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May | June 2020

Young Adults with Cancer Tap into Long-Distance Support



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Association of Community Cancer Centers

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The Official Journal of the
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FROM THE EDITOR

How to Combat a Virus

BY JENNIE CREWS, MD, MMM, FACP



As you know, Seattle has been in the thick of the COVID-19 outbreak since late February, and we stood up our Incident Command System then. The situation here got very difficult, very quickly. Some of the many challenges my hospital and health-care system faced included limited personal protective equipment, intensive care units rapidly reaching capacity, and postponing or delaying outpatient visits. We also recognized the value of early palliative care involvement. At the University of Washington, all patients over age 65 with co-morbidities and confirmed or suspected COVID-19 received a palliative care consult to discuss end-of-life wishes.

We also had medical oncologists and staff test positive, and we experienced significant workforce issues.

Understanding that what we were facing in Seattle would soon impact practices, hospitals, and healthcare systems across the nation, I immediately shared some practical advice in a personal email sent from ACCC Executive Director Christian Downs. It bears repeating:

- Take social distancing seriously.
- Formulate your policies and procedures now on testing algorithms.
- Establish testing locations, such as drive-through screenings.
- Screen all patients at the door so you can isolate symptomatic patients and evaluate for testing.
- Limit visitors and do not allow symptomatic visitors to enter your facility.
- Consider telehealth options.
- Have ready patient education materials.
- Inventory personal protective equipment and test kits and ensure that you have a good supply chain.
- Define “out of work” and “return to work” for those who are identified as a person under investigation or anyone who has tested positive.

- Define essential and non-essential personnel at your cancer program so you can determine who can feasibly work from home.
- Create a labor pool from non-essential personnel who may be called in to back up staff in areas that do not require practice licensure.
- Establish human resource policies on how you will pay furloughed employees.
- Look at increasing your capacity by moving routine patients out and develop the criteria you will use to decide which patients can be deferred.
- Cancel business travel and consider vacation freezes.
- Examine childcare options as schools and daycares will close. Consider setting up a site like Craigslist where staff can identify needs and others can offer help.

With the understanding that instances like the COVID-19 outbreak may in fact be our “new normal,” my team looked to disseminate our experience and lessons learned to the benefit of the wider medical community, including in an online article in the *Journal of the National Comprehensive Cancer Network*.

I'd like to end by sharing some bright spots from this experience, including huge medical community support and rapid deployment of innovative care delivery, such as telemedicine. Humans are resilient, and we rise generously to the occasion in times like these. In the sage words of Fred Rogers, “All of us, at some time or other, need help. Whether we're giving or receiving help, each one of us has something valuable to bring to this world. That's one of the things that connects us as neighbors—in our own way, each one of us is a giver and a receiver.”¹ We would all do well to embrace that attitude. 

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1. James G. 45 Quotes from Mr. Rogers That We All Need Today. Available online at: inc.com/geoffrey-james/45-quotes-from-mr-rogers-that-we-all-need-today.html. Last accessed March 18, 2020.

ACCC—Get to Know Us, We Love to Help!

BY RANDALL A. OYER, MD



It is a pleasure and privilege to serve as your 2020-2021 ACCC President. I have been a member of ACCC since 2006. My organization, Lancaster General Health, now part of the University of Pennsylvania Health

System, has been an ACCC member for a quarter of a century. When I joined my organization in 2006, I was charged with developing a cancer program and building a cancer center. Looking for resources and guidance from the broader oncology community, I was quickly attracted to ACCC's mission of education and advocacy for the multidisciplinary team because cancer care requires a high-functioning team. I needed to know how to construct new programs, and I just as quickly learned that ACCC is the "how-to" organization.

My cancer center recognized the need to develop financial advocacy, social work, and nutrition programs, and all of the programs we built were informed by information gleaned from other ACCC members and ACCC itself. My team and I attended (and we still do) both the ACCC Annual Meetings and the ACCC National Oncology Conferences, where we learned from other cancer programs and networked with social workers, financial counselors, dietitians, administrators, and other knowledgeable professionals who generously shared their own experiences, challenges, and successes. I believe that what we built in Lancaster, Pennsylvania, has the feel of our community, meets and exceeds the needs of our patients and families, and sprang into action fully functional and effective, in part because of what we learned from ACCC.

My cancer program team has wanted to develop a geriatric oncology program. We read the literature and understood the need and benefit of screening geriatric patients for co-morbidities, poly-pharmacy, frailty, and caregiver needs. We are, of course, not alone, and ACCC recognized this need and put together a task force of geriatric oncology experts to develop a roadmap to grow or build a geriatric oncology program. I am excited that my team is using this ACCC resource as of this writing.

Next on my agenda is to develop a surgical oncology program that better understands

the needs of our patients, our surgeons, and our community. And once again, ACCC is leading the way with a fine surgical oncology pre-conference that brought together experienced surgical oncologists and program directors who shared their insights, tips, and cautions at the recent ACCC 46th Annual Meeting and Cancer Center Business Summit.

Now ACCC is hearing from our members about gaps in community research. In our 2019 "Trending Now in Cancer Care" survey, one in four programs reported that they partnered with another organization to develop or enhance their clinical research programs. Most community programs have fewer than 10 percent of their patients on clinical trials. We have a serious imbalance in our clinical trials work; our patients are in the community, yet the trials are at academic medical centers. I believe that ACCC is uniquely situated to close this gap, which is why I chose the following for my 2020-2021 President's Theme: *Community Oncology Can Close the Gap in Cancer Research: Here's How.*

Over the next 12+ months, ACCC will work to develop an infrastructure to assist cancer centers amplify, augment, and/or develop a clinical research program. We will develop a glossary of clinical research terms for patients and physicians. We will prepare a guide describing how to open trials. We will create a roadmap for where and how to find trials including National Cancer Institute/Cancer Therapy Evaluation Program, NCI Community Oncology Research Program, industry, and investigator-led trials. We will also generate mentorship opportunities, pairing together programs that are successfully engaged in research and programs that would like to do research. Our members have shared that they also want resources on:

- How to improve care and access for traditionally underserved people.
- Sensitivity awareness and understanding of the needs in geriatric oncology.
- Precision medicine and how to employ molecular diagnostics to bring the latest targeted treatments to patients.

In closing, I would like to share something that I heard at my first ACCC meeting. After registering, I went to the welcome reception. I knew no one and was greeted by then-ACCC President Dick Reiling, a surgeon, who said to me, "Welcome. ACCC needs you and you need us." And you know what? Dr. Reiling is right. So, I'm going to say the same thing to all of you. Please join us in our work. 

Coming in Your 2020 ONCOLOGY ISSUES

- ▶ Developing a Model of Risk Modification for Breast Cancer Using Integrative Oncology
- ▶ Helping Patients Navigate the Clinical, Psychosocial, and Financial Aspects of Cancer Care
- ▶ Electronic Multidisciplinary Conference (eMDC): Case Planning in the Virtual Space
- ▶ Developing and Implementing a Radiation Oncology App to Improve the Patient Experience
- ▶ Implementing Genetic Cancer Screening and Testing in a Medically Underserved Community
- ▶ Food Security: A Key Component in One Practice's Financial Advocacy Program
- ▶ Researching the Use of Virtual Reality (VR) in the Oncology Infusion Clinic
- ▶ Optimizing Provider Access in the Rural Healthcare Setting by Utilizing a Physician-Advanced Practice Provider Model
- ▶ Built to Care: Cancer Centers for the Future
- ▶ The Role of Nurse Practitioners in Clinical Research
- ▶ Cybersecurity in Oncology Practices
- ▶ Management of Hospital Admissions for Checkpoint Inhibitor IrAEs

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 **ACCC COVID-19 Resource Center
& Listserv**

The latest news from ACCC leadership and information and insight from other leading cancer care organizations. Resources include links to peer-reviewed articles like, “Managing Cancer Care During the COVID-19 Pandemic: Agility and Collaboration Toward a Common Goal.” Share these resources with your staff. Then join the conversation. How is your program or practice being impacted by supply shortages, patient scheduling, staffing issues, and more? Post your experiences and advice on the ACCCEXchange listserv at, mynetwork.acc-cancer.org. Members are already posting information, as well as questions such as, “COVID 19: What Is YOUR Practice Doing?” and “Community Spread: PPE for Patients in Infusion.” Keep up to date at acc-cancer.org/COVID-19.

 **ACCC Comprehensive Cancer Care
Services Matrix**

In 2019 ACCC launched a national Comprehensive Cancer Care Services Survey, outcomes of which were used to develop this tiered matrix of recommendations that cancer practices and programs of varying sizes and resource levels can use to benchmark and advocate for service line growth. Provision of these key services can elevate patient care and the patient experience; reduce healthcare costs; improve care coordination; and help differentiate your cancer program in your marketplace. Download the matrix today at acc-cancer.org/surveymatrix. Then share it with your team and submit feedback on these recommendations to matrix@acc-cancer.org.

 **Waste Not, Want Not**

Medicare and private health insurers combined waste nearly \$3 billion worth of cancer drugs each year. So how can ACCC members help? The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute began addressing the issue of wasted oral cancer therapy drugs in January 2020, when it launched a program enabling cancer patients to donate prescribed oral oncolytics they no longer need for use by other patients who cannot afford their prescribed medications. Learn more at acc-cancer.org/blog-waste-not-want-not.

 **What's Trending in Cancer Care?**

On this episode of CANCER BUZZ, Randall A. Oyer, MD, ACCC President and Medical Director, Oncology Program, Penn Medicine Lancaster General Health, and Ashley Riley, MPH, Consultant, Advisory Board's Oncology Roundtable, discuss the results of the 2019 Trending Now in Cancer Care Survey. Listen to the full episode at acc-cancer.org/podcast.

fast

Five Key Areas to Engage Your Physicians



1. Program Building with APPs: Working together, physicians and APPs can define care team models, develop inpatient and outpatient staff models, establish workload, and define clinical roles and appropriate acuity limits. They can also identify specific APP position opportunities, create recruitment plans, and participate in recruitment efforts.

2. Compensation and Productivity Improvements: Responsibilities include identifying individuals or groups whose productivity is not consistent with compensation, interviewing them to identify impediments to aligning compensation with productivity or other priorities, proposing solutions to those barriers, and reviewing how well current incentive compensation aligns with value-based payment initiatives and recommending improvements.

3. Quality and Utilization Initiatives: Responsibilities include identifying where new clinical protocols can address payer opportunities, such as reducing re-admissions, developing those protocols, operationalizing and reinforcing the protocols at the practice level, and monitoring physician performance against protocols and standards.

4. Front-End Revenue Cycle Solutions: Improving the completeness and quality of information that goes into the EHR—documenting visits and procedures, coding, and charge capture—can help maximize revenues. The work group assigned to identify these front-end opportunities should include administrators, clinicians, and revenue cycle staff. Develop metrics linked to incentive compensation (e.g., closed visits and up-to-date work queues).

5. Referral Loss Initiatives: Responsibilities include collecting data on referral patterns, holding discussions about opportunities or impediments to referrals, making process changes or improvements, and identifying recruiting.

Source: Veralon. Physician Engagement in Employed Physician Enterprises: Going Deeper. veralon.com.

facts



Greater mindfulness is associated with lower pain, fatigue, and psychological distress in women with metastatic breast cancer, a recent study found.

Source. Zimmaro LA, et al. Greater mindfulness associated with lower pain, fatigue, and psychological distress in women with metastatic breast cancer. *Psychooncol.* 2019 Sep 11. doi: 10.1002/pon.5223.



Health Insurance Eating up a Larger Share of Our Incomes

Both health insurance costs and deductibles are growing faster than median income. For middle-income people with employer insurance, the combined cost of premium contributions and deductibles amounted to **11.5%** of income in 2018, up from **7.8%** in 2008. In **42** states, premiums and deductibles were **10% or more** of the median income, compared to only 7 states in 2008.

Source. The Commonwealth Fund. Trends in Employer Health Care Coverage, 2008–2018: Higher Costs for Workers and Their Families. [commonwealthfund.org/publications/2019/nov/trends-employer-health-care-coverage-2008-2018](https://www.commonwealthfund.org/publications/2019/nov/trends-employer-health-care-coverage-2008-2018).

R-E-S-P-E-C-T

A recent study found that non-white, low-income, and uninsured patients were less likely to report being treated with respect and more likely to view healthcare professionals' knowledge of culture as important, which highlights deficiencies in providing access to culturally appropriate care for these populations. Study authors conclude: medical schools should consider improving the pipeline of diverse healthcare professionals and increasing efforts to eliminate structural racism that persists in the healthcare delivery system

Source. Blewett LA, et al. Patient perspectives on the cultural competence of U.S. health care professionals. *JAMA Netw Open.* 2019;2(11):e1916105. doi:10.1001.

Nurses Most Trusted Profession for 18th Consecutive Year



Americans say they trust nurses more than any other profession, according to an annual Gallup survey released this year. Nurses are viewed as having “very high” or “high” ethical and honesty standards by 85% of the public—19 points higher than any other profession and significantly higher than professionals such as business executives, who are trusted by only 20% of Americans.

Source. Annual Gallup Poll. news.gallup.com/poll/274673/nurses-continue-rate-highest-honesty-ethics.aspx.



ISSUES

What Can Be Done?

BY CHRISTIAN G. DOWNS, JD, MHA



Over the last several months one healthcare issue has been the focus of attention, globally, nationally, locally, and personally: COVID-19.

Though it is too soon to comprehend all of the lessons learned from the pain, suffering, deaths, and devastation the novel coronavirus 2019 has brought, we are reminded that diseases do not discriminate: a virus has no morals or ethics. COVID-19 is communicable and highly contagious. Cancer is not. Despite this significant difference, our weapons against COVID-19 are already familiar to those in the cancer community: research, education, prevention, screening, early diagnosis, and treatment. We depend on our clinician scientists, multidisciplinary teams, and frontline healthcare professionals to educate us, diagnosis us, treat us, and care for us. In the midst of the COVID-19 emergency, each of us had to adjust to a “new normal,” follow healthcare mandates, and accept uncertainty.

COVID-19 has given us a harsh, real-time understanding of why population health is a critical issue—in our communities, cities, states, nation, and the world. If the importance of our healthcare infrastructure was ever in question, COVID-19 has made the answer clear. Modernizing our healthcare delivery system is essential. Over recent months our hospitals, clinics, physician practices, and healthcare workforce have been on the frontlines, caring not only for COVID-19 patients but for all those with acute and chronic illnesses. Cancer programs and practices in communities large and small have responded by sharing information and

effective practices, leveraging telemedicine and telehealth, creating new workflows and policies, and implementing new procedures to keep cancer patients as safe as possible and to minimize treatment disruptions.

Every segment of the oncology ecosystem has had to quickly adapt and innovate to minimize the impact of COVID-19 on patients with cancer.

Professional societies have opened access to content in clinical journals and on their websites. For links to the latest information from the American Society of Clinical Oncology, American Society of Hematology, American Pharmacists Association, American Society for Radiation Oncology, National Comprehensive Cancer Network, Oncology Nursing Society, Society for the Immunotherapy of Cancer, and others, visit acc-cancer.org/COVID-19.

Federal agencies have worked tirelessly to provide needed updates and information on changes to policy, regulations, and reporting requirements in response to the COVID-19 public health emergency. In March, the Centers for Medicare & Medicaid Services issued:

- Updates to coverage and payment related to COVID-19.
- FAQs on catastrophic health plan coverage, essential health benefits coverage, COVID-19 tests, and provider enrollment relief.
- Coverage and benefits related to COVID-19 for Medicaid and CHIP.
- Expanded telehealth coverage for Medicare.
- Medicaid telehealth guidance for the states.

- Relaxed quality reporting requirements.

The Centers for Disease Control and Prevention and the Food and Drug Administration have provided information and tools for clinicians and consumers on prevention, treatment, and progress in curbing the spread of COVID-19; critical updates on management of oncology clinical trials in the midst of the epidemic; updates on the drug supply chain; and more.

ACCC mobilized by creating the ACCC Coronavirus Response webpage (acc-cancer.org/coronavirus), updated continually, providing quick access to information from these organizations, as well as resources from patient advocacy organizations. ACCC members continue to offer support, post peer-to-peer questions, and share strategies on the ACCCExchange online forum.

In the words of Senator Debbie Stabenow (D-MI) as she addressed the ACCC 46th Annual Meeting & Cancer Center Business Summit, “For every one of us, healthcare is not political. It’s personal.” Senator Stabenow urged oncology professionals to stay engaged in policy and advocacy: “When you speak up, people listen. You can and must remain engaged and help us move forward in a positive way. I know this can be done.” Going forward, the oncology community must focus on what can be done to advance and protect our healthcare delivery infrastructure. 

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



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compliance

Understanding Supervision Changes to Therapeutic Services

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

Since April of 2000 the Centers for Medicare & Medicaid Services (CMS) has required direct supervision of therapeutic services in the hospital outpatient setting.

Setting the Stage

In calendar years 2009, 2010, and 2011, CMS continued to clarify what direct supervision means and the expectations for meeting the requirements. During that time critical access hospitals (CAHs) and many rural hospitals pushed back, citing difficulty in being able to staff or hire appropriate physicians for all therapeutic services to meet the requirement. Many stakeholders specifically called out specialty services, such as radiation oncology, as difficult to find appropriately trained physicians with expertise for more rural locations.

Based on this feedback, over the years CMS has enforced and then not enforced the need for direct supervision of all therapeutic services in CAHs and, most recently, rural hospitals with 100 or fewer beds. The most recent round of non-enforcement for CAHs and rural hospitals with 100 or fewer beds expired Dec. 31, 2019. Prior to that date, CMS reviewed the requirement for direct supervision across the board to all hospitals—regardless of size or location.

As a refresher, **general supervision** is defined as “procedure is furnished under the physician’s overall direction and control, but that the physician’s presence is not required during the performance of the procedure.”

Direct supervision is defined as “the

physician or nonphysician practitioner must be present on the same campus where the services are being furnished.”¹ Additionally, for direct supervision, the physician must be able to respond without interval of time and not be providing another service for which he or she cannot step away from.

Proposing and Finalizing a Change

During this review, CMS expressed concern that there were two tiers to supervision for the same exact services: general supervision applied for CAHs and rural hospitals with 100 or fewer beds and direct supervision for all other hospitals. Additionally, the agency indicated that it was not aware of any data or information that would lead them to believe that the application of only general supervision in the designated areas has affected the services or care of patients. To alleviate these differences, CMS proposed one supervision standard (general supervision) for all hospital outpatient therapeutic services provided in hospitals, including CAHs, and specifically sought comments on whether services, such as radiation therapy and chemotherapy administration, should be excluded.

After review of comments submitted to the proposed ruling, CMS finalized for calendar year 2020 and subsequent years to change the generally acceptable minimum required level of supervision for all hospital outpatient therapeutic services to general supervision, including radiation therapy and chemotherapy administration. This means

that the same minimum level of supervision is required for all hospitals and CAHs.

The agency did stress, however, that changing to general supervision will not prevent any of the hospitals from providing services under direct supervision when the physician administering that service determines that it is appropriate to do so. Many therapeutic services provided in the outpatient setting are highly complex and need direct supervision of the qualified physician. However, hospitals and physicians now have the ability to set the supervision level they believe is appropriate, resulting in direct or personal supervision for some outpatient therapeutic services.

Other Considerations

Hospitals and physicians must consider hospital policies, CAH Conditions of Participation, and state scope of work regulations, as well as state and federal laws, which may and do define supervision requirements for certain services and supersede the changes in supervision level as indicated by CMS. For example, brachytherapy and Gamma Knife services are still bound by Nuclear Regulatory Commission and Agreement State Program regulations for the presence of the physician and authorized user.

Additionally, for radiation oncology these changes only pertain to the supervision of the technical services. Physician work and personal presence for the work are not the same as supervision. Many radiation oncology codes have both technical and

professional components. To bill and receive the professional component, physicians must personally provide their services at the time and location where the services are rendered and billed. CMS does not list radiation oncology services as available through telemedicine. There is no indication at this time whether commercial payers have or will adopt this change or expectation in supervision of outpatient therapeutic services provided to their beneficiaries.

Typically, any changes to supervision are addressed by the Hospital Outpatient Payment Panel, and CMS indicated that it will continue to seek the panel's advice for appropriate supervision levels of hospital outpatient services. CMS also indicated that it will retain the ability to adjust the supervision levels of individual hospital outpatient services to something more intensive than general supervision through the usual notification of changes and comment periods of the rules.

The Medicare Payment Advisory Committee strongly encouraged CMS to monitor outpatient therapeutic services that Medicare beneficiaries receive to ensure that the quality of care is not compromised and error rates do not increase due to lack of physician presence and supervision of services.

CMS also noted that failure of a physician to provide the adequate supervision in accordance with hospital and CAH Conditions of Participation would not cause payment to be denied for that service, but consistent violations of the supervision requirements would result in corrective action plans and finally in termination of the hospital or CAH from Medicare participation for ongoing failure to comply.

It is important to note that the change to general supervision applies only to the hospital setting; direct supervision is still the regulation in the office and/or freestanding

facility setting. The expectation of direct supervision in the office/freestanding facility is outlined in the *Medicare Benefit Policy Manual*, Chapter 15, which states, "Direct supervision in the office setting does not mean that the physician must be present in the same room with his or her aide. However, the physician must be present in the office suite and immediately available to provide assistance and direction throughout the time the aide is performing services."²

Some specialty organizations have shown support to these CMS changes, whereas others have expressed concern and opposition. In addition, some specialty societies are working together to address the changes in the hope that CMS will make considerations for services like radiation therapy and chemotherapy administration and reverse or change the policy. For example, the American Society for Therapeutic Radiology and Oncology (ASTRO) released a letter regarding its stance on the changes. Within the letter ASTRO indicated that it was opposed to the new policy affecting therapeutic services. The full statement can be found at astro.org/ASTRO/media/ASTRO/Daily%20Practice/PDFs/ASTROGuidanceCMSGeneralSupervisionPolicy.pdf.³ Additionally, the American Medical Association *2020 Current Procedural Terminology Manual* still indicates that chemotherapy and therapeutic services typically require administration under direct supervision. The administration includes "patient assessment, provision of consent, safety oversight, and intra-service supervision of staff."⁴

Moving forward, radiation and medical oncology departments should review their supervision policies. CMS has left the decision ultimately up to hospitals and physicians to determine the most appropriate supervision level for services in the hospital setting based on practice patterns. Keep in mind, however, that these changes

made by CMS do not apply to commercial payers that have not yet adopted a similar policy. For those practicing in the office and/or freestanding setting, direct supervision is still required for therapeutic services—this has not changed. Additionally, it is important to watch for any updates. With the push by some specialty societies to make changes to the minimum supervision level for radiation therapy and chemotherapy administration, it is possible that there could be new or updated guidance during 2020 or beginning for 2021. 

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

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tools



Approved Drugs

- On March 30, the U.S. Food and Drug Administration (FDA) approved **Imfinzi® (durvalumab)** (AstraZeneca, astrazeneca.com) as a first-line treatment for adult patients with extensive-stage small cell lung cancer in combination with standard-of-care chemotherapies, etoposide plus either carboplatin or cisplatin (platinum-etoposide).
- On March 11, the FDA approved **Opdivo® (nivolumab)** and **Yervoy® (ipilimumab)** (Bristol-Myers Squibb, bms.com) to treat hepatocellular carcinoma in patients who have been previously treated with sorafenib.
- On March 2, the FDA approved **Sarclisa® (isatuximab-irfc)** (Sanofi Genzyme, sanofigenzyme.com) in combination with pomalidomide and dexamethasone for adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.
- On March 24, Samsung Bioepis Co., Ltd. (samsungbioepis.com) announced that the FDA has approved a 420-mg multi-dose vial of **Ontruzant® (trastuzumab-dttb)**, a biosimilar referencing Herceptin® (trastuzumab).

Drugs in the News

- Takeda (takeda.com) announced that the FDA granted priority review for a supplemental new drug application (sNDA) to expand the use of **Alunbrig® (brigatinib)** as a first-line treatment for patients with anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer as detected by an FDA-approved test.
- Blueprint Medicines (blueprintmedicines.com) announced that the FDA extended the date for its new drug application (NDA) seeking accelerated approval of **Ayvakit™ (avapritinib)** for the treatment of adults with fourth-line gastrointestinal stromal tumor.
- Agenus Inc. (agenusbio.com) announced that the FDA has granted fast track designation for **balstilimab (PD-1)** in combination with **zalifrelimab (CTLA-4)** for the treatment of patients with relapsed or refractory metastatic cervical cancer.
- The Janssen Pharmaceutical Companies of Johnson & Johnson (janssen.com) announced the submission of a supplemental biologics license application (sBLA) to the FDA seeking approval of **Darzalex® (daratumumab)** in combination with **Kyprolis® (carfilzomib)** and dexamethasone for relapsed/refractory multiple myeloma.
- The Janssen Pharmaceutical Companies of Johnson & Johnson (janssen.com) announced that the FDA granted breakthrough therapy designation for **JNJ-61186372 (JNJ-6372)** for the treatment of patients with metastatic non-small cell lung cancer with epidermal growth factor receptor Exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy.
- Kite (kitepharma.com) announced that the FDA accepted the biologics license application (BLA) and granted priority review designation for **KTE-X19**, an investigational CAR T-cell therapy for the treatment of adult patients with relapsed or refractory mantle cell lymphoma.
- Bristol-Myers Squibb (bms.com) announced that the FDA has accepted for priority review its BLA for **lisocabtagene maraleucel (liso-cel)**, an autologous anti-CD19 CAR T-cell immunotherapy with a defined composition of purified CD8+ and CD4+ CAR T-cells for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after at least two prior therapies.
- PharmaMar and Jazz Pharmaceuticals (pharmamar.com, jazzpharma.com) announced that the FDA accepted for priority review an NDA seeking accelerated approval for **lurbinectedin** for the treatment of patients with small cell lung cancer who have progressed after prior platinum-containing therapy.
- Biocon Ltd. (biocon.com) and Mylan (mylan.com) announced that the FDA has accepted Mylan's BLA for **MYL-14020**, a proposed biosimilar to Avastin® (bevacizumab), for review under the 351(k) pathway.
- Puma Biotechnology, Inc. (pumabiotechnology.com) announced that the FDA approved an sNDA for **Nerlynx® (neratinib)** in combination with **capecitabine** for the treatment of adult patients with advanced or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.
- Astellas Pharma Inc. and Seattle Genetics, Inc. (astellas.com, seattlegenetics.com) announced that the FDA has granted breakthrough therapy designation for **Padcev™ (enfortumab vedotin-efyv)** in combination with

Merck's anti-PD-1 therapy **Keytruda® (pembrolizumab)** for the treatment of patients with unresectable locally advanced or metastatic urothelial cancer who are unable to receive cisplatin-based chemotherapy in the first-line setting.

- Roche (roche.com) announced that the FDA has accepted a BLA for the fixed-dose combination of **Perjeta® (pertuzumab)** and **Herceptin® (trastuzumab)** with hyaluronidase, administered by subcutaneous injection in combination with intravenous chemotherapy for the treatment of eligible patients with HER2-positive breast cancer.
- Roche (roche.com) announced that the FDA has accepted an sBLA and granted priority review for **Tecentriq® (atezolizumab)** as a first-line monotherapy for people with advanced non-squamous and squamous non-small cell lung cancer without epidermal growth factor receptor or anaplastic lymphoma kinase mutations with high PD-L1 expression, as determined by PD-L1 biomarker testing.
- Kura Oncology, Inc. (kuraoncology.com) announced that the FDA has granted fast

track designation to **tipifarnib** for the treatment of adult patients with relapsed or refractory angioimmunoblastic T-cell lymphoma, follicular T-cell lymphoma, and nodal peripheral T-cell lymphoma with T follicular helper phenotype.

- Seattle Genetics, Inc. (seattlegenetics.com) announced that the FDA has accepted for priority review an NDA for **tucatinib** in combination with **trastuzumab** and **capecitabine** for treatment of patients with locally advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received at least three prior HER2-directed agents separately or in combination, in the neoadjuvant, adjuvant, or metastatic setting.
- Karyopharm Therapeutics (karyopharm.com) announced that the FDA has accepted its sNDA seeking accelerated approval for oral **Xpovio® (selinexor)** tablets for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, who have received at least two prior therapies.

- GlaxoSmithKline (gsk.com) announced that the FDA accepted an sNDA seeking approval of **Zejula® (niraparib)** as a maintenance treatment in the first-line setting for women with advanced ovarian cancer who responded to platinum-based chemotherapy regardless of biomarker status.

Approved Genetic Tests and Assays

- Roche (roche.com) announced that the FDA approved **CINtec® PLUS Cytology** as the first biomarker-based triage test for women whose primary cervical cancer screening results are positive for the human papillomavirus using the cobas® 4800 Human Papillomavirus Test.
- Roche (roche.com) announced that the FDA has granted breakthrough device designation to the **Elecsys® GALAD score**. This algorithmic score combines gender and age with the biomarker results of the Elecsys AFP, AFP-L3, and PIVKA-II and is intended to aid diagnosis of early stage hepatocellular carcinoma. 

spotlight

Peoples Cancer Institute Dalton, Georgia



Peoples Cancer Institute in Dalton, Ga., opened its doors on Jan. 6, 2020. The 46,000 square foot comprehensive facility sits three stories high on the campus of Hamilton Medical Center, the flagship affiliate of Hamilton Health Care System. Hamilton Medical Center is a not-for-profit hospital that serves Dalton and the surrounding communities in northwest Georgia. Accredited by the Commission on Cancer, the institute centralizes patient-centered care and outpatient cancer services in one convenient location.

By Design

Prior to the opening of Peoples Cancer Institute, Hamilton’s cancer care components—diagnostics, clinics, infusion,

and radiation—were located throughout its campus. The goal of integrating all outpatient cancer care services under one roof was the driving force behind the expansion of the oncology program into its newly constructed building. The process was conducted with the needs of the patient, community, and staff in mind. With the opening of the new facility, patients with cancer no longer need to navigate multiple sites in and around the campus to access care.

In early 2015, Hamilton Medical Center’s medical and administrative team came together to analyze the demographics of its catchment area, services provided, and the space limitations it was facing. As the planning process for the new cancer institute began, Hamilton Medical Center’s leadership

and staff engaged its community to provide feedback throughout every step of its design. For example, the initial design did not include a physical connection to the main hospital. After focus groups expressed concerns, Hamilton Medical Center’s leadership worked with the city council to close a public road and facilitate the construction of a walkway physically connecting the new cancer institute to the main hospital, streamlining patient and staff access.

“This connector is a physical representation of the partnership between our community and Hamilton Medical Center,” shares Jane Snipes, executive director, Whitfield Healthcare Foundation, which provides fundraising support to Hamilton Health Care System.

Community feedback is also reflected in the interior design of the new facility. Hamilton Medical Center listened to patients and caregivers, including those who received cancer care elsewhere.

“We heard patients loud and clear,” says Ernie Elemento, vice president, Hamilton Health Care System. “They did not want to sit in a chair for hours receiving chemotherapy while staring at a wall.” Today, patients receiving treatment in one of the 20 semi-private infusion recliners have expansive views of Dalton through floor-to-ceiling windows that provide abundant natural light. Six additional chairs are private, allowing patients privacy if they prefer.

Our Floor Plan

Peoples Cancer Institute is staffed by three medical oncologists, two radiation oncologists, one radiologist, and one nurse



practitioner. In addition, Peeples Cancer Institute employs pharmacists, clinic nurses, infusion nurses, nurse navigators, radiation therapists, mammogram technologists, social workers, researchers, tumor registrars, and many other vital staff members.

Radiation oncology services are located on the first floor. Equipped with a state-of-the-art Varian™ Truebeam™ Linac and 4D computed tomography simulator, the cancer institute offers a variety of radiation therapy treatment modalities, including intensity-modulated radiation therapy, stereotactic radiosurgery, stereotactic body radiation therapy, and 3D and high-dose rate brachytherapy.

The second floor houses the main reception area, a contemporary waiting area including a bistro, the medical oncology clinic space, and a lab draw station. Also located on this floor is Women's Imaging, offering the latest in 3D mammography, stereotactic biopsy, and ultrasound.

The cancer institute's 26-chair ambulatory infusion center and dedicated infusion pharmacy occupy the third floor. The pharmacy is centrally located within the infusion space, facilitating communication and collaboration between pharmacy and nursing staff. This pharmacy exclusively supports the ambulatory infusion suite, where all outpatient infusions are performed. Though the pharmacy does not currently provide oral oncolytics, the cancer institute is working toward opening an accredited specialty pharmacy within its current retail pharmacy space.

With oncology services together on three floors, "all physicians now have space in this new facility to collaborate on patient care," explains Snipes.

The Patient Experience

When guests enter Peeples Cancer Institute, they are welcomed by a friendly greeter who is equipped to answer questions and escort them where needed. Many who visit the institute choose to enjoy a coffee, smoothie, or snack from the in-house bistro located in the spacious lobby specifically designed to provide a calm, relaxing atmosphere.

"First impressions are important, and our intent is to clearly convey a feeling of confidence, tranquility, and healing. Our main lobby has more similarities with a

high-end hotel than it does a cancer center," describes Elemento.

"Every aspect of Peeples Cancer Institute is focused on the needs of our patients and families so that we provide an outstanding patient experience and the best clinical outcomes," says Jeff Myers, president and CEO of Hamilton Health Care System. "Our goal is to foster collaboration, communication, and education among physicians and our medical teams to advance and enhance our care for patients. They are our number one priority."

Patients are referred to the institute from various physician groups throughout the region. Radiation therapy patients are scheduled for simulations, with treatment beginning a week later. Patients prescribed chemotherapy follow the prior authorization process and are scheduled for treatment. Because the institute opened in early 2020, these processes are continuously evolving to meet the specific needs of patients with various disease sites and stages.

With Hamilton Medical Center connected directly to the institute, its general surgeon can biopsy patients with suspicious lumps right away. This allows for staff to move patients quickly through the navigation process so that there is no gap between diagnosis and treatment.

To provide patients access to the latest research and medications, a research coordinator is training to help provide information and access to clinical trials.

A social worker meets with all new patients so that they can have a primary contact and access to her services throughout their treatment journey. The social worker is also available to help patients find transportation and financial assistance.

The institute is seeking to hire a nutritionist to provide nutrition services.

All supportive care services at Peeples Cancer Institute are free to patients.

Looking Ahead

Peeples Cancer Institute will soon offer genetic screening and genetic counseling services. Patients identified as high risk are given immediate access to a certified genetic counselor through tele-genetics. The new facility is completely wired and ready for



telehealth, and the tele-genetics program is the first step in utilizing these new features.

Peeples Cancer Institute is also planning to expand its menu of supportive care programs. A donor's gift is making it possible for the institute to begin planning an immersive arts and healing program that will bring music and art to its patients and caregivers. This artwork will complement existing pieces from local and regional artists, which currently adorn the institute's walls.

A therapy dog visits the infusion center weekly, and the cancer institute is looking to start a pet therapy program that will allow therapy dogs to visit with patients throughout the facility.

Growing its supportive care services allows the institute's staff to support patients "emotionally, mentally, and physically throughout their cancer treatment journey," explains Rita Harris, service line administrator, Peeples Cancer Institute.

Through community engagement, personalized interactions, and patient-focused design, Peeples Cancer Institute provides patients and families the highest quality care close to home. 

Young Adult Patients Tap into Long-Distance Support





Having shown to reduce distress in patients with cancer, support groups are the backbone of supportive oncology care.^{1,2} However, though support groups can be a useful coping mechanism for patients, the effectiveness of such groups tends to be limited by distance and high attrition rates. Not surprising, when arriving at the University of Colorado Cancer Center in 2014, I noticed that attendance at support groups was low, a trend reflected in current literature.³ In fact, many support groups at the cancer center were being canceled due to low turnout. In response, I partnered with my colleague, Benjamin Brewer, PsyD, to address the issue.

Getting Started

Dr. Brewer and I proposed creating an online video support group to enable patients with cancer who would otherwise have difficulty attending such groups to participate virtually. Many patients being treated at the University of Colorado Cancer Center are prevented from physically attending support groups by a variety of obstacles, including living long distances from the center, having transportation issues, being unable to take time away from work or family, and suffering from side effects that prevent them from traveling.

Our first hurdle in creating a virtual support group was to establish a foundation of reliable technology. Without dedicated tech support in our cancer center, we knew that we had to find an easy, user-friendly approach. The hospital's information tech-

Group facilitators are also responsible for monitoring and responding to high-risk statements from individual group members. For example, facilitators engage participants in personal conversations after a group discussion if anyone expresses suicidal or homicidal ideation.

nology group suggested that we use Zoom as our video conferencing platform because it was secure, Health Insurance Portability and Accountability Act compliant, low-cost, and easy to use. Because Dr. Brewer and I were unfamiliar with Zoom, we recruited colleagues to test the software to ensure that we had appropriate devices and bandwidth, to see what Zoom's visual aesthetic looked like, and to become familiar with various software functions. We also tested the invitation function and the ease of accessing meetings.

Securing Remote Access

Because we did not know which devices support group participants would use to access Zoom, or the reliability of participants' internet connections, we could not be certain whether individual participants would be able to reliably access the group. There was also the possibility that participants may not possess the necessary hardware at all—though data show smartphone ownership rising to 68 percent of adults in the United States in 2015 (up from percent 35 percent in 2011), that still left a substantial gap of 32 percent of the population without smartphones.⁴ A grant from the Colorado Cancer Fund enabled us to remedy this problem and purchase tablets—on which we installed Zoom—for each pilot participant to use to access the group.

Young adults with cancer are considered an “orphaned population” in that they experience elevated levels of psychological distress, yet remain largely overlooked by cancer control, prevention, and quality-of-life investigations in the United States.⁶⁻⁹

Our second access concern was the reliability and speed of participants' internet access, given Colorado's geographic diversity. Colorado has few dense metro areas, with 47 of Colorado's 64 counties designated as rural.⁵ Of the 47 rural counties, 23 are further designated as frontier, meaning that they are sparsely populated rural areas isolated from population centers and services, with a population density of six or fewer person per square mile.⁵ Even if participants had online access, unreliable internet service could result in poor connections. Paused or interrupted communications would be particularly bothersome in the context of the emotional exchanges that can take place in support groups. We therefore decided to screen potential participants for the required broadband access by having them complete internet speed tests from their specific locations.

Our next challenge was how to secure the privacy of our participants in a virtual space. In traditional face-to-face support groups, facilitators can control the environment, adjusting the arrangement of the room and positioning chairs so that participants can be assured of the privacy of their communications. Allowing participants to choose their environment introduced a new variable in that other people may be present without being seen, meaning that group members could be overheard. To avoid this possibility, we encouraged group members to use headphones equipped with microphones, which we provided with each tablet.

Doing so would help better preserve confidentiality by avoiding the possibility of overheard conversations and encouraging participants to be strategic in choosing their locations during group sessions. Headphones would also decrease background noise and thus aid in maintaining participants' attention.

A New Dynamic

We anticipated that switching from face-to-face to a virtual video platform would change the dynamic of the group. For example, support group facilitators are used to observing participants' body language and managing distractions that can interrupt the group if not quickly addressed. Our facilitators understood that a video chat group would only allow them to observe participants from the shoulders or neck up and that they might subsequently miss subtle cues. Facilitators would now need to gauge facial expressions in a grid of the participants' faces. (Zoom's video interface enables a video presentation in which nine participants can see one another simultaneously in a 3 × 3 grid.) For that reason, we limited the group to eight participants so that everyone (eight participants and two facilitators sharing a screen) could be seen at the same time (see Figure 1, right).

Group facilitators are also responsible for monitoring and responding to high-risk statements from individual group members. For example, facilitators engage participants in personal conversations after a group discussion if anyone expresses suicidal or homicidal ideation. The facilitator would likely discuss imminent risk and make a follow-up plan for personal support. Additionally, facilitators often ask participants who are disruptive or found to not be a good fit for a group to stay after the group to privately discuss behavioral expectations or more appropriate referrals.

Being unable to physically remain after an online group to have crucial conversations, we needed an alternative plan to help keep participants safe. Our solution was to require participants to provide phone numbers and home addresses so that we were able to follow up after video sessions if we had concerns about personal harm or felt the need to have a private conversation. Having this information also gave us a way to contact local authorities if a participant expressed imminent danger to self or others.

Personal connections can form among participants when they are outside of the support group. For example, it is common for participants to exchange contact information, grab refreshments with other group members, and/or meet up for social events. With Zoom, when the host of the meeting ends a session, it disconnects all participants without giving them the option to stay afterward and converse. Our group members missed these opportunities to make connections with one another, so they asked facilitators to use group time to exchange personal contact information. Many did keep in touch with one another and even met in person after the pilot program ended.

The Pilot Program

Though we considered many specific patient populations for our pilot, one group was particularly attractive. Young adults

Figure 1. Visual Representation of Video Feed Screen



with cancer are considered an “orphaned population” in that they experience elevated levels of psychological distress, yet remain largely overlooked by cancer control, prevention, and quality-of-life investigations in the United States.⁶⁻⁹ The fact that young adults have a higher rate of smartphone and tablet ownership than other demographic groups and that young adults who have been diagnosed with cancer are already familiar with sharing and expressing themselves online suggested to us that this group may markedly profit from virtual health services.^{4,10} For this reason, we targeted individuals ages 18-40 for the pilot program.

The University of Colorado Cancer Center has a large catchment area, frequently drawing patients for care into the Denver metro area from surrounding states. To be legally authorized to provide psychology and social work services, licensing laws require

providers to have professional jurisdiction in the state in which a patient is located when the services are rendered. For that reason, group participants had to be physically present in Colorado during group sessions. Thus, we limited ourselves to recruiting and enrolling only Colorado residents.

The eight participants enrolled in our virtual support group resided in eight different counties in Colorado, allowing us to reach a large, diverse geographic region (see Table 1, page 18). The fact that the participant who had the longest drive time to the cancer center did not live the greatest number of miles away is indicative of the nature of the mountain driving and rural roads that can impact ease of transportation in Colorado. Less predictable but not uncommon are delays due to wildlife crossings, falling rocks, mud slides, avalanches, snowstorms, and other adverse weather events.

We screened potential participants over the phone, asking them questions about their comfort using tablets and having them perform high-speed internet access tests at home. All accepted group members were sent Wi-Fi-enabled tablets equipped with Zoom software. Headphones with built-in microphones were also provided. Participants were sent welcome emails from the group facilitators, with directions on how to join the support group. Additional emails reminded participants of each upcoming session.

The group met virtually for six consecutive weeks, with each session lasting 90 minutes. As participants joined each session, they were assigned a space in the 3 × 3 screen layout so that everyone could see one another (Figure 1, page 17). At the first group meeting, participants were prompted to generate a list of topics they wanted to cover over the course of the six-week pilot program. An oncology social worker and an oncology psychologist facilitated each session, which consisted of a member check-in followed by a discussion of the topics suggested by support group participants.

Lessons Learned

Turnout for the virtual support group was high for each of the six sessions. No participants dropped out of the group, and few missed any session (see Table 2, below). When we asked for feedback, participants told us that they liked the virtual support group and felt comfortable participating in it.¹¹ Our experience was that meeting virtually did not prevent group members from bonding with one another. Further, various participants exchanged contact information and met one another in person.

We found that the virtual aspect of the group increased access for this population.¹¹ Participants shared that their often poor physical health—which could result in immunosuppression, feeling ill, or being hospitalized—and the distance to the cancer center would likely have prevented them from participating in the support group in person.¹¹

There were some inevitable drawbacks to meeting virtually rather than in person. At times, participants were distracted. Family members, pets, and electronics could vie for participants’ attention, and it was evident from their expressions when someone ceased concentrating on the group. Group facilitators also had to adapt to a virtual meeting space. They said that facilitating a virtual group was more difficult than doing so in person, where body language was easier to read through physical positioning, interpersonal spacing, and nonverbal communication.¹² Group facilitators also noted that they could get distracted at times by seeing themselves on the screen, causing a sense of self-consciousness that is not present in a face-to-face group.¹²

On the positive side, facilitators shared that obtaining large meeting rooms and cleaning up afterward were no longer necessary.¹² Facilitators were also happy with the participants’ consistent attendance and the opportunity to provide needed services to vulnerable individuals located in geographically remote areas.¹² Additional detailed results about the group were recently published in the journal *Palliative and Supportive Care*.¹¹

Additional Discussion

Our pilot offers a unique approach to oncology support groups. Though many such groups are open (people can start or stop at any time) and ongoing (they are offered indefinitely), we started with a small, closed, screened group of patients and provided them the tools they would need to participate in a six-week program.

The success of the virtual support group program led us to adapt it to meet the needs of other patient groups. We currently offer multiple virtual support groups using Zoom. Though one group is entirely virtual, others are in-person/virtual hybrids that offer participants the option of attending sessions either remotely or in person. Many participants tell us that they would be unable to participate in their support groups if they did not have the option to do so virtually. For patients who do not have access to the technology that would allow them to participate in support groups virtually, Zoom offers the option to call in via phone. This audio-only option has enabled us to offer support groups to an even larger number of patients.

Table 1. Participant Geographic Information from Pilot Program

County of resident	Arapahoe, Boulder, Douglas, Eagle, El Paso, Jefferson, Larimer, Las Animas
Distance from participant’s home to cancer center	Average: 148 miles Range: 25 miles to 406 miles
Drive time from participant’s home to cancer center (without traffic)	Average: 2 hours and 56 minutes Range: 38 minutes to 6 hours and 18 minutes

Table 2. Virtual Support Group Participation

Number of Weeks (Out of 6)	Number of Participants (Out of 8)
1 week	8 participants present
2 weeks	6 participants present
3 weeks	7 participants present

Much of our relatively slow adoption of virtual support groups comes from our facilitators' hesitation to embrace this new meeting platform. Facilitators cite being unfamiliar with conducting virtual groups, feeling apprehensive of using new technologies, and feeling unable to read nonverbal cues as reasons for their hesitancy to lead virtual support groups.

Though it is inevitable that some subtle communications will be lost in a virtual support group, our pilot has demonstrated that group connections can be made online, and we can effectively bring this service to patients who may otherwise be unable to benefit from it. For cancer programs interested in launching a similar virtual support group, we offer these tips:

- Know your state's jurisdiction and licensing laws. Depending on your profession and the states in which your facilitators are licensed, the laws governing telemedicine can differ widely.
- Health insurance billing is complicated. Laws about insurance coverage for telemedicine are ever-changing and are often regulated at the state level, further complicating national efforts to make available virtual healthcare offerings. One option is to start with a non-billable virtual support group. A free support group can be offered remotely without having to deal with the rules of insurance reimbursement.
- Select a platform that is easy to use for both facilitators and the participants. Facilitators should practice with colleagues until they feel comfortable with the platform before introducing it to patients.
- Anticipate and prepare for what could go wrong and make contingency plans. For example, we wanted the ability to respond to patients who express suicidal or homicidal ideation during a session. To counter this risk, we obtained the home addresses and telephone numbers of all participants. Decide how best to respond to unanticipated risks by having a plan in place to address them remotely.
- Take the plunge. You might not feel fully ready, and you may never feel that way. But if having a larger reach, improving access, and decreasing health disparities outweigh your discomfort, take the steps to adopt virtual support groups in your cancer program. 

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“Prescribing” Exercise and Nutrition in Cancer Care



Effectively “prescribing” exercise and nutrition alongside oncology treatment appears to have uncertainties. Wellness is comprised of an array of activities—exercise, physical activity, nutrition, sleep, meditation, and mindfulness—and has the largest effect across the life spectrum. Therefore, as more evidence is showing, all the activities encompassed under the wellness umbrella can be applied to cancer prevention and the cancer care continuum.

When talking about cancer prevention, people generally think of preventing the disease. However, cancer prevention should not merely focus on pre-cancer. Clinicians and oncology providers should also discuss ways to reduce the risk of disease prior to disease initiation, as well as reducing the risk of progression and recurrence with retention of quality of life (QoL). To assist patients and survivors with improving their QoL, oncology-centric physical activity and nutritional plans are essential to maintaining a healthy lifestyle. Accordingly, exercise and nutrition should be viewed as a necessary “prescription” for patients.

Unfortunately, many cancer care team members do not know that wellness in its entirety can be applied across the cancer care continuum—pre-cancer, pre-treatment, treatment, post-treatment, and during metastatic treatment. It is important for providers to know exactly why patients need physical activity and nutrition, and that evidence-based recommendations can and should be incorporated into a cancer center’s comprehensive wellness program. In this article, we hope to demystify the process of incorporating these plans into oncology practice for multidisciplinary cancer teams.

Currently, about half of the U.S. population is unaware that there is a direct link between obesity and cancer; therefore, education between providers and patients is key to combating this rising public health threat.

Examining the Evidence

Chronic diseases, such as obesity, play a large role in potentially acquiring or worsening cancer related symptoms in patients.¹ Traditionally, obesity has been defined as a body mass index (BMI) greater than 30 kg/m². Today, obesity is further categorized into 3 classes: Class 1 (BMI = 30.0-34.9 kg/m²), Class 2 (BMI = 35.0-39.9 kg/m²), and Class 3 (BMI greater or equal to 40.0 kg/m²). BMI is calculated using a person’s body weight and dividing it by the square root of their height. If not already incorporated into the electronic health record (EHR) in a clinic, BMI can easily be calculated manually (weight in kilograms divided by the square root of height in meters) or using an online BMI calculator.

Over the course of 26 years, overweight and obesity rates have risen dramatically in the United States. Data from the 1988-1994 National Health and Nutritional Examination Survey (NHNES) found 56 percent of adults aged 20 years or older were overweight or obese.² In contrast, 2016 NHNES data reported that overweight and obesity status affects nearly 7 in 10 Americans, with 36.5 percent of Americans classifying as obese.³ In age groups 2-19 years, we see a prevalence rate of 18.5 percent; affecting 13.7 million children and adolescents.⁴ These trends are similar to smoking trends before and after a landmark study showed that smoking was directly linked to lung cancer.⁵ Currently, about half of the U.S. population is unaware that there is a direct link between obesity and cancer; therefore, education between providers and patients is key to combating this rising public health threat.⁶

To prevent and further diminish the effects of cancer, our first recommendation is that patients should participate in a reasonable amount of exercise and physical activity throughout the week.

Obesity risk factors can be subdivided into unhealthy lifestyle and environments, age, family history/genetics, race/ethnicity, and sex.⁷ However, the dramatic increases in overweight and obesity rates among Americans over the last 26 years can most likely be attributed to an increase in portion size and decrease in activity levels. Figure 1, right, illustrates the concept of energy balance. When you eat more calories than you burn, your risk of gaining weight increases. When energy intake begins exceeding energy expenditure, weight gain occurs and continues to rise if not corrected through energy expenditure.⁸ Conversely, burning more calories than you eat increases your likelihood of losing weight. Patients may ask why they have not lost weight while regularly exercising. In turn, it is important to ask about their eating habits to further educate these patients about energy balance. In fact, tracking food intake has been shown to be one of the most effective weight loss strategies.⁹

Obesity is linked to higher risks of cancer. In a 2002 monograph, the International Agency for Research on Cancer (IARC) declared overweight and obesity as causes of several cancers.¹⁰ In 2012 it was estimated that 28,000 new cases of cancer in men (3.5 percent) and 72,000 in women (9.5 percent) were due to overweight or obesity.¹¹ According to the American Cancer Society, excess body weight is thought to be responsible for about 8 percent of all cancers in the United States, as well as about 7 percent of all cancer deaths.¹²

In 2014, it was estimated that annual medical costs in the United States for treating obesity were about \$150 billion.¹³ On average, individual medical costs may be 41.5 percent higher in obese patients than those of normal weight. Obese persons may also see higher absenteeism from work and medical bills—41 percent higher than those without obesity.¹⁴ These costs may be an added burden for patients who already pay for cancer-related treatments and sacrifice work hours to participate in treatment.

Similar to the general public, obesity rates among cancer survivors is increasing. NHNES data showed the prevalence of obesity in cancer survivors increased significantly from 22.4 percent to 31.7 percent from 1997 to 2014.¹⁵ Although these data are often contrary to what the general population thinks, providers are seeing firsthand these concerning trends in cancer clinics and programs. As healthcare providers, we want to see this trend decrease and providing wellness solutions will help to right the ship.

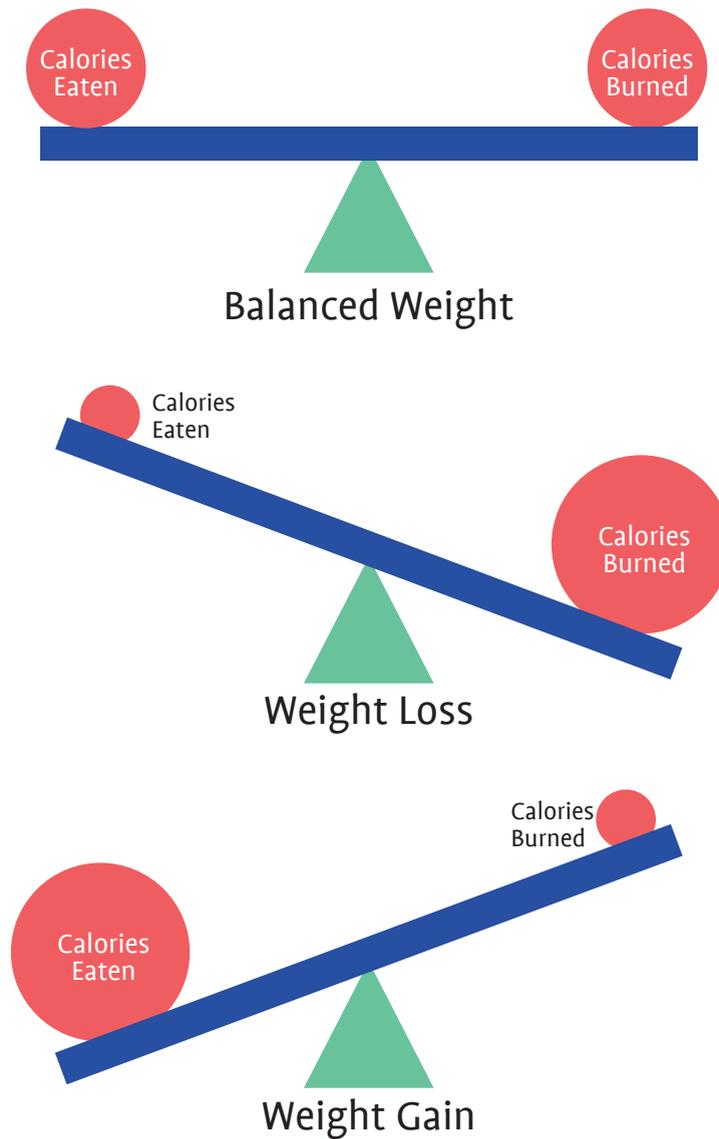
These increases pose a major problem because obesity is linked to increases in cancer recurrence, death, comorbidities, treatment related symptoms, and a decrease in quality of life.¹⁶ Overweight and obese cancer patients may also increase their risk of acquiring other cancers. Examples include esophageal, liver, kidney, stomach, colorectal, gallbladder, pancreatic, ovarian, endometrial, post-menopausal, breast, and advanced prostate cancer.¹ Evidence is also showing that obesity may be associated with a decrease in treatment effectiveness. It is well known that increasing physical activity and maintaining a healthy diet are effective in weight management. Therefore, the solution is simple: providers must begin “prescribing” exercise and nutrition to cancer patients.

The Effects of Physical Activity

To prevent and further diminish the effects of cancer, our first recommendation is that patients should participate in a reasonable amount of exercise and physical activity throughout the week. Patients may see improved mobility in daily activities alongside better physical and mental health, and mood enhancements.¹⁷ However, only 30 percent of cancer survivors are meeting physical activity recommendations.¹⁸ When utilized alongside a healthy lifestyle, it is possible that physical activity may be a more affordable treatment and preventative option against obesity, cancer, and other comorbidities, compared to costlier operations, medications, and treatments.

Exercise and physical activity act as a protectant against acquiring additional cancers, co-morbidities, cancer treatment symptoms, cancer recurrence, and death.¹⁸ Epidemiologic evidence shows that physical activity can reduce the risk of breast cancer by about 20 to 40 percent, colon cancer by at least 20 percent, and endometrial cancer by about 20 to 30 percent, proving that exercise and physical activity are important aspects of cancer care.¹⁷ Physical activity also has positive effects on cancer biology in the body’s many systems. It affects internal mechanisms and pathways, such as hormonal pathways, inflammatory pathways, immune-related pathways, metabolic mechanisms, and physiologic mechanisms. From this information, teams of scientists are now

Figure 1. Illustration of the Concept of Energy Balance



working to identify the most biologically effective type, duration, and dose exercise. However, what we absolutely know is that movement is key.

It is important to note that the term “exercise” does not have the same meaning for every patient. For most, exercise is defined as planned, structured, and repetitive movement designed specifically to improve or maintain physical fitness. Thus, when talking to cancer patients about exercise, providers should focus on the word “movement.” Movement can mean going to the gym or lifting weights, but the term is not limited to those activities. Providers simply telling cancer patients to “exercise” may not be as effective as explaining to them specifically *how* to move or do

physical activity. Through personal experience, prescribing “movement” to cancer patients has proven to be more successful than prescribing “exercise.” This may be in part to the notion that as humans, we move every day. Therefore, movement may appear to be a simpler, achievable task when compared to discussing exercise.

Studies show that decreasing one’s sitting time can now be more important than vigorous exercise in decreasing the risk of cancer.¹⁹ In other words, risk of cancer is increased when there is little to no exercise alongside ample sitting time throughout the day.¹⁹ Consider asking your cancer patients to focus on decreasing their sitting time as an alternative to increasing their exercise

time. Sitting time may be part of a patient's job, for example, in an office environment. Offer your cancer patients specific recommendations to reduce their sitting time, such as having a desk that can be converted to work both sitting and standing, or asking patients to get up and walk at regular intervals to get water or to talk to a person in their office versus emailing or calling. A simple alarm on a watch or cell phone can be a great reminder to get up and move. For those who would like to track the number of steps they have achieved, there are many fitness trackers in all price ranges on the market. Rather than immediately striving towards 10,000 steps, the goal should be to increase the numbers of steps gradually each week. This will not only achieve increased physical activity but also keep a sense of accomplishment and therefore motivation.

It is important for providers to stay up-to-date on current evidence-based recommendations. Statistics show a frequent occurrence of eating disorders among cancer patients due to the overemphasis on food by doctors and family members while patients are starting treatment.

While patients are in clinic, providers should be identifying and implementing ways to help patients, and their caregivers, move more. Patients and families could use the time waiting for an appointment to walk around and a simple text could let them know when to return for their appointment. If deemed safe, patients should be allowed to move and/or walk during chemotherapy treatments. A small portable pedal exercise could be used during chemotherapy to allow for movement while sitting for their treatment.

Although sedentary behavior will still occur in environments like at home, patients should aim to increase their energy expenditure to balance and ultimately decrease their sedentary lifestyle.¹⁸ Healthcare providers should be mindful that definitions of physical activity will be different between patients with different thresholds. Even if the patient can only accomplish 10 minutes of light walking, it is still more beneficial than having no mobility at all.

The Effects of Nutrition

Similar to physical activity and exercise, it is important to know your patients and familiarize yourself with their eating habits. Nutrition is another major aspect of wellness that can help reduce risk of cancer due to overweight or obesity. Providers need to be clear with cancer patients about the differences between nutrition,

diet, and dieting. “Nutrition” is the act or process of receiving appropriate amounts of nutrients. This includes protein, fat, carbohydrates, vitamins, minerals, and water as a means of survival.¹⁸ A “diet” simply refers to what one eats and drinks daily. On the other hand, “dieting” refers to restricting oneself to a specific diet for the goal of losing weight. A “nutritious diet” is what everyone should strive for and what providers should be communicating to their patients.

When undergoing a diet modification program to lose weight, patients should set a maintainable goal in reducing their energy intake. Desirable calories consumed per day is currently recommended at 1,600-2,400 per day for adult women and 2,000-3,000 per day for adult men. Patients should also aim to lose 1-2 pounds per week. These numbers may be adjusted depending on the patient and their specific needs at the time of modification.²⁰

Most patients struggle to maintain a nutritious diet. Unfortunately, many believe that any nutritional or diet program is safe and effective at lowering risk and recurrence for cancer, so long as it also reduces weight. This is a common myth. Many patients may also find it easier to find a specific diet plan and follow it. Due to these popular myths surrounding diet and nutrition, providers need to start with basic education for their cancer patients—discussing the basics of healthy nutrition and suggesting patients track their daily intake. By helping patients understand the differences between nutrition and diet and empowering them with knowledge, patients can then ask necessary questions and be a part of a shared decision-making process. Providers should also discuss moderation in diet, as it is common for patients to disregard the idea of moderation either because of misconceptions in the media or the misconception that exercise burns many more calories than it does. Unfortunately, a 10-minute walk does not burn off the calories of a burger or candy bar.

Patients should be aware that by consuming proper nutrients alongside their physical activity routine, their body can feel better and build energy and stamina at faster rates. Overeating causes weight gain and unhealthy habits, and moderating such will make it easier to incorporate healthy food choices into a patient's diet.

It is important for providers to stay up-to-date on current evidence-based recommendations. Statistics show a frequent occurrence of eating disorders among cancer patients due to the overemphasis on food by doctors and family members while patients are starting treatment.²¹ Anorexia and bulimia, for example, are the most common eating disorders found in breast cancer patients. With this knowledge, physicians should also screen for eating disorders during cancer treatment and regular check-ups.

Dispelling Popular Myths

Patients may enter a cancer program believing that they need to become vegetarian or vegan to have a more nutritious diet or, in some cases, to beat cancer. However, while some evidence exists, the data is not robust enough to support any one specific diet. Providers should ensure that patients do not worry about these and other weight loss specific diets (e.g., Keto-, Paleo-, Low-Carb-, and Atkins-diets) so long as they are eating a nutritious diet, daily.

Patients may also believe negative myths about the benefits of exercise during cancer treatment. Many are unaware that exercise is safe during treatment and that exercise is likely to decrease the negative side effects of treatment, while increasing quality of life. A list of common myths can be found in Figure 2, below.

Similar to myths among patients, lack of information can take place at the clinical level. One example of this is the benefits of prehabilitation.²² Prehabilitation is a perfect window of opportunity to begin to get patients active and ready for cancer treatment, especially during possible treatment delays. The more prehabilitation offered to cancer patients—simply getting them to move—the more likely patients are to keep physically active during treatment. Further, cancer patients who undergo prehabilitation prior to surgery have shown to have better surgical and treatment outcomes.²² Patients enrolled in prehabilitation are also more likely to stay on treatment longer and not stop treatment due to negative symptoms.²² Overall, the data has shown that prehabilitation is an ideal window of opportunity to make a positive difference to cancer patients.

Prescribing Physical Activity

Before prescribing exercise, or movement, providers must first be able to differentiate between moderate activity and vigorous activity in order to educate their patients effectively. Providers and their patients can use the “talk test” to determine if this activity falls under moderate or vigorous activity. This test is an easy, low-resource method that takes into account the patient’s current level of fitness. During moderate activity, patients can talk but cannot belt out their favorite song during the activity, such as a brisk walk. If, during a brisk walk, patients cannot say more than a few words without pausing for a breath, the activity should be considered vigorous for these patients. This sort of communication is key when explaining current exercise, or movement, recommendations to patients. Moderate activity may also include activities such as water aerobics, general gardening, and slow-paced bicycling. Vigorous, in contrast, may include jogging, swimming laps, singles tennis, aerobic dancing, jumping rope, and hiking uphill. Activities will differ for oncology patients, but the overall goal is for each patient to be physically active to the best of their abilities.

Figure 2. Common Physical Activity Myths During Cancer Treatment

1. Myth: Exercise is not safe during cancer treatment.

Truth: Being physically active is highly recommended during treatment.

2. Myth: Patients shouldn’t worry about exercising after being diagnosed with metastasis.

Truth: Exercise decreases negative side effects and increases quality of life.

3. Myth: Exercise exacerbates symptoms of treatment.

Truth: Exercise decreases fatigue, depression, anxiety, nausea, and pain.

4. Myth: Patients should not continue their same level of activity.

Truth: Activity should be a consistent yet dynamic component care.

5. Myth: Patients cannot stop once they start exercising.

Truth: Breaks are okay...flexibility based on tolerance.

6. Myth: Exercise doesn’t make a difference after diagnoses or treatment.

Truth: Exercise increases treatment effectiveness and quality of life and decreases risk of recurrence, progression, mortality, and morbidity.

Current cancer risk reduction recommendations include at least 150-minutes of moderate intense activity or 75-minutes of vigorous intense activity each week, or a combination of the two.²³ This activity does not need to be done all at once, and most providers prefer it to be spread out throughout the week. That said, activity needs to be done, at minimum, 10-minutes at a time. An example could mean moving at a moderate rate (walking) for 10-minutes, 15-times throughout the week for some patients. As mentioned previously, if patients do not know if their activity is moderate, have them perform the talk test. The idea is always to communicate movement in a way that is non-judgmental and approachable. It is okay if a patient starts with 10-minutes once a week and works up from there. Through non-judgmental and encouraging communication, patients are more likely to reach the recommended goal.

Many cancer patients may need a little extra help with a physical therapist or an occupational therapist to determine how to safely and effectively fit in some type of movement into their daily lives.

Providers should also find activities that patients want to perform, as opposed to mandating an activity. Whether their preference is walking their dog, gardening, or going to the gym, encourage patients to be active in forms of their choosing. As previously discussed, movement, or physical activity, can take shape in many forms. Make sure to ask patients what activities they enjoy and show them how those activities can be a form of physical activity. As a final reminder, patients need to decrease their sitting time. This one action is arguably the biggest—and most effective—change they can make.

When prescribing physical activity, remember to tell patients to start slow, take their time, and always consider side effects and timing. By starting smaller, moderate activities, patients can then work toward more vigorous activity. Patients need to know that activity is allowed to ebb and flow. The week of chemo-infusion may not be the best week to do the most exercise for one patient, but the next week after or the week before may be a more ideal time. Then, with each infusion, activity might become easier once maintained. Just because patients need to take a break from their routine, does not mean they have to give it up completely. Reminders of how physical activity positively affected patients prior to the break will encourage them to continue.

While it is important that patients do partake in physical activity or movement, providers should be considerate of precautions pertaining to patient safety. Providers should remind patients not to go to a busy gym during infusions due to decreased immune-function, but to instead perform home exercises or

participate in clinic-run programs. Fall prevention is paramount. Depending on the baseline fitness of the patient, some may be more prone to falling than others. For patients wanting to be active during chemotherapy, but are at high-risk of falling, providing a pedal machine while they are sitting is ideal. For patients where the risk is not as high, allowing them to walk alongside a wall with a handrail while holding their IV pole would be beneficial. The idea is to be creative in ways of providing movement options that are safe and feasible within the clinical setting. It is also important to remind patients to be aware of potential side effects that may inhibit their activity, such as neuropathy. However, it is equally important to give patients potential solutions, such as using a recumbent bike, the handrail attached to a wall, or even a walker or cane.

Make sure to also look at pre- and post-surgery precautions, or consider physical and occupational therapy for patients. Many cancer patients may need a little extra help with a physical therapist or an occupational therapist to determine how to safely and effectively fit in some type of movement into their daily lives. This scenario is also one where prehabilitation may prove to be most useful.

For those patients who are already active or for those who are open to increasing their activity level, in addition to the benefits of movement, providers should advise patients to incorporate strength training for both muscle health and bone strength. Without going to the gym, simple exercises can be done at home such as using soup cans as arms weights or the wall for pushups. For the legs, squats with a chair or wall for balance can be done. Patients should be advised to gently stretch after all strength exercises.

Providers should help patients determine their limitations and safe exercises to practice. During treatment, the discussion of movement after treatment should begin so that patients have a plan. After treatment, patients may exercise in different environments (i.e. home, clinic, fitness center) and should be taught how to utilize basic resources in different scenarios. This may include adapting a routine walk around their hospital unit into a routine walk around the patient's house or block. These conversations can happen within an appointment or casually during the hours of chemotherapy infusions or time spent walking from the waiting room to the exam room. Once staff and providers are educated on the key information above, informative yet casual conversations may make large impacts on patient knowledge, motivation, and implementation of healthy lifestyle choices.

Prescribing Healthy Nutrition

Regarding nutrition, eating healthy starts with consuming a variety of foods to get optimal nutrition and nutrients. These include proteins, fats, carbohydrates, water, vitamins, and minerals. This is especially important for cancer patients. Patients may start small and allow their diet to grow. For patients who like to garden, providers can encourage physical activity in the garden and improve their diet by planting a variety of vegetables to use in their meals. Poor eating habits should not be stopped immediately, as cutting these types of behaviors altogether may

have a greater potential for relapse into old habits. Moderation is key.

Providers should understand that the nutrition needs of patients will vary from person to person and, just like physical activity, may ebb and flow, depending on the timing the treatment. Especially when patients are in the middle of a treatment that causes abdominal distress, the “optimal” diet may be intolerable during that time. Keeping the discussion of nutrition informative while non-judgmental and motivational is crucial. For special needs, a nutritionist or dietitian with expertise in oncology can help providers and patients be creative in ways to get the nutrition needed depending on the type of cancer, treatment, and side effects the patient is experiencing. Some general recommendations and tips providers can offer to their patients are listed in Figure 3, page 28.

Another good tip to tell patients is to be mindful while eating—that is if they feel less than ideal after consuming a specific food or drink, that item should most likely be decreased or cut from their diet. Further, if they feel amazing right after but then feel a “crash” an hour later, that item may also be one to decrease or cut. The opposite is also true with foods that make the body feel well for a sustained amount of time.

As part of regular check-ups, patients should have their diets monitored and do their best to stay within a healthy diet. This will not only help during treatment but initiate good habits for after treatment.

Providers should also remind patients to keep hydrated, especially those who may be experiencing vomiting or diarrhea. Patients should be advised to drink about eight 8-ounce cups of liquid each day. Showing patients what 8 ounces looks like will help with adherence since a common misconception is that you need eight “glasses” which contain more ounces. All liquids (soups, milk, and even ice cream and gelatin) count toward fluid goals; however, striving for water and limiting highly caloric beverages is best.

Some patients may choose to drink alcohol. Drinking alcohol is safe when consumed in moderation; however, consumption should be limited to no more than 1 drink per day for women and no more than 2 drinks per day for men. One drink is defined as: 12 ounces of beer (5 percent alcohol), 5 ounces of wine (12 percent alcohol), 1.5 ounces of 80-proof liquor (40 percent alcohol). The percent of pure alcohol varies within and across beverage types. Although the standard drink amount is helpful for following health guidelines, they may not reflect customary serving sizes.²⁴ For example, while a 12-ounce run of the mill beer (5 percent alcohol) is considered 1 drink, a 12-ounce Indian Pale Ale (IPA; 9 percent alcohol) is 1.8 drinks. Similarly, given the alcohol content, a typical margarita is about 1.8 drinks and others with extra ingredients may be up to 2.7 drinks. Patients can cut out the daily IPAs or cocktails and replace them with a lighter drink to slowly decrease alcohol consumption. It is important for patients to be cautious of over pouring. Additionally, if a patient does not drink, they should not start.¹⁸

An easy way of remembering this overall prescription is “M&Ms”—movement, moderation, and mindfulness. If providers

and community wellness programs can utilize “M&Ms” as a foundation in educating their patients, they will produce a successful wellness program with regular participants who are motivated to stay involved. Not only will it will create a difference in patients, it will also create a very healthy community within your cancer program.

Building a Program

When building any new program, always start small—do not try and implement a massive program right out of the gate. Instead, start with a framework and build from there. You will need buy-in from your entire cancer program, especially from those staff who have direct patient contact. Reach out to your physical and rehabilitative therapists as they are a great resource and should be a part of any comprehensive cancer program. With stakeholder buy-in, cancer programs can develop programs in-house to meet the exercise, movement, and nutritional needs of their cancer patients.

An easy place to start is with education. To improve overall health in clinics, we suggest educating staff, incorporating dietitians and nutritionists into the care team, establishing relationships with community wellness providers, providing social support groups, and developing in-house programs.¹⁸ The more providers and staff that are educated in the clinic, the more chances there are to have the casual conversations with patients about their health and well-being.

When prescribing physical activity and nutrition, providers should recognize the positive impact of social support among patients. Social support is a major reason why people either do or do not stick with physical activity or a nutrition regimen. You may find that starting a support group focused on wellness within the clinic is another way to begin your program. For example, establishing a chemo-buddy program for patients to be physically active together, eat healthier, and help hold each other accountable.

Participating in research is also highly beneficial to patients. Research can provide resources that your cancer program might not have that a principal investigator can bring, thus, working towards improving each patient’s recovery. Research can also attract new patients and partners, and it can support your prescription for exercise and nutrition. If an opportunity to take part in a research study arrives, we suggest encouraging your patients to join.¹⁸

Some tips for building your wellness program:

- Before you start, conduct a self-assessment of your existing resources. You may be surprised with what you find.
- Next, appoint a lead person, liaison, and/or program champion. Having a point person is incredibly helpful in the long-term. They can oversee program development and implementation and delegate appropriately.
- You also want to research—see what is out there. You do not always need to reinvent the wheel. See what other cancer programs, in clinics and in the community, are doing around exercise and wellness for their patients and reach out to those programs to see how your clinic can get involved. The field

Figure 3. General Nutrition Recommendations and Tips to Tell Patients

- **Choose foods and beverages in amounts that help achieve and maintain a healthy weight.**
- **Limit consumption of processed meats and red meats.**
- **If you choose to eat red meat, select lean cuts and eat smaller portions.**
- **Choose lean meats and/or fish.**
- **Try substituting a couple of meals with plant-based foods.**
- **Eat at least 2¹/₂ cups of vegetables and fruits each day.**
- **Try for a variety of color when choosing your vegetables and fruits.**
- **Choose 100% juice if you drink vegetable or fruit juices.**
- **Choose whole grains instead of refined-grain products.**
- **Limit consumption of refined carbohydrate foods including pastries, candy, sugar-sweetened breakfast cereals, and other high-sugar foods.**
- **Limit the amount of fat in your meals by choosing a lower-fat cooking method like baking or broiling.**

of wellness is ripe with collaborative opportunities because providers know that they cannot do the work alone. You can partner with established wellness programs, either among hospitals and clinics or other outside programs in the community.

- Finally, remember to include all forms of wellness in your wellness program—exercise, physical activity, nutrition, sleep, meditation, and mindfulness—as this will encourage optimal health outcomes among your cancer patients.

Once you begin to prescribe exercise, or movement, and nutrition at your cancer programs, it is critical to track your results and gather outcomes data, including patient reported outcomes. These data will allow you to show return on investment to your program and patients that, in turn, will allow you to grow your wellness services and contributions to new research. 

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Reducing Revenue Loss and Patient Financial Toxicity with a Pharmacy-Managed Pre-Certification and Denials Management Program





In an era of soaring drug prices, payers have developed complex strategies to manage costs and ensure clinically appropriate prescribing in the outpatient environment.¹⁻³ Some of the most frequently used strategies include requiring prior authorization before treatment and implementing medical coverage policies with clinical criteria outlining coverage parameters. Because providers are unable to bill for a drug prior to dispensing it, institutions are often left balancing the need to start expensive treatments with uncertainty about reimbursement. A proactive approach to understanding and complying with payer-mandated requirements is vital to ensuring that millions of dollars in treatments are not lost to payer denials.

In 2018 CEOs responding to a national Advisory Board survey indicated that cost control is the number one priority for healthcare systems.⁴ Whether through expense reduction or revenue growth, there is intense focus, now more than ever, on developing a sustained plan for margin protection.⁴ Payer cost containment strategies not only help protect institutional margins, but they also impact patient care—clinically and financially.

In a 2018 American Medical Association survey of more than 1,000 physicians, 28 percent said that issues with the prior authorization process in their institutions have affected patient care delivery and led to serious adverse events, including death,

To adequately address patient financial toxicity, institutions must assume responsibility for ensuring that patients understand their insurance coverage and anticipated out-of-pocket expenses. Institutions should also have procedures in place to navigate the pre-certification process and prevent claim denials that may ultimately end up as the patient's responsibility.

hospitalization, disability/permanent bodily damage, and other life-threatening events.⁵ This finding underscores the necessity of an efficient and effective institution-wide prior authorization process, with content experts dedicated to this work.

Adverse clinical outcomes are not the only casualty of poor cost containment policies; patient financial toxicity, especially in cancer care, is also a significant outcome.⁶⁻¹⁰ Having high out-of-pocket treatment expenses can have the same consequences as compromised clinical care in that excess costs can decrease a patient's quality of life and hinder the delivery of care if a patient must decide between paying for treatment and funding other basic needs.

To adequately address patient financial toxicity, institutions must assume responsibility for ensuring that patients understand their insurance coverage and anticipated out-of-pocket expenses. Institutions should also have procedures in place to navigate the pre-certification process and prevent claim denials that may ultimately end up as the patient's responsibility.

Pharmacy Takes Center Stage

In 2009 the University of North Carolina (UNC) Medical Center significantly expanded its infusion services with the opening of the North Carolina Cancer Hospital in Chapel Hill. UNC also has cancer and infusion centers across the state to provide regional cancer care.

In 2016 an internal multidisciplinary quality improvement project examining Medicare infusion denials drew attention to the current process at UNC Medical Center for handling high-dollar infusion claims and denials. Until that time, the pharmacy department at UNC Medical Center handled pre-certification, and the hospital billing department at UNC Medical Center oversaw post-claim denial management, which is customary in most healthcare organizations.

Our pharmacy leadership believed that it would be more effective to transition our denials management process from hospital billing and into a closed-loop, collaborative system operated and managed by UNC Medical Center's Department of Pharmacy. The expanded pharmacy-managed pre-certification and denials management program that was subsequently created incorporates three discrete elements: a pre-certification program, a denials management program, and a continuous quality improvement program (see Figure 1, right). Six key steps were essential to creating and implementing the pre-certification program:

1. Developing an institutional pre-certification policy
2. Determining process owners
3. Building a streamlined process
4. Engaging pharmacy operational areas
5. Optimizing manufacturer-supported patient assistance programs
6. Developing a proactive medical necessity policy review.

After first transitioning denials management from hospital billing to the pharmacy department, we launched our pharmacy-led denials management program by hiring a pharmacist dedicated to working Medicare infusion denials. Shortly afterward, the

pharmacist also assumed responsibility for denials from commercial payers and Medicare Advantage plans. We then added a denials specialist to the team to handle the expanding workload.

This pharmacist/denials specialist team is currently responsible for appealing denied drug claims and working with payers to resolve billing and claim processing issues that have resulted in these denials. The team assesses each denial, documents root causes, and tracks each one through to its final determination. Vital to the denial management program's success is the role that operational pharmacists play in ensuring adherence to the institutional policy for verifying that pre-certification referrals are authorized prior to dispensing. To support this effort the denials management pharmacist holds monthly meetings with operational leaders to share area-specific denial data. This includes information about drug- and payer-specific details as well as the root causes of individual denials. These meetings enable area leaders to stay aware of key drug and payer coverage trends and to collaborate in developing and implementing proactive multidisciplinary workflow changes.

This closed-loop collaboration model also enables continuous quality improvement among the pre-certification and denials management teams. In weekly meetings, representatives from both teams discuss the payer trends they observe during pre-certification and in denials data. This forum gives participants the opportunity to collaborate in developing, optimizing, and assessing front-line processes.

New Processes for a New Approach

As part of transitioning the responsibility for pre-certification to the pharmacy department, our organization implemented a mandatory medical benefit pre-certification program in our outpatient settings. Central to this program are the requirements that:

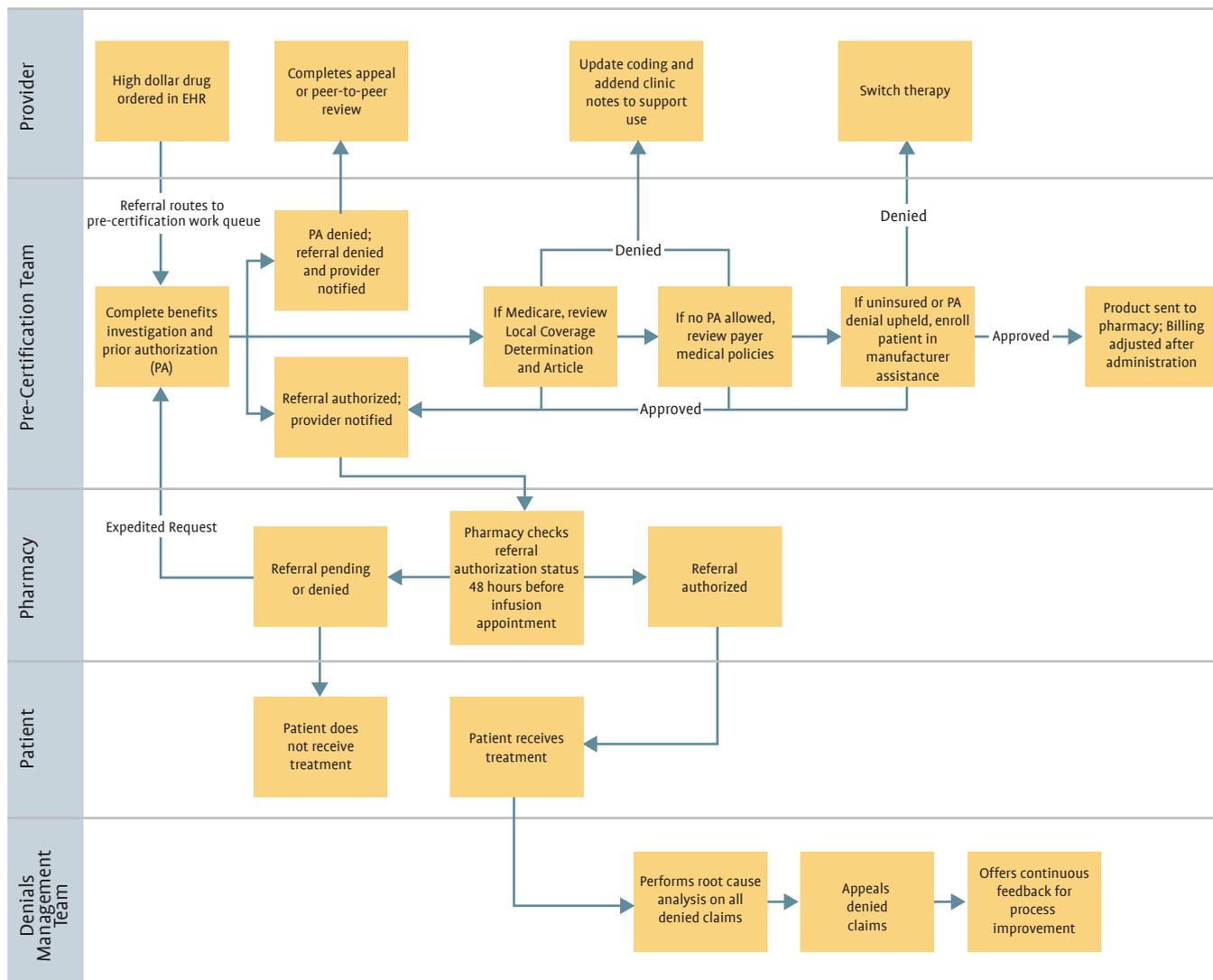
1. Outpatient medical benefit orders (e.g., infusion drugs) be entered seven days prior to treatment to allow time for pre-certification
2. Drugs are not dispensed until pre-certification is obtained.

Implementing these requirements was challenging. It required the support of senior leadership and physician administration to send the message that, in addition to protecting revenue, this policy would mitigate the risk that treatments would go uncovered and potentially leave patients responsible for their medical costs.

At the time, the UNC Medical Center pharmacy department's Medication Assistance Program team—staffed by advanced pharmacy technicians—was already overseeing prescription benefit prior authorizations, co-pay assistance for select specialty drug therapies, and the pharmacy's internal charity care program. It was logical to add responsibility for medical benefit pre-certification to this group, because team members were already familiar with the processes this task required.

Because we were launching a new electronic health record (EHR) when we created the medical pre-certification program, our pharmacy administration collaborated with leadership from

Figure 1. Standardized Workflow Process for Medical Benefit Pre-Certification and Denials Management Program



our information technology department to develop a referral process for outpatient infusion drug orders. The information technology team built into the EHR a referral order that is automatically sent to the pre-certification team whenever an order for a high-dollar infusion drug is generated.

These referrals are routed to a work queue managed by the pre-certification team. Once technicians receive a referral, they complete a benefits investigation to determine the patient's expected insurance coverage and out-of-pocket responsibility. If the payer requires a prior authorization, the technician will retrieve pertinent clinical information about the patient from the EHR

and/or contact the prescriber for additional information. The technician will then submit the prior authorization request and track it through to completion.

All documentation is completed within the EHR and is transparent to all members of the healthcare team. Once an order is approved, the referral status is marked as authorized, which indicates to the operational pharmacy staff that a patient has been approved for treatment. The system sends an electronic message to the ordering provider communicating the approval. If a prior authorization request is denied, the technician works with the provider to appeal the decision.

The Last Line of Defense

Engaging the pharmacy operational areas is key to ensuring that high-dollar drug doses are not dispensed prior to authorization by the pre-certification team. This is the last line of defense in confirming that the dose is expected to be covered by the payer prior to it being administered to the patient. To accomplish this, the operational area team (pharmacists in the compounding area, preparing and dispensing drug product) reviews the outpatient infusion center schedule at least 48 hours before the scheduled treatment date. If the scheduled therapy is not authorized by then, the operational area team communicates with the pre-certification technician to rush the authorization, if possible, and/or communicates with the clinical and scheduling teams to have the patient's infusion appointment re-scheduled.

The automatic referral infrastructure developed for pre-certification also serves as a platform for identifying patients who qualify for manufacturer patient assistance programs. Following pre-certification, if a patient is identified as uninsured, or if his or her treatment is not covered by insurance, the pre-certification technician partners with the patient and provider to apply to the manufacturer for assistance. If the application is approved, the technician is responsible for ordering the product prior to each treatment date and coordinating billing adjustment. This enrollment is vital to certify drug access at no cost to the patient.

In 2018 our institution recognized the need to embed additional proactive reviews into our pre-certification process. The need for this was evident when our denial data increasingly indicated that payers that do not require prior authorization will still deny claims based on their published medical policies. In response to this growing trend, we implemented an additional step for referrals that did not require prior authorization in which a pharmacist reviews medical policies and assesses clinical documentation to confirm alignment. If permitted by the payer, the technician may request a pre-determination, essentially a proactive review of medical records by the payer.

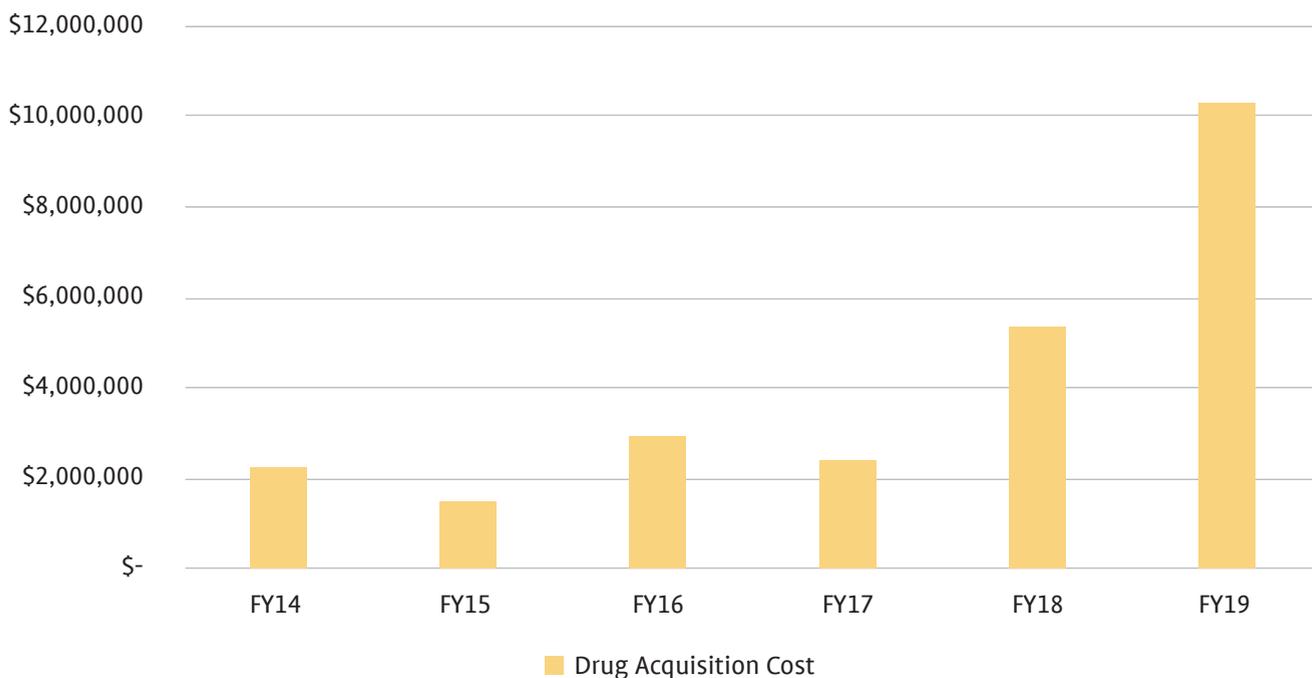
New Collaborations

Key to the continuous quality improvement strategy of this effort is the development of collaborative relationships among the various health system teams central to the pre-certification and denials process.

The transfer of denials management from the hospital billing, revenue cycle, and patient financial services team at UNC Medical Center to the pharmacy-led denials management team created an organic partnership between these groups. Pharmacy's active engagement in denials management has also led to its close collaboration with the health system denials management team. Initially created in response to specific quality improvement concerns, this relationship has grown with pharmacy's expanding

(continued on page 36)

Figure 2. Drug Expense Savings Through Manufacturer Patient Assistance Program Enrollment*



*These data represent manufacturer-provided medications offsetting drug expense to the institution and on behalf of patients. Drug acquisition cost is based on 340b drug price to UNC Medical Center.

Figure 3. Denials Management Program Financial Impact (July 2018-June 2019)

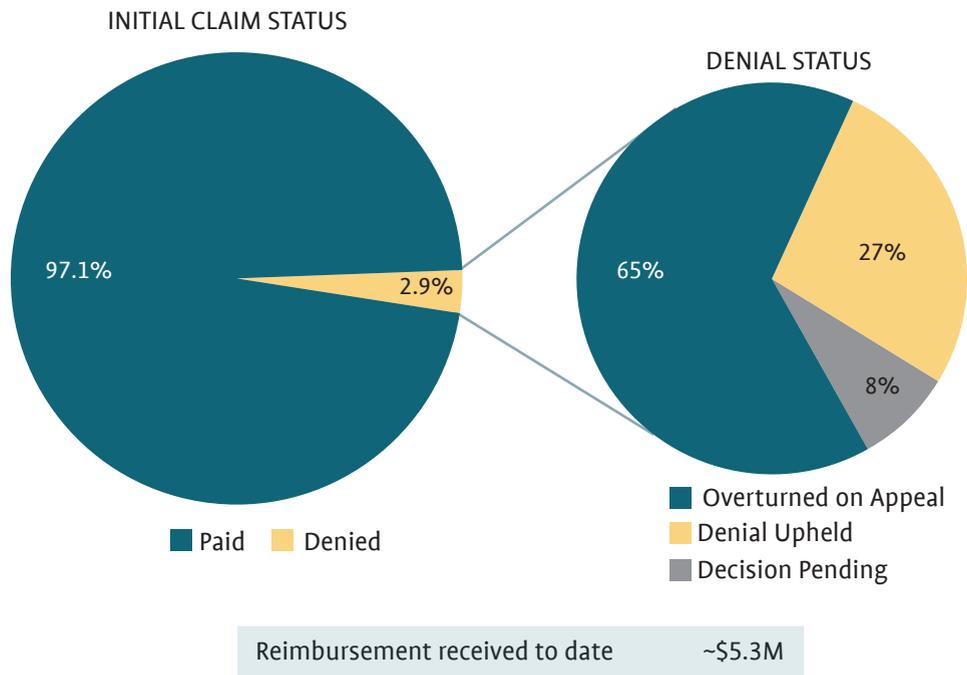
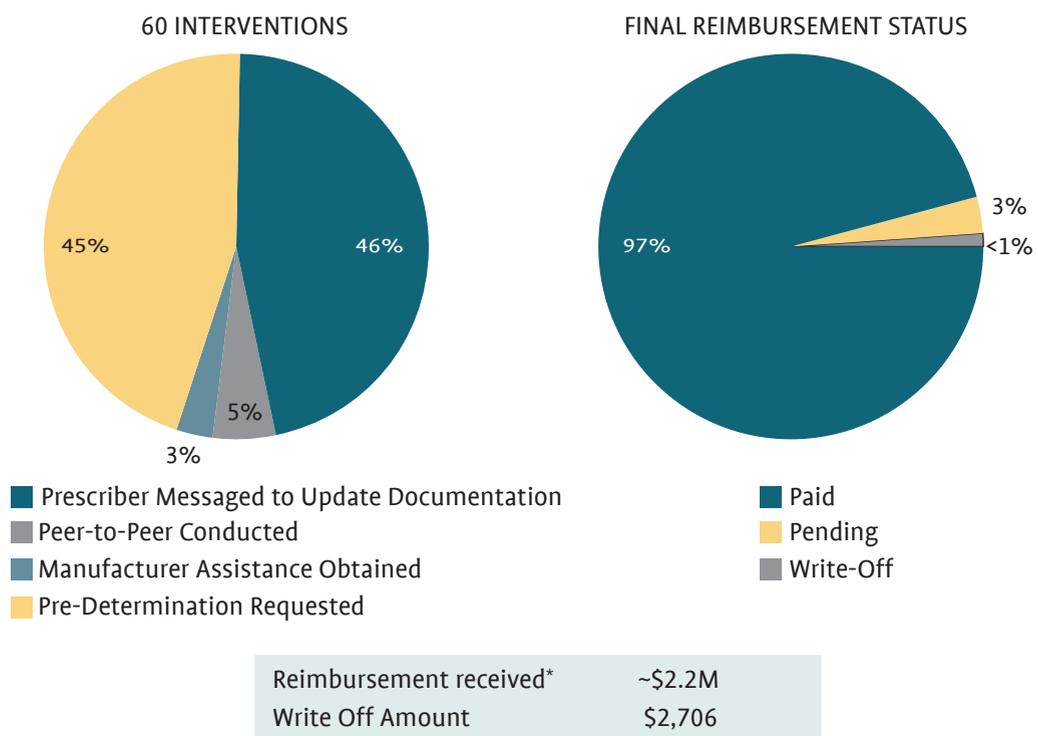


Figure 4. Medical Necessity Proactive Review Financial Impact (September 2018-February 2019)



*Reimbursement = Doses given within 6 weeks of initial dose

(continued from page 34)

efforts to decrease the denial rate, mitigate institutional revenue loss, decrease patient financial toxicity, assess current processes, and foster front-end change.

The pre-certification and denials management team has also developed a working relationship with the health system managed care team at UNC Health with which it has worked to handle new issues arising from the market introduction of high-dollar, niche drugs and from new trends in payer denials and reimbursement. Because accurate claim coding is also essential to avoiding denials, the pharmacy team works routinely with representatives from the health information management and coding team to ensure streamlined, accurate coding of high-dollar infusion claims.

A Wise Investment

As of October 2019, our pre-certification program has grown from a four-member team to 13 employees, including:

- Seven certified pharmacy technicians who complete more than 11,000 pre-certifications per year, the majority within 72 hours of when the drug is ordered
- Four certified technicians dedicated to enrolling patients into manufacturer assistance programs
- One medical necessity specialist
- One technician supervisor.

When patients are uninsured or when drugs are prescribed for off-label use, the pre-certification and post-treatment denials management processes include enrolling patients into manufacturer-supported patient assistance programs. Program enrollment in these programs in fiscal year 2019 resulted in \$10.2M in annual drug cost savings to our institution based on drug acquisition cost. Figure 2, page 34, highlights the \$24.8M total drug cost savings we have achieved since program creation.

With our streamlined denials management program with clinical pharmacist oversight, more than 65 percent of denied claims are overturned upon clinical appeal or payer reprocessing, resulting in more than \$5.3M in actual reimbursement annually (see Figure 3, page 35). The combined work of the pre-certification and denials management teams also minimizes institutional revenue loss to less than 0.75 percent of the annual outpatient infusion revenue stream.

Our proactive, pre-claim medical necessity reviews affect treatments responsible for more than \$4M in annual institutional drug reimbursement. Figure 4, page 35, highlights the number of drug orders evaluated for medical necessity from September 2018 to February 2019. Of the 232 drug orders, 60 required interventions, including asking the provider for additional documentation, requesting pre-determination, organizing peer-to-peer calls between the prescriber and payer representative, and enrolling the patient in manufacturer assistance programs. To date, treatments undergoing proactive medical necessity review have resulted in only one case of post-treatment drug revenue loss.

The UNC Medical Center pharmacy-managed, closed-loop medical benefit pre-certification and denials management program represents an innovative and unique approach to mitigating the patient financial toxicity and institutional revenue risk associated with payer cost containment strategies for high-dollar outpatient administered drugs. The institutional financial stewardship and patient financial savings since program implementation demonstrate a best practice that can be replicated at other institutions. 

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Association of Community Cancer Centers

Medical Marijuana (Cannabinoid-Derived Products) for Cancer Patients



Cannabis, also known as marijuana, or called a vast number of other slang terms like weed, herb, pot, grass, bud, ganja, and Mary Jane originated in Central Asia but is grown worldwide today. Cannabis use for medicinal purposes dates back at least 5,000 years, with the earliest reported use being in China around 2700 BC for the relief of pain and cramps.¹

In the United States, cannabis is still a controlled substance and is classified as a Schedule I agent (a drug with a high potential for abuse and currently no accepted medical use). The U.S. Food and Drug Administration (FDA) has not approved cannabis as a treatment for cancer or any other medical condition. By federal law, the possession of cannabis is illegal, except within approved research settings. However, a growing number of states, territories, and the District of Columbia have enacted laws that decriminalized the recreational and/or medicinal use of marijuana in that specific area.

Cannabis is the fastest growing industry in the world. According to Arcview's market research, regulated marijuana sales in North America totaled \$6.9 billion in 2016. Sales are projected to increase to \$21.6 billion by the year 2021.² Over the last few decades, there has been significant interest in the potential use of marijuana for a variety of medical conditions. There are more than 60 U.S. and international health organizations that support granting patients immediate legal access to medicinal marijuana under a physician's supervision.³

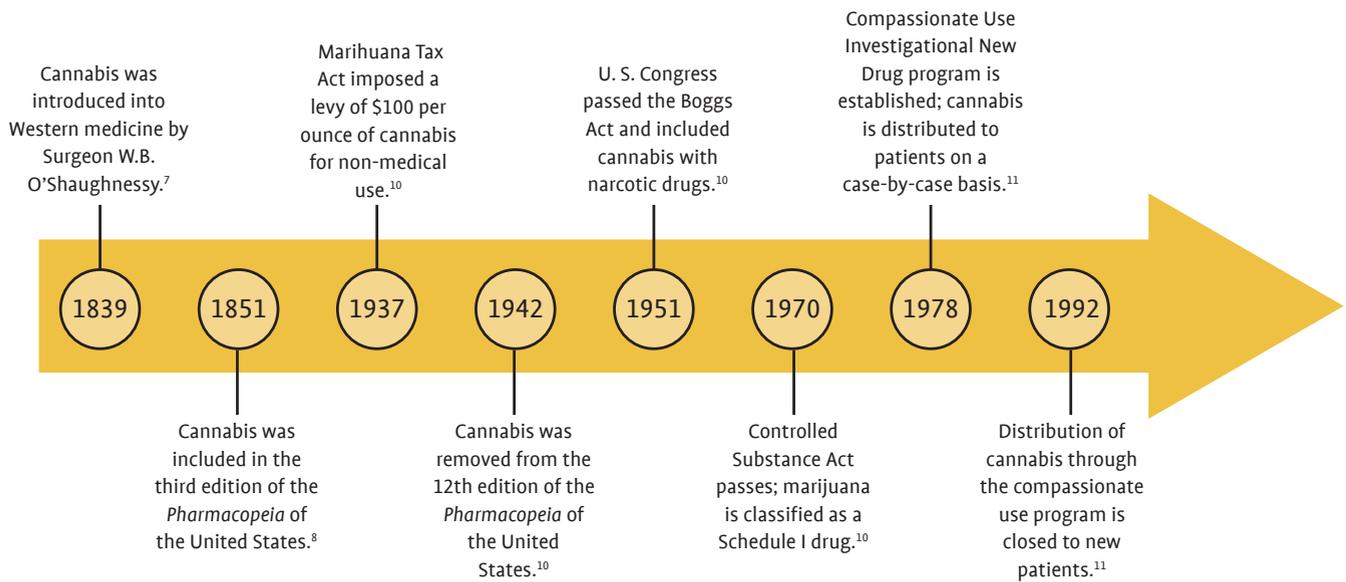
This article is intended to provide a general introduction and overview regarding some of the important aspects and contemporary issues encountered when navigating the field of medical marijuana.

Each state has its own list of the qualifying conditions for which it will allow patients to use medical marijuana. These qualifying conditions are different in each state; however, in many states a number of conditions are cancer related—chemotherapy-induced nausea and vomiting, anxiety, hepatitis C, HIV/AIDS, cachexia (wasting syndrome), and inflammatory bowel disease.

History and Overview

Cannabis is a genus of the family Cannabaceae and has generally been recognized to contain three main species: *sativa*, *indica*, and *ruderalis*. *Cannabis sativa* and *Cannabis indica* are both prevalent in the United States and other parts of the world. *Cannabis sativa* has been employed for thousands of years, primarily as a source of a stem fiber (both the plant and the fiber, termed *hemp*) and a resinous intoxicant (the plant and its drug preparations, commonly termed *marijuana*).⁴

Figure 1. A Timeline of Cannabis History in the United States



Traditionally, *Cannabis sativa* plants are tall, reaching heights of up to 20 feet, loosely branched, and have long, narrow leaves. On the other hand, *Cannabis indica* plants are short and densely branched and have wider leaves.

The cannabis plant produces a resin containing compounds called cannabinoids. Cannabinoids, also known as phytocannabinoids, are chemicals in cannabis that cause drug-like effects in the body, including the central nervous system and the immune system. To date, more than 100 different cannabinoids have been identified. Among these, 9-tetrahydrocannabinol (THC) has received the most attention for being responsible for the intoxicated state (psychoactive) sought by recreational cannabis users. Another active cannabinoid is cannabidiol (CBD), which may relieve pain and lower inflammation without causing a “high” from the THC.⁶ The highest concentration of cannabinoids is found in the female flowers of the plant.

In general, marijuana refers only to the parts of the plant or derivative products that contain substantial levels of THC. Under U.S. law, cannabis plants with very low levels of THC (no more than 0.3 percent) are not considered marijuana but instead are industrial hemp.

Cannabis use for medicinal purposes dates back thousands of years ago. It was introduced into Western medicine in 1839 by W.B. O'Shaughnessy, a surgeon who learned of its medicinal properties while working in India for the British East India Company. Its use was credited with reported analgesic, sedative, anti-inflammatory, antispasmodic, and anticonvulsant effects.⁷

In 1851, cannabis was included in the third edition of the

Pharmacopoeia of the United States (USP). Subsequent revisions of the *Pharmacopoeia* described in detail how to prepare extracts and tinctures of dried cannabis flowers to be used as an analgesic, hypnotic, and anticonvulsant.⁸

Cannabis was included in marketed products sold in the United States by Eli Lilly and Company and other pharmaceutical companies for the treatment of a variety of conditions and/or disorders, including insomnia, migraines, and rheumatism.⁹

Growing concerns about cannabis in the early 1900s resulted in it being outlawed in several states, and the U.S. Treasury Department introduced the Marihuana Tax Act in 1937. This Act imposed a levy of \$1.00 per ounce for the medicinal use of cannabis and \$100 per ounce for non-medical use.¹⁰ In 1942, the American Medical Association removed cannabis from the 12th edition of the *Pharmacopoeia of the United States*.¹⁰ In 1951, Congress passed the Boggs Act, which for the first time classified cannabis with narcotic drugs.¹⁰ With the passage of the Controlled Substances Act in 1970, cannabis was classified by Congress as a Schedule I drug. Drugs that are Schedule I are distinguished as having no currently accepted medicinal use in the United States. Other Schedule I substances include heroin, lysergic acid diethylamide, mescaline, and methaqualone.¹⁰ Despite its designation as having no medicinal use, cannabis was distributed by the U.S. government to patients on a case-by-case basis under the Compassionate Use Investigational New Drug program established in 1978. Distribution of cannabis through this program was closed to new patients in 1992.¹¹ Figure 1, above, shows a timeline of cannabis's history in the United States.

Legal Status: Federal and State Laws

Although federal law prohibits the use of cannabis, some states have enacted laws that legalized the recreational and/or medicinal use of marijuana in that specific state.⁶ In 1996, California voters passed Proposition 215, making California the first state in the United States to permit the use of medical marijuana.¹² Colorado and Washington became the first two states to legalize the recreational use of cannabis in 2012.

States with Medical and Recreational Marijuana Laws

As of November 30, 2019, 33 states, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands have passed medical marijuana laws (see Figure 2, page 42).¹³ Among them, 10 states, the District of Columbia, and Guam also have legalized marijuana for recreational use. Those 10 states are Alaska, California, Colorado, Maine, Massachusetts, Colorado, Nevada, Oregon, Vermont, and Washington.¹³

States with Medical Cannabidiol (CBD) Laws

There are an additional 14 states—Alabama, Georgia, Indiana, Iowa, Kansas, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee, Texas, Virginia, Wyoming, and Wisconsin—where the use of medical marijuana has not been legalized but a medical CBD law allowing for the use of cannabis extracts that are high in CBD but minimum in THC has been passed.¹³ This is only in instances where a patient with a state-qualifying condition is recommended CBD by his or her provider.¹³

Individual state laws are all different. Under Florida's medical CBD law, state-qualified patients (patients with cancer or experiencing muscle spasms or seizures) may possess cannabis strains containing 10 percent or more of CBD and no more than 0.8 percent of THC.¹³ In Texas, the THC limit is set at no more than 0.5 percent and CBD no less than 10 percent in oil preparations.¹³ Currently, there are only three states in the United States that do not allow the use of any form of medical marijuana—Idaho, Nebraska, and South Dakota.¹³

It is important to have an understanding of the laws in your state. Regardless of what state you live in, you should not buy or send cannabis through the mail because the drug is still federally illegal. The U.S. Post Office, a federal government agency, will confiscate the marijuana, and the sender may be arrested and prosecuted.

State Legislature Conditions for Medical Use

Each state has its own list of the qualifying conditions for which it will allow patients to use medical marijuana. These qualifying conditions are different in each state; however, in many states a number of conditions are cancer related—chemotherapy-induced nausea and vomiting, anxiety, hepatitis C, HIV/AIDS, cachexia (wasting syndrome), and inflammatory bowel disease. Other conditions include glaucoma, Tourette's syndrome, multiple sclerosis, Alzheimer's disease, and chronic pain.

To purchase and use either medical marijuana or medical CBD in states where it is legal, patients are usually required to register and apply for a card with the state's Department of Health. There

is a fee for applications, and each state has different limits on the amounts patients are permitted to purchase. In most cases, the purchasing cost of medical marijuana or medical CBD is not covered by insurance.

To become a certified marijuana physician, a physician must hold an active license, take a required course, and pass an exam. This process varies by state. After completion of the state requirements, physicians may apply for certification.

Dispensing of Medical Marijuana or CBD

Thirty-three states and the District of Columbia have passed legislation legalizing marijuana for medical use. Of those, five have established a role for pharmacists in the dispensing process:¹⁴

- Arkansas requires every marijuana dispensary to appoint a pharmacist consultant.
- Connecticut permits only pharmacists to apply for and obtain a marijuana dispensary license.
- Minnesota permits only pharmacists to give final approval for the distribution of medical marijuana to a patient.
- New York requires a pharmacist to be on the premises and supervise the activities within a marijuana dispensing facility whenever the facility is open or in operation.
- Pennsylvania requires primary marijuana dispensing facilities to have a physician or pharmacist on site when the facility is open to receive patients and caregivers.

Under federal law, no individual, including pharmacists, can legally dispense medical marijuana, even in states that have passed medical marijuana legislation. Absent a change to federal law, pharmacists involved in the current dispensing process may ask themselves whether their license is at risk for dispensing a federally prohibited drug or, if the medical marijuana is seized, whether they will be prosecuted. Unfortunately, there are no answers at this point.

Cannabinoid-Derived Pharmaceutical Products

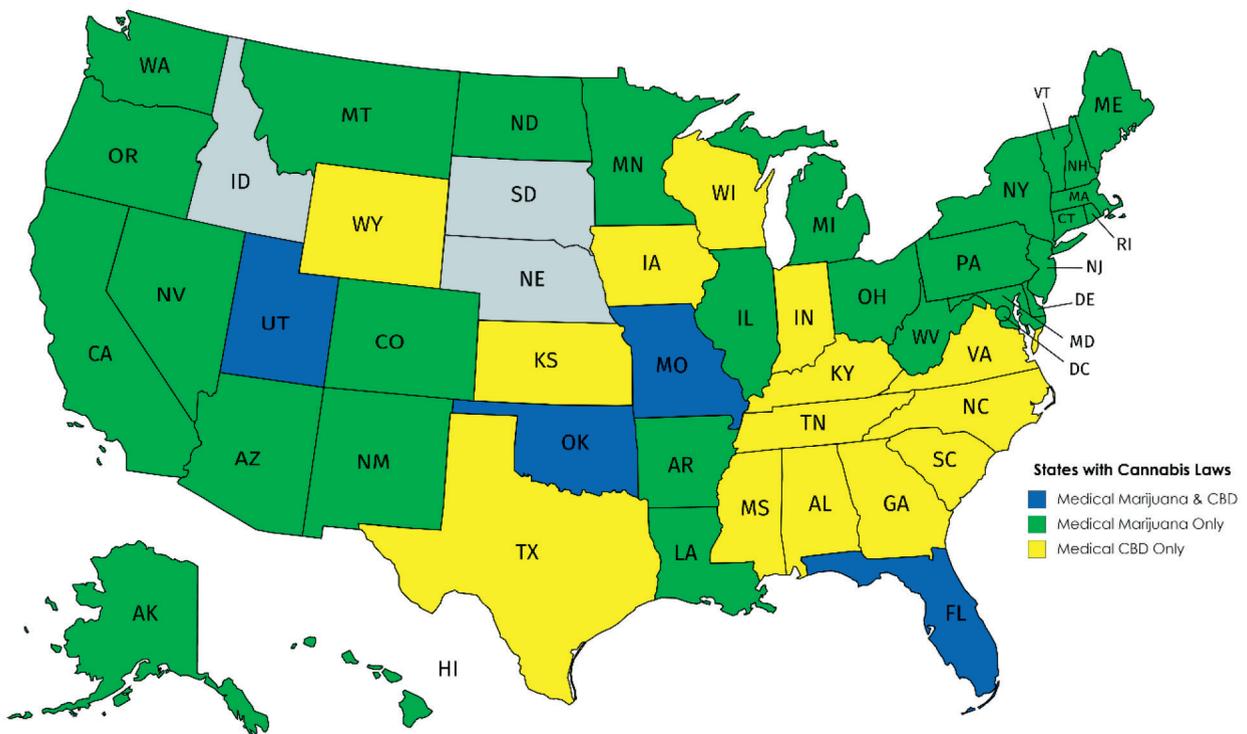
The FDA has approved four drugs that are based on natural cannabinoids (see Table 1, page 43); one is currently under investigation.⁷

Cannabinoid-Derived Non-Pharmaceutical Products

Cannabis is a flowering plant. Once mature, the plant's leaves and flowers are covered with trichomes, tiny glands of resinous oil containing cannabinoids and terpenes, which provide physical and psychoactive effects.¹⁵ Cannabis leaves and flowers are consumed in several forms: dried flower buds or various types of concentrated, loose, or pressed resin extracted from the flowers or leaves through a variety of methods, including:

- **Kief** is a powder made from trichomes removed from the leaves and flowers of cannabis plants that is used for smoking.
- **Hashish** is a paste-like substance, a collection of compressed or concentrated trichomes, that is used for smoking, ingestion by food, or inhalation with a vaporizer.
- **Hash oil** is a mix of essential oils and resins extracted from mature cannabis foliage that is used for smoking or inhalation with a vaporizer.

Figure 2. U.S. States and Territories That Have Approved the Medical Use of Marijuana and CBD



- *Cannabis edibles* are usually ingested or eaten when added to brownies, cookies, dressings, and other foods. They can also be brewed into a tea or other beverage.
- *Cannabis oil* is a cooking oil infused with cannabinoids usually used to help create cannabis edibles.
- *Cannabis tincture* is an extract of cannabinoids with ethanol alcohol for use in droplet amounts that are absorbed through the mucous membranes in the mouth.
- *Sublingual spray* is similar to the tincture (above) but is placed under the tongue for use.
- *Cannabis topicals* are topical creams, lotions, ointments, and patches that have cannabis (THC or CBD) in it.

Unlike most pharmaceutical products, cannabis products are not standardized in composition, formulation, or dose. This means that there is not yet a way to know exactly what and how much THC or CBD is in each pill or spray. It will usually take experimentation with product types and dosages to determine the right dose for individuals and their purpose. Digesting cannabis (not smoking or absorbing it) also metabolizes the cannabinoids somewhat differently, which can produce different subjective effects, depending on the individual.

The effects of THC, the psychoactive effect, are delayed by 30 to 60 minutes after eating or drinking marijuana-infused products compared to just seconds or minutes after inhaling marijuana smoke or vapor.^{12,13} The effects from ingestion can last up to 10 hours for some people. One should not drive due to impaired coordination that can lead to unsafe driving.

When oral cannabis is ingested, there is a low (6 percent to 20 percent) and variable oral bioavailability. Peak plasma concentrations of THC occur after 1 to 6 hours and remain elevated with a terminal half-life of 20 to 30 hours. Taken by mouth, 9-THC is initially metabolized in the liver to 11-OH-THC, a potent psychoactive metabolite.^{16,17}

Inhaled cannabinoids are rapidly absorbed into the bloodstream with a peak concentration in 2 to 10 minutes, declining rapidly for a period of 30 minutes and with less generation of the psychoactive 11-OH metabolite.^{16,17}

In some states where marijuana has been legalized, smokable products are excluded. In New York, the law permits qualified patients to possess a 30-day supply of cannabis-infused, non-smokable products, with only non-smokable preparations allowed.¹⁸

Table 1. FDA Approved Cannabinoid-Derived Pharmaceutical Products

Substance	Route of Administration	Descriptions	Indications
Synthetic compounds			
Dronabinol (Marinol)	Oral capsule	Synthetic THC	For chemotherapy-induced nausea and vomiting or to stimulate appetite in AIDS wasting syndrome
Dronabinol (Syndros)	Oral solution	Synthetic THC	For chemotherapy-induced nausea and vomiting or to stimulate appetite in AIDS wasting syndrome
Nabilone (Cesamet)	Oral capsule	Synthetic THC	For chemotherapy-induced nausea and vomiting or to stimulate appetite in AIDS wasting syndrome
Natural product-derived compound			
Epidiolex	Oral oil	Concentrated CBD oil (98 percent CBD) from <i>Cannabis</i> extract	For the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome
Nabiximol (Sativex) FDA Fast Track (approved in the United Kingdom, Canada, and other countries)	Oromucosal spray	Ethanol <i>Cannabis</i> extract of TCH: CBD (in a 1:1 ratio). Extract from two <i>Cannabis</i> plant varieties	Symptomatic relief of multiple sclerosis and as an adjuvant analgesic for cancer pain

Marijuana smoke irritates the lungs. Frequent marijuana smokers can have many of the same problems as tobacco smokers, such as a daily cough, mucus, more chest colds, and a higher risk of lung infection. Some of the cancer-causing chemicals in tobacco smoke are also in marijuana smoke. Marijuana smokers may also inhale deeper and hold the smoke in their lungs longer. Therefore, marijuana smokers’ lungs may be exposed to more chemicals that can cause cancer. Lung tissue from regular marijuana users shows signs of pre-cancerous changes.¹⁹ However, several studies have failed to show that marijuana smokers have a higher risk of lung cancer. More studies about marijuana smoking and lung cancer are needed.²⁰

Knowledge Gaps

According to survey results published in the *Journal of Clinical Oncology* in 2018 titled “Medical Oncologists’ Beliefs, Practices, and Knowledge Regarding Marijuana Used Therapeutically: A Nationally Representative Survey Study,”²¹ Ilana M. Braun and colleagues concluded that a significant percentage of oncologists who recommend medical marijuana to their patients did not feel knowledgeable enough to do so. This survey was mailed in November 2016 to a nationally representative, random sample

of 400 medical oncologists. Main outcome measures included whether oncologists:²¹

- Reported discussing medical marijuana with patients
- Recommended medical marijuana clinically in the past year
- Felt sufficiently informed to make such recommendations.

The survey also queried oncologists’ views on medical marijuana’s comparative effectiveness for several conditions (including its use as an adjunct to standard pain management strategies) and its risks compared with prescription opioids. The overall response rate was 63 percent. Of all participants who responded, more than half (55 percent) practice in states where medical marijuana is legal. Key findings from the survey include:²¹

- Eighty percent of oncologists conducted discussions about medical marijuana with their patients; 78 percent reported that these conversations were most frequently initiated by patients and their families.
- Forty-six percent of oncologists recommended medical marijuana clinically.
- Seventy percent of oncologists did not feel sufficiently informed to make recommendations regarding medical marijuana.

- Sixty-seven percent viewed it as a helpful adjunct to standard pain management strategies; a majority viewed it as presenting a lower risk than opioids for overdose death (75 percent) and addiction (52 percent).
- Sixty-five percent thought that medical marijuana is equally or more effective than standard treatments for anorexia and cachexia.

This study identified a concerning discrepancy between oncologists' self-reported knowledge base and their beliefs and practices regarding medical marijuana. Those findings are clinically important and suggest critical gaps in research, medical education, and policy regarding medical marijuana.

Important questions concerning medical marijuana must be addressed, especially given that medical marijuana laws are popular on a state level. Cancer is a “qualifying condition” recognized by almost all states that have medical marijuana legislation. Marijuana use has the greatest impact to oncology than any other specialty.

Because cannabis is a Schedule I controlled substance, clinical trials face a huge barrier. Randomized controlled trials of whole-plant medical marijuana have not been done among patients with cancer yet, so oncologists often extrapolate from evidence in clinical trials carried out on other diseases, as well as from clinical trials carried out with pharmaceutical synthetic cannabinoids or cannabinoids-derived products. To advance the field, we need to catch up with science, regulation, and, very important, education for healthcare providers, including physicians, pharmacists, nurses, and others. 

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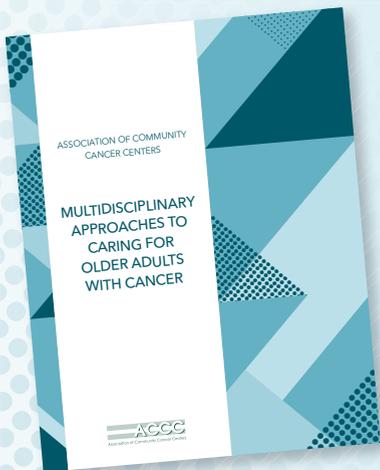
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Five Key Strategies to Improve Your Pharma Rep Education

In addition to providing the latest, most comprehensive information about drugs and technologies, pharma reps who visit your practice can share important updates about new drug regimens, protocols, labeling, indications, financial assistance programs, and clinical trials. Though many providers place moderate to severe access restrictions on visits from pharmaceutical reps, others who are challenged to keep up with new clinical advances amid increasing demands on their time find this education to be valuable—if done right. Here are five strategies to help improve the value of your pharma education.

1. Define Your Reps

The term *industry rep* is fairly nonspecific because it includes pharma and biotech reps, device reps, lab reps, and service reps. Within those categories are physicians working as medical science liaisons, nurses working as nurse educators, and others serving as reimbursement specialists or account executives. Every practice is unique; thus, to realize value from your pharma rep education, consider what strategic additions they can offer your team. Your practice's specific needs or questions should dictate which of these individuals have access to physicians and staff. To help in this effort, develop and maintain an accurate database of contact information, including each rep's full name, title, company, products, phone number, and email, to allow for instant access whenever a question or issue arises.

2. Create a Pharma Rep Policy

A defined, transparent policy communicates to reps what information is most important to your practice. The policy details what information is needed, when it is needed, and how frequently reps are able to meet with physicians and staff. It clearly outlines parameters, expectations, and limitations. An effective rep policy should contain the following elements:

- A description of why your providers and staff see pharma reps; for example, to learn about new indications and U.S. Food and Drug Administration-approved data or research or to learn about available and/or upcoming clinical trials.
- The specific type of reps your practice allows to visit; for example, nurse educators or reimbursement specialists.
- How reps can schedule appointments at your practice.
- Areas of the practice that are restricted to reps, such as exam rooms, nursing stations, waiting rooms, and labs.
- Whether the practice allows reps to bring food and, if so, information on food allergies, preferences, and spending restrictions per person.
- How and when reps can provide drug samples.
- Consequences for not following the rep policy.
- Restrictions on patient contact, such as prohibiting reps from observing or having direct contact with patients at all times.

3. Leverage Technology

Many practices cite administrative burden as one of the biggest barriers to effective pharma rep visits, yet tools exist that can help practices remove that barrier. For example, our online tool, RxVantage, allows practices to create meeting slots that reps self-schedule. The platform automatically enforces visitation policies, and your practice controls how often each type of rep may book appointments. Additionally, your physicians and staff can access a digital rep directory and instantly message the appropriate pharma rep whenever a question or concern arises. Leveraging this type of technology frees up front office staff to focus on patient-related tasks and will make rep visits to your practice more productive for your physicians and staff.

4. Incorporate Best Practices for Conducting Meetings

Proven methods from other industries can help practices increase both the productivity of pharma rep meetings and the quality of education. For example, require reps to submit topics in advance of meetings to ensure that your providers receive relevant education, supplemental materials, and research that is based on clinical studies and evidence-based medicine. With advance notice of the education your providers want or the challenges they face with a specific product, reps can gather and provide relevant, U.S. Food and Drug Administration-approved information up front instead of having to follow up on requests after the meeting. Designate someone to take notes, or even record the presentation, to help share the information across the organization.

5. Create a Feedback Loop

Time is an incredibly valuable resource, and pharma rep meetings are only as helpful as the education and information presented. As such, practices should track and record the usefulness of each rep visit. Review this feedback regularly to ensure that time is well spent and that reps are providing value. As appropriate, share feedback with reps to encourage collaboration. Communication is key in any relationship, so letting your pharma reps know what is and is not working will help establish a mutually beneficial relationship.

Mal Milburn is business development director-oncology at RxVantage, a free, cloud-based solution that connects healthcare providers with life science experts and resources, when they need them, to improve patient care.

Making the Business Case for Hiring a Financial Navigator

By Lori Schneider and Christina Fuller

In the U.S., cancer is one of the most expensive diseases to treat, second only to heart disease,¹⁻³ and cancer-related expenses are rising.⁴⁻⁵ In fact, cancer patients experience a higher out-of-pocket financial burden than those with other chronic diseases.⁶ For people with cancer, figuring out how to pay for treatment is one of their greatest concerns.⁷ As many as 47% of people with cancer in the U.S. report “catastrophic” levels of financial hardship.⁸ Today, even insured patients struggle to pay for cancer treatment, resulting in a condition termed “financial toxicity.”⁹ In a 2015 national census survey of cancer programs, 90% reported an increased need to help patients with co-pays or co-insurance; 82% reported an increased need by patients to better understand insurance; 79% reported an increase in the number of under-insured patients; and 73% reported an increase in the number of patients needing help with their prescription drug expenses.¹⁰ To address these concerns many cancer programs have developed and implemented financial navigation programs.

THE PROBLEM

The number of insured patients is increasing, but these patients are paying more out of pocket for cancer care due to increased cost sharing. Insurers have shifted some of the cost burden to patients through higher deductibles and increased co-payments and co-insurance, resulting in higher out-of-pocket expenses.^{11,12} One study of 254 insured cancer patients found that 75% applied for drug co-payment assistance, 42% reported a significant or catastrophic financial burden, 68% cut back on leisure activities, 46% reduced spending on food and clothing, and 46% used savings to defray out-of-pocket expenses; to save money, 20% took less than the prescribed amount of medication, 19% partially filled prescriptions, and 24% avoided filling prescriptions altogether.⁹ Another study found that the financial toxicity resulting from the high cost of cancer care is almost as deadly as cancer itself, with cancer patients going bankrupt nearly 80% more likely to die than patients who avoid bankruptcy.¹³ This study also found that certain cancers had significantly higher mortality rates; prostate cancer patients who filed for bankruptcy were almost twice as likely to die and bankrupt colorectal cancer patients were 2.5 times more likely to die compared to patients not facing bankruptcy.¹³ A large study of 19.6 million cancer survivors found that 28.7% of cancer survivors reported financial burden, and financial burden was associated with lower physical and mental functioning scores, as well as depressed mood and concern for cancer recurrence.¹⁴

THE SOLUTION

Financial navigators employ a proactive approach with patients and families, sharing out-of-pocket costs, screening for financial stressors and barriers, and identifying resources to help reduce patient financial toxicity. Leveraging shared-decision making, financial navigators, social workers, providers, patients, and families can work together to determine a treatment course that will not only best meet the patient’s needs

but also look to reduce costs.¹⁵ In addition to reducing financial toxicity and stress for patients and families, effective financial navigation can protect the revenue stream of the cancer program by optimizing reimbursement and reducing patient debt and charity write-offs.¹⁶⁻¹⁸ Developed by an Expert Advisory Committee of experienced financial navigators and cancer program leaders, ACCC's Financial Advocacy Guidelines provide rationale and strategies for building an infrastructure for comprehensive financial navigation services.¹⁹

REDUCING PATIENT FINANCIAL TOXICITY & PROTECTING THE CANCER PROGRAM'S BOTTOM LINE

The key to successful financial navigation is early intervention. A widely accepted model of financial navigation has two key components: 1) optimizing health insurance coverage and 2) optimizing external assistance programs.²⁰ This model can help reduce patient financial toxicity and ensure the cancer program is able to collect on services provided.²⁰

Financial navigators can work closely with social workers, nurses, and other staff to ensure that patients schedule all the necessary appointments, have transportation to and from appointments, and are connected to resources to help with everyday bills.¹⁸ Financial navigators can also work with physicians to develop and update disease-specific clinical pathways to be consistent with NCCN guidelines and to document treatment standardization for payers.¹⁸

Financial navigators carry out many tasks that can help reduce financial toxicity, including:^{16,18,21}

- Working with patients to optimize insurance, researching additional Medicare program assistance, and enrolling eligible patients in Medicaid.
- Verifying current insurance coverage, including out-of-pocket costs, deductibles, and/or coinsurance.
- Providing patients and families an overview of their treatment costs.
- Identifying available co-pay, foundation, and pharmaceutical assistance and helping patients enroll in the appropriate program(s). This could include completing and submitting applications to determine eligibility and submitting charges to programs on behalf of patients. Access to co-pay and financial assistance helps patients feel supported and confident, provides hope, and reduces psychological stress.²²
- Acting as the patient's direct point of contact for all insurance and billing concerns.

Financial navigation is not only a service to assist the patients; it also guarantees that the cancer program is going to get paid for services rendered. Financial navigators can perform medication, radiology and imaging, and molecular lab testing pre-authorizations to verify coverage and reimbursement, protecting patients from unnecessary costs and the cancer program from incurring possible bad debt or charity write-offs.¹⁸

To help mitigate risks related to financial toxicity (bad debt, charity write-offs, etc.), cancer programs should initiate cost-of-care discussions with patients and offer education on how to develop an economic game plan to reduce potential financial-related burden.^{21,23}

Financial navigators can help strengthen your cancer program's bottom line. For example, navigators at one large physician practice leveraged EHR technology to 1) capture patients at the time an order is placed; 2) establish communication with patients; 3) follow up on patient accounts; and 4) track billing to co-pay assistance programs and foundations.²⁴ In one year, financial navigators tripled patient enrollment in co-pay and foundation assistance programs, helping to reduce patient expenses by \$4.1 million dollars.²⁴

DEMONSTRATING THE ROI OF FINANCIAL NAVIGATORS

Mosaic Life Care Medical & Radiation Oncology, St. Joseph, Missouri, uses this formula to demonstrate ROI (return on investment) of its financial navigators:

$$\frac{\text{Revenues from Investment} - \text{Cost of Investment}}{\text{Cost of Investment}} \times 100 = \text{ROI} (\%)$$

In FY 2017-2018, this program brought in more than \$1 million from co-pay assistance and free drug programs. Subtracting the salary of its oncology financial navigator (\$30,000) brings this amount to \$970,000. After dividing \$970,000 by the salary (\$30,000) and multiplying by 100, this program saw an ROI of 3,233% from its financial navigator. In FY 2018-2019, assistance from co-pay assistance and free drug programs was \$1.5. Following that same formula, the ROI of its financial navigator is 4,900%.

CASE STUDY ONE²⁵

The Cowell Family Cancer Center at Munson Healthcare, Traverse City, Mich., has operated a financial navigation program since 2013. The program's two financial navigators conduct insurance optimization, assist with insurance and other program enrollment, and seek out alternative forms of

financial assistance through foundations and free drug programs. The navigators serve 20% of the patient population and secure an estimated \$4 million in aid each year. The cancer center uses a financial navigation platform that automates and streamlines the financial navigation process. During an eight-month pilot of this platform, the cancer center found that of the 244 patients who received financial navigation services, 74% received one or more forms of assistance. Financial navigators secured a combined total of \$3.5 million in “approved savings” (defined as the total value of aid secured through the financial navigation process); \$1.5 million of this savings accounted for community benefit (defined as direct patient benefits, such as aid to offset living expenses, transportation costs, provide free or replacement drugs, or aid for services that are not billed by the hospital, such as oral drugs); and \$260,000 contributed to revenue increase (a direct benefit to the cancer center).

CASE STUDY TWO¹⁷

After a six-month financial navigation pilot, Lacks Cancer Center, Grand Rapids, Mich., saved more than \$265,000 and decreased out-of-pocket patient expenses by more than \$700,000, the cancer center approved an FTE financial navigator. During the subsequent three years, the cancer center’s health system achieved the following outcomes:

- Year 1: 218 patients received navigation services, reducing out-of-pocket responsibility for patients by more than \$2.6 million and saving the hospital system more than \$1 million in reduced charity and bad debt.
- Year 2: 168 patients received navigation services, and a second .8 FTE financial navigator was hired. Out-of-pocket responsibility for patients was reduced by more than \$4 million and saved the hospital system \$2.5 million in reduced charity and bad debt.
- Year 3: 211 patients received navigation services, reducing out-of-pocket responsibility for patients by more than \$5 million and saving the hospital system \$3.7 million in reduced bad debt and charity.

CASE STUDY THREE²¹

Akron General Medical Center, McDowell Cancer Center, Akron, Ohio, developed a unique patient navigation program, which reduced psychosocial distress, secured \$1.35 million in direct financial assistance to patients that would otherwise not have been available, and reduced institutional bad debt. At the cancer center a two-person team: a resource counselor (an oncology social worker) and a reimbursement specialist work

together to meet the psychosocial and financial needs of its cancer patients. The reimbursement specialist conducts a benefits investigation for all new patients prior to the start of treatment; all patients also complete the National Comprehensive Cancer Network (NCCN) Distress Thermometer. The resource counselor uses these data to conduct a brief psychosocial assessment—also prior to initial therapy. For patients with more complex needs, the resource counselor completes a comprehensive psychosocial assessment. Patients are assigned a case-complexity rating to help with monitoring and ongoing follow-up. The resource counselor closes the loop by providing immediate and long-term intervention(s) or making the appropriate referrals to address identified needs.

IMPLEMENTING A FINANCIAL NAVIGATOR POSITION

Once you’ve made the decision to hire a financial navigator, be sure to provide this new FTE with the tools and resources to succeed. A good first step is to take the ACCC Financial Advocacy Boot Camp modules, a dynamic online curriculum that financial navigators can take at their own pace to acquire key knowledge and skills in areas like enhancing communication with patients and other members of the clinical team; improving insurance coverage; and maximizing external assistance (accc-cancer.org/FANBootcamp). The Bootcamp teaches a shared decision-making approach that takes into account the risks, benefits, and alternatives to the available treatments or procedures and seeks to balance the physical (e.g., transportation to visits, length of time spent at clinics), financial (patient out-of-pocket costs), and physiological (side effects) burdens associated with cancer treatment.

As stated previously, responsibilities of the financial navigator are two-fold: 1) helping uninsured and underinsured patients access available resources and 2) protecting the cancer program’s revenue.¹⁶ While financial navigator tasks and responsibilities are dependent on the unique needs of the specific patient population and cancer program, key responsibilities could include:^{16,18,21}

- Insurance verification and optimization
- Cost of care estimates, including out-of-pocket costs to patients
- Screening to identify unmet financial needs
- Referral to other services as needed (i.e., social work, psychosocial)
- Enrollment assistance for co-pay, pharmaceutical, and foundation assistance programs
- Prior-authorization screening and tracking

- Verification of pathway compliance
- Compliance check for medical necessity
- Collection of supporting evidence-based literature and inclusion in the medical record
- Coverage denial appeals support
- Off-label use support. ●

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A publication from the 2019 ACCC Institute for the Future of Oncology: Collaborate. Educate. Compensate. A Prescription for Sustainable Cancer Care Delivery.

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

The ACCC Financial Advocacy Network is the leader in providing professional development training, tools, and resources to proactively integrate financial health into the cancer care continuum and improve patient access to care for a better quality of life.

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Making the Business Case for Hiring a Registered Dietitian Nutritionist

Suzanne Dixon, MPH, MS, RDN; Gretchen Gruender, MS, RDN, CSO; Kelay Trentham, MS, RDN, CSO, FAND; and Elaine Trujillo, MS, RDN

Nutrition plays a critical role in cancer prevention, treatment, and survivorship, and the registered dietitian nutritionist (RDN) is an integral member of the multidisciplinary cancer care team. RDNs help educate patients and the public about nutrition before, during, and after a cancer diagnosis. RDNs provide healthy eating tips for cancer prevention; educate patients on strategies for eating well and managing side effects during treatment; and provide nutritional strategies to address late effects of cancer and its treatment and to prevent cancer recurrence.

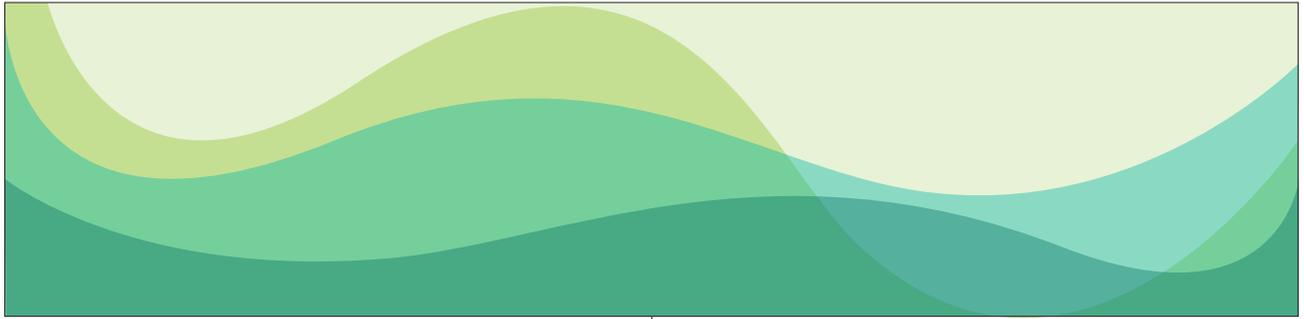
THE PROBLEM

Up to 80% of all cancer patients develop clinical malnutrition at some point in their treatment, with more than half exhibiting nutritional impairments at their first oncology visit.¹⁻⁵ In fact, an involuntary weight loss of just 5% of body weight decreases survival in cancer patients.⁶⁻⁷

The side effects and toxicities from cancer treatments, such as chemotherapy, radiation, and surgery, as well as anorexia, fatigue, and impaired metabolism can lead to poor nutritional status and malnutrition. Poor nutritional status is associated with decreased tolerance to chemotherapy and radiation treatment in adult oncology patients.⁸ Cancer patients who experience weight loss have more treatment breaks, experience more severe side effects from their treatment, and require more and longer hospitalizations; those who maintain their weight and nutritional status experience fewer therapy and treatment breaks.⁹ Additionally, malnutrition is associated with lower quality of life (QOL), and higher morbidity, mortality, and other variables that increase the cost of oncology care.^{4, 6-7, 10-14}

THE SOLUTION

Early and timely nutrition intervention, nutrition counseling, and appropriate use of nutrition supplementation is cost effective and can result in positive patient outcomes,¹⁵ including reducing or eliminating the side effects of therapy.¹⁶ The Academy of Nutrition and Dietetics Oncology Evidence Analysis project recommends that cancer patients be screened regularly for malnutrition, and, if indicated, provided medical nutrition therapy with individualized nutrition assessment, prescription, and counseling as the first line of nutrition intervention.¹⁷ Access to an RDN with experience in oncology nutrition, medical nutrition therapy, and symptom management can help patients maximize nutrition, maintain functional status, and protect QOL.¹⁸



IMPROVING QUALITY OF CARE & REDUCING HEALTHCARE COSTS

According to the National Cancer Institute, early screening and comprehensive assessment of risk for malnutrition is increasingly recognized as imperative in the development of standards for quality of care in oncology practices.¹⁹ Patient-centered care recognizes that treating patients for cancer requires adequate nutrition to help patients:¹⁸

- Tolerate prescribed treatment
- Avoid complications
- Maintain functional capacity
- Heal from their treatment
- Protect quality of life.

The goal of nutrition screening is two-fold: 1) early identification of malnourished and at-risk individuals in need of nutrition-related interventions; and 2) generation of comprehensive nutritional assessment by a trained nutrition professional, such as an RDN, to include ongoing monitoring for optimal clinical outcomes.²⁰⁻²¹

Medical nutrition therapy and nutrition interventions that actively manage preventive and secondary causes of anorexia and target maximizing food intake are integral in multimodal therapy. Such inclusive therapies are shown to improve QOL and tolerance to cancer treatments.²² Nutrition counseling, controlled use of oral nutritional supplements, and appropriate utilization of tube feeding are associated with prevention and reduction of malnutrition in oncology patients.²³

Access to an RDN and nutritional support has also been shown to improve the experience of patients treated with surgery; pre-operative nutritional support helps to maintain proper nutritional status and reduce the number and severity of post-operative complications compared to patients without such support.²⁴

The negative medical and financial impacts of malnutrition are significant. Compared to well-nourished patients,

malnourished patients have been shown to have longer hospital stays and were more likely to be readmitted within 15 days.²⁵ Conversely, implementation of a dietitian-led nutrition support clinic can lead to improved QOL, as well as reductions in hospital readmissions, tube-related complications, and healthcare costs.²⁶

CASE STUDY ONE²⁷

Establishment of a weekly nutrition clinic at Beaumont Cancer Institute, Royal Oak, Mich., had a positive impact on patient QOL, improved patient education efforts, and reduced the cost of care. The success of this nutrition clinic allowed the department of radiation oncology to incorporate a permanent dietitian into the program. This staff member addresses the needs of head and neck cancer patients, and also provides services to other patients who can benefit from continual education about nutritional health during treatment. Today, Beaumont Cancer Institute continues to support nutritional consultations for all its multidisciplinary clinics, as well as other educational opportunities, such as cooking classes and resources for picking healthy options while grocery shopping.

CASE STUDY TWO²⁸

Telehealth has transformed the way RDNs provide nutrition counseling. Baton Rouge General Medical Center Pennington Cancer Center, Baton Rouge, La., developed a model where its dietitians use virtual counseling to provide medical nutrition therapy. Telehealth nutrition counseling sessions take place while the patient is at the cancer center and/or radiation oncology center for treatment, eliminating patients having to schedule additional appointments to see an RDN. Most patients (95%) found the telehealth program beneficial and 84% of patients preferred telehealth visits to on-site visits.

REIMBURSEMENT & BILLING

Medical nutrition therapy (MNT) is evidence-based intervention provided by RDNs to prevent, delay, or manage diseases and conditions; nutrition education counseling and counseling are components of MNT. There is reimbursement (fee-for-service) for MNT in the outpatient setting, as well as revenue streams in value-based payment arrangements that could be allocated for an RDN to provide MNT. Since 2013, there is coverage and payment for a broader range of conditions, including oncology.²⁹ According to the National Business Group on Health, “Benefit plans should provide coverage for nutrition counseling and medical nutritional therapy for individuals with a diagnosis of cancer. Provider network should include registered dietitians, including registered dietitians who are Board-certified specialists in oncology (CSO).”³⁰ Some states include MNT benefits for Medicaid enrollees.

Cancer programs can use medical necessity requests to improve access to care when a patient’s policy includes a benefit for MNT but does not specifically include cancer-related diagnoses or associated complications.³¹ Completing a medical necessity request also allows providers the opportunity to have initial and follow-up visits considered in one request; approvals improve access to care and reduce work associated with denied claims.

While Medicare Part B (outpatient) includes a benefit for MNT for only three conditions: diabetes, chronic kidney disease, and kidney transplant, many beneficiaries enroll in Medicare Advantage plans, which can offer additional benefits that could include coverage for MNT for other diagnoses, including cancers. More than 20 million Medicare beneficiaries (34%) were enrolled in Medicare Advantage plans in 2018.³² Three Current Procedural Terminology (CPT®) codes are used to submit claims to payers or to track encounters using statistical claims; these codes are also used when MNT is delivered via telehealth:

- **97802:** MNT; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes.
- **97803:** MNT; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes.
- **97804:** MNT; group (2 or more individuals), each 30 minutes.

ALTERNATIVE PAYMENT MODELS & VALUE-BASED PAYMENTS

MNT is a cost-effective intervention that cancer programs can leverage in the context of alternative payment models and value-based payments to improve care, decrease avoidable costs, and overcome barriers to nutrition care inherent in fee-for-service. Ideally, the cost of providing MNT is factored into the total cost of care in these contracts. Efforts are underway at various provider organizations, including ACCC, to ensure that MNT is included in whatever bundled payment methodologies are developed by public and private payers to reimburse for comprehensive cancer care services.

TIPS FOR ESTABLISHING A FINANCIALLY VIABLE NUTRITION PROGRAM

1. Collaborate with an RDN to launch or grow your outpatient nutrition program.
2. Engage and collaborate with internal key players and departments, including all relevant stakeholders (e.g., contracting, billing, providers, medical assistants or other personnel), when exploring and implementing nutrition services.
3. Credential RDN with payers, as appropriate.
4. Confirm provider agreements include MNT CPT codes, as well as the provision for MNT provided via telehealth, if applicable. To understand the telehealth landscape in your state visit telehealthresourcecenter.org.
5. Review payer medical policies/guidelines and billing guidelines for nutrition counseling.
6. Check MNT benefits for every patient before providing care.
7. When developing alternative or value-based payment models, allocate a portion of these payments to MNT.
8. Consider self-pay and/or financial assistance for nutrition counseling.
9. Consider grant funding, if applicable. Some cancer programs offer nutrition counseling to patients at no or reduced cost through special programs; consult with your compliance experts to determine if this is possible in your care setting.
10. Build nutrition outcome measures into your program. Identify outcomes meaningful to patients, providers, and payers and use these data to evaluate the return on investment of MNT.

For the oncology dietitian, additional resources related to payment can be found at eatrightpro.org/payment. Another resource for local information is the Academy of Nutrition and Dietetics' state reimbursement representative. ●

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Making the Business Case for Hiring a Board-Certified Genetic Counselor

By Stephanie A. Cohen, MS, LCGC

As many as 5% to 10% of all cancers are hereditary; some cancer types, such as ovarian cancer, have an even stronger association. Individuals with a hereditary cancer predisposition may face a high lifetime risk of cancer, may be affected at a younger age, and may have associated cancers that are more aggressive. Identifying these individuals can improve surveillance and preventive efforts, ultimately saving lives.¹ Today, genetic counseling is a key service along the entire cancer care continuum, from prevention to screening to treatment and into survivorship.²

THE PROBLEM

The National Comprehensive Cancer Network (NCCN) and the U.S. Preventive Services Task Force (USPSTF) provide criteria for genetic testing referrals.^{3,4} Unfortunately, studies suggest that more than half of patients who qualify for genetic counseling are not referred to these services and/or do not get offered genetic testing.^{5,6} One barrier is the lack of physician knowledge about genetics and comfort with ordering and interpreting genetic tests.⁷ Interpretation of test results can be complicated; interpretation errors have resulted in inappropriate surveillance and management, and, in a few extreme cases, inappropriate prophylactic surgery.^{8,9}

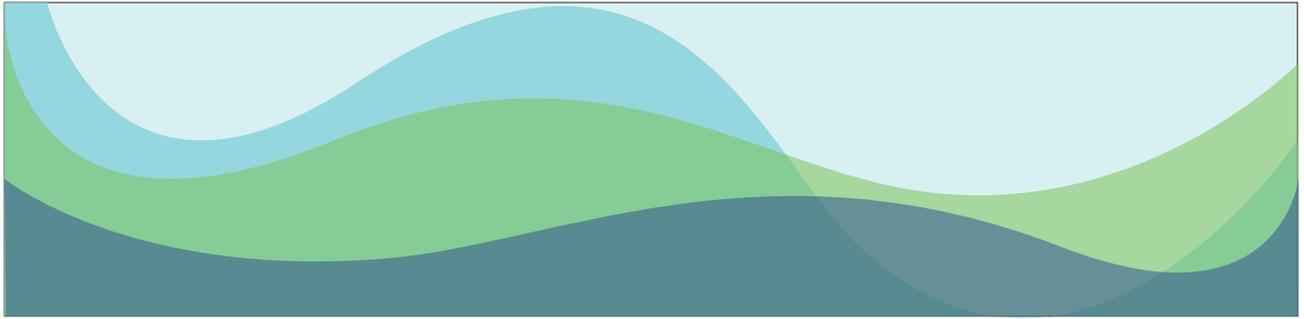
THE SOLUTION

Adding a genetic counselor to your cancer care team can help ensure that the appropriate patients have access to appropriate genetic testing and follow-up care.^{10,11} Genetic counselors are healthcare providers uniquely trained to:

- Assess risk for cancer based on personal and family history
- Help patients understand their testing options
- Facilitate appropriate genetic testing
- Discuss how results can be used for medical management according to national guidelines
- Help physicians incorporate genetic test results into a patient's care plan
- Provide long-term follow-up and tracking for changes in variant interpretation and surveillance recommendations.

IMPROVING QUALITY OF CARE & REDUCING HEALTHCARE COSTS

Access to a genetic counselor can improve patient health outcomes, increase patient satisfaction, avoid unnecessary costs, and decrease liability. Specifically:



- A genetic counselor can ensure that the appropriate tests are ordered; errors can occur in the absence of a genetic counselor.¹²⁻¹⁵
- Individuals who are identified with a pathogenic variant in a hereditary cancer gene may be able to extend their life expectancy and reduce their cancer risk through chemoprevention and/or prophylactic surgery.^{16,17}
- Use of breast MRI among women with a BRCA mutation aids with early detection and potentially saves cancer treatment costs and lives.¹⁸
- At-risk patients need to adhere to guidelines. Without a program to manage and follow these individuals, many patients fail to take advantage of evidence-based information that may assist with cancer prevention and early detection.¹⁹
- Patients with a cancer diagnosis have opportunities for different treatments and/or clinical trials.²⁰⁻²²
- Cascade testing of affected relatives can help identify at-risk individuals before they get cancer, resulting in improved outcomes such as lower cancer incidence, saved treatment costs, and saved lives.²³⁻²⁷

PROGRAMMATIC BENEFITS

Increased surveillance and preventive measures for individuals with a hereditary cancer predisposition can produce downstream revenue for the hospital system. This additional revenue can be used to support hiring staff. It has been estimated that for every patient found to carry a pathogenic variant in a hereditary cancer predisposition gene, approximately four additional family members are also carriers.²⁸ Downstream revenue is estimated to provide at least a 1.69-fold return on investment, when considering individuals identified with hereditary breast syndrome, ovarian cancer syndrome, and Lynch syndrome.²⁹ Other programmatic benefits genetic counselors offer include the ability to:

- Educate patients so that they can make more informed

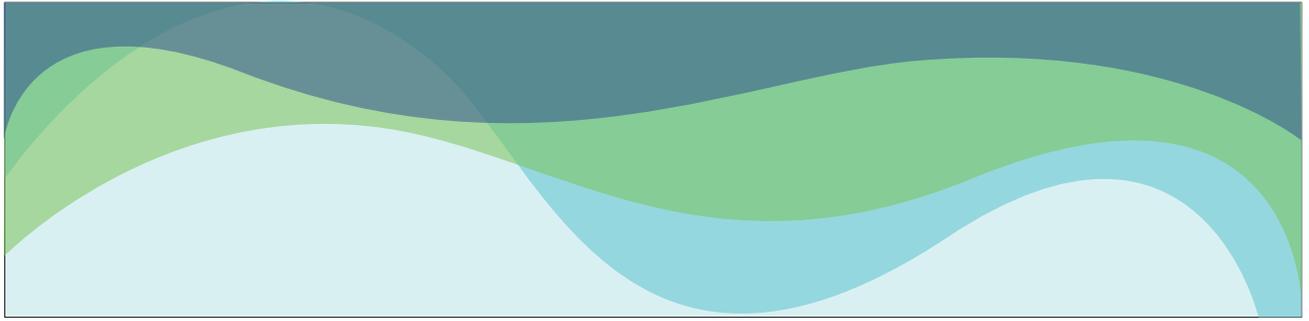
healthcare decisions, improving patient engagement and satisfaction.³⁰

- Educate physicians so that they can use genetic information to best treat their patients.
- Ensure that quality genetic testing is provided to the right patient using the right test in a high quality laboratory, and that results are interpreted accurately.¹¹
- Provide appropriate long-term follow-up for patients and their family members.
- Track patients over time, contribute to the collection of program metrics, and participate in quality improvement initiatives.
- Support Commission on Cancer (CoC) requirements.
- Help differentiate a cancer program from its competitors and enhance the cancer program's reputation within the physician and at-large community.

IMPLEMENTATION CONSIDERATIONS

Establishing a cancer genetics risk assessment program requires an investment of time and resources, and physician support is critical to success of the program.³¹ Not every program will look the same, due to different resources, clinic set-ups, and staffing. Clinical and programmatic components to consider when establishing a successful cancer genetics risk assessment program include:

1. Patient identification
2. Physician referrals
3. Physical space and/or telemedicine equipment to provide pre/post-test genetic counseling
4. Physical space for provider offices
5. Front office support for scheduling, insurance authorization, and clerical work
6. Access to EHR and technology support for telehealth equipment
7. Documentation of the cancer genetics consult
8. Patient billing



9. Financial support for staff (including licensure, credentialing, membership fees, and continuing education)

Genetic counseling and testing services do not have to be provided in a traditional in-person model. Several different service delivery models are in use across the country, including telephone, group, and web-based/telemedicine genetic counseling.³²

CASE STUDY: USING DATA TO JUSTIFY HIRING A GENETIC COUNSELOR

Step 1: Calculate expected patient volume. Collect data on your annual breast, ovarian, prostate, pancreatic, and colon cancer cases and estimate the number who are eligible for genetic counseling and/or testing. Approximately 5% to 10% of all cancers are hereditary, or more specifically, consider all diagnoses that will need genetic counseling and/or testing, for example breast cancers diagnosed at or under age 50. Collect data on your mammogram and colonoscopy volume. Approximately 5% to 10% of patients seen in a mammography unit³³⁻³⁴ and 14% of patients seen in a colonoscopy suite are considered high risk³⁵ and would benefit from a genetics evaluation.

Step 2: Estimate downstream revenue. Approximately 10% of patients tested will have a positive result. As many as four (potentially healthy) relatives of a gene-positive patient will also test positive, requiring additional surveillance and/or prophylactic surgery.²⁹ One study found that almost 30% of women with a BRCA mutation had an MRI within 1 year of testing, almost 80% had a mammogram, and just over 20% had mastectomy.³⁶ Individuals with Lynch syndrome need a colonoscopy every 1 to 2 years and women should consider prophylactic TAH-BSO.³⁷

Step 3: Estimate cost savings. For BRCA mutation carriers, prophylactic surgery can reduce breast cancer risk

by 85% and ovarian cancer risk by 69% to 100%.³⁸ For Lynch syndrome carriers, hysterectomy and bilateral salpingo-oophorectomy can reduce risk for endometrial and ovarian cancer by up to 100%.³⁹

Step 4: Estimate revenue generated from billing genetic counseling appointments.

Step 5: Calculate the estimated programmatic costs. These include genetic counselor salaries⁴⁰; support staff salary; physical space and overhead; and CE, licensing fees, and membership dues for clinical staff.

Using the above process and based on 25 patients with BRCA1/2 and 10 with Lynch syndrome from 2013 to 2014, one health-care system calculated a total downstream revenue of \$757,641 (\$16,836 per patient), and estimated a \$2,371,402 cost savings from cancer prevention due to prophylactic surgeries.³⁰

BILLING & REIMBURSEMENT

There is a billing code specifically for genetic counselors to use when providing genetic counseling services, although challenges do exist. Many private payers will reimburse the CPT code 96040 (per 30-minute unit). This can be billed as a professional fee or as a facility fee, depending on the location of the provider. While Medicare does not yet recognize genetic counselors as healthcare providers, there is a proposed bill at the Federal level to reimburse genetic counselors at 85% of the physician fee schedule ([nsgc.org/p/cm/ld/fid=612](https://www.nsgc.org/p/cm/ld/fid=612)). In the meantime, programs may consider charging a reduced “cash” fee for Medicare recipients or applying for grant funding to cover the cost of a genetic counseling visit. Each cancer program will need to determine the most appropriate billing model for its given situation, based on institution-specific credentialing guidelines, types of providers and payers, and/or state licensing requirements. ●

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Website: augonc.com

The Cancer Center of Hawaii

Honolulu, Hawaii
Delegate Rep: Carolyn Voulgaridis, BSN, JD
Website: tccoh.com

Hawaii Pacific Health

Kapi'Olani Medical Center

Honolulu, Hawaii
Delegate Rep: Elizabeth Wright, DNP, MSN, RN, OCN
Website: hawaiiapacifichealth.org/kapiolani

Hawaii Pacific Health

Pali Momi Medical Center

Aiea, Hawaii
Delegate Rep: Elizabeth Wright, DNP, MSN, RN, OCN
Website: hawaiiapacifichealth.org/pali-momi

Hawaii Pacific Health

Straub Medical Center

Honolulu, Hawaii
Delegate Rep: Elizabeth Wright, DNP, MSN, RN, OCN
Website: hawaiiapacifichealth.org/straub

Hawaii Pacific Health

Wilcox Medical Center

Lihue, Hawaii
Delegate Rep: Elizabeth Wright, DNP, MSN, RN, OCN
Website: hawaiiapacifichealth.org/wilcox

Intermountain Healthcare

Intermountain Cancer Center

Salt Lake City, Utah
Delegate Rep: Craig Nielsen, MBA, BSRT(T)
Website: intermountainhealthcare.org/services/cancer-care

Kaiser Permanente Washington

Seattle, Wash.
Delegate Rep: Kathy Kronmal, BSN, MBA
Website: wa.kaiserpermanente.org/html/public/specialties/cancer

Mercy Health

Anderson Hospital

Cincinnati, Ohio
Delegate Rep: Elaine Wiseman
Website: mercy.com/locations/hospitals/cincinnati/mercy-health-anderson-hospital

Mercy Health

Clermont Hospital

Batavia, Ohio
Delegate Rep: Elaine Wiseman
Website: mercy.com/locations/hospitals/cincinnati/mercy-health-clermont-hospital

Mercy Health

Springfield Regional Medical Center

Springfield, Ohio
Delegate Rep: Pilar M. Gonzalez-Mock, RN, MS
Website: mercy.com/locations/hospitals/springfield/springfield-medical-center

Pardee Hospital

Pardee Cancer Center

Hendersonville, N.C.
Delegate Rep: Carol Brown, CTR, ABA
Website: pardeehospital.org/care-treatment/cancer

ACCC Surgical Oncology Pre-Conference

On March 4, 2020, attendees at the ACCC 46th Annual Cancer Center Business Summit had the chance to attend one of two pre-conferences. Here are highlights from the Surgical Oncology Pre-Conference.

Increasing the number of subspecialists (e.g., breast surgeons, gynecologic oncologists) was identified as the top opportunity to realize cancer program return on investment (ROI) by respondents to ACCC's 2019 *Trending Now in Cancer Care* survey. This pre-conference explored what achieving ROI may entail with sessions on effective models for integrating surgical oncology services into freestanding practices and hospital-based cancer programs.

Loren Rourke, MD, MHCM, FACS, and Lawrence D. Wagman, MD, FACS, FPCS (hon), level-set the discussion by delineating the commonalities and differences between surgical oncology and medical oncology services. Dr. Rourke, chief surgical officer, US Oncology,

and Dr. Wagman, surgical oncologist, City of Hope, Upland, and regional medical director for the Inland Empire, helped to plan the day's agenda.

Among the considerations regardless of care setting:

- Program/practice marketplace: What is needed in your community? Where are there gaps in care or expertise?
- Physician champion: Do you have physician leadership buy in?
- Recruitment: What are the oncologic surgeon skill sets needed and what care gaps will you fill?
- Infrastructure: Understand the needs of surgical oncology services and assess whether your program is adequately resourced.
- Marketing: How will you spread the word about your surgical oncology services?

As a first step, Dr. Wagman advised, “See what you need, see what your resources are, and see what you can do with what you have.” Pre-conference presentations demonstrated that ROI will come, but integrating surgical oncology services is not a simple or fast process and requires multifactorial assessment. The investment yields multiple benefits. “Bringing services together is beneficial from the patient quality perspective. It’s good for patients and for physicians,” Dr. Wagman said, citing the benefits of streamlined access to care and multidisciplinary collaboration.

The process of bringing these specialties together is much easier when physicians are employed than practicing in the community, noted Dr. Rourke. Areas of overlap between specialties can be a prickly issue. In sorting this out, “there is no right or wrong answer”; however, she emphasized, “These conversations have to take place upfront.”

Lucy Langer, MD, president, Compass Oncology, a 40-physician practice, shared steps for effective integration of surgical oncology services into an independent freestanding practice. In today’s turbulent healthcare landscape, top-of-mind concerns, Dr. Langer said, are how to survive the multiple pressures exerted on practices and ensuring the practice’s future viability.

Diversifying the practice’s portfolio by bringing surgeons on board is one strategy for addressing viability, Dr. Langer said. Cancer clinics considering this option need to proceed carefully to mitigate risk. This includes assessing patient volumes, practice infrastructure, and surgical oncologists’ practice needs and learning to “speak the same language,” she said. When a surgeon says, “I need a scheduler, it [means something] very different from a medical oncology scheduler.” This is just one example of the challenges of effectively integrating specialties with diverse processes and workflows.

When integration is done well, bringing surgeons into the practice offers the opportunity to partner with gynecologic oncologists and surgeons who are upstream, and also more effectively partnering with referral sources, she said.

Compass Oncology’s secret to successful integration? Dr. Langer shared the following tips:

- Bring surgeons into the practice as equals.
- Acknowledge the differences between medical and surgical oncology.
- Learn what your surgeons need and work to adapt quickly.
- Provide leadership opportunities for surgeons, including involvement in governance (e.g., a guaranteed seat on board).
- Acknowledge the challenges to getting the compensation formula “right” and have the flexibility to adjust.

Joseph J. Bennett, MD, FACS, chief of surgical oncology, Helen F. Graham Cancer Center & Research Institute, presented lessons learned

through development of a highly successful surgical oncology program within a hospital cancer center. As in the practice setting, the process begins with assessment, he said. “Do you need a surgical oncology program? What disease site will be your focus?”

Next, consider what your surgical oncologists want to do. These highly trained physicians want opportunities to use their specialized skill sets. At the same time, oncologic surgeons want to work in multidisciplinary care, Dr. Bennett said. “Surgical oncology is a team sport.”

Among the considerations and challenges that have to be resolved along the path to developing a successful surgical oncology service are the following:

- Employment model—Hospital-employed? Private practice? Hybrid?
- Infrastructure to support surgical oncology.
- Culture change for surgical oncologists—providers may feel threatened by the start of a surgical oncology program and a new model of integrated services.
- Referral patterns—navigating changes.
- Performance expectations—setting and maintaining these.
- Need to evolve.
- Recruitment of surgical oncologists.

Pre-conference presentations on integration of services across care settings demonstrated that ROI can be realized, but building a successful program takes time and commitment. Equally important to success in all settings: physician champions, supportive leadership, and patience.

Rounding out the pre-conference, Dr. Rourke focused the discussion on the role of surgical oncology in breast cancer. Referencing the surgical, medical, and radiation oncology pillars of cancer care and the need for coordination and integration of care delivery, she said, “The patient is sitting on a three-legged stool. If one leg isn’t working well, the patient falls off the stool.”

There is no one-size-fits-all solution to integration of breast surgeons into the cancer program, she said. “It depends on where you live, the market you’re in.” However, breast surgeon integration into the multidisciplinary cancer team is the new standard of care, Dr. Rourke emphasized.

“It’s less about who owns what in terms of continuum of care and more about can we get all these resources around the table [to benefit the patient],” she said.

“It takes a village to bring breast surgery into any environment—hospital-based or community cancer center. Breast surgeons are comfortable being part of the team. Not any one person makes this work, it’s administrators, clinicians, and staff all working together for the benefit of patients.”

ACCC Radiation Oncology Pre-Conference

From transitioning to value-based care to effectively onboarding new members of the care team, the ACCC Radiation Oncology Pre-Conference covered current and near-term challenges facing the field of radiation oncology. The half-day multi-session program was held in conjunction with the ACCC 46th Annual Meeting & Cancer Center Business Summit in Washington, D.C.

The pre-conference kicked off with in-depth look at current payment models in radiation oncology and discussion of anticipated changes to the Center for Medicare & Medicaid Services' (CMS) proposed Radiation Oncology (RO) Model. CMS released the proposed RO Model in July 2019, and the agency is expected to release the final RO Model this spring. Vivek Kavadi, MD, of US Oncology, reminded attendees that the start date for the final model is slated for July 2020—a mere four months away.

Given this “extremely aggressive timeline,” Dr. Kavadi encouraged hospitals and practices to waste no time preparing for the transition. He recommended that radiation oncology programs adopt a “guideline-driven” approach to their implementation of the RO Model so that it is applicable to all cancer types and can be better used as a vehicle to improve quality of care.

Presenter Amar Rewari, MD, MBA, a radiation oncologist at Adventist HealthCare, noted that CMS is looking to improve its prior authorization process, which will impact not only radiation oncology but also medical oncology and pharmacy. Prior authorizations can be the biggest challenge for radiation oncology providers in both non-academic and academic settings, he said. This aligns with ACCC's 2019 *Trending Now in Cancer Care* survey findings where 49 percent of respondents reported payer reimbursement requirements as leading the top five threats to cancer program growth and 48 percent ranked transition to value-based payment in second place. Many patients experience treatment delays due to unanticipated authorization issues, Dr. Rewari noted; automating the prior authorization process can help to streamline the workflow.

“With the transition to value-based care, documentation will be a key component,” he said. To prepare, he suggested that programs take an in-depth look at how the RO Model will potentially impact their practices or programs. Dr. Rewari stressed that automated documentation can enable a smoother auditing process, be used to help better determine payment rates, and be the ultimate justification for rate reviews.

Speaker Ed Kline, MS, CNMP, RT(N)ARRT, founder of RadPhysics Services LLC, addressed the importance of effective incident reporting systems in radiation oncology programs. Safety issues, he noted, are more prevalent in radiotherapy than in other specialties. Being able to promptly and efficiently register patient safety events gives programs the ability to respond swiftly when time is of the essence, said Kline. But the perfect should not be the enemy of the good: “Developing a culture that focuses on reducing risk rather than overemphasizing ‘zero’ harm goals will improve risk-related outcomes.”

Looking to the future Kline said that artificial intelligence and machine learning will be important in risk reduction. “Automation has the potential to predict high-risk error situations and can be built into already-established workflows, ultimately closing the gap in radiotherapy-related errors and injuries.” One of the current significant barriers to error reporting, added Kline, is fear of reprimand. Technologies like automation can take that issue out of the equation.

Presenting on how health system expansions, mergers, and acquisitions can affect the radiation oncology service line, Bryan Schmalhofer, MBA, RT(R)(T), identified the onboarding process as an area ripe for potential mismanagement if not handled well. “Onboarding already-established cancer centers into a new [health] system’s organizational culture, mission, and vision can be challenging and sometimes dysfunctional,” he cautioned. The key to managing this type of change, he said, is identifying physician champions who will encourage staff engagement and buy-in, particularly from providers.

When joining with or becoming part of another organization, breaking down the silos within and across the health system and promoting an openness to clinical differences is essential, said Schmalhofer. Organizational leadership that is willing to evaluate and take into account center-specific workflows, barriers, and staffing is likely to experience a smoother expansion or merger process. Recognizing and respecting each cancer center’s unique culture and workflow will help leadership better integrate new organizations into existing management structures. “The ‘mothership’ should not drive clinical workflows,” said Schmalhofer. “The ultimate goal is treating the patient, which takes a unique approach in each location.”

Continuing the discussion with a focus on patient-centered care, Toby Bressler, PhD, RN, OCN, shared the story of her program’s integration of an advance nurse practitioner role into the care team. “Radiation oncology nurse practitioners are the newest advance practice nurses in oncology practice,” said Dr. Bressler, director of nursing for oncology and clinical quality and assistant professor of medical oncology at the Icahn School of Medicine at Mount Sinai. With customized education and well-planned integration into the team—often overseen by a radiation oncologist or medical oncology nurse already with the practice—Dr. Bressler said that advance nurse practitioners can play a key role in coordinating care and promoting positive patient outcomes.

Dr. Bressler has implemented a program at Mount Sinai to onboard and educate nurse practitioners who have little to no prior clinical oncology experience. She emphasized that creating an individualized professional development plan for each nurse helps identify ongoing learning needs and sets individual expectations. At her program each nurse practitioner is given the goal of obtaining AOCNP certification. Today, said Dr. Bressler, the majority of the nurse practitioners in her program have successfully obtained certification on their first try.

Concluding the pre-conference, John Lefkus, president of RAD Technology Systems, focused on the challenges around keeping current with improvements in radiation oncology technology. As with the other pillars of cancer treatment, radiation oncology technology continues to evolve and improve. Keeping pace with advances can be costly, said Lefkus, and cancer centers can find themselves paying off a new linear accelerator long after the technology begins to age. However, there are alternatives to capital acquisition. Rather than making high-price tag investments in new tech, cancer centers can consider short-term solutions such as leasing options. “A temporary solution can have its advantages,” he said. “Using an operation

lease instead of a capital purchase can be a better choice.”

According to Lefkus, RAD Technology’s minimal and removable foundation system is an example of a type of temporary solution that can help cancer centers maintain patient capacity, mitigate staff loss, and create an easier conversion for future technologies. “Innovation in care does not require permanent concrete add-ons,” said Lefkus. “Temporary options can be just as beneficial.”

With the first RO Model around the corner and uncertainty clouding the reimbursement outlook, radiation oncology programs may want to investigate and expand on available options to support quality care delivery.

Highlights of the ACCC 46th Annual Meeting & Cancer Center Business Summit



More than 800 attendees from across the nation joined ACCC at the Washington Hilton in Washington, D.C., March 4-6, for a conference that explored the convergence of business, policy, and technology in cancer care. Attendees walked away with tangible takeaways to better develop and streamline their services, market their programs, and keep their costs in check.



Keynote speaker Susan Dentzer, Senior Policy Fellow at the Duke-Margolis Center for Health Policy, opened the meeting On Thursday, March 5, with an engaging address in which she discussed the technology and innovations that can improve the delivery of cancer care beyond hospital or practice walls. She demonstrated to attendees that the future of oncology

telehealth is already here, but barriers to access and innovation continue to stand in the way of realizing the power of technology to improve efficiency, reduce redundancies, and increase provider and patient satisfaction



After the opening keynote, Senator Debbie Stabenow (D-MI) (center) took to the podium. “For every one of us, healthcare is not political, it is personal,” she declared. Randall Oyer, MD (right), welcomed Senator Stabenow and was later sworn in as ACCC President 2020-2021.



Conference attendees mingled in the Exhibit Hall with more than 70 meeting sponsors and exhibitors who showcased their pharmacological, technological, and clinical innovations.

Highlights of the ACCC 46th Annual Meeting & Cancer Center Business Summit



With three-quarters of meeting respondents responding in live polling that they perceive our healthcare system “to be resting on shaky ground,” policy experts Kavita Patel, MD, MS, a non-resident Fellow in economic studies at the USC-Brookings Schaeffer Initiative for Health Policy and vice president of Johns Hopkins Medicine; Paul Edattel, principal of Todd Strategy, LLC; and Dennis A. Cardoza, director of public affairs at Foley & Lardner LLP, shared their views on how the November elections will (or will not) impact federal healthcare policy.



In Friday’s first session, Lori Marcus, the direct-to-patient workstream lead at the Kraft Precision Medicine Accelerator, and Anne Quinn Young, MPH, chief marketing and development officer at the Multiple Myeloma Research Foundation, described how the Kraft Precision Medicine Accelerator project—the product of a generous endowment to Harvard Business School by the Kraft family—aims to speed the development and delivery of precision medicine therapies and clinical trials.



At the March 6 ACCC House of Delegates meeting, delegate representatives from ACCC member programs listened to ACCC President Randall Oyer, MD (L), introduce the ACCC 2020-2021 President’s Theme: “Community Cancer Centers Can Close the Gap in Cancer Research: Here’s How.” Learn more at acc-cancer.org/president. Also pictured: ACCC Immediate Past President Ali McBride, PharmD, MS, BCOP.



Throughout the conference, attendees networked with one another and exchanged ideas in an effort to bring new solutions to their own practices and programs.

Highlights of the ACCC 46th Annual Meeting & Cancer Center Business Summit



An attendee asks a follow-up question about the Kraft Precision Medicine Accelerator's innovative crowdsourcing model for engaging patients with information on clinical trials.



Attendees learned what lies ahead for alternative payment models from an expert panel moderated by Alexis Finkelberg Bortniker, a partner at Foley & Lardner LLP. Panelists Anne Hubbard, director of health policy at the American Society for Radiation Oncology; Ted Okon, executive director of the Community Oncology Alliance; Lalan Wilfong, MD, vice president of Texas Oncology; and Dr. McAneny offered their retrospective thoughts on the Oncology Care Model, which is now winding down. Though everyone agreed that the model had its flaws, they also agreed that it had long-term, positive effects on the delivery of oncology care.



In the following session, a distinguished panel shared their insights into the crucial role that supportive services play in comprehensive cancer care. Panel members agreed that to achieve comprehensive, holistic, patient-centered care, a team-based approach includes all services listed in the ACCC Comprehensive Cancer Care Services matrix released at this meeting. Cancer practices and programs of varying sizes and resource levels can use this tiered matrix of recommendations to benchmark and advocate for service line growth. Provision of these key services can elevate patient care and the patient experience; reduce healthcare costs; improve care coordination; and help differentiate your cancer program in your marketplace. Download the matrix (acc-cancer.org/surveymatrix), share it with your team, and submit feedback on these recommendations to matrix@acc-cancer.org.



Closing out the conference, Debra Patt, MD, MPH, MBA, an executive vice president of Texas Oncology and editor-in-chief of *JCO Clinical Cancer Informatics*, encouraged attendees to use clinical decision support as a necessary “nudge” to clinicians to prescribe evidence-based treatment. “Oncology is a totally different field than it was just a decade ago,” said Dr. Patt. In an environment of more cancer subtypes, an increasing number of available treatments, new combined therapies, the treatment of cancer as a chronic disease, and spiraling costs, we need to make decision support as efficient and effective as possible.

views

Simple Talk

Support for families when a parent has cancer

BY SARAH JOHNSON, MSW, LICSW, OSW-C, AND ALI CAIN, MSW, LICSW, OSW-C

Allina Health is a nonprofit healthcare system in Minnesota and western Wisconsin consisting of 13 hospitals, 90 clinics, and various community-based services. The Virginia Piper Cancer Institute embodies whole-person care, one of Allina Health's core values. Our cancer program is dedicated to caring for patients' physical health and their psychosocial well-being.

As oncology social workers, we demonstrate this holistic, patient-centered approach through our Simple Talk Program, which centers on treating the whole patient alongside the whole family. Simple Talk provides an opportunity for parents to meet with social workers, in person or over the phone, to discuss their fears and concerns about cancer, while learning how to best communicate with and support their children.

Our program was inspired by the book *Simple Talk for Tough Times*¹ by social worker Marcia Carlson, MSW. Published in 2013, the book gives practical advice on how to communicate with and support children with a family member who is diagnosed with cancer. Parents in our cancer program are offered the *Simple Talk*¹ book, usually at the time of their initial diagnosis; however, it is available to everyone, at any time. Patients do not need a referral to receive a copy.

Carlson writes, "The diagnosis acts like an 'elephant in the room.' It is something big that everyone is aware of, but no one wants to talk about."

Program Development

Ongoing requests from medical providers wanting resources for their patients with

children made it clear that this was an unfulfilled need in our cancer program. Our social workers also received requests from parents asking for support with these conversations. To meet these unmet needs, our social workers developed the Simple Talk Program, named in honor of Carlson's work. Today, our Simple Talk Program provides families with the tools they can use to communicate with and support one another through a cancer diagnosis and treatment.

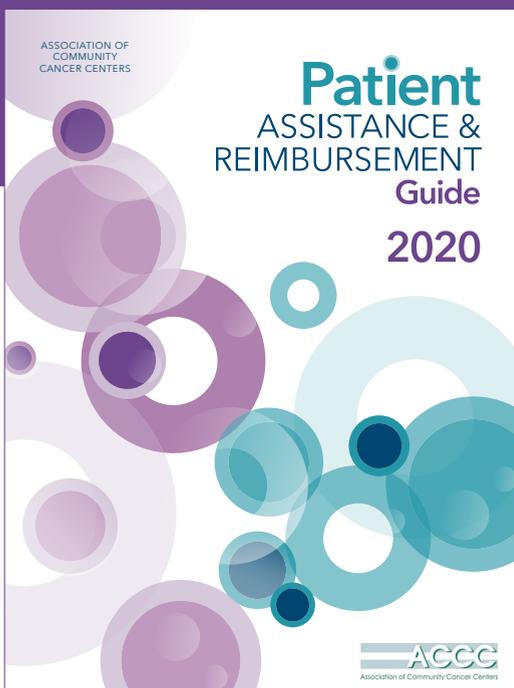
When families are referred to Simple Talk, they are connected with an oncology social worker who helps them decide on the resources that will best meet the family's needs. Often these referrals occur at the onset of a new diagnosis, when parents worry about "breaking the news." During this session, patients are provided psycho-education related to child development—for example, children's understanding of illness and information processing, children's normal reactions, coping techniques, and recommended language use, among other supports. As social workers, we spend time answering questions, coaching patients through difficult conversations, and helping them prepare to answer their children's questions. We also make age-appropriate recommendations for education, online resources, books, journals, and drawing materials.

Young children often benefit from picture books. Seeing an animated picture of a radiation machine or where on their parent's body the cancer is located can help children understand and comprehend complex information. We find that teenagers are often interested in online resources, like the riprap "when a parent has cancer"² website

(continued on page 68)



Help patients find the financial assistance they need.



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



(continued from page 66)

(riprap.org.uk) or guided journals to help express their thoughts and feelings.

When we meet with parents, we review typical reactions and questions their children may have. For example, younger children (four to seven years old) may ask, “Did I cause the cancer?” and “Can I still hug mommy?” whereas teenagers may not ask questions at all and opt to spend more time with friends. Reviewing child development and cognitive understanding of illness, grief, and loss can be helpful for parents in understanding how their children think, process, and feel.

A distinct component of the Simple Talk Program is the delivery process, as well as who is invited to participate. The program can involve one or both parents but can also include other important adult figures in a child’s life. Sometimes parents choose to involve their children in a follow-up visit with the social worker, as well. Many parents report that face-to-face conversations are more beneficial because they are able to process their own fears and concerns, and they walk away with a plan and strategy for approaching these difficult conversations with their children.

Growing the Program

In 2019 I (Sarah Johnson) created a journal titled *Our Family’s Journey: A Guided Journal for a Child Who Has a Loved One with Cancer* because I recognized that children do better with hands-on materials. This journal provides a colorful, fun, and safe place for children to draw or write their feelings, thoughts, and questions about their loved one’s cancer at their own pace and comfort level. Some of the topics the journal addresses include feelings, emotions, their support circle, the importance of self-care, asking questions, and the idea that it is okay to have fun even during a difficult time. Our social workers educate parents about the journal during their Simple Talk session, demonstrating ways in which parents can use the journal, so they can introduce it to their children at home.

Response from patients about the Simple Talk Program has been incredibly encourag-

ing and positive. Patients have expressed relief in having tools and techniques to share with their children throughout this change in their lives. Parents are comforted in learning that there is not one perfect way to support children; rather, emphasis is placed on acknowledging each child’s uniqueness and a family’s different and varying needs.

In a conversation with her social worker, one parent voiced concern about the eventual hair loss she would experience and how her family would react. We gave this patient take-home tools to help alleviate her children’s worries and answer their questions, including two children’s books about moms experiencing hair loss from chemotherapy to take home and share with her children (*Nowhere Hair* by Sue Glader and *Chemo Cat* by Cathy Nilon).^{3,4}

Virginia Piper Cancer Institute recognizes that a cancer diagnosis extends beyond the patient and affects his or her whole support system. One of the greatest initial fears for parents diagnosed with cancer is the welfare of their children. The Simple Talk Program is our response to these fears and concerns. We believe that delivering effective cancer care needs to include specialized support for parents. Parents and children alike deserve to feel prepared, empowered, and cared for while on their path to healing. 

Sarah Johnson, MSW, LICSW, OSW-C, and Ali Cain, MSW, LICSW, OSW-C, are oncology social workers at the Virginia Piper Cancer Institute, Minneapolis, Minn.

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4. Nilon C. *Chemo Cat*. Ravenna Press; 2007.



As an oncology social worker for the past 11 years, a common theme I have consistently heard from newly diagnosed parents is “What do I tell my kids about my cancer and how will this impact their childhood?”

Since the development and implementation of the Simple Talk Program, I have seen relief and reassurance when parents learn there is help, support, and guidance in addressing their concerns. For me, one of the great feelings as a member of their cancer team is to witness them finding hope and building confidence to tackle their fears and worries.

Sarah Johnson, MSW, LICSW, OSW-C



I work with families to assess their needs and provide tools in the form of books, online resources, conversation guides, and one-on-one coaching to offer the right resources, at the right time. This work certainly pulls at the heartstrings, yet it is deeply satisfying to be given an opportunity to remind people of their strengths and capabilities. I help enforce, and sometimes restore, a parent’s confidence by highlighting the position they are in to provide the connection and comfort their children need.

For many parents I work with, their children are both their greatest source of strength and deepest sense of angst when facing a cancer diagnosis. Simple Talk has provided me a more holistic response to the unique challenges parents with cancer face.

Ali Cain, MSW, LICSW, OSW-C



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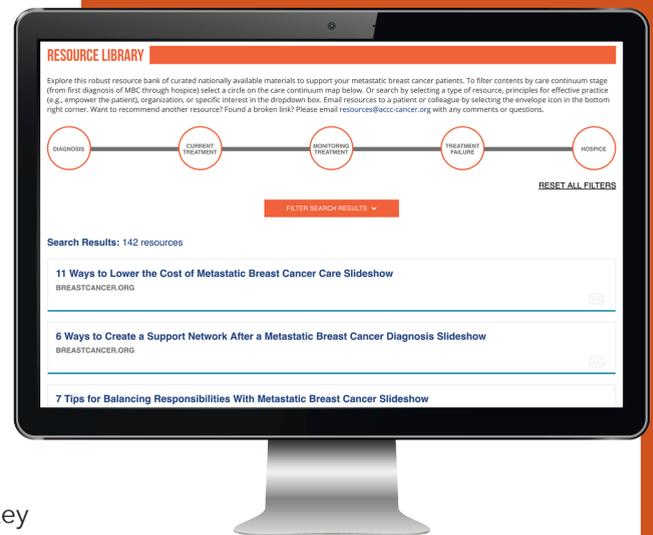
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- Building upon the patient support workbook, the **Effective Principles in Action** publication explores how three cancer programs are implementing the six key principles and taking action to empower patients.



Find the resources your patients need today at acc-cancer.org/MBCresources

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The Association of Community Cancer Centers (ACCC) is the leading education and advocacy organization for the multidisciplinary cancer team. ACCC is a powerful network of 25,000 cancer care professionals from 2,100 hospitals and practices nationwide. ACCC is recognized as the premier provider of resources for the entire oncology care team. For more information visit acc-cancer.org or call 301.984.9496. Follow us on Facebook, Twitter, and LinkedIn, and read our blog, ACCCBuzz.