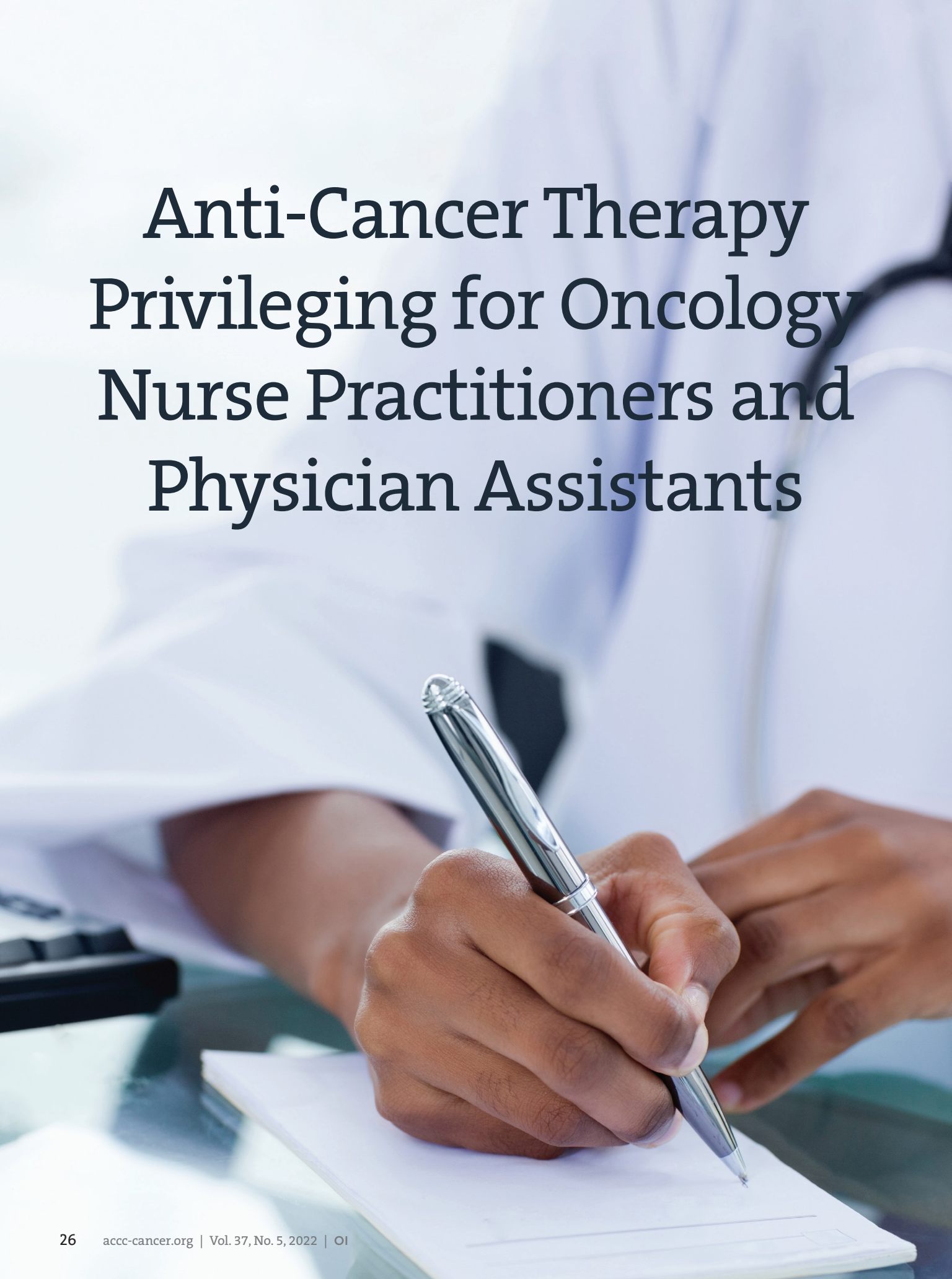
Anti-Cancer Therapy Privileging for Oncology Nurse Practitioners and Physician Assistants



BY ARCHANA AJMERA, MSN, ANP-BC, AOCNP

As a multidisciplinary organization, the Association of Community Cancer Centers (ACCC) advocates for all members of the oncology care team to work at the top of their licensure. In January 2021, ACCC released a statement on the value of oncology advanced practice providers (APPs) that emphasizes the integral role they have in expanding access to and delivery of quality cancer care, "*APPs work with their physician colleagues to provide safe, cost-effective care. APPs improve practice workflow and efficiency, enabling physicians to care for more patients and focus on those who need complex care.…Optimizing models of care that include APPs as team members who can practice at the full scope of their license strengthens the ability of a [cancer] practice to provide multidisciplinary, comprehensive care to more individuals.*"[1]

In the spring of 2021, ACCC and Harborside hosted a "Virtual Summit to Define the Role of Oncology Advanced Practitioners in Equitable Cancer Care Delivery." An invited group of thought leaders, including oncology nurse practitioners (NPs) and physician assistants (PAs), advanced degree nurses, oncology pharmacists, patient advocates, and physicians, came together to discuss the ways in which APPs might advance health equity in oncology care. Summit participants agreed that APPs are often the healthcare professional most engaged in accruing patients to clinical trials. Additionally, because APPs are directly involved in patient care and symptom management, they are well positioned to help bring forward patient-voiced barriers to trial enrollment and the real-world challenges faced by study participants. Of note, a recent study focused on the role of APPs to enhance clinical research. Of the total APPs who responded, 90 percent indicated that APPs should play a role in clinical research and 73 percent wanted to become more involved in this research.[2]

At present, one stumbling block to advancing the role of APPs in cancer care delivery is existing regulatory and practice variability. For example, advanced nursing practice is regulated at the state level and, therefore, scope of practice, regulations, and licensure vary state to state.[3] Not only is there a lack of standardization for scope of practice across the United States, but within each state an NP's role and practice scope are further delineated by their employers—health systems, hospitals, and oncology practices. For PAs as well, licensed healthcare facilities, such as hospitals, surgical centers, and others, have a role in defining their scope of practice.[4] As a result, these APPs may be hindered from practicing to the full extent of their education, training, and competencies.

For more than a decade, the U.S. healthcare system has been warned of an impending oncologist shortage that is projected to occur as the population continues to age and the demand for cancer services increases. As integral members of the cancer care team, APPs play a pivotal role in the rapidly evolving oncology ecosystem, bolstering access to quality care as anti-cancer treatments become more numerous and complex.[5] APPs provide cancer care along the full continuum, from prevention, screening, and diagnosis to novel therapies, clinical trials, symptom management, and end-of-life care.[5]

In an *American Society of Clinical Oncology* (ASCO) *Educational Book* article, "Collaborating with Advanced Practice

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Providers: Impact and Opportunity," authors Heather M. Hylton, MS, PA-C, DFAAPA, and G. Lita Smith, DNP, RN, ACNP-C, characterize an optimally functioning care team: "…each member of the team performs those duties consistent with the fullest extent of his or her license (as applicable), education, training, experience, and competency. This leads to the formation of teams that are cost-effective, provides assurance that the patient's and caregiver's needs are being met by the most appropriate members of the team, establishes accountability, eliminates duplicative work effort, and ensures each member of the team is performing at the functional level intended."[5]

Broadly speaking, APPs are involved in direct patient care in either a co-management clinical model or an autonomous (independent) model.[5] In a co-management model, APPs see patients together with a physician. In an autonomous model, APPs manage patients collaboratively with physician colleagues but maintain an independent clinic schedule and see patients without a physician physically present (in accordance with state law, regulations, and facility or practice policy).[5] A third approach, the mixed-methods model, is a hybrid co-management and autonomous model.[5]

When I came to the University of California San Diego (UCSD) in 2017, I was surprised to learn that intravenous (IV) anti-cancer therapy prescriptive privileging was not an option for NPs at the Moores Cancer Center. This lack of privileging contrasted with my previous APP practice experiences at the University of California at San Francisco and Massachusetts General Hospital in Boston.

Although the UCSD Moores Cancer Center employs both co-management and autonomous practice models, the institution did not privilege APPs (NPs or PAs) to sign orders for IV anti-cancer therapies. Only oral anti-cancer therapy renewal orders were allowed to be signed by APPs. When a physician and APP manage patients collaboratively through an independent practice model, the inability to sign orders can contribute to delays in providers' clinics and infusion center workflow. These delays—waiting for orders to be signed—lead to longer patient wait times and slow clinic schedules. In turn, these slowdowns can negatively impact patient and provider satisfaction and the care experience.

In June 2018, Rana R. McKay, MD, genitourinary medical oncologist, and I launched an initiative to propose a policy change at UCSD Moores Cancer Center that would create a process for NPs and PAs to become privileged to sign IV anti-cancer therapy orders. The proposed policy change did not establish a compulsory process that required these clinicians to attain privileging, but it would provide the opportunity to pursue privileging for those who were interested. At a large National Cancer Institute-designated comprehensive academic institution, such as UCSD Moores Cancer Center, the policy change would need buy-in from all stakeholders—medical staff executive committee, pharmacy and therapeutics committee, infusion leadership, nursing leadership, and physician leadership. An important first step was anticipating potential objections and preparing evidence-based support for our proposed change. The process we followed is outlined below.

Describing the Current State

First, we summarized the current models of APP (NP and PA) practice at UCSD Moores Cancer Center, which included co-management and independent clinics. For APPs who practiced in a co-management setting, privileging to sign IV anti-cancer therapy orders was not a priority, because the oncologist was always present with the APP in the clinic. The cancer program at UCSD Moores Cancer Center is organized by disease site. For some disease teams—for example, where the physician and APP always see the patient together—there would not necessarily be increased efficiencies from APP privileging. However, for high-volume disease sites in which treatments are highly protocolized, including standard-of-care therapies, APP privileging to sign IV anti-cancer therapy orders could help expand patient access to care and the timeliness of infusion orders being signed—ultimately leading to improved patient and provider satisfaction. At the start of our initiative, UCSD Moores Cancer Center policies permitted oncology APPs (NPs and PAs) to order:

- Hormonal therapy
- Oral cancer-directed therapies
- Bone-targeted therapies
- Blood transfusions
- Hydration
- Electrolytes
- Anti-emetics.

APPs were NOT able to:

- Sign anti-cancer therapy continuation orders
- Change anti-cancer treatment parameters
- Give "okay to treat" or "hold" orders
- Change the date for antineoplastic agents.

As a next step, we clearly identified the problem that the new policy would address: The APPs' lack of ability to sign orders was contributing to delays in clinic and infusion center workflow. These delays were also having a negative impact on patient satisfaction and their care experience.

Crafting the Proposal

Under the proposed policy change, eligible APPs who were deemed competent would be granted privileges to:

- Sign continuation of anti-cancer therapies according to the attending oncologist's established treatment plan.
- Sign continuation of an anti-cancer treatment plan and date changes.
- Give "okay to treat" or "hold" orders if outside of parameters, after communicating with an attending oncologist (with documentation in [the electronic health record] Epic).

The proposed policy further stated that:

- APPs may not dose-escalate therapies without the attending oncologist's co-signature.
- APPs may not initiate the first cycle of an anti-cancer therapy order.
- Clinical trial orders would be at the discretion of the study's principal investigator.

Included in the proposal were the following eligibility requirements, criteria for competency assessment, and supporting evidence for credentialing for NPs and PAs (see box titled "Supporting Evidence," page 30).

Determining APP Eligibility

- APP must have knowledge and ability to demonstrate clear understanding of relevant regimens in their practice.
- APP must have a valid California Furnishing License. (Note: NPs who want to prescribe in California must apply for a furnishing number. The California Board of Registered Nursing issues the furnishing number that allows the NP to "order" or furnish drugs and devices to patients using approved standardized procedures.[6])
- APP must have a minimum of three years of oncology experience.
- APP with less than three years of oncology experience must complete the Oncology Nursing Society (ONS)/Oncology Nursing Certification Corporation (ONCC) Chemotherapy Immunotherapy Certification Course. Then UCSD Moores Cancer Center nursing leadership and their attending/supervising oncologist must perform final sign off for APP eligibility for this credentialing.

Competency Assessment

- APP deemed eligible must sign 20 anti-cancer treatment orders under the direct supervision of their attending oncologist.
- APP with less than three years of oncology experience must complete the ONS/ONCC Chemotherapy Immunotherapy Certification Course *and* a total of 20 anti-neoplastic treatment orders under the direct supervision of their attending oncologist.
- Continued proficiency will be assessed at re-credentialing (every two years) and tracked through the UCSD Moores Cancer Center medical staff office.

Finally, to be privileged, the disease site team as a whole must agree that the eligible APP is competent and that team members are comfortable allowing the APP to be privileged.

Our Results

Since the start of the program in 2019, half (52 percent) of eligible oncology APPs have applied for and received privileging. (Currently, 9 of 14 ambulatory hematology/oncology APPs are credentialed.)

With the new privileging policy in place and COVID-19 pandemic waivers increasing options for virtual visits, we were able to create urgent care clinics that are more accessible for our patients. Traditionally, scheduling would have allowed for dedicated acute care clinic time in specific clinic rooms at a brick-and-mortar cancer center. With the flexibilities of telemedicine, it is possible to schedule a video-based urgent-care clinic as needed. With our provider clinics fully scheduled, if APPs are able to provide a few more slots per week for acute visits, patient access is improved. By intervening earlier, we can help patients with cancer manage their symptoms before they escalate.

Next Steps: ACCC Survey

ACCC is slated to launch a national survey—in collaboration with UCSD Moores Cancer Center and the Advanced Practitioner Society for Hematology and Oncology—in September 2022. This survey will help us understand current practices around where and when APPs are privileged to sign orders for IV and/or oral anti-cancer therapies, what privileging requirements are in place, what course work and didactic learning is required, competencies that must be demonstrated, and processes and requirements to maintain privileging. OI

Archana Ajmera, MSN, ANP-BC, AOCNP, helps treat people with prostate cancer, renal cell carcinoma, urothelial carcinoma, testicular germ cell tumors, and penile carcinoma at the University of California San Diego Moores Cancer Center in San Diego, Calif. Her scope of practice includes collaborating with her physician colleagues in physical evaluations, diagnosis, treatment, symptom management, supportive care, and end-of-life care.

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Supporting Evidence

The 2009 and 2011 ASCO/ONS Chemotherapy Administration Safety Standards definitions of a licensed practitioner who can order chemotherapy state that such an individual includes "physicians, advanced practice nurses (nurse practitioner or clinical nurse specialist), and/or physician assistants as determined by state law."[7,8]

Domain 3: Ordering, Preparing, Dispensing, and Administering Chemotherapy

Under domain 3 of the ASCO/ONS safety standards,[9] the following are stated:

- 3.1. The healthcare setting defines standard chemotherapy regimens by diagnosis with references.
- 3.2. The healthcare setting verifies institutional review board approval of research regimens.
- 3.3. Orders for chemotherapy are signed manually or by using electronic approval by licensed independent practitioners who are determined to be qualified by the healthcare setting.
- 3.4. The healthcare setting has policy for managing chemotherapy orders that vary from standard regimens. The policy requires a supporting reference and/or authorization by a second licensed independent practitioner.
  - 3.4.1. The rationale for an **exception order** is documented in the medical record.
- 3.5. The healthcare setting has a policy for chemotherapy orders that ensure:
  - 3.5.1. Verbal orders are not allowed except to hold or stop chemotherapy administration.
  - 3.5.2. New orders or changes to orders, including changes to oral chemotherapy regimens, for example, dose adjustments communicated directly to patients, are documented in the medical record.

The National Academy of Medicine's *The Future of Nursing: Leading Change, Advancing Health*[10] states:

- **Recommendation 1. Remove scope-of-practice barriers.** Advanced practice registered nurses should be able to practice to the full extent of their education and training. (See also, Assessing Progress on the Institute of Medicine Report The Future of Nursing.[11])

From a UCSD Moores Cancer Center internal and national survey of institutions, below are institutions that privilege APPs to order established anti-cancer treatment plans:

- University of California (San Francisco, Los Angeles, Irvine)
- Stanford Health Care
- Massachusetts General Hospital
- Northwestern Medicine
- Mayo Clinic
- Dana-Farber Cancer Institute.

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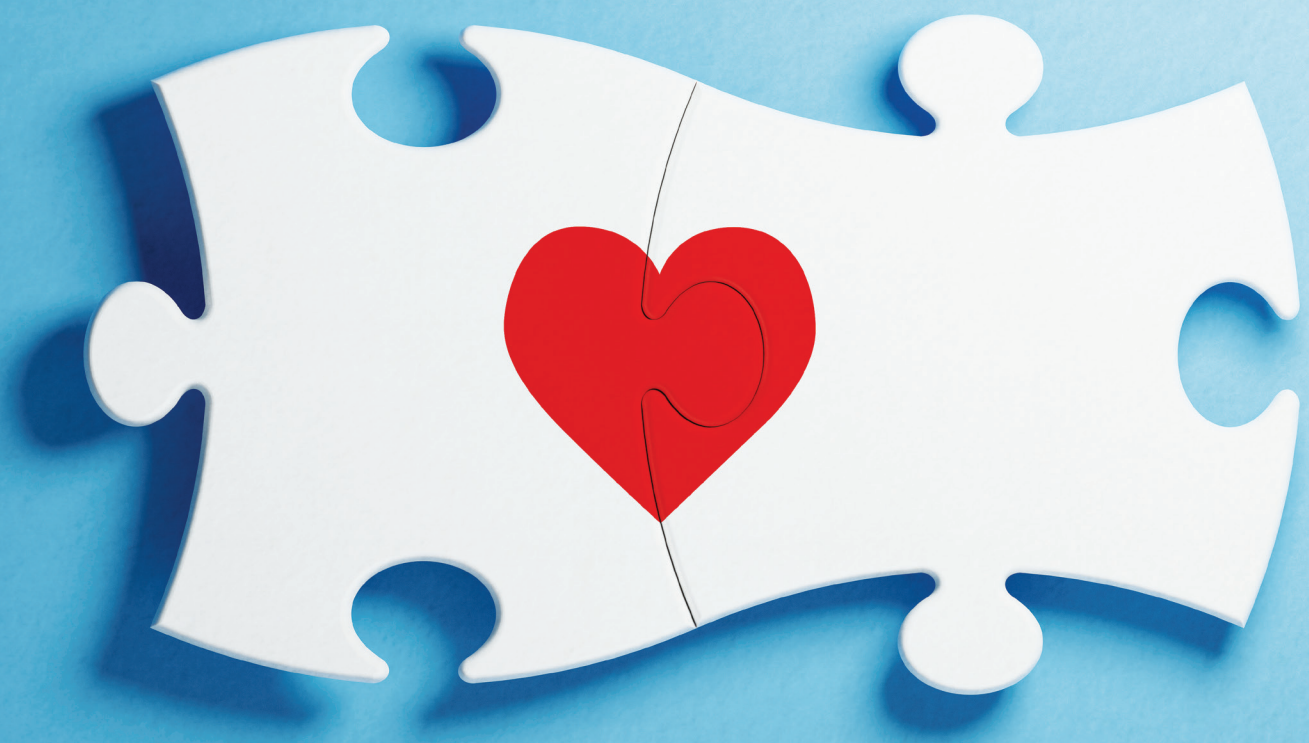
The **ACCC Financial Advocacy Network** is the leader in providing professional development training, tools, and resources that will empower providers to proactively integrate financial health into the cancer care continuum and help patients gain access to high quality care for a better quality of life.

Association of Community Cancer Centers

All of Me



BY MADDELYNNE PARKER

Bridging the sexual health communication gap in cancer care

Cancer and its treatment impact patients in many ways, beginning before a diagnosis and lasting long through survivorship. One, often overlooked, side effect of cancer—whether it be from surgical, medical, or radiation treatment—relates to patients' sexual health. Cancer can impact a person's physical anatomy, hormonal status, emotional and psychosocial well-being, and intimate relationships. Addressing these concerns is a field of medicine called oncosexuality, including minimizing the negative effects of anti-cancer treatment on patients' sexual function and pleasure and assisting patients with sexual impairments that result from their treatment. Further, patient-provider discussions on cancer's sexual health impact(s) are critical and must happen before treatment plans are finalized. The American Society of Clinical Oncology recommends having these conversations and prescribing related treatments, and the National Comprehensive Cancer Network includes sexual health-care in its survivorship guidelines.[1,2] Despite this national guidance, the sexual health communication gap between providers and patients persists.

Clinical Rational

Veronika Kolder, MD, is an associate professor emeritus and former medical director of the Menopause and Sexual Health Clinic, Department of Obstetrics and Gynecology at the University of Iowa Hospitals and Clinics. She explains that in addition to the domains of sexual health impacts listed above, a web of interrelated changes can overwhelm patients. Figure 1, page 35, illustrates the various impacts that cancer and its treatment can have on an individual's sexual health.

> It is critical that patients with cancer be educated early about cancer's relation to their sexual health and referred appropriately to address any concerns that come up throughout their treatment.

Due to anatomical changes from surgery to treat cancer, certain parts of the body may need to be removed to improve a patient's chance of cure or remission. This is true for many types of cancer, such as uterine or bladder cancers, among others. Specific to ovarian cancer, pre-menopausal patients whose ovaries are removed as a part of their cancer treatment will experience induced menopause post-operation. These patients will have dramatic hormonal changes that they may not be prepared to address. Hormones are important for bone, cardiovascular, and sexual health, but the surgical removal of the ovaries in females or the prostate in males for treating cancer may be necessary. "It would be naive of us to believe that cancer treatments would not affect sexual health," explains Amy Pearlman, MD, a urologist, clinical assistant professor, and director of the Men's Health Program at the University of Iowa Hospitals and Clinics. "It has some to do with surgical technique, but it also has to do with anatomy and the anatomy in the pelvis that's responsible for sexual health."

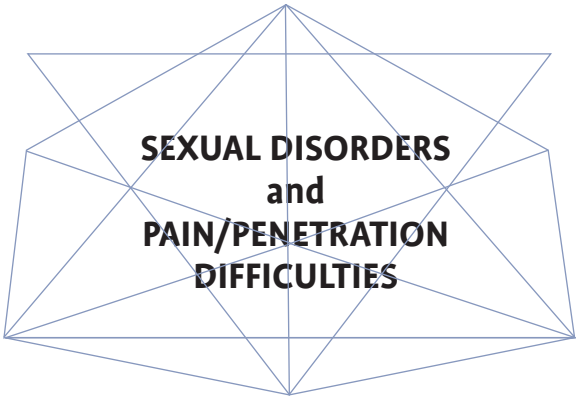
Dr. Veronika Kolder (left) and Erin Sullivan-Wagner (right).

Additionally, chemotherapy, radiation, and hormone therapy often have a direct impact on patients' sexual health. Dr. Kolder explains that radiation therapy as a treatment for cancer affects the tissues in the body that are being targeted. "Unfortunately, when the vagina is irradiated, it becomes raw, more scarred, and smaller," she says. "In combination with reaching menopause, either naturally or through radiation or chemotherapy, it is a setup for significant pain problems related to penetration." The same goes for men. If radiation treatment targets any area in the pelvis, patients may have sexual health concerns.

On the other hand, chemotherapy can affect brain signaling and make patients feel tired. "It's a normal response to not want to have sex if you're exhausted from work or treatment," explains Dr. Pearlman. "You have this sort of compounded effect. None of the therapies that we use to treat cancer are going to improve sexual function, and a lot of patients are getting one or multiple of these therapies." Finally, hormone therapy—especially considering its use for prostate cancer treatment—decreases testosterone levels, which is an important hormone for optimal sexual health in males.

Furthermore, any patient in active treatment or survivorship may experience emotional and relationship effects because of their cancer. If a patient with cancer was previously working full time and solely providing for their family, their partner may then be required to financially support the family and take on the caregiver role during active treatment. Patients with sexual partners may also have their connection(s) tested because of cancer. "The unspoken look that one partner gives another, a little hug and squeeze, or bringing coffee in the morning, those little messages and the touch that are your love languages with your partner get eroded and have to be rethought and reinvented after things change sexually," says Erin Sullivan-Wagner, a survivor of anal cancer. Patients may experience worsening body image, self-esteem, and stamina, which can further impact relationships. Therefore,

Figure 1. The Web of Sexual Problems for Patients with Cancer*



DECREASED DESIRE
Anxiety related to cancer
Fatigue
Cancer-related stress
Body image problems
Fear of cancer being contagious/fear of recurrence
Memory and concentration problems

PAINFUL SEX
Nerve damage
Vulvovaginal atrophy
Vaginal stenosis
Inability for penetration
Pain with genital touch
Vulnerability to infection
Pelvic floor hypertonus
Vaginismus

UNSATISFYING ENCOUNTER
Partner role/change caregiving
Partner role uncertainty
Partner fear of harming
Partner stress
Sexual script uncertainty
Excessive focus on intercourse/orgasm
Unresolved relational conflict

STIMULATION
Decreased stamina
Skin sensitivity changes
Sexual script changes
Partner sexual dysfunction
Partner communication problems

DECREASED AROUSAL
Decreased lubrication
Hormone change

DECREASED ORGASM
Loss of genital skin sensitivity
Genital skin hypersensitivity
Partner communication problems
Numbness
Antidepressant therapy effect

*Image recreated with permission from Sarah Shaffer, DO, obstetrician gynecologist and clinical assistant professor, Obstetrics and Gynecology at the University of Iowa Hospitals and Clinics.

it is critical that patients with cancer be educated early about cancer's relation to their sexual health and referred appropriately to address any concerns that come up throughout their treatment.

Enter Erin

Sullivan-Wagner is a wife, mother, and cancer survivor. She was diagnosed with anal cancer in 2008 and was treated with chemotherapy and radiation therapy at the University of Iowa Hospitals and Clinics. "I was told I wouldn't have sexual health side effects as a result of my radiation therapy because I was young, healthy, and sexually active," she says.

Sullivan-Wagner's treatment was successful, and she was cancer free in just two months. Like millions of patients who survive their cancer diagnosis, she now lives with the sexual dysfunction caused by her cancer and treatment. "My husband was extremely supportive throughout treatment and accompanied me at every appointment," she explains. "At the first follow-up appointment six weeks after my last radiation treatment, we were given the green light to resume sexual activity, specifically intercourse. We were told to go slow and use plenty of lubricant. We did, but the pain was immediate and severe. It felt like he was tearing through my skin. We tried repeatedly over the next month and had the same results: every attempt at penetration ended with me unable to stand the pain."

Sullivan-Wagner reported her concerns to her oncologist at her next follow-up appointment and was referred to the cancer program's radiation team for evaluation, who then referred her to a gynecologist. By this time, Sullivan-Wagner was six months into survivorship. In August 2008, a pelvic exam revealed a web of scar tissue inside her vagina, and she was diagnosed with vaginal stenosis. After minor surgery in September to open her vagina, Sullivan-Wagner was told to "use it or lose it." For the first time since she was diagnosed, Sullivan-Wagner was given

Despite national guidance, healthcare providers are not educating patients on the relationship between sexual health and cancer, nor are patients being appropriately referred to allied professionals when necessary.

dilation tools, vaginal estrogen, skin protectants, and burn cream to treat her sexual health side effects. Despite months of treatment adherence, Sullivan-Wagner states, "All attempts at intercourse ended the same way: severe pain almost immediately and sometimes blood on the bed sheets." Pelvic rehabilitation therapy for the vagina's muscles, lidocaine to deaden the pain, and anti-anxiety prescriptions did not resolve the problem. Sullivan-Wagner's search for answers lasted years with no success.

Throughout follow-up and additional treatments, Sullivan-Wagner's husband became disappointed, frustrated, and concerned, thinking that he was hurting his wife at every attempt of intercourse. Because Sullivan-Wagner's oncologist told her not to expect sexual health problems from her anti-cancer treatment, she and her husband were surprised when they immediately had issues and every suggested treatment failed. When she was prescribed anti-anxiety medication, it was then that her husband wondered whether her care team thought the problem was all in her head. "I see now that my husband and I needed counseling, but I didn't realize it at the time," she says. "Instead, we gradually spent less time doing activities that used to lead to sex and eventually stopped going on vacations and spending time alone together." She notes that she and her husband continued the routines of their daily lives, such as attending their children's activities, eating dinner together, and sleeping in the same bed. But both noticed that they were no longer connected in the same way they had been before her cancer. "Gradually, my obsession with finding a solution to the sexual pain gave way to fatigue and defeat," explains Sullivan-Wagner. "My husband started questioning my desire and love for him. We grew apart." As shown by Sullivan-Wagner, couples dealing with cancer often have their sexual scripts tested or diminished to a point that they need to be reworked or rewritten. These sexual scripts can be an unspoken look that one partner gives another, a kiss or squeeze, or anything that causes a non-sexual situation to become sexual. These small messages are a part of a couple's love language and can get eroded throughout the course of cancer treatment. As such, Sullivan-Wagner's story is no exception. In 2016, she and her husband separated and spent three and a half years living apart.

Though it took eight years (2008 to 2016), Sullivan-Wagner eventually received closure. "I remember the appointment where the specialist held my hand and told me in a soft, consoling voice that too much time had passed between the end of my cancer treatment and the evaluation and treatment to address my radiation and menopausal damage," she recalls. "They said, 'You waited too long. I am sorry.'" An examination showed that it was not the vaginal stenosis that was the main problem; instead, it was tissue scarring at the hymenal ring. The dilator size Sullivan-Wagner could tolerate did not stretch the opening of her vagina enough to comfortably accommodate penetration, as her skin was repeatedly torn open during intercourse. "The elasticity at my vaginal entrance was gone and no amount of estrogen was going to help me," she says. "My problem was irreversible. I needed to grieve and finally had been given permission to move on."

The Problem

As a life coach for cancer survivors, Sullivan-Wagner learned that most of her clients had sexual health concerns after their cancer treatment that were not being addressed. "It wasn't that they were being told something wrong," says Sullivan-Wagner. "They just weren't being told anything at all and were missing the opportunity to prevent, address, and resolve their issues." Both Sullivan-Wagner and Dr. Kolder agree that sexual health is a quality-of-life concern. Furthermore, both state that these conversations should be brought up during patient-provider discussions on the side effects of anti-cancer treatment (e.g., bladder or bowel symptoms) or impacts on patients' quality of life. These conversations are necessary to empower those impacted by cancer to maintain agency over their sexual health, which is essential for health, quality of life, and personhood, especially when losses in function and pleasure are likely.[3]

Though Sullivan-Wagner brought her sexual health concerns to her providers' attention, she notes that often patients who are in survivorship and have sexual health concerns are reluctant to go back to their care team with questions. "They may be invested in being the 'good patient.' The one who does well, is grateful, and does not complain," she explains. "Patients often are not sexually active during active radiation and chemotherapy and are unaware that they have issues until they are in survivorship, and that may be too late. Or they may not know where to start and lack the medical vocabulary to describe their experiences." Healthcare providers cannot assume that patients will bring up their sexual health concerns at their medical appointments. Therefore, these conversations need to be normalized for patients and providers alike, so expectations can be set and patients know where to turn to for help.

Dr. Kolder also shares that medical communication has only become a formal part of medical education in recent decades. When she was in medical school, a single one-hour lecture addressed sexual history, sexual orientation, and gender expression. Many programs today, such as the Carver College of Medicine at the University of Iowa, require small group workshops with facilitators and simulated patient actors to allow students to practice having these difficult conversations with patients. "Communicating about sex and breaking bad news are two of the most challenging conversations medical professionals will

All of Me presenters with conference attendees in Mason City, Iowa.

have with patients," she says. "In the oncology setting, specifically when providing anticipatory guidance about the sexual health impacts of cancer, medical professionals need to be comfortable doing both."

A New Idea

In 2010, Sullivan-Wagner immersed herself in patient advocacy. "I got certified as a life coach and founded a patient advocacy business: After Cancer, Solutions for Sexual Health," she explains. "I coached patients, joined survivor groups, and presented my story at conferences." Looking to make a difference in patients' lives on a larger scale, Sullivan-Wagner joined the Iowa Cancer Consortium and co-chaired its Quality of Life Implementation Group. She then applied for its grant funding to develop sexual health educational materials for healthcare professionals. After being turned down, Sullivan-Wagner continued to look at how she could help others just like her. She knew she needed collaborators and, in 2014, approached Dr. Kolder, who immediately understood and related to Sullivan-Wagner's passion for addressing the sexual health communication gap in cancer care. In 2016, the two collaborated with their supporters on writing their first successful grant application to the Iowa Cancer Consortium. This grant was the first of five approved by the consortium for the *All of Me Iowa* project—a project that bridges the communication gap between healthcare providers and patients on the intersection of sexual health and cancer via education, resources, workshops, and conference presentations.

As Dr. Kolder brought expertise on the female side of sexual health, both women knew they needed to also consider and address men's health. They invited Bradley Erickson, MD, a urologist at the University of Iowa Hospitals and Clinics who specializes in the surgical treatment of erectile dysfunction, to join them in developing a presentation to bring awareness to the oncology nursing community. Due to competing priorities, Dr.

Erickson eventually took a step back from the project and introduced the *All of Me* team to Dr. Pearlman, who is now a key collaborator and representative of men's health.

All of Me

Sullivan-Wagner and Dr. Kolder co-founded *All of Me* in reaction to Sullivan-Wagner's cancer experience. And her story corroborates many persisting truths in oncology, including:

- Patient access to oncologists is limited, especially in rural states like Iowa.[4]
- Increasing access to sexual healthcare for people impacted by cancer has been slow, particularly for women.[5,6]
- Oncology nurses and advanced practice providers are increasingly providing survivorship care that includes sexual healthcare.[7]
- Long-term survivors of cancer want information about sexual health.[8]
- Sex therapists and treatments may be under-recommended.[9]
- Education improves providers' perceptions of having enough knowledge and training to provide sexual healthcare.[10]

Despite national guidance, healthcare providers are not educating patients on the relationship between sexual health and cancer, nor are patients being appropriately referred to allied professionals (e.g., mental health and sex therapists, urologists, gynecologists, etc.) when necessary. "No time and no privacy are the barriers that we kept hearing about during our awareness-raising lectures and focus groups," explains Dr. Kolder. "It was the same as in the literature. If we were going to make a difference on implementation, at a minimum, we would have to overcome those two barriers."

Sullivan-Wagner and Dr. Kolder chose to name the project *All of Me* to underscore that sexual healthcare is a part of comprehensive cancer care, and their work quickly began through communication workshops, conferences, and pilot studies across Iowa. They brought formal education to oncology care teams, including advanced practice providers, nurses, social workers, radiation and physical therapists, nurse navigators, and mental health professionals. "In Iowa, most oncologists were too busy, too uncomfortable, or both to take on sexual health," says Dr. Kolder. "We needed to focus on the professionals who were most likely to embrace this care." The program has since expanded to encompass anyone who has a relationship with oncology patients at any point of the cancer care continuum.

All of Me is not the first to address sexual healthcare in oncology, but it is the first statewide, non-profit education program focusing on this concern. And as its collaborators continued to refine the program with workshop and conference participants' feedback, it has become an expert-driven and accessible resource for medical care teams across many disciplines. Treating sexual health problems has always involved multiple specialties that need to coordinate care across departmental silos, says Dr. Kolder. Therefore, it is vital that conversations around sexual health be normalized within medicine and between patients and providers.

With this need identified, *All of Me* was created to address three key care components:

1. Normalizing conversations around sexual healthcare
2. Setting patient expectations regarding the sexual health impacts of their disease and treatment
3. Referring patients to allied professionals via defined pathways.

In developing the education and tools needed for these three components, Sullivan-Wagner and Dr. Kolder partnered with experts from their original target group. This dynamic program now includes a turnkey, half-day, accredited workshop that is hosted within a cancer program or practice and an eight-week, module-based educational program, including videos, teaching aids, and other resources. Among other disciplines, *All of Me's* workshops have featured:

- Local sex therapists
- An ear, nose, and throat surgeon who has human papilloma virus expertise
- An expert on systemic racism in healthcare
- A Veterans Administration sexual trauma researcher
- Cancer program administrators
- Financial navigators.

Getting the Message Right

The first and arguably the most important component of the *All of Me* program is normalizing conversations on sexual health and helping staff create their own 30-second message that allows them to appropriately inform patients without having to get into any details of their sexual history. "Here was a universal message about the impact of cancer on sexual health," says Sullivan-Wagner. "It was short, simple, generic, and 'vanilla.'" Medical professionals can use this message within any area patients are seen (e.g., clinic room, hallway, reception area, infusion suite) and with whomever may accompany them (e.g., caregiver, child, parent). Sullivan-Wagner explains that the *All of Me* 30-second message is not meant to start an in-depth conversation with patients but to make them aware that there is a relationship between cancer and sexual health.

By acknowledging to patients with cancer that sexual health issues are common, expected, and an important quality-of-life concern for most people, the issue is normalized. Patients need to know that sexual health problems are healthcare problems—that it is appropriate to bring these issues up to their healthcare providers. Furthermore, patients may not care at the time of their diagnosis, but it can matter later during or after their treatment. Addressing sexual health ensures patients know where to bring their questions and can prevent or reduce long-lasting effects.

Next, the program's collaborators needed to ensure that oncology professionals are educated on the timing of this message. Medical professionals should tack sexual health onto any discussions regarding the short- and long-lasting effects of cancer treatment, as well as whenever quality of life is discussed with patients. Dr. Kolder emphasizes, "Along with urinary and bowel

side effects, the impact of treatment on sexual health has to be brought up each time side effects of treatment or quality of life are discussed."

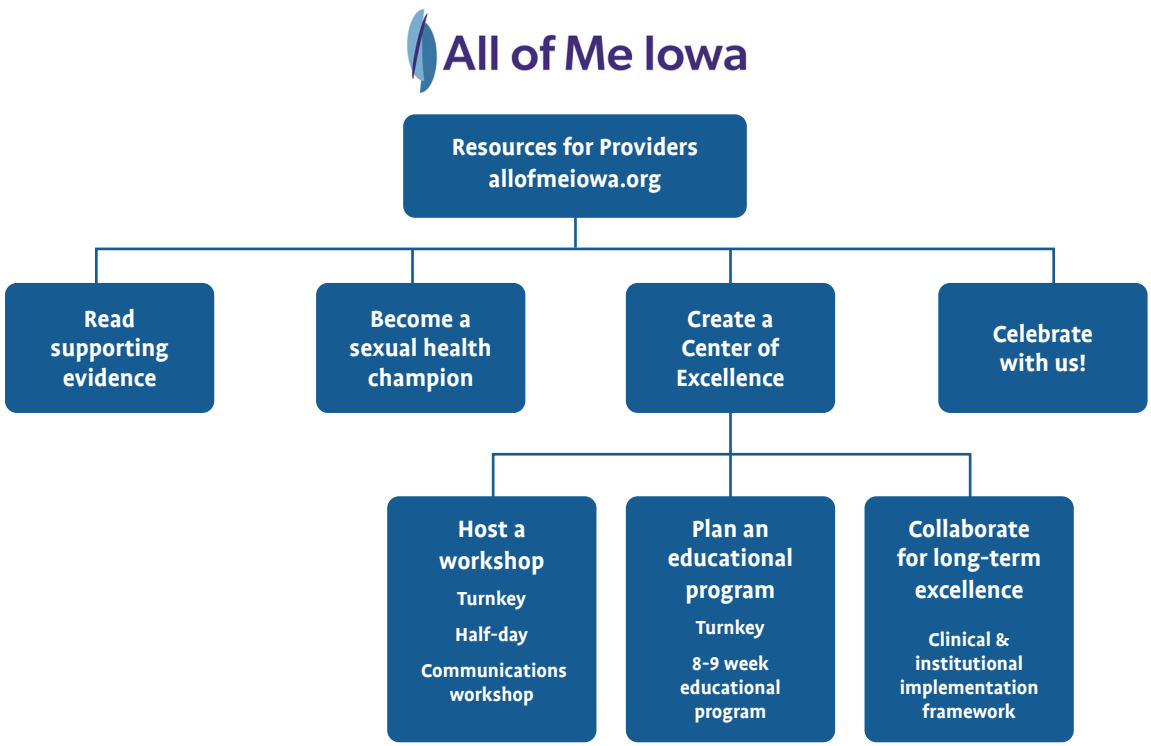
Unique to the *All of Me* project, program participants learn what their 30-second message needs to include, write it in their own words, and practice it in a safe setting with a facilitator and simulated patient actor. During these practice rounds, more challenging scenarios are identified and acted out to ensure that program participants are prepared for patients' reactions or concerns.

In assisting medical providers in closing out these conversations, project collaborators designed an education aid—available in English and Spanish—for oncology staff to share with patients as they end their sexual health conversations. This aid provides further information for patients to read on their own time. It directs them to the *All of Me* website (allofmeiowa.org) and other resources. "Having something in your hand takes the eye contact away from each other on this awkward topic that I may be feeling uncomfortable about," says Sullivan-Wagner. "It's easy to say, 'Take this home. Read it. If you have any questions, please bring them back to us. This is something that we expect that you might care about, and we care about it, too.'"

Addressing Patients' Concerns

After sharing *All of Me's* 30-second message and brochure, patients may immediately ask for more information. Dr. Kolder explains that this is especially likely if more information on sexual health could influence patient-provider discussions on treatment plans. These patients should be scheduled for an immediate appointment with an internal expert. Other patients who request more information at a later date should be scheduled for an appointment with an identified expert or have their oncologist refer them to an appropriate allied professional. "Because counseling about what to expect is more complicated and needs to be personalized to patients' circumstances, staff should set patient expectations—also known as providing anticipatory guidance—within a private setting where one can ask about their sexual health information," says Dr. Kolder. She notes that staff do not need to tease out patients' sexual orientation or complicated relationship statuses. Instead, they should simply ask whether patients are sexually active and, if so, whether they are with men, women, or both. This will inform the referrals needed to meet patients' needs, such as determining whether an LGBTQ+ welcoming professional would be more appropriate.

Figure 2. *All of Me* Provider Resources Website Flowchart



When addressing patients' sexual health concerns, Dr. Kolder also emphasizes the need for chunking and checking. *All of Me* program participants are taught how to break these conversations into bite-sized chunks for patients to easily digest and how to check in to ensure that patients understand the information that is being shared.

Referring Patients to Appropriate Resources

The third and final key to implementing sexual healthcare is referring patients as needed. According to Dr. Kolder, "One of the unexpected bonuses of conducting our early workshops and piloting the educational program was the personal connections participants made with each other, often within their own institution. Just a few hours together helped providers connect with like-minded colleagues, learning what type of referrals they welcome."

By hosting workshops across Iowa, Sullivan-Wagner and Dr. Kolder learned that *All of Me* needed additional resources to further support oncology staff. Therefore, they created a roadmap for referrals worksheet that included a template and instructions, along with sample emails, for soliciting information from internal, community, and area-based providers. Mental health professionals, social workers, physical therapists, ostomy specialists, occupational therapists, speech therapists, pharmacists, urologists, urogynecologists, gynecologists, spiritual services, and support groups who welcome individuals or couples impacted by cancer and sexual problems are included as part of this tool, and it is customized to each cancer practice or program.

Further, *All of Me* has broadened its referral template to include introductory videos of local mental health professionals, sex therapists, and social workers, who share their experiences in working with people impacted by cancer. By splicing these videos together, *All of Me* gives local oncology professionals an easy way to meet other community-based specialists.

Provider Impact

Over the last six years, *All of Me* has been shaped by feedback from completed workshops, conferences, and three pilot studies. The largest of these pilots was hosted by St. Anthony's Regional Hospital in Carroll, Iowa. Led by nursing leadership, St. Anthony participants completed a nine-week study of the *All of Me* education program. "The preliminary results suggested that when comparing pre- and post-pilot confidence, across all domains of sexual healthcare implementation that were evaluated, providers showed significant improvement," says Dr. Kolder. "We found that people were ready for this level of detail regarding treatment and referral because they were already convinced of the need for normalizing these conversations and the importance of sexual healthcare in oncology."

Though *All of Me's* tools were originally created for oncology professionals, the program and its resources, including the 30-second message, are not limited to oncology. For example, Dr. Pearlman—an *All of Me* collaborator since 2019—brought the 30-second message to her colleagues at the University of Iowa Hospitals and Clinics' Department of Urology. In teaching her colleagues the 30-second message, Dr. Pearlman increased referral rates to her clinic, ensuring that patients with cancer are being treated for their sexual health concerns. "A lot of these staff are seeing our oncology patients and are helping me in my clinic," says Dr. Pearlman. "So, there's an opportunity for them when they're checking patients in, getting their vitals, and talking with patients to bring sexual health up and provide resources."

In summarizing her role in the *All of Me* program and its impact on how she practices today, Dr. Pearlman states: "It's changed how I counsel patients and how I counsel other providers. I tell them that if they [providers] are treating someone with a pelvic cancer, it would be naive of us to believe that those cancer treatments would not affect sexual health. We must bring up these common concerns, but we don't have to be the ones to treat it [the concern], we just have to address it, and we can do that in 30 seconds and provide a brochure. Everyone wins."

Additionally, Dr. Kolder shares that two of the project's collaborators have gotten an advanced degree (an advanced registered nurse practitioner and a doctor of nursing practice), and others have conduced relevant research after being inspired by the project.

All of Me Today

Since its inception, *All of Me's* collaborators have accumulated many teaching aids and created their own patient-facing materials. These materials were added to the *All of Me* website as they were developed, and, because of the COVID-19 pandemic, the program's collaborators were forced to reconfigure their workshops and educational materials for the virtual setting.

Since then, Sullivan-Wagner and Dr. Kolder have reformatted their materials, making the program's website design intuitive and easy to navigate. Provider resources are now better organized, so visitors can quickly access the content they need (Figure 2, page 39). The website also includes step-by-step instructions for hosting the *All of Me* accredited half-day workshop and eight-week education program. Website visitors can access the referrals roadmap worksheet, instructions for making a video to introduce local mental health and sex therapists to oncology professionals, clinical and institutional frameworks for sexual healthcare implementation, and recordings of past conference presentations.

Looking Ahead

As the program's website work and accreditation is finalized, Sullivan-Wagner and Dr. Kolder are continuing to explore how *All of Me* can ensure that patients are given much-needed information regarding the side effects their cancer and/or treatment may have on their sexual health and that medical professionals are setting expectations and referring to allied professionals when appropriate. As some cancer programs and practices address this topic in survivorship care, it can still be considered a new supportive care mission. Dr. Kolder emphasizes the need for addressing the impacts of cancer and its treatment on patients' sexual health at the time of their diagnosis, when treatment options are being discussed and preventive strategies can be put in place. "Sooner is better than later applies here, too," she says. "The erosion of

intimate relationships due to failing to address sexual health can affect marriages and children's well-being."

Sullivan-Wagner adds, "Our dream is to partner with a software developer to create an app for patients and healthcare providers about the sexual health impacts of cancer." This app would allow an individual to enter their basic information (i.e., sex, age, cancer, stage, treatment), consider their menopause status if applicable, and output a list of potential side effects related to their sex and intimacy, along with evidence-based treatments. "Such an app would go a long way toward addressing another challenge: the need for professionals from many different fields to have a host of oncosexuality information on-hand during patients' visits. This personalized information is needed to provide anticipatory guidance," says Sullivan-Wagner.

Since presenting to oncology professionals at conferences and workshops across Iowa, *All of Me* has gained interest among healthcare professionals across the United States. When asked whether she would consider expanding *All of Me* on a national scale, Sullivan-Wagner said that is her intention. "I hope to partner with national organizations that are interested in educational programs for their cancer centers, clinics, and practices. Our work will not be complete until addressing sexual health is standard practice in the cancer care setting, as national guidance recommends." OI

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Living Well After Cancer

BY GABRIELLE RIAZI, MPH; MIKE ALPERT; SARAH FLORES, BS; DANIELLE KLINE, MPH; HALEY ALLEN; ADITI VYAS, PHD; DENISE JOHNSON, MS; AND JESSICA CLAGUE DEHART, PHD, MPH

A feasibility study on how this community-based program impacts physical and metabolic health

In Brief

Though survivors of cancer frequently experience residual physiological and psychological symptoms post-treatment, cancer programs and practices often lack the resources to effectively address these conditions. *Living Well After Cancer* is a community-based wellness program offered to patients outside the clinical setting, allowing survivors of all cancer types the opportunity to mitigate these symptoms. This study examined the feasibility of the program and its impact on multiple factors, including metabolic measures, body composition, and physical fitness, which were assessed at baseline and at week 13. Study participants were recruited at a *Living Well After Cancer* orientation. A total of 88 participants consented, with 79 individuals (90 percent) presenting for baseline assessments and 65 individuals (82 percent) returning for post-program testing. Participation in *Living Well After Cancer* was associated with a significant decrease in several metabolic measures and an increase in physical fitness in cancer survivors.

Currently, there are more than 15 million cancer survivors in the United States and over 20 million are expected by 2026.[1] Due to early detection and treatments, the number of cancer survivors continues to grow exponentially each year. However, after active anti-cancer treatment, many of these survivors experience increased physical and psychological symptoms related to their chemotherapy regimen, radiation, and other types of treatment. Though many symptoms dissipate following the completion of treatment, some persist in the long term. These long-term symptoms, also known as "collateral damage,"[2] include pain, neuropathy, fatigue, weight gain, depression, anxiety, and cognitive decline. Though increased survivorship signals positive advancements in cancer care, it also places growing demands on the cancer programs and practices that provide active treatment to patients. After successful therapies, patients often look to these same institutions for survivorship care, including symptom management. However, these institutions are frequently overwhelmed by the number of patients on active treatment and cannot fully attend to the needs of cancer survivors due to lack of resources. Additionally, the programs that are available are often cancer and/or stage specific (i.e., metastatic breast cancer survivorship programs) and thus do not meet the needs of many cancer survivors.[3-6]

Program Description

The Claremont Club's *Living Well After Cancer* program in Claremont, Calif., uses a community-based approach to meet patients' needs outside the clinical setting. Certified trainers, a

dietitian, and other professionals help cancer survivors manage and mitigate long-term symptoms. Open to all survivors of cancer, the program was founded in 2005 and has reached approximately 1,340 individuals over the course of 15 years. Each program lasts 13 weeks and participants attend one-hour exercise classes at The Claremont Club twice weekly, alternating between aerobic exercise, strength training, and specialty classes (e.g., yoga, water aerobics).

In addition to the structured exercise regimen the program provides, participants are afforded the social support of their peers in the community. Cohorts, separated by gender, attend the same weekly meetings and develop a support system throughout the 13-week program. Evidence demonstrates that social support and social integration may be associated with reduced overall mortality.[7] Specifically, members of a shared social network may encourage one another to engage in healthy lifestyle modifications, such as increased physical activity, improved nutrition, and regular attendance of follow-up visits.[8] Not only does the *Living Well After Cancer* program facilitate social support through this cohort model, but the program also encourages participants to enroll with a companion, typically a family member or other close individual, thus enhancing opportunities for increased social connectedness and accountability. Through its 13-week structure, the *Living Well After Cancer* program aims to demonstrate to survivors the relationship between exercise, quality of life, and metabolic measures.

Thus far, the data supporting the program's success have been anecdotal. A partnership between The Claremont Club, City of Hope, and Claremont Graduate University provided evidence-based data for *Living Well After Cancer*'s success in improving metabolic health, function, and quality of life. The purpose of this study was to determine the feasibility of conducting pre- and post-intervention testing with program participants. It also examined the effect of the wellness program on body measurements, fasting glucose, hemoglobin A1c (HbA1c), cholesterol, lipids, chronic inflammation, blood pressure, and physical fitness.

Study Methods

Using a quasi-experimental design, the pilot study assessed the feasibility of conducting pre- and post-intervention testing of *Living Well After Cancer* participants. During testing, participants were asked to fill out questionnaires, agree to a body composition assessment, and give drops of blood from finger pricks for metabolic measures before and after program completion. City of Hope's institutional review board approved the protocol and informed consent. Furthermore, all methods were performed in accordance with relevant guidelines and regulations for research involving human subjects. End points were assessed at baseline and post-program (week 13).

Participants and Recruitment

Eligible participants consisted of cancer survivors (all disease types and stages at diagnosis) who were enrolled in The Claremont Club's *Living Well After Cancer* program. Recruitment occurred between Sept. 19, 2017, and Feb. 26, 2019, at the program's orientation sessions that were held at the beginning of the four cohorts (September 2017, February 2018, September 2018, and February 2019). All participants provided written, informed consent.

Outcome Measures

Feasibility and Adherence

To assess feasibility, researchers monitored the number of people who consented and the number of people who attended their baseline testing. To evaluate adherence to the data collection and wellness program protocols, researchers monitored the number of participants who attended their post-testing and the number of program sessions each individual attended.

Body Measurements

Weight, body mass index, and body fat percentage were measured using the InBody270, a body composition analyzer. Participants' chest circumference was measured to the nearest 0.5 cm around the widest portion of their chest, and their waist circumference was measured to the nearest 0.5 cm around their umbilicus. Arm circumference was also measured to the nearest 0.5 cm at the midpoint between participants' olecranon process and acromion, and thigh circumference was measured to the nearest 0.5 cm at the point where participants' fourth digit lies on the thigh while standing with their hands along their sides. Lastly, participants' ankle circumference was measured to the nearest 0.5 cm at the point directly above their lateral malleolus.

Fasting Glucose and Hemoglobin A1c

Clinical research assistants obtained participants' fasting blood from finger pricks and analyzed them immediately using the Contour® Next EZ blood glucose monitoring system (fasting glucose) and A1CNow+ multi-test A1c system (hemoglobin A1c).

Cholesterol and Lipids

Clinical research assistants used the fasting blood from the finger prick to measure total cholesterol, high-density lipoprotein cholesterol, and triglycerides, using the CardioChek® cholesterol analyzer kit. Participants' low-density lipoprotein (LDL) cholesterol was calculated using the results from the previous three measures.

Blood Pressure

Participants' blood pressure was measured at baseline and post-program (13 weeks) using the Omron® BP785.

Physical Fitness

Participants' level of physical fitness was assessed at baseline and post-program (13 weeks) using a hand dynamometer, which measures an individual's isometric grip force/hand grip strength.

Inflammation

Clinical research assistants obtained participants' fasting blood for a micro-erythrocyte sedimentation rate assay designed to serve as a surrogate marker for chronic inflammation. The micro-erythrocyte sedimentation rate method was adapted from papers that developed and used this method previously.[9,10] Briefly, for each patient sample, a 1:4 dilution of 3.8 percent sodium citrate

blood sample was drawn up using a microhematocrit heparin capillary tube and allowed to stand un-disturbed on a sealant rack for 20 minutes. Readings of the sedimented erythrocytes derived from this method were then converted to the Westergren erythrocyte sedimentation rate equivalent using the following formula: $x = 2.819 \times y + 1.346$ (where x = sedimentation per hour, and y = 20-minute reading of clear plasma level using micro-erythrocyte sedimentation rate).

Covariate Measures

Physical Activity and Dietary Assessments

Participants' physical activity history was assessed at baseline and post-program using a validated questionnaire. Three-day dietary records—two weekdays and one weekend day—were completed at baseline using a self-reporting form. Dietary records were also completed at baseline and post-program within 24 hours of participants' testing session via a self-reported form.

Medical History

Participants self-reported their cancer-related information, including the type of cancer, age at diagnosis, disease stage, histologic grade, treatments and symptoms, and diagnosed chronic conditions, using a questionnaire that was given at baseline and post-program.

Exercise Intervention

All participants completed the same 13-week supervised exercise program. Participants committed to meeting for one hour at The Claremont Club every Tuesday and Thursday. Tuesday sessions focused primarily on cardio and strength training, and Thursday sessions consisted of specialty classes like yoga or aquatics. All sessions were led by a certified (American College of Sports Medicine, National Strength and Conditioning Association, or National Council on Strength & Fitness) exercise trainer. Attendance at these sessions was monitored to determine adherence. Participants in the program were given free memberships to The Claremont Club to use for themselves and their immediate family.

Statistical Analyses

Researchers computed percent change relative to baseline for all fitness, body measurement, and metabolic measurement variables. Means are expressed with a standard deviation. Changes from baseline to post-program were evaluated using paired t tests. Analyses were run on participants who had both pre- and post-measurements. The level of significance in all statistical analyses was set at $p < 0.05$. Post-hoc analyses included stratification by cancer diagnosis, sex, and program adherence. Data analyses were performed using SPSS software (version 25, SPSS, Inc., Chicago, Ill.).

Study Results

At each orientation session, researchers gave a brief introduction to the study and explained that 20 participants would be enrolled. Eighty-eight participants provided written informed consent (Figure 1, below). Of those, 79 participants attended baseline testing (90 percent) and 65 participants returned for their post-program testing session (82 percent).

Table 1, page 46, depicts the baseline characteristics of the program's participants. Of the 79 participants who attended baseline testing, 14 participants did not complete the program. Most participants were non-Hispanic/Latino (n = 58; 73.42 percent), and the primary diagnosis was breast cancer (n = 50, 63.29 percent). On average, participants were 58 years of age or older, and a majority were college-educated, married/partnered, and did not have children under 18 years of age at home. Of the

Figure 1. Flowchart of Enrollment, Drop Out, and Completion.

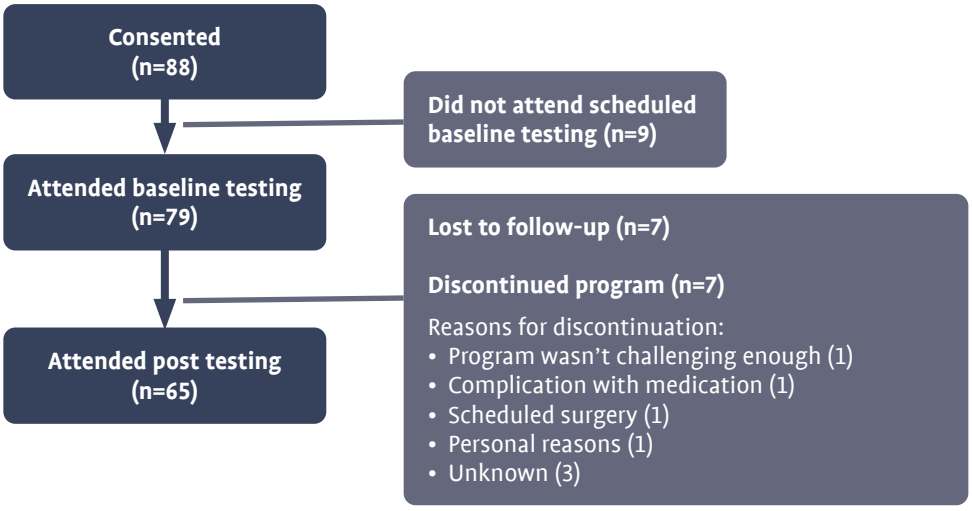

Table 1. Baseline Characteristics of the Sample (n = 79)

Variable	Mean	SD
Age (mean years)	58*	10.82
Variable	**Size (n)**	**%**
Gender		
• Female	65	82.28
• Male	14	17.72
Ethnicity		
• Hispanic/Latino	16	20.25
• Not Hispanic/Latino	58	73.42
• I'd rather not say	2	2.53
• Not reported	1	1.27
Race		
• White/Caucasian	55	69.62
• Black/African American	2	2.53
• Asian/East Indian	4	5.06
• American Indian or Alaska Native	1	1.27
• Multi-racial	8	10.13
• Other	3	3.80
• I'd rather not say	5	6.33
• Not reported	1	1.27
Education		
• High school or less	5	6.33
• Vocational, some college, or 2-year associate's degree	29	36.71
• 4-year college	16	20.25
• Graduate/professional school	26	32.91
• I'd rather not say	2	2.53
• Not reported	1	1.27
Marital Status		
• Never married	8	10.13
• Married, in a civil union, domestic partnership, or living as married	53	67.09
• Divorced/separated	12	15.19
• Widowed	5	6.33
• Not reported	1	1.27
Primary Cancer Diagnosis		
• Breast	50	63.29
• Others	28	35.44
• Not reported	1	1.27

*Calculated for the 78 participants who returned the demographic baseline questionnaire.

65 participants who completed the program, 60 percent maintained an 80 percent or higher adherence rate to the program throughout the 13 weeks. No difference in demographics was observed between the cohort that completed the program (n = 65) and the full cohort enrolled at baseline (n = 79).

Table 2, right, lists the baseline and post-program follow-up changes in metabolic measures. Total cholesterol decreased significantly at post-program follow-up compared to baseline, with a mean difference of –15.03 mg/dL (p = 0.006). Compared to baseline, LDL cholesterol and triglyceride levels displayed downward trends at post-program follow-up. However, when stratifying by sex, among males (n = 12), triglycerides decreased significantly compared to baseline, with a mean difference of –26.58 mg/dL (p = 0.025). When stratifying by adherence levels, those who adhered 80 percent or more to the program protocol demonstrated a significant decrease in LDL cholesterol, with a mean difference of –15.62 mg/dL (p = 0.040).

Table 3, right, lists the baseline and post-program follow-up changes in fasting glucose and HbA1c, stratified by clinical classification (fasting glucose: normal = less than 100 mg/dL, pre-diabetes = 100 mg/dL-125 mg/dL, and diabetes = greater than 126 mg/dL; HbA1c: normal = less than 5.7 percent, pre-diabetes = 5.7 percent to 6.4 percent, and diabetes = greater than 6.5 percent). Fasting glucose did not demonstrate any significant increases or decreases for any of the strata. However, when examining HbA1c levels, those in the normal range at baseline demonstrated a significant increase (M_{diff} = 0.28 percent; p < 0.001). However, from a clinical standpoint, this increase did not move the normal range group to a pre-diabetic range. Both the pre-diabetic and diabetic at baseline groups did not demonstrate any significant changes in HbA1c values. Similarly, when stratifying by sex, among females, HbA1c decreased significantly compared to baseline, with a mean difference of –0.21 percent (p = 0.018; data not shown).

As shown in Table 4, page 48, erythrocyte sedimentation rate levels for the group (third and fourth cohorts only) decreased significantly compared to baseline, with a mean difference of –2.82 (p = 0.020). When stratifying by age, the erythrocyte sedimentation rate for the younger group (less than 50 years of age, n = 5) decreased dramatically and significantly compared to baseline, with a mean difference of –7.05 (p = 0.030). Additionally, the calculated erythrocyte sedimentation rate values were used as a surrogate marker for assessing chronic inflammation in 29 participants. Participants who had erythrocyte sedimentation rate values higher than the normal range for their age and gender were categorized as having chronic inflammation. Normal range was defined as:

- Females younger than 50 years old = 0 mm/hr to 20 mm/hr
- Females 50 years of age or older = 0 mm/hr to 30 mm/hr
- Males younger than 50 years old = 0 mm/hr to 15 mm/hr
- Males 50 years of age or older = 0 mm/hr to 20 mm/hr

Overall, seven participants were categorized with chronic inflammation at baseline, of which five showed a dramatic reduction in erythrocyte sedimentation rate back to the normal range at

Table 2. Changes in Participants' Metabolic Measures

Outcome Variable	*n*	Baseline Mean (SD)	Post-Program Mean (SD)	Mean Difference	*p* Value
Systolic blood pressure	65	121.86 (16.32)	123.06 (14.98)	1.20	0.377
Diastolic blood pressure	65	79.55 (8.31)	79.68 (8.33)	0.12	0.850
Total cholesterol (mg/dL)	65	194.89 (41.19)	179.86 (44.59)	−15.03	0.006
HDL (mg/dL)	65	60.06 (17.33)	58.11 (19.19)	−1.95	0.392
Triglycerides (mg/dL)	65	135.49 (68.15)	121.38 (63.94)	−14.11	0.058
LDL (mg/dL)	65	107.87 (36.28)	98.49 (42.42)	−9.37	0.073

HDL = high-density lipoprotein; LDL = low-density lipoprotein; mg/dL = milligrams per decilitre; SD = standard deviation

Table 3. Changes in Participants' Glucose and HbA1c

Outcome Variable		*n*	Baseline Mean (SD)	Post-Program Mean (SD)	Mean Difference	*p* Value
Glucose	Normal range at baseline	32	90.31 (6.96)	90.47 (12.88)	0.16	0.940
	Pre-diabetic range at baseline	31	108.97 (6.86)	105.84 (18.15)	−3.13	0.312
	Diabetic range	2	169.00 (28.28)	174.50 (26.16)	5.5	0.170
HbA1c	Normal range at baseline	56	5.04 (0.46)	5.32 (0.41)	0.28	<0.001
	Pre-diabetic range at baseline	3	6.17 (0.23)	5.87 (0.45)	−0.30	0.423
	Diabetic range	1	7.10	6.50	−0.60	—-

HbA1c = hemoglobin A1c; SD = standard deviation

post-program follow-up. Only one participant who was categorized in the normal range at baseline presented as having chronic inflammation at post-program follow-up.

Table 5, page 49, lists body composition and physical fitness measures at baseline and post-program follow-up. At follow-up, participants displayed a significant increase of right hand grip strength, with a mean difference of 4.04 lb ($p = 0.001$). In addition, participants displayed a significant increase of left hand grip strength, with a mean difference of 2.64 lb ($p = 0.025$). Although not significant, waist circumference (cm) and weight (lb) displayed slight downward trends at post-program follow-up compared to baseline. When stratifying by gender, among females ($n = 53$), right arm measurements decreased significantly compared to baseline, with a mean difference of –0.36 cm ($p = 0.023$).

Study Discussion

This study aimed to examine the feasibility of conducting pre- and post-testing of a 13-week, supervised, community-based exercise program on metabolic measures, body composition, and physical fitness in a population of cancer survivors. Overall, feasibility was observed among 82 percent of the 79 participants who returned for their post-testing. Furthermore, researchers found preliminary evidence for the efficacy of the *Living Well After Cancer* program on metabolic measures and physical fitness. Namely, erythrocyte sedimentation rate (inflammation), total cholesterol, and grip strength (left and right hands) all demonstrated significant improvements at the post-program testing session. Conversely, the program was not associated with a

(Continued on page 49)

Table 4. Changes in Participants' ESR Levels Post-Intervention (*n* = 29)

Total *n*	Baseline-Intervention Mean (SD)	Post-Intervention Mean (SD)	Mean Difference	*p* Value
29	16.07 (8.80)	13.25 (7.30)	-2.82	0.020
Participant	**Age**	**Gender**	**Baseline ESR**	**Post-Intervention ESR**
1	29	F	6.98	5.57
2*	42	M	**19.67**	8.39
3	45	F	12.62	6.98
4*	46	M	**25.31**	12.62
5	47	F	8.39	4.17
6*	50	F	**23.90**	15.44
7	52	F	22.49	15.44
8	52	F	19.67	6.98
9	53	F	12.62	5.57
10	53	F	19.67	**30.95**
11	54	F	8.39	8.39
12	55	F	23.90	19.67
13	55	F	6.98	9.80
14	58	F	11.21	11.21
15	58	F	9.80	12.62
16	58	M	5.57	5.57
17	58	F	16.85	15.44
18	61	M	12.62	9.80
19	62	M	**30.95**	**28.13**
20	63	M	**21.08**	**21.08**
21	65	F	8.39	12.62
22	66	F	6.98	8.39
23	67	M	8.39	6.98
24	69	F	16.85	15.44
25	71	F	9.80	11.21
26	72	F	21.08	18.26
27*	72	F	***39.40***	19.67
28	74	F	5.57	8.39
29*	76	F	**30.95**	29.54

Values in bold indicate ESR value higher than normal for the participant's age/gender category.
Normal range defined as: females <50 years = 0 mm/hr-20 mm/hr, females >50 years = 0-30 mm/hr, males <50 years = 0 mm/hr-15 mm/hr, and males >50 years = 0 mm/hr-20 mm/hr. ESR = erythrocyte sedimentation rate; SD = standard deviation

Table 5. Changes in Participants' Body Composition and Physical Fitness

Outcome Variable	*n*	Baseline Mean (SD)	Post-Program Mean (SD)	Mean Difference	*p* Value
Right hand grip strength (lb)	63	57.56 (17.40)	61.60 (17.68)	−4.04	0.001
Left hand grip strength (lb)	64	54.81 (18.00)	57.45 (17.11)	−2.64	0.025
Chest (cm)	65	99.30 (12.50)	99.14 (12.86)	0.16	0.664
Waist (cm)	65	95.45 (14.63)	95.09 (15.55)	0.36	0.561
Right arm (cm)	65	26.30 (3.88)	26.09 (3.58)	0.21	0.152
Left arm (cm)	65	26.18 (4.05)	26.09 (3.63)	0.08	0.576
Right thigh (cm)	65	52.91 (7.41)	52.17 (7.26)	0.74	0.214
Left thigh (cm)	65	52.70 (7.47)	52.69 (6.78)	0.02	0.954
Right ankle (cm)	65	19.77 (2.15)	19.77 (2.10)	0.00	1.000
Left ankle (cm)	65	19.92 (2.19)	19.85 (2.07)	0.08	0.486
Weight (lb)	65	170.83 (44.33)	170.37 (44.19)	0.46	0.535
Body mass index	65	28.00 (6.23)	27.76 (6.08)	0.24	0.226
Body fat (%)	65	37.12 (9.16)	36.73 (8.81)	0.39	0.275

cm = centimeters; lb = pounds; SD = standard deviation

(Continued from page 47)

significant impact on body composition. However, when examining these results by gender, right arm measurements and triglycerides decreased significantly for females and males, respectively, after 13 weeks.

The results observed here parallel the results of several other studies that examine the effects of similar exercise programs on metabolic measures and body composition. In a pilot study by Nuri and colleagues, a 15-week combination exercise training program significantly improved metabolic measures among 29 post-menopausal survivors of breast cancer.[11] Similarly, Dieli-Conwright and colleagues found that a 16-week resistance and aerobic exercise program attenuated metabolic variables among 100 survivors of breast cancer.[12] However, both studies found significant changes in body composition variables, such as body weight, body mass index, and waist to hip ratio, whereas this study did not.

The lack of significant findings regarding body composition could be attributed to several reasons. First, the *Living Well After Cancer* program lasted a total of 13 weeks, compared to the 15- and 16-week durations of the other studies' interventions. Second, our program afforded participants two weekly supervised exercise sessions, whereas others offered three to four days of supervised sessions, which is more closely aligned with the American College of Sports Medicine and American Cancer Society exercise guidelines for survivors of cancer.[13] Lastly, Nuri et al. and Dieli-Conwright et al. utilized randomized control trial designs,[11,12] as opposed to the single-arm, quasi-experimental design used in this study. Taken together, these procedural and design differences could be the reason for the lack of significant changes in body composition that was observed in this study. However, despite these differences, our study observed significant differences in several outcome variables, demonstrating that even moderate amounts of exercise can impact metabolic measures whether significant changes in body composition are observed or not.

Given that significant improvements in several metabolic outcome variables were observed, it is important to note several strengths of this study. First, previous studies, including the two trials cited above, typically conduct exercise interventions in a controlled lab setting. In comparison, the framework used by the *Living Well After Cancer* program allows participants to be in the community and engage in healthy lifestyle behaviors in a setting that is familiar to them—a local health and wellness center. This setting change increases the likelihood that participants will feel more comfortable continuing their efforts beyond the program's duration. Though several recent studies aimed to address

This study found that measures of metabolic changes can yield significant results even when assessments of body composition and physical fitness do not.

the physical and psychosocial needs of cancer survivors in a community-based setting like the *Living Well After Cancer* program, many failed to include metabolic measures as indicators of a successful survivorship program.[4-6,14-16] This study found that measures of metabolic changes can yield significant results even when assessments of body composition and physical fitness do not. Therefore, it is important to include metabolic measures in studies when examining the impact of community-based wellness programs utilized by cancer survivors to fully assess how these programs can mitigate the sequalae associated with treatment.

Second, this study used instruments that do not require a laboratory for specimen processing. All instruments were purchased online and are accessible to the public. In addition to this convenience, study staff could quickly process participants' blood from finger pricks and receive immediate results, allowing for time efficiency. The community-based setting and instrument accessibility allow similar studies to be conducted outside the controlled environment of a lab, as seen in other studies.

Though these findings provide support for the *Living Well After Cancer* program, there are a few limitations that warrant discussion. First, this study lacked active recruitment, thus resulting in possible selection bias. In other words, individuals who self-select for a program that requires a twice-weekly exercise commitment might be more inclined to adhere to healthy lifestyle behaviors than those who do not self-select. Second, the single-arm, quasi-experimental design used in this study did not include a control group. For this reason, it is difficult to determine whether the observed improvements were due to participation in the program or the cancer survivorship trajectory in general.

Lastly, though this study used hand grip strength as an indicator of physical fitness, it did not include a six-minute walk test to assess cardiorespiratory fitness in this population—a measure frequently used by other studies in this research area.[4,14,15] By including this measure in the program, future sessions would be better equipped to assess its impact on multiple areas of physical fitness. Therefore, to address these limitations, future studies should implement a randomized controlled trial design and include the addition of the walking test. Other items for future studies to consider include having a control group to identify a program's impact more fully on markers of cancer survivorship and implementing a third timepoint. Because the *Living Well After Cancer* program encourages long-term lifestyle changes, there is a need to follow up with participants after the post-program testing session (e.g., three months post-program completion) to determine whether the program's results continue beyond 13 weeks.

Overall, these findings provide preliminary evidence for the *Living Well After Cancer* program as an effective strategy to mitigate the long-term symptoms cancer survivors develop after treatment. As a community-based program, it removes the burden of having to offer these services in the clinical setting and increases access to community resources that may lead to improved survivors' health and well-being. Future trials are needed to explore more fully participants' changes in metabolic measures and body composition. Ultimately, a randomized intervention trial is needed to determine the *Living Well After Cancer* program's impact on the cancer survivorship trajectory. OI

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Disclosure of Interest

The authors have no conflicts of interest or competing interests to declare.

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Coping with COVID-19 in Patients with Lung Cancer

BY ELIZABETH S. VER HOEVE, MA; SARAH N. PRICE, PHD; TARA K. TORRES, MA; HEIDI A. HAMANN, PHD; AND LINDA L. GARLAND, MD

In Brief

Patients with lung cancer commonly experience high symptom burden and unmet supportive care needs, placing them at increased risk for psychosocial morbidities. This study assesses coping strategies and psychosocial well-being in patients with lung cancer, who are facing multiple stressors, specifically their cancer diagnosis and the COVID-19 pandemic. To do so, researchers assessed COVID-19-related burden, coping, and psychosocial well-being in 65 patients with lung cancer who were receiving treatment at a National Cancer Institute (NCI)-designated comprehensive cancer center between August 2020 and June 2021. Most patients worried that their cancer status increased their risk for COVID-19 illness. Cross-sectional patient-reported outcomes data indicated that prior experience with a chronic stressor (i.e., diagnosis and treatment for lung cancer) may have enhanced patients' resilience toward the management of stressors, including the COVID-19 pandemic.

The COVID-19 pandemic has yielded devastating effects worldwide,[1] with risks for contraction, hospitalization, and death disproportionately felt by certain subpopulations.[2,3] From the outset, lung cancer patients were warned about their heightened likelihood of severe illness and death if exposed to the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)[4] due to comorbidities, such as chronic obstructive pulmonary disease and cancer treatment history, including thoracic surgery.[5-10] Indeed, research conducted during the first year of the COVID-19 pandemic confirmed that patients with lung cancer, particularly those undergoing active treatment, experienced significantly higher rates of hospitalization relative to healthy adults and more fatalities than patients with other types of solid tumor cancers.[8,9] Prior to the pandemic, numerous studies also identified associations between lung cancer and psychological distress, including stigmatization, symptom burden, and unmet medical and psychological needs.[11-16] Specifically, relative to patients with other cancer types, patients with lung cancer often reported higher levels of distress at cancer diagnosis[15] and experienced a higher risk of suicide,[16] suggesting that these individuals may be at greater risk for psychosocial morbidities during an acutely stressful event like a global pandemic. This confluence of physical and psychosocial vulnerabilities suggests the need for investigation into how patients with lung cancer have coped—mentally and physically—during the COVID-19 pandemic.

Lazarus and Folkman's transactional model of stress and coping was designed to assess the impact of psychological stressors by balancing an individual's appraisal of a stressful event with the actions they take to cope with the event.[17] This model identifies coping as a dynamic process influenced by an individual's cognitive appraisal of a stressful event and explores the various outcomes mediated by the use of different coping strategies.[17] Specifically, this model examines how individuals interpret their perceived susceptibility, given the severity and relevance of a particular stressor, how they interpret their perceived control and self-efficacy over that stressor's outcome can influence their psychological outcomes (e.g., anxiety, depression), and the coping strategies they choose to employ to meet the demands of a particular situation.[18,19]

Emerging data suggest that individuals with heightened COVID-19 health risks are more likely to experience increased psychological distress.[20] For example, healthcare workers in Italy

Utilization of effective coping strategies has been linked to better health and psychosocial outcomes in patients with a variety of cancer diagnoses.[23-25]

with higher COVID-19 risk perception had greater levels of psychological worry compared to the general public.[21] Likewise, a recent qualitative study of individuals living with long-term physical health conditions (e.g., cancer, cardiovascular disease) identified overarching COVID-19-related themes, including high levels of fear and anxiety associated with heightened perceptions about the consequences of being infected with COVID-19.[22]

The coping strategies that patients with cancer employ, based on their threat appraisal, can influence their psychosocial outcomes. Utilization of effective coping strategies has been linked to better health and psychosocial outcomes in patients with a variety of cancer diagnoses.[23-25] Conversely, a recent meta-analysis found that patients with cancer who characterized their cancer diagnoses as a harm or loss often relied on ineffective coping techniques, such as avoidance coping (e.g., behavior designed to avoid thinking or feeling about a stressor).[24,26] For example, patients with breast cancer who engaged in avoidant-style coping behaviors reported greater physical symptom burden.[25] Similarly, newly diagnosed patients with lung cancer who endorsed avoidant coping styles reported higher levels of anxiety and depression.[23] Understanding how patients with lung cancer cope within the context of dual stressors (having a history of lung cancer and living during the COVID-19 pandemic) may:

- Reveal which strategies are most effective for coping with challenging circumstances
- Elucidate associations between psychological coping and mental health outcomes
- Help guide improved patient-centered cancer care.

This study assesses appraisal of risk, psychological distress, and coping behaviors during the COVID-19 pandemic among patients with lung cancer.[27]

Method

Patients and Recruitment

Between August 2020 and June 2021, the principal investigator (Garland) at an NCI-designated comprehensive cancer center (Banner University Medical Center, University of Arizona Cancer Center) invited English-speaking patients with lung cancer in active treatment or follow-up care to participate in this study. Patients completed electronic surveys and consent forms through a secure link via REDCap. This study was approved by the University of Arizona's institutional review board, and analyses were performed using SPSS version 27.

Measures

Demographics and Disease History

Demographic characteristics included gender, race/ethnicity, age, marital status, employment, highest level of education, housing status, and insurance status. Cancer history characteristics included stage at diagnosis, type of lung cancer, and treatment history.

COVID-19 Experiences and Burden

The *COVID-19: Impact of the Pandemic and HRQOL in Cancer Patients and Survivors*[27] questionnaire has been recommended for use by the National Institutes of Health Office of Behavioral and Social Sciences Research.[28] This instrument includes 19 descriptive questions and 36 five-point Likert scale items to assess patients' perceived COVID-19 burden. Perceived COVID-19 Burden includes seven subscales that measure:

- Financial hardship (4 items; e.g., "I have experienced financial difficulties.")
- Healthcare disruption (2 items; e.g., "My general medical care has been disrupted or delayed.")
- Disruption to daily activities (3 items; e.g., "I have been unable to perform my typical daily routines like work, physical or leisure activities.")
- Perceived benefits (4 items; e.g., "I have deeper appreciation for life.")
- Functional social support (4 items; e.g., "I have received emotional support from family or friends when needed.")
- Perceived stress management (5 items; e.g., "I am able to recognize thoughts and situations that make me feel stressed or upset about COVID-19.")
- Satisfaction with providers (2 items; e.g., "My healthcare providers have taken the necessary measures to address COVID-19.")
- COVID-19 anxiety (6 items; e.g., "I worry about the possibility of dying from COVID-19.")
- COVID-19 depression (6 items; e.g., "I have experienced feelings of social isolation or loneliness.").

A Total COVID-19 Burden score reflected the average of all 36 items (items 15 to 16 and 24 to 36 were reverse coded); higher scores (range: 0 to 4) indicated greater burden. Psychometric properties of this questionnaire are preliminary.[28]

The Brief COPE

The *Brief COPE*[29] contains 14 subscales: acceptance, emotional support, humor, positive reframing, religion, active coping, planning, instrumental support, venting, denial, substance use, behavioral disengagement, self-distraction, and self-blame. Higher scores (range 2 to 8) indicated greater utilization of a strategy.

Open-Ended Responses

First, participants who responded "yes" to "I have used my experience in coping with cancer to deal with COVID-19" were asked to explain (via free-text response) how their cancer experience helped them cope during the pandemic. Second, participants who reported a change in the type or frequency of their coping strategies (using the *Brief COPE*) since the onset of COVID-19

were asked to indicate which strategies they now used more/less frequently.

PROMIS® Anxiety-4a and Depression-4a

PROMIS Anxiety-4a and PROMIS Depression-4a are standardized, validated measures[30,31] normalized to the U.S. adult population. Each scale includes four items measured via five-point Likert scales; scores are summed and normed to obtain a standardized *T*-score for general anxiety and general depression. Higher scores signify a greater extent of a symptom.

Results

Descriptive Analyses

Patient Characteristics

Of 130 patients approached, 65 (50 percent) consented and provided survey data (see Figure 1, below). The average age of participants was 69 years; the majority identified as female (66.2 percent), non-Hispanic White (81.5 percent), and married or partnered (58.5 percent), with 49.2 percent reporting educational attainment of at least a bachelor's degree. Most patients had Stage III or Stage IV disease (53.8 percent), and 69.2 percent were diagnosed with non-small cell lung cancer (see Table 1, page 56).

COVID-19 Experiences

Most patients (89.2 percent) had at least one general risk factor for severe COVID-19 illness, and 15.4 percent had specific risk factors, such as exposure to COVID-19+ individuals (6.2 percent) or recent travel to COVID-19 hotspots (7.7 percent). Approximately one-third of patients (33.8 percent) were formally tested for COVID-19. Only five patients (7.7 percent) reported exposure to someone who tested positive, and only one patient (1.5 percent) tested positive with a mild case that did not require hospitalization. Patients generally reported spending less time outside compared with their normal routine (79.4 percent) and experienced a reduction in the amount of work they were able to accomplish (69.2 percent). Some patients (38.5 percent) canceled general medical appointments, and a minority (6.2 percent) avoided a visit to the emergency room or urgent care even when medical attention was warranted. Most patients attended all cancer appointments (in-person or telehealth) during the pandemic (72.3 percent).

Perceived COVID-19 Burden

Most patients (86.1 percent) reported experiencing disruptions to their daily social interactions, with some unable to perform typical daily routines (40.6 percent) and some unable to adequately take care of family members or friends (15.6 percent; see Table 2, page 57). However, few reported financial hardships (23.1 percent), most indicated minimal healthcare disruptions due to COVID-19 (76.6 percent), and most felt as though their healthcare team had taken the necessary measures to address COVID-19 (67.2 percent). Most participants reported feeling anxious (58.5 percent) and concerned that their cancer status put them at greater risk of dying from COVID-19 (72.3 percent), yet most believed that the pandemic would not impact their personal cancer care (64.6 percent), and a minority felt they had no control over how COVID-19 impacted their lives (43.1 percent). Approximately one-third reported changes in sleep patterns (n = 23; 35.4 percent), eating behavior (n = 24; 36.9 percent), and difficulty concentrating (n = 19; 29.2 percent). At the same time, most participants reported feeling a deeper appreciation for life (67.7 percent) and a greater

Figure 1. Study Recruitment Process

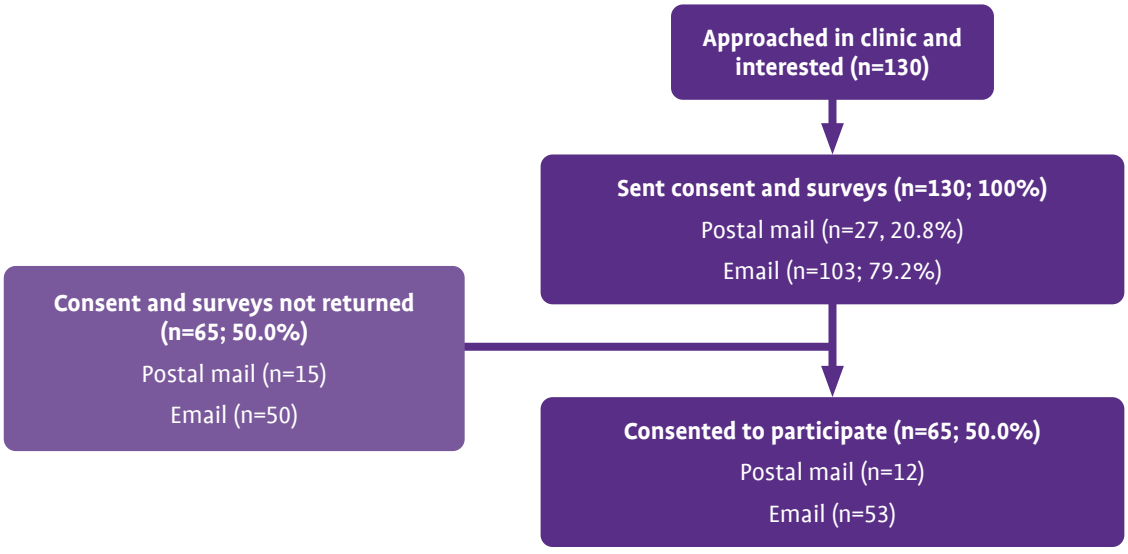

Table 1. Demographic and Disease Characteristics (*N* = 65)

	Mean, SD or *n* (%)
Age	69.03, 7.80
Gender	
Female	43 (66.2)
Male	22 (33.8)
Race/Ethnicity	
Non-Hispanic White	53 (81.5)
Hispanic (any race)	4 (6.2)
Non-Hispanic Black/African American	5 (7.7)
Asian	1 (1.5)
Bi-racial/multi-racial	2 (3.1)
Marital Status	
Single	6 (9.2)
Married/cohabitating	38 (58.5)
Divorced/separated	17 (26.1)
Widowed	4 (6.2)
Education	
High school degree/GED	17 (26.2)
Some college	6 (9.2)
Associate's degree/2-year degree	10 (15.4)
Bachelor's/4-year degree	22 (33.8)
Graduate degree	10 (15.4)
Cancer Stage	
Stage I	8 (12.3)
Stage II	12 (18.5)
Stage III	14 (21.8)
Stage IV	21 (32.3)
Unknown	10 (15.1)
Lung Cancer Type*	
NSCLC	45 (69.2)
SCLC	11 (16.9)
Neuroendocrine/other/more than one type	6 (9.2)
Cancer Treatment*	
Radiation	
Never	20 (30.8)
Current	7 (10.8)
Completed	37 (56.9)
Chemotherapy	
Never	8 (12.3)
Current	17 (26.2)
Completed	39 (60)
Surgery	
Never	34 (52.3)
Current	30 (46.2)

NSCLC = non-small cell lung cancer; SD = standard deviation; SCLC = small cell lung cancer.
*Not all percentages equal 100 percent due to missing data

level of acceptance (69.2 percent), with most participants receiving emotional support from friends and family (69.2 percent), engaging in relaxation practices (80 percent), relying on information-seeking (81.5 percent), re-examining negative thoughts (84.6 percent), and using self-care practices (84.6 percent). Total COVID-19 burden was not associated with any demographic or disease characteristics. Given the rapidly evolving situation with the pandemic, a one-way analysis of variance on total COVID-19 burden was conducted to confirm that participants who completed the survey in 2020 did not differ significantly from those who completed the survey in 2021, F (1, 63) = 0.164, p = 0.687.

Coping Strategies During COVID-19

Among the 14 coping strategies available to individuals facing challenges in their lives, acceptance, active coping, and emotional support were most endorsed. The least endorsed coping strategies were substance use, denial, and self-blame (Table 3, page 58). Most patients reported using the same coping strategies before and during the pandemic, although 22 patients (33.8 percent) reported changing their coping strategies since the start of the pandemic, relying more frequently on religion (24.6 percent), self-distraction (25.6 percent), acceptance (20 percent), and positive reframing (18.5 percent) and less frequently on venting (16.9 percent), self-blame (15.4 percent), distraction/avoidance (12.3 percent), and denial (12.3 percent). The majority of participants (84.6 percent) reported that previous experiences with cancer helped them cope with the COVID-19 pandemic. Qualitative free-text responses from 28 patients (Table 4, page 59) convey how patients' experiences with cancer helped them cope with COVID-19, as indicated by recurring themes of appreciation, patience, and acceptance. Three exemplary quotes are included below:

> *"I have been more focused on the present moment and accepting life as is since I've had cancer, and that helps with COVID-19, too."*

> *"Follow directions for COVID (mask, stay home, etc.) and stick to FDA [U.S. Food and Drug Administration] directions like my oncologist's directions."*

> *"I cannot control the cancer's final outcome, but I can do my part and let God do the rest. Same will be true for COVID-19."*

COVID-19 Total Burden, Coping Strategies, and Psychosocial Outcomes

Average PROMIS *T*-scores for general anxiety (M = 53.59, SD = 9.05, range, 40.3 to 77.9) and depression (M = 51.19, *SD* = 8.3, range, 41 to 69.4) for this sample of patients with lung cancer were within one standard deviation of national averages for normed populations of healthy individuals. Among the demographic and disease characteristics, only female gender was associated with greater anxiety (r[63]=0.377, p=0.002) and depression (r[64]=0.334, p=0.007). Patients with higher total COVID-19 burden experienced greater general anxiety (r = 0.489,

Table 2. COVID-19 Subscales and Total Burden Associated with PROMIS Anxiety and Depression

Impact of COVID-19	Number of Patients (n)	Mean (SD)	Skew Statistic (SE)	PROMIS Anxiety	PROMIS Depression
COVID-19 Total Burden	**65**	**1.65 (0.34)**	**0.792 (0.297)**	**0.489****	**0.414****
Financial hardship	61	1.15 (0.11)	0.868 (0.306)	0.306*	0.285*
Healthcare disruptions and concerns	63	1.13 (0.09)	−0.091 (0.302)	−0.059	0.001
Disruptions to daily activities and social interactions	63	2.23 (0.08)	0.093 (0.302)	0.297*	0.294*
Perceived benefits	63	2.66 (0.71)	−1.139 (0.299)	−0.155	−0.038
Functional social support	62	2.82 (0.08)	−0.946 (0.304)	0.049	0.081
Perceived stress management	63	2.94 (0.06)	−2.327 (0.302)	0.198	0.295*
Provider communication	64	2.47 (0.90)	−0.783 (0.299)	−0.129	−0.127
COVID-19-specific anxiety	63	2.51 (0.86)	−0.05 (0.302)	0.493**	0.359**
COVID-19-specific depression	59	1.87 (0.93)	−0.08 (0.311)	0.663**	0.694**

Missing values from the COVID-19 Total Burden Score were replaced with the series mean.
*Correlation is significant at the 0.05 level (two-tailed).
**Correlation is significant at the 0.01 level (two-tailed).
SD = standard deviation; SE = standard error

$p < 0.001$) and general depression ($r = 0.414$, $p < 0.001$; see Table 2). Total COVID-19 burden was also correlated with greater use of planning, instrumental support, venting, behavioral disengagement, and self-blame (Table 3). Greater general anxiety was associated with greater use of religion, planning, instrumental support, venting, denial, substance use, behavioral disengagement, and self-blame (Table 3). Greater general depression was associated with greater reliance on planning, instrumental support, venting, denial, substance use, and self-blame (see Table 3). Patients with lung cancer who reported higher levels of general anxiety tended to experience greater financial hardship, disruption to daily activities, COVID-19-specific anxiety, and COVID-19-specific depression. Patients who reported higher levels of general depression tended to experience greater financial hardship, disruption to daily activities, perceived ability to manage stress, COVID-19-specific anxiety, and COVID-19-specific depression (Table 2).

Discussion

The majority of patients with lung cancer in this sample recognized their heightened health risks due to COVID-19 and utilized adaptive coping strategies to mitigate those risks, thus demonstrating effective management of COVID-19-related distress. Strong resilience factors seemed to underlie these patients' appraisals of COVID-19, with most participants capitalizing on social support and engaging in gratefulness, perspective-taking, and self-care behaviors. Patients strongly endorsed the behavioral coping strategies of acceptance, active coping, and emotional support, and the majority identified having used these strategies to cope with cancer and continuing to apply these same strategies to the novel COVID-19 stressor. Although perceived COVID-19 burden was generally low in this sample, patients with higher perceived COVID-19 burden relied on less effective coping strategies, including more venting and behavioral disengagement, and reported higher generalized anxiety and depression, suggesting that these patients' selection of particular coping strategies may impact their psychosocial well-being in response to challenging situations.

According to Lazarus and Folkman, individuals' interpretations of the severity and relevance of stressors and of their control over those stressors' outcomes can influence the coping strategies they choose to employ, which in turn can shape the stressor's actual impact on their lives.[17] In this sample, levels of general anxiety and depression were not found to be significantly higher than those levels found in normed populations of healthy controls, suggesting that these participants' high utilization of appropriate coping behaviors and their realistic perceptions of the pandemic's impact on their daily lives may have guided improved management of psychosocial distress.

Table 3. Correlations Between Coping Strategies and COVID-19 Total Burden, Anxiety, and Depression

Coping Strategies	Mean (SD)	COVID-19 Total Burden	PROMIS Anxiety	PROMIS Depression
Acceptance	6.44 (1.63)	−0.019	0.022	−0.056
Emotional support	5.38 (1.36)	0.063	0.171	0.146
Humor	3.59 (1.58)	0.157	0.057	0.214
Positive reframing	4.87 (1.61)	0.156	0.227	0.055
Religion	5.18 (2.26)	0.116	0.306*	0.148
Active	5.79 (1.45)	0.206	0.191	0.053
Planning	5.05 (1.81)	0.291*	0.332*	0.316*
Instrumental support	4.33 (1.54)	0.323**	0.428**	0.333**
Venting	3.61 (1.32)	0.334**	0.479**	0.41**
Denial	2.5 (1.2)	0.16	0.467**	0.326*
Substance use	2.37 (0.97)	0.232	0.391**	0.353**
Behavioral disengagement	4.40 (1.17)	0.265*	0.308*	0.176
Self-distraction	5.19 (1.53)	0.048	0.216	0.098
Self-blame	3.16 (1.59)	0.403**	0.505**	0.534**

*Correlation is significant at the 0.05 level (two-tailed).
**Correlation is significant at the 0.01 level (two-tailed).
SD = standard deviation

This study is not without its limitations. Due to recruitment challenges during the pandemic, our sample size was relatively small and, therefore, results may not be generalizable to all patients with lung cancer. Most of the participants reported a relatively high educational status, partnered relationship status, and financial security (suggesting higher socio-economic status), factors that may have partially protected these patients from increased COVID-19 risk impact.[32] Our cross-sectional design also limits generalizability and our ability to make strong statistical inferences. Finally, this study utilized a relatively new measure (the *Impact of the COVID-19 Pandemic and HRQOL in Cancer Patients and Survivors*[27] questionnaire) that was developed quickly to measure real-time patient experiences within the context of the unfolding pandemic. Although the measure has understandably undergone limited psychometric testing given the need for rapid implementation, the use of this measure represents a significant strength because it has been vetted and endorsed by the NIH as a patient-reported outcomes measure of COVID-19 burden[27,28] and because it was designed specifically for use with patients with cancer.

Despite the known stressors associated with COVID-19, patients with lung cancer in this study maintained protective appraisals and coping strategies that may have buffered them against the negative psychosocial consequences (i.e., anxiety and depression) commonly reported by a variety of individuals and groups throughout the COVID-19 pandemic.[33,34] Importantly, our cross-sectional patient-reported outcomes data indicate that prior experience with a chronic stressor (i.e., diagnosis and treatment of lung cancer) may have enhanced resilience toward management of future stressors like the COVID-19 pandemic. As future studies reference our results and the field continues to generate data on the psychosocial well-being of patients with cancer during the pandemic, the generalizability of our findings will be strengthened. Ultimately, identifying and understanding the coping strategies utilized by patients with lung cancer during a global pandemic may guide clinicians and researchers as they attempt to conceptualize resiliency within the context of stress and psychosocial well-being. OI

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Table 4. Summary of Free Choice Responses Related to Patients' Coping Strategies

Strategy Theme	Number of Times Endorsed	Exemplary Quotes
Acceptance	20	*"Do not worry until there is something to worry about. Patience—the world does not run on your schedule."* *"I accept others' opinions and responses much more now...I feel I have become much less judgmental and opinionated."* *"Having a cancer diagnosis, I realized I can only take care of myself and 'let it be.' Same for COVID- I can take the precautions and then 'let it be.'"*
Drawing on inner strength and skills learned from their cancer experience	11	*"I have learned to relieve stress through new activities adopted after the cancer diagnosis (baths, yoga, breathing exercises, increased reading)."* *"If I can survive cancer, I can survive anything."*
Appreciation for life	5	*"I suspect I appreciate the true meaning of my mortality a lot more than...a normal human who behaves and plans as though they will live forever."* *"Every day is a gift and should be enjoyed no matter what. There is always something good in a day!"* *"I thank God every day that I am still alive."*
Connection with others and the present moment	5	*"Using technology to communicate with friends/family."* *"Making sure that I connect with friends and family more. Trying to be more supportive of friends and family. Trying to make more time to just sit and think."*

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Conflicts of Interest

The authors have no conflicts of interest to disclose.

Ethics Approval

This study was approved by the University of Arizona's Institutional Review Board (IRB No. 2004563860).

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MAKING AN IMPACT

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2021 IMPACT REPORT

The oncology community grappled with significant issues in 2021, from health disparities and delayed cancer screenings to the well-being of healthcare providers and workforce shortages.

Because every cancer program and practice were impacted differently, the Association of Community Cancer Centers (ACCC) listened to its stakeholders and responded with a wealth of tools, resources, and education initiatives based on expressed member needs.

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ACCC
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ACCC 2021 Financial Advocacy Network Summit

What's Ahead

The Association of Community Cancer Centers (ACCC) Financial Advocacy Summit is an annual opportunity for members to connect and discuss the current and critical issues impacting financial advocacy. The Summit was held virtually in September 2021. Over the course of three days and three 90-minute sessions, 43 financial advocacy stakeholders gathered to tackle key issues that were identified by the ACCC Financial Advocacy Network Advisory Committee and member feedback. Discussion topics were:

- Screening for risk of financial distress
- Advocating for equitable cancer care
- Scope of financial navigation and advocacy services.

Each session comprised a facilitated large group discussion and breakout sessions to tackle specific questions and garner member feedback. After each breakout session, the groups reconvened to recap their small-group discussions.

Attendance was by invitation only and limited to facilitate active conversation. Summit participants represented a wide range of settings, such as hospital, practice, and community-based organizations. Participants included administrators, financial navigators and counselors, social workers, pharmacists, and other advocates in specialized roles like registration, patient access, and billing compliance.

Aimee Hoch, LSW, a financial navigator at Grand View Health, Sellersville, Penn., introduced the first topic (Session 1, right) by sharing about the financial navigation program at her facility. She framed distress screening as assessing the various sources of patients' financial burden to intervene where needed so that patients can participate in *all* aspects of their care.

Hoch identified common financial triggers of distress, including out-of-pocket expenses, missed work or inability to work, loss of income, building medical debt, and existing prior debt(s). She and many attendees agreed that patients' psychological responses to distress can include concern or stress about their wages, income, and how to pay for their expenses, which can result in the inability to fully participate in their cancer care, shared decision-making, appointments, and/or support groups.

Session 1. Screening for Risk of Financial Distress

Description: Traditionally, underserved patient populations face increased risk of financial distress. Financial distress screening is important to identify interventions that can mitigate or prevent financial toxicity for patients with cancer, but screening practices vary. During this session, participants discussed barriers to and effective practices for implementing financial distress screening.

Objectives: Gather feedback to inform an action plan between ACCC and its partners to improve or clarify financial distress screening implementation at member institutions.

Together, these issues can lead to coping behaviors that interfere with optimal treatment like skipping medical appointments, supportive care opportunities, or medication due to costs.

During the breakout sessions, participants discussed how screening for financial distress happens in their facilities, as well as which tools and skills work versus those that do not.

- *Who to screen?* It often is not possible to screen every patient and defining the right subset of patients to target is challenging. Some patients may not self-identify as needing financial help because they are embarrassed, overwhelmed, or do not realize that there is a problem with covering their treatment-related costs. Additionally, some patients may need assistance later in their care and not realize that help is available. If financial navigators rely on insurance coverage or other financial indicators to determine who is at high risk for financial distress, they may miss patients who could benefit from assistance. It helps to ensure that healthcare providers and clinic staff know how to refer patients to a financial navigator if a relevant concern is indicated.
- *When to screen?* When patients are overwhelmed about their finances, they cannot fully participate in their treatment planning. Screening patients early for financial distress helps them begin treatment in a better place mentally. Continuing to assess for distress periodically throughout treatment can help proactively identify issues when changes occur in patients' treatment plan, insurance coverage, disease status, etc.
- *How to screen?* Summit attendees identified a variety of methods, including use of the COST tool,[1] National Comprehensive Cancer Network Distress Thermometer,[2] and Patient Health Questionnaire (PHQ)-2[3] and/or PHQ-9.[4] Participants agreed that a mixture of these tools and strategies yield the best results.
- *Importance of building trust.* Regardless of one's screening processes, building relationships with patients makes it much easier to ask difficult questions, especially for underserved patients who may struggle with their own trust in the American healthcare system. Financial naviators should help patients understand that they are not alone in facing financial concerns related to their anti-cancer treatment and how financial navigation services can help.
- *Importance of clear communication.* Helping patients understand their insurance benefits and estimated financial burden up front is an important early step in the cancer care continuum. If patients have insurance, they may assume that paying for their care will not be a problem. This is not always the case, especially if patients do not fully understand their insurance benefits. Clarity and education may also help patients feel more comfortable with asking for help from a financial navigator.

Areas of Focus

Participants agreed that they want better tools and processes for screening patients for financial distress, no matter their cancer program or practice size or location. While there are effective elements within existing tools, these tools need to be refined. Ideas include:

- Create one concise ACCC tool using the "best" parts of identified, existing distress screening tools.
- Develop screening checklists using identified risk factors for financial toxicity and weaving checklists into a screening tool.
- Identify three to four questions that could be asked of all patients to identify their level of risk for financial toxicity.
- Create or improve access to electronic health record tools that would allow financial navigators to be notified of new consults, denials or loss of insurance, and alerts of an overage for a pre-set outstanding balance threshold.

Next Steps

Based on the needs expressed by summit participants, the Financial Advocacy Network's Education Task Force will integrate the development of tools and resources to optimize financial distress screening into its 2022 priorities. Discussion input has also been integrated into the financial distress screening portion of ACCC's Financial Advocacy Services Guidelines revision (see Session 3. Scope of Financial Navigation Services).

Session 2. Advocating for Equitable Care

Description: Financial toxicity is often driven by social determinants of health, rising costs of care, longer treatment durations, and the current health insurance landscape. Financial navigators see firsthand how these issues impact patient care and play a critical role in mitigating financial hardship. Awareness, recognition, and promotion of the role of financial navigators must be central to any health system, commercial, agency, and/or government policy that promotes equitable, affordable cancer care. ACCC members and partners identified strategies to amplify the voices of financial navigators and the patients they serve.

Objectives: Discuss the importance of cancer care and the need for policy stakeholders to understand and value the role financial navigators play in advancing health equity. Identify opportunities to align with ACCC partners on policy initiatives and identify training, resources, and/or materials needed to support members' engagement in advocacy.

Rebecca Kirch, executive vice president of Policy and Programs at the National Patient Advocate Foundation, and Becky Shipp, principal at Becky Shipp Consulting, spoke on the current advocacy landscape. They explained that United States healthcare policy typically backburners financial and social needs to focus on disease-directed treatment. Further, the federal approach to care access and affordability has historically focused on insurance reform, which does not address challenges to accessing high-quality comprehensive benefits. One potential strategy to elevating the needs for financial navigation services is to integrate these programs into existing federally funded programs, such as the Temporary Assistance for Needy Families or Social Services Block Grant, as well as targeted case management. Political advocacy plays a critical role in expanding access to financial navigation services and Congress will not make necessary changes to these programs without being asked. The same goes for state and local leaders and policymakers. Financial navigators' experience and stories can be extremely influential in building support for greater access to financial navigation services in the policy areana.

Many summit participants had advocacy experience and shared what has worked for them to amplify the role and value of financial navigation at several levels.

Advocacy Strategies

Audience: Who needs to understand financial navigation's impact on health equity?

- Health system leadership
- Cancer program leadership and department chairs
- Care team members
- Local, state, and federal legislators and health agencies
- Policy makers
- Payers
- Manufacturers.

Advocating Internally

How to effect change within a facility or health system?

- Have patience and be prepared to keep pushing. The redundancy and repetitiveness of your message for supporting financial navigation is important when trying to reach your leadership.
- Data and patient stories are effective tools to get your message across.
- Identify and involve the right champions (e.g., physicians, leadership, etc.). These people can often vouch for why financial navigation is important to your patients and institution.
- Including the patient voice in your message can be effective. For example, Press Ganey results have strong influence and are often heard loudly by cancer program or practice leadership and decision makers.

Advocating Externally

How to effect change beyond your facility or health system?

- Engage in opportunities to write letters to your local and state representatives
- Sit on advisory committees for advocacy organizations
- Submit "letters to the editor" to healthcare- and oncology-specific journals/media
- Testify at hearings.

Areas of Focus

Participants are eager to engage in policy and advocacy conversations and activities. In the summit's registration survey, 60 percent of participants indicated that they are "very interested" and 20 percent indicated that they are "slightly interested" in engaging in these conversations and activities. During the summit session, participants identified resources that they need to feel confident in their advocacy efforts:

- An "Impact of Financial Navigation" one-pager with talking points
- Education on health equity (e.g., how to assess social determinants of health in the community)
- Templates for reporting impact data to cancer program or health system leadership
- Templates for letters or presentations that broadly define financial navigation, as well as details on related, more specific topics
- 101-style training for policy-related advocacy
- Coaching and mentoring by experienced financial navigators
- Written or video stories about the unmet need for financial navigation services in cancer care.

Next Steps

ACCC is developing resources to support advocacy efforts to ignite change at multiple levels. In addition to making the case for increased investment in financial navigation services at the facility level, these resources will support broader policy engagement at the federal and state levels by engaging in ACCC's annual Virtual Hill Day and connecting with the Oncology State Societies at ACCC.

Session 3. Scope of Financial Navigation Services

Description: Cancer programs and practices, researchers, and industry look to ACCC's Financial Advocacy Services Guidelines as a primary resource for defining the scope of financial navigation services and setting the how-to on shaping formal financial navigation programs. ACCC members and stakeholders discussed the scope of financial navigation services and shared the organization's launch of a consensus-based approach for updating its guidelines.

Objectives: Gather feedback and build alignment around goals for financial navigation services, as well as identify champions and individuals who are committed to supporting this effort.

The current ACCC Financial Advocacy Services Guidelines were published in 2018, but the role of financial navigators has changed dramatically since. Despite progress, the field is still struggling with consistency and clarity on terms and scope of practice. Lori Schneider, 2021 Chair of the Financial Advocacy Network and oncology operations manager at Green Bay Oncology, provided background about the development of the original guidelines. She then introduced ACCC's plan to revise these guidelines in 2022. During this session, participants discussed the goals of financial navigation and provided input on priorities to drive the guidelines revision process. Participants agreed that the revised guidelines must integrate the following guiding principles:

- Patient-centeredness and value
- Health equity
- The functions of financial navigation
- Competency measurements.

Goals of Financial Navigation

Revising the financial advocacy guidelines requires consensus on the goals of financial navigation. Participants agreed on the following goals:

- Relieve or reduce patient stress and financial burden associated with cancer care
- Help patients understand their insurance benefits, financial liability for cancer care, and available resources
- Improve access to care and ensure equitable care
- Increase patient adherence to treatment plans by removing barriers to participation in their care
- Help patients make insurance coverage decisions that align with their goals, including elevating financial navigators to be part of shared decision-making conversations. This way, financial toxicity is considered as a quality-of-life factor in care decisions when appropriate
- Advocate for policy change by payers, pharmaceutical manufacturers, and other state and federal stakeholders.

Core Functions and Competencies for Financial Navigators

Regardless of current inconsistencies in the names and titles of the staff who provide financial navigation services, participants identified a few key concepts and skills that a financial navigator should be able to do:

- Understand the services provided and the system in which financial navigation work is done
- Communicate with patients in basic, non-jargon terms
- Educate patients about their insurance benefits
- Understand key concepts (e.g., prior authorization, insurance regulations and optimization, revenue cycle)
- Consider how a variety of staff can work together to create support, from social workers and pharmacy staff to clinical (nurse) and non-clinical (lay) navigators. These staff can work collaboratively with financial navigators to meet the financial navigation program's goals.

Not every cancer program or practice has the capacity to offer comprehensive financial navigation services. Summit participants discussed the benefit of establishing different levels of financial navigation services for programs and practices that correspond to their already available services and that keep in mind their size, resources, and staff experience. By using levels like gold, silver, and bronze, a gold level program could mean offering a full suite of comprehensive financial navigation services to patients, whereas a bronze level program could mean offering a standard set of necessary services.

Certification

Participants discussed the potential value of creating a formal certification focused on financial navigation, which would help standardize the role and elevate the field. Certification is a complex process that can take time, so it is critical to fully consider the value a certification holds for financial navigators. Discussion also focused on how to ensure the right stakeholders and partners are involved in the creation of a certification program to minimize redundant efforts. For example, the American Society of Clinical Oncology has a new certification related to patient-centered care, but the American College of Surgeons Commission on Cancer

accreditation could also be a place to house financial navigation credentialing.

Areas of Focus

Additional resources and needs discussed during the summit session included developing the following:

- A facility-specific, simple introduction of financial navigation services, targeting other members of the healthcare team as well as patients to clarify the role and value of financial navigators and increase utilization. This includes introducing the financial navigators on staff that are available to help patients.
- Strategies to integrate the patient perspective into ACCC's Financial Advocacy Services Guidelines. This could come directly from patients or by partnering with foundations and organizations that work directly with patient groups.
- A financial estimate tool to help patients understand what their costs may be and that can be used by financial navigators and patients alike.
- Strategies to integrate identification of disparities or gaps to accessing these services.
- Metrics and tracking to measure and communicate impact, including how to show return on investment for financial navigation services. Consider additional values that are difficult to measure like the patient experience, patient stress level, and access to care.

Next Steps

The process of revising ACCC's Financial Advocacy Services Guidelines, including the integration of the guiding principles defined above, is already underway. ACCC is leading the guidelines update process via a consensus-building methodology known as a Delphi panel. This process will allow ACCC to collect expert-based judgments and identify consensus on the guidelines where there is little to no available and established knowledge in oncology financial navigation services.[5] A Guidelines Development Committee has already met, and the committee has established its Delphi panel of experts who will complete questionnaires to develop the guidelines content throughout 2022.

Closing Thoughts

The ACCC Financial Advocacy Network boasts an engaged membership of financial navigators who have already begun to move actions identified during the 2021 Financial Advocacy Summit forward through task force and committee work in the coming years.

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Association of Community Cancer Centers

ACCC Welcomes Its Newest Members

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Website: christushealth.org/locations/oncology-institute

Coastal Cancer Center
Myrtle Beach, S.C.
Delegate Rep: Emily Touloukian, MD
Website: coastalcancercenter.com

Dell Children's Blood and Cancer Center of Central Texas
Austin, Tex.
Delegate Rep: Rudy Garcia III MPH
Website: dellchildrens.net/childrens-blood-and-cancer-center

NYU Langone Hospital-Perlmutter Cancer Center
Mineola, N.Y.
Delegate Rep: Marc Braunstein MD, PhD
Website: nyulangone.org/locations/perlmutter-cancer-center/about-perlmutter-cancer-center

Salinas Valley Memorial Hospital
Salina, Calif.
Delegate Rep: Thelma Baker MSN
Website: svmh.com/services/cancer-care

Sentara Martha Jefferson Cancer Care Center
Charlottesville, Va.
Delegate Rep: Crystal Chu
Website: sentara.com/hospitalslocations/locations/martha-jefferson-hospital/medical-services/cancer.aspx

UNC Health Blue Ridge Cancer Center
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Delegate Rep: Taylor Parsons
Website: unchealthblueridge.org/locations/profile/cancer-center

University Hospital, Cancer Center
Washington, DC
Delegate Rep: Carla Williams, PhD
Website: huhealthcare.com/healthcare/hospital/departments/medicine/divisions/hematology-oncology

USMD Optum Care Oncology & Infusion
Irving, Tex.
Delegate Rep: Yalane Jackson
Website: usmd.com/services/services-specialty-care/cancer-care-infusion.html

ACCC and ASCO Release Tools to Help Cancer Programs Diversify Clinical Trials

On July 25 the Association of Community Cancer Centers (ACCC) and the American Society of Clinical Oncology (ASCO) jointly released resources to help research sites increase the racial and ethnic equity, diversity, and inclusion in cancer clinical trials. The Just ASK™ Training Program and Site Self-Assessment are available free of charge and represent a full and complementary set of resources that can help research sites address barriers to participation in cancer clinical trials among racial and ethnic populations that have been historically underrepresented.

- The ASCO-ACCC Equity, Diversity, and Inclusion Research Site Self-Assessment helps research sites identify systemic areas that are known to affect the diversity of clinical trials and provides site-specific recommendations to modify rules and procedures. Access this tool online at: redcap.asco.org/surveys/?s=MNXW38WFA3.
- The Just ASK™ Training Program identifies opportunities for change at the individual level and provides real-world examples to enhance understanding of participants. Access this training program online at: accc-cancer.org/just-ask-course.
- The Just ASK™ Training Facilitation Guide provides guidance to continue the conversation around implicit biases after the initial training. Download it today at: accc-cancer.org/docs/projects/asco-accc/accc-asco-training-just-ask.pdf.

ICYMI: Webinar on CY 2023 HOPPS and MPFS Proposed Rules

On August 11 Teri Bedard, BA, RT(R)(T), CPC, executive director, Client & Corporate Resources, Revenue Cycle Coding Strategies, Inc., and Matt Devino, MPH, director, Cancer Care Delivery and Health Policy, Association of Community Cancer Centers, outlined key proposals in the CY 2023 Medicare Physician Fee Schedule (MPFS) and Hospital Outpatient Prospective Payment System (HOPPS) proposed rules and how these proposed changes to Medicare payment will impact oncology practices, freestanding cancer centers, and hospital-based cancer programs in 2023. accc-cancer.org/2023-OPPS-MPFS.

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Improving Patient Communication Using the Ask Me 3® Tool

Ask Me3® encourages patients to ask 3 simple questions each time they talk to their care team. ACCC has created a video to demonstrate how the cancer care team can most effectively use this tool with patients.

Visit accc-cancer.org/ask-me-3-tool to view this video

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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 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 additional strategies to improve patient-provider communication, please visit accc-cancer.org/health-literacy.

Funding and support provided by Lilly Oncology.

Fertility Preservation for Women with Cancer

BY JAMES GRIFO, MD, PHD

As the program director at the New York University (NYU) Langone Fertility Center and chief executive physician at Inception Fertility, my passion lies in reproductive endocrinology and infertility. I pursued a doctor of medicine and doctor of philosophy degree in obstetrics and gynecology because this best combined my desire to help others with my interests while having an impact on science. These fields focus heavily on translational medicine, so I am constantly researching and improving treatments.

I am passionate about helping patients have the families they desire and continuing to innovate treatments and science that will lead patients to optimal outcomes. I have pioneered techniques like the preimplantation genetic diagnosis and preimplantation genetic screening, which examine specific genes and chromosomal numbers in early embryo development. These procedures can be used to determine whether an embryo has genetic abnormalities that can put a pregnancy at risk and increase the odds of miscarriage or of a child being born with health problems. Both techniques require the removal of cells from the embryo, also known as embryo biopsy, and are considered safe procedures. In 1992, I performed the first embryo biopsy that led to a live birth in the United States.

Egg Freezing and *in vitro* Fertilization

Currently, my focus is on assisted reproduction—helping people with fertility issues through the use of egg freezing technology and *in vitro* fertilization. I believe that people, and women especially, need more fertility options because they should not be confined to the rules of "mother nature" that have not evolved along with societal norms, such as having babies at a younger age rather than when women feel ready for them, whether it be due to relationship or financial factors. More women today understand how their age and other factors (e.g., personal beliefs, life goals, etc.) impact their reproductive health. They want to take greater control over their biological clock. My team and I at NYU Langone continue to research fertility preservation and develop, as well as improve, techniques that will help individuals and/or couples have a baby when they are ready.

Specialists in our program at NYU Langone Fertility Center were early adopters of egg freezing technology and have pioneered its development since. Egg freezing, also known as human oocyte cryopreservation, is a procedure that preserves a woman's eggs so that she may use them in the future. It allows women to postpone pregnancy to a time that makes the most sense for them, including for the purposes of starting a family after cancer treatment. Egg freezing also increases the chances of healthy pregnancy for women who may decide—or need—to delay childbirth because the eggs will keep their youth once frozen. For example, a woman who freezes her eggs at age 33 and decides to use those eggs at age 40 will likely have the same chances for a healthy pregnancy that she had at 33 years old.

The first baby to be born using egg freezing at NYU Langone was in July 2005. Since then, we have seen an increase in the use of our egg freezing services.

Fertility Preservation in Oncology

For someone who has yet to experience parenthood or, perhaps, has not yet finished building their family, infertility can be another devastating side effect of a cancer diagnosis. Fertility preservation has proven to be an effective measure in ensuring that these individuals have fertility options should they decide to pursue pregnancy after completing their anti-cancer treatment.[1] My team and I recently published a first-of-its-kind, 15-year study[2] showing that egg freezing is a viable option for anyone looking to preserve their fertility. For patients with cancer, especially for the adolescent and young adult patient population, news of their fertility preservation options can be comforting and give them hope that they can have a baby after cancer.

Unfortunately, cancer treatments negatively impact patients' fertility health, and fertility is just one more area that can be emotionally overwhelming for patients on their cancer journey. Because the female fertility preservation process can take a few weeks, it is important for women to consider their options as soon as they receive a cancer diagnosis. Generally speaking, female fertility declines with age and this impacts not only egg quantity but also egg quality. It

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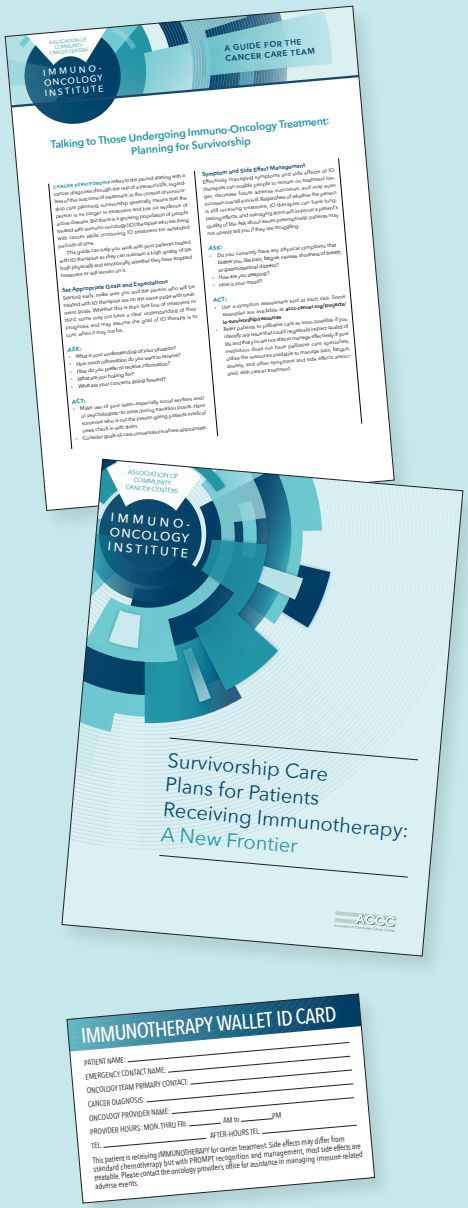

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Access these resources and more at accc-cancer.org/immunotherapy

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

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

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Association of Community Cancer Centers

(Continued from page 70)
is recommended that women undergo egg freezing when in their late 20s to early 30s, which will give them the most optimal outcomes should they decide to pursue pregnancy after age 35. But recent findings show that women who freeze their eggs at a later age can also be successful. A groundbreaking new study,[3] led by me and my team, found that 70 percent of women who froze their eggs when they were younger than 38 years old and had at least 20 eggs thawed at a later date had a baby. Based on clinical experience, this study also reports that 211 babies were delivered from egg freezing and found that a considerable number of the women in the study had more than one child after egg preservation.

Therefore, presenting fertility preservation options to patients with cancer early in their care is a vital component to addressing their psychosocial health, especially considering that fertility concerns may not present until they are in survivorship.

It is necessary for an oncologist or a member of the multidisciplinary team to act swiftly upon a new diagnosis to immediately present to patients their fertility preservation options, so patients have time to consider their options and future plans. By having an open conversation, patients can be empowered to take the appropriate steps to preserve their fertility without compromising the urgency of their anti-cancer treatment.

Once patients complete their treatment and want to begin fertility treatment after having their eggs frozen, they should begin conversations with their oncologist and fertility provider to determine an appropriate timeframe to being the process.

My team and I have had great success in performing fertility preservation. We conducted a study to further explore the success of egg freezing as a fertility preservation option for women and found a high rate of success, where more than 95 percent of the frozen eggs survived the thawing process and 57 percent of patients in the study went on to deliver babies.[4]

Though egg freezing is a viable option for women of many ages, it is imperative for those with cancer to freeze their eggs prior to starting chemotherapy. By doing so, their eggs will not be impacted by damage from their anti-cancer treatment, nor will they age due to the loss of time between the treatment and when it is determined safe to begin the pregnancy process. Indeed, the Prelude Network has helped many survivors of cancer have babies using frozen eggs.

Keys to Success

As with other clinical supportive care services, fertility preservation is not a free service. Unfortunately, egg freezing is rarely covered by insurance, but patients should always contact their insurance providers to see whether they have fertility preservation coverage. For those who pay out of pocket, there are more options to help them access treatment. I recommend speaking with a fertility clinic's financial counselor about their payment options.

And one of the most important things a cancer program or practice can do to help their patients is educate staff about the various fertility preservation options for men and women, so they can arm patients with the different options available to them immediately. This information will help patients make an informed decision sooner with the guidance of a medical professional, which will, in turn, allow patients to quickly preserve their fertility without compromising the start of their cancer treatment.

For those who do not know where to start, I can help. NYU Langone Fertility is part of Inception Fertility's clinical network—the largest provider of fertility services in North America. Oncology professionals can direct their patients to any one of our centers, where our reproductive endocrinologists can share more about patients' fertility preservation options and answer any questions they may have about their fertility. OI

James Grifo, MD, PhD, is the program director at the New York University (NYU) Langone Fertility Center and chief executive physician at Inception Fertility in New York, New York.

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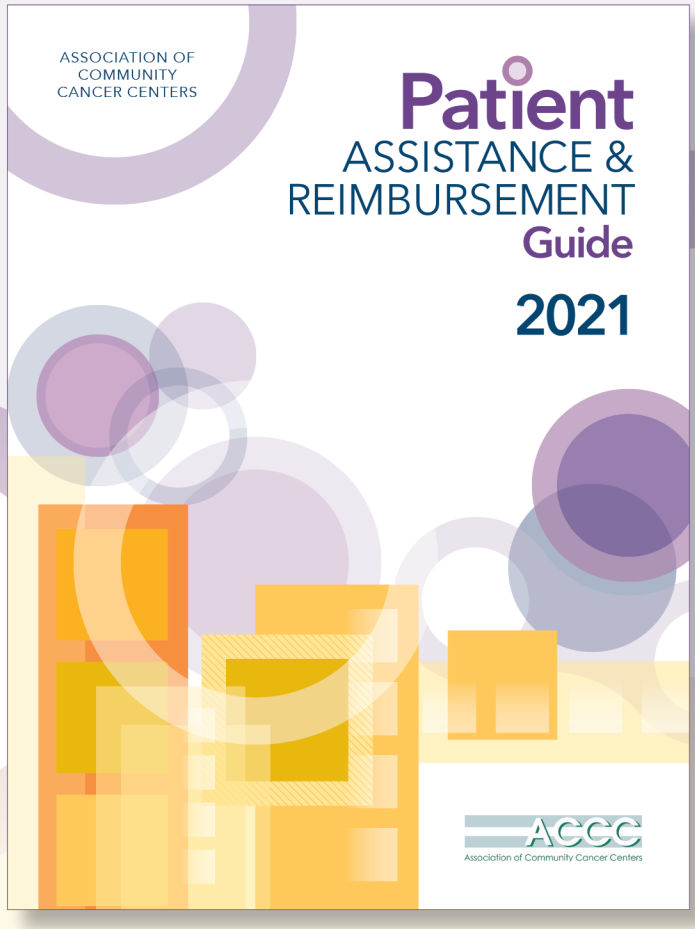
Help patients find the financial assistance they need.

The *ACCC Patient Assistance & Reimbursement Guide* provides the latest patient assistance information, including an updated financial navigation flowchart to help you streamline your daily processes.

Download the most up-to-date version at accc-cancer.org/PatientAssistanceGuide or scan this QR code:



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