ONCOLOGY ISSUES

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

March | April 2019

Robotic Bronchoscopy

Will this new technology lead to earlier and more accurate diagnosis of lung nodules?

ACCC
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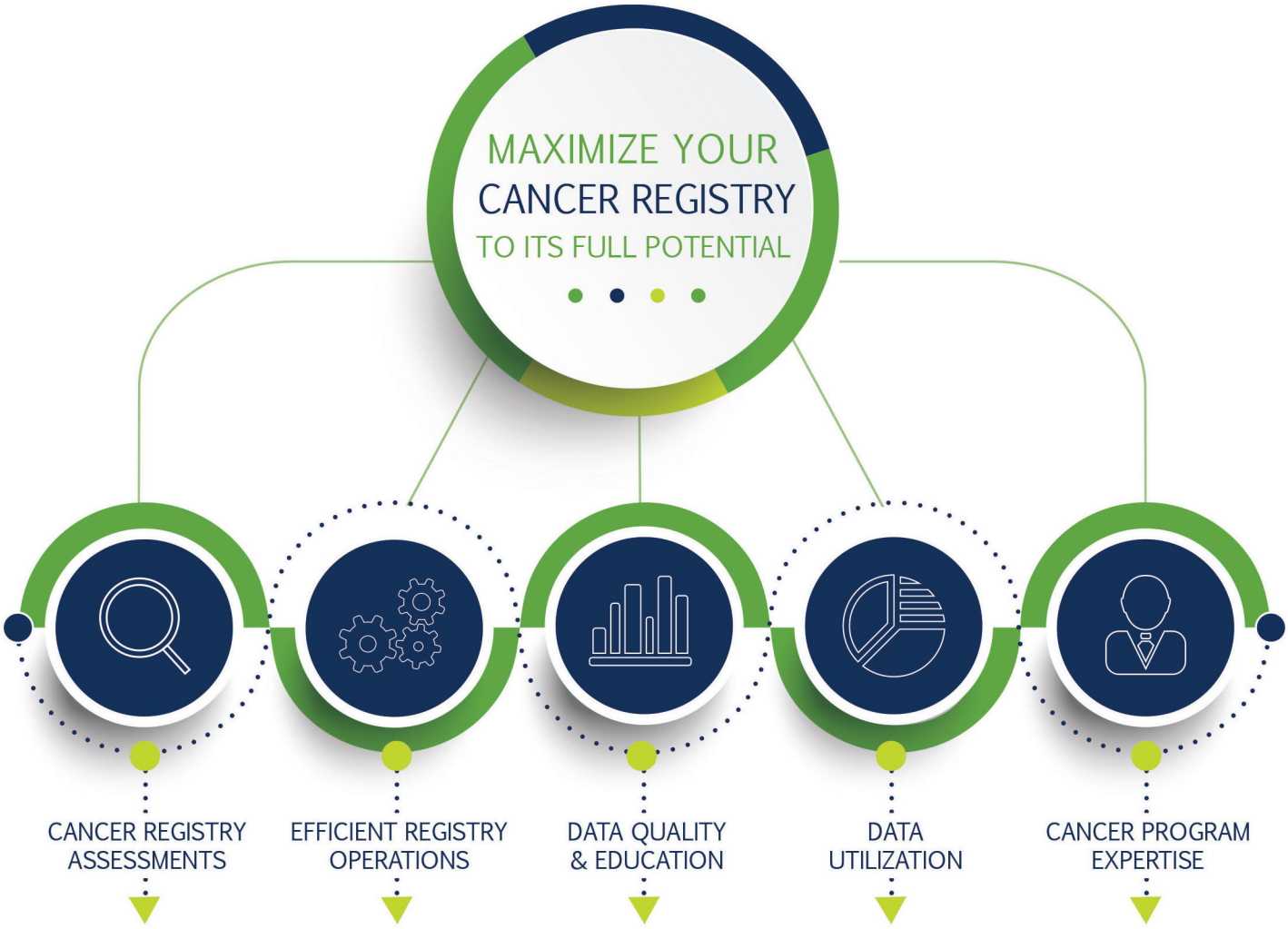
CHAMPS Oncology



"Since CHAMPS Oncology completely assumed our cancer registry functions, we've experienced enhanced casefinding, abstracting, follow-up, data quality, custom reporting and analytics, as well as human resource oversight, including cancer registrar onboarding, training, and continued education. As a result of the timeliness and integrity of our cancer data, we've been able to utilize our data to look at market share, patient / caregiver distance traveled for services and other elements to develop our five-year strategic plan.

I would highly recommend CHAMPS Oncology to other cancer centers throughout the country. They were terrific throughout the RFP process, during the staff transition and post go-live, providing high-quality service that's very timely and professional."

- Brad Bott, MBA, CCRP, director, Oncology Clinical Program, Intermountain Healthcare

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ACCC
Association of Community Cancer Centers

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FROM THE EDITOR

A More Personalized Approach to Survivorship Care?

BY JENNIE R. CREWS, MD, MMM, FACP

Since the 2005 publication of *From Cancer Patient to Cancer Survivor: Lost in Transition* by the Institute of Medicine (now the National Academy of Medicine), the healthcare community has become more aware of the needs of cancer survivors and responded by developing survivorship services and programs. Though these survivorship programs incorporate different models of care, the backbone is providing the patient with a survivorship care plan, a document that intuitively should enhance understanding of both the care received and the transition back to primary care and ultimately improve outcomes. Yet, there is limited evidence that survivorship care plans do so. A recently published article in *The Oncologist* may shed some light on why and guide us on future design of survivorship programs.[1]

The study, a cross-sectional needs assessment of cancer survivors, found heterogeneity in the survivors' needs that fell into four clusters:

- Low needs
- Mainly physical needs
- Mainly psychological needs
- Both physical and psychological needs.

The low-needs cluster of survivors was the largest, representing 40 percent of the 292 respondents, and half of this group (20 percent) had no needs identified. The authors concluded that a measurable benefit of survivorship care plans in randomized trials may be diluted by this population of survivors with low or no needs.

More importantly, this study highlights the need for a tailored approach to survivorship care that would identify those survivors with physical and psychological needs and direct resources toward this population. A survivorship screening tool—like a distress screening tool—could help triage survivors so that low- and no-need survivors could be provided a survivorship care plan as part of a regular follow-up visit and high-need survivors could be referred to a survivorship specialist for a more intensive counseling session. This approach would help cancer programs provide survivorship care tailored to the individual patient's needs and concentrate valuable resources where they are most needed.

The provision of survivorship care can also be challenging for cancer programs. From inadequate reimbursement for survivorship care services to overly burdensome accreditation standards and requirements, cancer programs struggle to provide survivorship care in the most impactful, cost-effective manner to an exponentially expanding patient population. To help ease some of these burdens and better align with patient-centered care delivery, accrediting organizations should use these data to develop more appropriate survivorship standards that truly meet the needs of cancer survivors rather than assuming a one-size-fits-all approach. OI

Reference

1. de Rooij BH, Park ER, Perez GK, Rabin J, et al. Cluster analysis demonstrates the need to individualize care for cancer survivors. *Oncologist*. 2018;23:1474-1481.

ACCC PRESIDENT'S MESSAGE

Turning Off Turnover

BY TOM GALLO, MS, MDA

As ACCC President 2018-2019, I have dedicated my term to identifying the sources of burnout among multidisciplinary cancer care providers and improving the resilience of oncology care teams across all care settings. We've taken great strides in just a year.

In the newly released results from the *2018 Trending Now in Cancer Care* survey, a collaboration between ACCC and the Advisory Board's Oncology Roundtable, numerous causes for burnout were identified, including workflow inefficiencies, heavy workloads, and a lack of proper work-life balance.

Though stemming burnout at the source is vital work, it is also important to recognize and alleviate symptoms as they appear. One such symptom is decreased workforce retention. Survey data identified "personal reasons" as the number one reason why physicians, advanced practitioners, and nurses left their jobs, but other factors contributed to turnover, including:

- Too many bureaucratic tasks (physicians and advanced practitioners)
- Difficulties with employer and/or health system (physicians and administrators)
- Compensation (advanced practitioners and nurses)
- Inflexible scheduling or lack of scheduling options (nurses).

These results are indicative of the systemic frustrations that cancer care professionals face every day. Caring for patients in various stages of serious illness is difficult enough as is; organizational and healthcare-wide inefficiencies only compound these issues. Learn more at **accc-cancer.org/trends**.

Before we can begin to address the causes and effects of burnout, we need to know how pervasive this problem is among members of the multidisciplinary cancer care team. In January 2019 ACCC invited members to take the Mini Z burnout survey, a clinically validated tool developed by the American Medical Association. Results from this survey can be found on pages 56-57 of this edition of *Oncology Issues*. In the article, Julie Oehlert, DNP, RN, chief experience officer at Vidant Health, explores the many facets of burnout and resiliency—both personal and institutional—and how healthcare leaders can take the next steps toward ensuring a healthy and resilient workplace. Future articles in *Oncology Issues* will detail programs and resources that ACCC members have developed to foster resiliency and wellness in their cancer care teams.

The issues of resiliency, burnout, and workplace inefficiencies also took center stage in a Deep Dive Workshop at the ACCC 45th Annual Meeting & Cancer Center Business Summit on March 20-22. Attendees who participated in the workshop listened to case studies and participated in group exercises designed to identify individual and organizational behaviors that can bolster resilience and reduce burnout at their programs and practices.

In my final President's Message column, I want to thank the ACCC staff and members who have worked diligently to address these issues that are crucial to the future of cancer care. "Reflect, Renew, Reignite: Creating a Resilient Oncology Team in Your Community" is not just a slogan for me; it is a statement of purpose that drives my work. To stay on top of ACCC's efforts to support oncology team well-being, visit **accc-cancer.org/resilience**. OI

Coming in Your 2019 *ONCOLOGY ISSUES*

- Improving Cancer Screening and Treatment Through a Focused Prostate Evaluation Program
- A Model Colon Cancer Awareness Screening Event
- Utilizing Bedside Yoga as a Non-pharmacological Intervention for Cancer Patients
- ArtsCare: Professional Artists and Musicians as Members of the Multidisciplinary Cancer Care Team
- The Oncology Pharmacy Navigator: A New Best Practice Model for Managing Medications
- Right Place, Right Provider, Right Time: Implementing Our 24-Hour Cancer Clinic
- Cancer Crushing Prevention and Early Detection
- Improving Care of Advanced Cancer Patients with a Dedicated Palliative Radiotherapy Team
- Implementing a Clinical Assessment and Rapid Evaluation (CARE) Clinic
- Meeting the Information Needs of Veterans with Cancer
- Improving the Tumor Board Experience with Technology
- Implementing Medical Scribes in a Community Cancer Center
- PSA Utilization at a Safety-Net Hospital Before and After the 2012 USPSTF Recommendation
- Chemotherapy Stewardship: The Evolving Role of Pharmacists

more online @ accc-cancer.org

PUBLICATION

Trending Now in Cancer Care

Read results from the ninth annual ACCC survey, conducted in partnership with the Oncology Roundtable. Top threats to future cancer program growth: reimbursement requirements from payers, cost of drugs and/or new treatment modalities, and uncertainties in drug pricing reform policies. Top opportunities for ROI include care coordination, the addition of sub-specialists, symptom management, and screening services. Learn more at accc-cancer.org/trends. Survey highlights are open access; full survey results are restricted to ACCC members.

WEBINAR

Acute Lymphocytic Leukemia Updates from ASH

Watch experts discuss data and key takeaways from seven clinically significant acute lymphocytic leukemia abstracts presented at the American Society of Hematology 2018 meeting, and then catch additional programs in this series on demand at accc-cancer.org/ALL-care. These webinars, an environmental scan publication, and resources are part of ACCC's Multidisciplinary Acute Lymphocytic Leukemia Care education project.

PUBLICATION

Multidisciplinary Hepatocellular Cancer Care

Nationally, death rates from liver cancer have increased by nearly three percent each year since 2000. A new publication from the ACCC Multidisciplinary Hepatocellular Cancer Care education project explores the current landscape of hepatocellular cancer diagnosis and treatment and opportunities to improve care delivery for this vulnerable patient population. Learn more at accc-cancer.org/hcc.

BLOG

The Art of Managing Acute Lymphocytic Leukemia

"Beyond integrating the science, managing the nuanced journey for patients with acute lymphocytic leukemia exemplifies the art of medicine," writes Sandra Kurtin, PhD, ANP-C, AOCN, assistant professor of Clinical Medicine, adjunct clinical assistant professor of Nursing, The University of Arizona. In this ACCCBuzz blog post, she shares insights gleaned from 30 years of caring for patients with acute lymphocytic leukemia. Read more at accc-cancer.org/acccbuzz.

PUBLICATION

New Name; Same Mission

In 2018 the ACCC Immuno-Oncology Institute received a new name and a new web presence. Learn about the genesis of the Institute's Working Groups, takeaways from the Institute Working Group summit held in September, and next steps in "Immuno-Oncology: Connecting Science, Policy, and Real-World Care Delivery" available at accc-cancer.org/immunotherapy.

fast

Safety First

Nearly **9** out of **10** respondents to a national survey of physicians, nurses, and healthcare executives say their organizations are successfully improving the safety of patients. But real problems remain, including:

- "Ineffective information technology" (data quality, patient matching, reporting) and the related "lack of real-time warnings for possible harm events," which requires technology—**30%**
- "Lack of resources," including staffing and budget—**27%**
- "Organization structure, culture, or priorities"—**19%**
- "Lack of reimbursement for safety initiatives"—**10%**
- "Changes in patient population and practice setting"—**9%**

Source. Health Catalyst. healthcatalyst.com.

Medicare Patients Concerned about Coverage & Costs

More than one-third (**37%**) of surveyed Medicare beneficiaries say they have skipped or delayed medical care to save money; half (**51%**) worry about their ability to afford their deductibles and copayments. Biggest worries:

- The cost of deductibles and copayments—**51%**
- The cost of dental and vision coverage—**44%**
- The cost of Medicare insurance premiums—**42%**
- The cost of prescription drugs—**42%**
- Access to preferred doctors and hospitals—**40%** and **34%**
- Paying for long-term care—**34%**

Source. eHealth, Inc. news.ehealthinsurance.com/_ir/68/20188/Concerns%20About%20Costs%20and%20Coverage%20in%20Medicare%20-%20eHealth%20Survey.pdf.

facts

Is Your Disaster Plan Up to the Task?

- Slightly **more than half** of surveyed healthcare providers believe their organization's disaster plan is comprehensive enough to cover a variety of scenarios both inside the organization and across the community.
- Less than **1/3** (**29%**) of surveyed specialty care providers who provide critical treatment to individuals with chronic diseases report that they have a comprehensive disaster plan in place.
- More than **1/3** of clinicians surveyed said that calling by phone is their top method for communicating with pharmacies, EMS units, patients and families, local authorities, and community health providers in times of disaster.
- Organizations preparing for an impending disaster still rely heavily on paper, with **most** advising patients to keep copies of their medical records.
- Just **40%** of respondents believe their EHR has sufficient information available to take care of all patients during a disaster.
- **45%** of respondents view telehealth as an effective option to provide care to patients across the community during or immediately after disasters or emergencies. However, **more than half** expressed concerns that connectivity and other technical issues could impact the reliability of telehealth.
- Only **27%** believe their organization has deployed adequate telehealth capabilities.

Source. A survey by DrFirst.com. To receive survey results, email to research@drfirst.com.

New study suggests chemotherapy may lead to early menopause in women with lung cancer, concluding that women with lung cancer who desire future fertility should be educated about risks and options before starting treatment.

Source. Cathcart-Rake EJ, et al. Amenorrhea after lung cancer treatment. Menopause. 27 August 2018. doi: 10.1097/GME.0000000000001199.

How Much Do Men Really Know About Testicular Cancer?

- Nearly **half** of **1,000** men, ages 18 to 45, surveyed do not perform self-exams.
- **63%** of men surveyed were not aware that testicular cancer is the most common form of cancer in men ages 15 to 44.
- Nearly **30%** reported never being informed that self-exams were necessary and important.
- **34%** reported never giving themselves a self-exam for testicular cancer because they wouldn't know how to perform one.
- Nearly **2/3** would check themselves regularly if the importance of self-exams had been made clear to them.

Source. The Center for Advocacy for Cancer of the Testes International (CACTI). cacti.org/our-research/testicular-cancer-survey.

What You Need to Know About the Future of Cancer Care in the United States

BY BLAIR BURNETT

Healthcare remains a top priority, not only for the Trump Administration, but also for most registered voters in the United States. A poll from the *Washington Examiner* released at the end of 2018 found that 71 percent of American voters classify healthcare as a "very important" issue in the 2019 landscape.

Cancer care, specifically, has experienced several tumultuous years, with drug pricing and entitlement reform dominating conversations and affecting patient coverage and access. It is a widely held view that two years into any presidential administration, many of the large regulatory pushes begin to take effect. Entering the second quarter of 2019—with a dramatically different Congress—here's a quick peek at what to expect for your program, your patients, and oncology delivery overall in the coming months:

- ***Drug pricing reform will continue to be a top priority.*** In May 2018 we saw a flood of proposals from Secretary of Health and Human Services Alex Azar and other members of the administration's healthcare leadership focused on tackling the rising cost of drug prices. Over the summer, serious transformation was proposed to Medicare Part B, Medicare Part D, and the commercial space. October 2018 saw the release of the administration's International Pricing Index model in an advanced notice for public rulemaking that would tie some of the most expensive drugs in Medicare to an "international standard." Patient and provider groups, including ACCC, have voiced concern over this proposal, as well as potential changes to the Medicare Part D protected classes, formulary design, and rebate system, calling attention to many access issues faced by cancer patients across the country. We expect to see a follow-up proposed rule on the International Pricing Index model this April or May.

  In 2018 drug pricing reform also saw significant action in the regulatory landscape. The Centers for Medicare & Medicaid Services (CMS) issued back-to-back policy memos in August: one allowing Medicare Advantage plans to integrate step therapy as of Jan. 1, 2019, and a second memo announcing changes to Medicare Part D plans slated for 2020. However, with a series of hearings from various House and Senate committees early in 2019, we expect drug pricing reform to garner new possible solutions coming from a Congress flexing increased legislative oversight.
- ***The administration's regulatory agenda will begin to provide more answers than questions.*** Two years into the Trump Administration, expect to see not only a continued push on regulatory efforts relating to drug pricing reform but also continued utilization of CMS, as well as the Center for Medicare and Medicaid Innovation (CMMI), in payment reform efforts. Many of the alternative payment model efforts that came out of CMS/CMMI under the Obama Administration held fast to voluntary models. With Alex Azar at the helm of Health and Human Services, we should expect to see even more models coming out of these centers—not all of them voluntary. As Medicaid expansion efforts grow in many purple states, we also expect the continuation of work requirement waivers to reduce this potentially growing pool.
- ***Telehealth will be in the spotlight.*** More than half of all U.S. hospitals and practices have some sort of telemedicine or virtual health component to their program, according to the American Telehealth Association. In particular, over recent years, telehealth has become increasingly central to the conversation about rural healthcare delivery. The 2019 Outpatient Prospective Payment System and Physician Fee Schedule final rules saw the expansion of virtual health coverage, and we are seeing increased efforts in Medicare and Medicaid to account for the rising use of telehealth across the country. As programs across the country grapple with the consistently changing healthcare delivery landscape and infrastructure, telehealth is becoming an integral part of the cancer care delivery infrastructure.

All of us in the oncology community can agree that the future of cancer care in the United States will bring change. ACCC's policy team will continue to keep members prepared for whatever that change may bring. OI

Blair Burnett is senior policy analyst at ACCC.

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AUC Consultation Is on Its Way

BY MELODY W. MULAIK, MSHS, CRA, RCC, CPC, FAHRA

Ready or not, the requirement to consult Centers for Medicare & Medicaid Services (CMS)-approved Appropriate Use Criteria (AUC) when ordering advanced imaging studies is on its way and is slated to go into effect on Jan. 1, 2020. Technically, 2020 is a testing year, and 2021 will be the first year that CMS begins tracking data to identify ordering patterns and concerns. That said, many organizations are well underway with the implementation of new processes and systems that impact ordering advanced imaging studies to prepare for this new requirement.

This new regulation was created by the Protecting Access to Medicare Act of 2014 (PAMA), which specifically requires CMS to establish a program to promote the utilization of AUC for advanced diagnostic imaging services. Advanced imaging services include diagnostic computed tomography, magnetic resonance, and nuclear medicine exams, including positron emission tomography. Ordering physicians and practitioners ("ordering professionals") will be required to consult AUC for all advanced imaging studies billed under the Medicare Physician Fee Schedule (PFS), the Hospital Outpatient Prospective Payment System (OPPS), and the Ambulatory Surgical Center Payment System, including those performed in a physician office, hospital outpatient department (including emergency department), independent diagnostic testing facility, or ambulatory surgery center. Keep in mind that if your organization owns advanced diagnostic equipment that is utilized for diagnostic studies, then the AUC consultation and reporting requirements will apply.

AUC are designed to help clinicians select the most appropriate imaging study for a patient with a particular diagnosis or presenting symptom. CMS can only approve AUC that are developed or endorsed by ***provider-led entities*** such as national professional medical specialty societies. In most cases the AUC will be evidence-based. Table 1, right, is a current listing of qualified provider-led entities.

Once a provider-led entity is listed as qualified, all of the AUC developed or endorsed by that entity are considered to be "specified AUC" for purposes of the PAMA requirements.

An ordering provider will access AUC through a ***clinical decision support mechanism*** to conduct the necessary consultation for ordering the appropriate imaging service for the patient. The clinical decision support mechanism is an electronic portal, such as a module in an electronic health record (EHR) or a web-based system. The clinical decision support mechanism will pull information about the patient from the EHR and/or the ordering provider will enter information, and the clinical decision support mechanism will provide immediate feedback about the appropriateness of the proposed imaging exam. Table 2, right, is a current listing of qualified clinical decision support mechanisms; Table 3, page 10, is a current listing of clinical decision support mechanisms with preliminary qualification.

Priority Clinical Areas and Exceptions

At a minimum, each clinical decision support mechanism must include criteria for the following ***priority clinical areas*** that account for a significant percentage of advanced imaging exams paid by Medicare:

- Cancer of the lung (primary or metastatic, suspected or diagnosed)
- Coronary artery disease (suspected or diagnosed)
- Suspected pulmonary embolism
- Headache (traumatic and non-traumatic)
- Hip pain
- Low back pain
- Shoulder pain (to include suspected rotator cuff injury)
- Cervical or neck pain.

The list will continue to expand in the future.

Note the following exceptions to the AUC consultation requirement. The requirement does *not* apply to imaging exams performed on inpatients and paid under Medicare Part A. It also does not apply to patients with emergency medical conditions, whether confirmed or suspected, or when the ordering physician or practitioner has received a hardship exception. Any ordering professional experiencing insufficient Internet access, EHR, or clinical decision support mechanism vendor issues or extreme uncontrollable circumstances (including natural or man-made disasters) will not be required to consult the AUC using a qualified clinical decision support mechanism. These circumstances will be self-attested at the time of placing the order.

(continued on page 10)

Table 1. Current Listing of Qualified Provider-Led Entities*
American College of Cardiology Foundation
American College of Radiology
Banner University Medical Group-Tucson University of Arizona
CDI Quality Institute
Cedars-Sinai Health System
High Value Practice Academic Alliance
Intermountain Healthcare
Massachusetts General Hospital, Department of Radiology
Medical Guidelines Institute
Memorial Sloan Kettering Cancer Center
National Comprehensive Cancer Network
Sage Evidence-based Medicine & Practice Institute
Society for Nuclear Medicine and Molecular Imaging
University of California Medical Campuses
University of Pennsylvania Health System
University of Texas MD Anderson Cancer Center
University of Utah Health
University of Washington School of Medicine
Virginia Mason Medical Center
Weill Cornell Medicine Physicians Organization

*As of June 2018. Source: cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html.

Table 2. Qualified Clinical Decision Support Mechanisms*
AIM Specialty Health ProviderPortal® (free tool available)
Applied Pathways CURION™ Platform
Cranberry Peak ezCDS
eviCore healthcare's Clinical Decision Support Mechanism
MedCurrent OrderWise™
Medicalis Clinical Decision Support Mechanism
National Decision Support Company CareSelect™ (free tool available)
National Imaging Associates RadMD
Sage Health Management Solutions Inc. RadWise®
Stanson Health's Stanson CDS
Test Appropriate CDSM (free tool available)

*As of June 2018. Source: cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html.

Table 3. Clinical Decision Support Mechanisms with Preliminary Qualification*
Cerner CDS mechanism
Evinance Decision Support
Flying Aces Speed of Care Decision Support
Infinx CDSM
LogicNets' Decision Engines
New Century Health's CarePro
Reliant Medical Group CDSM

*As of June 2018. Source: cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html.

(continued from page 8)

If medical necessity is met, CMS will pay for advanced imaging studies regardless of whether they meet appropriateness criteria during the consultation process. Eventually CMS will identify the top 5 percent of ordering professionals who are consistently failing to follow AUC recommendations for studies involving priority clinical areas outlined above. Under PAMA, these "outliers" will be required to obtain prior authorization for any advanced imaging studies they wish to order for Medicare patients. Currently, lung cancer is the only oncology diagnosis on the priority clinical area list but the list will be expanding, and it is anticipated that additional oncology-related clinical conditions will follow.

When first released, PAMA called for ordering professionals to begin consulting AUC by Jan. 1, 2017, but that deadline has been pushed back several times. In the 2018 PFS final rule, CMS announced that the AUC consultation requirement will not go into effect until Jan. 1, 2020. Though questions and concerns have been raised about the "administrative burden" of this requirement, because it was enacted by Congress, to change or eliminate it would literally take a new act of Congress, which is not anticipated to occur at this time.

Voluntary Reporting Period

To encourage organizations to get ready as soon as possible, a voluntary reporting period began in July 2018 and will run through December 2019. During this time AUC consultation is not required, but "early adopters" may opt to begin on a voluntary basis. The reporting requirement to communicate to CMS that the consultation occurred lies with both the imaging facilities and interpreting providers, as communicated to them by the ordering professional. During this voluntary reporting period only, the AUC consultation is communicated, not the results of the AUC consultation itself (i.e., whether the order was approved or denied). In an integrated system where the consultation and orders are documented electronically, this is a relatively seamless process, but if paper orders are utilized, additional work is required to relay this information.

Educational and Operations Testing Period

Beginning in January 2020, CMS will launch a one-year "educational and operations testing period." During this time, ordering professionals must consult AUC, and furnishing professionals (the imaging facility and the interpreting providers) must report information about the consultation (mechanism and consultation result). In this testing period, claims will be paid regardless of whether the claim includes the required information. However, starting in 2021, payment will be denied if claims from the furnishing professionals (both facility and interpreting provider) lack the required AUC information unless one of the previously listed exceptions—for example, medical emergency—applies. (See page 8 for the list of exceptions.)

During the 2020 rulemaking cycle, CMS will develop a series of G codes and modifiers that must be applied to the claims during the testing period. The G code will indicate the mechanism consulted and the modifiers will indicate at an exam level (abdomen computed tomography, positron emission tomography, etc.) whether the exam was recommended, not recommended, or not applicable (inpatient, emergent, etc.). The ordering provider will be responsible for reporting this information to the imaging facility and the interpreting provider.

During this one-year "educational and operations testing period," CMS will continue to pay claims whether or not the information contained on the claims is completely accurate. For this initial testing period, the

ordering professional will consult AUC through a qualified clinical decision support mechanism, and furnishing providers will report the corresponding G codes and modifiers on their claims (facility and physician). CMS has not indicated how long the G codes and modifiers will be utilized for claims-based reporting.

However, in the 2019 PFS final rule, CMS indicated that the agency will continue to consider future opportunities to use a unique claim identifier number generated by the clinical decision support mechanisms themselves, but did not commit to a specific timeline. When this occurs, the AUC reporting program would shift to a more registry-based program, much like the Medicare Access and CHIP Reauthorization Act quality reporting.

Of note, in the 2019 PFS final rule, CMS clarified that if the referring physician does not personally perform the consultation, then "when delegated by the ordering professional, clinical staff under the direction of the ordering professional may perform the AUC consultation with a qualified clinical decision support mechanism." The ordering physician is still responsible for the consultation because it will be his or her National Provider Identifier reported on the claim. It is also the ordering physician who would be identified as an outlier and be subject to prior authorization requirements based on the ordering patterns.

AUC consultation is upon us, and it is not just an imaging problem or an ordering provider issue. Ordering providers, imaging facilities, and interpreting physicians must work hand in hand to establish effective and efficient processes to meet this regulatory requirement. Everyone deserves to be paid appropriately for services rendered and avoid being on the "outlier" list due to ordering concerns. OI

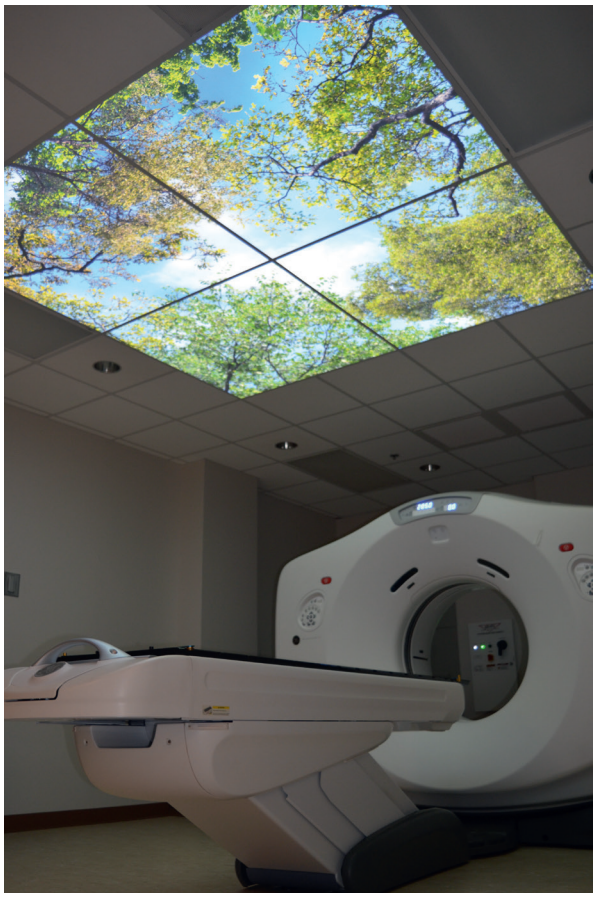
Melody W. Mulaik, MSHS, CRA, RCC, CPC, FAHRA, is the president of Coding Strategies, Inc., and Revenue Cycle Inc., Powder Springs, Ga.

spotlight

John H. "Jack" Burbage, Jr. Regional Cancer Care Center

Berlin, Md.

Located just a few miles away from the Atlantic Ocean, the John H. "Jack" Burbage, Jr. Regional Cancer Care Center serves parts of Sussex County, Delaware, Maryland's Eastern Shore, and the eastern shore of Virginia. Seeing upwards of 350 new medical oncology patients each year, the Regional Cancer Care Center previously occupied two suites of a medical office building, with space amounting to less than 2,000 square feet. In order to provide quality care to a growing, aging population—employment opportunities in Worcester County do not traditionally attract younger residents, and the area is a destination for retirees—Atlantic General Hospital, which owns the Regional Cancer Care Center and employs its staff, decided to build a new facility specific to oncology on the hospital's main campus. On June 27, 2018, the doors to the new 18,000-square-foot building opened for operations; the grand opening was held on July 11, and the new cancer center received accreditation from the Commission on Cancer in the same month.



Located on the Delmarva Peninsula near Ocean City, a popular vacation destination, the Regional Cancer Care Center is uniquely positioned to serve a disproportionately tourist population. Two-thirds of cancers treated at the center are melanomas, and many patients come from other areas of the country to continue treatment while taking a beach vacation. Local patients come from up to 50 miles away to receive treatment in this rural part of the state.

According to Katie Collingsworth, financial counselor at the Regional Cancer Care Center, the cancer center receives a great deal of community support. Patients will often visit the center on non-treatment days to see their caregivers. The number of patients seen has increased exponentially since the new building's opening, and Collingsworth says that the new cancer center is happy to accommodate patients they could not have seen in their former location.

Comprehensive Rural Cancer Care

The centerpiece of the new single-story building is its central lobby, with medical oncology, radiation oncology, and the infusion clinic all accessible from one location. The Regional Cancer Care Center is staffed by two medical oncologists, one radiation oncologist, and five nurses. With its expansion, the cancer center went from three medical oncology examination rooms to five and from five infusion chairs to eight with two private rooms. A dedicated oncology pharmacy is located on site.

The radiation suite is equipped with an Elekta Versa HD linear accelerator for the delivery of stereotactic body radiotherapy and radiosurgery and a GE 16-Slice CT scanner for diagnostic purposes. When the cancer program changed buildings, a local radiation oncology practice was acquired by Atlantic General Hospital, and its six employees were incorporated into the health system. As its need for oncology services continues to grow, the hospital is looking at new staffing models and has hired a mid-level provider to alleviate workload concerns.

Navigation is a central component of the cancer center's approach to patient care. On their first appointment, patients meet only with their physician and a nurse navigator so that patients are not overwhelmed with information. Financial counselors screen all patients requiring treatment and review chemotherapy orders for available assistance. Once treatment has started, a chaplain, a dietitian, and members of the palliative care team meet with patients to complete the multidisciplinary cancer care team. "Timing is everything," says Collingsworth.

The Regional Cancer Care Center also has a robust suite of supportive services on-site, including massage therapy, Reiki, and yoga; the center is currently researching ways to expand these services. The cancer center hosts two support groups: Women Supporting Women and Look Good, Feel Better in partnership with the American Cancer Society. An ambulance entrance at the new facility allows inpatients at Atlantic General Hospital to be transported to the cancer center for chemotherapy treatments as needed.

A Strong Academic Partnership

Even with its comprehensive services, the Regional Cancer Care Center sometimes encounters high-complexity cases that require specific expertise. In cases like these, Atlantic General Hospital can refer patients to the University of Maryland Medical System for second opinions. This partnership also grants the cancer center patients greater access to clinical trials. Though no patients at the Regional Cancer Care Center are currently enrolled, eligible patients are discussed at biweekly tumor boards and referred to the trials program as appropriate.

As part of an ongoing partnership with the university health system, the Regional Cancer Care Center also offers telemedicine and genetic counseling services to patients who may be unable to make the two-and-a-half-hour drive into central Maryland. "It's been a huge help to our patients," says Patricia Marks, director of Atlantic General Hospital.

tools

Approved Drugs

- On Jan. 31, the Food and Drug Administration (FDA) approved **Alimta® (pemetrexed for injection)** (Eli Lilly and Company, lilly.com) in combination with pembrolizumab and platinum chemotherapy for the first-line treatment of patients with metastatic non-squamous non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations.
- On Dec. 20, the FDA approved **Asparlas™ (calaspargase pegol-mknl)** (Servier Pharmaceuticals LLC, servier.com) as a component of a multi-agent chemotherapeutic regimen for acute lymphoblastic leukemia in pediatric and young adult patients aged one month to 21 years.
- On Jan. 14, Exelixis, Inc. (exelixis.com) announced that the FDA has approved **Cabometyx® (cabozantinib)** for patients with hepatocellular carcinoma who have been previously treated with sorafenib.
- On Dec. 21, the FDA approved **Elzonris™ (tagraxofusp-erzs)** (Stemline Therapeutics, stemline.com) for blastic plasmacytoid dendritic cell neoplasm in adults and in pediatric patients two years and older.
- On Dec. 14, Celltrion, Inc. (celltrion.com) and Teva Pharmaceutical Industries Ltd. (tevapharm.com) announced that the FDA has approved **Herzuma® (trastuzumab-pkrb)**, a biosimilar to Herceptin®, for the treatment of HER2-overexpressing breast cancer for certain indications.
- On Jan. 28, the FDA approved **Imbruvica® (ibrutinib)** (Janssen Biotech, Inc., janssen.com; Pharmacyclics LLC, pharmacyclics.com) in combination with obinutuzumab for treatment-naïve patients with chronic lymphocytic leukemia/small lymphocytic lymphoma.
- On Dec. 19, the FDA granted accelerated approval to **Keytruda® (pembrolizumab)** (Merck & Co., Inc., merck.com) for adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma.
- On Dec. 19, the FDA approved **Lynparza® (olaparib)** (AstraZeneca, astrazeneca.com) for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy.
- The FDA has approved **Ontruzant® (trastuzumab-dttb)** (Samsung Bioepis Co., Ltd., samsungbioepis.com), a biosimilar to Herceptin®, for the adjuvant treatment of HER2-overexpressing breast cancer, metastatic breast cancer, and metastatic gastric cancer or gastro-esophageal junction adenocarcinoma in patients who have not received prior treatment for metastatic disease.
- The FDA has approved **Sprycel® (dasatinib)** (Bristol-Myers Squibb Co., bms.com) to include the treatment of pediatric patients one year of age and older with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia in combination with chemotherapy.

Drugs in the News

- ASLAN Pharmaceuticals (aslanpharma.com) announced that the FDA has accepted its investigational new drug application for **ASLAN003**, a potential first-in-class treatment for acute myeloid leukemia.
- EMD Serono (emd-serono.com) and Pfizer Inc. (pfizer.com) announced that the FDA has accepted its supplemental biologics license application (BLA) and granted priority review to **Bavencio® (avelumab)** in combination with axitinib for patients with advanced renal cell carcinoma.
- BioLineRx Ltd. (biolinerx.com) announced that the FDA has granted orphan drug designation to its lead oncology candidate, **BL-8040**, for the treatment of pancreatic cancer.
- Janssen Biotech, Inc. (janssen.com) announced that the FDA has approved a split-dosing regimen for **Darzalex® (daratumumab)** for the treatment of patients with multiple myeloma, allowing healthcare providers to split the dosing into two days.
- Equillium (equilliumbio.com) announced that the FDA has granted orphan drug designations for **EQ001 (itolizumab)** for the prevention and treatment of acute graft-versus-host disease.
- Gritstone Oncology (gritstoneoncology.com) announced that the FDA has granted fast track designation to **GRANITE-001** for the treatment of colorectal cancer.
- Merck & Co. (merck.com) announced that the FDA has accepted a new supplemental BLA for **Keytruda® (pembrolizumab)**

as monotherapy or in combination with platinum and 5-fluorouracil chemotherapy for the first-line treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma.

- Roche (roche.com) announced that it had submitted a supplemental BLA to the FDA for **Kadcycla® (trastuzumab emtansine)** for adjuvant treatment of people with HER2-positive early breast cancer with residual disease after neoadjuvant treatment.
- Merus N.V. (merus.nl) announced that the FDA has accepted the investigational new drug application for **MCLA-145** for the treatment of solid tumors.
- Mustang Bio, Inc. (mustangbio.com) announced that the FDA has granted orphan drug designation to **MB-102 (CD123 CAR T)** for the treatment of blastic plasmacytoid dendritic cell neoplasm, a rare and incurable blood cancer.
- Daiichi Sankyo (daiichisankyo.com) announced that the FDA has accepted a new drug application and granted priority review for **pexidartinib** for the treatment of adult patients with symptomatic tenosynovial giant cell tumor.
- Roche (roche.com) announced that the FDA has accepted the company's supplemental BLA for **Tecentriq® (atezolizumab)** in combination with Abraxane® (albumin-bound paclitaxel; nab-paclitaxel) and carboplatin for the first-line treatment of people with metastatic non-squamous non-small cell lung cancer who do not have EGFR or ALK genomic tumor aberrations.
- Samumed, LLC (samumed.com) announced that the FDA has granted orphan drug designation to **SM08502** for the treatment of pancreatic cancer.
- TG Therapeutics, Inc. (tgtherapeutics.com) announced that the FDA has granted breakthrough therapy designation to **Umbralisib (TGR-1202)** for the treatment of adult patients with marginal zone lymphoma who have received at least one prior anti-CD20 regimen.

Devices in the News

- ArcherDX, Inc. (archerdx.com) announced that the FDA has granted breakthrough device designation to the **ArcherDX companion diagnostic assay**, a sequencing-based test intended for detection of somatic alterations in circulating tumor DNA present in plasma and in RNA or DNA derived from formalin-fixed paraffin-embedded cancer tissue.

Genetic Tests and Assays in the News

- Myriad Genetics, Inc. (myriad.com) announced that the FDA has approved **BRACAnalysis CDx®** to identify patients with advanced ovarian cancer who have a germline BRCA mutation and are eligible for first-line maintenance therapy with Lynparza® (olaparib) following response to platinum-based chemotherapy.
- 23andMe, Inc. (23andme.com) announced that the FDA has authorized the use without prescription of their **MUTYH-Associated Polyposis report** for genetic health risk report of the rare condition associated with increased risk of colorectal cancer.
- Illumina, Inc. (illumina.com) announced that the FDA has granted breakthrough device designation for **TruSight™ Oncology Comprehensive**, a pan-cancer assay currently in development that is designed to detect known and emerging solid tumor biomarkers.

Robotic Bronchoscopy

BY AMY HINDMAN

New technology that holds the promise of earlier and more accurate diagnosis of lung nodules

Lung cancer is the leading cause of cancer deaths worldwide, with more patients dying every year from the disease than from prostate, breast, and colon cancers combined. Early identification, staging, and diagnosis are critical to improving lung cancer outcomes.

Survival rates in lung cancer largely depend on the stage at diagnosis. According to the American Lung Association's 2014 "Trends in Lung Cancer Morbidity and Mortality" report, from 2004 to 2010, the average five-year survival rate for localized lung cancer was 54.0 percent compared to 16.8 percent overall and 4.0 percent for a distant tumor.[1] However, the report notes that only 15 percent of individuals with lung cancer are diagnosed at an early stage when the cancer is localized.[1]

Fox Chase Cancer Center in Philadelphia, Pa., is at the forefront of innovation, so it is not surprising that this former Association of Community Cancer Centers Innovator Award recipient is one of only three institutions in the country to implement a new technology that holds promise for patients with lung cancer and those on the cancer care team who help to treat them and manage their care.

Though a variety of diagnostic options are currently available for lung cancer, "all have limitations in accuracy, safety, or invasiveness," said Christopher J. Manley, MD, director of interventional pulmonology at Fox Chase. "These limitations can lead to false positives, false negatives, or side effects such as pneumothorax (collapsed lung) and hemorrhage, which may increase healthcare costs and extend hospital stays." The Monarch Platform could change that.

> The Monarch Platform combines traditional endoscopic views into the lung with computer-assisted navigation based on three-dimensional models of the patient's own lung anatomy, providing physicians with continuous bronchoscope vision throughout the entire procedure.

The new tool, a flexible endoscopic technology developed by Auris Health, Inc., in Redwood, Calif., enables physicians to diagnose, and eventually treat, hard-to-reach, small peripheral

Christopher J. Manley, MD, director of interventional pulmonology at Fox Chase.

lung nodules with greater precision than ever before. It was cleared by the U.S. Food and Drug Administration in March 2018.

How It Works

The Monarch Platform combines traditional endoscopic views into the lung with computer-assisted navigation based on three-dimensional models of the patient's own lung anatomy, providing physicians with continuous bronchoscope vision throughout the entire procedure.

"Early detection and diagnosis of lung cancer is critical to improving survival. The Monarch Platform enhances our ability to evaluate, diagnose, and ultimately treat lung cancer by providing improved reach, vision, and control for minimally invasive bronchoscopic procedures," said Dr. Manley, who works with a multidisciplinary cancer care team at Fox Chase to employ minimally invasive techniques for diagnosis and treatment of lung cancers early on in diagnosis and staging and then in the later stages of the disease in palliation of symptoms. Diagnosis and staging includes bronchoscopy, which is the process of navigating through the airways using flexible, fiberoptic cameras to look at lung tumors and lung nodules, in order to diagnose lung cancer. He is one of the first physicians in the country to use the Monarch Platform in a clinical setting.

He describes the process of the biopsy of a lung nodule in detail and what a patient experiences during the procedure itself: "The Monarch is a robotic platform but it's also electromagnetic, meaning we create a magnetic field around the patient, which tells us where the robotic arm is in a space, and if we can link that to a high-quality, high-resolution CT scan, we can then tell where we are in the airways, and that helps us guide the catheter or robotic arm out to the lung nodule for biopsy," said Dr. Manley. "The patient gets a CT scan, which can be done anywhere, and it's loaded into the system; patients come in prior to the procedure and meet with one of us in clinic for consultation, and then the day of the procedure, they're taken off to sleep by the anesthesiologist; we advance our thin robotic camera down through the airways, navigate out to the lung nodule, and then do our biopsies. And at the same time, we can look at the lymph nodes under ultrasound; we can place our fiducial markers or gold seeds to help with delivering radiation, and that sort of thing."

This may sound like business as usual in terms of the process for biopsy and diagnosis of lung nodules; however, the difference is that it provides a level of accuracy not available previously. Although technology has advanced significantly since the development of the earliest robotics platforms used in medicine, the Monarch Platform is designed to address the limitations of current technology.

It is an improvement over endoscopic tools in the past because previous platforms "used the electromagnetic field to help guide us to the nodule, similar to a GPS for your car, but they didn't give us a robotic arm, which offers increased dexterity and movement and freedom to move in 360 degrees through the airways," Dr. Manley said. "Also, because the robotic arm is stable and stationary, it's easy to direct and won't get moved off course or adjusted without us meaning it to. This stability makes our biopsies very consistent, and controlling the catheter is very easy to do."

Training and Implementation

The evolution of these technologies has been ongoing for years, from the first flexible bronchoscopy to the first endobronchial ultrasound, to the first electromagnetic navigational platforms; these skills are taught to interventional pulmonologists at specialty fellowships, which follow critical care training, including all of the different platforms: how they work; what their limitations are; what their benefits are; and how to deploy them safely.

The Monarch system is similar to previous platforms, but there are also many differences. For 12 months, Dr. Manley traveled to the Monarch headquarters in California for formalized training, working first in rubber and foam models and then in human cadavers, until he was able to use the machine, travel out to simulated nodules, perform biopsies, and perform ultrasounds effectively. After that, Dr. Manley and his team felt that it was safe to move forward and institute this technology at Fox Chase.

In order to implement the Monarch Platform, there were many moving parts, yet Dr. Manley said that the process was seamless. The Monarch and Auris team flew out to Philadelphia from California, bringing with them a large technical team who worked closely with Fox Chase staff, including its technology team, endoscopy staff, endoscopy nursing staff, nurse educators, and physical plant staff over the course of a week-long installation and education process.

The Monarch is used to assess lung nodules that cannot be reached by traditional bronchoscopy. Even the very first cases were extremely successful. "We did six cases in our first two days. They went very smoothly, and we've been off and running since," Dr. Manley said.

Patient Safety and Outcomes

The top priority is ensuring safety for patients, and that means measuring outcomes and feedback. The team at Fox Chase is looking closely at how the machine works, whether it is doing what it is intended to do safely and effectively, and analyzing the large amount of data that it provides, such as nodule size and location, time of navigation, biopsy results, and whether there were any complications.

"In these early cases, there's been significant concentration on patient safety and moving through the airways with good effect," Dr. Manley said. "The next step is looking at how quickly we're able to get out to the nodule that we're trying to biopsy, and whether we're able to do that faster, with a high level of safety, because the benefit of this device is that it will make the procedures shorter so it's less anesthesia for the patient, hopefully fewer biopsies for the patient, and complete diagnosis and staging in one short anesthetic period."

What's the Cost?

The price tag on such an investment is expensive, and the Monarch Platform was funded by donors at Fox Chase. Although there was a large capital purchase upfront, the return is seen in the level of patient-centered care Fox Chase is able to provide, which does not exactly have a price tag.

"In terms of a return on our investment, it's always hard to measure what the benefit is and what in terms of a dollar amount we should expect," said Dr. Manley. "The one aspect that we are concentrating on is trying to determine what the benefit is to our patient, and so despite the high initial cost to acquire the machine, if we can provide superior care with a shorter anesthetic period, a safer procedure, and better outcomes, then the cost will be worthwhile."

The procedure is covered by insurance, and no pushback is anticipated from insurers, Dr. Manley said.

Use at the Community Level

Whether this technology can be implemented outside of an academic setting remains to be seen, but it is possible with the right support. "I think that technologies like these are best used at high-volume centers," Dr. Manley said. "Our success comes from our consistency, and we have a dedicated team that performs bronchoscopies every day; we have dedicated respiratory therapists; specialized cytologists, specialized pathologists; technicians; an anesthesia team that's familiar with how the procedure works; how long it should be; what complications can occur; and so, to me, the more important thing is the team behind me." In other words, yes, it is replicable, but only within certain parameters—namely, a specialized multidisciplinary team of cancer care providers.

Impact on Patients, Cancer Care as a Whole

The impact on patient-centered care is the bottom line. "What's important to remember is that early diagnosis of lung cancer is very, very important, so diagnosing a nodule when it's very small and easy to remove or easy to treat will give us better outcomes for our patients. Having a robust lung cancer screening program combined with a platform like this, which provides rapid and safe diagnoses with a high diagnostic yield, really helps us make an intervention early in our patients' lives," said Dr. Manley. "The significant benefit, the significant improvement in outcomes, is going to be from that early diagnosis and staging, so I think that's going to have sweeping changes on the cancer care for a

User touching the Monarch Tower's displays touch screen.

Full view powered on with stowed arms on Monarch Cart.

User holding Monarch controller.

The team at Fox Chase is looking closely at how the machine works, whether it is doing what it is intended to do safely and effectively, and analyzing the large amount of data that it provides, such as nodule size and location, time of navigation, biopsy results, and whether there were any complications.

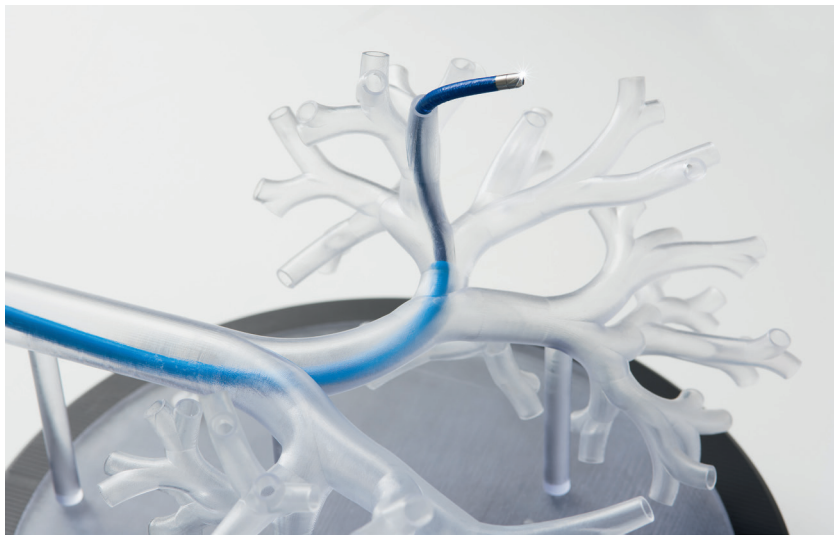
lot of our patients because they're going to be treated earlier and their outcomes should be better."

What, then, does this mean for the future of lung cancer care, and how does it change the dialogue around lung cancer diagnosis and patient outcomes? "The landscape of cancer care is changing very rapidly, and we're finding out that we can institute technologies to have an impact early, and the earlier we can have the impact, the more it's felt, and the better the outcomes, so I think that the landscape of cancer care as I see it will have more robust screening programs, earlier interventions, more tailored therapies," Dr. Manley said. "All of these technologies that have come out in the last five years and especially the new robotic platform that we're using at Fox Chase, I think it enables us to make those early impacts in a noninvasive way, and as the landscape continues to evolve, we're going to be trying to bring technologies that benefit our patients." OI

Amy Hindman is a freelance writer with more than 10 years of experience writing in technology, healthcare, and oncology.

Reference

1. American Lung Association. Trends in lung cancer morbidity and mortality. Available online at: lung.org/assets/documents/research/lc-trend-report.pdf. Last accessed January 3, 2019.



Scope coming out of lung model.

Full view of Monarch Platform.

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Advance your delivery of patient-centered care with the

HEALTH LITERACY GAP ASSESSMENT TOOL

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A full report will be emailed upon completion. All results are confidential.

WHY TAKE THE ASSESSMENT?

1. Identify areas where simple quality improvement measures will enhance patient-centered care.
2. Understand if education efforts are effective for your patient population.
3. Create a case for leadership on the need to ensure alignment to standards created by the National Academy of Medicine (formerly, the Institute of Medicine).

ASSESSMENT DOMAINS INCLUDE:

- Health Literacy Program
- Staff Training
- Health Information
- Navigation
- Technology
- Quality Measurement and Improvement

Access robust resources for each domain online.

American Cancer Society | American College of Surgeons: Inspiring Quality: Highest Standards, Better Outcomes. 100+years | AONN Academy of Oncology Nurse & Patient Navigator | Cancer Support Community: A Global Network of Education and Hope | Health Research for Action, UC Berkeley | NPAF National Patient Advocate Foundation

Funding & support provided by Lilly | ONCOLOGY

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ACCC
Association of Community Cancer Centers

The **Association of Community Cancer Centers (ACCC)** is the leading advocacy and education organization for the multidisciplinary cancer care team. ACCC is a powerful network of 24,000 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 the ACCC website at accc-cancer.org or call 301.984.9496. Follow us on Facebook, Twitter, and LinkedIn, and read our blog, ACCCBuzz.

Development of a Model Precision Cancer Therapies Program in a Community Setting

BY MARC R. MATRANA, MD, MS, FACP, AND JULIA L. COOK, PHD

An enduring partnership between Ochsner Health System and TGen on a phase I clinical trials program

Cancer in Louisiana is a significant problem, with both incidence and death rates from the disease far surpassing national averages.[1] In fact, the problem is so pervasive that the region between Baton Rouge and New Orleans through which the Mississippi River flows is commonly referred to as "Cancer Alley." The etiology of the problem is multifactorial and includes environmental exposure, lifestyle issues, and hereditary predispositions.

Physicians and non-clinical leaders at Ochsner realized that progress in the fight against cancer can only be made through research and that patients in the region had very limited access to a full range of cancer clinical trials. Ochsner had been an early National Cancer Institute Community Oncology Research Program site, bringing cooperative group and late-phase pharmaceutical cancer trials to its patients for decades. But in order to access early phase clinical trials at a dedicated center, patients had to travel to either Houston or Birmingham—a five- to six-hour drive in both directions. This option was impossible for most and impractical for all patients in the area. As a result, the Ochsner Precision Cancer Therapies Program was born of great necessity.

We recognized early on that the many challenges and nuances of running early phase trials required a dedicated center. Early phase trials are different for several reasons, including:

When the Ochsner Precision Cancer Therapies Program was in its planning phases and early after its launch, we took several important steps to set a tone for success.

In Brief

Two years ago, Ochsner Health System, the leading healthcare provider in Louisiana, made a bold move in opening the region's only early phase cancer clinical trials program. From the beginning, it was clear that identifying a partner with complementary experience and expertise was critical to accelerating the program's development. After much research and consideration, Ochsner partnered with the Translational Genomics Research Institute (TGen) of Phoenix, Ariz., a leading innovator in the field. The Ochsner Precision Cancer Therapies Program has rapidly grown to be an outstanding success.

View of the Mississippi River from the fifth-floor infusion suite lobby of the Benson Cancer Center.

The infusion suite at the Benson Cancer Center has 42 infusion chairs.

- Many unknowns. Often the proper dose of a new drug has not been defined, nor have the toxicities
- Intense monitoring. Phase I trials require intense monitoring and heavy oversight from sponsors and the U.S. Food and Drug Administration
- Demanding protocols. Protocols are often very demanding for staff and patients, including:
  - Intense pharmacokinetic measurements (i.e., 15-minute lab draws)
  - Multiple required consults (i.e., weekly eye exams, frequent cardiology evaluations)
  - Intense imaging schedules
  - Triplicate electrocardiograms with every dose of drug for some trials
  - Time-intensive functions (i.e., near-daily follow-up for most, weekly visits for others)
  - An overwhelming amount of computer and/or paperwork
  - Extensive discussions to convince sponsors to bring their best new agents to our program.

Despite the challenges, we were motivated to bring the best possible clinical care to our patients, and we quickly identified the resources and infrastructure that would be required to sustain the Ochsner Precision Cancer Therapies Program. These included:

- Medical expertise
- Nursing expertise
- Regulatory affairs expertise
- Specimen processing expertise
- Experimental pharmacy (frequently audited)
- Dedicated physical facilities with space for monitors
- Administrative support
- Special equipment for specimen processing and labs
- Interventional radiology cooperation for specimen acquisition
- Budget and contracts
- Legal infrastructure that understands the limits of intellectual property
- Networks of contacts and industry partners.

Early Initiatives

When the Ochsner Precision Cancer Therapies Program was in its planning phases and early after its launch, we took several important steps to set a tone for success. First, we arranged regular steering committee meetings between Ochsner, TGen, and other stakeholders to guide oversight and strategy. We also set up regular pipeline meetings to discuss new leads for interesting studies, potential partnerships with scientists and pharmaceutical companies, and the progress of the studies during initiation. We made a concerted team effort to convince sponsors to bring new agents and new trials to us, and we undertook extensive staff training at every level.

One of the most important actions we took, which continues today, was to establish weekly Phase I rounds. During these meetings, every member of the team—including lab technicians,

data coordinators, pharmacists, nurses, supervisors, physicians, investigators, and the director—meet to discuss each study open and in the pipeline and every patient enrolled on an early phase study or potentially eligible for a study. We also review every upcoming site initiation visit and site qualification visit and make relevant general announcements. Every team member's voice is heard and valued.

Early Organizational Structure and Site Description

As part of our efforts to establish an early phase cancer trials program, Ochsner Cancer Institute research staffing was organized into two distinct pathways: general oncology (core industry-sponsored and cooperative group studies) and Ochsner Precision Cancer Therapies Program (early phase studies, novel reagents, precision therapy trials). When we began our partnership with TGen, we were very fortunate to already have a robust, well-staffed clinical research program in general oncology. In year one of the Ochsner Precision Cancer Therapies Program initiative, we hired two nurses, a data coordinator, a regulatory coordinator, and a lab technician.

Marc Matrana, MD, a member of Ochsner's Hematology-Oncology Department who had trained at MD Anderson Cancer Center, was recruited as medical director of the Ochsner Precision Cancer Therapies Program with 40 percent protected research time. He was joined by two other physicians—Drs. Laura Finn and Robert Ramirez (20 percent protected research time each)—and a nurse practitioner who also devoted 40 percent time to the Ochsner Precision Cancer Therapies Program and supported Dr. Matrana in the clinic. Key additional support—without which the program could not have been developed—was provided by the nurses, cancer registry coordinators, and other anatomic site-specific general oncology team members that provided guidance and expertise to the new Ochsner Precision Cancer Therapies Program staff. It would not have been possible to launch a successful early phase program of this magnitude without a prior established robust research program.

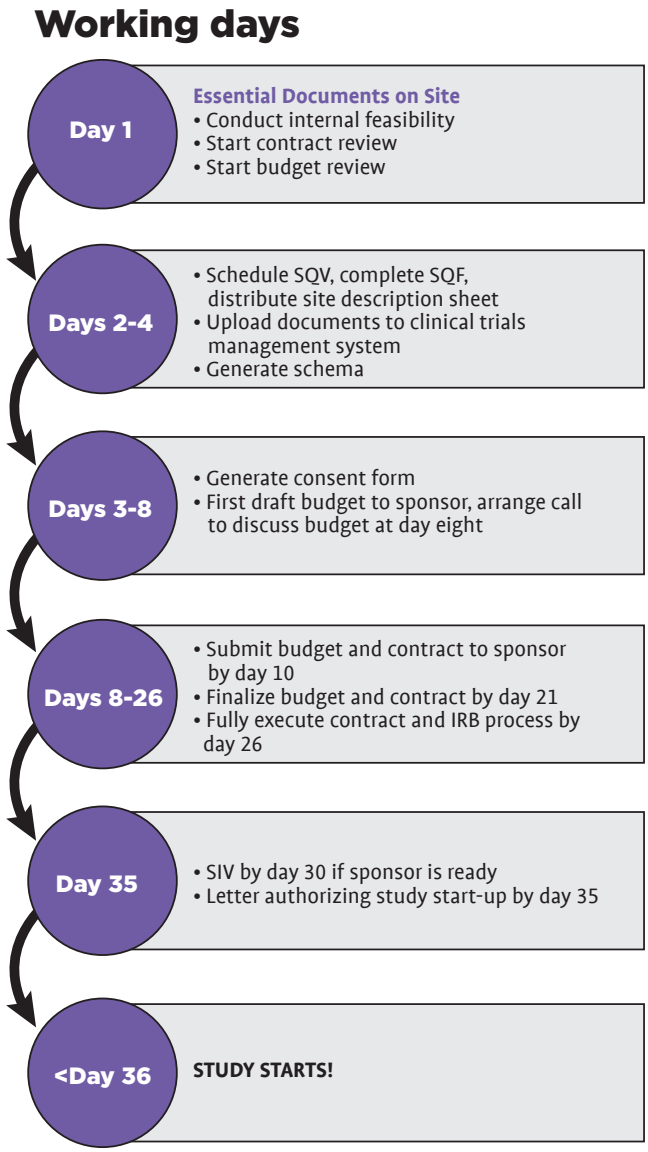
Due to space limitations in clinical areas, the workspace for Ochsner Precision Cancer Therapies Program research staff was centralized in a building adjacent to the Benson Cancer Center. The oncology clinics are within Benson Cancer Center, as is the infusion area and oncology clinical laboratory.

Process Optimization: The Budget and Contract Office

At the inception of the partnership, our TGen colleagues worked with us to review and optimize our processes. They reviewed our job descriptions, audited our prescreening logs, reviewed our study budgets, and evaluated our infusion center and investigational pharmacy, among other roles.

At that time, our centralized budget and contract office (which serves research across the organization) was typically completing contracts within 90 to 120 days. We worked with our partners and our internal office to devise a plan to reduce turnaround time to 36 days from the time that all essential documents are loaded into our clinical trials management system to the time that the study launches (see Figure 1, below). We hired one additional staff member for the budget/contract office to selectively accelerate Ochsner Precision Cancer Therapies Program study activation without compromising turnaround time for non-Ochsner Precision Cancer Therapies Program studies.

Figure 1. Contract and Budget Time to Study Start-Up



Typical time to study start-up for Ochsner Precision Cancer Therapies Program is less than 40 days from receipt of all sponsor materials. SQV = site qualification visit; SQF = sponsor feasibility; SIV = site initiation visit.

One of two private rooms at the Precision Cancer Therapies Program for administration of complex infusions.

The Precision Cancer Therapies Program laboratory, where patient blood and tissues are processed.

The Ochsner Precision Cancer Therapies Program office entrance area from the first floor of the Benson Cancer Center. These rooms were added in year two of the initiative.

Process Optimization: Site Description for Sponsors

The Ochsner Precision Cancer Therapies Program initiative led us to re-evaluate, revise, and refine our site description and presentation for sponsor site qualification visits. The current material is in a branded, glossy two-pocket folder and contains key program elements and practical materials, including:

- A map of Benson Cancer Center
- A map of the Ochsner campus
- General site specifications for the oncology clinic, chemotherapy infusion, electronic health record, and record retention
- Protocol training
- Institutional Review Board (IRB) statement of compliance
- Association for the Accreditation of Human Research Protection Programs accreditation certificate
- IRB roster
- IRB panel meeting dates and submission deadline dates
- Informed consent process
- Research education requirements for study staff
- IRB external serious adverse events reporting
- Research pharmacy
- Study drug destruction guidance
- Intravenous bag and administration information
- Chemotherapy infusion—pharmacy site blinding guidance
- Radiology specifications
- Laboratory send-out equipment
- College of American Pathologists accreditation and Clinical Laboratory Improvement Amendments certification.

The site description folder has been very popular with our sponsors and adds to the overall perception of an organized and professional clinical trials site.

Process Optimization: Sponsor Feasibility Form

Sponsors typically require that provider organizations like Ochsner complete information in a feasibility form that assures sponsors that we have the appropriate physicians, patient population, and resources to partner effectively on a given study protocol. Within a few months of launch, it became apparent that the Ochsner Precision Cancer Therapies Program (and Ochsner Cancer Institute as a whole) also needed an internal form to ensure that trials we were considering were reasonable for Ochsner and that the sponsoring partners were reliable and of high caliber. Some of the specific problems that led to the conclusion that we should better evaluate our partners and trials included the following:

- Several studies closed at the national level immediately after we opened them at Ochsner—launching new studies requires significant time and resource input (budget and contract office, research office, regulatory coordinator, physician, and lead nurse time).
- Sponsor medical monitors were not always readily available—we found them to be difficult to track and slow to respond, and contact information was not always correct.
- Sponsor research monitors were not always optimally informed regarding studies.

- Concerns were expressed by our pathology department and laboratory—they required a more substantial advance notification to prepare for trials in which their participation was required.

In response to these challenges, we generated a feasibility form that must be completed by the industry sponsor for our consideration before we agree to accept a study. The questions on the form include, but are not limited to, the following:

- Expected enrollment for trial (all phases/cohorts)
- Current number of subjects enrolled (all phases/cohorts)
- Rate of enrollment
- Study start date
- Date of first subject enrolled
- Proposed "closed to enrollment" date
- Total number of sites planned
- Total number of sites currently open (nationally or internationally)
- Number of additional sites projected to open
- Is the medical monitor located in the United States? If not, where is it located?
- What central IRB is used?
- Are computed tomography/positron emission tomography/magnetic resonance imaging/labs conducted within standard of care?
- Are there any special requirements for scans, labs, etc.?
- Are there any pending amendments to the IRB or protocol?
- When are the new documents expected?
- Are there any special pathology requirements (fresh tissue, slides, etc.)?
- Is an ophthalmologist required?

Completion of this form by our sponsors before the site qualification visit has improved our selection process and greatly reduced frustrations caused by decisions made with inadequate information.

Process Optimization: Internal Feasibility and Trial Selection

It is challenging to enroll patients into cancer clinical trials. Enrollment, even to those trials that would seem on the surface to be good study matches based on disease status and patient population, may be difficult due to the precise and detailed intricacies of the enrollment criteria. The challenge is greater yet for precision studies in which genetic criteria are restricted. Therefore, a robust internal feasibility assessment is critical to reduce non-enrolling trials, which are costly mistakes for both the provider organization and the sponsor.

For several years, Ochsner General Oncology held protocol review and monitoring committee meetings that reviewed all incoming trial opportunities for pertinence to the program. The cover sheet included questions related to disease relevance, patient population, sponsor, research category, and therapeutic intent. The review process functioned well for about two years, after which the meetings lost momentum—in part because the committee members had competing priorities and in part because the disease-specific expertise required in cancer, given its many disease subspecialties, was difficult to adequately capture in a static review team. An alternative review process was clearly needed for both the Ochsner Precision Cancer Therapies Program and general oncology areas.

Consequently, a group of physicians, administrators, and research leaders worked together to create a virtual protocol review committee in which study protocols are forwarded with a circulation document to key stakeholders. The recommendation from each party is recorded on the form (Figure 2, page 28), and the time frame for the circulation is five working days. If, at the end of five days, there is concordance from stakeholders, the regulatory coordinator will inform the primary investigator (PI) and move to next steps with the sponsor. If there is discordance, the medical director provides guidance. This new process has led us to reduce the number of trials that we commit to initiating and focus on trials that better serve our patients.

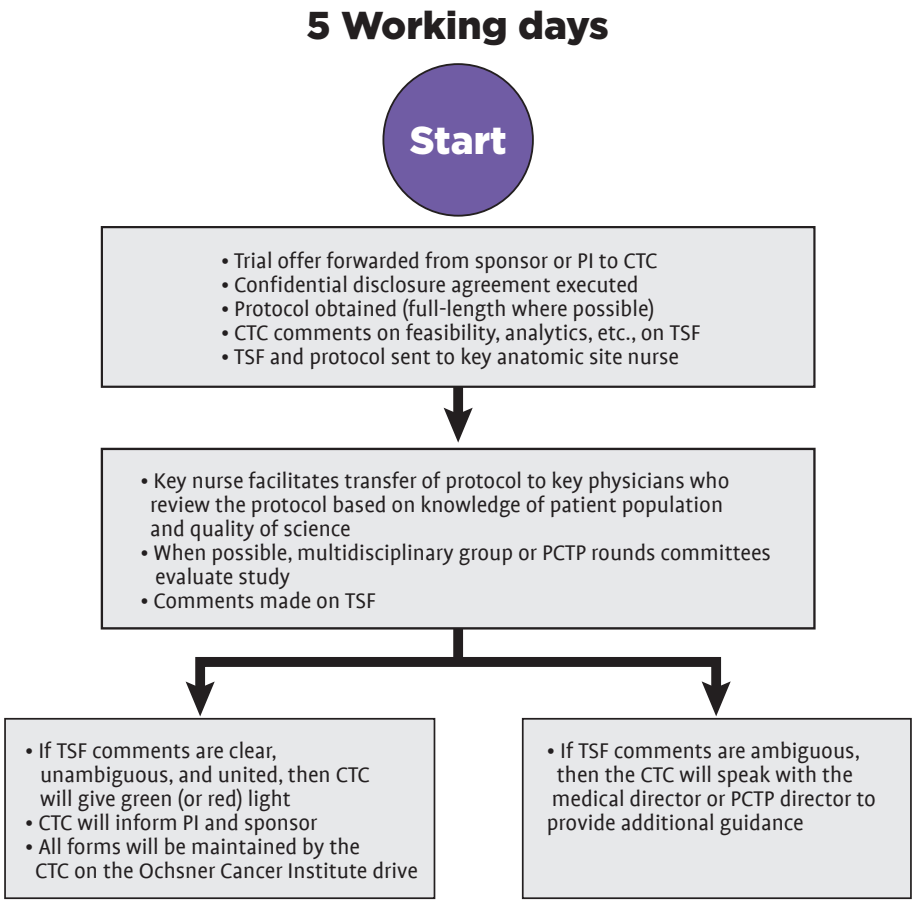
Year One: Trials and Enrollment

Though the official launch of the Ochsner Precision Cancer Therapies Program occurred in April 2017, our internal program clock started on Jan. 1, 2017. We fell slightly short of our goal of 48 patient accruals in early phase novel studies, enrolling only 42 in year one (Figures 3a and 3b, page 29). However, we opened 28 Precision Cancer Therapies Program trials in 2017, exceeding our goal of 25. These trials covered many different subspecialties, including hematologic malignancies, solid tumors with specific defined mutations, squamous cell carcinoma of the lung, metastatic pancreatic cancer, renal cell carcinoma, ovarian and fallopian cancers, melanoma, and breast cancers, among many others. Our average patient enrollment over the first year was 3.5 patients per month, ranging from 2 to 8 patients per month (Figure 3b, page 29). A total of 38,427 pre-screening events were required to enroll 42 patients in these highly specialized trials (0.1 percent). Note that, within a given pre-screening session, individual patients were pre-screened for many studies.

Year One: Philanthropy

Obtaining philanthropic support was an important goal to offset the high costs of starting and maintaining the Ochsner Precision Cancer Therapies Program. An inaugural $1 million gift from former Entergy chief executive officer and Ochsner Precision Cancer Therapies Program patient Wayne Leonard set the tone for further gifts. In order to recognize Leonard and his wife, Jackie, our Ochsner Precision Cancer Therapies Program clinic was named in their honor. A $1 million gift from environmental attorneys Stuart Smith and Barry Cooper followed. This money was earmarked for an endowed professorship in experimental therapeutics to help support the Ochsner Precision Cancer Therapies Program medical director's research time. An additional $350,000 gift for experimental therapeutics research and 450 smaller gifts were received during the program's first year. Days before his death, Wayne Leonard gave an additional $250,000 to further support the initiative. A close working relationship

Figure 2. Trial Selection Process: Five Working Days



Trial selection process is five working days from protocol receipt to final decision regarding interest and suitability of study for the PCTP. Note: Budget may still be a barrier to trial launch. CTC = regulatory coordinator; PCTP = Precision Cancer Therapies Program; TSF = trial selection form.

between Ochsner Precision Cancer Therapies Program staff and our cancer center philanthropy officer was vital to successful fundraising.

Year One: Marketing and Outreach

Spreading the word to patients and providers that "new hope" had arrived in our region was crucial. We worked with our marketing, communications, and business development teams to execute detailed plans for outreach. These included physician presentations through field trips to satellite sites and outside practices in order to meet providers and introduce the Ochsner Precision Cancer Therapies Program. We engaged in speaking tours through various forums and venues across the region. We conducted television and radio interviews, launched ads in various publications, created online videos, engaged social media outlets, and published articles about the Ochsner Precision Cancer Therapies Program. We also hosted a full-day off-site CME event around issues of precision cancer medicine and early phase trials that was attended by about 85 providers, nurses, and other stakeholders from the region. We further created a website, dedicated email address, and a toll-free hotline to centralize contact from interested individuals. Our scheduler/concierge continually works with the research nurses to follow up every inquiry.

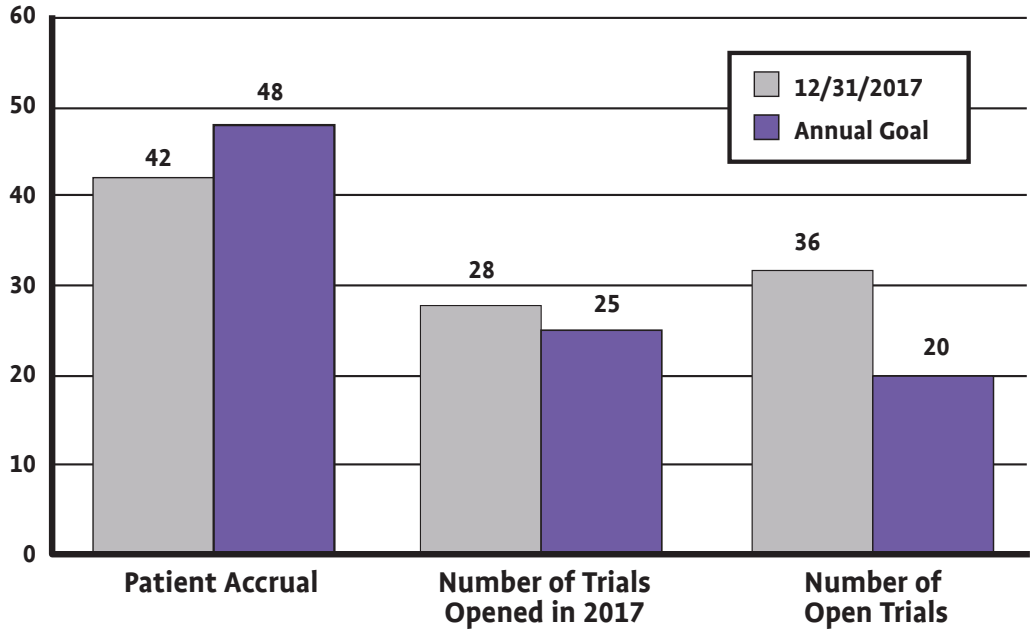
Year Two: Programmatic Updates

In year two, Ochsner Precision Cancer Therapies Program offices were repurposed from existing space on the first floor of Benson Cancer Center, marking the first Ochsner Precision Cancer Therapies Program-dedicated space. The Ochsner Precision Cancer Therapies Program was also enhanced with the addition of new staff and sites. We added a third investigational pharmacist for research; additional pharmacy assistance was required to manage the increasing number of studies opened within the program.

Moreover, in year two, we began opening select Ochsner Precision Cancer Therapies Program studies at other Ochsner

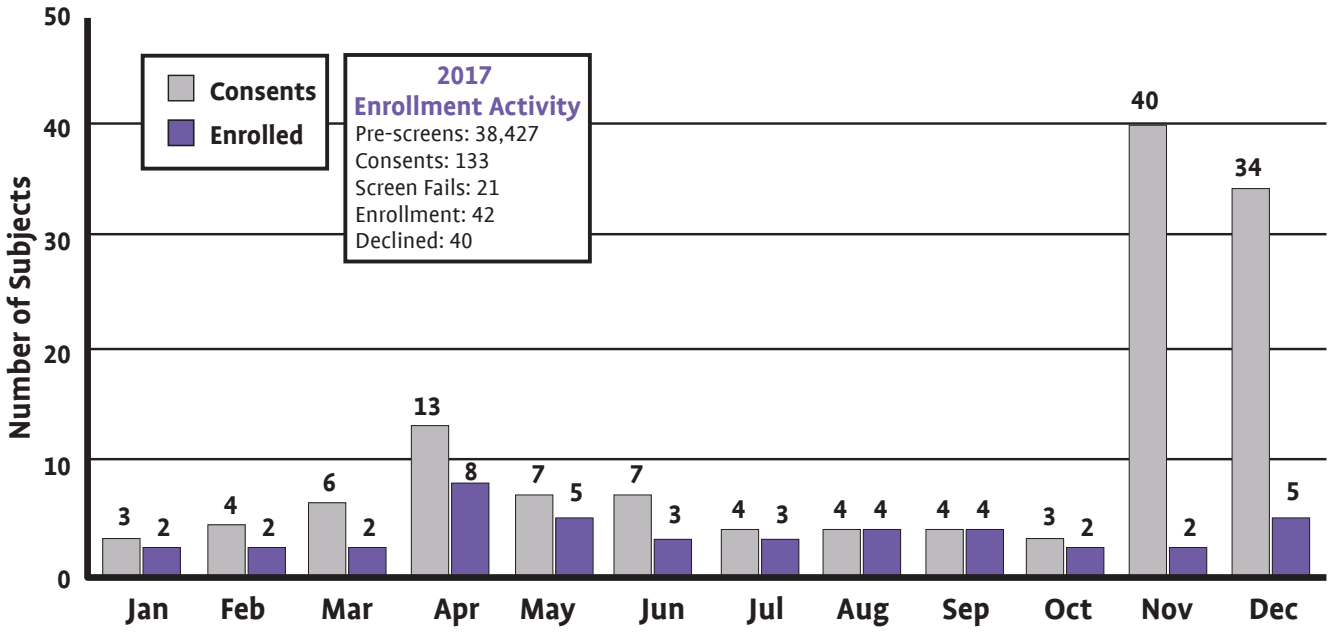
(continued on page 30)

Figure 3a. Precision Cancer Therapies Program Trials and Accruals vs. Annual Goals: Year One (2017)



"Open Trials" reflects some trials that were opened in Ochsner General Oncology and moved under the Ochsner Precision Cancer Therapies Program umbrella after program launch. "Trials Opened" refers only to those opened initially as Ochsner Precision Cancer Therapies Program studies.

Figure 3b. Monthly Patient Enrollment in Precision Cancer Therapies Program: Year One (2017)



Ochsner Precision Cancer Therapies Program reception area where guests and families are interviewed for early-phase study participation.

Ochsner Precision Cancer Therapies Program conference room, where patient cases are reviewed and future directions are determined.

(continued from page 28)

campuses, Kenner and Baton Rouge, requiring additional pharmacy assistance. The laboratory assistant was upgraded to a laboratory technician to better manage complex studies. Ochsner Precision Cancer Therapies Program Rounds was formalized in year two, and attendance substantially increased. Trial selection decision support tools were developed for key areas—including breast, gastrointestinal, genitourinary, gynecologic, hematologic, lung, and solid tumors—and updated and distributed to providers monthly.

Year Two: Trials, Enrollment, and Academics

Though we failed to meet our enrollment goal in year one of the initiative, we far exceeded our goal in year two (see Figures 4a and 4b, page 31). Our goal for 2018 was to enroll 60 patients in Ochsner Precision Cancer Therapies Program studies; we actually enrolled 106 (76 percent positive variance). Our 2018 goal for new trials was lower than our 2017 goal, because our plan was to strategically open studies that both filled trial gaps and were optimized for our patient population. In fact, due to physician enthusiasm for the many early phase trial opportunities presented to our program, we opened 38 trials in 2018. In the second year of the program, therefore, our patients have had opportunities to participate in more than 60 novel trials across a wide range of cancer areas.

Our academic efforts also grew significantly in year two. Our physicians co-authored 11 abstracts and three full-length publications related to early phase novel therapies under investigation at Ochsner in 2018, compared to two abstracts in 2017. For each of these, Ochsner investigators participated as a full partner in these studies and made significant academic contributions.

Future Directions

As the Ochsner Precision Cancer Therapies Program grows and expands to new areas, our goals remain patient focused. We plan to:

- Greatly accelerate the development of new, more effective, less toxic, and more personalized therapies for cancer patients in the Gulf South and beyond.
- Expand precision medicine and routine free or low-cost next-generation sequencing across our network and region and expand to other medical disciplines as appropriate.
- Continue to build our world-class team and identify the best talent at every level, including recruiting new physician talent to meet the needs of our growing research patient population.
- Create new partnerships with scientists and industry to increase innovative breakthroughs and clinical trial opportunities for Ochsner patients.
- Identify additional philanthropic opportunities to further support our work and accelerate the growth of our program.

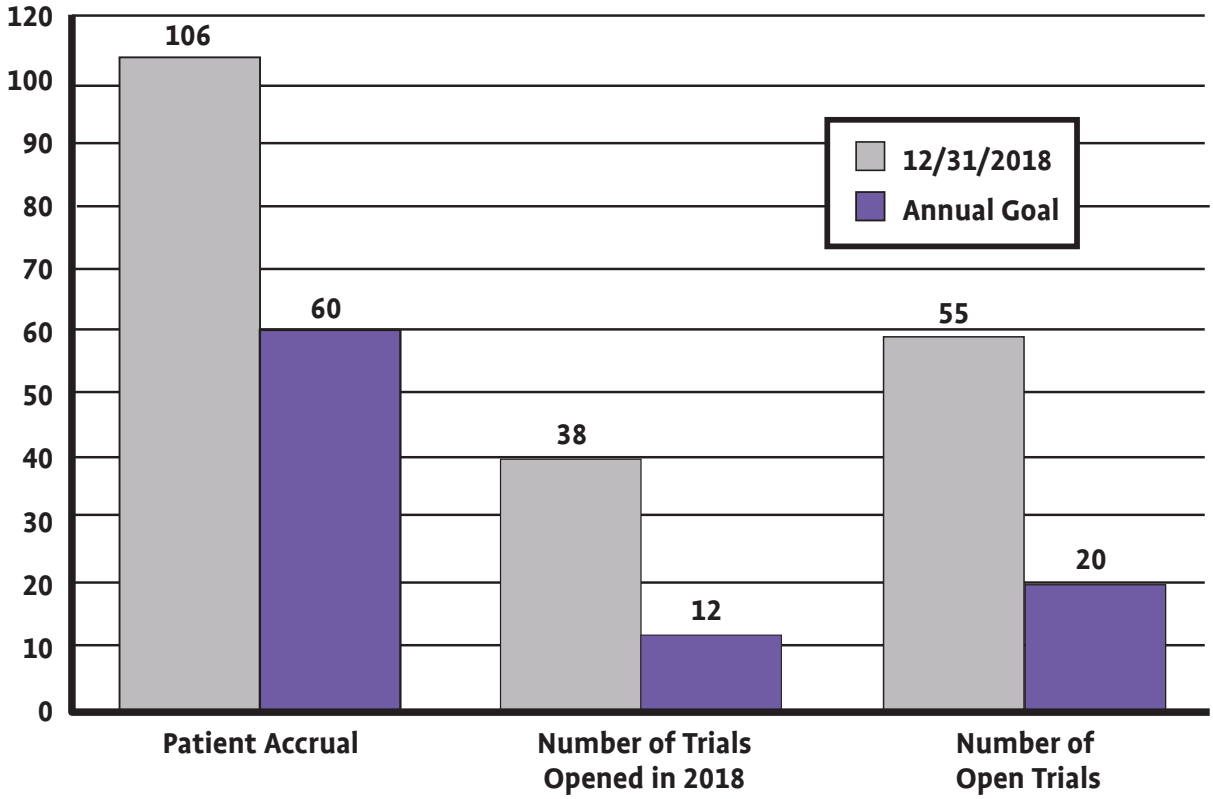
The Precision Cancer Therapies Program will continue to get the word out to patients and providers in the Gulf South region that "new hope" in the future of cancer care and research is here. OI

Marc R. Matrana, MD, MS, FACP, is medical director, Ochsner Precision Cancer Therapies Program, and Julia L. Cook, PhD, is director, Institute for Clinical Research-Oncology, Ochsner Cancer Institute, New Orleans, La.

Reference

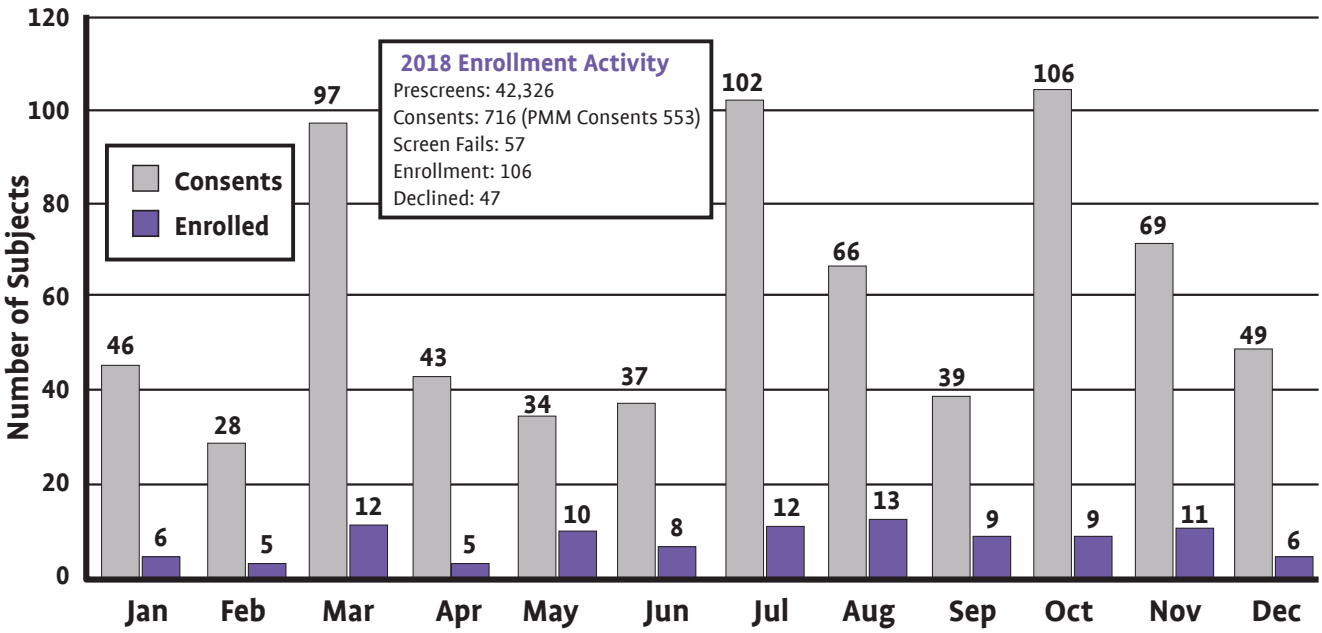
1. American Cancer Society. Cancer Statistics Center: Louisiana. Available online at: cancerstatisticscenter.cancer.org/#!/state/Louisiana. Last accessed January 7, 2019.

Figure 4a. Precision Cancer Therapies Program Trials and Accruals vs. Annual Goals: Year Two (2018)

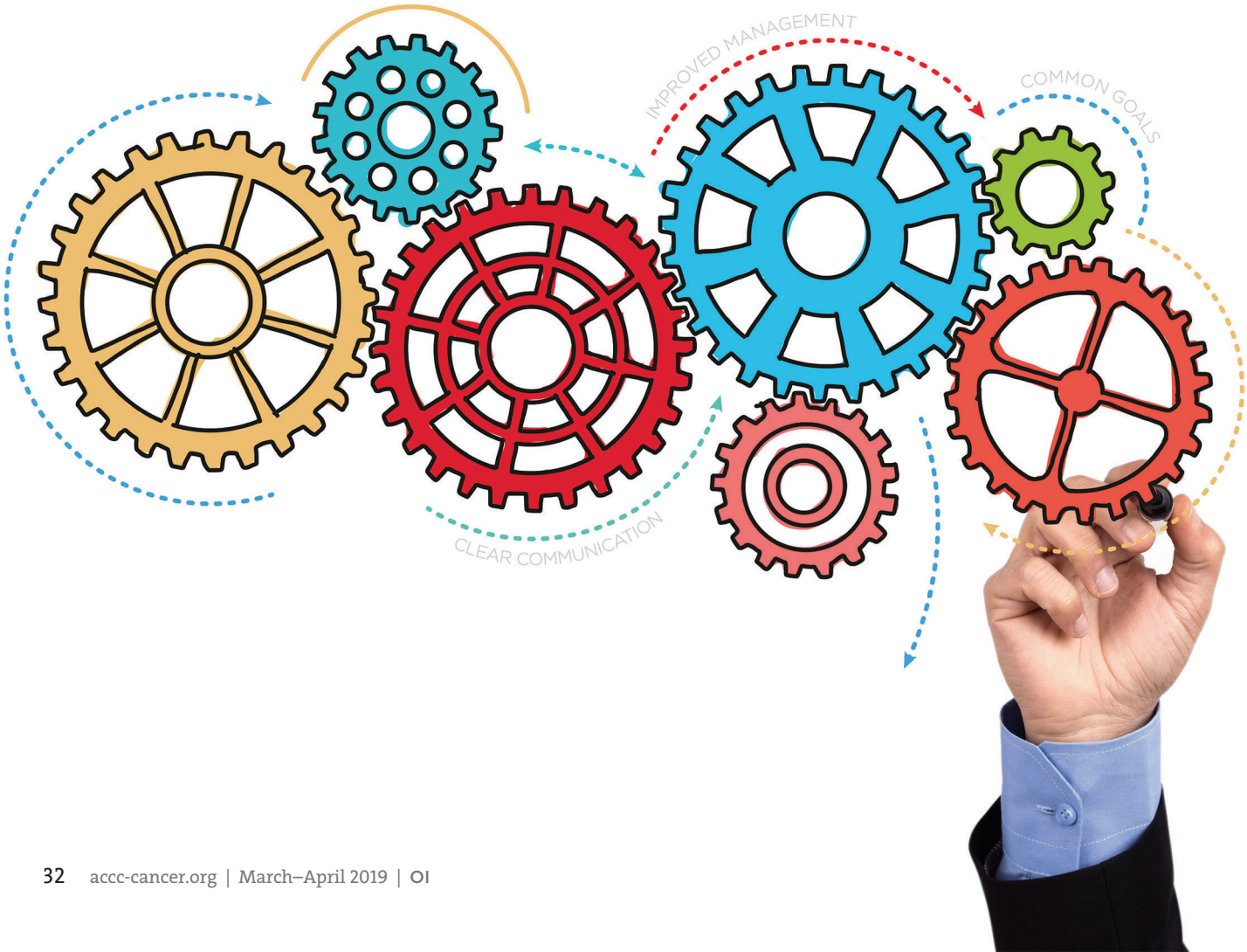


"Open Trials" reflects some trials that were opened in Ochsner General Oncology and moved under the Ochsner Precision Cancer Therapies Program umbrella after program launch. "Trials Opened" refers only to those opened initially as Ochsner Precision Cancer Therapies Program studies.

Figure 4b. Monthly Patient Enrollment in Precision Cancer Therapies Program: Year Two (2018)



One Best Practice:
Streamlining Workflow, Unifying Staff, and Reducing Redundancy



BY ELIZABETH KOELKER, MHA, FACHE

In December 2016, Kettering Health Network opened a new five-story, 120,000 square foot cancer center on the campus of Kettering Medical Center, the network's flagship hospital. The community's response to the opening of the cancer center was overwhelming. More than 1,000 guests were present for the VIP ribbon cutting, and over 3,000 community members attended the public opening—even though it was scheduled on a wintry evening in the middle of the week.

Southwest Ohio was excited and supportive of the new cancer center, but behind the scenes, the road to opening was bumpy. Discussions and planning of the cancer center spanned over a decade. A series of starts and stops, shifting scope and definitions, and conflicting expectations from key stakeholders made the initiative, at best, an interesting journey.

A Service Line Approach

In late 2013, Kettering Health Network chose to reorganize business operations by service lines—grouping care by the disease state (i.e., cardiology, oncology) rather than by department (i.e., diagnostics, surgery). Oncology was chosen as the first service line to deploy. Nearly all oncology physicians were already employed by the network, so it was perceived to be the "easiest" starting point. The project to build a cancer center had finally gotten off the ground with an approved strategy, design, and capital allocation. Now it was time for the oncology service line to unite and rebrand under the name Kettering Cancer Care.

When administrative leaders began evaluating the rollout of this new service line approach, it became evident that a massive overhaul of the oncology division would be required for successful implementation. The leadership team identified four major issues:

1. Division and internal competition between the employed oncology physician groups
2. Major communication deficits, both clinically and interpersonally
3. Inefficient management of resources, supplies, and operations
4. Insufficient infrastructure to meet the volume demands.

> This lack of unification alone would have been a challenge, but the situation was compounded by employed physicians competing against each other. This culture of competition and confrontation was so pervasive that some physicians would refer patients out of network for treatment to avoid sending a referral to a colleague in another oncology subspecialty.

It was imperative that the oncology service line unite and develop a single best practice for cancer business operations. We were charged with building a cancer center that could operate in a future "ideal" state when the present state of oncology operations was broken. By the end of the three-year transformation, we had built a new cancer center where all oncology practices in Kettering Health Network operate and collaborate. This, however, was more than a construction project; it required a massive cultural shift to increase engagement, efficiency, and create collaboration.

Challenge 1. Division and Competition Between Physician Groups

Prior to the service line overhaul, all physician groups operated independently: medical oncology practices were separate; gynecologic oncology was separate; radiation oncology was separate. These physicians did not even have one standing meeting on the calendar together. They were completely siloed.

Due to the siloed operations of the physician practices at the time, however, there was no cross-coverage for staffing. On any given day, one practice could be overstaffed and flexing employees to home while another practice one floor above was at critical staffing levels and in dire need of those highly specialized employees who were sent home.

This lack of unification alone would have been a challenge, but the situation was compounded by employed physicians competing against each other. This culture of competition and confrontation was so pervasive that some physicians would refer patients out of network for treatment to avoid sending a referral to a colleague in another oncology subspecialty. Division ensued over MD versus DO credentials; further conflict was born of the wide clinical variation between the practices. One group had an in-house pharmacy and pharmacist, another did not. One practice lacked basic technology like infusion pumps, while another group enjoyed the "luxurious" physician-nurse dyad model. Overwhelmingly, the lack of willingness to pool or share resources exacerbated all issues.

Challenge 2. Lack of Communication

Lack of communication between oncology physicians was difficult to tackle in and of itself; an even larger problem was the lack of communication to referring physicians and even emergency and hospital departments. There were no centralized or shared medical records. Some practices had brought their own electronic health records (EHRs) with them when they were acquired by Kettering Physician Network; others had no EHR and wrote everything, including chemotherapy orders, by hand. Because of this, when an oncology patient was sent to the emergency department or admitted to the hospital, collaborating physicians had no information regarding which chemotherapy or immunotherapy drugs the patient was on, recent labs or images, or any information at all regarding the patient's plan of care.

Challenge 3. Inefficient Management of Resources

Prior to 2013, the oncology service line director had changed four times in four years—a lack of consistent administrative leadership resulted in a lack of efficient management. Oncology employees have a high level of specialization, training, and education required to work with this specific group of patients who may be emotionally fragile. Nurses require specialized education and training to administer chemotherapy, and other certifications and qualifications are regulated to ensure a high-quality cancer care department. In cancer care, you cannot just "float" staff or pull from a general labor resource pool.

Due to the siloed operations of the physician practices at the time, however, there was no cross-coverage for staffing. On any given day, one practice could be overstaffed and flexing employees to home while another practice one floor above was at critical staffing levels and in dire need of those highly specialized employees who were sent home. There was a great amount of duplicate work being done, both in the clinical and front and back office operations. We were not maximizing our human resources.

Challenge 4. No Infrastructure for Growth

All of these issues were compounded by a lack of necessary infrastructure. When each physician practice was acquired, they were placed, separately, in office space that was retrofitted to try to accommodate the unique needs of cancer patients. Chemotherapy treatment can involve a 30-minute injection, but it also can be a grueling six-hour day of transfusions. Because each practice was placed in a space that was not designed specifically for cancer patients, they had no choice but to offer infusion services in one big open room with recliners that all faced each other. There were not even curtains to separate the patient chairs. If a patient began experiencing a reaction or side effects while receiving treatment, a nurse would bring a foldout screen to try to provide some privacy. To compound the issue, there was no space for a family member or support person to join the patient during treatment. At one point, some of the practices were setting up folding chairs in an adjacent hallway to access ports or administer an injection because the number of daily patients surpassed the availability of infusion chairs.

Unfortunately, the rate of cancer is rising in southwest Ohio, along with an aging population. Cancer incidence is climbing, underscoring a need to expand care. However, even if every other challenge could be solved to streamline operational inefficiencies, we did not have the infrastructure required for the inevitable growth in the community.

Outlining the Goals

We first approached this overhaul by identifying the need for a cultural shift to a network, or single best practice, approach. Instead of each practice operating independently, we needed to:

- Reduce clinical variation
- Define industry standards
- Move forward together on practicing standards

Kettering Health Network aims to be known for being the best in the marketplace for care, so we first had to define what it took to be the best and then achieve and even surpass that level of quality.

Because of the longstanding division between physician practices, we came to understand that the way to achieve a real shift in mindset would be to restructure practice-level leadership. Up until this point, everyone held titles that were specific to their practice—that is, each practice had its own manager and leadership structure. In the new model, job descriptions, titles, and responsibilities reflected a network or service line-wide role. Manager A was given responsibility for cancer infusion across the network; manager B was in charge of oncology clinics across the network; manager C would be in charge of the business offices for oncology across the network. We wanted to do away with the siloed mindset. Everyone would have responsibility and accountability for multiple sites and locations. We could no longer afford to operate under an "everyone-for-themselves" mentality.

We also knew that communication between practices and hospitals was essential. The practices would have to transition to a centralized EHR. Even though this might make physicians less efficient in their charting initially, and even though there was some perception that the software might not be as optimal for use in an oncology setting as their current system, translating the EHR to the hospital was not optional. At the time, physicians were paid under a productivity model, so their ability to see more patients translated to more income. In attempts to minimize the disruption to their workflow and to ensure that the solution we were proposing was one that could garner buy-in, the decision was made to "freeze" physician productivity at a base-store rate for a set period of time to enable physicians to contribute to building the new EHR. People are more likely to support what they help build, and we took this mindset to heart and attempted to engage the physicians, pharmacists, and clinical care team in a real way, encouraging them to directly plan and build their future.

But the catalyst for real change came in recognizing the dire need for a new cancer building. Volume, incidence, and market share were dramatically increasing, but we had nowhere to put the patients. People from every area came together to provide input on the design of a new cancer center: physicians, nurses, clinicians, administrative leaders, cancer patients, cancer survivors, and loved ones. We needed to design a future space that would not only achieve but surpass the industry standard for care and privacy.

The transition to a new physical space provided the perfect opportunity to begin implementing "one best practice." The variation for completing a task and the ever-shifting expectations that changed from physician to physician left the staff with stress and anxiety, making more inadvertent errors and performing with decreased productivity. For example, at the start of this project, there were 49 different patient appointment types that schedulers could make for cancer patients. It was too confusing; we needed to define one streamlined way of working and make expectations clear.

This process did not go perfectly; there was resistance, there were breakdowns, and not every physician or staff member stayed. But we could not allow our measure of success to become confused or misled; it was acceptable for employees or physicians to self-select out of the new service line model. We were building a culture of patient-focused care that needed to set the industry standard for the very best.

Taking Action: From Disparate to Unified

As we embarked on building a new facility, it became clear that we would not be able to accomplish this feat without working as a unified team. The need for a new physical space served as the impetus for change. We began to eliminate legacy practices to create a single, multidisciplinary group of Kettering Cancer Care. In the planning process for the construction of the cancer center, we created a patient advisory council to ensure patient-centered care, designed by patients for patients.

We cross-trained all staff to work at every location throughout the network to maximize productivity. Despite initial resistance, we started seeing increased volume due to decreased internal competition and greater access to care. As we continued to move forward, our team engaged with Process Excellence, our internal consultants and experts on LEAN initiatives, a set of processes and philosophies that aim to reduce waste and create maximum value for patients, to guide and advise on the project design and future state of the operational workflow. Eventually, in June 2016, six months prior to opening Kettering Cancer Center, we launched

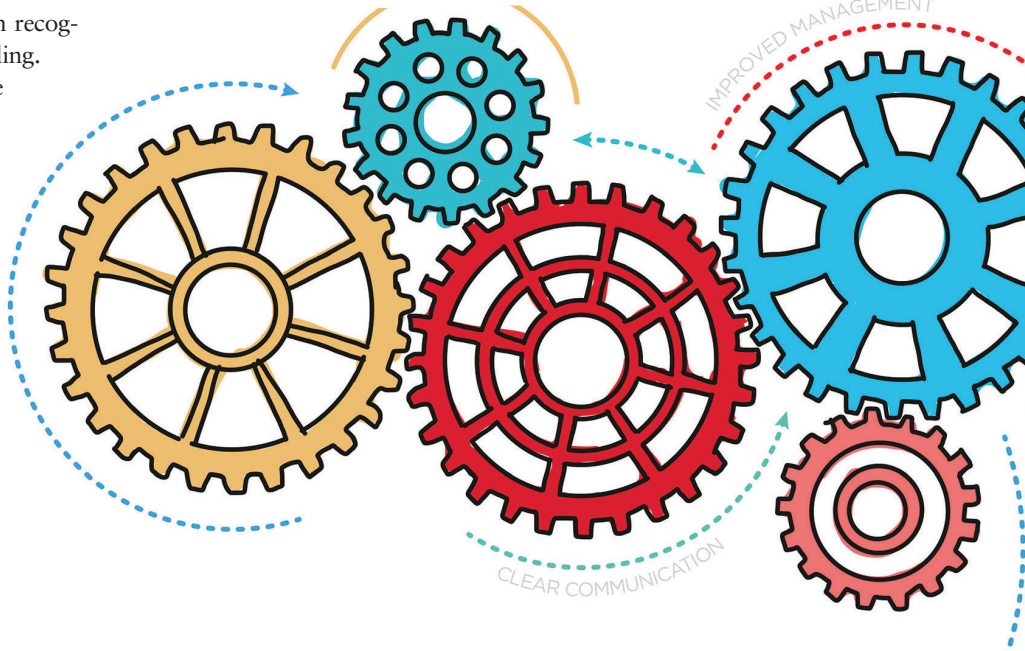
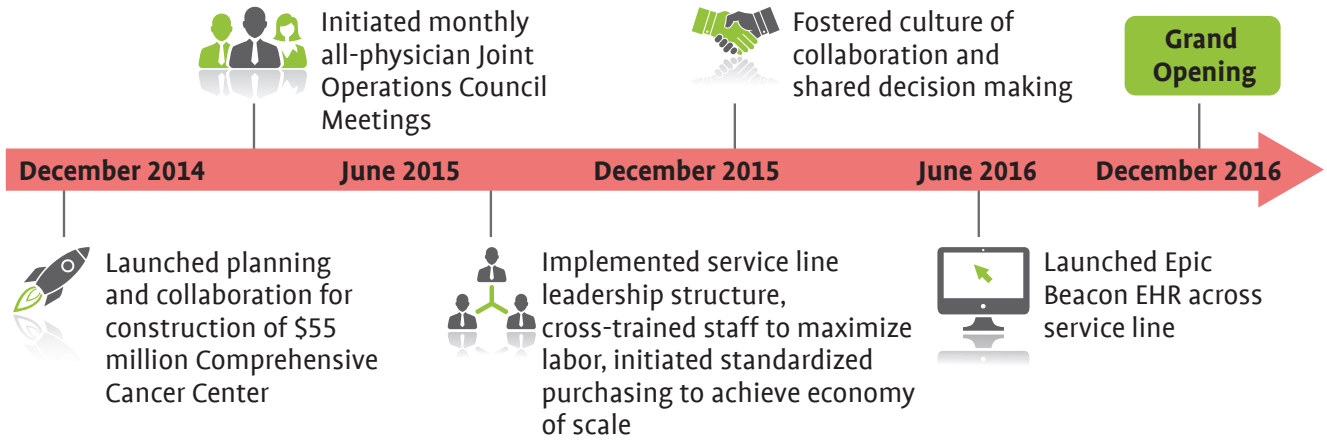


Figure 1. Timeline of One Best Practice Model



Epic Beacon, an EHR system, to increase efficiency in locating records and improve communication with collaborating physicians. It was made clear to physicians that there would be no space built for physical records in the new cancer center—the EHR was the new standard. Figure 1, above, is a timeline of the journey to our One Best Practice Model.

The Impact: Streamlined Operations, Increased Volume, Decreased Competition

Kettering Cancer Center opened in December 2016. The oncology service line achieved our five-year growth projection in the first five months. In a year and a half, we have had to add nine additional physicians to the oncology service line just to keep pace with the demand for care.

Volume of consults per week has significantly increased and, with it, efficiency has also increased. In the clinic and infusion setting, volume has grown 28 percent with the addition of eight full-time equivalents. Breast cancer screening and imaging volume is up 38 percent to date with the addition of only 0.7 full-time equivalents. The streamlining of clinical operations and processes has allowed us to accommodate for this growth while achieving economy of scale.

When designing the cancer center, we implemented monthly meetings to discuss the process development and design of the cancer center. Those meetings have since evolved to focus on clinical operations, patient satisfaction, and quality metrics. We formulated an oncology quality review team led by physicians. There are now medical directors for each area—radiation oncology, medical oncology, surgical oncology, etc.—who are empowered to make decisions representing their divisions.

The changes we made were important for improved quality of care, but they also were vital in transforming the internal culture. Employee and physician engagement is currently at an all-time high, because we have fostered pride, ownership, and accountability. Our employee engagement has moved from the 54th percentile to the 87th percentile. In turn, patient satisfaction is now in the 90th percentile.

The First Example of Unification

Like many healthcare networks across the country, Kettering Health Network has a color-coded uniform that represents roles on the care team. Nursing wears blue; environmental services wears tan; therapy wears purple; etc. Prior to moving into Kettering Cancer Center, employees expressed a desire for their own color of uniform to represent cancer care. This kind of request had been presented to the executive leadership team before by other service lines and divisions and it had never been granted.

As executive director for oncology, my top priorities were the creation of the service line and construction of the new cancer center. I told employees that if they gathered the data—go to Human Resources, find out the parameters, achieve consensus among yourselves, and come up with the proposal—then I would lobby to the executive team for this change. But this had to be their project. I would advocate for them, but it was their project to undertake. This was the first project in years that employees came together for.

After they presented me with their findings, I scheduled a meeting to pitch the idea to the executives in the network knowing that several other divisions had asked for the same result with no success, emphasizing our focus on building a new culture. Not only did the executive team grant the request, but they provided a stipend for every employee to purchase a new Kettering Cancer Care uniform. By the time we moved into the new building, each employee was wearing a brand-new turquoise uniform to mark that they were part of the oncology care team.

The uniform color, though it may seem like a small and possibly insignificant detail, became the cultural shifting point. Now we *looked* unified, and looking the part is sometimes half of the battle. That color and those three embroidered words across the uniform—Kettering Cancer Care—were a source of pride for our unified workforce.

Lessons Learned

Today, we are known as one entity: Kettering Cancer Care. When patients come for their treatment, they do not just interact with one nurse who cares for them; they interact with multiple caregivers who all want to be part of their extended family. When the quality of working relationships grows, the quality of care for the patient can also improve.

One of the most unexpected measures of success has been noticing how employees introduce themselves or communicate over the phone. Before, staff would indicate, "I work for Dr. So-and-So," or "I am the scheduler for practice X." Now we hear "I work for Kettering Cancer Care"—and it is always said with pride and a sense of achievement.

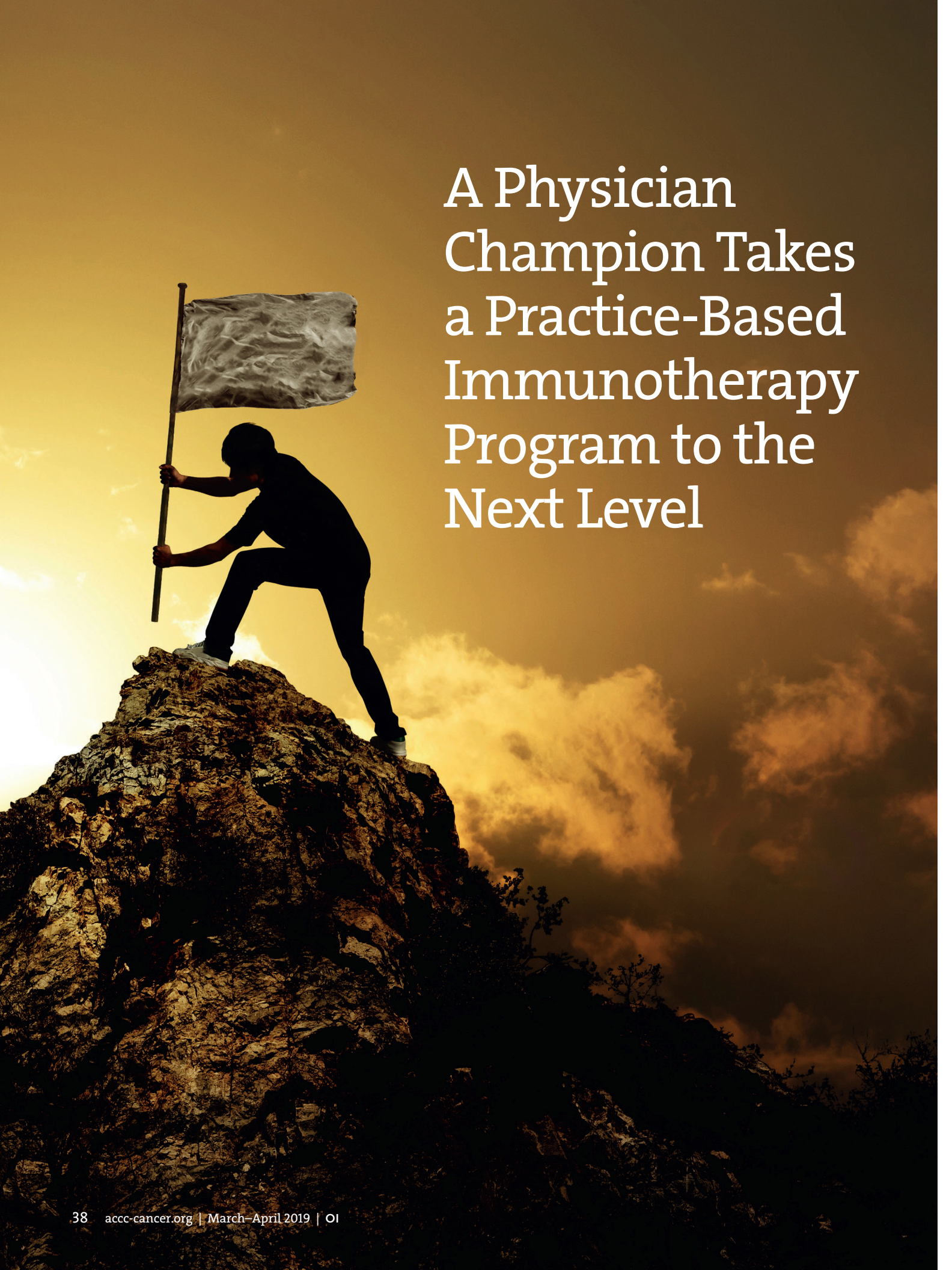
For others looking to conduct a similar overhaul of the the oncology service line, to break down existing silos, and to streamline best practices, I offer a few lessons learned:

1. We shared a unifying motivation. When we were tempted to engage in old conflicts and to operate independently, everyone could be brought back to the unifying goal: we are here to do what is best for cancer patients. Kettering Health Network does not simply want to be good at cancer care, we want to be the best in our community.
2. Kettering Health Network is a faith-based organization. While working on building this new culture, there was an underlying ground rule that we would treat each other with respect. Being a faith-based organization means nothing if we do not hold each other accountable for how we interact.
3. The executive leaders of the network believed in this project. At any point, if the executive leadership team had thrown up any barriers, we never would have accomplished such growth. Leadership initially offered to give $30 million to the building of the cancer center—they ended up contributing $66 million. Our leadership believed that we could be better and they gave us everything we needed to accomplish it.

Finally, none of this growth would have been possible without a unified commitment to work harmoniously, a vision for the future of oncology care, and the courage to become who we want to be. The landscape of cancer care is changing and the rate of cancer is increasing, and we need to be humble enough to change and grow so that we can offer the very best cancer care to patients. OI

Elizabeth Koelker, MHA, FACHE, is executive director for Oncology at Kettering Health Network in Dayton, Ohio.

A Physician Champion Takes a Practice-Based Immunotherapy Program to the Next Level



BY TRACY VIRGILIO, RN, MSN, OCN

In late 2016, decreased reimbursement and the decision to participate in the Center for Medicare and Medicaid Innovation's Oncology Care Model (OCM) meant our Sidney Kimmel Cancer Center, Philadelphia, Pa., had to improve and streamline its triage processes. Patient safety had also become an issue. Incoming calls were recorded in an antiquated system, notes were often lost in the shuffle, or messages were not returned until late in the day.

Accordingly, our team (composed of Allison Zibelli, MD; myself; and several nurses and nurse practitioners) set out to create its first set of symptom algorithms to improve the overall symptom experience of its patients. The clinical algorithms were based on Oncology Nursing Society's *Putting Evidence into Practice* cards and National Comprehensive Cancer Network guidelines. To develop these algorithms and ensure that they reflected the holistic care provided, the Sidney Kimmel Cancer Center team solicited feedback from nurses, nurse providers, and physicians. At the same time, our team collaborated with John Sprandio, MD, to adopt algorithms based on daily symptom management protocols utilized at his Pennsylvania practice, Consultants in Medical Oncology and Hematology.

In June 2017, as Sidney Kimmel Cancer Center was on the verge of launching these clinical algorithms, our oncologists returned from the American Society of Clinical Oncology Annual Meeting, with data that demonstrated a survival advantage in all cancer types when patients received proactive symptom management between office visits.[1] This groundbreaking study on the use of technology for symptom management reported the following data:

Bottom line: patients who were intensely monitored by nursing had a survival benefit that exceeded the survival advantage provided by five out of six medications approved by the U.S. Food and Drug Administration in 2016 to treat cancer.

- 31 percent more patients in the self-reporting arm experienced quality of life benefits
- 7 percent fewer patients in the self-reporting arm visited the emergency department (ED)
- Median survival for patients in the self-reporting arm was five months longer.

This research reaffirmed what earlier studies have shown—that early symptom management is key in improving the quality of life for cancer patients. It enables patients to stay more functional, which is known to be associated with better survival. Symptom monitoring also improves control of chemotherapy side effects, allowing more intense and longer duration cancer treatments. Proactively monitoring patient symptoms prompts clinicians to

Standing, left to right: Jessica Thomas, RN, BSN; Samantha Asher, RN, BSN. Sitting, left to right: Tracy Virgilio, RN, MSN, OCN; Erin Sharpe-Mills, CRNP.

intervene earlier, before symptoms worsen and cause serious downstream complications. Symptom management also decreases ED visits and admissions. Bottom line: patients who were intensely monitored by nursing had a survival benefit that exceeded the survival advantage provided by five out of six medications approved by the U.S. Food and Drug Administration in 2016 to treat cancer. The American Society of Clinical Oncology 2017 data confirmed the need to implement algorithms at our institution to improve patient care.

Implementation

In July 2017, our practice introduced step one of its high-touch process: chemotherapy algorithms, which are used by our triage nursing team (Figure 1, page 41). A triage nurse fields the calls from the patient and runs through the symptom map to manage the symptom. At the same time, the nurse will review the chart for current medication(s), the treatment plan, previous symptoms, and prior management. Once the appropriate symptom map is exhausted, the nurse re-educates the patient, closely monitors the patient, and/or consults with the physician or advanced care provider to determine the final intervention (i.e., prescription, same-day visit, or referral to the emergency department).

The next step in our process was the implementation of new technologies: the first was a symptom application (app) giving patients and their caregivers a phone-based platform at home to report symptoms electronically in real time. Should the symptoms trend too high, the patient or caregiver is prompted to call our triage line. The patient or caregiver will then discuss symptoms with the triage nurse and determine next steps based on the clinical pathway (see Figure 2, page 42).

The second technology implemented was the EPIC electronic health record (EHR) system hospital-wide, allowing medical oncology access to patient information from all over the hospital and from four additional practice sites. The EHR allowed our team to streamline processes even further—or so we thought—until we realized that triage messages were getting mixed together with non-clinical messages, with no indication of which message was a priority. Patient safety again became an issue.

All calls for the department come into a central phone room. Post-EPIC implementation, our team developed a protocol for staff who answer calls. When the call is answered, it is identified as scheduling, non-clinical, or clinical. All symptom-related calls go to a triage nurse or covering nurse as soon as possible. This workflow allowed for an improvement of approximately 85 percent in routing messages to the appropriate team and overall improvement for answering symptoms calls within 30 minutes or less.

Our team also made the decision to build a triage note in the EHR that included the use of smart phrases to capture the following information in order to track these data:

- Type of symptom
- Start of symptom
- Severity of symptom
- Advice given to patient (i.e., monitoring, same-day visit, ED, or admission).

Recognizing the Need for Immunotherapy-Specific Triage Pathways

At the same time our team was creating the new triage symptom note, the Sidney Kimmel Cancer Center was hosting an Association of Community Cancer Centers Immuno-Oncology Visiting Experts program. At this program, our team recognized the need to adopt immunotherapy-specific algorithms, introducing triage tracking and immunotherapy patient identifiers into our day-to-day operations. Our team understood the importance of identifying immunotherapy patients early in the triage process to allow for quick medical interventions to manage symptoms. For our team, immunotherapy-specific algorithms are a "24/7" process, not a "during normal clinic business hours" process.

Because the side effects for patients on immunotherapy present much differently than those patients on chemotherapy and pose very different challenges, our nurses and providers needed point-of-care, immediate access to resources that support early recognition and management of immune-related adverse events. Our first project leveraged the EHR so that all cancer patients receiving immunotherapy are identified immediately—24 hours a day—via bright yellow banners in the top right-hand side of the first page of their chart.

Next, physician champion Ryan Weight, DO, and our melanoma nursing team worked together to develop two sets of immunotherapy triage algorithms: one for on-call physicians and one for nurses. The on-call algorithms follow specific clinical guidelines, which provide non-oncology physicians the tools to properly identify and triage immunotherapy patients in a timely fashion to circumvent an ED visit. Upon completion, the nursing team created immunotherapy nursing triage algorithms based on the Sidney Kimmel Cancer Center physician guidelines and the melanoma management supplement published in the *Clinical Journal of Oncology Nursing*.[2] These algorithms guide nursing staff in assessing over the phone any patient on immunotherapy and empower nurses to recognize any potential life-threatening

(continued on page 42)

Figure 1. Chemotherapy Algorithm

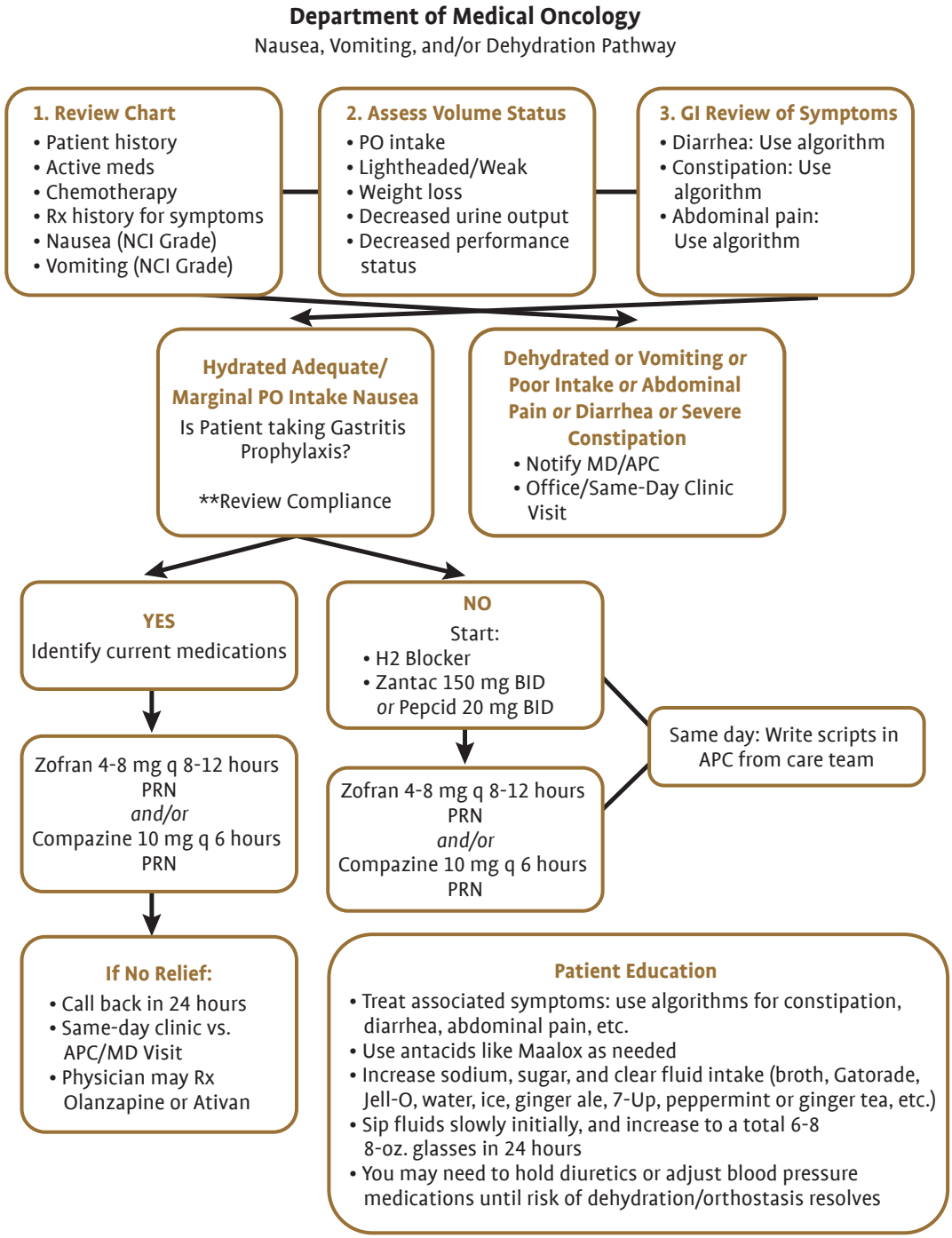
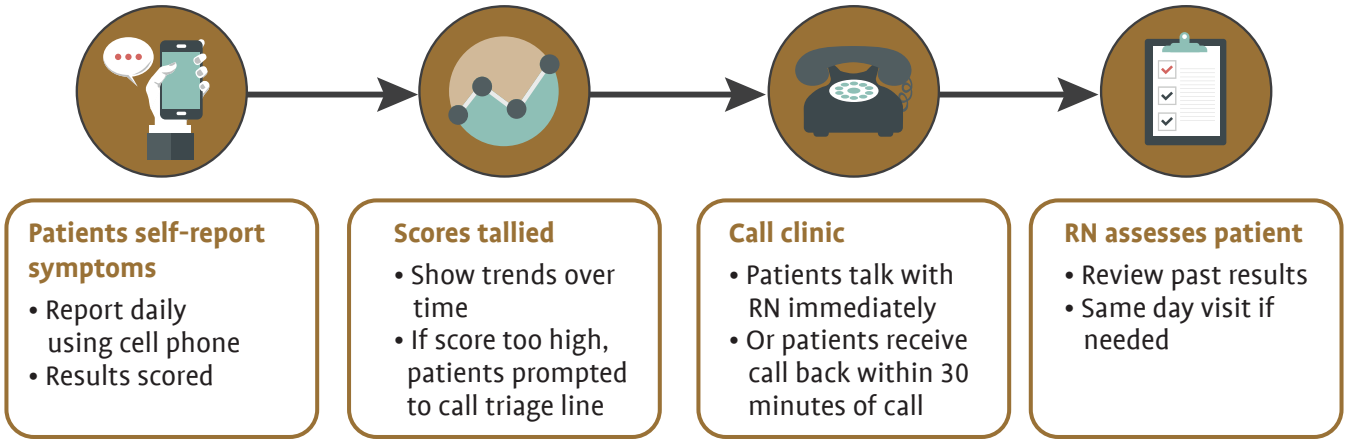


Figure 2. Implementation of the Symptom Management App



This project was not without its barriers. Two of the main challenges were low staffing resources and the lack of a dedicated triage nurse, thus leading to an influx of calls that could not be addressed until late in the day due to busy clinics.

(continued from page 40)
reactions and intervene appropriately. Our immunotherapy nursing triage algorithms include but are not limited to:

- Skin toxicity
- Gastrointestinal toxicity
- Hepatotoxicity
- Mucositis
- Type I diabetes
- Pneumonitis.

Our immunotherapy nursing triage algorithms include a nursing assessment encompassing chart review, patient feedback, patient education, and toxicity grading. Similar to our chemotherapy algorithms, patients may be managed at home, seen the same day, or admitted to the ED, depending on the severity of the symptom(s) present. Our team modified the original "triage symptom note" to include immunotherapy symptoms for additional tracking purposes (Figure 3, right).

Results

This project was not without its barriers. Two of the main challenges were low staffing resources and the lack of a dedicated triage nurse, thus leading to an influx of calls that could not be addressed until late in the day due to busy clinics. The EPIC dashboard showed an increase in turnaround time for managing symptoms, as well as an increase in severity of the symptom. Currently we are again reviewing the triage role and continue to enhance our processes and workflows. As part of our OCM practice transformation, the OCM project director runs a weekly triage symptom and outcome report that includes all elements of the triage note. The report is reviewed by nursing leadership to determine whether the management of the patient was appropriate and then escalates any concerns to our physician champions for further review. All triage notes are reviewed weekly for nurse compliance, modification of algorithms, and continuing education.

The above initiatives, developed by Dr. Weight and the Melanoma nursing team, have helped Sidney Kimmel Cancer Center transform our practice and improve outcomes and the overall quality of patient care. Some of the results we have noted include:

- Prompt response to symptom management
- Nursing empowerment
- Enabling nurses and nurse providers to work at the top of their license
- Greater patient satisfaction.

Figure 3. Modification of Triage Symptom Note in EHR

Symptom Immunotherapy 29400

- IO arthralgias (joint pain)
- IO colitis (inflammation of colon)
- IO diabetes
- IO diarrhea
- IO endocrinopathy
- IO hepatitis
- IO mucositis
- IO myocarditis
- IO nephritis
- IO neurological
- IO pneumonitis
- IO rash
- IO thyroiditis
- IO xerostomia
- L-D chemo-embolization
- L-D immuno-embolization
- L-D radio-embolization

Note. IO = immunotherapy; L-D = liver-directed.

Our program is still in the infancy stage of reviewing ED and admission data to determine whether the triage process has decreased visits. However, we do know that this process was implemented on a much smaller scale at our sister site, with a 12 percent decrease in ED visits.

At Sidney Kimmel Cancer Center we will continue to review the processes. For example, as we integrate the navigation team into our workflow, we realize that our patients may reach out to navigators as an additional resource. We are currently discussing the triage process with the clinical navigation team. Afterwards, we will likely modify our education processes and workflows to ensure that patients are assessed and triaged and data is captured according to our protocols. OI

Sidney Kimmel Cancer Center would like to thank Dr. Ryan Weight and the Melanoma team for all of their hard work on this important project. Without them, this project would not be possible.

Tracy Virgilio, RN, MSN, OCN, is nurse manager, Ambulatory Care Department of Medical Oncology, Sidney Kimmel Cancer Center, Thomas Jefferson University Hospital, Philadelphia, Pa.

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Implementation of Drug Vial Optimization to Reduce Drug Waste

BY LINDSEY B. AMERINE, PHARMD, MS, BCPS; SCOTT W. SAVAGE, PHARMD, MS; ERINN C. ROWE, PHARMD, MS; ROWELL DANIELS, PHARMD, MS, FASHP; JOHN M. VALGUS, PHARMD, MHA, BCOP; RICHARD REDDING, BA, CPHT; AND STEPHEN F. ECKEL, PHARMD, MHA, BCPS

In 2009 the University of North Carolina (UNC) Medical Center opened the North Carolina Cancer Hospital to serve as the premier location for oncology patients in the state. For the Department of Pharmacy, this required combining three existing pharmacy locations that prepare hazardous drugs for oncology patients into one location. Located on the third floor of the North Carolina Cancer Hospital, the Cancer Hospital Infusion and Inpatient Pharmacy prepares hazardous drugs for all outpatient and inpatient units at UNC Medical Center and non-hazardous drugs for outpatients within the North Carolina Cancer Hospital. This includes preparations for adult and pediatric patients.

Rationale for Drug Vial Optimization Need

All health systems across the country are looking for ways to reduce the cost of patient care. Unlike other health system departments where salary dollars are the largest expense, the largest expense at departments of pharmacy are medications; therefore, the focus in pharmacy is to reduce drug expense.

As a department, focused efforts had already been made to optimize contracts and move therapies to lower cost alternatives when appropriate. Pharmacists were embedded into medical teams and ensured that the most appropriate and cost-effective regimen was selected for each patient. In addition, efforts were underway to improve operational efficiency and decrease waste within the pharmacy.

It was recognized that the Department of Pharmacy was discarding partial vials of medications per United States Pharmacopeia (USP) <797> recommendations. Pharmacy sought to quantify the amount wasted and determine whether there was a method to safely use the remaining amount.

> The concept for a closed-system transfer device is to protect employees by not allowing hazardous drug or vapor contamination to escape the vial.

To prepare a chemotherapy or hazardous sterile preparation, the pharmacy uses mostly single-dose vials from manufacturers. Vials often contain more drug than the patient needs; on other occasions, several vials are needed to generate a patient's full dose. Because of this, the pharmacy ends up with a remaining partial drug vial. Based on pharmacy compounding guidelines within the *United States Pharmacopeia Chapter* <797>, this partial amount can be used for another patient up to six hours after it has been opened.[1] After this beyond-use date, the vial must be discarded even if drug is remaining. This guideline is based on the theory that after six hours, growth of microbial contamination could occur in the vial.[2] However, this theory is based on using solely a syringe and needle to withdraw drug from the vial.

North Carolina Cancer Hospital, Chapel Hill, N.C.

Our pharmacy uses a closed-system transfer device, BD PhaSeal™, to prepare chemotherapy and hazardous drugs. UNC had used PhaSeal for several years prior to the opening of the North Carolina Cancer Hospital. The concept for a closed-system transfer device is to protect employees by not allowing hazardous drug or vapor contamination to escape the vial.[3] Because PhaSeal utilizes an airtight seal to prevent vapors from coming out of the vial, no transfer of environmental contaminants should enter the vial. The ability of PhaSeal to prevent microbial ingress has been studied and well documented; studies show that the device extends a vial's sterility from 6 hours to 168 hours (seven days).[4-6] The phrase "drug vial optimization" is used to describe the extension of a single-use vial's sterility up to seven days or the drug's chemical stability, whichever is shorter, when using the PhaSeal closed-system transfer device. This maximizes the useful life span of a drug within a single-dose vial and presents a significant opportunity for cost savings.

Drug Vial Optimization Implementation

UNC Medical Center's Department of Pharmacy implemented a comprehensive drug vial optimization program in October 2011. The comprehensive program includes:

- Use of the PhaSeal closed-system transfer device.
- A compendium resource to determine the beyond-use date of each single-dose vial.
- Maintenance of institutional practices and procedures in accordance with USP <797> (i.e., hand hygiene and garbing, aseptic technique, cleaning and disinfecting, and International Organization for Standardization standards for air and environmental quality).
- Monthly quality assurance testing.

Drug vial optimization was implemented in three phases: pre-implementation, implementation process, and post-implementation.

Drug Vial Optimization: Pre-Implementation

Three key structural elements were needed prior to the implementation of drug vial optimization to ensure risk mitigation with the program:

1. Site-specific sterility testing
2. Development of a process to identify beyond-use dates for each single-dose vial
3. Staff competency and training.

The site-specific sterility testing was done in accordance with the internally validated study that determined the ability to extend beyond-use dates of single-dose vials to the drug's chemical stability or a maximum of seven days.[4] Having internal sterility data is fundamental to the risk mitigation of the program, because it ensures the air quality environment, allows for the extension of sterility, and follows the previously mentioned allowance within USP <797>. Because each oncology disease state clinic at North Carolina Cancer Hospital is scheduled to occur at least every seven days, the drugs would likely be used in a seven-day time frame.

The development of a process to identify beyond-use dates for single-dose vials is critical to ensure that a vial is not used past the drug's chemical stability or seven-day maximum. Staff used a hazardous drug compendium that detailed the specifics for each product (see Table 1, right). The column "Vial Beyond-Use Date" previously listed six hours for all single-dose vials based on the ability to be stored at room temperature or under refrigeration. This column of the compendium was updated with the drug's chemical stability (or a maximum of seven days) using the package insert, documents from the company's medical affairs division on extended chemical stability, and primary literature. References for where the information was obtained are listed next to each drug on the main document (not listed in the example shown) for quick reference and transparency. Because this compendium is used by all technicians and pharmacists preparing and checking chemotherapy and hazardous drugs, drug vial optimization was able to be incorporated into the normal workflow comfortably. In addition, a calendar was placed underneath the clock in the cleanroom for staff to identify the current date and determine the date and time of a vial's beyond-use date. A sticker purchased from a commercial healthcare retailer had previously been used to keep track of the reconstitution diluent (if applicable), concentration, and beyond-use date of the vial. This same sticker was used to write the date and time for the new beyond-use date of the vial. Pharmacists verified the accuracy of the beyond-use date as part of their final product-checking process.

Staff training occurred in the weeks leading up to drug vial optimization implementation. Though most of the staff had participated in the internal sterility testing, it was still important to ensure that everyone understood and complied with drug vial optimization to maintain patient safety. Training modules were built for all pharmacists and technicians. Each individual then took a written exam to ensure their understanding of drug vial optimization. A passing score of 100 percent was required because

Table 1. Example from the Cancer Hospital Compounded Sterile Products Stability Compendium

	Vial Beyond-Use Date	
Drug	**Refrigerate**	**Room temperature**
Abatacept (Orencia) (H)	24 hours	24 hours
Bortezomib (C)—subcutaneous administration	7 days	n/a

(C) = chemotherapy, (H) = hazardous.

Our multidisciplinary Pharmacy and Therapeutics Committee required monthly quality assurance testing as part of the risk mitigation program to ensure that sterility of the single-dose vials was in accordance with the initial sterility testing.

the safety components were too critical to have any lingering questions. Individuals who did not pass were required to repeat the training modules and retake the exam to achieve a perfect score. Twenty-three of the 24 staff (96 percent) passed on the first attempt; the one individual who did not pass on the first attempt passed on the second following retraining.

Drug Vial Optimization: Implementation

Integration of drug vial optimization into the existing workflow was critical to ensuring that partial vials were used first and for the appropriate duration prior to opening a new vial. The process is described in Figure 1, page 48. Key elements in the workflow included having a sticker on the vials to keep track of the appropriate beyond-use date and using a partial bin container. A bin was placed in the middle of the cleanroom checking table for the pharmacist to place the partial vial in after checking the product. Drugs that required refrigeration were placed in the refrigerator in the front of the drug-specific storage location. Staff was trained to look in the partial vial bin first and then look in the front of the drug-specific storage location within the cleanroom prior to opening a new, unused vial.

This process was implemented manually as described and has since transitioned to an automated process. With the implementation of BD Pyxis™ IV Prep—a medication workflow software—a label prints out for each partial vial and assigns a unique number to that vial. When that drug is to be prepared again, the system directs the technician to use that specific vial to ensure that partial vials within the beyond-use date are used first. The process can be done using either manual or automated tracking.

Drug Vial Optimization: Post-Implementation

Our multidisciplinary Pharmacy and Therapeutics Committee required monthly quality assurance testing as part of the risk mitigation program to ensure that sterility of the single-dose vials was in accordance with the initial sterility testing. Each month, 10 partial single-dose vials are randomly selected for quality assurance sterility testing. Each vial must contain 1 mL of drug, because 0.5 mL is plated on a trypticase soy agar plate and 0.5 mL is plated on a sheep blood agar plate. This process is repeated for all 10 vials. Plates are incubated at 37°C and evaluated for microbial growth at 24 hours, 48 hours, and seven days. Any positive results are speciated by the Epidemiology Department. In addition, a hazardous waste log is kept to track any changes in waste.

Our Results

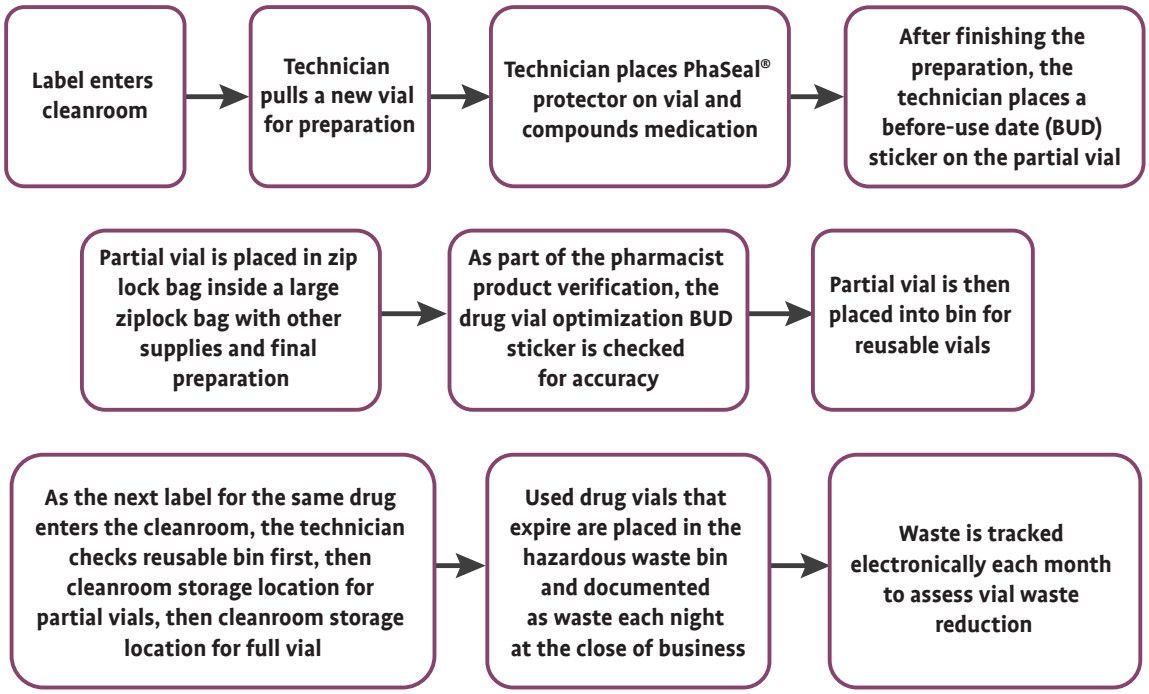
Prior to implementation in 2011, drug waste was calculated for 19 drugs, which had a range of drug chemical stability from 30 minutes to more than seven days. This meant that drug vial optimization would impact several drugs on the list but not all would have a beyond-use date of the seven-day maximum. This represents a realistic sample of the overall compendium.

As of June 2018, drug waste through the use of drug vial optimization for the original 19 drugs measured has decreased 94 percent when compared to 2011 (see Figure 2, page 49). This continued decrease results from sound implementation infrastructure with an embedded and fully optimized process, as well as primary literature demonstrating drugs' chemical stability to be longer than stated in the package insert.

Extrapolated to the full chemotherapy drug budget (all hazardous and chemotherapy agents including, but not limited to, the 19 drugs), drug vial optimization has saved $43.8 million in drug expense (see Figure 3, page 49). The institution's average acquisition price for each drug was calculated and then used to determine the average cost per milligram (cost of drug divided by milligram per vial). The total waste per drug was recorded monthly and then summed for each fiscal year; the total annual waste per drug was then multiplied by the cost per milligram,

(continued on page 50)

Figure 1. Standardized Workflow Process for Drug Vial Optimization Implementation



2018 ACCC Innovator Award-Winning Team. Left to right: Scott Savage, PharmD, MS; John Valgus PharmD, MHA, BCOP; Lindsey Amerine, PharmD, MS, BCPS; Erinn Rowe, PharmD, MS; Stephen Eckel, PharmD, MHA, BCPS; Richard Redding, BA, CPhT. Not pictured: Rowell Daniels, PharmD, MS, FASHP.

Figure 2. Annual Cost of Drug Waste with 19 Drugs Measured Each Year

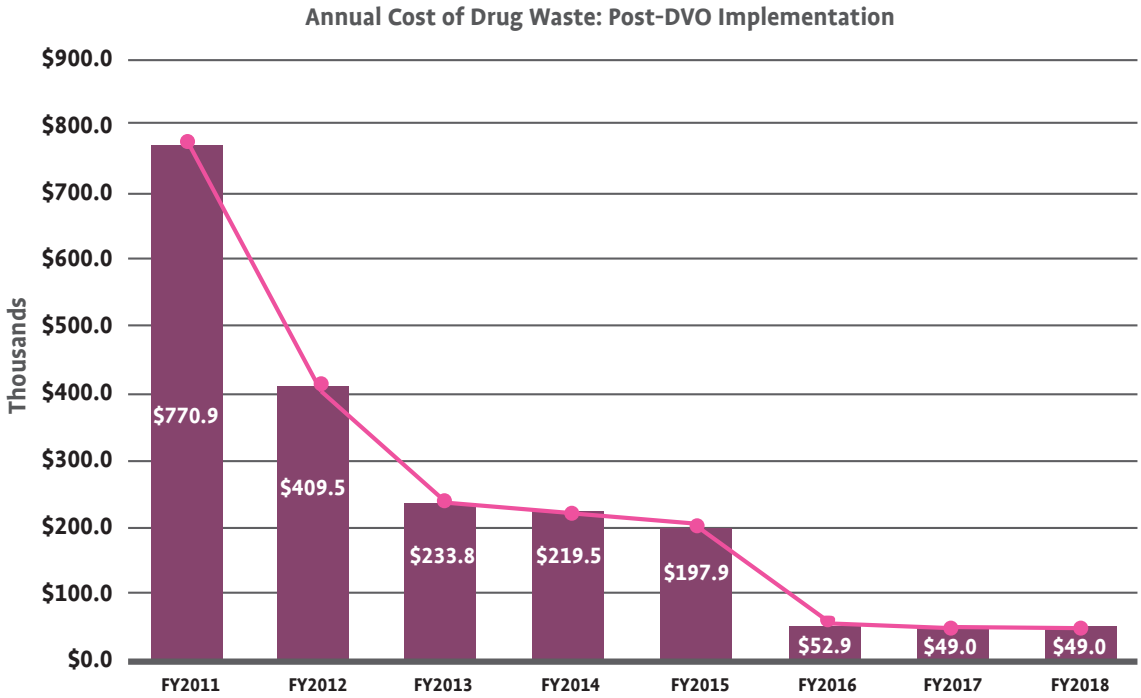
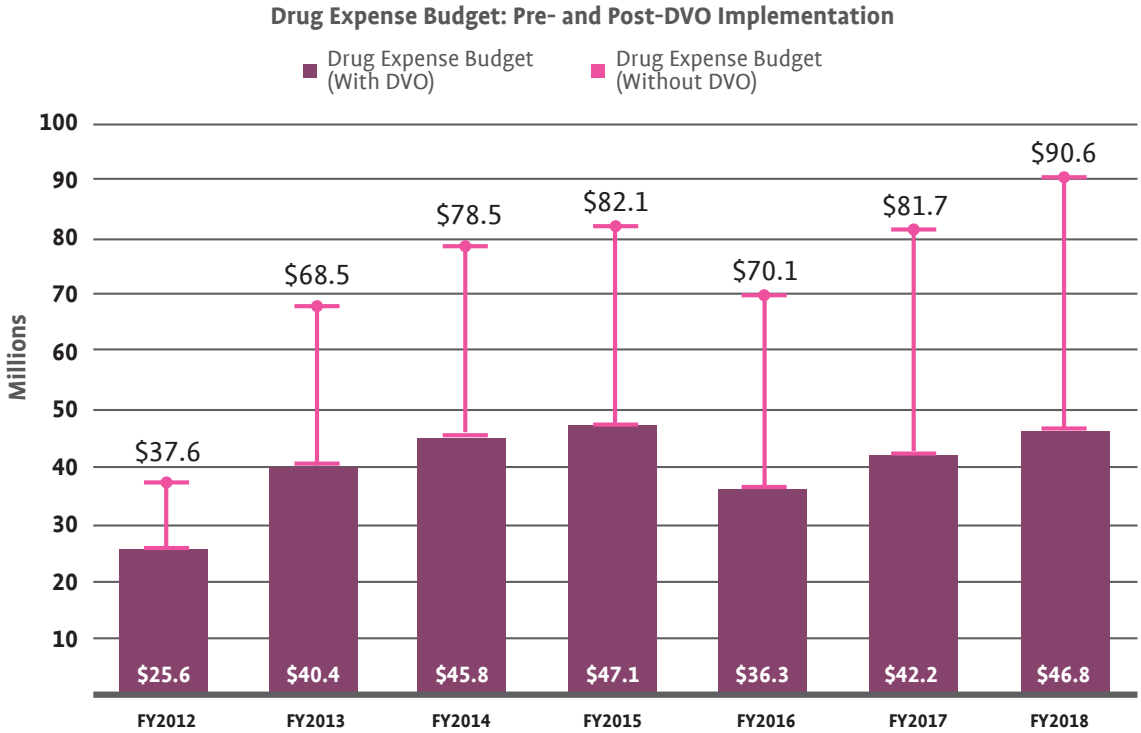


Figure 3. Financial Impact of Drug Vial Optimization (DVO) on Drug Expense Budget



Cancer Hospital Infusion and Inpatient Pharmacy at North Carolina Cancer Hospital

(continued from page 47)

resulting in the cost of waste per drug. For fiscal year 2018 (July 2017-June 2018), the chemotherapy drug budget was $46.8 million. If drug vial optimization had not been utilized, the drug budget would have been $90.6 million.

Since October 2011, monthly quality assurance testing has continued to ensure risk mitigation with the program. This testing is done within pharmacy. Only two plates have shown contamination of single isolates, which were determined by Epidemiology to be user contaminants. With only 2 plates out of 1,680 plates tested showing contamination, the contamination rate is 0.12 percent, which is less than the previous literature contamination rates of 1.86 percent, 1.8 percent, and 0.3 percent.[4-6]

The implementation of drug vial optimization represents an innovative and unique approach to addressing increased drug waste and is the first to be implemented in the United States. The cost savings of greater than $43 million annually—along with the risk mitigation strategy of this initiative—is a best practice that can be modeled at other institutions. OI

Disclosure Statement

Lindsey Amerine served on the Advisory Board for Becton, Dickinson and Company.

Lindsey B. Amerine, PharmD, MS, BCPS, is director of Pharmacy; Scott W. Savage, PharmD, MS, is regional director of Pharmacy; Rowell Daniels, PharmD, MS, FASHP, is vice president of Pharmacy Services; John M. Valgus, PharmD, MHA, BCOP, is assistant director of Pharmacy; Richard Redding, BA, CPhT, is a certified pharmacy technician; and Stephen F. Eckel, PharmD, MHA, BCPS, is associate director of Pharmacy, University of North Carolina Medical Center. Erinn C. Rowe, PharmD, MS, is pharmacy manager, Augusta University Health, Augusta, Ga. Amerine is also associate professor of Clinical Education; Savage is also executive associate dean and associate professor of Clinical Education; Daniels is also associate professor of Clinical Education; Valgus is also assistant professor of Clinical Education; and Eckel is also associate dean for Global Engagement and clinical associate professor, UNC Eshelman School of Pharmacy, Chapel Hill, N.C. Savage is also regional director of Pharmacy, Chatham Hospital, Siler City, N.C.

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Removing the Blame from Burnout

BY ACCC EDITORIAL STAFF

The benefits of addressing clinician and staff stress on an institutional level

"Caring for cancer patients can be a drain—physically, intellectually, and emotionally," says Association of Community Cancer Centers (ACCC) President Tom Gallo. "This is true for each member of the multidisciplinary cancer care team, starting with the receptionist who greets patients daily to the physician in whose hands patients place their trust." This is the reason why Gallo, an experienced cancer program administrator, chose "Reflect, Renew, Reignite: Building a Resilient Oncology Team in Your Community" for his 2018-2019 president's theme.

Burnout among U.S. healthcare clinicians is a national concern. The National Academy of Medicine established an Action Collaborative on Clinician Well-Being and Resilience in 2017 to raise awareness and identify approaches to reverse the trend.[1] *Burnout* is described by the Academy as "a syndrome characterized by a high degree of emotional exhaustion and depersonalization (i.e., cynicism) and a low sense of personal accomplishment at work."

To address what many see as an epidemic of burnout in the medical community, ACCC has joined the Action Collaborative and its network of more than 60 organizations. This four-year effort aims to raise the visibility of clinician burnout; improve understanding of challenges to clinician well-being; and advance evidence-based, multidisciplinary solutions to improve patient care by caring for the caregiver.

To gauge the level of burnout in the multidisciplinary cancer care team, ACCC recently surveyed its membership using the clinically validated Mini Z survey developed by the American Medical Association. Results from this survey can be found on pages 56-57. ACCC has created a hub for team well-being resources on accc-cancer.org/resilience. This article sets the stage for a series of articles in *Oncology Issues* in which member programs will share steps they are taking to improve resiliency and combat burnout.

> However well-intentioned, stress management workshops, individual trainings in mindfulness, and exercise programs suggest that there are "solutions" to workplace stress that are effective only if individuals try hard enough.

Individuals vs. Institutions

Julie Oehlert, DNP, RN, chief experience officer at Vidant Health in Greenville, North Carolina, says that the burnout experienced by individuals in oncology care teams in particular can have

damaging effects on the workplace environment and on patient care. "When you are treating patients who are facing difficult life choices or who may not live through treatment, there are specific issues to keep in mind," says Oehlert. "Cancer treatment is ongoing and can last months or years. While other specialties such as surgery are episodic, cancer patients may have long-term relationships with their providers, which can be either a stressor or a source of joy."

Leaders do not have to look far to see the financial repercussions of an unhealthy workplace.[3] Stressed-out clinicians are more likely to make medical errors, affecting quality care and the risk of malpractice suits. Job dissatisfaction increases the rate of turnover and early retirement.

Oehlert says that when it comes to addressing burnout and promoting well-being in the healthcare workplace, there are two schools of thought. The first focuses on the individual. "Some organizations tell individual clinicians and support staff that if they take care of themselves, they will be okay," explains Oehlert. "They tell people to get enough sleep, get enough exercise, and eat healthy."

But this way of thinking can imply that ameliorating burnout and its damaging effects is the sole responsibility of the individual.[2] However well-intentioned, stress management workshops, individual trainings in mindfulness, and exercise programs suggest that there are "solutions" to workplace stress that are effective only if individuals try hard enough. These strategies often ignore the organizational causes of workplace stress, eliciting cynicism among patient care staff.

Rather than focus on the individual, says Oehlert, healthcare organizations would do better to adopt the school of thought that views burnout as a symptom of an institution-wide problem. "Addressing the problem of burnout is more complex than simply treating the individual," says Oehlert. "The working environment should be conducive to promoting health in the workplace. The team environment should be healthy and compassionate."

The Primacy of Empathy

If patient care staff are overwhelmed with administrative burdens and must rush through patient encounters to be able to accomplish what is expected of them, Oehlert says that the first casualty will be the provider's sense of empathy. The ability to feel and express empathy, says Oehlert, is at the core of cancer treatment. If clinicians and staff are not empathetic, both patient experience and quality of care suffers. "And cancer patients, in particular, need all of the empathy we can muster," Oehlert emphasizes.

Poor patient experience is a key indicator of a potentially unhealthy workplace. When clinicians and support staff are stressed, that stress spreads, and patients inevitably feel it. Without the empathetic care that satisfied staff are likely to provide, patient outcomes can suffer. "Without empathy in patient care, there are a lot of pieces that don't fall into place," Oehlert explains. "For example, if I don't have empathy for my patients, I may not dig deeper into why they don't show up for treatment or why they don't follow care plans. I may not notice if they are disheveled or if they have poor hygiene. We can miss key health issues if we are not able to pay attention to the patients in front of us."

Connecting the Dots for Leadership

Recognizing that widespread stress, burnout, and depression are all symptoms of a dysfunctional workplace is one thing; persuading leadership to do something about it is another. An organization's leaders can take steps to change entrenched but harmful institutionalized behaviors. Staff can urge their support by presenting to leaders how an overly stressful workplace can negatively affect quality care, patient experience, and even the bottom line. Far from being an afterthought, preserving employee wellness should be a proactive effort on behalf of an organization's leadership, according to Oehlert.

Leaders do not have to look far to see the financial repercussions of an unhealthy workplace.[3] Stressed-out clinicians are more likely to make medical errors, affecting quality care and the risk of malpractice suits. Job dissatisfaction increases the rate of turnover and early retirement. And high levels of depression are associated with higher incidences of alcohol abuse and suicidal ideation.

"Healthcare leaders should take a long, hard look at the literature on what causes burnout and the effect it has on staff and patients," says Oehlert. "The organization must see value in addressing burnout on an institutional level. That can be a hard pill to swallow, given how we have traditionally personalized this problem. But until healthcare executives believe this is just as much a priority as our quality goals and fiscal goals, organization-wide efforts will not get the funding and resources they deserve to support organizational goals."

The Vidant Experience

Oehlert says that the leadership of Vidant Health understands the organization-wide repercussions of burned-out patient care staff. By making both team and patient experience an organizational imperative, Vidant's leaders have signaled their prioritization of staff wellness as essential to their mission. "Vidant has made the experience of patients, team members, and providers a key success strategy," says Oehlert.

Oehlert says that one of an organization's most important tasks is to help leadership connect the dots between the experience of staff members and the performance of the organization as a whole. "Leaders have to be aware of the long-term effects of burnout and lack of empathy," says Oehlert. "What does this

cost the organization? How high is turnover? How many patients do not return due to poor experiences? How many physicians retire early because of workplace stress? There are hard numbers associated with these realities. Our leadership gives them as much attention as financial and quality measures."

Vidant dedicates organizational resources to gauge indicators of organizational stress, collect relevant data, and respond to it by setting goals and promoting awareness. "To persuade staff to take this seriously, we are educating our workforce through the metrics that measure the prevalence of burnout and its ramifications," says Oehlert. "Once you make a case for change that includes everyone's interest, the organization can work together on common goals."

Oehlert says that Vidant's executives attend workshops called "Leader Connection," during which they participate in sessions on how to best connect with their teams to build productive relationships and cultivate effective communication. During "Mindful Mondays," these leaders set aside meeting-free afternoons to spend with members of patient care teams. "Our leaders have begun to lead differently, and our team members have noticed," says Oehlert. "Vidant has seen increases in institutional engagement, lower incidences of burnout, and positive movement in physician engagement."

When talking about her experiences at Vidant, Oehlert always comes back to empathy as the touchstone of quality cancer care. She says that empathetic physicians and nurses provide the best possible clinical care; empathetic therapists and social workers get the best possible outcomes; and empathetic desk staff provide the best possible service. And, of course, patients who are on the receiving end of that empathy are more satisfied with their care, making them more likely to follow their care plans and enjoy a better quality of life.

"Empathy is where everything originates in delivering quality care," affirms Oehlert. She also recognizes that being empathetic takes a degree of emotional energy that only happy, healthy caregivers can deliver: "We must first treat our caregivers if we are to treat the ones they care for." OI

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3. Dyrbye LN, Shanafelt TD, Sinsky CA, et al. Burnout among health care professionals: a call to explore and address this underrecognized threat to safe, high-quality care. Available online at: nam.edu/burnout-among-health-care-professionals-a-call-to-explore-and-address-this-underrecognized-threat-to-safe-high-quality-care. Last accessed January 23, 2019.

What the Literature Tells Us

According to the 2019 *Medscape National Physician Burnout, Depression & Suicide Report*, nearly 44 percent of today's physicians say that they experience burnout, a syndrome most often characterized by a high degree of emotional exhaustion, cynicism, and a low sense of personal accomplishment.[1] The consequences of burnout are real; it is associated with early retirement, alcohol use, and suicidal ideation. In high concentrations, a burned-out staff can negatively affect an entire organization.[2]

According to the National Academy of Medicine (formerly the Institute of Medicine), depression is one of the most common results of long-term burnout, with approximately 39 percent of physicians reporting that they experience it. Thirty-five percent of the respondents to the Medscape survey say that their depression makes them easily exasperated with patients, and 16 percent say that they express their frustration in front of patients.[1] Fourteen percent of survey respondents say that their depression causes them to make errors they would not ordinarily make.[1] It is not surprising, then, that research has connected burnout to low patient satisfaction, reduced health outcomes, and increased costs.[2]

Of course, burnout is not only the province of physicians; significant numbers of all types of clinicians and patient support staff say that they are depressed or anxious due to workplace stressors. Thirty-four percent of hospital nurses report experiencing burnout, and medical receptionists say that they feel caught between the demands of patients and physicians, with 68 percent reporting verbal abuse from patients.[2] In a 2013 survey of 508 employees working for 243 healthcare employers, 60 percent reported burnout, and 34 percent said that they planned to look for a different job.[2]

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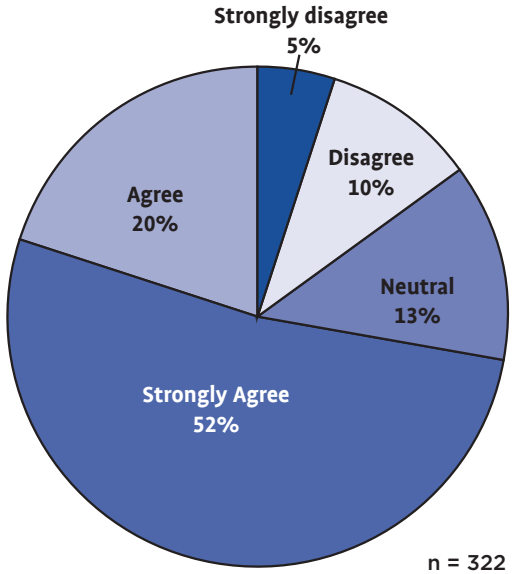
2. Bodenheimer T, Sinsky C. From triple to quadruple aim: care of the patient requires care of the provider. *Ann Fam Med.* 2014;12:573-576.

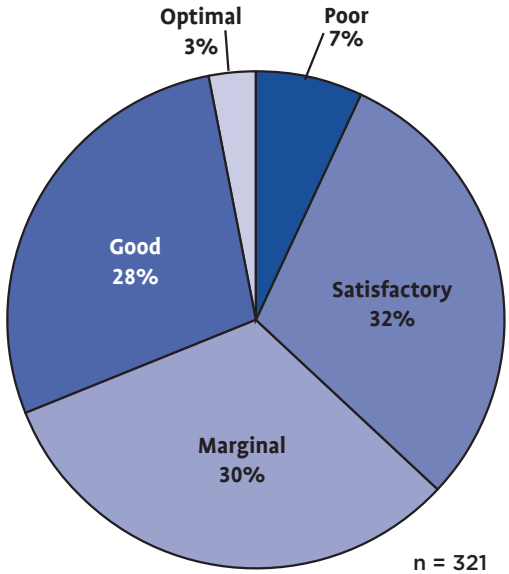
What ACCC Members Shared in Our 2019 Mini Z Burnout Survey

Overall, I am satisfied with my current job



n = 322

My control over my workload is



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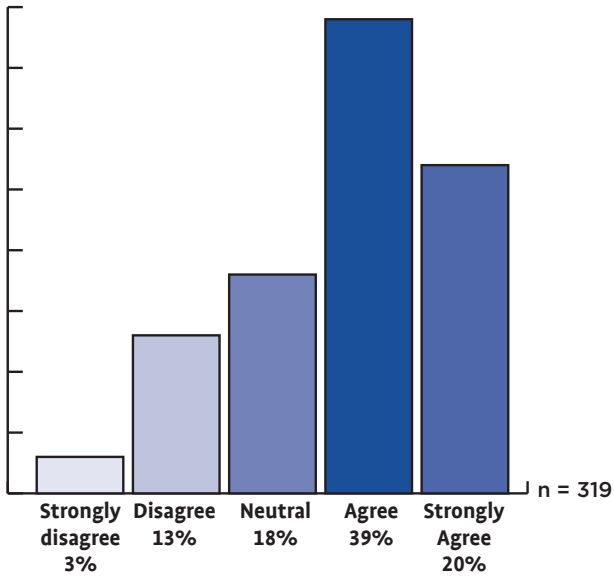
I feel a great deal of stress because of my job



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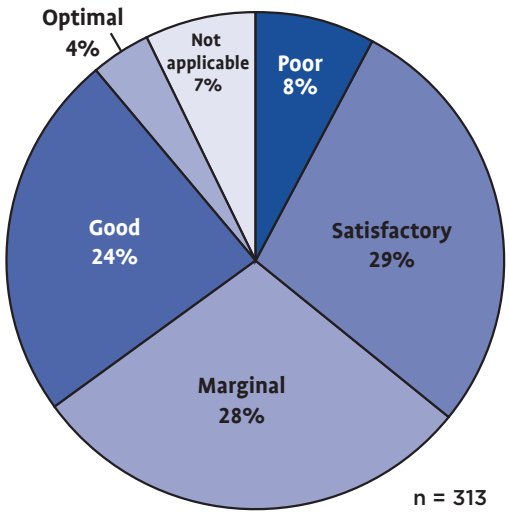
Sufficiency of time for documentation is



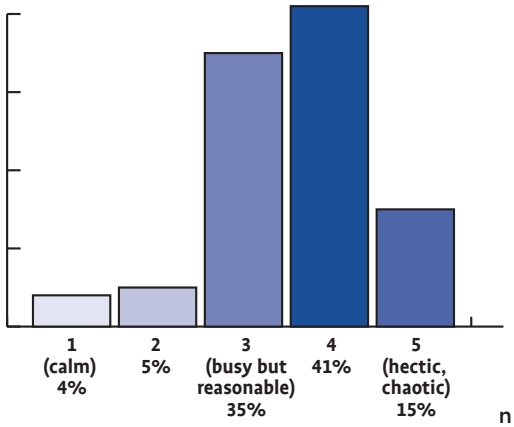
n = 313

Using my own definition of "burnout"

• I enjoy my work; I have no symptoms of burnout.	12%
• I am under stress, and don't always have as much energy as I did, but don't feel burned out.	36%
• I am definitely burning out and have experienced 1 or more symptoms of burnout, e.g., emotional exhaustion.	33%
• The symptoms of burnout that I am experiencing won't go away; I think about work frustrations a lot.	16%
• I feel completely burned out; I am at the point where I may need to seek help.	3%

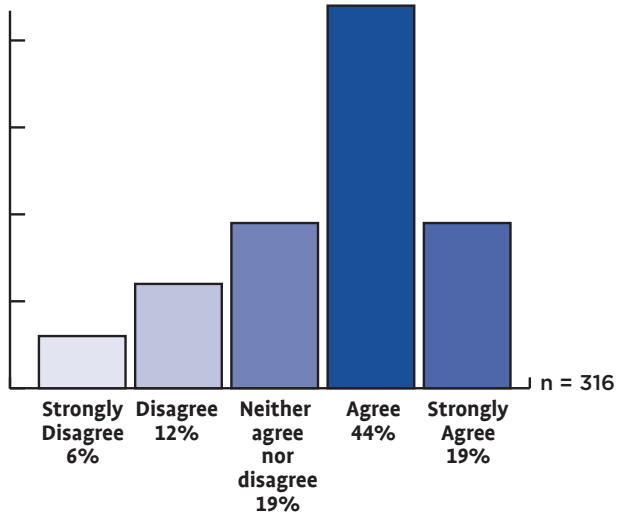
n = 321

This number best describes the atmosphere in my primary work area

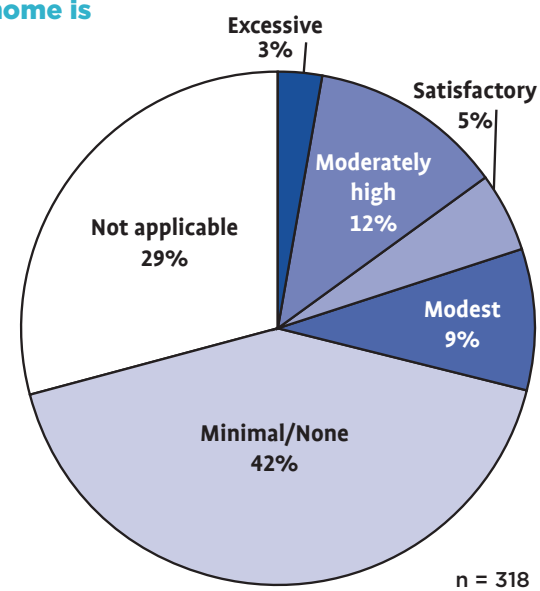


n = 318

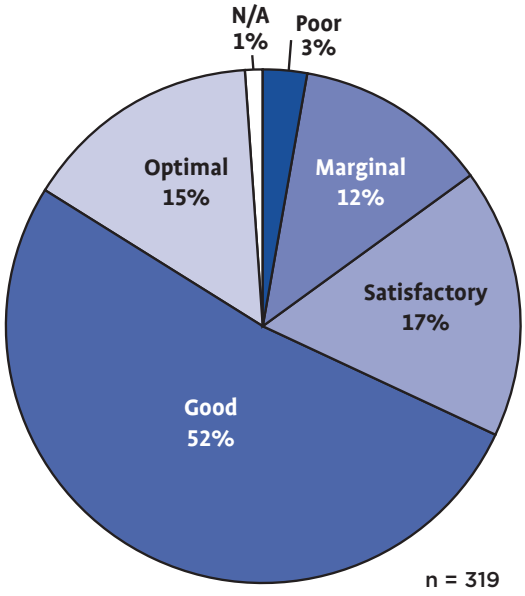
My professional values are well aligned with those of my department leaders



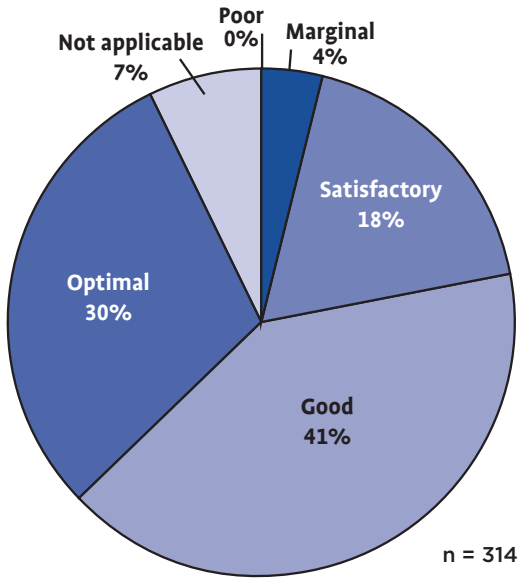
The amount of time I spend on the EHR at home is



The degree to which my care team works efficiently together is



My proficiency with EHR use is



ACCC Welcomes Its Newest Members

Cancer Center of South Florida
Lake Worth, Fla.
Delegate Rep: Jennifer Pugh, CPA
Website: cancercenterofsouthflorida.com

Colquitt Regional Medical Center Edwards Cancer Center
Moultrie, Ga.
Delegate Rep: Matthew Clifton, PharmD
Website: colquittregional.com/our-services/oncology

Highlands Oncology Group, PA
Fayetteville, Ark.
Delegate Rep: Jeff Hunnicutt, CEO
Website: highlandsoncologygroup.com

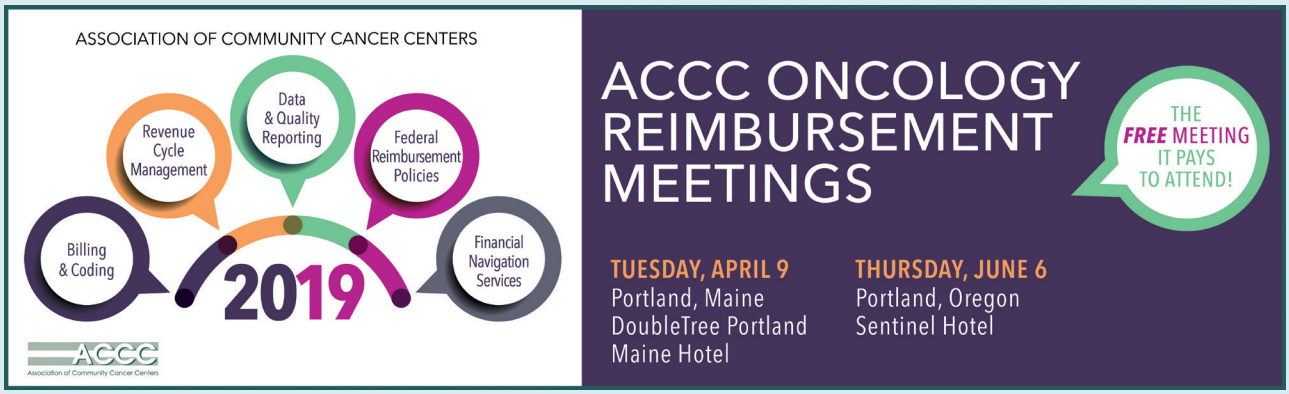
Montefiore Einstein Center Cancer Care
Bronx, N.Y.
Delegate Rep: Barbara Binder, BSN, MA
Website: montefiore.org/cancer

Providence St. Mary Regional Cancer Center
Walla Walla, Wash.
Delegate Rep: Hall Grimes
Website: washington.providence.org/clinics/providence-st-mary-regional-cancer-center

Quincy Medical Group Cancer Care
Quincy, Ill.
Delegate Rep: Diane Gerards-Benage, CMPE
Website: quincymedgroup.com/medical-services/cancer-care

Southern Cancer Center, PC
Daphne, Ala.
Delegate Rep: Lauren Peltis, MSN, OCN
Website: southerncancercenter.com

The University of Texas Dell Medical School LIVESTRONG Cancer Institutes
Austin, Tex.
Delegate Rep: Sarah Hall, MHA
Website: utexas.edu/academicas/dell-medical-school



Save the Dates! ACCC Oncology Reimbursement Meetings

Tuesday, April 9, 2019
Portland, Maine

Thursday, June 6, 2019
Portland, Oregon

ACCC Oncology Reimbursement Meetings help you navigate the annual changes in oncology reimbursement and regulations, provide tools to strengthen your program's operations, and accelerate your knowledge on which measures you can take now—and down the road—to succeed in this rapidly changing landscape.

All members of the cancer care team who deal with oncology business and reimbursement will benefit from this meeting. Gain a comprehensive perspective in just one day of sessions:

- Review the latest trends in oncology coding and billing based on the 2019 Medicare final rules.
- Assess financial strategies to track and improve the financial health of your cancer program.
- Gain insight into upcoming coding and reimbursement challenges related to financial counseling, compliance, and authorizations in medical and radiation oncology.
- Identify opportunities to improve the financial navigation services at your cancer program.
- Investigate the impact of federal health policies on your cancer program.

The Breast Cancer School for Patients

Improving outcomes with video education

BY JOHN WILLIAMS, MD

Women newly diagnosed with breast cancer must make rapid treatment decisions. "*Do I benefit from a breast MRI? Should I have BRCA genetic testing or a genomic assay?*" Online resources for patients do provide information; unfortunately, this information is scattered, unorganized, and presented as outdated text and stock images. These websites are hard to navigate and largely ineffective at helping patients obtain better quality cancer care.

Over the years, family and friends have called me for advice about their breast care. After a quick conversation, these individuals were empowered to ask their own doctors exactly what was needed. Patients simply receive better care when they understand and know the questions to ask about complex topics such as breast cancer.

Most healthcare facilities provide information online and offer handouts to patients at their facilities. I suggest that cancer programs, professional organizations, and physicians should pivot toward "teaching" patients how to obtain quality, cutting-edge care in their own communities. Specifically, our profession should engage patients with sophisticated video-based patient education. That is why I created the Breast Cancer School for Patients (breastcancercourse.org). This type of innovative patient educational platform can address some of these missing links in our efforts to provide better quality breast cancer care in the United States.

Video is Now Essential

Online platforms such as healthcare websites or Facebook get four times the engagement with video posts than with text alone. More importantly, the retention of "video" health content far exceeds written content. In this manner, medical information can be *translated* for patients. Physicians do this when they talk to their patients. The difficulty comes with developing a comfort level speaking in front of a camera. Once I overcame that awkwardness and created a video studio, it became an easy, low-cost way to create educational content.

The Breast Cancer School for Patients' innovative two- to ten-minute video "lessons" about important breast cancer topics give patients the tools they need to engage their breast cancer specialists. Patients can now watch a video and print out lesson notes and specific questions to ask their doctors about 50 cancer-related topics. If patients or caregivers want more detail, each topic has links to evidence-based websites to learn more. At the Breast Cancer School for Patients, women or family members can learn as little or as much as they want about any aspect of their unique breast cancer situation.

Organization is Everything

We have designed separate video courses on every stage of treatment to focus on the crucial decisions that patients will have to make. As patients move from biopsy to surgery, chemotherapy to radiation, or hormone therapy to survivorship, we teach patients and caregivers key concepts to make sure that they are getting high-quality cancer care in their own community.

Cutting-edge tests and treatments are often overlooked when explaining breast cancer treatment. We created a course, "Cutting-Edge Advances," with video lessons and content about BRCA genetic testing, genomic assays, and NAPBC breast centers, to name a few. Recently, we've added a video about the TAILORx clinical trial results, which help identify more women who can avoid chemotherapy.

Analytics are Important

It is essential to define success by both the quality of the content and the analytics of the online platform. When we launched our website, **breastcancercourse.org**, traffic was slow. Our YouTube videos turned out to be much more popular, with 150,000 views and an average watch time of more than five minutes per view over the first 8 weeks. The analytics told us that our individual videos would ultimately be the driver of traffic to our larger, comprehensive website. Facebook and social media will become ever more important to succeed in patient advocacy outreach. Video content is now the "standard of care." Cancer programs and healthcare facilities must stay abreast of these platforms to successfully engage the public to walk through their doors for their own cancer care.

Treatment methods are always advancing, and research is constantly uncovering

new information. It is difficult enough for healthcare systems and physicians to keep up. In my opinion, it is also our duty, as leaders in cancer care, to find innovative solutions to educate patients on receiving high-quality cancer care in their own communities through online patient education. We encourage other organizations and institutions to do the same.

John Williams, MD, FACS, is a breast surgeon and founding physician of the Novant Health UVA Breast Center, Haymarket, Va. He is the creator of the Breast Cancer School for Patients, which can be found at **breastcancercourse.org**.

The Breast Cancer School for Patients

This not-for-profit video platform is the first "school" for patients in healthcare. The disparity of quality breast cancer care can be improved by a bottom-up approach through educating patients to become "experts" in their own breast cancer diagnosis.

- ***Video courses:*** Information is presented in the sequence of care encountered by patients. Courses about breast imaging, surgery, oncology, and radiation are the most important.
- ***Sophisticated platform:*** Healthcare content must be presented in an engaging fashion with images, video, and quality content. Be prepared to improve platforms in the future.
- ***Host all videos on YouTube:*** It is essential that any video content be public and searchable. This drives traffic and search engine rankings.

REGISTER NOW!

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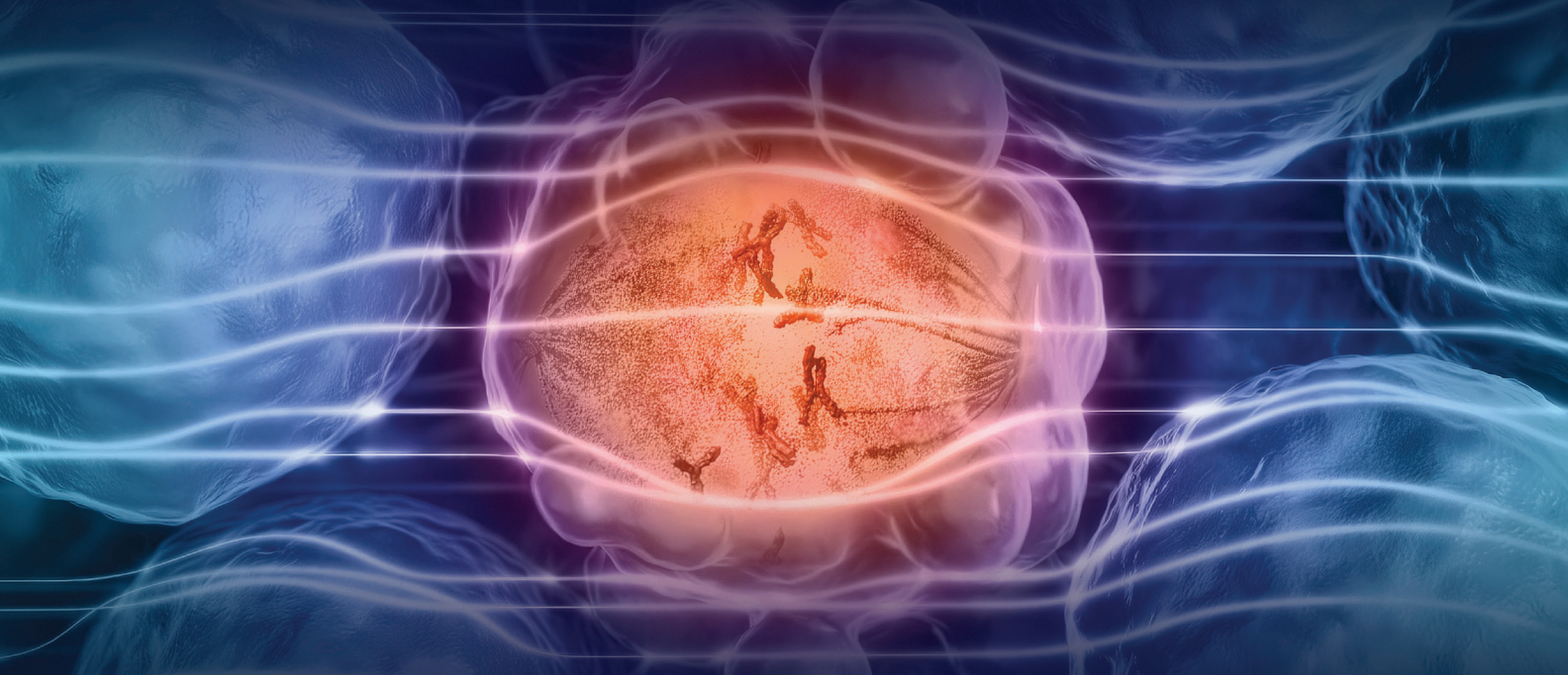
Novocure® is conducting clinical trials using TTFields (alternating electric fields) to selectively kill cancer cells in solid tumors.[1]

When delivered at 150 kHz, TTFields may relentlessly attack and selectively kill dividing cancer cells by causing a cascade of effects at multiple phases in the cell cycle, which prevents mitosis.[1-4]



The METIS trial for patients with 1-10 newly diagnosed brain metastases as a result of non-small cell lung cancer (NSCLC) is now enrolling.[1]

This phase III trial is studying the efficacy and safety of TTFields at 150 kHz + the best lung cancer standard of care (including chemotherapy) following standard stereotactic radiosurgery (SRS).[1,5]

Eligible patients should be ≥18 years of age and newly diagnosed with 1 inoperable brain metastasis, or 2-10 previously untreated brain metastases from NSCLC, and with brain metastases that are amenable to SRS.[1,5]

ENROLL YOUR PATIENTS TODAY

Visit novocuretrial.com for enrollment information

Email clinicaltrials@novocure.com with trial questions

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References: 1. ClinicalTrials.gov. Bethesda (MD): U.S. National Library of Medicine. Effect of TTFields (150 kHz) in non-small cell lung cancer (NSCLC) patients with 1-10 brain metastases following radiosurgery (METIS). NCT02831959. https://clinicaltrials.gov/ct2/show/NCT02831959. Updated January 15, 2019. Accessed January 23, 2019. **2.** Gutin PH, Wong ET. Noninvasive application of alternating electric fields in glioblastoma: a fourth cancer treatment modality. *Am Soc Clin Oncol Educ Book*. 2012:126-131. **3.** Kirson ED, Dbalý V, Tovarys F, et al. Alternating electric fields arrest cell proliferation in animal tumor models and human brain tumors. *Proc Natl Acad Sci USA*. 2007:104(24):10152-10157. **4.** Gera N, Yang A, Holtzman TS, Lee SX, Wong ET, Swanson KD. Tumor treating fields perturb the localization of septins and cause aberrant mitotic exit. *PLOS ONE*. 2015.10(5):e0125269. doi:10.1371/journal.pone.0125269. **5.** Novocure Data on File. NovocureTrial.com. METIS. 2018.

This is an investigational trial. TTFields has not been approved by the US FDA for treatment of brain metastases.