ONCOLOGY ISSUES

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

January | February 2019

CRISPR-Directed Gene Editing in a Community Cancer Center

ACCC
Association of Community Cancer Centers

INNOVATE. ACHIEVE. INSPIRE.

ACCC INNOVATOR AWARDS CALL FOR ENTRIES

In its ninth year, the **Association of Community Cancer Centers Innovator Awards** honor Cancer Program Members for their ingenuity and pioneering achievements in oncology.

Innovations should advance the goals of improving access, quality, and value in cancer care delivery.

Some suggested areas of focus are:

- New Models in Care Coordination
- Process and Quality Improvement Initiatives
- Community Outreach, Prevention, and Screenings
- Telehealth and Virtual Care Models
- Financial Advocacy and Navigation
- Supportive Care Services
- Provider Resiliency and Well-Being
- Patient Engagement and Shared Decision-Making Strategies
- Immuno-Oncology Implementation

Applicants must be affiliated with ACCC as a Cancer Program Member.

Winners will be selected through a peer review process.

Winners are recognized and will present present their innovations at the **ACCC 36th National Oncology Conference,** October 30 – November 1, 2019, in Orlando, FL, and will be featured in our peer-reviewed journal, *Oncology Issues*.

Winning cancer programs will receive regional and national exposure as their innovations are shared with oncology care providers, the broader healthcare community, and national press outlets.

CRITERIA FOR SUBMISSIONS

1. Is your program ***innovative***, creating positive change for your patients and staff?
2. Does this innovation advance patients' access to quality cancer care?
3. Does your program demonstrate value to patients and payers?
4. Can your innovation be replicated in other community-based cancer programs?
5. Does your innovation look to eliminate inefficiencies and reduce cost of care?

DEADLINE FOR SUBMISSIONS: March 8, 2019

For details, the application form, and to learn about past Innovator Award winners, please visit accc-cancer.org/innovator.

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DEPARTMENTS

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Association of Community Cancer Centers

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FROM THE EDITOR

Telehealth: Cancer Care at a Distance

BY JENNIE R. CREWS, MD, MMM, FACP

There is growing enthusiasm for the use of telehealth in oncology. In addition to patient-driven factors, for example the need to mitigate transportation challenges for cancer patients and families, and economic factors—payers believe that utilization of telehealth may help reduce healthcare costs—new cancer treatments, such as immunotherapies, require greater patient monitoring and tracking that may be more conveniently (and economically) provided via telehealth.

Telehealth may even lead to better outcomes. A study published online in May 2017 in the *Journal of Clinical Oncology* showed improved survival in lung cancer with remote symptom monitoring, and use of such patient-reported outcomes in other tumor types is under evaluation.

Patient satisfaction with telehealth is well documented in primary care. Anecdotally, the same is true in oncology. In my previous practice, we had a robust tele-oncology consult service. Our surveys showed that most patients were "satisfied" to "highly satisfied" with the service and would recommend it to others.

However, broad adoption of telehealth in the field of oncology is low due to both perceived and real barriers, including operational expertise and acceptance by patients and providers. Most cancer programs are familiar with teleconferencing but have less experience with other forms of telehealth, such as:

- Asynchronous store-and-forward technology for reviewing patient data
- E-consults between providers
- Remote patient monitoring
- Virtual visits.

However, patient demand for convenience and research demonstrating improved outcomes is driving cancer programs to think outside the traditional model of cancer care and consider these technologies as crucial components to care delivery.

Arguably, the largest barriers to adoption of telehealth are regulatory and legal constraints. There are state-to-state differences in licensing requirements, allowed services, definition of the originating site (where the patient is located), and payment. Forty-nine states currently have some form of Medicaid reimbursement for telehealth, and 39 states have laws governing payment for telehealth by private payers; however, specifics vary by state and few states have strict payment parity laws. The burden of provider licensing has decreased with the creation of the Interstate Medical Licensure Compact, but not all states currently participate.

Traditionally, Medicare had limited reimbursement for telehealth, but the 2019 Hospital Outpatient Prospective Payment System and Physician Fee Schedule rules are broadening coverage. Reimbursement will be allowed for virtual check-in visits between a provider and an established patient following consent, if the virtual visit does not occur seven days prior to an E&M visit, one day following an E&M visit, or on the soonest available date (a term that the Centers for Medicare & Medicaid Services acknowledges is not well defined but will be defined by monitoring. For more on this, see the "Compliance" column on pages 8-25). Starting Jan. 1, 2019, the Medicare program will also cover certain medical services delivered via asynchronous telemedicine technologies.

Overall, I believe that these regulatory updates are a win for telehealth, and I hope that they will encourage broader adoption of this technology in oncology care delivery. Getting patients the care they need—without the burden of arranging travel or taking time off from work or school—will increase patient satisfaction and improve efficiency of care delivery. OI

Resolving to be Resilient

BY TOM GALLO, MS, MDA

As we enter a new calendar year, now is traditionally the time in our lives when we reflect on the last 12 months, note where we have succeeded, and determine where we still need to make improvements. The same can also be applied to our workplace—as 2019 is now upon us, we can assess how our cancer programs succeeded in delivering quality cancer care to our patients last year and what we can do even better. For many programs that improvement must begin with us.

In any workplace, burnout is a serious concern. It robs us of our creativity, our patience, and our compassion. Because of the continual interactions we have with patients with serious, often terminal diagnoses, cancer care providers are especially vulnerable to the effects of burnout. According to a 2017 Medscape survey, nearly half of all oncologists reported experiencing symptoms of burnout due to a combination of factors including increased workload. Another study found that one-third of physician assistants in oncology experienced burnout despite high reported rates of job satisfaction.

As members of the multidisciplinary cancer care team, it is crucial that we work together to avoid the fatigue that can rob a vulnerable population of high-quality care. This was the impetus behind my President's Theme of "Reflect, Renew, Reignite: Creating a Resilient Oncology Team in Your Community." At the ACCC 35th National Oncology Conference in Phoenix this past October, we heard from several experts on how best to fight back against burnout and build resilience within cancer care teams. So as we begin a new year, I offer this key advice on building resilience:

- ***Choose joy.*** Featured speaker Vicki Hess, RN, MS, suggests that we look inward, find what brings us joy at work, and incorporate it into our workload. For some, it might be developing relationships with patients; for others, it may be implementing quality improvement initiatives. Whatever your joys, making them a part of your daily work can help alleviate the symptoms of burnout.
- ***Spread appreciation.*** According to Hess, one simple way to build resilience is through staff appreciation. It feels good to be praised or recognized for one's work, and it also feels good to express your appreciation for others—a win-win scenario.
- ***Let it go.*** Negative attitudes and responses typically yield more negativity, exacerbating burnout. Taking a step back and releasing frustration can be a powerful way to enact personal change. On an organizational level, getting chronic complainers involved in problem-solving processes can bring about valuable changes while also reducing individual negativity.
- ***Address burnout from the top down.*** In a pop-up poll conducted at the National Oncology Conference, 93 percent of attendees reported that their cancer program or practice did not measure staff or clinician burnout. Julie Oehlert, DNP, advised that it will be impossible to hit the Institute for Healthcare Improvement Triple Aim without also improving the health and well-being of staff, something that Oehlert accomplished as chief experience officer at Vidant Health. Says Oehlert, "How we [the healthcare team] experience each other begets the patient experience."

ACCC will continue to work on behalf of oncology providers to discover and promote strategies to improve wellness and foster resilience within the cancer care team. If you have implemented strategies in your cancer program, we'd love to hear about them! Visit accc-cancer.org/home/connect/member-news-submission/ and share your story with us. 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
- *One Best Practice*: Streamlining Workflow, Unifying Staff, and Reducing Redundancy
- Implementing Medical Scribes in a Community Cancer Center
- Utilizing Bedside Yoga as a Non-pharmacological Intervention for Cancer Patients
- ArtsCare: Professional Artists and Musicians as Members of the Multidisciplinary Cancer Care Team
- Partnering to Deliver Precision Cancer Therapy in the Community
- The Oncology Pharmacy Navigator: A New Best Practice Model for Managing Medications
- Combating Rising Drug Prices & Waste Through Drug Vial Optimization
- 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

more online @ accc-cancer.org

RESOURCE

Immuno-Oncology Web Portal Launched

New and emerging cancer immunotherapies continue to reshape treatment options. For multidisciplinary team education and resources that go beyond a clinical understanding of immuno-oncology advances and deliver real-world implementation strategies, check out the ACCC Immuno-Oncology Institute web portal at accc-cancer.org/immunotherapy. Discover resources to support your program, staff, and patients receiving treatment with immuno-oncology. Read the ongoing IO Insights series for the big-picture perspective on this game-changing field.

PUBLICATION

Metastatic Breast Cancer: Effective Principles in Action

Could your cancer program do a better job communicating with metastatic breast cancer patients? ACCC's Metastatic Breast Cancer education project now features an interactive resource library, plus read how three cancer programs are optimizing patient-provider communication. See what's new at accc-cancer.org/metastaticbreastcancer.

WEBINAR

OPPS and PFS Updates 2019

2019 Medicare payment rules went into effect on Jan. 1, 2019. Did you miss ACCC's policy webinar with "need to know" highlights from the Outpatient Prospective Payment System and Physician Fee Schedule and Quality Payment Program rules? Need a refresh? Webinars and rule summaries are available at mynetwork.accc-cancer.org/viewdocument/2019-cms-opps-pfs-qpp-final-rules.

CME/CE

Host a Grand Rounds at Your Program

ACCC is partnering with the Oncology Nursing Society (ONS) and The France Foundation to support a series of live Grand Rounds/Tumor Boards on PARP Inhibitors: Advancing Personalized Medicine for Metastatic Breast Cancer Patients. Apply today to host a subject matter expert at your program to lead a one-hour accredited session, CME, CE, MOC credit available. Learn more at accc-cancer.org/projects/parpinhibitors/overview.

RESOURCE

New Resources on Blood Cancers

Visit the new blood cancers web section. Learn about the ACCC education project on acute lymphocytic leukemia (ALL). Find new resources under ACCC's Multidisciplinary Multiple Myeloma Care project, including blog posts in ACCCBuzz. Go to accc-cancer.org/blood-cancer.

fast

5 Key Actions to Help Combat the Opioid Epidemic

1. Mandating prescriber education
2. Implementing opioid prescribing guidelines
3. Integrating prescription drug monitoring programs into clinical settings
4. Improving data collection and sharing
5. Increasing availability of opioid use disorder treatment

Source. National Safety Council. Prescription Nation. safety.nsc.org/prescription-nation-facing-americas-opioid-epidemic.

Few Approve How President Trump and Congress Are Addressing Prescription Drug Costs

- **3/4** of Americans consider the cost of prescription drugs in the U.S. to be "unreasonable."
- Only **23%** approve of how President Trump is dealing with the high cost of prescription drugs.
- Only **20%** approve of what Democrats are doing; **16%** approve of how Republicans are handling the issue.
- Out of 6 issues, **78%** of Americans identified addressing healthcare costs as their highest priority, compared to jobs and the economy (**76%**), national security (**71%**), the environment (**63%**), immigration (**51%**), or trade (**38%**).
- **65%** percent said they are "extremely" or "very concerned" about the high cost of prescription drugs.

Source. A survey conducted by NORC at the University of Chicago with funding from West Health Institute. norc.org.

facts

Key Advances in the AACR Cancer Progress Report 2018

- **22** treatments for cancer were approved for the first time by the FDA or approved for new types of cancer between Aug. 1, 2017 and July 31, 2018.
- The U.S. cancer death rate declined by **26%** for adults from 1991 to 2015, which translates to almost **2.4** million lives saved.
- The cigarette smoking rate among U.S. adults has fallen to **14%**, down from 42% in 1965, due to education and policy initiatives.

Public Health Challenges in the AACR Cancer Progress Report 2018

- The number of new cancer cases in the U.S. is predicted to rise from **1.7** million in 2018 to **2.4** million in 2035, due largely to the increasing number of people age 65 and older.
- HPV vaccination could prevent nearly all cases of cervical cancer—and many cases of oral and anal cancer—but less than **50%** of U.S. adolescents ages 13 to 17 are up to date with the recommended vaccination series.
- Advances against cancer have not benefited everyone equally; cancer health disparities are some of the most pressing challenges posed by the disease.

Source. AACR Cancer Progress Report. cancerprogressreport.org/Pages/default.aspx.

Survey Finds 93 Percent of First Responders Say Mental Health is as Important as Physical Health

- More than 8 in 10 (**83%**) believe that people who receive counseling generally get better.
- However, nearly half (**47%**) feel that there would be repercussions on the job for seeking professional counseling.
- Among those who feel this way, repercussions of seeking counseling included receiving different treatment from coworkers (**53%**) or supervisors (**52%**) and being perceived as weak by colleagues and/or peers (**46%**).

Source. University of Phoenix. s3.amazonaws.com/communicationteamdeliverables/UOPX_First+Responders+and+Mental+Health.png.

Physicians Unwilling to Recommend Their Profession

- **7** out of **10** physicians are unwilling to recommend their chosen profession.
- More than **1/2** of physicians say they are contemplating retirement within the next five years; **1/3** of those are under the age of 50.
- **61%** of physicians believe EHRs are having a negative impact on their workflow, with many suggesting that EHR requirements are a major cause of burnout.
- **54%** of physicians believe EHRs have had a negative impact on the physician-patient relationship.
- **1/2** of physicians believe value-based care and reimbursement will have a negative impact on overall patient care.

Source. Future of Healthcare Survey. thedoctors.com/future.

Make Your Voice Heard at ACCC Capitol Hill Day

BY BLAIR BURNETT

Every two years American voters go to the polls to participate in national elections. This fall's mid-term elections resulted in a major paradigm shift and an entirely different congressional class. With this shake-up in Washington, D.C., new voices are demanding to be heard. Make yours one of them.

Each year, in conjunction with the ACCC Annual Meeting and Cancer Center Business Summit, we bring dozens of ACCC members to Washington, D.C., for our Capitol Hill Day. Across the board, these members have enjoyed this unique opportunity to meet with their legislators and congressional staffers and talk about the challenges—and successes—at their cancer programs or practices. Most importantly, our members share how much they value these in-person meetings so that they can advocate on behalf of cancer patients and their families.

So why is it more important than ever to attend ACCC Capitol Hill Day in 2019? Over the past year and a half, this country has seen large shifts in health policy as both the Trump Administration and Congress examine the best way to address healthcare reform. Oncology as a specialty is not immune to these major changes, as we have already seen through the Administration's drug pricing reform proposals. For example, in October the Trump Administration released a three-pronged proposal to overhaul Medicare Part B and tackle rising drug costs with the expectation that a formal proposed rule would be released in spring 2019. ACCC has expressed overarching concerns about the impact of this proposal on the entire cancer care delivery infrastructure and, in particular, those programs and practices that see a high percentage of Medicare, Medicare-only, and dual-eligible patients. If you missed our webinar on this topic, you can view the webinar on-demand and access the presentation slides at mynetwork.accc-cancer.org/viewdocument/december-5-2018-webinar-medicare.

Then in November, the Centers for Medicare & Medicaid Services announced a proposed rule to amend the Medicare Advantage program (Part C) and Prescription Drug Benefit program (Part D). Top-line takeaways from the proposed rule include:

- Proposed reform to Medicare Part D's "protected" therapeutic classes.
- A new requirement in Medicare Part D to allow for increased transparency between patient and provider with provision of out-of-pocket cost obligations for prescription drugs whenever a prescription is written.
- A continued push to allow for and implement "step therapy" in Medicare Advantage plans for Part B drugs. The proposed rule also states the potential to infuse prior authorizations within this pool as well.
- Proposed implementation of a "statutory requirement" that would prohibit pharmacy gag clauses in Part D.

In December, ACCC issued a policy statement expressing deep concerns regarding the impact of the Centers for Medicare & Medicaid Services' proposed Medicare Advantage and Part D rule on the country's oncology care delivery infrastructure.

As you can see, healthcare delivery is at a crossroads. It is critical that those on the frontlines of cancer care provide input on where we go next to protect patient access to quality cancer care. ACCC's annual Capitol Hill Day is organized so that participants have face-to-face meetings to share their perspectives and advocate on behalf of their patients and their cancer programs. In 2018 ACCC members representing 26 states walked the halls of the House and Senate, participating in nearly 100 congressional meetings. Participants addressed legislative efforts and the impact that new mandates would have on cancer care delivery in their home communities.

Due in part to ACCC member advocacy before, during, and after the 2018 ACCC Capitol Hill Day, we were proud to see the Palliative Care & Hospice Education Training Act (H.R. 1676/S. 693) move to the Senate, signaling a push toward more comprehensive access to palliative care in the years to come. This year, we are in a new legislative session with dozens of newly elected legislators to engage. Taking time away from your program or practice to attend is a scheduling feat, but know that your story and your patients' stories make a difference. Legislative action and the policies that shape oncology delivery do not happen in a vacuum. Adding your voice to your fellow ACCC members will help leverage the challenges and solutions you experience daily at your program or practice to become a catalyst for positive change.

ACCC makes it easy to participate. Everyone who attends the 2019 ACCC Capitol Hill Day will receive an orientation and hands-on training. You'll know what to expect and be well prepared for your scheduled visits with your legislators and their staff. For more information, go to accc-cancer.org/capitolhillday or email bburnett@accc-cancer.org. We look forward to welcoming you to Washington, D.C., on Wednesday, Mar. 20, 2019, and advocating together on behalf of all patients with cancer and their families. OI

Blair Burnett is senior policy analyst at ACCC.

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Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on the condition of the patient. The use of the above codes does not guarantee reimbursement. Health care providers are encouraged to contact payers to confirm code adoption and approved usage prior to submitting claims.

Reference: 1. Centers for Medicare & Medicaid Services. Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. November 2, 2018.

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2019 Oncology Coding Update

BY TERI BEDARD, BA, RT(R)(T), CPC, AND TAMARA SYVERSON, BSRT(T)

Coding updates have been finalized by Medicare for calendar year (CY) 2019. In comparison to previous years, the code changes outlined for CY 2019 are not significant for oncology, but it is important to be prepared and ensure coding practices and chargemasters are updated to reflect any necessary code changes. The following outlines oncology-specific coding changes.

New and Revised Procedure Codes

Coding guidelines for imaging services under the wing of radiology were updated for CY 2019 to reiterate that image guidance is not separately billable when it is included in a base service; many primary services indicate image guidance is included in the definition of the code. When imaging is *not* included in a primary procedure, it may be separately reported, but there are documentation requirements for the codes. Documentation should include images in the medical record and description of the image guidance provided in the procedure report. In addition to the updated guidelines, below are several new, revised, and deleted codes applicable to services provided to oncology patients.

The following codes have been added for CY 2019:

- **77046**: Magnetic resonance imaging, breast, without contrast material; unilateral
- **77047**: Magnetic resonance imaging, breast, without contrast material; bilateral
- **77048**: Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral
- **77049**: Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral
- **99451**: Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a written report to the patient's treating/requesting physician or other qualified healthcare professional, 5 minutes or more of medical consultative time
- **99452**: Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified healthcare professional, 30 minutes
- **G2012**: Brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified healthcare professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion.

The following codes have been revised for CY 2019:

- **77021**: Magnetic resonance imaging guidance for needle placement (e.g., for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation
- **77022**: Magnetic resonance imaging guidance for, and monitoring of, parenchymal tissue ablation
- **77387**: Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed
- **99446**: Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 5-10 minutes of medical consultative discussion and review
- **99447**: Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 11-20 minutes of medical consultative discussion and review
- **99448**: Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21-30 minutes of medical consultative discussion and review
- **99449**: Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review.

The following codes have been deleted for CY 2019:

- **0190T**: Placement of intraocular radiation source applicator (List separately in addition to primary procedure)
- **76001**: Fluoroscopy, physician or other qualified healthcare professional time more than 1 hour, assisting a non-radiologic physician or other qualified healthcare professional (e.g., nephrostolithotomy, ERCP, bronchoscopy, transbronchial biopsy)
- **77058**: Magnetic resonance imaging, breast, without and/or with contrast material(s); unilateral
- **77059**: Magnetic resonance imaging, breast, without and/or with contrast material(s); bilateral

Modifiers

Effective April 1, 2018, the Centers for Medicare & Medicaid Services (CMS) deleted modifiers that were applied to biosimilars to identify the manufacturer. CMS created individual HCPCS codes effective April 1, 2018, for the biosimilar biologicals to identify each manufacturer separately; therefore, the modifiers were no longer necessary. The deleted modifiers include:

- **ZA**: Novartis/Sandoz
- **ZB**: Pfizer/Hospira
- **ZC**: Merck/Samsung Bioepis

Drug Codes

New codes for therapeutic radiopharmaceuticals will go into effect Jan. 1, 2019. These will replace the current codes for the same therapeutic radiopharmaceutical.

New codes 2019:

- **A9513**: Lutetium Lu 177, dotatate, therapeutic, 1 millicurie
- **Q2042**: Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Deleted codes in 2019:

- **C9031**: Lutetium Lu 177, dotatate, therapeutic, 1 millicurie
- **Q2040**: Tisagenlecleucel, up to 250 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion

Table 1 below shows code changes from CY 2018 to CY 2019 for drugs specific to oncology/hematology services. OI

Table 1. CY 2018 to CY 2019 Code Changes for Drugs Specific to Oncology/Hematology Services

CY 2018 HCPCS CODE DELETED DEC. 31, 2018	CY 2019 LONG DESCRIPTOR	CY 2019 HCPCS CODE BEGINS JAN. 1, 2019
C9016	Injection, triptorelin extended release, 3.75 mg	J3316
C9024	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	J9153
C9028	Injection, inotuzumab ozogamicin, 0.1 mg	J9229
C9030	Injection, copanlisib, 1 mg	J9057
C9033	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	J1454
C9463	Injection, aprepitant, 1mg	J0185
C9464	Injection, rolapitant, 0.5 mg	J2797
C9467	Injection, rituximab 10 mg and hyaluronidase	J9311
C9468	Injection, factor ix (antihemophilic factor, recombinant), glycopegylated, Rebinyn, 1 i.u.	J7203
C9492	Injection, durvalumab, 10 mg	J9173
N/A	Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose	Q2042
Q9993	Injection, triamcinolone acetonide, preservative-free, extended-release, Microsphere formulation, 1 mg	J3304
Q9995	Injection, emicizumab-kxwh, 0.5 mg	J7170
N/A	Injection, mogamulizumab-kpkc, 1 mg	C9038

2019 Hospital Regulatory Update

BY TERI BEDARD, BA, RT(R)(T), CPC, AND TAMARA SYVERSON, BSRT(T)

The Hospital Outpatient Prospective Payment System (HOPPS or OPPS) is one of the Medicare payment systems that applies to facility-based settings, including hospitals, ambulatory surgical centers (ASCs), critical access hospitals (CAHs), and excepted off-campus provider-based departments (PBDs). The Centers for Medicare & Medicaid Services (CMS) indicated in the CY 2019 OPPS final rule that the overarching goal is *"to make payments for all services under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item."* To accomplish this goal in the past few years, CMS has continued to package more ancillary services into what are considered primary services, establishing reimbursement for the primary service only. Another route taken by CMS to control spending is to neutralize payments, reimbursing for the same service in a manner that is "neutral" to where it was performed—hospital, physician office, or ASC.

CMS estimates expenditures for CY 2019 will be approximately $74.1 billion—an increase of approximately $5.8 billion from CY 2018 OPPS payments. There is an increase in payments rates of 1.35 percent under the Outpatient Department (OPD) fee schedule. This increase will mean approximately a 1.4 percent increase for urban hospitals and a 1.3 percent increase for rural hospitals. The CY 2019 conversion factor was finalized at $790.49 for hospitals meeting the Hospital Outpatient Quality Reporting (OQR) Program requirements; CMS will decrease the conversion factor by 2 percent for hospitals that fail to meet quality reporting requirements. The overall estimated expenditures also take into consideration a 0.8 percent decrease in reimbursement for the multifactor productivity (MFP) adjustment and the required 0.75 percent decrease due to the Affordable Care Act for years 2010 through 2019.

Certain rural sole community hospitals will continue to see a rural adjustment factor of 7.1 percent applied to OPPS payments for CY 2019 and subsequent years. This payment adjustment will continue to exclude separately payable drugs, biologicals, and devices paid under the pass-through payment policy. ASC payments were finalized to increase by 2.1 percent for those meeting quality reporting under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program.

Frontier state hospitals will continue to apply a wage index of 1.000 for CY 2019, and 11 cancer-designated hospitals will continue to receive additional payment adjustments. The payment-to-cost ratio (PCR) used to determine the payment adjustments for cancer hospitals was weighted to account for the 1.0 percent decrease required by the 21st Century Cures Act, resulting in a PCR of 0.88 for CY 2019. Additionally, CMS will provide outlier payments to hospitals to mitigate the financial risk associated with some high-cost procedures and services. In order to qualify for the additional outlier payment, the cost of the procedure must exceed 1.75 times the ambulatory payment classification (APC) payment and exceed it by more than $4,825. If the threshold is met, then 50 percent of the difference between the cost and APC payment will be an additional payment to the hospital.

APC Two-Times Rule Exceptions

CMS identified several APCs in violation of the two-times rule for CY 2019. Two were new since the proposed rules were released, and one was resolved without intervention. The two-times rule does not allow codes to be assigned to an APC where the highest costing code is more than two times that of the lowest costing code. When a two-times rule violation is identified, CMS and the Hospital Outpatient Payment (HOP) Panel will reassign codes or create a new APC. When determining if there is a two-times-rule violation, CMS only considers Healthcare Common Procedure Coding System (HCPCS) codes that are significant based on the number of claims.

For CY 2019, CMS made exceptions for all the two-times-rule violating APCs, meaning no adjustments or movement of codes to other APCs was required to balance the codes of highest and lowest cost. This exception included the three APCs related to oncology services: **APC 5612** (Level 2 Therapeutic Radiation Treatment Preparation), **APC 5691** (Level 1 Drug Administration), and **APC 5692** (Level 2 Drug Administration).

Site-Neutral Payments for Hospital Outpatient Clinic Visits

In response to the Bipartisan Budget Act of 2015, CMS established new guidelines to address the difference in reimbursement payments for the exact same procedure between varying places of service—primarily hospital, ASC, and physician office. The Act set Nov. 2, 2015 for the establishment of any new provider-based departments (PBDs) and the distance (250 yards) the new department could be from the main buildings of the hospital and still receive payment rates established under OPPS. Due to what was considered the alarming rate of hospitals acquiring physician practices and the tendency for PBDs of a hospital to be paid more than a physician office setting, changes were made.

Excepted off-campus PBDs are settings which were established and billing for services prior to Nov. 2, 2015 and are within the previously set distance of 35 miles. Excepted off-campus PBDs are paid at the OPPS full established rate for each service and are considered "grandfathered" into the payments under OPPS, even if the new distance threshold is not met. Non-excepted off-campus PBDs are settings that were established on or after Nov. 2, 2015 and are outside the newly set distance of 250 yards from the main buildings of the hospital. Non-excepted PBDs are paid under the Physician Fee Schedule (PFS) but are still considered a facility setting for the purposes of following guidelines about supervision, packaging, and more.

CMS's practice of neutralizing payments for services based on utilization is not new. It first occurred in the CY 2008 OPPS/ASC final rule. At that time, the agency had concerns about expenditures for some hospital outpatient services that showed significant growth. As a result, CMS established a set of packaging policies intended to encourage efficiency and potentially control future growth in the number of OPPS services. Effective CY 2008, CMS packaged seven categories of services and items specific to primary diagnostic or therapeutic modalities believed to be ancillary or supportive, including the packaging of imaging services in radiation oncology into treatment delivery.

In CY 2015, CMS introduced another method of spending control with the introduction of comprehensive APCs (C-APCs). CMS expanded the packaging of services to include items involved in many same-day or surgical procedures. To do so, CMS designated a primary service and packaged all ancillary services reported on the same claim into the primary service, meaning no separate payment for ancillary services. The idea was to make OPPS more like a prospective payment system and less like a per-service fee schedule.

The OPPS is the fastest growing sector of Medicare payments out of all of payment systems under Part A and B. The growth rate—approximately 8 percent each year—is concerning to CMS. Total spending for the OPPS is projected to increase by more than $5 billion—from $70 billion in CY 2018 to nearly $75 billion in CY 2019. This increase is approximately twice the estimated spending of CY 2008.

For CY 2019, CMS expressed concerned about code **G0463** (Hospital outpatient clinic visit for assessment and management of a patient), which is the most widely reported code under the OPPS. CMS proposed a site-neutral method for controlling *"unnecessary increases in the volume of covered outpatient department services."* The agency believed the increase in reporting of code **G0463** was related to the payment incentive in the high-cost setting and that these services could be provided effectively and safely in a low-cost setting. By reducing the rate to one equivalent to the PFS rate, CMS looked to remove the incentive and decision about where to perform the service so it has the most favorable financial impact.

For CY 2019, CMS proposed to use a PFS payment rate for code **G0463** when billed in excepted off-campus PBDs, setting reimbursement for this code at 40 percent of the HOPPS rate—the same reimbursement amount for non-excepted off-campus PBDs.

After review of comments, the agency is moving forward with the payment adjustment for code **G0463** in excepted off-campus PBDs, but the agency will implement this change over 2 years. When a reduction is greater than 20 percent for a given year, the reduction is phased in over time. In CY 2019, the reimbursement rate for **G0463** in an excepted off-campus PBD will be 70 percent of the HOPPS full rate. In CY 2020, the reimbursement rate for **G0463** will be the PFS rate for the service, equating to 40 percent of the full HOPPS rate—unless the PFS rate is changed.

Only on-campus hospital outpatient departments will be reimbursed at the full OPPS value for code **G0463** in CY 2019. Excepted off-campus PBDs would continue to report **G0463** with the modifier **PO**.

Oncology Comprehensive APCs

C-APCs were first implemented in CY 2015 and have continued to grow and evolve since that time. Primary services are designated with a status indicator code of "**J1**" or for certain coding scenarios, with "**J2**" to identify the C-APC. All ancillary codes with status indicators of "**S**," "**T**," or "**V**" are packaged into the C-APC and are not separately reimbursed.

In CY 2019 and subsequent years, CMS is continuing to apply the C-APC payment methodology, "**J1**," and certain "**J2**" status indicators to reflect the C-APC designation. New C-APCs were finalized for CY 2019, but none were specific to or included services for oncology. CMS did receive several comments requesting the discontinuation of the C-APC payment policy for several brachytherapy insertion procedures and single session stereotactic radiosurgery (SRS) procedures. Commenters also requested that CMS include Current Procedural Terminology (CPT) code **77301** for IMRT planning on the list of other codes reimbursed separately with SRS, stating the service has become more common in single fraction SRS planning. The following is the response by CMS to the requests by commenters for changes to the C-APCs impacting radiation oncology, brachytherapy, and stereotactic radiosurgery:

"At this time, we do not believe that it is necessary to discontinue the C-APCs that include brachytherapy insertion procedures and single session SRS procedures. We continue to believe that the C-APC policy is appropriately applied to these surgical procedures for the reasons cited when this policy was first adopted and note that the commenters did not provide any empirical evidence to support their

claims that the existing C-APC policy does not adequately pay for these procedures. Also, we will continue in CY 2019 to pay separately for the 10 planning and preparation services (HCPCS codes 70551, 70552, 70553, 77011, 77014, 77280, 77285, 77290, 77295, and 77336) adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC based technology when furnished to a beneficiary within 1 month of the SRS treatment for CY 2019 (82 FR 59242 and 59243)."

Payments of Drugs, Biologicals, and Radiopharmaceuticals

Each year, CMS assesses the drug packaging threshold. For CY 2019, CMS finalized the packaging of drugs and biologicals estimated to have a per-day administration cost of less than or equal to $125. In other words, the agency will only pay separately for items with an estimated per-day cost greater than $125, with the exception of diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs and biologicals, radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies or devices when used in a surgical procedure.

CMS also finalized the proposal to continue the policy of making packaging determinations on a drug-specific basis rather than by HCPCS code for codes that describe the same drug or biological in different dosages. For all other drugs and biologicals that have HCPCS codes describing different doses, CMS aggregated the CY 2017 claims data and pricing information at average sales price (ASP) plus 6 percent for all HCPCS codes that describe each distinct drug or biological. This provided the mean units per day with respect to the HCPCS code with the lowest dosage descriptor. For other drugs and biologicals that have HCPCS codes describing different doses, CMS multiplied the weighted average ASP plus 6 percent per unit across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological; this determined the estimated per-day cost of each drug or biological at less than or equal to the proposed CY 2019 drug packaging threshold of $125.

CMS did not receive any public comments related to this proposal; therefore, it was finalized without modification. The drugs and biologicals commonly used in oncology for which this final packaging status applies for CY 2019 are listed in Table 2 below.

For CY 2019, CMS will continue the current policy, in effect since CY 2013, to pay for separately payable drugs and biologicals at ASP plus 6 percent. These separately payable drugs and biologicals are listed in Addenda A and B to the final rule. CMS will also continue to pay for separately payable non-pass-through drugs acquired with a 340B discount at ASP minus 22.5 percent.

Table 2. HCPCS Codes to Which the CY 2019 Drug-Specific Packaging Determination Methodology Applies

CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR	CY 2019 STATUS INDICATOR (SI)
C9257	Injection, bevacizumab, 0.25mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

For drugs or biologicals with insufficient data on sales price during the initial sales period, payments will be based on wholesale acquisition cost (WAC). The Social Security Act states that certain payments must be made with a 6 percent add-on; however, the Act does not require the same add-on amount when utilizing WAC-based pricing. To be consistent with the CY 2019 PFS proposed rule, CMS proposed to use a 3 percent add-on instead of a 6 percent add-on for WAC-based drugs in the hospital outpatient setting. For drugs and biologicals acquired under the 340B Program, the 340B Program rate (WAC minus 22.5 percent) would apply.

After consideration of the comments received, CMS finalized its proposal without modification. Starting Jan. 1, 2019, a 3 percent add-on will be used instead of a 6 percent add-on for drugs paid based on WAC.

CMS previously finalized the payment policy for biosimilar biological products based on the payment allowance of the product as determined under the Social Security Act in CY 2016 and CY 2017. For CY 2019, CMS proposed to continue the policy from CY 2018, making all biosimilar biological products eligible for pass-through payment, not just the first biosimilar biological product for a reference product. CMS also proposed to pay non-pass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP.

Upon review of the public comments, CMS finalized its proposal without modification to make all biosimilar biologicals products eligible for pass-through payment, not just the first product for a reference. CMS will also pay non-pass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent rather than that of the reference product's ASP.

As proposed, CMS also finalized to expire pass-through status of 23 commonly-used oncology drugs and biologicals on Dec. 31, 2018. These drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by this date. Table 3, page 14, identifies the drugs and biologicals to be removed from the pass-through list.

For CY 2019, CMS will continue to pay for 45 commonly-used drugs and biologicals, plus an additional 4 drugs and biologicals that were extended pass-through status for an additional 2 years even though they reached the 3-year maximum, at ASP plus 6 percent. The additional 4 drugs and biologicals were required to be extended pass-through by additional legislation. CMS will continue to update pass-through payment rates on a quarterly basis through the its website. Table 4, page 15, lists the drugs and biologicals that will remain on the pass-through list for CY 2019.

340B Drug Discount Program

In the CY 2018 OPPS final rule, CMS finalized the policy to pay for drugs purchased under the 340B Drug Discount Program (not including drugs on pass-through payment status or vaccines) at the rate of ASP minus 22.5 percent—a dramatic reduction to the previous rate of ASP plus 6 percent. CMS stated the goal is to make Medicare payments for separately payable drugs more in alignment with resources expended by hospitals to acquire the drugs while also recognizing the intention of the 340B Program: to allow hospitals to stretch resources and provide access to care for Medicare beneficiaries and other patients.

For CY 2019, CMS proposed to continue the policies as finalized in CY 2018 with a few exceptions. As previously addressed, CMS proposed to pay biosimilar biological products at minus 22.5 percent of the biosimilar's ASP, not the reference drug's ASP. Drugs not purchased under the 340B Program will continue to be paid at ASP plus 6 percent. Hospitals will continue to report drugs purchased through the 340B Drug Discount Program with modifier **JG** on the same claim line items as the drug HCPCS code. Additionally, rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals continue to be excepted from the 340B payment adjustment and will report modifier **TB** for 340B-acquired drugs on claim forms and paid at ASP plus 6 percent.

For CY 2019, CMS finalized the proposal without modification and will continue to apply policies implemented in CY 2018 with the exception of the methodology in calculating payment for 340B-acquired biosimilars.

New for CY 2019, CMS proposed to apply the 340B Drug Payment Policy to non-excepted off-campus PBDs. Due to provisions in the Bipartisan Budget Act of 2015, non-excepted off-campus PBDs as of Nov. 2, 2015 had not billed for services to CMS and were outside of 250 yards from the main building of the hospital. Since these departments are not considered outpatient departments of the hospital, they are currently paid under the PFS. For this reason, CMS did not apply the 340B payment policy to non-excepted off-campus PBDs in CY 2018; however, because hospitals can acquire drugs and biologicals under the 340B Program for use in a non-excepted off-campus PBD, CMS felt this could result in incongruity between payment amounts, depending on where drugs were provided. Accordingly, due to the potential for hospitals to move services from excepted off-campus PBDs to non-excepted off-campus PBDs and to be paid at a higher rate, thereby creating a non-neutral payment structure, CMS proposed changes. CMS proposed to pay under the PFS an amount equal to ASP minus 22.5 percent for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program and furnished and billed by non-excepted off-campus PBDs of a hospital.

CMS received comments from organizations representing oncology practices, pharmaceutical research and manufacturing companies, a large network of community-based oncology practices, and health insurers supporting the proposal. A pharmaceutical company commented, *"the 340B Program has grown beyond its original intent and needs to be refocused to better meet the needs of vulnerable patients."* This commenter indicated there is an incentive to

Table 3. Drugs and Biologicals for Which Pass-Through Payment Status Expires Dec. 31, 2018

CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR	FINAL CY 2019 STATUS INDICATOR	FINAL CY 2019 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE
J7202	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 i.u.	K	9171	10/01/2016
J7207	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 i.u.	K	1844	04/01/2016
J7209	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per i.u.	K	1846	04/01/2016
J9022	Injection, atezolizumab, 10 mg	K	9483	10/01/2016
J9145	Injection, daratumumab, 10 mg	K	9476	07/01/2016
J9176	Injection, elotuzumab, 1 mg	K	9477	07/01/2016
J9205	Injection, irinotecan liposome, 1 mg	K	9474	04/01/2016
J9295	Injection, necitumumab, 1 mg	K	9475	04/01/2016
J9325	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	K	9472	04/01/2016
J9352	Injection, trabectedin, 0.1 mg	K	9480	07/01/2016
Q5101	Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram	k	1822	07/01/2015

shift administration of drugs from excepted to non-excepted off-campus PBDs to secure higher payment.

Some commenters, including organizations representing community oncology practices, indicated, *"the opportunity for 340B-participating hospitals to get substantial revenue from cancer drugs has created financial incentives for hospitals to expand oncology services, notably through the acquisition of independent community oncology practices,"* which results in *"further fueling the program's staggering growth."* Commenters also cited a report that states, *"over the last decade, 658 community oncology practices have been acquired by hospitals, and 3 out of 4 of these acquisitions were by hospitals already eligible for the 340B Program."* The commenters believe that growth in Part B drug spending has been driven by higher payments in the hospital outpatient setting.

Upon review of comments received related to this proposal, CMS finalized it without modification, making payment for separately payable 340B-acquired drugs furnished by non-excepted off-campus PBDs of a hospital under the PFS, setting the payment rate for those drugs at ASP minus 22.5 percent. In addition, starting Jan. 1, 2019, non-excepted off-campus PBDs of a hospital paid under PFS will be required to report modifier **JG** on the claim line identifying drugs purchased under the 340B Program.

Brachytherapy Sources

CMS will continue to use costs derived from CY 2017 claims data to set the CY 2019 payment rates and base the payment rates for brachytherapy sources on the geometric mean unit costs for each source. Brachytherapy sources, unless otherwise noted, are assigned status indicator "**U**." Codes with status indicator "**U**" are not packaged into C-APCs; the sources are paid separately in addition to the brachytherapy insertion code in the hospital setting.

One commenter expressed concern over the significantly fluctuating rates for low-volume brachytherapy sources over the years. A request was made for CMS to use the general OPPS methodology of cost-based claims data to set the relative payment rates. CMS responded that per the CY 2012 final rule period, the payment for brachytherapy sources for OPPS relies on the concept of averaging; this may result in a payment that is more or less than the actual estimated cost of providing the service. However, CMS believes this process is adequate for setting

Table 4. Drugs and Biologicals with Pass-Through Payment Status in CY 2019

CY 2018 HCPCS CODE	CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR	CY 2019 STATUS INDICATOR	CY 2019 APC	PASS THROUGH PAYMENT EFFECTIVE DATE
C9016	J3316	Injection, triptorelin extended release, 3.75 mg	G	9016	01/01/2018
C9024	J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302	01/01/2018
C9028	J9229	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018
C9030	J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018
C9033	J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018
C9463	J0185	Injection, aprepitant, 1mg	G	9463	04/01/2018
C9464	J2797	Injection, rolapitant, 0.5 mg	G	9464	04/01/2018
C9467	J9311	Injection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018
C9468	J7203	Injection, factor ix (antihemophilic factor, recombinant), glycopegylated, Rebinyn, 1 i.u.	G	9468	04/01/2018
C9492	J9173	Injection, durvalumab, 10 mg	G	9492	10/01/2017
J1627	J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017
J2350	J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017
J7179	J7179	Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rco	G	9059	01/01/2017
J7210	J7210	Injection, factor viii, (antihemophilic factor, recombinant), (afstyla), 1 i.u.	G	9043	01/01/2017
J9023	J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017
J9034	J9034	Injection, bendamustine hcl (Bendeka), 1 mg	G	1861	01/01/2017
J9203	J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018
J9285	J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017
N/A	Q2042*	Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	04/01/2018
Q2041	Q2041	Axicabtagene Ciloleucel, up to 200 million autologous anti-CD19 CAR T cells, including leukapheresis and dose preparation procedures, per infusion	G	9035	04/01/2018
N/A	Q2042*	Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	04/01/2018
Q9993	J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, Microsphere formulation, 1 mg	G	9469	04/01/2018
Q5106	Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-ESRD use), 1000 units	G	9097	10/01/2018
Q9995	J7170	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018
N/A	C9038	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019

*HCPCS code Q2040 (Tisagenlecleucel, up to 250 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion) will be deleted on December 31, 2018 and will be replaced by Q2042 (Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose) on January 1, 2019.

Table 5. CY 2015-2018 OPPS Payment for Brachytherapy Sources

CY 2019 APC	SHORT DESCRIPTOR	CY 2015 OPPS PAYMENT RATE	CY 2016 OPPS PAYMENT RATE	CY 2017 OPPS PAYMENT RATE	CY 2018 OPPS PAYMENT RATE
2616	Brachytx, non-str, Ytrrium-90	$15,582.68	$16,021.70	$16,507.73	$16,717.59
2632	Iodine I-35 sodium iodide	$13.25	$7.14	$29.93	$26.65
2634	Brachytx, non-str, HA, I25	$85.81	$85.18	$120.52	$117.66
2635	Brachytx, non-str, HA, P103	$25.81	$35.24	$25.70	$25.94
2636	Brachy linear, non-str P103	$19.44	$14.24	$18.65	$27.08
2638	Brachytx, stranded, I-25	$42.42	$38.09	$37.97	$34.73
2639	Brachytx, non-stranded, I-25	$37.05	$36.64	$35.70	$34.66
2640	Brachytx, stranded, P-103	$65.50	$68.78	$73.22	$78.72
2641	Brachytx, non-stranded, P-103	$67.93	$66.23	$65.45	$64.27
2642	Brachytx, stranded, C131	$105.39	$86.59	$87.61	$87.89
2643	Brachytx, non-stranded, C-131	$54.71	$52.18	$59.19	$87.40
2645	Brachytx, non-str, Gold198	$37.31	$45.54	$135.30	$122.61
2646	Brachytx, non-str, HDRIr-192	$272.38	$294.04	$281.58	$294.59
2647	Brachytx, NS, NonHDRIr-192	$53.73	$93.11	$33.83	$19.16
2648	Brachytx planar, p-103	N/A	N/A	$4.69	$4.69
2698	Brachytx, stranded, NOS	$42.42	$38.09	$37.97	$34.73
2699	Brachytx, non-stranded, NOS	$19.44	$14.24	$18.65	$19.16

Note: N/A reflects brachytherapy APCs that did not have a payment rate for a payment year because the brachytherapy source did not have an established C-code.

the rates, even though this may result in variations to rates year-to-year for low-volume brachytherapy sources when compared to sources that are reported with a higher number of claims.

Additionally, CMS provided data that showed that reimbursement for sources has been relatively consistent from CY 2015 to CY 2018. CMS also believes this provides incentive to hospitals to provide brachytherapy services with greater efficiency. Table 5 above reflects the OPPS payment rates over the last four years as set by CMS and provided within the final ruling.

CMS assigned code **C2645** (Brachytherapy planar source, palladium-103, per square millimeter) status indicate "**U**" (Brachytherapy Sources, paid under OPPS; separate APC payment) and used external data like invoice price to establish the APC payment for the code in CY 2019. CMS also finalized assigning status indicator "**E2**" (Items and Services for Which Pricing Information and Claims Data Are Not Available) to source code **C2644** (Brachytherapy cesium-131 chloride) because this code was not reported on CY 2017 claims; therefore, CMS was not able to set a rate per the standard methodology.

Device Pass-Through Application for the SpaceOAR System

CMS received seven applications for specific devices to be granted pass-through payment status for CY 2019. One of the applications submitted was for a new device category for transitional pass-through payment status by Augmenix, Inc., for the SpaceOAR® System. The FDA granted a De Novo request for the SpaceOAR System and identified it as a class II device. CMS sought comments on whether the SpaceOAR System met the newness criterion.

For a new device to be considered for pass-through status, it must meet several criteria. One criterion is that there cannot already be a category to which the device could be included, and it cannot have been paid as an outpatient service as of Dec. 31, 1996. After reviewing comments, CMS did not identify an existing pass-through category and indicated the system did meet this eligibility criterion. Another criterion is that CMS must evaluate if the cost of the device; three cost significance criteria must be met. CMS believed all cost criteria were met. CMS could not find that the device met this criterion: the device substantially improves the diagnosis or treatment of an illness or injury or improves function to a malformed body part when compared to other options or devices that are similar.

Further, CMS indicated concerns within the rules about the phase 3 trial, the inclusion of only low- to moderate-risk prostate cancer patients, and failure to use a clinical outcome as the endpoint. The agency indicated it is unclear that the SpaceOAR System is superior to other existing biodegradable biomaterials used for spacing of the prostate and rectum for radiotherapy treatment. CMS stated it is also unclear if there is further reduction in radiation dose effects with the added use of the SpaceOAR System, translating to a substantial clinical improvement maintained over time when compared to the patients who did not receive the SpaceOAR System as part of their treatment course.

Additional review of treatment plans by an independent lab did not quell the agency's questions and concerns that the planning supported low toxicity in the group that received the SpaceOAR System relative to the control group of standard practices. Instead CMS stated the independent review *"further calls into question the direct role of the SpaceOAR System in reducing toxicity versus more precise planning protocols and the importance of adhering to guidance protocols."*

After review of all the criteria and public comments, CMS did not believe the SpaceOAR System qualified for pass-through status because it did not meet the substantial clinical improvement criterion, even though there may be clinical benefit for certain patients. Therefore, the application for pass-through status in CY 2019 was not approved.

Payment for Therapeutic Radiopharmaceuticals

New drugs, biologicals, and radiopharmaceuticals are granted pass-through status by Medicare as a means of establishing a transitional payment until enough data is acquired to determine if the new agent is to be paid separately or packaged into an APC. For CY 2019, CMS proposed to continue providing payment for diagnostic and therapeutic radiopharmaceuticals granted pass-through payment status based on ASP methodology, as CMS considers these to be drugs under the OPPS. The ASP methodology is the ASP plus 6 percent; however, if no ASP data is available, CMS proposed to provide pass-through payment at WAC plus 3 percent. If this data is not available, then payment will be 95 percent of average wholesale price (AWP).

Commenters requested that CMS explore ways to compensate hospitals for the high expenses of overhead and handling costs associated with radiopharmaceuticals. CMS stated that the payment rate of ASP plus 6 percent is appropriate for radiopharmaceuticals with pass-through payment and that this amount appropriately accounts for the acquisition cost and associated handling and compounding costs.

CMS finalized to pay for all pass-through therapeutic radiopharmaceuticals at ASP plus 6 percent. CMS will also rely on CY 2017 mean unit cost data derived from hospital claims when ASP data is not available for therapeutic radiopharmaceuticals.

Radiopharmaceutical Lutetium 177 (Lu-177)

CMS introduced a new Category III code (**C9031**) effective July 1, 2018 for Lutetium 177, but as part of the CY 2019 ruling, a new code was assigned: **A9513** (Lutetium Lu 177, dotatate, therapeutic, 1 mCi). Radiopharmaceutical Lu-177 is used for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors, including foregut, midgut, and hindgut neuroendocrine tumors in adults. The recommended treatment course is to give 200 mCi by IV infusion over 30 minutes every 8 weeks for a total of 4 doses.

Radiopharmaceutical Lu-177 was granted pass-through status on July 1, 2018, meaning for no longer than 3 years from that date, Lu-177 will be reimbursed at ASP plus 6 percent as long as there is ASP data. If there is no ASP data, then reimbursement is set at WAC plus 3 percent; if no WAC data is available, then reimbursement is set at 95 percent of the most recent AWP. OI

2019 Physician and Freestanding Facility Regulatory Update

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The Medicare Physician Fee Schedule (PFS) is one of the Medicare payment systems that applies to physicians (even those employed by hospitals) and non-facility-based settings including physician offices, freestanding facilities, and non-excepted off-campus provider-based departments. Reimbursement under the PFS is based on relative value units (RVUs), which represent the work, practice expense (direct and indirect), and malpractice values assigned to each code. The RVUs are then factored with geographic practice cost indices—the geographic locale as identified by Medicare—to determine the exact payments based on location. Finally, and still a factor for calendar year (CY) 2019, the conversion factor (CF) is set by the Centers for Medicare & Medicaid Services (CMS) each year; this value, when multiplied into the equation of RVUs for a given code, will convert the value to a recognized dollar amount.

CY 2019 is the final year in which the conversion factor will be adjusted by CMS to contribute to the overall reimbursement under the PFS. Per the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), 2019 is the final year the CF will be adjusted to account for Medicare payments. Beginning in CY 2020, the CF will freeze per the value set in CY 2019, and reimbursement for CYs 2020–2025 will be based on quality reporting under the Quality Payment Program (QPP).

Each year CMS must operate within a budget of $20 million above or below the estimated reimbursement impacts. When CMS estimates that impacts from reimbursements will result in an over-budget situation, a budget neutrality factor is applied. Typically, these over-budget situations result from CMS adjusting reimbursement for mis-valued codes, resulting in increased payments. Per MACRA, the CF was to increase by 0.5 percent from CY 2018, but the Bipartisan Budget Act of 2018 changed this to 0.25 percent. To calculate the CF for CY 2019, CMS calculated using the CY 2018 CF of $35.9996, applying the statutory update of 0.25 percent while also applying a budget neutrality adjustment of -0.14 percent. The finalized CF for CY 2019 is calculated at $36.0391, a slight increase from CY 2018.

Even with the slight overall increase by CMS, both hematology/oncology and radiation oncology will experience slight decreases for CY 2019. Both are estimated to see a combined impact of -1 percent overall. These decreases are related to the RVUs finalized for many of the codes associated with each specialty (see Table 6, page 19).

RVU Updates

Malpractice RVUs attempt to quantify the risk associated with a given specialty in alignment with the premiums paid by that specialty in relation to the services performed and reported through claims data. For CY 2019, CMS requested feedback related to the next update to malpractice RVUs as required by CY 2020—specifically, how improvements in the way specialties in state-level raw rate filings data are cross-walked to the CMS specialty codes, which are used to develop specialty-level risk factors and medical practitioner RVUs. CMS received comments in response to the request and indicated the suggestions would be considered for future rulemaking—specifically the CY 2020 required update.

Practice expense (PE) accounts for the resources provided by the physician and practitioner, including office rent and personnel wages, but excluding expenses for malpractice. PEs are further classified into direct and indirect. Direct PE categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expenses, and all other expenses.

For CY 2019, CMS proposed changes to address inconsistencies resulting from alerts from the Relative Value Scale Update Committee (RUC). Per the RUC, 165 Current Procedural Terminology (CPT) codes are billed with office visits more than 50 percent of the time in the non-facility setting; these codes have more minimum multi-specialty visit supply packs (**SA048**) than post-operative visits included in the global period for the respective code. CMS indicated that either the inclusion of the E/M services was not accounted for in the code's global period, or the minimum multi-specialty visit supply pack approved for these codes was not assessed for overlap with the E/M supply pack (**SA047**). The RUC felt the overlapping supply packs were duplicative and requested adjustment by CMS.

Upon review, CMS proposed to refine the quantity of the minimum multi-specialty

Table 6. CY 2019 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) SPECIALTY	(B) ALLOWED CHARGES (MILLIONS)	(C) IMPACT OF WORK RVU CHANGES	(D) IMPACT OF PE RVU CHANGES	(E) IMPACT OF MP RVU CHANGES	(F) COMBINED IMPACT*
Hematology/Oncology	$1,741	0%	-1%	0%	-1%
Radiation Oncology and Radiation Therapy Centers	$1,765	0%	0%	0%	-1%

*Column F may not equal the sum of columns C, D, and E due to rounding.

packs in order to align the number of visit packs with the number of post-operative visits included within the codes. Included in the 165 codes outlined is **CPT 38220** for diagnostic bone marrow aspiration. CMS has finalized the proposal to align the number of minimum multi-specialty visit packs with the number of post-operative office visits proposed—with the exception of **CPT 43200**, which is reported for esophagostomy procedures.

CMS contracted to a third party to review pricing and values for equipment, supplies, and labor of services provided as part of the direct PE values for codes in CY 2019. This new pricing methodology and the values finalized for CY 2019 will impact radiation oncology. One example is the pricing for the stereotactic radiosurgery (SRS) system stereotactic body radiotherapy (SBRT), reflected under **ER083** (Supply/Equipment Code). CMS indicated that the value reflected in the proposed ruling was improperly priced because a specific component was omitted—the value of the linear accelerator. CMS indicated the value in the CY 2019 PFS proposed rule only included the value for equipment purchased to retrofit a system to perform SBRT, not the pricing for the linear accelerator itself. The SBRT pricing was updated to include the linear accelerator in the final rule pricing, but there is still a decrease in value for CY 2019. Additionally, the treatment planning system equipment value—HDR afterloader treatment equipment—also saw a decrease in value, while the brachytherapy treatment vault saw an increase finalized for CY 2019.

Table 7, page 20, lists the radiation oncology-specific supply and equipment codes with price changes based on feedback from commenters resulting in additional research into pricing for CY 2019.

CMS received comments regarding the direct PE RVU changes proposed for the Healthcare Common Procedure Coding System (HCPCS) codes **G6001-G6015** reported for IGRT (image-guided radiation therapy) and radiation treatment delivery in the office setting, which were felt to be inappropriate. As outlined in the Patient Access and Medicare Protection Act (PAMPA) and the Bipartisan Budget Act of 2018, the direct PE values shall be the same for CYs 2017, 2018, and 2019 as established in CY 2016. The proposals by CMS for CY 2019 reflected changes to the direct PE RVUs.

CMS disagreed, indicating that the value changes were in response to the market-based study of commercial pricing for the supply and equipment inputs, which are not protected by the statutory provisions in the congressional legislation. CMS also indicated that the overall effect of incorporating new pricing in calculating payment rates results in higher overall RVUs on the whole for these codes than relying on previous years' values. These codes reflect an increase in RVUs and therefore an increase in reimbursement:

- **G6001**: IGRT (a global increase of $29.42)
- **G6002-26**: professional component for stereoscopic x-ray guidance IGRT (an increase of $0.45)
- **G6015**: IMRT MLC-based treatment (an increase of $5.10)
- **G6016**: IMRT compensator-based treatment (an increase of $5.10).

The remaining G-codes reflect decreases in the direct PE RVUs and an overall decrease in reimbursement.

Superficial Radiation Therapy (SRT)

For CY 2019, CMS posted a request for comment regarding superficial radiation therapy (SRT) treatment code **77401**. In CY 2015, significant changes were made to code **77401** (Radiation treatment delivery, superficial and/or ortho voltage, per day). As a result, many ancillary services, such as clinical treatment plan, devices, planning, physics, and management, are excluded from being billed with the treatment delivery code.

CMS sought comments on the possibility of creating multiple G-codes specific to the services associated with SRT. The codes would be used separately to report services such as SRT planning, initial patient simulation, treatment device design, and construction associated with SRT, SRT management, and medical physics consultation. CMS wanted to know the thoughts of stakeholders on creating G-codes similar to the structure of other radiation treatment delivery services, such as HCPCS code **G6003** (Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: up to 5 mev). CMS also considered contractor pricing for the new G-codes, since this would bypass the usual national assignment of

Table 7. Radiation Oncology-Specific Supply and Equipment Prices Updated in Response to Comments

SUPPLY AND/OR EQUIPMENT CODE	DESCRIPTION	CY 2018 PRICE	PROPOSED CY 2019 PRICE	FINAL CY 2019 PRICE
ED033	Treatment planning system, IMRT (Corvus Peregrine 3D Monte Carlo)	$350,545	$157,394	$197,247
ER003	HDR Afterload System, Nucletron - Oldelft	$375,000	$111,426	$132,575
ER083	SRS system, SBRT, six systems, average	$4,000,000	$931,965	$2,973,722
ES052	Brachytherapy treatment vault	$175,000	$134,998	$193,114

rates utilizing input from the CPT Editorial Panel and the RUC. Since the codes would be created by CMS and not through the normal process for coding changes, this option was seen as an interim approach to a coding gap until it could be addressed by the CPT Editorial Panel and the RUC.

Many commenters stated that there should be recognition of new technology such as image-guided superficial radiation therapy (IGSRT) as it is more advanced than standard SRT technology. Other commenters suggested G-codes to represent the work of various components of SRT services, but that IGSRT specifically should not be billed with superficial treatments. Other commenters requested a professional component to code 77401 to account for physician work.

CMS indicated it would take into consideration all of the submitted comments, but the agency continues to believe and reiterates that input from the American Medical Association (AMA) and RUC process is the ideal way to develop coding specificity and evaluation. CMS is not making any changes but continues to direct stakeholders and providers to the fact that appropriate E/M codes may be reported as supported and appropriate to the course of treatment; this currently accounts for the professional work associated with SRT.

Potential Model for Radiation Therapy

As discussed previously, PAMPA, which was enacted on December 28, 2015, outlined that radiation therapy treatment delivery and imaging services require the Secretary of Health and Human Services to develop an episodic alternative payment model (APM) for payment under the Medicare program. The episodic APM would outline reimbursement for the G-codes, which are in effect under the PFS through Dec. 31, 2019.

A radiation therapy payment model is needed by the agency effective Jan. 1, 2020. CMS delivered a report to Congress in November 2017 discussing the status of radiation therapy services and payments. The report also reviewed model design considerations for a potential APM for radiation therapy services. CMS believes that radiation oncology is a promising area of healthcare for bundled payments.

CMS did not finalize a payment model for CY 2019 or outline specifics for a payment model for CY 2020. Instead, the Center for Medicare & Medicaid Innovation (CMMI) will continue to use public information regarding commercial initiatives and stakeholder feedback to assist in payment model development, implementation, refinement, and design.

On Nov. 8, 2018, CMS announced that a mandatory payment model specific to radiation oncology would soon be unveiled, but the agency did not give a specific timeline for release. This is a change from legislation, which indicated a voluntary payment model.

Evaluation and Management (E/M) Guidelines

According to CMS, E/M visits account for approximately 40 percent of the allowed charges for PFS services, and 20 percent are office or outpatient E/M visits. This accounts for a high expenditure by CMS for services to beneficiaries. In CY 2018 rulemaking, CMS requested feedback and comments on how to best update and change E/M guidelines.

Stakeholders have long commented on the need for change due to the outdated and administratively burdensome guidelines. CMS agreed, and in the CY 2018 proposed rules indicated that the history and physical exam were the most outdated of the guidelines given current clinical practices, technology advances, and the use of EHRs in the documentation process. CMS requested feedback from stakeholders on how best to approach the changes and what changes to make, admitting this would be a multi-year process.

In the CY 2019 proposed rules, CMS outlined sweeping changes to new and established patient E/M guidelines. After considerable feedback, CMS indicated thousands of comments were received, and CMS is delaying many of the more significant E/M changes until CY 2021. CMS did outline several changes for CY 2019, which are summarized as follows along with the finalized E/M changes in CY 2021.

Due to complexity and the need for providers and stakeholders to be prepared for the upcoming changes, it is important to be aware and prepare to ensure a smooth transition. In a call summarizing the three main PFS final rule changes, CMS indicated it is working on an FAQ related to E/M services based on comments by stakeholders. CMS expects this FAQ will be available before the end of CY 2018.

E/M Changes for CY 2019

To ease documentation burden for practitioners, CMS finalized a proposal effective for CY 2019—for new and established patient E/M outpatient visits, practitioners do not need to re-enter information into the medical record on the patient's chief complaint and history that has already been entered by ancillary staff or the beneficiary. The practitioner can indicate in the medical record that the information was reviewed and verified. This is optional for practitioners as a means of reducing any documentation redundancy. If a practitioner chooses to continue the documentation of the chief complaint and history, it is at the practitioner's discretion.

Additionally, key components of history and exam for established patients and only those corresponding items that have or have not changed since the last visit would be documented. This would replace the need to document all the components as outlined in the current guidelines. Practitioners would still be expected to conduct medically necessary inquiries and exams of the patient in order to support the visit and gather the necessary information; however, if documentation to support the repetitive components has been reviewed elsewhere, the components would not need to be repeated. Practitioners would still need to review the documentation in the medical record, update as necessary, and document that the practitioner reviewed the information.

To eliminate duplicative efforts and notations in the medical record, CMS is simplifying teaching physician E/M service documentation requirements. CMS is adjusting language to indicate that medical records must document the teaching physician was present at the time the service is furnished. E/M service may be documented with a note in the medical record made by a physician, resident, or nurse. CMS also eliminated the requirement that the teaching physician document the extent of his or her participation in the review and direction of services. A new paragraph would be added to the guidelines to require the teaching physician to document the extent of the participation and direction of services provided to the beneficiary. The extent of the participation can be demonstrated by notes in the medical record by a physician, resident, or nurse.

For CYs 2019 and 2020, CMS will continue with the current coding and payment structure for E/M outpatient office visits. Practitioners are to continue using the 1995 or 1997 E/M guidelines—with the exception of the previously mentioned redundant data recording.

Due to changes in technology, patients and physicians alike have changed expectations about how information—both in quality and quantity—is exchanged. One of the services increasing in volume is a brief check-in service provided to determine whether an office visit or other service is needed. Currently, when this kind of service is provided prior to an office visit, it is bundled into the payment for the office visit. However, there are circumstances where the check-in does not result in an actual office visit to which the service can be bundled. When brief check-ins are used correctly, they can prevent unnecessary office visits, resulting in reduced costs and waste.

Effective for CY 2019, CMS will begin separately reimbursing for a newly-defined physician service using communication technology. This service would be billable when a physician or other healthcare provider has a brief face-to-face check-in with a patient via communication technology to assess whether the patient's condition requires an office visit. Code **G2012** (Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified healthcare professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion) will begin Jan. 1, 2019.

As with other services, medical necessity is needed to support the work and billed check-in. CMS will also allow audio-only real-time telephone interactions in addition to synchronous, two-way audio interactions that are enhanced with video or other kinds of data transmission. Phone calls that only involve clinical staff are not billable with code **G2012**, as this code requires direct interaction between the patient and billing practitioner.

Practitioners must also obtain verbal consent from the patient to indicate that they approve the physician to bill for these services and note this in the medical record. If the brief check-in originates from a related E/M service provided within the previous 7 days by the same physician or other practitioner, the service is bundled into the E/M services. In the event that a brief check-in leads to an E/M service with the same physician or practitioner, it would be considered part of the pre- or post-visit time and is not separately billable.

The brief check-in service will only be available to established patients due to the need for familiarity with the patient. CMS is not requiring any service-specific documentation requirements for this service, only that the services must be medically necessary and reasonable in order to be reimbursed.

E/M Changes for CY 2021

Based on comments and feedback, CMS has finalized choices to E/M documentation for CY 2021:

- Continue to utilize the framework of the 1995 or 1997 guidelines
- Utilize a framework based around medical decision-making (MDM) as the main component
- Utilize a time-based framework.

These changes would allow practitioners to better select the type of documentation based on the type of visits performed. For some practitioners, a time-based framework would better support the type of work and visits provided to patients. Other practitioners who are comfortable with the 1995

or 1997 guidelines would be able to continue this approach to documenting the E/M visits for outpatients.

CMS believes that adjusting documentation practices will lessen the burden to practitioners by no longer documenting components irrelevant to the visit or those that are burdensome to include. The changes would also mean that CMS would not have to create another set of standardized guidelines as happened in 1995 and 1997. Regardless of which method a practitioner selects to document the E/M visit, CMS would apply the same new reimbursement values to outpatient services.

Current CPT codes (**99201–99215**) will still be reported on the claim form by the practitioner to reflect the level of visit the practitioner believes was provided to the beneficiary—regardless of the type of documentation framework selected. These choices will allow for consistency in code reporting and consistency when billing to non-Medicare payers, as it is unclear how commercial payers will react to these changes or if they will implement the newly-extended timeline for activation.

CMS will use the code reported to apply the appropriate reimbursement from one of three levels. In CY 2021, CMS will reimburse the Level 1 codes of **99201** and **99211** at a separately designated rate. Levels 2-4 (**99202–99204** and **99212–99214**) will be reimbursed the same amount regardless of level supported, and Level 5 codes (**99201** and **99215**) will be reimbursed at a separate level. The reimbursement of Level 5 outside of Levels 2-4 is a change from the CY 2019 proposed ruling. CMS indicated that there was a need to recognize the work and resources provided to patients at the highest-level visit separate from other levels.

CMS will be implementing a minimum level of documentation for Levels 2-4 if the practitioner selects to continue using the already established guidelines of 1995 or 1997 requirements or an MDM framework; in other words, at minimum at least Level 2 documentation must be met. If time is the selected framework, CMS will require the billing practitioner to document the medical necessity of the visit and that the practitioner personally spent the current typical time associated with the individual codes. CMS will also be engaging the public to further assist in refining policies.

In CY 2021, Level 5 visits for payment purposes will continue with the current framework for a Level 5 visit under the 1995 or 1997 guidelines or the current definition of Level 5 MDM. Time will also be available as a means for documenting a Level 5 visit. The documentation of a Level 5 visit based on time will account for the medical necessity for the visit and note that the practitioner personally spent at least the typical time associated with Level 5 CPT coding reported for the new or established patient visit. There will be no intra-service time associated with Level 5 visit codes. CMS is finalizing the typical time associated with CPT codes **99205** or **99215** when counseling and/or coordination of care accounts for more than 50 percent of the face-to-face physician/patient encounter.

Due to the significant changes and the impact that some specialties may experience, CMS is adding additional measures to better capture resource costs and offset their impact. The first add-on code accounts for complexity, one for primary care and another for other specialties; neither is required nor restricted by physician specialty. The codes are specifically intended to describe services that some clinicians practicing in some specialties are more likely to perform than others. The G-code for primary care will not be summarized here as they are intended for use in specialties such as family medicine, internal medicine, pediatrics, and geriatrics.

The code CMS finalized for specialized complexity is expected to be used mostly by practitioners in the code descriptor but is not limited to those specialties. Add-on code **GCG0X** (Visit complexity inherent to evaluation and management associated with nonprocedural specialty care including endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, interventional pain management, cardiology, nephrology, infectious disease, psychiatry, and pulmonology) (Add-on code, list separately in addition to level 2 through 4 office/outpatient evaluation and management visit, new or established) is to be used beginning CY 2021.

CMS provided an example in which an oncologist sees a patient to discuss their cancer diagnosis and the treatment plan, including surgical and chemotherapy options. Since the E/M focuses on oncologic care, the physician would report the specialty add-on code in addition to the E/M visit code. The physician's specialty should be reflected on the claim form, and the medical record would support the diagnosis and clinician's assessment and plan for the visit. According to CMS, this information would be sufficient documentation; the visit met the description of the non-procedural specialty care complexity, and no other additional documentation would be needed.

Currently there are CPT codes (**99354** and **99355**) to account for prolonged services. The minimum time to meet the threshold in order to bill **99354** is one hour. Many stakeholders commented it is difficult to meet this threshold and that it is an impediment to many specialties in reporting the codes. Given the changes to Levels 2-4, CMS created a new HCPCS code for CY 2021 to represent prolonged E/Ms:

- **GPRO1** (Prolonged evaluation and management or psychotherapy service[s] beyond the typical service time of the primary procedure in the office or other outpatient setting requiring direct patient contact beyond the usual service; 30 minutes) (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service).

This code may be billable by oncologists given the nature of some E/M visits, but only with codes in Levels 2-4, it is not allowed with Level 5 E/M visits.

CMS did not finalize the proposal to reduce payments when multiple services are performed on the same date of service. CMS established separate podiatric E/M visit codes or standardized allocation of PE RVUs for codes that describe these services.

Payment Rates for Non-Excepted Off-Campus Provider-Based Departments

The Bipartisan Budget Act of 2015 established new guidelines to address the difference in reimbursement payments for the exact same procedure between varying places of service—primarily hospitals, ambulatory surgical centers (ASCs), and physician offices. The Act set Nov. 2, 2015 for the establishment of any new provider-based departments (PBDs) and the distance (250 yards) the new department could be from the main buildings of the hospital and still receive payment rates established under the Hospital Outpatient Prospective Payment System (HOPPS). Due to what was considered the alarming rate of hospitals acquiring physician practices and the tendency for hospital PBDs to be paid more than a physician office setting, CMS made changes.

Excepted off-campus PBDs are settings that were established and billing for services prior to Nov. 2, 2015, and which are within the previously set distance of 35 miles. Excepted off-campus PBDs are paid fully at the HOPPS established rate for each service (excepting clinic visit code **G0463**) and considered "grandfathered" into HOPPS payments even if the new distance threshold is not met. Non-excepted off-campus PBDs are settings that were established on or after Nov. 2, 2015, and which are outside the newly set distance of 250 yards from the main buildings of the hospital. Non-excepted PBDs are paid under the PFS but are still considered a facility setting for the purposes of following guidelines about supervision, packaging, and more.

For CY 2019, CMS will continue with the PFS Relativity Adjuster (reimbursement) of 40 percent of the HOPPS rate for non-excepted off-campus PBDs. This is the same rate that was applied in CY 2018.

Additionally, non-excepted off-campus PBDs will continue to bill for services on the UB04 claim form and apply the modifier **PN** to billed services. Non-excepted off-campus PBDs are still subject to hospital supervision rules and other practice guidelines. Radiation oncology departments will continue to bill for daily treatments and image guidance in the non-excepted off-campus PBD setting using the G-codes used by freestanding facilities, with modifier **PN** applied to each billing through the end of CY 2019 as mandated by law. The G-codes for daily treatment (**G6003-G6015**) and image guidance (**G6001**, **G6002**, **G6017**, and **77014**) are not paid at 40 percent of the HOPPS rate; instead they are paid at the technical non-facility rate under the PFS. Hospital on-campus departments and excepted off-campus PBDs continue to bill the CPT codes for daily treatment (**77402**, **77407**, **77412**, **77385**, and **77386**) and image guidance code **77387** where appropriate.

Changes to Part B Drugs

Per the requirements in the Social Security Act, many Medicare payments for drugs and biologicals include an add-on payment set at 6 percent of the volume-weighted average sales price (ASP) or wholesale acquisition costs (WAC). While the Act does not indicate what is included in the add-on payment, CMS believes it includes services related to drug acquisition that are not separately paid, such as handling, storage, and drug distribution mark-ups. Concerns were raised related to this practice within the MedPAC June 2015 Report to Congress, since more revenue can be generated for expensive drugs and may create an incentive. This report also stated that administrative complexity and costs are not proportional to the price of the drug.

The Act specifies the use of the add-on percentage for ASP; however, this same percent has also been applied to the WAC in specific situations. These situations include single source drugs where the payment is made using the lesser of the ASP or WAC; drugs and biologicals where ASP during the first quarter of sales is unavailable, and drugs where pricing determined by Medicare Administrative Contractors (MACs) does not appear on the ASP pricing files and new drugs.

CMS addressed that the ASP includes various discounts such as volume discounts, prompt pay discounts, and rebates; however, the WAC is defined as the manufacturer's list price to wholesalers and direct purchasers and does not include these discounts. As a result, the WAC typically exceeds the ASP and results in higher dollar payments.

For CY 2019, CMS proposed to utilize a 3 percent add-on in place of the current 6 percent add-on for WAC–based payments for Part B drugs made under the Act. CMS indicated that the proposal is consistent with the MedPAC's recommendations from its June 2017 Report to Congress. CMS noted that the number of new drugs priced using the WAC is limited; however, the average difference between WAC- and ASP-based payments for three recently approved drugs was 9 percent, including one biosimilar biological product. Excluding the biosimilar, the difference was 3.5 percent. The findings of the CMS review were in agreement with MedPAC findings. CMS anticipates this reduction will result in a savings to the Medicare program by bringing payment amounts for new drugs closer to acquisition costs.

While CMS provides examples of differences between the WAC- and ASP-based payment limits, the agency indicated it is not able to estimate the true savings over time, as it is not known how many new drugs and biologicals will require partial-quarter pricing or how many of the Part B claims will be paid. CMS also mentioned that contractor-priced drugs and drugs and biologicals billed using miscellaneous or not otherwise classified codes, such as **J3490** and **J3590**, cannot be calculated. Of the three drugs assessed by Medicare, Part B payments for individual doses ranged from $3,000 to $10,000; proposed changes would have resulted in $100 to $300 savings per dose.

CMS explained that this change would likely decrease co-payments for individual beneficiaries prescribed new drugs. CMS states, *"A 3 percentage point reduction in the total payment allowance will reduce a patient's 20 percent Medicare Part B copay-*

ment—for a drug that costs many thousands of dollars per dose, this can result in significant savings to an individual. The proposed approach would help Medicare beneficiaries afford to pay for new drugs by reducing out of pocket expenses and would help counteract the effects of increasing launch prices for newly approved drugs and biologicals."

In response to commenters, CMS indicated the markup defined by the Act does not specify what the add-on represents; however, CMS is interested in striking a balance between financial concerns related to costs and concerns about financial incentives that can lead to excessive drug use. CMS indicated that if the add-on is intended to account for increased handling, storage, and other overhead costs, these are not proportional to the current price of the drug. The add-on is proportional only to the price of the drug, and the difference between the acquisition cost and payment can be hundreds to thousands of dollars. As a result, CMS is concerned that this will lead to financial incentive for use of new Part B drugs. CMS also expressed concern with the costs of new drugs and the assumption that these drugs have higher overhead costs than those under ASP-based payment.

After considering the comments received, CMS finalized its proposal to reduce the add-on percentage for WAC-based payments for new drugs effective Jan. 1, 2019. CMS also noted this policy is consistent with the President's budget and the previous MedPAC's analysis and recommendations in the June 2017 Report to Congress. CMS also clarified this policy does not apply to single-source drugs or biologicals paid under the Act where payment is made using the lesser of ASP or WAC. The Act requires a 6 percent add-on regardless of payment under the WAC or ASP amount.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The appropriate use criteria (AUC) program was mandated as part of PAMA and MACRA and outlined that CMS must establish a program to promote appropriate use criteria for advanced diagnostic services. This program covers the ordering of advanced diagnostic imaging services, e.g., CT, MRI, and nuclear medicine, including PET).

In the CY 2019 final rule, CMS reaffirmed the mandatory Jan. 1, 2020 implementation date. The first year will be an "educational and operations testing period" with an official go-live date of Jan. 1, 2021. To meet this time frame, CMS will develop a series of G-codes and modifiers during the 2020 rulemaking cycle that must be applied to the claim. The agency will continue to pay claims whether or not the information or the agency on the claim is completely accurate.

CMS did indicate it will continue to consider future opportunities to use a unique claim identifier (UCI) number, but did not commit to a timeline or transition towards UCI. The advantage of a UCI is that this information would come straight from the clinical decision support mechanism (CDSM) instead of manual intervention to assign G-codes and modifiers. Additionally, CMS is not indicating how long it will use the G-code with modifier approach to claims-based reporting.

During the initial testing period, ordering professionals will consult AUC through a qualified CDSM, and furnishing providers will report the corresponding G-codes and modifiers information on their claims (facility and physician).

CMS finalized its proposal to add independent diagnostic testing facilities (IDTFs) to the list of applicable settings. The services provided in an IDTF require physician supervision, and written orders must be furnished. CMS believes this means the IDTF is a provider-led outpatient setting and appropriate to be added to the list. Additionally, CMS believes that adding IDTFs to the list will ensure the AUC program is in place across outpatient settings where advanced diagnostic imaging is provided. Other applicable settings include a physician's office, hospital outpatient department (including the emergency department), and an ambulatory surgery center (ASC).

CMS finalized its proposal that any ordering professional experiencing insufficient internet access, EHR or CDSM vendor issues, or extreme and uncontrollable circumstances (including natural or manmade disasters) would not be required to consult the AUC using a qualified CDSM, and the claim would not be required to list the AUC consultation information.

CMS confirmed these circumstances will be self-attested at the time of placing an advanced diagnostic imaging order. The claim submitted by the rendering provider and facility would report the necessary HCPCS modifier to reflect the hardship self-attestation.

After considering comments received, CMS changed its proposal regarding who would potentially be allowed to consult the AUC on behalf of the ordering provider. CMS revised its proposed language, clarifying that *"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 professional is still responsible for the consultation, as it is the NPI of the ordering physician reported on the furnishing professional claim form. Additionally, it is the ordering professional that would be identified as an outlier and subjected to prior authorization requirements based on ordering patterns.

Even though the program does not officially begin until Jan. 1, 2020, the testing period is currently in effect through Dec. 31, 2019. The initial list of outlier ordering professionals established in the CY 2017 PFS final rule did not change. This list of outliers impacts providers ordering advanced diagnostic imaging services for 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), cancer of the lung (primary or metastatic, suspected or diagnosed), and cervical or neck pain.

Quality Payment Program (QPP) Summary

CMS estimates approximately 798,000 clinicians would be MIPS-eligible clinicians for the 2019 MIPS performance period. This

estimate is an increase of nearly 148,000 from the estimated total in the CY 2019 proposed rule. CMS estimates payment adjustments will be approximately $390 million—negative and positive. Since the program is budget-neutral, the amount negatively adjusted from eligible clinicians is the amount used to positively adjust payments in CY 2021. If the majority of eligible clinicians meet and exceed the threshold and very few fail to meet the threshold, then the amount taken and paid out will decrease or be impacted.

CMS added six additional eligible clinicians to participate in the MIPS program for performance year 2019. CMS also aligned the determination period to be the same for the low-volume threshold, non-facing patient status, small practice status, hospital-based status, and ASC-based statuses. Finally, CMS changed the low-volume threshold criteria for CY 2019 performance year and future years to be:

- Those who have allowed charges for covered professional services less than or equal to $90,000;
- Those who provide covered professional services to 200 or fewer Part B-enrolled individuals; or
- Those who provide 200 or fewer covered professional services to Part B-enrolled individuals.

CMS created a low-volume opt-in that allows any eligible clinician or group who exceed one, but not all, of the low-volume threshold criteria to choose to voluntarily report by electing this option through the QPP portal. This opt-in would be irrevocable for the performance period, and clinicians that opt in will be subject to the applicable payment adjustment.

One adjustment impacting the CY 2019 payment year is a payment adjustment applied to Part B payments for covered services, excluding Part B drugs and other items furnished by the MIPS eligible clinician. Weighting of the performance categories is as follows:

- Quality (45 percent)
- Cost (15 percent)
- Improvement Activities (15 percent)
- Promoting Interoperability (previously Advancing Care Information) (25 percent).

The performance threshold is 30 points for CY 2019 performance period and set at 75 points for the additional exceptional performance threshold. Points below 30 will receive a negative payment adjustment (maximum of 7 percent) applied in the CY 2021 payment period. The positive payment adjustment can be up to 7 percent, but is required to remain budget-neutral; thus the adjustment may be less depending on the number of eligible clinicians who do not meet the threshold and are penalized. OI

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spotlight

Lahey Hospital & Medical Center Cancer Services

Burlington, Mass.

Lahey Hospital & Medical Center (LHMC) in Burlington, Mass., serves a densely populated area in eastern Massachusetts, southern New Hampshire, and southern Maine. Formerly Lahey Clinic, LHMC is an academic teaching center and one of five hospitals within the Lahey Health System. The LHMC cancer center is a key component of the Lahey Health Cancer Institute, created in 2014 to address the need for integrated and expanded cancer services across seven Lahey Health System cancer services sites.

Leveraging a Virtual Model

The LHMC cancer center is a virtual cancer center that includes LHMC's comprehensive oncology service line; in Burlington, those services are located throughout the hospital and include medical, surgical, and radiation oncology. Additional cancer services are offered at Lahey Medical Center in Peabody, Mass., where medical and radiation oncology are co-located, and in Derry and Salem, N.H., where medical oncology services are offered. This virtual cancer center sees more than 3,000 new analytic cases annually on an inpatient and outpatient basis and has 24 infusion bays in Burlington, with 109 additional infusion bays spread across the health system. The Burlington location is staffed by 12 medical oncologists, 4 hematologists, 7 radiation oncologists, 15 radiation therapists, 11 advanced practice providers, and 32 nurses.

The LHMC cancer center utilizes a site-specific focus, which brings providers together by disease site to address patient needs quickly, efficiently, and with a high level of expertise. This approach helped LHMC become accredited by the Commission on Cancer, the American College of Radiology, the National Accreditation Program for Breast Centers, and the Foundation for the Accreditation of Cellular Therapy for its autologous stem cell transplantation program.

Attracting Patients in a Competitive Marketplace

Massachusetts is a relatively homogeneous state with the highest rate of health insurance coverage in the country. As such, there are no immediate population-specific challenges to cancer care, but there is a great deal of competition among providers to deliver that care—there are more physicians per capita in Massachusetts than in any other state. To attract patients, LHMC has placed a premium on patient access, smoothing out insurance processes for patients, and easing patient intake, according to Andrea McKee, MD, chair of radiation oncology at LHMC. One example of this patient-focused approach is participation in the Centers for Medicare & Medicaid Services Oncology Care Model, which seeks to improve care coordination, quality, and access and reduce unplanned hospitalization for patients undergoing chemotherapy.

The LHMC cancer center has a dedicated oncology pharmacy and a robust clinical trials program, with 40 trials currently open for enrollment. Recently, the National Cancer Institute designated LHMC a recipient of the 2018 High Performing Site Initiative Award for excellence in patient accrual and quality of clinical trial data.

The program's intraoperative radiation therapy for breast cancers is another distinctive feature, as is its stereotactic radiotherapy program with a focus on liver cancers; the hospital's live liver donor team fields referrals for both transplants and hepatobiliary and pancreatic cancers.

Social work and psycho-oncology services are available for patients. Additionally, the LHMC cancer center offers complementary therapies such as Reiki, acupuncture, massage, and music and pet therapies. Look Good, Feel Better groups and support groups for lymphoma, leukemia, breast, and prostate cancers bolster these supportive services. Patients see rehab services during survivorship visits and have the option for these services at the time of their clinic visits.

On an operational level, through its multidisciplinary model of care teams, the LHMC cancer center undergoes continuous improvement for breast, lung, gastrointestinal, and gynecologic cancer services to ensure quality, patient-centric care. These teams are composed of clinicians, nurses, and nurse navigators across the health system, not just in locations that offer cancer services. The teams meet quarterly to discuss what improvements could be made across sites, develop standards and quality measures, and research new protocols.

A Screening Pioneer

LHMC was one of the first institutions in the country to implement a low-dose computed tomography program for lung cancer screening in 2011 following publication of the National Cancer Institute's National Lung

Screening Trial. Although there was not yet a code for reimbursement, LHMC's Rescue Lung, Rescue Life program recognized the immediate needs of its patient population and began providing lung screening as a community benefit until the Centers for Medicare & Medicaid Services established an insurance code in 2015. To date, LHMC has screened more than 5,000 patients—estimated to be 65 to 70 percent of their high-risk population—and detected more than 200 lung cancers, 85 percent of which were stage I or II. Thanks to the success of this program, LHMC now diagnoses more stage I lung cancers than stage IV lung cancers. Read more about this innovative program in the March/April 2014 *Oncology Issues* in the feature article "Rescue Lung, Rescue Life."

Lahey Health System also boasts a systemwide breast cancer screening program based on the Hughes risk assessment model. All patients undergoing mammograms receive a test on a tablet that determines a patient's risk profile. If patients are at 20 percent or greater risk of breast cancer, they meet with a nurse practitioner and discuss further screening options. The screening app also calculates a patient's risk of inherited genetic biomarkers such as BRCA 1 and 2 and refers patients to genetic counselors if suitable. "It's a nice way of helping women understand their risk and providing them with extra evaluation if needed," says McKee. OI

tools

Approved Drugs

- On Nov. 16, the U.S. Food and Drug Administration (FDA) approved **Adcetris® (brentuximab vedotin)** (Seattle Genetics, Inc., seattlegenetics.com) injection in combination with chemotherapy for adult patients with certain types of peripheral T-cell lymphoma.
- On Nov. 20, the FDA approved **Daurismo™ (glasdegib)** (Pfizer, Inc., pfizer.com) in combination with low-dose cytarabine for newly diagnosed acute myeloid leukemia in patients who are 75 years old or older or who have comorbidities that preclude intensive induction chemotherapy.
- On Nov. 6, the FDA approved **Empliciti® (elotuzumab)** (Bristol-Myers Squibb Company, bms.com) injection for intravenous use in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor.
- On Oct. 30, the FDA approved **Keytruda® (pembrolizumab)** (Merck & Co., Inc., merck.com) in combination with carboplatin and either paclitaxel or nab-paclitaxel as first-line treatment of metastatic squamous non-small cell lung cancer (NSCLC).
- On Nov. 9, the FDA granted accelerated approval to **Keytruda® (pembrolizumab)** (Merck & Co., Inc., merck.com) for patients with hepatocellular carcinoma who have been previously treated with sorafenib.
- On Oct. 23, the FDA approved **Khapzory™ (levoleucovorin)** (Spectrum Pharmaceuticals, Inc., sppirx.com) for injection for rescue after high-dose methotrexate therapy in patients with osteosarcoma; diminishing the toxicity associated with overdosage of folic acid antagonists or impaired methotrexate elimination; and the treatment of patients with metastatic colorectal cancer in combination with fluorouracil.
- On Nov. 2, the FDA granted accelerated approval to **Lorbrena® (lorlatinib)** (Pfizer, Inc., pfizer.com) for patients with ALK metastatic NSCLC whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease or whose disease has progressed on alectinib or ceritinib as the first ALK inhibitor therapy for metastatic disease.
- On Oct. 16, the FDA approved **Talzenna™ (talazoparib)** (Pfizer Inc., pfizer.com) for patients with deleterious or suspected deleterious germline BRCA-mutated, HER2-negative locally advanced or metastatic breast cancer.
- On Dec. 6, the FDA approved **Tecentriq® (atezolizumab)** (Genentech, Inc., gene.com) in combination with bevacizumab, paclitaxel, and carboplatin for the first-line treatment of patients with metastatic nonsquamous NSCLC with no EGFR or ALK genomic tumor aberrations.
- On Nov. 28, the FDA approved **Truxima™ (rituximab-abbs)** (Celltrion Inc., celltrion.com) as the first biosimilar to Rituxan® (rituximab) for patients with CD20-positive, B-cell non-Hodgkin's lymphoma to be used as a single agent or in combination with chemotherapy.
- On Nov. 2, the FDA approved **Udenyca™ (pegfilgrastim-cbqv)** (Coherus BioSciences, Inc., coherus.com) to decrease the chance of infection as suggested by febrile neutropenia in patients with nonmyeloid cancer who are receiving myelosuppressive chemotherapy that has a clinically significant incidence of febrile neutropenia.
- On Nov. 21, the FDA granted accelerated approval to **Venclexta® (venetoclax)** (AbbVie Inc., abbvie.com, and Genentech, Inc., gene.com) in combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia in adults who are age 75 years or older or who have comorbidities that preclude use of intensive induction chemotherapy.
- On Nov. 26, the FDA granted accelerated approval to **Vitrakvi® (larotrectinib)** (Loxo Oncology Inc., loxooncology.com, and Bayer, bayer.com) for adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase gene fusion without a known acquired resistance mutation, that are either metastatic or where surgical resection is likely to result in severe morbidity, and who have no satisfactory alternative treatments or whose cancer has progressed following treatment.
- On Nov. 28, the FDA approved **Xospata® (gilteritinib)** (Astellas Pharma US Inc., astellas.com) for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia with an FLT3 mutation as detected by an FDA-approved test.

Approved Devices

- On Oct. 16, Myriad Genetics, Inc. (myriad.com) announced that the FDA has approved **BRACAnalysis CDx®** to identify patients with HER2-negative metastatic breast cancer who have a germline BRCA mutation and are eligible for treatment with Talzenna.™
- On Dec. 7, iCAD Inc. (icadmed.com) announced that the FDA has cleared **ProFound AI™**, a cancer detection software for digital breast tomosynthesis, for commercial sale and clinical use in the United States.

Devices in the News

- Aethlon Medical, Inc. (aethlonmedical.com) announced that it has received breakthrough device designation from the FDA for the advancement of the **Aethlon Hemopurifier®**, a single-use device indicated for the treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard of care therapy and with cancer types in which exosomes have been shown to participate in the development or severity of the disease.

Drugs in the News

- The FDA has accepted for a review a supplemental new drug application (sNDA) for **Doptelet® (avatrombopag)** (Dova Pharmaceuticals, dova.com) for the treatment of chronic immune thrombocytopenia in patients who have had an insufficient response to a previous treatment.
- AbbVie Inc. (abbvie.com) announced that the FDA has accepted its sNDA for priority review for **Imbruvica® (ibrutinib) in combination with Gazyva® (obinutuzumab)** in previously untreated adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma.
- Incyte Corporation (incyte.com) announced that the FDA has accepted for priority review the sNDA for **Jakafi® (ruxolitinib)** for the treatment of patients with acute graft-versus-host disease who have had an inadequate response to corticosteroids.
- Taiho Oncology, Inc. (taihooncology.com) announced that the FDA has accepted and granted priority review for its sNDA for **Lonsurf® (trifluridine/tipiracil, TAS-102)** as a treatment for patients with previously treated its advanced or metastatic gastric adenocarcinoma, including cancer of the gastroesophageal junction.
- Loxo Oncology, Inc. (loxooncology.com) announced that the FDA has granted breakthrough therapy designation to **LOXO-292**, a selective RET inhibitor, for the treatment of patients with advanced RET fusion-positive thyroid cancer who require systemic therapy, have progressed following prior treatment, and have no acceptable alternative treatment options.
- AstraZeneca (astrazeneca.com) and Merck & Co., Inc. (merck.com) announced that the FDA has granted orphan drug designation to **Lynparza® (olaparib)** for the treatment of pancreatic cancer.
- AstraZeneca (astrazeneca.com) and Merck & Co., Inc. (merck.com) also announced that the FDA has accepted an sNDA and granted priority review for the approval of **Lynparza® (olaparib)** as a maintenance treatment in patients with newly diagnosed, BRCA-mutated advanced ovarian cancer who were in complete or partial response following first-line standard platinum-based chemotherapy.
- Mirati Therapeutics, Inc. (mirati.com) announced that it has submitted an investigational new drug application with the FDA to initiate a Phase I/II trial with the initial goal of evaluating the safety, tolerability, and pharmacokinetics of **MRTX849** in patients with advanced solid tumors.
- Daiichi Sankyo (daiichisankyo.com) announced that the FDA has accepted an NDA and granted priority review for **quizartinib** for the treatment of adult patients with relapsed/refractory FLT3-ITD acute myeloid leukemia.
- Genentech, Inc. (gene.com) announced that the FDA has accepted the company's supplemental biologics license application and granted priority review for **Tecentriq® (atezolizumab)** plus chemotherapy (Abraxane®) for the initial (first-line) treatment of unresectable locally advanced or metastatic triple-negative breast cancer in people whose disease expresses the PD-L1 protein, as determined by PD-L1 biomarker testing.
- Genentech, Inc. (gene.com) also announced that the FDA has accepted the company's supplemental biologics license application and granted priority review for **Tecentriq® (atezolizumab)** in combination with carboplatin and etoposide (chemotherapy) for the initial (first-line) treatment of patients with extensive-stage small cell lung cancer.
- UroGen Pharma Ltd. (urogen.com) announced that the FDA has granted breakthrough therapy designation to **UGN-101 (mitomycin gel)** for instillation for the treatment of patients with low-grade upper tract urothelial cancer.

Genetic Tests and Assays in the News

- Roche (roche.com) announced the global launch of the **VENTANA pan-TRK Assay**, a pan-TRK immunohistochemistry assay that identifies wild-type and chimeric infusion proteins while measuring the prevalence of TRK in tumor tissue.
- The **LeukoStrat® CDx FLT3 Mutation Assay** (Invivoscribe Technologies, Inc., invivoscribe.com), a diagnostic used to detect the FLT3 mutation in patients with acute myeloid leukemia, has been approved for an expanded indication as a companion diagnostic with Xospata (gilteritinib).

BY ERIC B. KMIEC, PHD

CRISPR-Directed Gene Editing in a Community Cancer Center

At a recent conference at the Vatican, Pope Francis reminded us that "not everything technically possible or doable is thereby ethically acceptable." When it comes to human gene editing, this statement is both timely and appropriate. The extraordinary speed with which the genetic tool Clustered Regularly Interspersed Palindromic Repeats (CRISPR) has entered the scientific arena and, in fact, the public discourse is astounding. This year, genome editing will be a central theme of the largest most influential biotechnology meeting in the world, BIO 2019, taking place in Philadelphia. The scientific sessions will include discussions of scale-up, manufacturing reimbursement, and perhaps most importantly, how innovative therapies will become accessible to all patients who seek such treatment. Rarely has a technological advance induced such widespread discussion in both scientific literature and the popular press.

With its simple design and elegant mechanism of action, geneticists often say that CRISPR has democratized human gene editing, because research labs throughout the world can design and utilize this tool without extensive training. However, it is one thing to be able to do something and quite another to be able to carry it out with high technical skill to avoid unintended consequences. As such, policymakers, ethicists, scientists, and the public are engaged in productive conversations about the regulation of CRISPR-directed gene editing. Having these important stakeholders take part in those conversations is a clear testament to the power of this technology and bodes well for its use as a game changer in the era of personalized medicine.

With its simple design and elegant mechanism of action, geneticists often say that CRISPR has democratized human gene editing, because research labs throughout the world can design and utilize this tool without extensive training.

In this article, I will discuss the emergence of gene editing as an approach to human genetic engineering and gene therapy, especially in the field of oncology, and why we should care about its rapid and often breathtaking development. I will discuss some of the challenges that remain in this young field, a field that has

made a surprisingly quick transition from bench to bedside. I will also touch upon the work that the Gene Editing Institute of the Helen F. Graham Cancer Center & Research Institute at Christiana Care Health System is doing to further research, education, and engagement with gene editing as a tool in the fight against cancer.

Breakfast Cereal or Breakthrough Genetic Tool?

Part of the popularity surrounding CRISPR likely arises in part from its acronym, which could be mistaken for a new type of breakfast cereal or a refrigerator feature that helps keep lettuce fresh. In reality, CRISPR is a string of nucleic acid bases (RNA) that pair with a cellular enzyme known as Cas9 (or related enzymes such as Cas12a) to form the active gene editing complex, CRISPR/Cas9 (see Figure 1, page 33). This complex is found in almost all bacteria,[1,2] where it is part of an adaptive immunity pathway used by bacterial cells to fight off viral infections (see Figure 2, page 33). For example, when a bacteriophage (virus) infects the cell, molecular scissors are activated and essentially chop up the infecting viral DNA.[3] The resulting fragments of viral DNA are inserted into the bacterial chromosome. Upon reinfection, these inserted viral segments instruct the bacterial cell that the same infection is beginning. The activated CRISPR complex then more rapidly fragments and destroys the incoming viral DNA. Simply stated, the bacterial cell remembers the first infection and is primed to attack during the second. In some ways, one can think of it as a form of bacterial vaccination.

The transition from a bacterial cell immunity pathway to human gene editing has evolved over the past five to seven years, when several laboratories began to experiment with CRISPR/Cas9 to either disable or repair human genes.[4,5]As is often the case in life, it is easier to destroy something than to repair it. Though we certainly would like to utilize gene editing to repair mutant genes, such as those involved in the pathogenesis of sickle cell anemia or cystic fibrosis, that repair event must be precise and is therefore more challenging.[6,7] CRISPR/Cas9 functions normally in the bacterial cell to only fragment, not repair or replace, the target DNA site, so it is quite an uphill struggle to achieve precise repair on side or offside corollary mutagenesis. This effect refers to CRISPR activity at non-targeted sites leaving behind a genetic scar or unintended genetic footprint. Most scientists believe that the most efficient use of CRISPR/Cas9 in human cells is obviously the destruction of the function of a gene, in a process known as *genetic knockout*. Though other cleavage complexes exist that do similar things (such as zinc finger nucleases and transcription activator-like effector nucleases[8]), CRISPR is the only tool that exists naturally. It also happens to be easier to synthesize and is likely to be able to be produced in levels great enough to enable the critical translational step of scale-up, an important, but often forgotten, step for human clinical applications.

The World Before CRISPR

Before CRISPR, it was largely believed that creating site-specific cleavage in human chromosomes was impossible, and research and development toward that goal was often met with significant criticism.[9,10] Conceptually, single-agent gene repair—or *gene editing*, as it is called today—takes place in a two-phase reaction: pairing/alignment and cutting/repairing/resolution. The major barrier to further development of gene editing was the low frequency with which gene editing events took place. Targeting of chromosomal DNA had been successful in yeast and bacteria, likely because one could employ a stringent selection process to identify converted clones. These selection protocols are less effective in mammalian cells, and the choice of selection agents is limited.

Because the frequency of gene repair in eukaryotic cells was so low, a significant focus was placed on modifying the metabolic pathways of the target cell to make it more amenable to gene editing activity. It became apparent to clinicians in the field that double-stranded DNA breaks catalyzed by anticancer drugs or programmable nucleases such as CRISPR could prepare the cell for higher levels of gene editing by altering the speed at which DNA replication takes place. Retarding the progression of these important cellular metabolic pathways enables the enzymes and regulatory factors to be prompted and stay active for longer periods of time. These same factors have now been shown to influence the frequency of CRISPR-directed human gene editing, so the field of genetic engineering is focused almost exclusively on CRISPR as a therapeutic agent for human gene editing.

CRISPR and Drug Discovery

David Wollenberg points out that pharmaceutical companies normally develop drugs to *reach* a broad spectrum of patient population; however, that goal cannot be called personalized (known as the "reach").[11] Diversity of patients is a key challenge for any broad-spectrum drug; this is even observed with new immunotherapy agents. The expanding databases that continue to educate us about the complexity of the human genome have brought about the possibility that we may be able to develop personalized therapeutics that can treat individuals on a case-by-case basis (known as the "richness"). Exciting, yes; practical, maybe. CRISPR-directed gene editing is at the forefront of this latter strategy, though significant technical challenges exist, particularly with the associated higher costs. Debate now swirls around who will pay for gene-edited cell therapies and when they should be utilized. CRISPR has already been utilized in diagnostic testing, including the identification of the Zika virus,[12] and as a sophisticated and accurate diagnostic assay that can advise primary care physicians as to the best course of treatment for an individual patient with cancer.[13] The field of cancer diagnostics is likely to evolve faster than cancer therapeutics, and it is possible that soon most effective cancer diagnostics will involve a gene editing component.

(continued on page 34)

Figure 1. The CRISPR/Cas9 Complex

The DNA helix illustrated in blue is bound by a specific piece of RNA known as CRISPR (cr)RNA, which is paired with a separate piece of RNA (tracrRNA) that localizes on a specific site on the DNA. The seed sequence of the crRNA consists of approximately 20 bases that align in homologous register to the specific DNA sequence of the target site. At one end of the target DNA sequence is the site known as Protospacer Adjacent Motif, which helps position the Cas9 protein (grey-shaded region) to execute DNA cleavage.

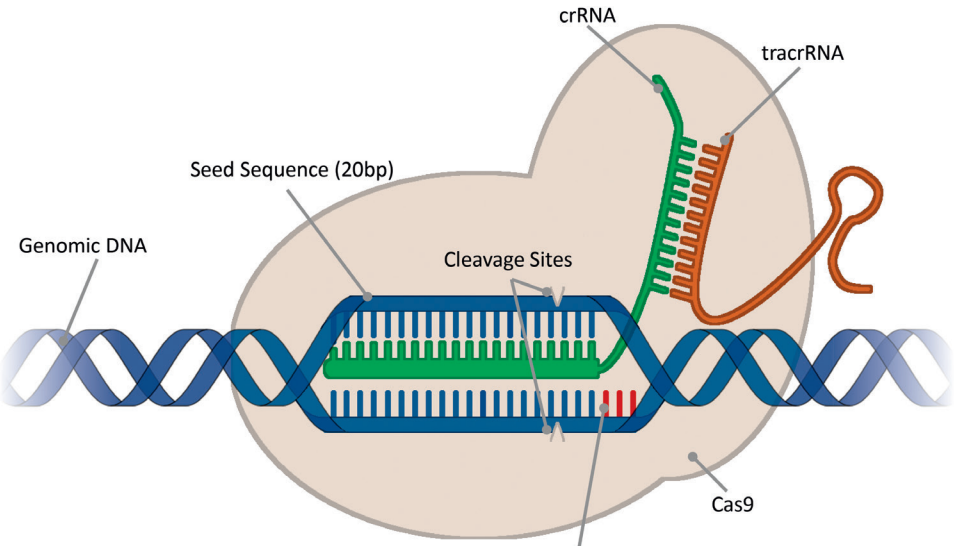
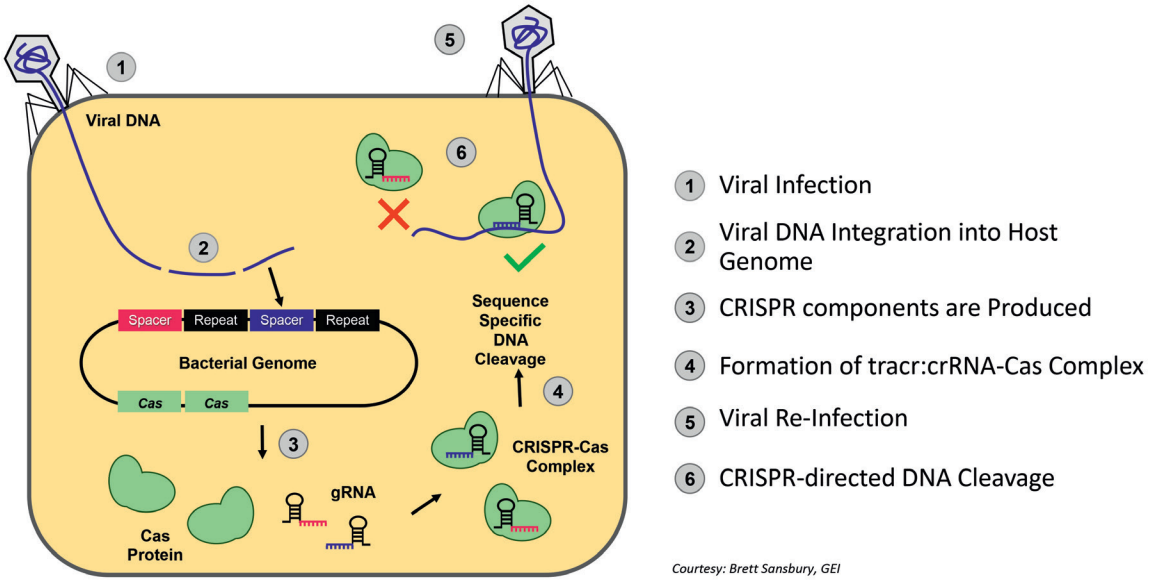


Figure 2. CRISPR/Cas9-Mediated Immunity in Bacteria

The infection and re-infection cycle is displayed with specific points where CRISPR is asked to fight off the viral infection. The explanation for each specific reaction step is placed on the right-hand side of the figure.



Courtesy: Brett Sansbury, GEI

(continued from page 32)

CRISPR has already helped to re-identify the targets for certain well-known drugs. For example, a recent CRISPR/Cas9 screen for the essential genes involved in tumor growth led to the discovery that the MELK protein, known to be an essential for tumor growth, does *not* in fact drive cell proliferation in cancer cells as previously thought.[14] As the era of personalized medicine begins, it will be critical to validate potential (and now previously identified) drug targets by using screening methodologies that act at the level of gene by these more robust genetic techniques.

The Challenge of the Human Genome

CRISPR-directed gene editing has made huge inroads into the areas of cancer diagnostics, drug discovery, and cancer therapy, and it will have a direct impact on accelerating the development of personalized medicine for all forms of human disease. Yet, as with most rapidly accelerating technologies, fundamental challenges still exist, at both the basic and translational levels.

Though CRISPR is a highly precise genetic engineering tool, it does have the inherent capacity to bind and cleave at non-specific (off-target) sites in the human chromosome. It is likely that off-site mutagenesis will remain an open question, because ensuring a patient that no off-site mutagenesis will take place is simply impossible. We also know from the way that biological systems function that, by and large, nothing is perfectly precise, and go/no-go decisions, when considering whether CRISPR/Cas9 should be incorporated into a therapeutic regimen, may come down to a risk- and cost-benefit analysis. Alternatively, the disruption of the coding region of a mammalian gene is at the heart of the power of the CRISPR technology, and when the objective is to simply knock out the gene, as in most strategies for cancer therapy, the impact and even the importance of off-site or on-site mutagenesis are significantly reduced.

For the implementation of CRISPR-directed gene editing in human therapeutics, finding an appropriate target DNA sequence may not be the only molecular challenge. The genome is dynamic in that transcription, replication, repair, and DNA modification are taking place continuously throughout the chromosomes, and these reactions pose additional barriers to the accurate activity of CRISPR. When developing strategies for gene therapy, it will also be important to consider the epigenome, which generally refers to the degree of methylation within promoter regions and coding regions of human genes.[15] This work is in its embryonic stages and its true impact has not been established. However, most scientists agree that the inherent complexity of the human genome may pose additional barriers to success.

Lastly, with the excitement surrounding the evolution of CRISPR, it is often forgotten that this genetic tool only executes double-stranded breakage—the first step of gene editing. DNA resection, processing, and subsequent activities leading to gene knockout or gene knock-in are reliant upon the cell's endogenous DNA repair and replication pathways. Unfortunately, these pathways were not designed to facilitate the genetic re-engineering of human chromosomes, so when a double-strand break occurs, the cell assumes that a chromosome has been broken and needs immediate repair, which often takes the form of reconnecting the chromosomes no matter what the cost. This action often leads to a loss of DNA because the re-ligation process is notoriously unfaithful. Thus, once again, DNA deletion or gene disruption is a more attainable goal for CRISPR-directed gene editing. Another important response to DNA damage, often in the form of DNA breakage, is the activation of the tumor suppressor gene p53. There is no evidence that CRISPR-directed gene editing induces tumorigenesis, but because the DNA damage response includes the activation of these tumor suppressor genes, significant caution should be exercised when advancing novel therapies toward the clinic in the absence of a full analysis of gene expression.

The Gene Editing Institute at the Helen F. Graham Cancer Center & Research Institute

The Helen F. Graham Cancer Center & Research Institute at Christiana Care serves Delaware and neighboring communities. Christiana Care has one of the busiest cancer programs on the East Coast, treating more than 70 percent of the cancer cases in Delaware. More than 223,000 patient visits are recorded annually, and the Helen F. Graham Cancer Center & Research Institute is projected to treat more than 3,000 new cancer cases this year alone. Christiana Care has already become a national leader in cancer clinical trials, with 24 percent of patients enrolled in one or more clinical research trials for the prevention, early detection, and treatment of cancer, compared to the national average of 4 percent.

The Gene Editing Institute was founded at the Helen F. Graham Cancer Center & Research Institute in 2015 with four core missions:

1. Carry out grant-funded innovative translational research on the use of gene editing in cancer with a central focus on elucidating the transformation pathways as well as developing innovative technological approaches for studying oncogenesis.
2. Provide a focused educational resource for undergraduate and graduate students, postdoctoral fellows, and faculty interested in understanding and learning about gene editing.
3. Provide a biomedical resource facility for the synthesis, hands-on training, and dissemination of gene editing technologies to undergraduate institutions as well as to advanced research laboratories throughout the world.
4. Engage in sustainable partnerships with life science companies and research institutions through license deals and joint ventures.

The Gene Editing Institute can provide technical assistance for biomedical and agricultural researchers and other community cancer centers interested in utilizing gene editing technologies, and it is hoped that it will establish itself as a center for technology development and clinical implementation of gene editing, as well as an educational resource for developing curricula in gene editing.

The overarching strategy was to embed the Gene Editing Institute in a community cancer center, so that interactions with

physicians within a truly clinical environment could be facilitated. This structure has already afforded the opportunity for the development of meritorious translational research projects. Funding for the Gene Editing Institute comes from the National Institutes of Health, the National Science Foundation, the Binational Industrial Research and Development Foundation, and partnerships with a wide range of biotechnology companies. The diverse missions of the Gene Editing Institute position the institute as a foundational platform upon which expansion and partnerships with other hospitals and organizations can now take place.

Gene Editing and Non-Small Cell Lung Carcinoma

The application of CRISPR-directed gene editing for cancer therapy is only at its beginning, and many strategies will undoubtedly be changed as the amount of information surrounding clinical implementation accumulates. There are essentially two ways to approach the therapeutic challenge. First is to remove the cells from the body, re-engineer them using CRISPR, and introduce them into the body to specifically attack the tumor. Work at the University of Pennsylvania focuses on liquid tumors, wherein T-cells are genetically modified *ex vivo* and then reintroduced into the body for the treatment of acute lymphoblastic leukemia and chronic lymphocytic leukemia.[16] Often referred to as personalized cellular therapy, this therapeutic strategy has received the U.S. Food and Drug Administration's prestigious Breakthrough Therapy designation.

The second approach is more complicated, involving the development of a CRISPR-directed gene editing strategy for solid tumors. Since this approach will involve *in vivo* delivery to tumor tissue buried in the body, increased challenges that surpass liquid tumor applications are present. One such trial, however, is beginning this year and is focused on the action of CRISPR/Cas9 to target HPV 16 and HPV 18 E6/E7 DNA. The constructs will be delivered with a gel that is locally applied to the HPV infected cervix, which opens the possibility of deposition of CRISPR complexes following surgical resection. The focus at present is on safety, and dosing regimen and the change in HPV 16 or 18 will be evaluated in Phase 1. It should be noted that a very similar trial (NCT01800369) using zinc finger nucleases already has finished and is entering the data collection phase. So, some exciting developments are beginning in the treatment of solid tumors. It is widely recognized that over 85 percent of patients with lung cancer seek care at community cancer centers, and in our opinion, these patients should have access to innovative therapies at their treatment site. Though there is substantial progress in treatment modalities including immunotherapy, the treatment is far from ideal.[17] Several other approaches to using gene editing centered primarily on liquid tumors,[16] but the development of gene editing for solid tumors has lagged.

The Gene Editing Institute's combinatorial approach to treating KRAS+ non-small cell lung carcinoma, which includes CRISPR-directed gene editing, is novel, and it is hoped that it will enable new scientific discoveries as well as reveal new translational challenges early on in the process. A team of gene editing scientists and oncologists at the Helen F. Graham Cancer Center & Research Institute has been shaping realistic research goals that include an increase in chemosensitivity and an arrest of tumor growth, which will hopefully result in an improvement in survival rate and quality of life for patients with lung cancer. It is possible that this approach could be effective in patients with locally advanced lung cancer or could be incorporated in the early stage of disease, particularly with patients who have received surgical resection and/or are concurrently receiving immunotherapy or radiation therapy.

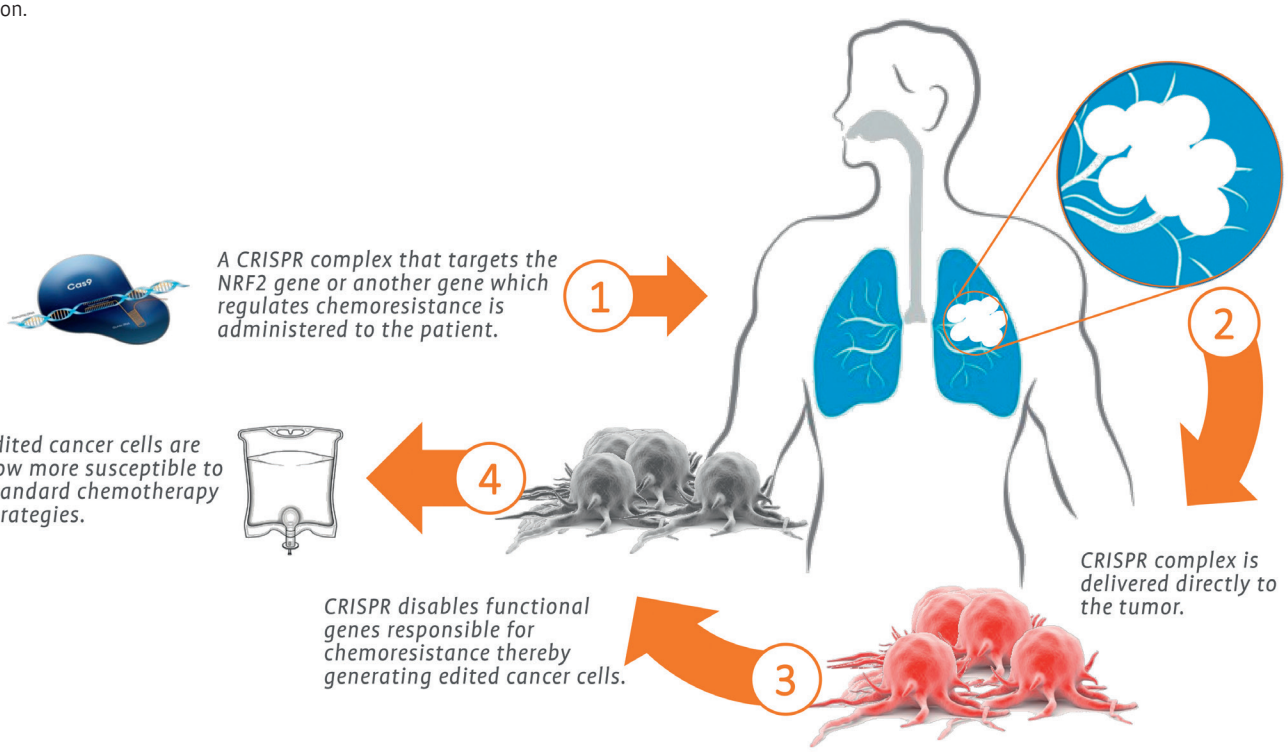
Chemotherapy remains an important option in the treatment of lung cancer, but issues involving chemoresistance and toxicity are often problematic with extended care.[18] Our goal is to establish a clear demonstration that genetic knockout of a gene encoding a transcription factor, such as NRF2 or any other gene controlling chemoresistance, improves the efficiency of chemotherapy. This discovery could potentially introduce a new weapon in the anticancer treatment armament. Because only 8 percent of NRF2 genes contain mutations in lung cancer, a set of established CRISPR molecules could be available on a standardized basis, turning this approach into an off-the-shelf therapy for most patients (see Figure 3, page 36).

Early results from this translational research project are quite encouraging; we can clearly observe an increase in chemosensitivity to cisplatin in a dose-dependent fashion in genetically re-engineered human lung cancer cells. Gene-edited human lung cancer cells proliferate at a slower rate than wild-type cells in the absence of drug treatment, but the combination of knockout cells and drug treatment leads to a cessation of tumor growth and maintenance of tumor size over the course of 16 days.

The major challenge of developing a CRISPR-directed gene editing for solid tumors such as lung cancer centers on one word: *delivery*. Despite billions of dollars of investment that have gone into the viral gene therapy arena, few viral vectors are suitable for tumor-specific delivery of therapeutic payloads especially to solid tumors. Several innovative strategies are being developed in order to provide a selective activity paradigm for CRISPR/Cas9 complexes designed to disable chemoresistance genes in lung tumor cells. There is mounting evidence that the DNA sequence of genomic targets within tumor cells is different than the DNA sequence of normal cells, and designing a CRISPR construct that specifically functions only when bound stably to the tumor cell DNA may sidestep the complexities and the well-known lack of specificity of viral or non-viral delivery systems. In addition, a rapidly emerging therapeutic delivery vehicle is the exosome, an extruded sub cellular particle surrounded by a membrane that can carry a variety of biomolecules. Tumor cells extrude these vesicles on a regular basis, and these particles returned to the tumor cell through some sort of molecular recognition. Thus, it is possible that exosomes can be captured from the primary tumor and packaged with the CRISPR/Cas9 complex, followed by targeted delivery to the tumor from whence the exosome arose.

Figure 3. A Potential Experimental Protocol for the Use of CRISPR-Directed Gene Editing for the Treatment of Non-Small Cell Carcinoma.

The CRISPR/Cas9 expression construct is introduced into the patient using a viral vector or by direct injection into the tumor. CRISPR-directed gene knockout takes place at specific target genes, such as NRF 2, to complement or sustain standard of care. Each step in the protocol is highlighted by the associated caption.



Can and Will Gene Editing be Regulated?

The regulatory landscape surrounding gene editing is both inconsistent and confusing. Very few regulations are in place, and no internationally agreed-upon rules have been laid down. In most cases, each country is evaluating how best to control the progression of gene editing in both somatic and ultimately germline activities on its own. The European Union has established a legal and regulatory framework for safeguarding the development of genetically modified organisms and protecting humans, animals, and the environment.[19] However, there is a fundamental question as to whether the CRISPR/Cas9 activity at the level of the chromosome is, in fact, true genetic alteration—in most cases, no additional DNA is added to the genome. The argument can be made that the CRISPR technique itself should not be regulated, but rather only the product.

CRISPR-directed gene editing has also accelerated the discussion surrounding the modification of germline cells such as eggs, sperm, fertilized eggs, and embryos due to its efficiency and precision. However, gene editing of human embryos faces significant and fundamental barriers. Germline editing is banned in Canada, and experiments involving germline editing in Germany are currently limited by the Embryo Protection Act, which prohibits using human embryos for basic research and the harvesting of embryonic cells. South Korea's Bioethics and Biosafety Act also prohibits genetic experimentation on human embryos. In 2017, the U.S. National Academy of Sciences and the National Academy of Medicine opened the door slightly by recognizing the potential for using gene editing in embryonic cells to treat serious genetic diseases in cases where embryo editing is the only reasonable option. There was also consensus support for carrying out basic research in embryo editing, but such experiments are prohibited using federal funds—there is a congressional prohibition on using taxpayer funds for research that destroys human embryos.[20] No clinical trial of human editing will be approved by the U.S. Food and Drug Administration.

The challenges of applying CRISPR-directed gene editing for human disease in a community cancer center are much higher when compared to those encountered at major medical centers that associated biomedical research arms. Resources are often limited, and embedded expertise is lacking. Yet, most patients seek treatment at community cancer centers and it raises the question of accessibility. Are the rapidly developing gene editing

therapies going to be available only to those people who can readily access them repeatedly? Such a situation creates another healthcare disparity and a bifurcation of treatment options. These therapies are going to be expensive and certainly risky. Thus, innovative therapeutic development should be carried out at community cancer centers so that the uniqueness of the population and its associated diversity can be incorporated into therapeutic design. There appears to be no reason why variance of Gene Editing Institute structure cannot be created and localized in community cancer centers to work together with oncologists who see the wide diversity of patients seeking cancer care. We hope that our model will begin a conversation as to how best to improve the accessibility of such breakthrough technologies to those who most need it.

In closing, it is informative and proper to return to the statement by Pope Francis: "Not everything that is technically possible or doable is ethically acceptable." CRISPR is a generational technology that can enable remarkable genetic engineering to treat, cure, and even prevent human disease, and first in line could be various forms of cancer. Most scientists draw a distinct line between somatic cell gene editing and germline cell gene editing, so treating cancer with some form of gene editing will remain the most approachable therapeutic strategy. However, as clinical applications of CRISPR mature and safety concerns wane, the question may turn itself around and become: Is it ethically acceptable *not* to do what is technically possible? OI

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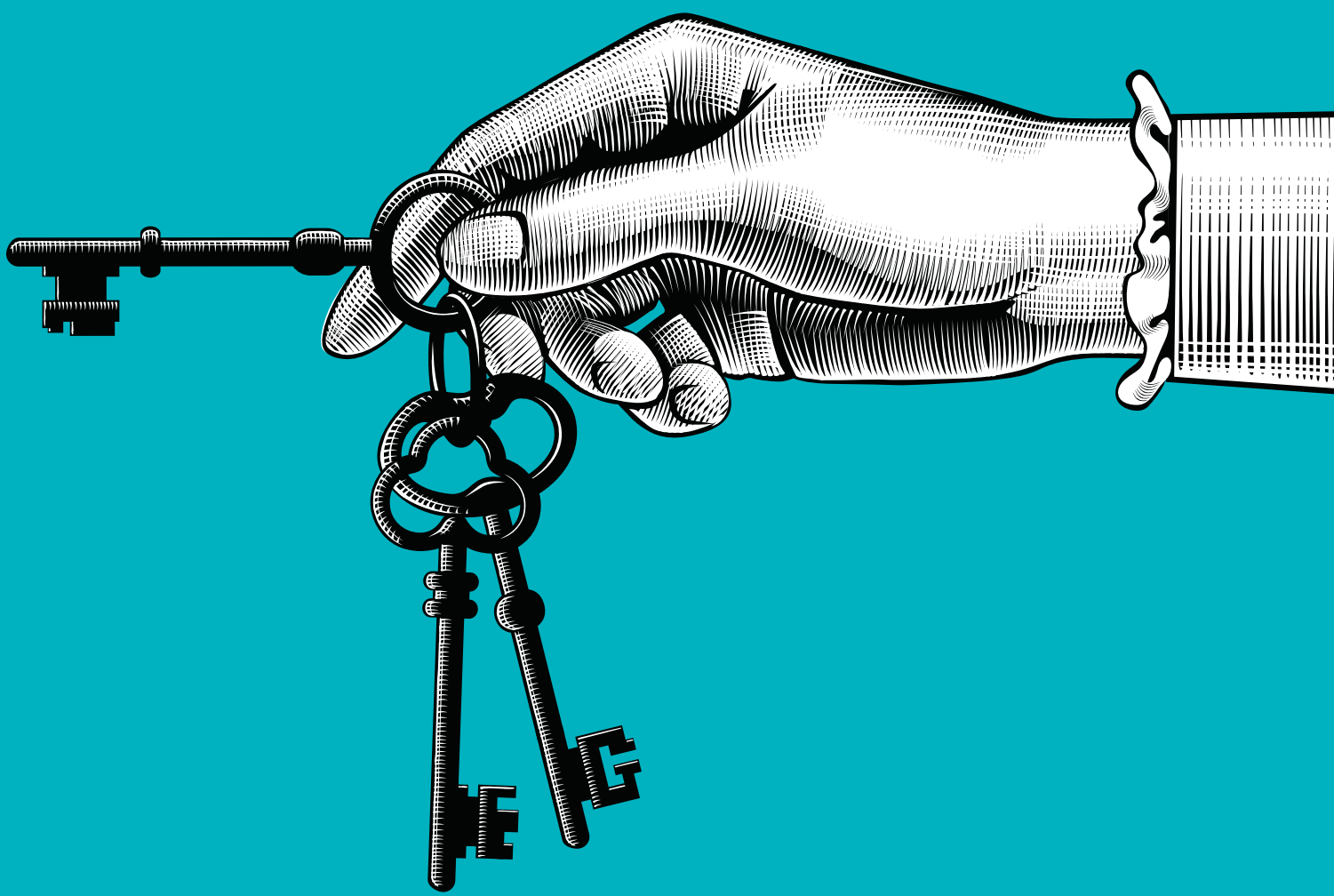
Technology Unlocks Untapped Potential in a Financial Navigation Program



BY CLARA LAMBERT, BBA, OPN-CG; SCOTT LEGLEITNER, BA, LPHT, SST; AND KATHLEEN LARAIA

Results of a pilot study at one community cancer center

Abstract

Background: Patients with cancer are experiencing rapidly rising out-of-pocket costs. The term *financial toxicity* has emerged to describe the negative impact of these costs on patients with cancer, such as impact on quality of life, treatment adherence, and greater risk of mortality. As patient out-of-pocket expenses have increased, hospitals have increasingly incurred bad debt resulting from unpaid financial obligations. Cancer programs have implemented financial navigation programs to ease the negative impact of financial toxicity on patients and the negative impact of lost revenue on healthcare organizations. The manual nature of financial navigation, however, has limited the ability for navigators to assist patients at risk for financial toxicity and demonstrate value for both patients and healthcare organizations. Though efforts are made to identify financially at-risk patients, most patients self-select into these types of programs. As a result, those with the greatest financial need or collection risk may not receive available assistance.

Objective: The objective of the pilot study was to analyze the effect of automating financial navigation programs using the TailorMed Financial Navigation Platform (tailormed.co).

Methods: The TailorMed Platform analyzed 4,616 patients at the Cowell Family Cancer Center, Traverse City, Mich. The software identified 244 "high-priority" patients based on high out-of-pocket responsibility, risk for financial toxicity, and qualification for available navigation opportunities. Financial navigators pursued assistance opportunities for these patients using the TailorMed Platform and accounted for the different forms of awarded assistance in patient benefits and organizational financial performance.

Results: The study ran for 8 months, during which 244 patients were reviewed by Cowell Family Cancer Center financial navigators. Of the 244 patients, 181 (74 percent) received one or more forms of assistance based on financial opportunities identified by the software. Financial navigators secured a combined total of $3,553,453 in "approved savings" (defined as the total value of aid secured through the financial navigation process); $1,524,562 of this savings accounted for community benefit (defined as direct patient benefits such as aid to offset living expenses, transportation costs, provide free or replacement drugs, or aid for services that are not billed by the hospital, such as oral drugs); and $259,593 contributed to revenue increase (a direct benefit to the cancer center). The financial navigation team also reported improvements in productivity, workflow, and internal organization alignment.

Conclusion: Technology can play a major role in advancing financial navigation programs by freeing financial navigators to focus on proactive financial counseling, decreasing out-of-pocket costs for patients, increasing revenue for healthcare organizations, and automatically tracking that value creation for management.

Financial Toxicity: A Growing Concern

In the United States, healthcare costs are expected to grow at an average rate of 5.6 percent within the next decade (2016-2025). Cancer represents a significant proportion of the total U.S. healthcare spending, accounting for roughly $87.8 billion dollars in 2014. For patients and their families, the costs associated with direct cancer care are constantly rising due to increases in cost-sharing and the percentage of private health insurance enrollees in high-deductible health plans.[1,2]

In a survey of patients with cancer, 20 percent of the respondents spent more than $10,000 out of pocket on treatment and medical care expenses. Approximately 1 in 10 patients stated that they had decided "to not have a recommended cancer treatment because it was too expensive;" this increased to 1 in 4 for individuals with an income of less than $40,000 a year.[3]

Research from Washington State has shown that patients with cancer are 2.65 times more likely to experience personal bankruptcy than those without cancer.[4] One startling follow-up study revealed that patients with cancer who declared bankruptcy had a 79 percent greater mortality risk than those who had not.[5] Since this revelation, researchers have focused on understanding the full impact of financial distress on health outcomes, with studies associating significant out-of-pocket costs with decreases in quality of life and treatment adherence.[6,7] The term *financial toxicity* was coined to describe the negative personal financial impact of cancer care, spurring additional research into how patients experience financial burden.[8]

Financial Challenges of Cancer Care Delivery

Though most research has focused on patients, we know that providers and healthcare organizations are also feeling the financial impact of increased cost sharing. A study aimed at understanding the provider burden found that for out-of-pocket patient obligations above $200, only 66.7 percent of the average balance was paid within a year, and 16.2 percent of the average balance was written off as bad debt.[5] *Bad debt* refers to debt that is deemed unlikely to be paid and is consequently written off as a loss. For high-cost care such as cancer treatment, this can amount to significant losses for the organization and is expected to increase as a result of evolving healthcare market dynamics, according to the Advisory Board.[9]

The Importance of Financial Navigation

Considering these challenges, healthcare providers are establishing financial navigation programs to ease patients' financial distress and mitigate organizational financial challenges. According to the Association of Community Cancer Centers Financial Advocacy Services Guidelines, financial navigators provide a range of services that include evaluation of health insurance benefits, identifying and enrolling patients in assistance programs, and providing financial education on health insurance coverage.[10,11]

The addition of financial navigation services holds a great deal of potential for both patients and providers. A study of financial navigation programs across four hospitals with trained financial navigators found that financial navigation can significantly benefit patients through decreased out-of-pocket expenditures and mitigate financial losses for healthcare institutions.[12]

However, there is significant variability among financial navigation programs and in the role of the financial navigator. The role itself is usually not well defined, staff often receive little to no financial navigation training, and navigators have a wide range of educational backgrounds. Because of the manual nature of the work, navigators' workflow is focused on serving patients who seek out assistance or are referred by other members of the care team (e.g., social workers); thus, navigators are not necessarily allocating their resources to patients at the highest risk of financial toxicity and bad debt.[13]

Financial Navigation at the Cowell Family Cancer Center

The Cowell Family Cancer Center at Munson Healthcare, the largest healthcare system in northern Michigan, has operated a financial navigation program since 2013. The program's two financial navigators conduct insurance optimization, assist with insurance and other program enrollment, and seek out other forms of financial assistance through foundations and free drug programs. The navigators serve 20 percent of the patient population and secure an estimated $4 million in aid each year.[14]

Financial navigation staff and administrators recognize, however, that the manual, multi-step, decentralized, and resource-intensive nature of their work places limitations on patient reach and program efficiency. Though efforts are made to identify financially at-risk patients, most patients self-select into the program. As a result, those with the greatest financial need or collection risk may not receive assistance.

An additional challenge identified by the cancer center's navigators and administrators is ongoing tracking of the program and the measurement of its benefit to the organization. Metrics such as "approved savings" do not necessarily reflect the program's actual contribution to organizational financial performance. This makes it difficult to measure the return on investment of the financial navigation program and convey its importance to senior leadership.

In January 2018, the Cowell Family Cancer Center piloted a new financial navigation platform, TailorMed, that automates and streamlines the financial navigation process. The eight-month pilot study's objective was threefold:

1. Evaluate how technology can be used to improve financial assistance for patients.
2. Evaluate the impact of using technology on financial navigation workflows.
3. Measure the associated benefits for organizational financial performance.

TailorMed Financial Navigation Platform

The TailorMed platform is a web-based software solution that interfaces with the cancer center's electronic health record (EHR) and uses clinical, insurance, and demographic data to project the patient's out-of-pocket expenses across the entire medical journey and enables the utilization of multiple cost reduction opportunities.

A patient's specific out-of-pocket estimation relies on real-time pricing data, the patient's insurance benefits (which are automatically investigated), and the actual orders that are recorded in the EHR for the diagnosis, treatment, and follow-up phases of the patient journey. The estimation is dynamic and is updated with any changes to the patient treatment plan and insurance coverage.

The platform supports a variety of cost reduction opportunities covering the full scope of financial navigation, including insurance optimization, enrollment in financial assistance programs, pharmaceutical-sponsored programs (e.g., co-pay assistance, free drugs, drug replacement), and government plans.

The platform enables a proactive financial navigation workflow by identifying "high-priority" patients with the highest out-of-pocket responsibility, financial toxicity, and billing risk. Patients are identified as high priority based on the following patient-specific data:

- *Diagnosis*. Diagnoses are investigated to identify diagnosis-specific optimization opportunities and identify patients with multiple conditions as potentially higher risk.
- *Treatment plan*. Treatment plans are used to screen for high-cost services (e.g., specialty drugs) and for uncovered services.
- *Insurance type*. Existing insurance policies are compared for potential optimization opportunities and their eligibility criteria (e.g., commercial insurance for co-pay assistance, Medicare eligibility for government plans).
- *Insurance benefits*. Insurance benefits are evaluated to identify cases of under-insurance (e.g., high cost-sharing or high-deductible plans).
- *Demographics*. Financial status is used to identify financial burden and risk levels as well as eligibility for available opportunities.

In addition to the financial navigation software, the TailorMed platform includes an analytics dashboard (TailorMed Financial Insights) that enables ongoing tracking, measuring, and reporting of key performance indicators.

Measuring the Impact of Financial Navigation

As part of the study, the Cowell Family Cancer Center developed a methodology to account for the various forms of assistance awarded to patients in the financial navigation program. Previously, tracking and measuring the outcome of financial navigation was mostly based on the "approved savings" metric. Though it provides some insight into the value of the financial navigation program, this metric does not accurately indicate how different types of savings contribute to the financial performance of the organization and is often perceived as inflated. This new methodology differentiates between "revenue increase" and "community benefit."

Community benefit includes aid which benefits the patient directly and not necessarily the hospital, such as aid that is intended to offset living expenses, provide free services (e.g., free or replacement drugs) or aid for services that are not billed by the hospital (e.g., oral drugs). "Community benefit" may be capped by the patients' out-of-pocket expenses for a certain service, while "approved savings" will capture the total value of the awarded assistance.

Revenue increase includes aid that benefits the financial performance of the hospital. This is aid that has a direct impact on the hospital's ability to collect revenue—in other words, expenses that would not have otherwise been paid by the patient and are either sent to collections or written off as bad debt by the hospital. Revenue increase is calculated based on the patient's individual medical and financial circumstances and subsequent likeliness to pay for all or part of their treatment-related expenses. Each savings type (e.g., manufacturer co-pay programs, premium assistance, insurance optimization, etc.) was evaluated to determine the direct contribution to the hospital revenue. For example, an approved free drug program would have different implications than an approved co-pay assistance program, as the financial risk to the hospital is different.

In addition to quantitative data analysis, qualitative data were collected over the course of the eight-month pilot through monthly feedback meetings, where management used the TailorMed Financial Insights dashboard to track relevant key performance indicators. During these meetings, team members were asked to assess the software and their responses were recorded. Feedback on ease of use, impact on workflow, and impact on productivity was collected.

Study Results

The financial navigator software analyzed 4,616 patients who visited the Cowell Family Cancer Center during the study period (see Figures 1-3, page 42, for demographic, insurance, and diagnosis distribution). Of those 4,616 patients, 244 were identified as high priority and were reviewed by financial navigators.

Of the 244 patients reviewed by the cancer center's financial navigators, 181 patients (74 percent) received at least one form of assistance. The remaining 63 patients were either ineligible for assistance due to their income or no available funds were receiving applications at the time.

In total, the approved savings for all 181 patients was $3,553,453—an average of $19,632 per patient, representing an increase of more than $2,000 of average savings per patient compared to previous years.[14] About $1,525,500 was attributed to community benefit or direct patient support, and $259,593 was measured as revenue increase.

Financial aid was obtained through the following six categories:

- Co-pay assistance programs (including manufacturer and foundation co-pay assistance)
- Free and replacement drug programs
- Living expenses (e.g., non-medical support)
- Insurance optimization
- Government programs
- Premium assistance programs.

(continued on page 43)

Figure 1. Gender Distribution (n = 4,616)

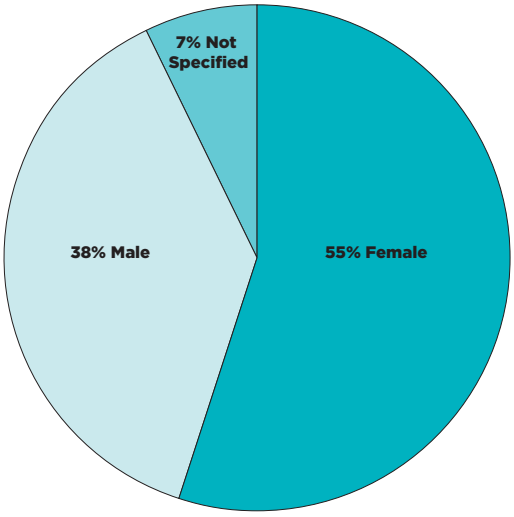


Figure 2. Payer Mix (n = 4,616)

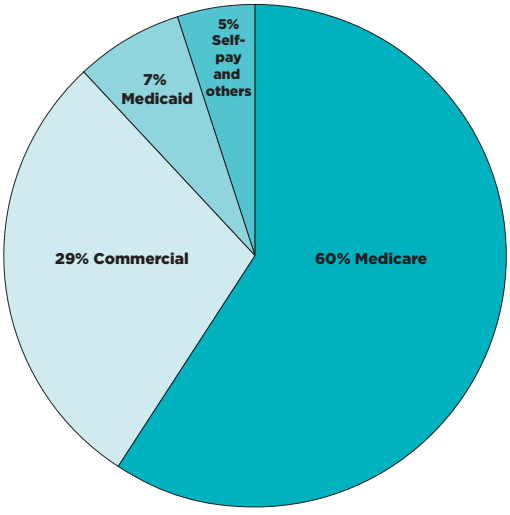
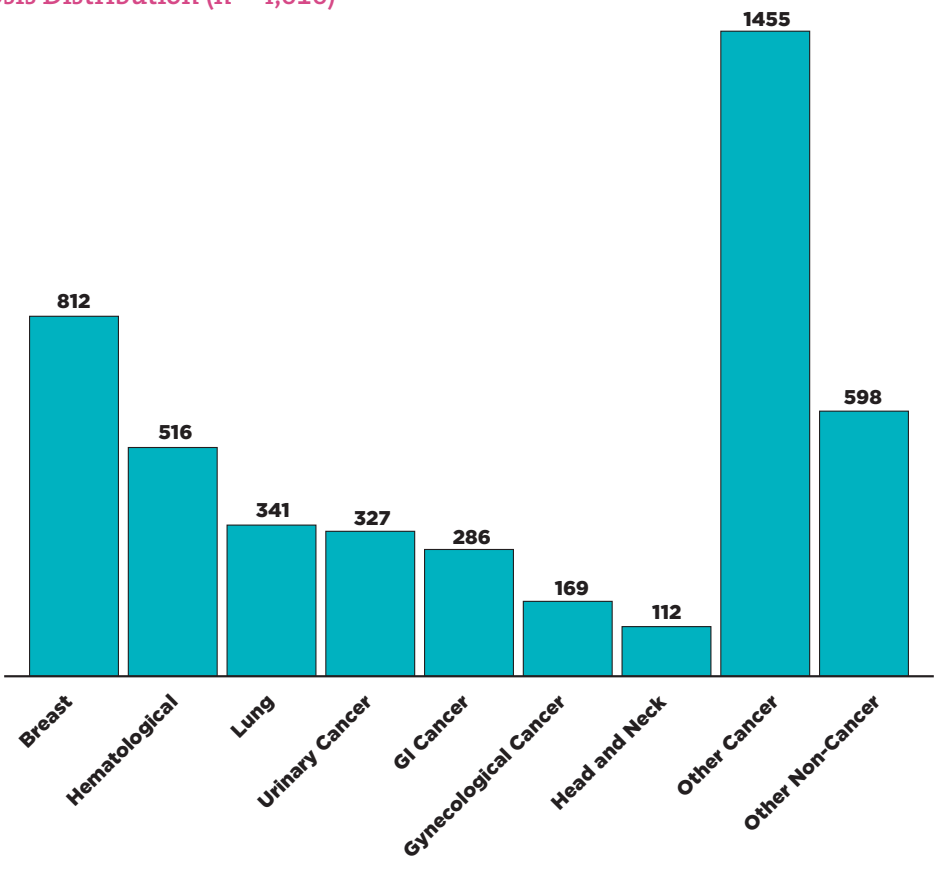


Figure 3. Diagnosis Distribution (n = 4,616)



(continued from page 41)

Financial assistance was used to support a variety of medical services that were part of the patient's treatment course. Figure 4, below, summarizes the distribution of medical services for the study population.

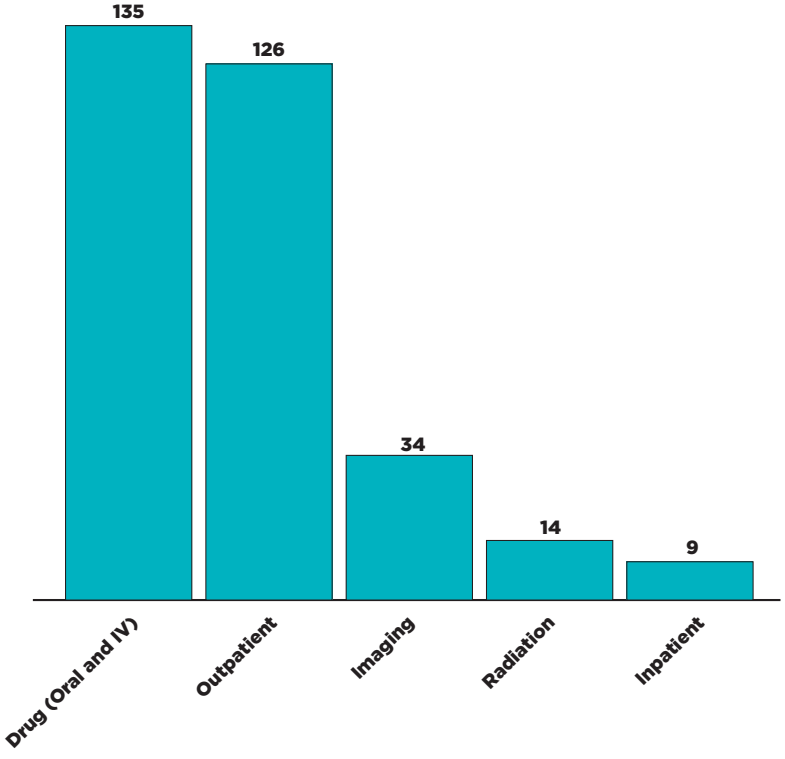
Of the 181 patients identified by the software as high priority, 52 patients (28.7 percent) received co-pay assistance, 8 patients (4.4 percent) were enrolled in government insurance plans, and 46 patients (25.4 percent) received free drug or drug replacement assistance; 74% of approved free drug programs were for oral drugs and 26% of approved free drug programs are for IV drugs. Eighty-five patients (47 percent) received assistance with living expenses, and 12 patients (6.6 percent) received other forms of assistance. Twenty-two patients (12.2 percent) received more than one form of assistance. Table 1, right, breaks down the distribution by assistance categories.

It is important to note that the pilot did not take place during an open enrollment period. Had the pilot taken place during open enrollment, there may have been an increase in the number of patients benefiting from insurance optimization. For patients who benefited from insurance optimization, the software suggested opportunities such as enrolling in Medicare (for patients turning 65) and enrolling existing Medicare patients in Medicare Part D, Medicare Advantage with Part D, or Medicaid. Figures 5-7, pages 44-45, show the demographic, insurance, and diagnosis distribution for the assisted population.

Table 1. Distribution of Assistance Categories

Intervention	Number of Patients	Average Savings per Patient ($)
Co-pay programs	52	12,582
Free drug programs	46	60,607
Insurance optimization	10	3,709
Government plans	8	4,000
Premium assistance	2	3,300
Nonmedical financial assistance	85	419

Figure 4. Distribution of Medical Services



In addition, the navigation team was able to begin tackling the transportation need at the cancer center, using the TailorMed Platform calculated transportation costs and the resources generated by the available navigation opportunities.

Further Discussion

This eight-month pilot study documented the use and impact of an automated financial navigation software.

Using the software, financial navigators at the Cowell Family Cancer Center were able to conduct an analysis of all active patients and determine their level of financial distress and potential impact of different financial navigation activities. Previously, with only two financial navigators, we largely relied on patients self-referring into the financial navigation program regardless of financial risk or potential match for aid opportunities. As a result, among the patients who were classified as high-priority, 74 percent received some form of financial assistance during the study. This percentage can be attributed to the financial navigation software's ability to identify patients for the navigation program, screening not only for those at risk of financial toxicity but also for eligibility for current aid opportunities.

Furthermore, the tracking and reporting capabilities of the software's analytics dashboard improved ongoing tracking and recording of the financial navigation process and its outcomes. Establishing an agreed-upon and sustainable method of measurement created alignment among financial navigators and cancer center administration and leadership, driving process improvement.

Through the software, existing workflows were evaluated and, in some cases, modified. Navigators no longer needed to manually search for relevant financial opportunities and keep track of the application status for each patient participating in the financial navigation program. The software allowed navigators to directly access any opportunities for which a patient was a match, displayed the entire life cycle of the application process, and allowed the navigator to immediately track the value of any captured benefit. Furthermore, the use of technology cut down on administrative work for the navigators by consolidating multiple work lists, spreadsheets, and applications.

Management also highlighted additional software capabilities that could potentially benefit financial navigation programs, suggesting that future iterations attempt to address inefficiencies in the tracking and ordering of free drugs and streamlining the billing process for approved financial resources.

Closing Thoughts

Rising healthcare costs in the United States continue to outpace growth in the gross domestic product. The burden of these staggering expenses is particularly acute for patients with cancer. Financial navigation has been looked to as one solution to mounting financial challenges for both patients and healthcare organizations. Though many financial navigation activities are done manually—limiting potential benefits of the program for both patients and the organization—it was our experience that automating the financial navigation processes helps to:

Figure 5. Gender Distribution (n = 181)

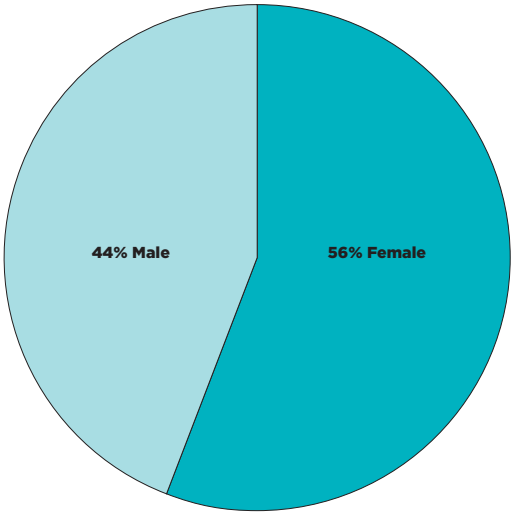
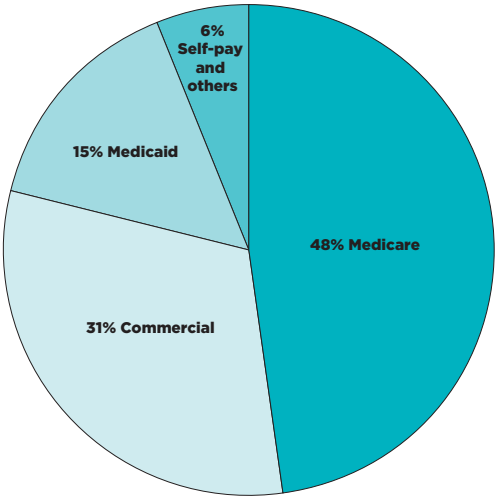


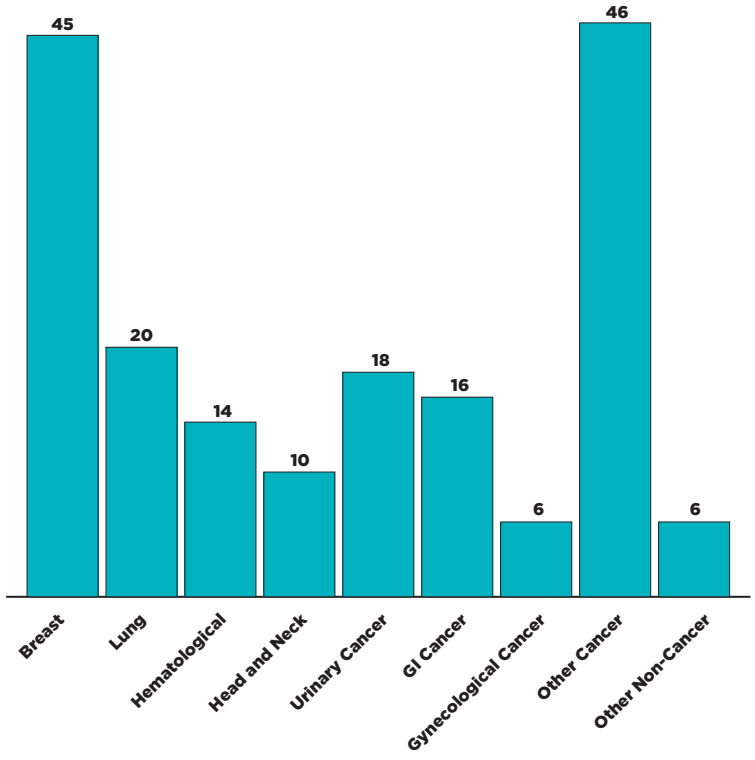
Figure 6. Payer Mix (n = 181)



- Secure additional financial assistance for patients.
- Reduce the workload associated with ongoing navigator tasks.
- Strengthen the focus on patient outreach and financial counseling.
- Accurately measure the impact of financial navigation on the organization's financial performance.

It is our conclusion that technology can play a major role in improving financial navigation services and programs at cancer programs across the United States by decreasing out-of-pocket costs for patients, increasing revenue for hospitals, and quantitatively measuring the "value" of these services, allowing management to collect and report on return on investment. OI

Figure 7. Diagnosis Distribution (*n* = 181)



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Providing Psycho-Education to Combat Fatigue

BY SHANNON MORTON, LMSW, MA; ALISON SNOW, PHD, LCSW, OSW-C;
ANTHONY H. BUI, MS3; AND MANJEET CHADHA, MD

A quality improvement pilot study with radiation oncology patients

Cancer-related fatigue is one of the most common symptoms associated with cancer and its treatment, specifically radiation treatment.[1] The National Comprehensive Cancer Network (NCCN) defines *cancer-related fatigue* as a distressing, persistent, and subjective sense of physical, emotional, and/or cognitive tiredness and exhaustion related to cancer that interferes with usual functioning.[2] Cancer-related fatigue can persist for months or years after the completion of treatment, and it occurs across a range of cancer types. Despite the prevalence of cancer-related fatigue, it remains underreported, underdiagnosed, and undertreated.[2] The impact of cancer-related fatigue on a patient's ability to function is significant, making the symptom distressing. Because fatigue is categorized as a distressing symptom for many patients with cancer, attention to interventions to decrease cancer-related fatigue is needed.[3]

Of the non-pharmacologic interventions for cancer-related fatigue, exercise has had the strongest evidence of a therapeutic benefit. Exercise improves a wide range of biopsychosocial outcomes in patients with cancer, but further research is needed to better understand the scope of benefits.

Non-Pharmacologic Interventions

Of the non-pharmacologic interventions for cancer-related fatigue, exercise has had the strongest evidence of a therapeutic benefit. Exercise improves a wide range of biopsychosocial outcomes in patients with cancer, but further research is needed to better understand the scope of benefits. Studies have demonstrated that patients who exercise are less tired, less depressed, and sleep better.[4] Patients with cancer significantly reduce the amount of exercise they perform during treatment due to disease-induced fatigue and side effects of treatment; however, exercise during cancer treatment has many positive effects.[4-6] NCCN consensus panel guidelines advise that patients and families be provided with anticipatory guidance about fatigue and recommendations for self-management, especially when beginning fatigue-inducing treatments such as radiation.[2] Two studies demonstrated that patients welcome psycho-educational interventions related to fatigue and will apply the skills they learn in order to manage fatigue.[7,8] Mitchell and colleagues suggest that interventions should also be directed at strengthening healthcare team members' skills in intervening with cancer-related fatigue.[9] A systematic and meta-analytic review of non-pharmacological therapies for patients with cancer suggested that both psychosocial and exercise-based therapies demonstrated potential for effectively decreasing cancer-related fatigue.[10]

Our Quality Improvement Pilot Study: Materials and Methods

Although it seems counterintuitive to many patients, increasing physical activity may reduce fatigue. Therefore, it was our goal to create a quality improvement (QI) initiative to address this misconception by educating patients on the positive impact of exercise during treatment. Oncology social workers at Mount Sinai Downtown Cancer Centers, which includes three distinct outpatient oncology practices within one hospital system, utilized the PDSA (Plan, Do, Study, Act) quality improvement tool for testing change. This model is implemented by developing a method to test the change (Plan), carrying out the test (Do), observing and learning from the consequences (Study), and determining what modifications should be made to the test (Act).

> It is important for physicians and other healthcare professionals to recognize and assess their patients for cancer-related fatigue so that interventions can be offered. At many cancer programs, exercise and wellness programs are offered free of charge, and patients need to be notified of the availability of existing resources at the center where they are receiving treatment and/or in the community.

Oncology social workers met with patients during their first 10 days of radiation treatment to provide psycho-education. Patients were given a folder that included an aerobics DVD tailored for patients with cancer (Move for Life), educational information on fatigue, and information on free exercise programs offered onsite and in the community. Free exercise classes were available to patients in all five boroughs of New York City, and yoga and tai chi were available onsite in the cancer center. During this initial meeting, patients were also asked whether they exercised. Exercise was defined by the patients' self-definition and therefore varied between patients.

Social workers spoke with patients a second time for a post-treatment follow-up phone call one week after completing radiation. At the time of the post-treatment call, social workers asked patients several questions about their exercise routines during treatment. This information allowed social workers to understand patients' exercise habits, as well as any barriers to exercising during treatment.

NCCN guidelines recommend that patients be evaluated regularly for fatigue using a brief screening instrument.[2] Our team selected the Brief Fatigue Inventory (BFI) to measure patients' fatigue.[11] The screening was administered during the social worker's initial visit with the patient and again over the phone one week post-treatment. The social workers first met with patients during the beginning of treatment, because the occurrence of fatigue increases with the number of weeks patients are treated with radiotherapy.[12] The purpose of the BFI is to assess severity of fatigue and the impact of fatigue on daily functioning in patients with cancer. The survey takes less than five minutes to complete. Patients are asked to rate their level of fatigue from 0, which indicates no fatigue, to 10, which indicates the worst fatigue imaginable. A global fatigue score is obtained by averaging all the items on the BFI.

Oncology social workers at our three outpatient cancer centers in New York City met with patients during their first week of radiation treatment in radiation oncology waiting rooms and treatment areas. From October 2016 through December 2017, patients with all cancer diagnoses were targeted for this QI pilot study. In January 2018, we implemented the PDSA quality improvement worksheet to test the changes made by the initial pilot and to help focus social work efforts in identifying target populations. As a result, patients receiving radiation therapy for breast or prostate cancer were targeted, because these individuals were more likely to participate in exercise programs. Only patients receiving at least six weeks of radiation treatment and who were able to communicate in either English or Spanish were included in the pilot. Patients with comorbid medical or psychological conditions that could limit the patient's ability to exercise were also excluded from participating. Social workers experienced difficulty reaching patients by telephone at the time of follow-up and therefore the number of post-treatment BFI scores was reduced. Due to space constraints, social workers were sometimes only able to meet with patients in waiting areas. There were no costs associated with implementing this program.

QI Pilot Study Findings

Complete data were gathered for 38 patients. Of those patients, 30 participants were female and 8 were male. The average age of our participating patients was 60; however, patient age ranged from 34 to 83 years old. Sixty-eight percent of the patients had breast cancer, 16 percent had prostate cancer, 13 percent had head and neck cancers, and 3 percent had gynecological cancers (see Table 1, page 49).

Patients who reported exercise during treatment had an average initial BFI score of 2.0 and average post-treatment score of 2.5. Patients who reported no exercise during treatment had an average initial BFI score of 3.1 and an average post-treatment BFI score of 2.9. The difference in post-treatment scores demonstrates that patients participating in exercise during radiation treatment report lower average BFI scores than patients who are not participating in exercise during radiation treatment. This is consistent with

(continued on page 50)

Table 1. Patient Demographics of the QI Pilot Study

Demographics	*N*	Percentage
Male	8	21
Female	30	79
Age		
30-40	2	5
41-50	5	13
51-60	10	26
61-70	15	39
71-80	5	13
81+	1	3
Diagnosis		
Breast	26	68
Prostate	6	16
Head and neck	5	13
Gynecological	1	3

Table 2. BFI Scores Pre- and Post-treatment

	N	Average Initial BFI Score	Average Post-treatment BFI Score
Patients who reported *exercise* during treatment	22	2.0	2.5
Patients who reported *no exercise* during treatment	16	3.1	2.9

Table 3. Self-Reported Barriers to Exercise

Self-Reported Barrier	*N*	Percentage
No barrier	16	42
Fatigue	8	21
Time constraints	7	18
Physical limitation	5	13
Dislike of exercise	2	5

(continued from page 48)
findings of other cancer-related fatigue studies, although it is not statistically significant. The data also showed that patients who exercised during treatment had an increase in fatigue post-treatment, whereas people who did not exercise had a decrease in fatigue post-treatment. One could infer that having a lower baseline BFI score might make patients more susceptible to experiencing fatigue during treatment and that exercise may prevent them from becoming as fatigued as they would had they not exercised (see Table 2, page 49).

Data were gathered on patients' methods and frequency of exercise. Patients most commonly reported walking and exercise classes as their preferred exercise, and most patients reported that they exercised two to three times per week. Patients also reported barriers to exercise during treatment, including time constraints, fatigue, dislike of exercise, and physical limitations. Patients also frequently expressed having no barriers to exercise but chose to not exercise during treatment (see Table 3, page 49).

Currently, our QI pilot only gathered two BFI data points for 38 patients. More participants are needed in order to generalize the findings and to assess the impact of our initiative. We experienced difficulties reaching patients post-treatment for the follow-up BFI assessment and, as a result, we were unable to gather full data on many patients for whom we obtained baseline data.

Closing Thoughts

It is important for physicians and other healthcare professionals to recognize and assess their patients for cancer-related fatigue so that interventions can be offered. At many cancer programs, exercise and wellness programs are offered free of charge, and patients need to be notified of the availability of existing resources at the center where they are receiving treatment and/or in the community. Oncology social workers, patient navigators, and advanced practice nurses often have access to this type of information. Furthermore, finding effective QI methods to test and evaluate interventions is essential for delivery of high-quality and high-value care. It is also important to highlight the role of exercise during cancer prevention, treatment, and survivorship. Oncologists should be encouraged to explain the health benefits, safety, and risks associated with exercise during treatment.

A future direction for this QI initiative may include collaboration with additional providers, such as nurses, to increase the dissemination of information to patients and to provide important clinical perspectives. Although this QI pilot project was limited by its small sample size, it has resulted in enough encouraging information to embark on a larger study. Our hope is to continue this initiative with the goal of reaching a greater number of patients. OI

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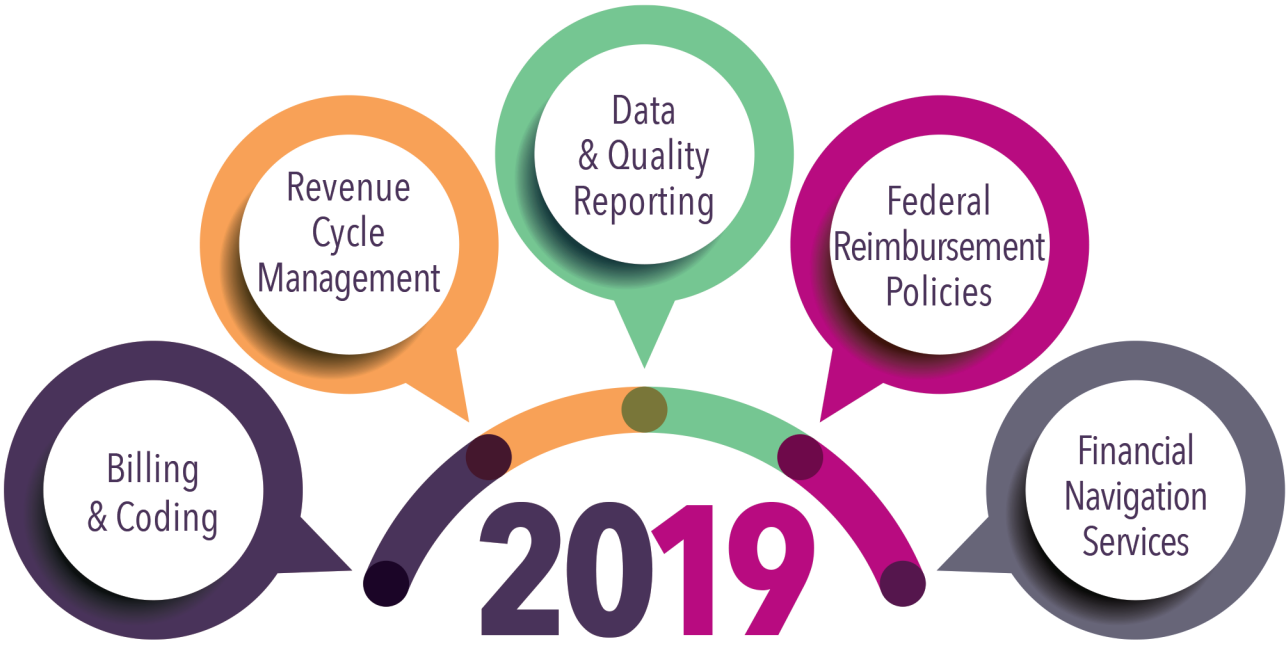

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Hoboken, New Jersey

TUESDAY, APRIL 9
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Maine Hotel
Portland, Maine

THURSDAY, JUNE 6
Sentinel Hotel
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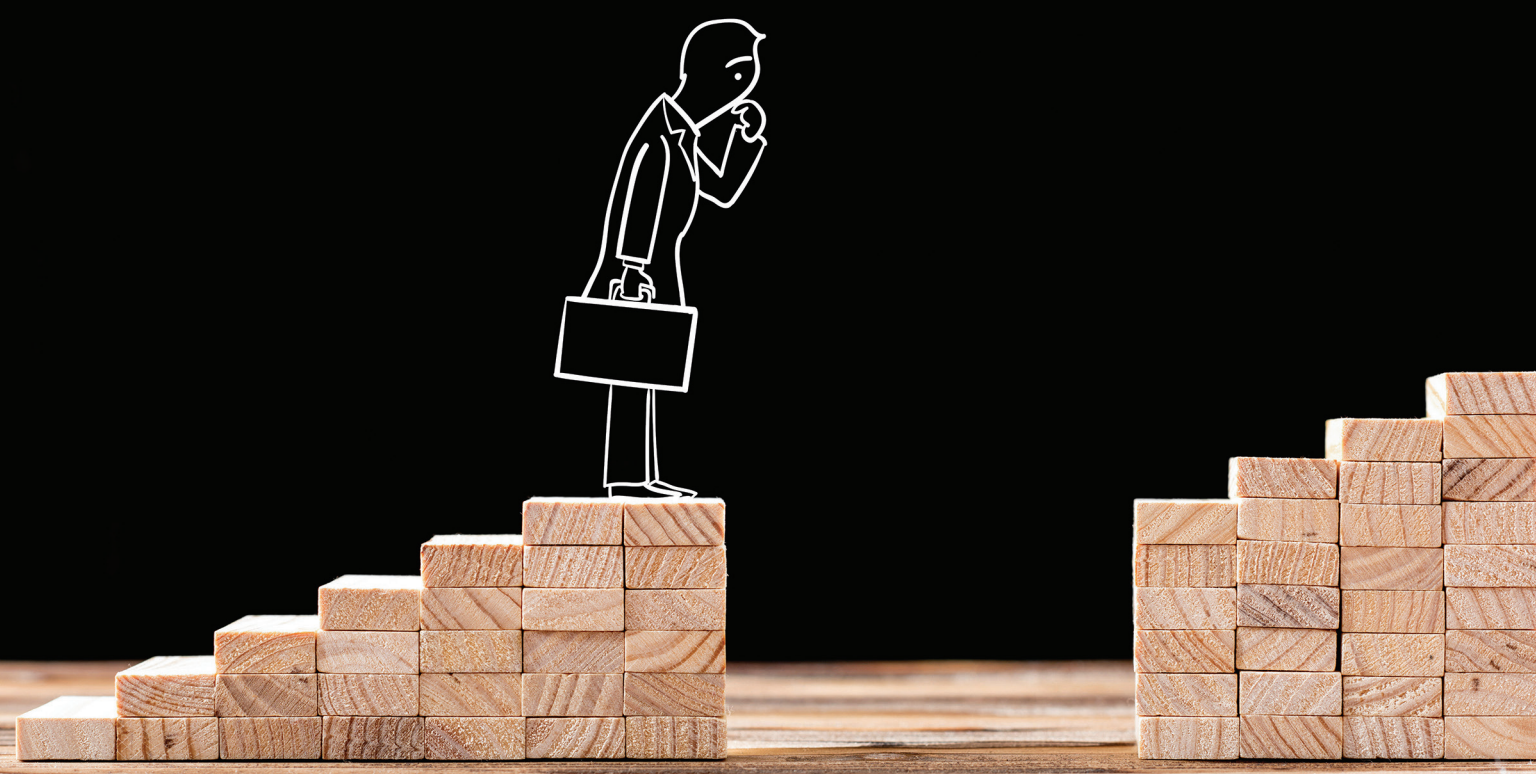

BY MONICA KEY, DNP, BSB-M, ANP-C, APRN, AOCNP

Discovery of an enhanced orientation process

In Brief

This original research project examined the national clinical issue of a practice gap by advanced practice providers (APPs) new to the oncology specialty as part of a continuous quality improvement (QI) project to discover how best to close this practice gap by enhancing existing orientation processes. Review of results in phase one of this continuous QI process identified many opportunities for improving current processes. APPs entering the oncology workforce need more than graduation from an advanced practice program; formal training is necessary to assist the new APP to practice safely in the complex field of oncology.

A *practice gap* is defined as the education, knowledge, and skills of a generalist advanced practice provider—who completed his or her advanced education in specific foci such as family, adult, geriatrics, women's health, or pediatrics—practicing oncology with little or no oncology education, knowledge, or skills.[1-4] A new advanced practice provider (APP) in oncology is defined as an APP practicing within one year of entry into specialty.[1]

The need for well-prepared advanced practice providers to enter the oncology workforce and practice safely involves more than graduating from an advanced practice program.[5-7] The national consensus model defines specific population foci for advanced practice providers but does not include specialty education.[8] Adding to the practice gap are more issues such as:[9,10]

- A shortage of oncology providers
- The continued increased growth in numbers of an aging population
- A great surge in cancer treatment options
- A larger cancer survivorship population
- Expanded access to healthcare through the Patient Protection and Affordable Care Act.

Taken in combination, these factors require healthcare organizations to create APP orientation, residency, or fellowship programs to bridge the gap from education to practice in oncology (see Table 1, page 54).[10,11]

Several primary care APP residency and fellowship programs exist in the United States to address this practice gap phenomenon.[12-17] These residency and fellowship programs have increased in number largely due to the enactment of the 2010 Patient Protection and Affordable Care Act, which allowed more people to receive healthcare services. However, within specialties such as oncology, these residency and fellowship programs are still in their formative stages. In addition, no best practices are yet established for addressing the practice gap in oncology.

The purpose of this original research project is to discover the essential components of an established oncology orientation program for APPs and identify additional orientation needs in

Table 1. Glossary of Terms[a]

Term	Definition
Fellowship	A planned, comprehensive program through which currently licensed APPs can acquire the knowledge, skills, and professional behaviors necessary to deliver safe, quality care that meets defined (organizational or professional society) standards of practice; may include organizational orientation; must include practice-based experience and supplemental activities to promote professional development.
Orientation	The educational process of introducing individuals who are new to the organization or department to the philosophy, goals, policies, procedures, role expectations, and other factors needed to function in a specific work setting.
Residency	A planned, comprehensive program through which currently licensed providers with less than 12 months of experience can acquire the knowledge, skills, and professional behaviors necessary to deliver safe, quality care that meets defined (organizational or professional society) standards of practice; must be at least six months, encompassing organizational orientation, practice-based experience, and supplemental activities to promote professional development.

[a]Data from the American Nurses Credentialing Center's 2016 Application Manual: Practice Transition Accreditation Program.[12]

order to further close the practice gap for APPs new to oncology. This effort is considered the first phase of a continuous QI process at a large oncology institute.

Setting the Stage: The Clinical Issue

There are several ongoing issues specific to the oncology specialty:[1]

- The increasing number of cancer diagnoses each year
- The increasing number of people living with or surviving cancer
- The impact of the healthcare system and its ongoing changes
- The location of available oncology clinics and providers across the nation.

In 2016 the American Society of Clinical Oncology (ASCO) estimated a 48 percent increase in oncology service need by the year 2020 with only a 14 percent increase in additional oncology providers in that same time,[2] resulting in a projected shortage of up to 4,000 oncology providers.[1] Additionally, fewer providers—specifically physicians—are opting to specialize in oncology.[18]

Thirty-six percent of practicing APPs in oncology have received oncology-specific content in their training program; among certified oncology APPs, 21 percent have received a graduate education focused in oncology.[1] According to an unpublished ASCO survey, even with minimal training, it takes an estimated 12 to 24 months before a new oncology APP begins to feel competent.[3]

It is unrealistic to require academic universities to meet the specific and comprehensive education needed for all types of medical specialties. This expectation is especially unrealistic considering the rapidly changing environment of healthcare and technology. Specialty knowledge can be obtained through specialty certification within graduate education or as a postgraduate effort[19]; thus, the burden of additional specialty education for APPs falls on the hiring oncology organizations. Specific oncology knowledge is needed within the first year of practice to avoid errors, near-misses, patient harm, or poor patient outcomes. APPs new to oncology need close supervision and a dedicated mentor to ensure patient safety.

A residency or fellowship program approach may be a viable option when constructed and supported with a process, team, and revenue stream.[16,20] Many oncology physicians are not familiar with the role of an APP and therefore may be unable or unwilling to provide basic oncology knowledge in a traditional one-on-one, on-the-job manner.[21] Further, physicians are no longer expected to provide all of the professional education and interaction when it comes to onboarding a new member to the oncology practice team. A few organizations have started their own oncology residency or fellowship programs for APPs or are in the process of creating their own program (see Table 2, page 56).

APPs continue to be one of the answers to address the healthcare provider shortage in oncology, and it is important to recognize how bridging the practice gap in oncology with a new APP will benefit not only the APP and oncology team but also the patient. The complexity of providing oncology services is supported further by the fact that a cancer diagnosis can encompass more than 200 different diseases.[22] A 2016 ASCO survey determined APPs in oncology believed that additional training is required before beginning their practice in oncology.

As leaders, all healthcare professionals are charged with setting the stage to optimize practice in any capacity possible. These include capacities outside direct patient care, such as orientation, training, and supporting fellowship or residency programs for new practitioners to ensure that all needs are being met. Just as medical students participate in residency programs and fellowships to build their experience and practice their skills, these same opportunities would benefit APPs.

Economic constraints, workforce shortages, and increasing pressure from regulating bodies for high-quality oncology care require a higher level of preparation for new APPs. The Institute of Medicine's *The Future of Nursing* report recommends that APPs (e.g., nurse practitioners) practice at the full capacity of their scope and recommends transition to practice programs to meet the growing needs of oncology patients.[23]

QI Clinical Setting and Target Population

The setting for this continuous QI project was Norton Healthcare in Louisville, Ky., a leading and innovative not-for-profit U.S. healthcare system. This system encompasses an oncology program, Norton Cancer Institute, with a presence at five large hospitals, seven oncology outpatient clinics, two oncology prompt care clinics, and three oncology radiation centers. Norton Healthcare encompasses a metropolitan area spanning two states and a population of more than 1,475,000. Norton Cancer Institute is made up of more than 30 oncology board-certified physicians, 35 APPs (33 nurse practitioners and two physician assistants), nurses, and ancillary staff.

Project Methodology

The planned intervention for this QI project was the use of a custom-designed survey. Surveys conducted for similar reasons from other oncology practices, academic, and national membership institutions were gathered for review and some survey questions were adapted and/or revised for this project with permission from the respective organizations.

A pilot effort with the new survey was conducted with two oncology APPs from a separate local oncology practice and a factor analysis was conducted to validate questions and content. Revisions to some survey questions and content were made for clarification and necessary changes were identified from this first pilot. A second pilot survey was sent to seven unique oncology APPs (nurse practitioners and physician assistants) who no longer worked at the same local oncology practice to ensure that clarifications on questions were addressed. Of the seven invitations sent to the second pilot survey group, five surveys were completed and returned. A second factor analysis was conducted to validate survey content.

Through this research process, it was determined that no existing instrument or tool exists to evaluate, measure, or provide best practices or guidelines on how to orient and train APPs new to oncology. In the past, oncology organizations evaluating this issue developed their own unique survey through workshops or taskforces. A mixed-methods approach for this study was used to obtain and assess quantitative and qualitative data.

The survey contained 47 questions and included demographic information, characteristics of roles, and functions of roles and facilitated open-ended questions and selectable answer questions. Reliability and validity were already determined by the two prior pilot efforts.

Results

The data collection process began in March 2018 and ended in April 2018. The survey was sent via electronic mail to 35 APPs practicing at a local, large oncology program that had an initial orientation process in place since 2014. A total of 17 surveys were completed, resulting in a 48 percent response rate.

The data analysis consisted of qualitative and quantitative methods used to draw inferences from the data.[24] Ongoing consultation with Dr. Suzette Scheuermann, a statistician at Spalding University, and Doctor of Nursing Practice (DNP) Faculty Lead Dr. Nancy Kern assisted to garner other data points on a regular basis during this process. I conducted several data analysis reviews with the raw data, narrative comments, and statistics to verify the common themes and final recommendations drawn from this effort.

Data revealed that approximately 82 percent of APPs had received an orientation for their oncology role. Just over 41

Table 2. Oncology APP Fellowship Programs in the United States[a]

Florida University of Miami Sylvester Comprehensive Cancer Center	No degree offered; one year long
Illinois Loyola University Chicago, University of Chicago	Degree offered; four-year program (part-time)
Missouri Children's Mercy Kansas City; Pediatric Hematology-Oncology Fellowship for Advanced Practice Nurses	No degree offered; three-year program
New Jersey Rutgers Cancer Institute of New Jersey; Oncology Nursing Fellowship	No degree offered; three-year program
New York Columbia University	Subspecialty program degree offered only to those re-enrolled in a master of science or doctor of nursing practice program
North Carolina Carolinas HealthCare System	No degree offered; one year long
North Carolina Duke University	Degree offered; one year long
Ohio The Ohio State University Comprehensive Cancer Center-Arthur G. James Cancer Hospital and Richard J. Solove Research Institute	No degree offered; one year long
Texas University of Texas MD Anderson Cancer Center	No degree offered; one year long
Texas Texas Children's Hospital	No degree offered; three months long

[a]Data from Alencar et al.[9]

percent of these same participants had an orientation process that lasted three months or less. The majority agreed that being knowledgeable in oncology was important to the oncology advanced practice role. Participants believed that an orientation process increased patient safety, increased confidence, and improved retention of APPs. Documentation involving three separate multi-page, hard-copy forms currently used in the existing orientation process was viewed as helpful but burdensome.

More than 50 percent of participants found the following aspects of the current orientation process to be most helpful:

- Rotating through the various clinic areas
- Precepting in the acute care setting (inpatient rounds in the hospitals)
- Observing care received by the cancer patient in the radiation oncology departments
- Formal online oncology education (such as the Oncology Nursing Society's Post-Masters Foundations in Cancer Care online course or the American Society of Clinical Oncologists' Advanced Practice Provider Oncology online courses).

Survey responses identified three top reasons why this orientation program is most helpful to the new APP:

1. It helps establish a foundation of oncology knowledge.
2. It builds skills and experience for safe care.
3. It creates an atmosphere for teamwork, including rapport-building with primary and ancillary staff.

The top 10 topics to include in the *initial* orientation process (defined as being within the first three months of the orientation process) were identified as being "important" to "very important" in the survey and are listed below in order of weighted importance:

1. Recognizing and managing cancer complications
2. Recognizing and managing oncology emergencies
3. Recognizing and managing drug toxicities
4. Developing critical thinking skills
5. Communicating with team members and others
6. Presenting case to team and/or primary oncologist
7. Ordering and interpreting procedures

8. Ordering and interpreting imaging
9. Ordering and interpreting lab tests
10. Ordering and interpreting bone marrow biopsies.

In addition, the top nine topics to include *after* the initial orientation process are listed below in order of weighted importance:

1. Work-up for possible progression of cancer
2. Ordering needed items (labs, imaging, etc.) for new cancer diagnoses
3. Assessing for cancer recurrence
4. Drug class knowledge
5. Using the electronic health record
6. Using the oncology treatment interface software
7. Prognostic indicators
8. Working up a new patient
9. Staging cancer.

It is important to note that the first 10 items ranked as most important in the initial orientation period were also ranked as being just as important after the initial orientation period. To reduce redundancy, these 10 items were excluded from the second list above.

The top three orientation topics cited as being most important to include were identified as:

1. Recognizing and managing oncology emergencies
2. Ordering and interpreting lab tests (such as pathology)
3. Ordering and interpreting imaging.

In addition, when asked whether there were elements to improve in the current orientation process, responses identified the following themes:

- More time with preceptors
- Creation of a fellowship program
- More physician involvement
- More structure during orientation
- Availability of mentors.

Overall, 94 percent of participants agreed that improvements and/or enhancements could be made to the existing orientation process. Themes from narrative comments to support their answers were compiled by identifying frequently repeated key words and concepts (see Table 3, right). The data revealed that 69 percent of the participants believed that they still needed additional training in oncology. This finding validated the importance of knowledge in oncology because the APPs in this target audience reported a mean of five years of experience in their current role as an oncology APP. Finally, 19 percent stated that they still are not confident in their current oncology role (see Table 4, page 58).

One of the limitations of this study was the use of self-reported measures for the responses in the survey. Some of the APPs may have had difficulty remembering the orientation process experienced in detail if much time had passed. The other limitation involved the small sample size (n = 17).

Table 3. Narrative Content Analysis: Common Themes Developed from Survey Comments[a]

Communication
Fellowship program
Keeping current in oncology knowledge
Mentors
More time with preceptors
Ongoing knowledge is vital
Physician involvement
Safety
Structure
Subspecialty content

[a]Themes listed in alphabetical order. The author conducted several data analysis reviews with the raw data, narrative comments, and statistics to verify the common themes and final recommendations drawn from this effort. From this, results were compiled, shared with the Spalding University DNP committee, and summarized. Themes from narrative comments to support survey answers were compiled by identifying frequently repeated key words and concepts.

QI Project Discussion and Conclusion

There is an ongoing national discussion in the oncology specialty for the need to intentionally develop an orientation process for APPs new to oncology.[3,6,11,25,26] This type of orientation is important for ongoing investigation because the oncology APP is considered a vital part of the oncology team.[27] Considering limited resources, a growing provider shortage, and the impact of people living longer with cancer,[25,26] many oncology programs continue to research and work together to help bridge this gap for all to benefit.[3,6,11,25,26] This QI project adds to the growing body of evidence for the need of orientation efforts in the oncology specialty to bridge the practice gap for APPs such as nurse practitioners and physician assistants.[26]

Orientation efforts are commonplace in any facility hiring new people to their team. Training for APPs is not standard practice in oncology programs. Currently, orientation efforts identified in the literature last two weeks or up to a year in total time; no best practices have been established. It is up to each oncology program to determine its needs when considering the orientation and training necessary for APPs new to the oncology specialty. The literature reflects this APP practice gap phenomenon as becoming an important one to address to improve care for oncology patients.

From the data analysis of the QI project, I make three conclusions. First, there was overwhelming agreement that improvements are needed in the existing APP orientation process. Second,

Table 4. Characteristics of Surveyed APPs (*n* = 17)

	Nurse Practitioners (*n* = 16) Physician Assistants (*n* = 1)	
Characteristics	**Mean[a]**	**Range**
Current age in years (*n* =12)	42	27-56
Years in current role (*n* = 14)	5	0-14
Total years of experience in oncology (*n* = 14)	10	1-20
Racial identity	***n* = 13**	**Percentage[b]**
White or Caucasian	12	92
Two or more races	1	8
Responses	**Yes**	**No**
Received an initial oncology orientation (*n* = 17)	14	3
Still in initial orientation period (*n* = 15)	1	14
Certified in oncology (*n* = 13)	7	6
Current orientation can be improved (*n* = 16)	15	1
Currently need additional oncology training (*n* = 13)	9	4
Reported still not confident in current role (*n* = 16)	3	13

[a]Mean of the sample (not all survey participants answered every question).

[b]Because of rounding, not all percentages total 100.

survey respondents identified 10 topics for oncology orientation content as crucial for learning and understanding within the initial first three months. Third, the realization that improvements needed will require more resources in the future led to short-term and long-term recommendations. Initial short-term recommendations include standardizing the process to build a consistent structure and develop a small number of baseline oncology competencies for new APPs to demonstrate by end of initial orientation. One long-term recommendation includes consideration for a feasibility study regarding residency or fellowship programs.

Additional themes emerged from the data: the need for better, proactive, and ongoing communication regarding the orientation process; more time with preceptors; and a more structured orientation process. The next step will be a second phase to continue efforts to improve APP orientation with consideration to the short-term and long-term recommendations previously discussed. OI

UPDATE: At time of this printing, our organization has now formed a special committee to support an improved onboarding, orientation, and integration program not only within the oncology specialty but also as a new offering throughout the entire organization, which encompasses more than 300 advanced practice providers across multiple specialties.

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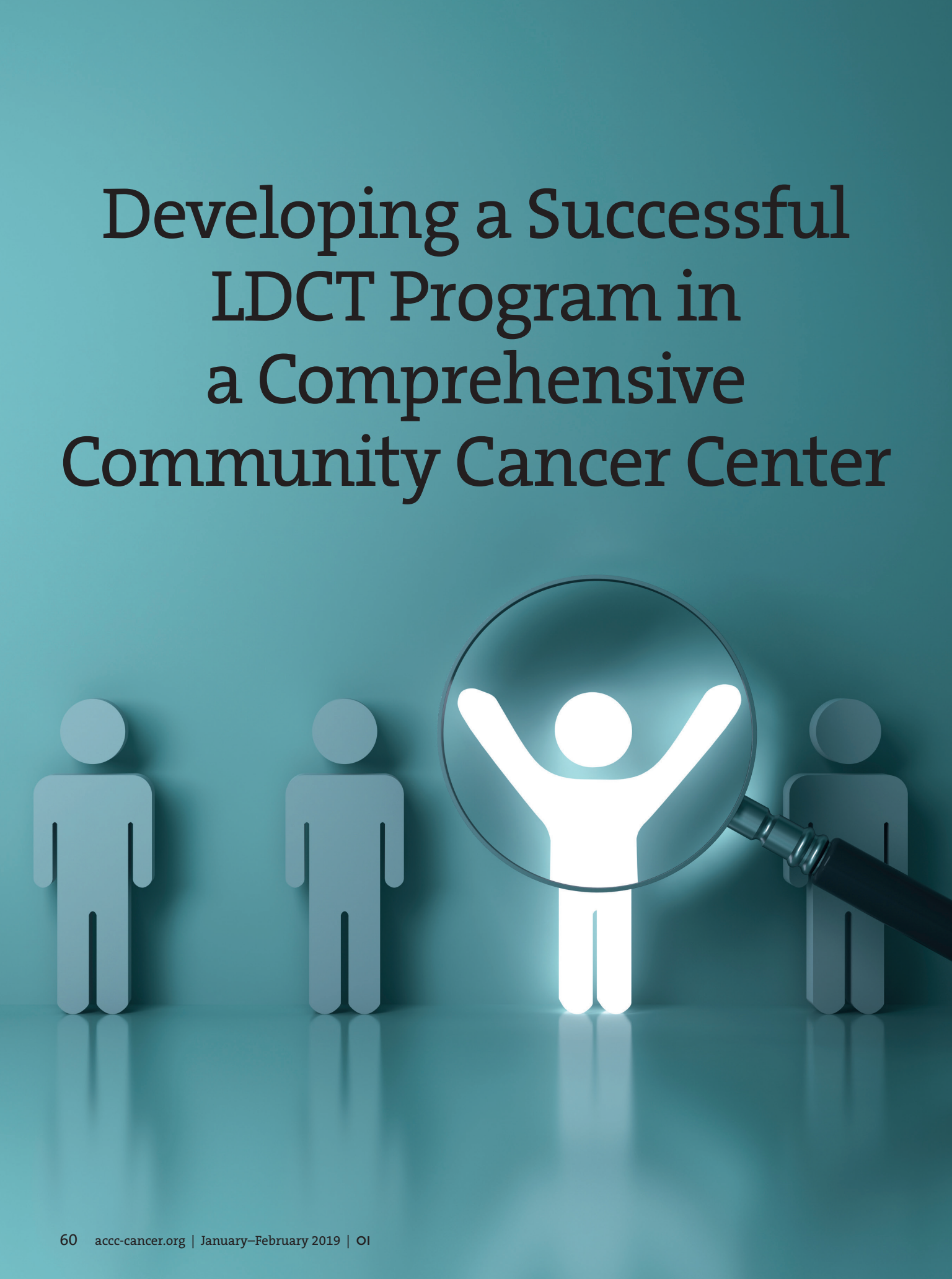
Developing a Successful LDCT Program in a Comprehensive Community Cancer Center



BY KALEEN KASSEM, BS, AND CHRISTINA LAIRD, MBA

Screening helps providers detect earlier stage malignancies in at-risk patients

Lung cancer is one of the leading causes of death in both men and women in the United States. The American Cancer Society estimates that lung cancer is responsible for 155,870 deaths each year—84,590 men and 71,280 women.[1] Research also shows that each year more people die of lung cancer than of breast, prostate, and colon cancer combined.[1] The number of lung cancer cases continues to rise annually, and the rates of survival remain relatively low.[2] In the United States, the five-year survival rate for lung cancer is currently 18 percent, which could be due to the lack of symptoms during the early stages and a lack of an effective screening test until recently.[3] Although controversy continues to exist regarding the effectiveness of low-dose computed tomography screenings (LDCT), recent research conducted by the National Lung Cancer Screening Trial showed a 20 percent decrease in lung cancer mortality with the use of annual LDCT screenings.[4]

Though LDCT screenings have become a critical tool in detecting earlier stage malignancies before symptoms even appear, there has been a consistent need for a comprehensive program to help decrease lung cancer mortality rates. A critical part of implementing such a program is providing an environment that supports patients—an environment free from the traditional stigma associated with smokers.

Though LDCT screenings have become a critical tool in detecting earlier stage malignancies before symptoms even appear, there has been a consistent need for a comprehensive program to help decrease lung cancer mortality rates. A critical part of implementing such a program is providing an environment that supports patients—an environment free from the traditional stigma associated with smokers.

The Lefcourt Family Cancer Treatment & Wellness Center

Lung cancer continues to be the leading cause of cancer deaths in Bergen County, N.J. According to a Bergen County Public Health Profile Report, 11.4 percent of Bergen County residents are smokers and 14.6 percent of New Jersey residents are smokers.[5] In an effort to reduce these statistics and provide a support environment for these individuals, Englewood Health created the Lefcourt Family Cancer Treatment and Wellness Center.

In March 2014, the Lefcourt Family Cancer Treatment & Wellness Center implemented an LDCT program with the help and guidance of chief of radiology, Mark Shapiro, MD. The Radiology Department and the Lefcourt Family Cancer Treatment and Wellness Center worked diligently to develop a program to:

- Target identification of patients appropriate for LDCT in primary care offices

- Follow these patients in terms of repeat scans or other follow-ups (our nurse navigator ensured that our patients had the proper follow-ups in a timely manner)
- Upgrade our computed tomography (CT) and scanner equipment to optimize dose and radiation exposure.

The eligibility criteria used at the institution mirrored the patient eligibility criteria posted on the American College of Radiology's (ACR) Lung Cancer Screening website.[6] In order for an individual to be evaluated within our LDCT screening program, the individual must be between the ages of 55 and 80, be asymptomatic, have a 30 pack-year or greater history of smoking, and be a current smoker or have quit within the last 15 years.[7] Nodules detected on the LDCT were then assigned a Lung-RADS clinical risk category based on ACR guidelines. As depicted in Table 1, below, the guidelines categorize patients based on the presence, size, and nature of nodules. Patients were screened prior to their first LDCT to make sure that they met all eligibility criteria.

Three scanners are used to perform the LDCT screenings: the GE Lightspeed VCT, Toshiba Aquilion, and Toshiba Prime. These scanners were chosen for use by the program because they can enhance patient safety utilizing low-dose radiation while providing high-quality CT images.

After patients appropriate for LDCT were identified, their results were then analyzed to assess the outcomes of the program thus far. Our analysis consisted of 823 patients who were seen between March 2014 and June 30, 2018. Patients were grouped into two categories: new and existing patients. New patients had never been to the institution prior to their LDCT screening; existing patients had been to the institution prior to their scan but had never received an LDCT chest screening previously. Grouping patients into these distinct categories allowed for the ability to keep track of the number of new patients we were receiving and measure the success of our LDCT program. There has been a total of 17 new patients in 2015, 34 new patients in 2016, and 92 patients in 2017.

The Cancer Center team was able to establish a prospective database examining multiple parameters, such as evolution of change in Lung-RADS classification, histology of tumors, follow-up rates, and overall success of the program.

Provider Buy-In and Staff Education

In 2014 physicians from Thoracic Medical Oncology, Radiology, Pulmonology, Thoracic Surgery, and Primary Care were recruited to guide the development of the LDCT program. This multidisciplinary approach ensured that the program had support from a wide range of disciplines.

Written awareness materials were sent out to referring physicians which included:

- Flyers
- PowerPoint presentations
- Additional educational information on the medical center's website and newsletter
- Email reminders
- Educational information presented by physicians during grand rounds
- A "Shine a Light" community engagement event dedicated to patients with lung cancer.

Table 1. ACR Assessment Categories (Condensed)

Category Descriptor	Category	Management
No nodules; definitely benign nodules	1	Annual screening in 12 months
Nodule with very low likelihood of becoming malignant	2	Annual screening in 12 months
Probably benign nodules with a low likelihood of becoming active cancer	3	Six-month follow-up scan
Suspicious findings	4A 4B 4X	Three-month follow-up scan or PET/CT CT/PET/tissue sampling

PET = positron emission tomography.

To further increase buy-in, referring physicians were contacted first and asked whether they were comfortable with us scheduling their patient for an LDCT screening if they were not already scheduled. This type of outreach allowed referring physicians to become part of the process rather than excluding them from their patient's care. It allowed them to continue to be the patient's advocate and first point of care.

Presentations during grand rounds were delivered on several different occasions by the chief of radiology, thoracic medical oncologists, and surgical oncologists. These sessions, along with physician educational dinners, were geared toward educating our internal physician community about the screening program benefits. To keep track of patient information, nurse practitioners developed an LDCT tracker in Excel to document patient demographic information, referring physician information, dates of scans, and follow-up information.

Physician champions also held educational dinners during which they told their peers about the program benefits for their patients. They showed National Lung Cancer Screening Trial data and details on the internal referral process. Education was not limited to dinners; it also included an annual symposium focused on lung cancer and lung cancer screenings.

Our physician referrals came from physicians within a variety of specialties. As seen in Figure 1, below, a large part of referrals came from pulmonary and internal medicine physicians. There was also a significant number of referrals from nephrology, infectious disease, hematology oncology, gastroenterology, and cardiology.

An important part of program implementation was educating the call center staff on eligibility requirements and scheduling procedures. Having the staff trained and comfortable with scheduling patients under this program made the process of recruiting new patients easier and more efficient.

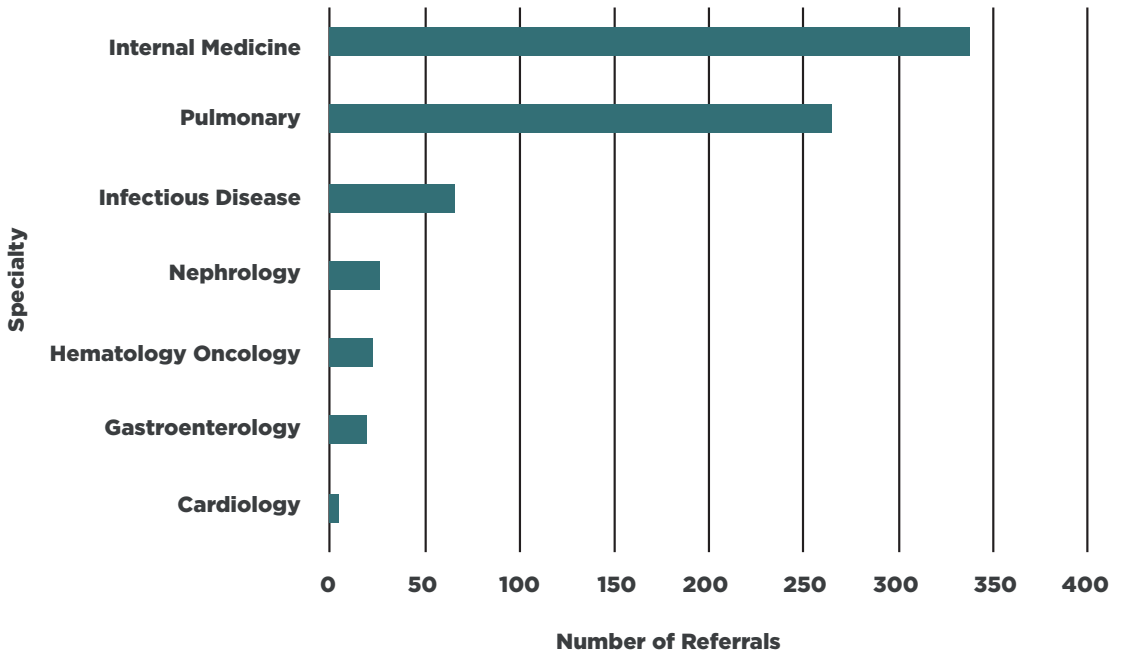
As the patient population continued to grow, an oncology patient navigator was appointed to oversee the patient follow-up spreadsheet and be responsible for contacting physicians and patients with follow-up information in addition to their existing responsibilities.

After screening hundreds of patients, the program relied heavily on a premed student from Ramapo College of New Jersey to build an Access database from the original Excel spreadsheet and work closely with navigation to send monthly follow-up letters to remind patients of their annual exams. The student was also responsible for updating the database weekly with new patient and follow-up scan information. In 2017 we updated the Access database to capture any nodules found and applicable follow-up information and included a portion in which we can document whether the patient was presented at our bimonthly cancer conference (a Commission on Cancer accreditation requirement).

In addition to direct referrals from providers, Lefcourt reached out directly to the community by promoting the LDCT program during National Smoke Out Day in November, posting ads in local newspapers and on social media. One full day of CT machines was reserved for free lung screenings (regardless of insurance coverage). Twenty patients were scheduled for scans on Smoke Out Day in 2016 and 30 were scheduled for scans on Smoke Out

(continued on page 65)

Figure 1. Physician Referral to Low-Dose Program by Specialty



Englewood Health, Main Campus, Englewood, N.J.

Christina P. Laird, MBA, administrative director and Jolynne Guidotti, MSN, BSN, OCN, oncology patient navigator, Lefcourt Family Cancer Treatment and Wellness Center at Englewood Health, review the Access database built to track LDCT screening patients.

(continued from page 63)

Day in 2017. This yielded one newly diagnosed cancer each Smoke Out Day.

Data and Results

A total of 1,087 scans were conducted. As a result of the continued success of the LDCT program, the highest number of patients was seen in 2017. A major goal was to identify frequency of pulmonary nodules. Of the scans, 487 showed the presence of pulmonary nodules. These nodules were found in 376 out of 823 patients (45.7 percent).

Using ACR guidelines,[7] 48 out of 823 patients were classified as high-risk individuals (4A, B, X; 5.83 percent). Table 2, below, reveals that most of the studied scans showed results that categorized patients as either Lung-RADS 1 or Lung-RADS 2 (low risk). These low-risk results totaled 89 percent of the total scans.

Table 3, below, demonstrates the histopathological characteristics of the tumors found, including cancer type and staging. Within the study period, 10 malignancies were found. These malignancies included one squamous cell carcinoma, five adenocarcinomas, one non-small cell carcinoma, one lymphoma, and two unknown types.

The youngest patient with a malignancy was 60 years of age, and the oldest patient was 77. Additionally, 7 of the 10 malignancies were found in males. The malignancies were found in different locations—three were found in the right lower lobe, two in the right upper lobe, two in the left lower lobe, and three in multiple sites. Case IV showed metastatic cancer originating in the lung and migrating to the lymph nodes. Case VII showed metastatic malignancy originating in the lung and migrating to

Table 2. Results of LDCT Scans

Lung-RADS	Number of Scans	Percentage of Total Scans
1	639	58.9
2	327	30.1
3	73	6.72
4	48	4.41

Table 3. Histopathology of Malignancies

Case	Type of Cancer	Location	Gender	Age	Stage	Treatment
I	Squamous cell carcinoma	Right lower lobe	M	66	IIIA	Surgery Radiation Chemotherapy
II	Adenocarcinoma	Right upper lobe	F	69	IIIA	Surgery Chemotherapy
III	Adenocarcinoma	Right upper lobe	M	74	IA	Surgery
IV	Metastatic non-small cell carcinoma	Multiple sites	M	75	IIIB	Chemotherapy
V	Adenocarcinoma	Left lung	M	77	IIIA	Surgery
VI	Adenocarcinoma	Right lower lobe	F	77	IA	Surgery Radiation
VII	Metastatic adenocarcinoma	Multiple sites	M	69	IV	Surgery Radiation
VIII	Metastatic lymphoma	Multiple sites	M	68	IIIA	Chemotherapy
IX	N/A[a]	Right lower lobe	F	60	N/A[a]	N/A[a]
X	N/A[a]	Left lower lobe	M	73	N/A[a]	N/A[a]

[a]Details of malignancy not available because patient was treated at another institution.

LDCT machine at the Lefcourt Family Cancer Treatment and Wellness Center.

the liver. Case VIII showed metastatic lymphoma migrating to the bone marrow and lungs (see Table 3, page 65).

With respect to pathologic staging, 3 out of 10 were noted to be stage III. There were also two primary adenocarcinomas that were found to be stage I. Three of the 10 malignancies were found to be non-lung primary and resulted in treatments such as chemotherapy and radiation. The last two malignancy stages were unknown because these patients were treated at another institution.

Although nodules were found in 45.7 percent of patients, only 25 biopsies needed to be performed. The details of these biopsies are noted in Figure 2, below.

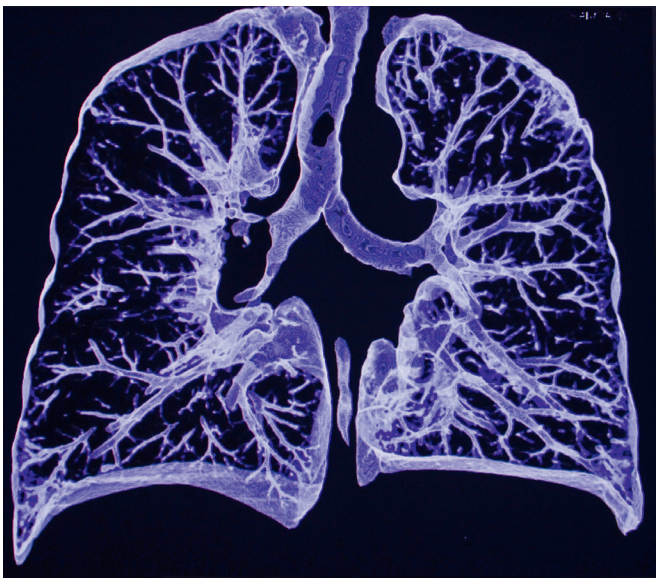
Lessons Learned

Implementing an LDCT program at Englewood Health has not only resulted in institutional growth, but has also provided us with valuable lessons from which other medical centers can learn.

First, it is critical to realize the importance of physician education. Because physicians are the ones referring patients and initiating the process of the scans, it is imperative to start with educating physicians on the importance and value of LDCT screenings.

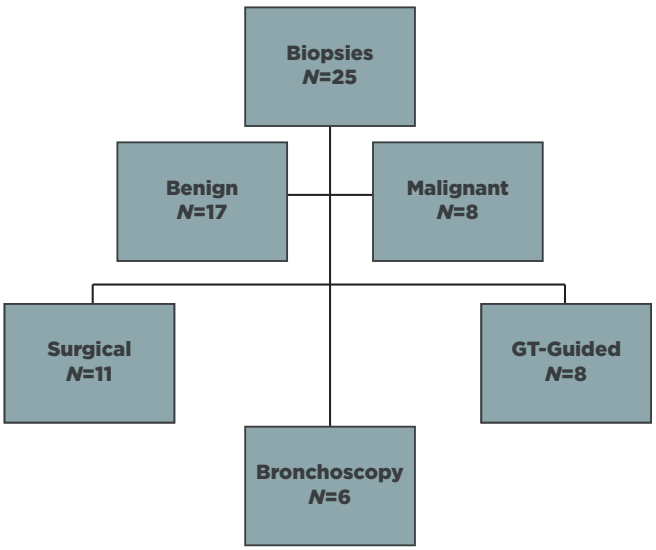
Physician champions also play a large role in educating the rest of the physician population. Dr. Shapiro, chief of radiology, is one such physician with a champion role in our LDCT program. As soon as Dr. Shapiro reviews a suspicious nodule, he immediately calls the primary physician. This simple action creates a sense of urgency and allows for follow-up to be done in a timelier manner.

To recruit physician champions, it is imperative for administrators to provide incentives to potential recruits. Administrators



Lungs visualized using an LDCT machine.

Figure 2. Results of High-Risk Nodule Evaluation



can develop physician champions by forming disease management teams, developing educational symposiums, hosting annual meetings, and bringing in visiting experts in the field. These activities can bring candidates to the forefront.

Another important part of building a successful LDCT program is making it convenient for physicians to refer new patients. To address this area, we implemented pre-made prescription pads that were sent out to physician offices and included in every follow-up letter to patients.

A valuable lesson learned is the importance of advertising to the community directly. National Smoke Out Day has become a success within the LDCT program at Englewood Health because we were able to reach out to the community directly through local newspapers. Through this event, the volume of patients being scanned annually for lung cancer has increased. Additionally, being open seven days a week has made it convenient for patients to schedule scans.

Collecting data proved to be a critical part of the overall process. Before the implementation of the Access database, most of the low-dose data was kept within an Excel sheet. This sheet would be filled out after the patient had come in for the scan and would include all patient demographics and scan results. Although this allowed for an organized system for tracking patients, it was not an effective system for keeping up with follow up scans. The implementation of the Access database has allowed for a much more organized and effective way of tracking patients and keeping up to date with follow up scans. The current protocol for collecting data first includes pulling a weekly report through Epic, the hospital's healthcare software system. This report includes all patients that have received an LDCT and includes all scan results along with patient information. The patients are then inputted individually into the Access database.

Lastly, becoming an accredited institution is vital. Patients search for the best accredited institutions for their care, and becoming accredited by the ACR in December 2015 has helped in the growth of the LDCT program. OI

Christina Laird, MBA, is administrative director of cancer center operations, and Kaleen Kassem, BS, is a research intern at The Lefcourt Family Cancer Treatment and Wellness Center at Englewood Hospital and Medical Center, Englewood, N.J.

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A Small, Island Community Hospital Removes Barriers to Lung Cancer Screening and Detection

BY DONNA DELFERA, RN; MICAYLA ALBERS; LYSLE AILSTOCK, MD;
AND CHARLES SHELTON, MD

Getting LDCT lung cancer screening to work within a network

The Outer Banks Hospital is a 21-bed critical access community hospital uniquely situated on a barrier island on the coast of North Carolina. A not-for-profit hospital and joint venture between Chesapeake Regional Medical Center in adjoining Virginia and Vidant Medical Group in Greenville, N.C., it is one of several community hospitals in eastern North Carolina that serve a local population of roughly 30,000 year-round residents. Because of the location and climate, the area continues to grow, especially among retirement-age people. Like many other communities across the country, the Outer Banks sees its fair share of lung cancer, and in most cases, patients present at later stages when therapies are less likely to have a curative effect. This can be daunting to both patients and their healthcare providers.

Like many other communities across the country, the Outer Banks sees its fair share of lung cancer, and in most cases, patients present at later stages when therapies are less likely to have a curative effect. This can be daunting to both patients and their healthcare providers.

Our Call to Action

In 2014, The Outer Banks Hospital decided to make cancer care a high priority, hiring a nurse administrator, Robin Hearne, to coordinate services at the hospital. Hearne embraced the challenge, and her first order of business was to create a Cancer Committee. The newly formed group conducted a review of the cancer types diagnosed or treated at the hospital, identifying lung cancer consistently as one of the top cancers in prevalence locally by site. Further analysis of the local registry data revealed a high preponderance of advanced stages among local lung cancers over the prior two years (95 percent presented as stages III/IV in 2013 and 88 percent as stages III/IV in 2014), which perhaps reflected a lack of thoracic services (Figure 1, page 71). In a hospital that is typical of a small community setting, patients are typically referred elsewhere for primary evaluation and diagnosis, and by the nature of the referral process they are usually scored in other tumor registries if early stage, where local therapy is also typically done and completed (e.g., a lobectomy). Nonsurgical patients (e.g., advanced stage patients who require services such as radiation and chemotherapy that *are* available locally) are then typically referred back to the community, creating some bias in staging for a community that treats lung cancers. Although this was a source of stage migration and potential bias, our Cancer Committee believed that analysis of the demographic data in our community highlighted a clear need to change the patterns of care for this disease. Accordingly, the Cancer Committee looked at the development and implementation of a low-dose computed tomography (LDCT) lung cancer screening program.

The Outer Banks Hospital is remotely located on a barrier island.

The detection rate of cancer in patients with abnormal Lung-RADS category 4 was markedly higher at The Outer Banks Hospital than elsewhere in the United States, again pointing to the idea that our LDCT program is likely being offered to a higher-risk population and that our process is quite efficient.

Getting Started

Because of its size and remote location, The Outer Banks Hospital does not possess the resources to support either a pulmonologist or a thoracic surgeon. The hospital typically sees 20 to 25 cases of lung cancer per year, and the majority are diagnosed outside the area for this reason. They are often late in presentation for this reason, and perhaps this accounts for some of the later stages. Therefore, in order to build an effective screening (and diagnostic) process, the hospital decided to partner with a larger thoracic program that had produced quality outcomes in the region for lung cancer, and Vidant Cancer Care nicely fit that bill.

Vidant Cancer Care is a Commission on Cancer-accredited comprehensive community cancer program in Greenville, N.C., that enjoys a great model for thoracic services. A tertiary care center that includes East Carolina University and Vidant Medical Group, Vidant Cancer Care is a center for excellence in lung cancer, which is its most common cancer by site in eastern North Carolina. Because The Outer Banks Hospital is part of a corporate network with Vidant Health, we used a hub-and-spoke wheel model that leveraged shared resources centrally in Greenville. Mark Bowling, MD, head of the pulmonary team at Vidant Cancer Care and champion of its low-dose CT program, agreed to help pilot the program at The Outer Banks Hospital beginning in December 2014. With Donna Delfera, the nurse navigator for the thoracic program at The Outer Banks Hospital, partnering with Dr. Bowling and his team at a larger center with all available and necessary services, this program goal was easily achievable.

Committing Hospital Resources

The Outer Banks Hospital agreed to commit resources to address this identified issue with smoking-related cancers, which are more common in our region (Figure 2, page 72). The decision was an

easy one because it did not require additional capital expenditures. (The hospital already had an existing computed tomography [CT] scanner [64 Slice GE] for diagnostic radiology services.) Administration engaged the support of the hospital's development council to assist with uninsured or underinsured patients who qualified for LDCT scans. At the time we began this program, Medicare had not yet approved reimbursement of LDCT. Roger Lever, MD, a hospitalist at The Outer Banks Hospital and former chair of the Cancer Committee, was an early local champion for this program, as was Dr. Lysle Ailstock, a body radiologist with Eastern Radiologists. It was their idea—made possible by support from the radiology department—to implement a pilot LDCT lung cancer screening program in this small community hospital.

Critical to the pilot program's success was Donna Delfera, RN, who was assigned as the site-specific nurse navigator for lung cancer, as well as for coordinating the LDCT screening pilot with Vidant Cancer Care. She coordinated every patient case and tracked them in a database. She reported back to the primary ordering physician all cases requiring follow-up based on significant or abnormal results (Lung-RADS category 3 and Lung-RADS category 4). The primary care physician then directed the workup and care efficiently, and patients were referred for surgical or further radiological evaluation as indicated. A "pulmonary nodule" clinic at Vidant Cancer Care in Greenville (2.5-hour drive) helped to facilitate efficient evaluation of these patients, as did access to a pulmonologist in adjoining Virginia. The LDCT lung cancer pilot was overseen with periodic reviews by a physician on the Cancer Committee.

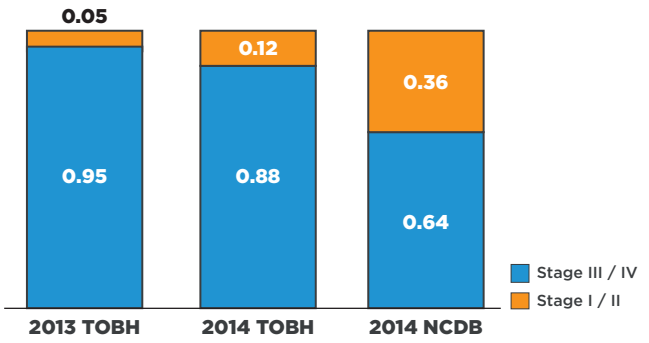
Engaging Local Providers

To engage local providers, the Cancer Committee sent a delegate (Dr. Shelton) out into the community with the nurse navigator to discuss the LDCT screening program and encourage support. Meetings were typically short and held at lunchtime, and food was provided to encourage attendance. In total, The Outer Banks Hospital was able to engage five primary care groups that see most of the local patients considered at risk. The Outer Banks Hospital also provided an educational program with continuing medical education to local primary care providers. The expert speaker panel included a pulmonologist (Dr. Bowling), a thoracic oncologist from Vidant Cancer Care, and a thoracic surgeon who outlined potential patient and provider benefits of an LDCT screening program.

Interim Analysis

The Outer Banks Hospital performed more than 350 LDCT scans in the first three years as part of the screening program, and it is by far still the leader in the network of local community hospitals. For a small community care facility that deals with a small volume of cancers (~115 analytical cases per year, all types combined), this success reflects local interest level in changing the patterns of care within the community and hitting high marks in quality metrics. Therefore, it was important for The Outer Banks Hospital to analyze data, report on outcome measures, and show how a small change in a rural hospital program can successfully translate into meaningful outcomes for the local population. To date the hospital has scanned more than 500 patients, with every case tracked in a lung cancer registry monitored by the American College of Radiology (ACR) since program inception.[1]

Figure 1. Lung Cancer Stage at Presentation



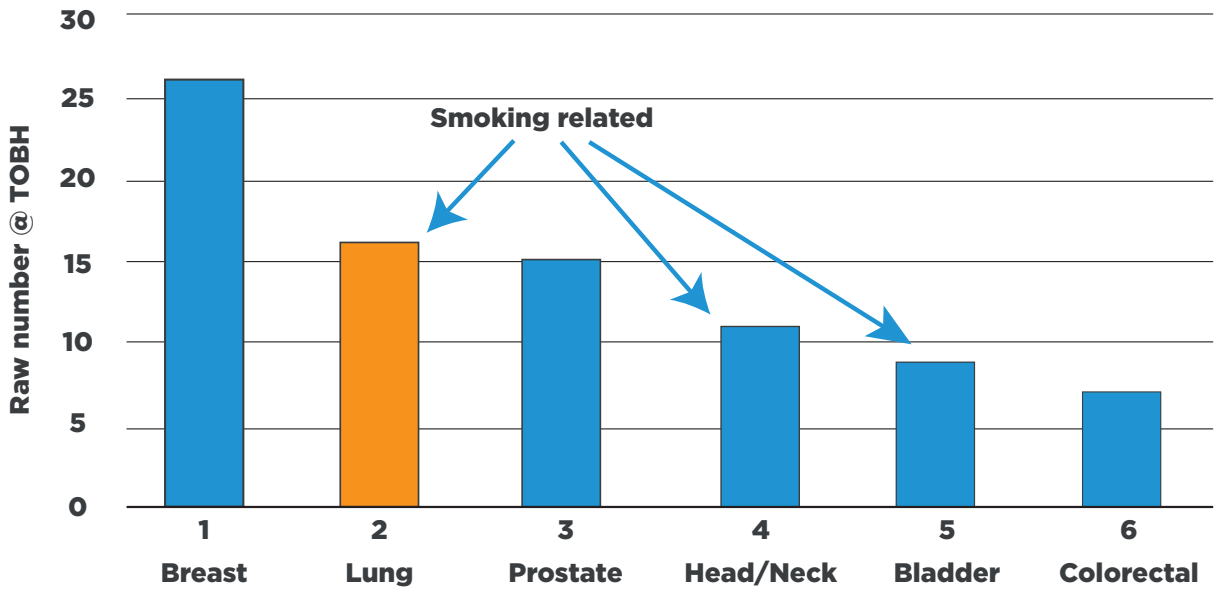
TOBH = The Outer Banks Hospital.

The first several cases were indicative of the final outcomes and highlighted the need for these services early on. Four patients were scanned in the first month of the program (December 2014), with two being read as Lung-RADS category 1 (lowest risk category) and two as Lung-RADS category 4 (the highest risk category). One of the two initial Lung-RADS category 4 patients was diagnosed with a small nodule that turned out to be a stage IA adenocarcinoma of the lung, treated surgically for cure in early 2015. The year-end data for 2014 therefore revealed four scans with one diagnosis of cancer, adding excitement to the program results early and highlighting its need.

One surprising result of the LDCT program was a high incidence of continued abnormal scans—much higher than expected after the first several years. For example, based on U.S. statistics provided by the American College of Radiology, the expected number of abnormal scans (Lung-RADs category 3 and 4) should have been 9 percent collectively based on national data[2] (5 percent for Lung-RADS category 3 and 4 percent for combined Lung-RADS category 4). The Outer Banks Hospital found combined rates of over 25 percent for these two groups spanning the first two years—much higher than the expected outcomes. Lung-RADS category 4, which is the highest risk group based on low-dose CT findings, includes subtypes 4A, 4B, and 4X—all of which were significantly higher in this community population as well.

More relevant, the detection rate of cancer in patients with abnormal Lung-RADS category 4 was markedly higher at The Outer Banks Hospital than elsewhere in the United States, again pointing to the idea that our LDCT program is likely being offered to a higher-risk population and that our process is quite efficient. One hundred percent of our Lung-RADS category 4X patients and 72 percent of our Lung-RADS category 4B patients had lung cancer diagnoses in the first year, which is extraordinarily high

Figure 2. Cancers in Our Region by Rank (Lung is Common)



TOBH = The Outer Banks Hospital.

by comparison to national ACR findings. (Expected results for screening population should be greater than 15 percent, but not to this large degree.)

For the pilot period analyzed, 11 lung cancers were detected in 10 patients. One patient had two cancers diagnosed a year apart (one was non-small cell carcinoma, and the other was small cell carcinoma). Six of these cancers diagnosed at The Outer Banks Hospital were stage IA (all adenocarcinomas), and five were stage IIIA. There were no patients with stage IV lung cancer detected by the LDCT screening program. According to Eastern Radiologists, which provided subspecialty interpretation of all images by fellowship-trained radiologists, these results supported a need to continue the LDCT program. Our cancer detection rate for this initial period (41.67 per 1,000) was significantly higher (eight times) than the national and regional average (5.44 per 1,000) according to ACR data[1] (Figure 3, page 73).

One challenge identified within our internal data review was scan compliance with recommended follow-up. For example, the ACR-recommended follow-up LDCT for a category 1 finding is one year. Sixty-five percent of the patients in year one of the LDCT program were not compliant with a follow-up LDCT (most were Lung-RADS category 1), and for year two of the LDCT program results were only slightly better at 60 percent noncompliance. This means that the majority of our patients were not continuing the screening process as originally intended. Most noncompliance came from patients feeling a false sense of security with a single scan, and some emanated from the primary providers recommending longer intervals between scans (e.g., 1.5 years) despite existing evidence-based screening guidelines. The Outer Banks Hospital looked to address this issue in late 2017 and early 2018 and recommended measures to improve compliance, including educating primary providers about the appropriate intervals and the need to continue to screen patients after the initial normal scans. To date, these efforts have helped improve our follow-up rate, but there is still much room for continued improvements in this quality measure.

A summer intern in public health from Eastern Carolina University, Micayla Albers, who collaborated on the LDCT program, noted another finding from data analysis—an opportunity for improvement in tobacco cessation. In year one, 100 percent of the LDCT patients were counseled by their primary care providers on tobacco cessation (we achieved this metric by incorporating it into the consent process); however, only 16 percent of screened patients were able to successfully quit. For year two of the LDCT lung cancer screening program, all patients were still counseled on the need to quit smoking, but only 1 percent (1 patient) quit because of the program. That one patient was someone with a newly found lung cancer who had to quit in order to undergo surgery for cure. We had no formal tobacco education program at that time and relied on the primary care providers to achieve those outcomes. This therefore became another project identified by The Outer Banks Hospital Cancer Committee, and in 2017 a formal tobacco cessation program was implemented following a proven model from MD Anderson

(continued on page 74)

Figure 3. Facility 103393: Regional Comparison

Jan-Dec 2016 with follow-up through September 2017

2016									
Measure		Your Facility (103393)		Rural		Community		South Atlantic Division	
		Rate	Num-Den	Rate	Num-Den	Rate	Num-Den	Rate	Num-Den
All Exams		97	97	24590	24590	90665	90665	32441	32441
Appropriateness of screening by USPSTF criteria		89.69	(87 / 97)	90.45	(22242 / 24590)	89.12	(80801 / 90665)	87.42	(28360 / 32441)
Smoking cessation offered		100.00	(97 / 97)	75.34	(18525 / 24590)	74.86	(67875 / 90665)	76.95	(24964 / 32441)
	Smoking cessation offered among current smokers	100.00	(55 /55)	83.46	(12706 / 15224)	83.91	(45027 / 53659)	84.11	(15347 / 18246)
Radiation exposure 1	Mean CTDIvol - Overall	5.62	(NA / 97)	3.61	(NA / 24590)	3.09	(NA / 90665)	3.20	(NA / 32441)
	Mean CTDIvol - Underweight (BMI <18.5)	3.82	(NA / 1)	2.64	(NA / 874)	2.74	(NA / 3421)	2.58	(NA / 1446)
	Mean CTDIvol - Normal (BMI of 18.5–24.9)	5.12	(NA / 22)	2.95	(NA / 6094)	2.56	(NA / 22788)	2.65	(NA / 8849)
	Mean CTDIvol - Overweight (BMI of 25–29.9)	5.78	(NA / 38)	3.21	(NA / 8037)	2.93	(NA / 30082)	2.93	(NA / 11239)
	Mean CTDIvol - Obese (BMI of 30 or greater)	5.84	(NA / 28)	4.46	(NA / 9178)	3.66	(NA / 32233)	4.09	(NA / 10438)
Radiation exposure 2	Mean DLP - Overall	213.87	(NA / 97)	100.71	(NA / 24590)	93.62	(NA / 90665)	95.62	(NA / 32441)
	Mean DLP - Underweight (BMI <18.5)	156.07	(NA / 1)	75.19	(NA / 874)	77.06	(NA / 3421)	77.50	(NA / 1446)
	Mean DLP - Normal (BMI of 18.5–24.9)	197.97	(NA / 22)	82.60	(NA / 6094)	79.02	(NA / 22788)	81.38	(NA / 8849)
	Mean DLP - Overweight (BMI of 25–29.9)	219.84	(NA / 38)	96.13	(NA / 8037)	89.76	(NA / 30082)	93.33	(NA / 11239)
	Mean DLP - Obese (BMI of 30 or greater)	217.71	(NA / 28)	119.18	(NA / 9178)	109.37	(NA / 32233)	114.03	(NA / 10438)
Abnormal Interpretation Rate	(Lung-RADS 3, 4a, 4b, 4x)	25.77	(25 / 97)	20.22	(4973 / 24590)	19.20	(17406 / 90665)	19.27	(6250 / 32441)
	Abnormal interpretation rate, at baseline exam	26.04	(25 / 96)	20.94	(4468 / 21340)	20.24	(15579 / 76961)	19.88	(5733 / 28840)
	Abnormal interpretation rate, at annual exam	0.00	(0 / 1)	14.57	(436 / 2993)	12.45	(1586 / 12737)	12.33	(401 / 3251)
Cancer Detection Rate (CDR) per 1000		41.24	(4 / 97)	5.00	(123 / 24590)	5.66	(513 / 90665)	4.59	(149 / 32441)
	CDR for prevalent cancers, detected at baseline exam	41.07	(4 / 96)	5.44	(116 /21340)	6.16	(474 / 76961)	4.82	(139 / 28840)

Future projects that everyone will learn from include finding ways to improve compliance with recommended follow-up scans in the time suggested, based on the category of findings. In this preliminary analysis, The Outer Banks Hospital lost more than half of the recommended follow-ups each year. Until the impact is made known to providers and consumers, patient noncompliance will remain a concern.

(continued from page 72)

Cancer Center, with improved results noted within a short time.[3]

Albers also conducted a financial analysis of the LDCT program, mainly for educational purposes as it related to public health outcomes. The Outer Banks Hospital believed that other small hospitals and administrators would be more excited about projects like this if they could see some impact on the bottom line. A cursory analysis was done on the revenue that the hospital generated through this program locally. This included LDCT, any follow-up scans (e.g., diagnostic positron emission tomography or CT), and any treatments generated from a diagnosis of cancer due to the screening program.

For this small hospital alone, the revenue for the two years (using no additional equipment or capital) amounted to roughly $750,000 of billed revenue and $500,000 of actual captured revenue (revenue from LDCT and follow-up scans and treatments of cancers locally at The Outer Banks Hospital). This averaged out to roughly $50,000 to $60,000 of captured revenue per cancer case diagnosed and treated locally (four cases), and Dr. Shelton estimated that the revenue for the cases referred outside The Outer Banks Hospital amounted to roughly $30,000 per patient (costs tend to be less for earlier stage cancer at diagnosis). Dr. Shelton estimated that the average revenue per screened patient seen downstream at The Outer Banks Hospital was just under $2,000, if all screened patients were included in the analysis, allowing the LDCT program to pay for itself—an important consideration for hospitals and administrators.

Future Considerations

Currently, The Outer Banks Hospital is looking at ways to improve the processes at its LDCT program. Several questions asked by the Cancer Committee included the following:

- Why do we see much higher rates of abnormal results (Lung-RADs category 4 findings and cancers) from LDCT in this rural population than elsewhere in the country?
- Are the results higher than normal rate of true positives because of an effective and efficient diagnostic workup process (e.g., partnership with Eastern Carolina University and the Leo Jenkins Cancer Center, aggressive endobronchial ultrasound, better radiology, better quality CT)?
- Are these results significantly higher than normal (i.e., more abnormal) because our population simply smokes more than others? Subset analysis revealed an average smoking rate of >50 pack-years in all screened patients for this LDCT population, which may be higher than elsewhere. Similarly, our smoking cessation rates are very poor, reflecting a higher-risk population as well (more addicted).
- Are these results higher because of other risk factors? Are there other contributing factors that we need to elucidate such as interaction of environment with smoking or genetics? (We had a high incidence of first-degree family members with lung cancer in our population of cancers.)

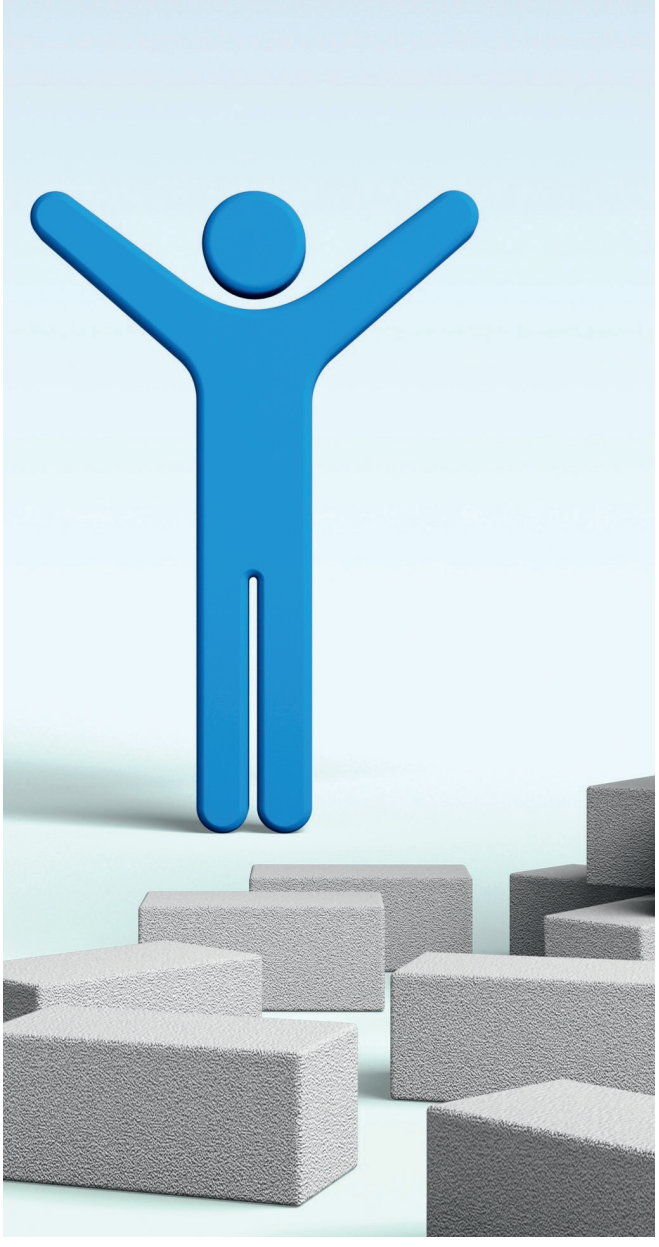
Ideally, LDCT screening picks up early stages (I/II) of lung cancer to be of the most benefit. A 2016 review of the stages of lung cancer from the tumor registry for The Outer Banks Hospital showed a fourfold increase in early lung cancer detection over the previous year. Specifically, in the preceding year (2014, when LDCT was not available), The Outer Banks Hospital saw 95 percent of its patients in stage III or stage IV lung cancer, with 5 percent in early stage (I or II). For the first time, in its 2016 annual registry review, The Outer Banks Hospital saw an increase in lung cancers being detected in early stages (I or II) within its annual registry to 20 percent, with 80 percent presenting in late stages (III or IV). Though there is more improvement to be made, The Outer Banks Hospital is already seeing further positive outcomes from its LDCT program. The 2017 registry review continues to show that this program is working at achieving its intended goal. For the year 2017, The Outer Banks Hospital performed 148 screening scans, and 100 percent of the cases detected by screening LDCT were stage I ($N = 2$), which is also improved over previous years (50 percent in year 1 were early stage, and 60 percent in year 2 were early stage). Though the overall detection rate has declined, as is typical of a screening program with time,[4,5] the majority of cases are now early stage, which is an improvement. These are, in theory, the patients who we think benefit the most by screening (Figure 4, page 75).

Future projects that everyone will learn from include finding ways to improve compliance with recommended follow-up scans in the time suggested, based on the category of findings. In this preliminary analysis, The Outer Banks Hospital lost more than half of the recommended follow-ups each year. Until the impact is made known to providers and consumers, patient noncompliance will remain a concern. Smoking cessation, which is the key to changing this disease through prevention, will become more

Figure 4. Update on Cancer Detection Rates and Stage

Year	Number LDCT	Long-RADS 4	Lung CA	Early Stage
2015	108	12	6	3 (50%)
2016	98	12	5	3 (60%)
2017	148	7	2	2 (100%)
Total first 3 years	354	31 (9%)	13 (3.7%)	8/13 = 61%

of a focus in future studies. Additionally, we are trying to assess the cardiac evaluation implications from LDCT screening from the incidental findings of coronary artery calcifications. Lastly, The Outer Banks Hospital recommends participating in a national registry to track all patients early to simplify processes and to validate the way in which the LDCT program is being managed. OI



Donna Delfera, RN, is nurse navigator; Micayla Albers is a public health intern and recent graduate from Eastern Carolina University; and Charles Shelton, MD, is Cancer Committee chair and an oncology physician, The Outer Banks Hospital, Nags Head, N.C. Lysle Ailstock, MD, is lead radiologist with LDCT for Eastern Radiology.

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Immuno-Oncology: Breaking Barriers, Exploring Solutions, Improving Patient Care

ACCC Immuno-Oncology Institute Virtual Visiting Experts Recap

Breaking Barriers

For many patients with cancer, immune checkpoint inhibitors represent a game-changing innovation. Each year approximately 270,000 cancer patients are treated with immuno-oncology (IO) agents, and today a majority of community oncologists are using IO agents in clinical practice. Since the first United States (U.S.) Food and Drug Administration (FDA) approval for ipilimumab in 2011, six checkpoint inhibitor agents are now approved for a range of indications, and two chimeric antigen receptor T-cell (CAR T-cell) therapies are approved for hematological malignancies. As these exciting advances move into mainstream clinical practice, the Association of Community Cancer Centers (ACCC) member survey data show that it remains complex for cancer care teams to integrate biomarkers into practice, select patients for IO therapy, and monitor treatment response and the emergence of immune-related adverse effects (irAEs).

Although IO therapies produce durable benefit for many patients, immunotherapy response entails a multi-step process that includes initial immunotherapy administration, immune cell activation and proliferation, and the effect of treatment on the tumor.[1,2] Response patterns pose monitoring challenges for clinicians, especially since patients can respond weeks to months following initial treatment and even modest response is often associated with overall survival benefit. At the same time, IO agents have unique immune-related toxicities. While these are relatively infrequent, irAEs can be potentially fatal and can occur up to two years after the last IO treatment dose. Many irAEs are challenging to recognize, in part because they were under-reported in clinical trials (e.g., musculoskeletal and cardiac adverse effects),[3] and in part because the presentation of some autoimmune irAEs (e.g., nephritis or diabetes) is often distinct from how these conditions present outside of the immunotherapy setting. Adding to the complexity, new indications are emerging and combination therapy continues to expand, bringing fresh challenges for identifying patients that would benefit from combination approaches over single agent therapy. Combination approaches also increase the potential for irAEs and reinforce the importance of developing sound monitoring strategies, as well as the need for biomarkers to determine irAE risk.

As immuno-oncology is increasingly integrated into community practice, experience with and knowledge of effective management of patients receiving IO therapies continue to grow. Thus, there is a clear need for ongoing education for clinicians and the entire multidisciplinary oncology care team. In response, the ACCC Immuno-Oncology Institute developed a multidisciplinary curriculum workshop bringing together faculty experienced in delivery of immunotherapy with cancer program staff in the earlier stages of IO integration. Over the past two years, these IO Visiting Experts Programs were hosted by ACCC Cancer Program Members nationwide. Faculty and participants engaged in discussions on the

WEBINAR FEATURED FACULTY:
Immuno-Oncology: Breaking Barriers, Exploring Solutions, Improving Patient Care

- Tanguy Seiwert, MD, Assistant Professor of Medicine, University of Chicago, Illinois
- Una Hopkins, RN, FNP-BC, DNP, Administrative Director, Cancer Program, White Plains Hospital, Center for Cancer Care White Plains, New York
- Vamsidhar Velcheti, MD, FACP, FCCP, Director of Thoracic Oncology, NYU Langone Perlmutter Cancer Center, New York
- Ali McBride, PharmD, MS, BCOP, Clinical Coordinator, Hematology/Oncology, University of Arizona Cancer Center, Department of Pharmacy, Arizona

Dr. Velcheti was formerly with Cleveland Clinic, Ohio

nuances and complexities of IO delivery, with a focus on advancements, operations, and effective practices.

To expand the reach of this highly successful IO Visiting Experts Program, key discussion points were distilled into a virtual interactive webinar presented in July 2018 by a multidisciplinary oncology faculty—comprised of an oncologist, administrator, nurse, and pharmacist. This article summarizes top-line takeaways from the webinar along with frequently asked questions on integrating immunotherapy into practice from Visiting Expert Program participating sites. Access the full webinar on demand at accc-cancer.org/io-breaking-barriers

Exploring Solutions

Effective Strategies for Monitoring and Managing irAEs

Monitoring patients' irAEs demands clinical vigilance by a broad multidisciplinary team that includes an expanded range of specialists with experience in the unique characteristics and management of irAEs. During his presentation, Dr. Vamsidhar Velcheti emphasized the value of identifying champions in each relevant specialty who can provide oversight, ensure staff and patient education, and implement locally relevant strategies that have potential to prevent adverse event escalation and reduce hospital admissions, which is ultimately key to reducing costs of care (Figure 1).[4]

Patients with emergent irAEs may seek care in a variety of settings [e.g., primary care, emergency room (ER), urgent care]; therefore, it is crucial to educate a wide range of staff about IO treatment and recognition of adverse events, including not only infusion nurses and internists or hospitalists, but also primary care physicians and ER providers, through tried and tested education strategies such as:

- "Lunch and Learn" sessions that partner with pharmaceutical companies or grand rounds and nursing rounds;
- Biweekly institutional tumor boards that encourage participation from regional oncologists and encourage active discussion of complex cases—this can be especially relevant for treating patients with IO who have pre-existing conditions for which there may be no data as yet; and
- IO sessions targeting ER fellows to provide an overview of irAE signs and symptoms in the first-line emergency setting.

ACCC has also developed resources to support community cancer programs in developing multi-specialty toxicity teams focused on irAEs. Additionally, patients need to be engaged participants in their care, educated on and aware of immediate, as well as, late-emerging or chronic side effects. Patients and caregivers need consistent education and reinforcement on the importance of reporting irAEs to their oncology care team and of having a contingency plan for managing adverse effects.

Figure 1. Effective Strategies for Monitoring and Managing irAEs

Finally, published guidelines on irAE management from the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), and the Society for Immunotherapy in Cancer (SITC), and information from pharmaceutical companies are available in downloadable formats for phones and tablets.

Clinical Trials and Biomarkers

Several biomarkers currently exist to identify response to checkpoint inhibitors including expression of programmed death ligand-1 (PD-L1), microsatellite instability (MSI), and tumor mutational burden (TMB). Currently, clinicians have little capacity to predict the onset of serious irAEs and autoimmune events. Thus, new classes of biomarkers and biomarker combinations to determine patients at high risk for irAEs are an active area of research. Among these biomarkers are targets such as auto-antibodies and canonical disease auto-antibodies, T-cell epitope spreading and auto-reactive T-cells, and the effects of microbiome diversity on immune repertoire and tolerance. Until these and other biomarkers are approved, the toxicity profiles of checkpoint inhibitors provide a useful decision-making resource to guide individualized therapy selection.

Improving Patient Outcomes

Financial Access, Reimbursement Processes, and Budgeting

Financial toxicity remains a significant operational barrier to IO treatment. For Una Hopkins, RN, FNP-BC, DNP, overcoming this hurdle means that individualized care must include allocating resources to support financial navigation for patients. While employing financial advocates or medication assistance coordinators is a significant investment for community cancer programs—as these services are not reimbursable—establishing this role within a cancer program mitigates the patient's distress, expands awareness of financial resources, and helps to ensure the sustainability of treatment. Dr. Hopkins also recommends identifying a point person from the financial or reimbursement staff to focus on IO agents and build expertise on the nuances of the various patient support programs, including manufacturer replacement programs, co-pay support programs, co-pay foundations, and patient assistance programs, in order to identify and liaise effectively with pharmaceutical partners.

These new agents are costly, so careful attention to reimbursement is an imperative operational concern. For example, new-to-market IO agents often lack a specific J Code (or in the case of drugs paid under the Hospital Outpatient Prospective Payment System, a C Code). To ensure accurate reimbursement, the financial team should establish clear approval, reimbursement, and billing processes (Figure 2), and designate a reimbursement specialist to liaise with pharmacy and regularly review approvals and denials (Figure 3).

The Role of the Oncology Pharmacy in Integrating IO Therapies to Clinical Practice

As more combination therapies emerge and sequencing options expand, and as payer approval becomes increasingly dependent on the results of PD-L1 and other forms of testing, it will be important for pharmacists, whose role extends across clinical care (Figure 4), to work hand-in-hand with oncologists and other members of the oncology team to select treatment, determine dosing, incorporate testing panels into the workflow, and secure access to treatment with immunotherapy.

Figure 2. Recommendations for Approval and Reimbursement Processes

APPROVAL PROCESS		PAYER APPROVAL PROCESS	
High Dollar Medication Approval Process	**Robust Off-Label Policy and Procedure**	**Physician/Advanced Practice Provider**	**Pharmacist Role**
• Full benefits investigation • Utilize pharma services if allowed per program policy • Prioritize staff resources to enroll every viable patient into a support program, regardless of on or off-label use	• Predetermine all off-label requests • Make patients aware of risks/benefits, including financial risk • Require patients to sign an Advance Beneficiary Notice or Notice of Non-Coverage • Use peer review process for appeal if needed	• Identify patient who may benefit from IO therapy • Participate in peer-to-peer conversations if needed • Discuss rationale for off-label use if applicable • Provide additional primary literature support if necessary	• Retrieve supporting literature • Monitor and review CMS approved compendia and national/local coverage • Track off-label use • Entry should trigger alerts to pharmacy director, P&T Committee chair, and reimbursement specialist team

Figure 3. Features of the Reimbursement Specialist Role

- Verify medical insurance
- Obtain copies of pertinent information from patient medical record (treatment plan, diagnostic studies, etc.)
- Retrieve supporting literature (if not already provided by team)
- Verify compendia and NCD/LCD support
- Identify appropriate ICD-10 code(s) and HCPCS code(s) for medications
- Draft letter of medical necessity (prescriber to sign)
- Fax letter and supporting evidence to payer
- Confirm payer has received information
- Continue to follow up until approval/denial received, have process in place to track these

While such access in many other countries is highly regulated and determined by technology assessments and other mechanisms, in the U.S., institutional formulary review plays a larger role. In the U.S. hospital Pharmacy and Therapeutics (P&T) Committees are another crucial mechanism for weighing institutional costs against putative clinical benefits, especially if there are small efficacy differences between therapies but there are other differences that might be important to consider (e.g., dosing schedules, route of administration). Care pathways also are another mechanism that can be used to optimize decisions on which therapies to carry on formulary.

When integrating IO into practice, the oncology pharmacy is a key resource for other critical operational concerns, such as inventory management, medication preparation, dispensing and distribution, and managing drug waste (e.g., through rounding or flat-dosing). Oncology pharmacists also provide oversight for medication safety, electronic medical record use, and compliance with risk and mitigation strategies. Finally, the oncology pharmacy plays a key role in managing off-label IO use in circumstances where there are no other treatment options for patients or where therapies are supported by NCCN guidelines but not yet FDA-approved, through, for instance, drug replacement programs. The recently enacted Right to Try legislation also enables terminally ill patients who have exhausted all other treatment options to seek access to Phase 1 investigational therapies, including immunotherapies.

Conclusion

Novel IO agents with differing mechanisms of action and combination immunotherapies will continue to improve overall outcomes for patients with cancer. As Dr. Tanguy Siewert observed: *survivorship is a good problem to have*. We didn't have people in lung cancer who survived 3-5 years and now we see patients with dramatic benefit and so we need to start thinking about survivorship.

Yet the rapid pace of advancement and the volume of information in the IO arena remains challenging for cancer care teams to absorb. Ongoing education will continue to be critical for the entire cancer care team, including non-oncology specialists, patients and caregivers. And the "good problem to have," survivorship, is also becoming an increasingly important issue in IO. As the number of survivors treated with IO grows, it is imperative to educate patients and their families not only about the potential benefits, but also the limitations of treatment. Finally, although the publication of evidence-based guidelines is a welcome development in irAE management, many questions remain about differences in irAEs among IO agents, the potential for prolonged duration of irAEs, and whether and how to re-challenge patients with immunotherapy following the development of irAEs. Therefore, toxicity teams and other strategies to manage irAEs are critical approaches to effectively managing irAEs and optimizing patient outcomes.

Alexandra Howson, MA, CHCP, PhD, Thistle Editorial, LLC, Contributor

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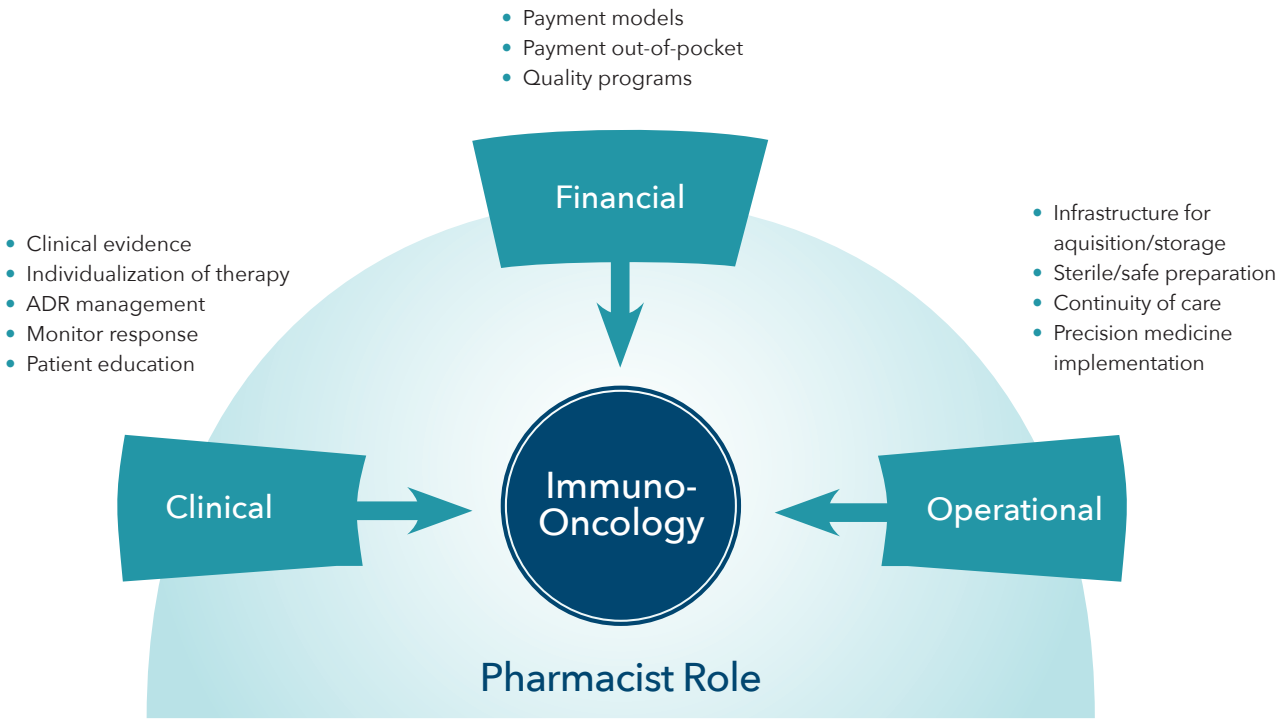
Figure 4. Pharmacist Role in Immuno-Oncology



The ACCC Immuno-Oncology Institute is supported by:

Bristol-Myers Squibb — Charitable Donation

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

Association of Community Cancer Centers

action

ACCC Welcomes Its Newest Members

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

(System Member)
Duke Cancer Network
Durham, N.C.
Delegate Rep: Jeff Heffelfinger, DMin, MSA, FACHE
Website: affiliations.dukehealth.org/services/cancer-network

(Part of Duke Cancer Network System)
Johnston Hematology Oncology
Smithfield, N.C.
Delegate Rep: Bryant Washington, MBA, MHA, BSN, RN
Website: dukehealth.org/locations/johnston-hematology-oncology-smithfield-duke-cancer-network

Gene Upshaw Memorial Tahoe Forest Cancer Center
Truckee, Calif.
Delegate Rep: James McKenna, MHA
Website: tahoecancercenter.com

Huntsman Cancer Hospital
Salt Lake City, Utah
Delegate Rep: Megan Provost
Website: healthcare.utah.edu/huntsmancancerinstitute

Moffitt Cancer Center
Tampa, Fla.
Delegate Rep: Mary Coffeen
Website: moffitt.org

Sutter Pacific Medical Foundation
Sutter Santa Rosa Oncology Department
Santa Rosa, Calif.
Delegate Rep: Jessica Sherwood, BSc, MBA
Website: sutterpacific.org/services/cancer.html

Save the Dates! ACCC Oncology Reimbursement Meetings

Thursday, March 7, 2019
Hoboken, New Jersey

Tuesday, April 9, 2019
Portland, Maine

Thursday, June 6, 2019
Portland, Oregon

The 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.

Free to ACCC members; non-members are invited to attend at the low registration rate of $149. Learn more at accc.cancer.org/ReimbursementMeeting.

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Remembering Lee E. Mortenson, DPA, MPA, MS

ACCC and the Oncology State Society Network mourn the loss of founding Executive Director Lee E. Mortenson, DPA, MPA, MS. After a brief battle with non-small cell lung cancer, Dr. Mortenson passed away on December 3, 2018, at his home in Tucson, Ariz., surrounded by his family. He is survived by his wife Carol, daughter Leia, son Lars, and their families.

In 1974, Mortenson convened a small group of clinicians seeking to dispel the myth that community providers were uninterested in and incapable of participating in state-of-the-art cancer care. On the occasion of ACCC's 30th anniversary in 2004, Mortenson described the impetus behind the Association's founding: *In 1974, when we first came together, medical oncology was not yet a formalized medical specialty. Congress and President Nixon had declared a war on cancer in 1971 and provided funding for a group of university-based comprehensive cancer centers. Some graduates of those university-based programs went into research, and some went into private practice. Many who went into private practice immediately realized that cancer care was on the verge of a radical shift, a whole new paradigm. . . . The Association's initial purpose was to spread the gospel of multidisciplinary care and teach other hospitals how to establish an oncology unit.*

ACCC would go on to become the mechanism through which clinical protocols and other oncology standards of care were developed and disseminated to community cancer programs across the nation. Led by ACCC, the community oncology care provider would emerge as an equal partner in the war against cancer.

"Lee was the right leader at the right time," said ACCC Executive Director Christian G. Downs, JD, MHA. "He was tenacious in fighting to support ACCC's commitment to patient access to quality cancer care close to home, while also contributing to advancing cancer care for the future. He brought ACCC to where we are today."

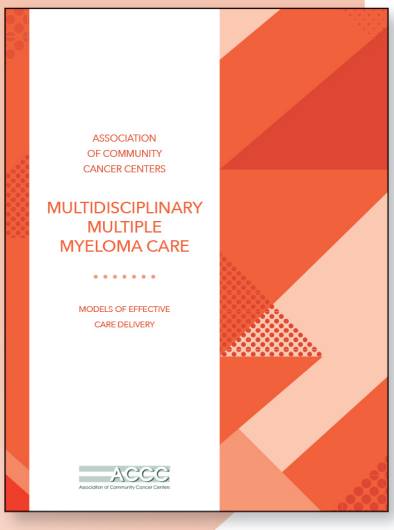
Dr. Mortenson served as ACCC Executive Director from 1974 to 2004. He was a visionary leader for ACCC, supporting the creation of an association that involved the whole multidisciplinary cancer team: physicians, administrators, nurses, social workers, data managers, radiation therapists, pharmacists, social workers, and advocates. Under his guidance, the Association evolved as cancer care delivery evolved, continuing to meet the needs of its multidisciplinary membership through conferences and meetings, ACCC's journal *Oncology Issues*, and innovative education programs.

Over the course of his 45-year career, Dr. Mortenson provided personal facilitation, leadership, mentoring, project analysis, and corporate development and analysis projects. He published more than 165 articles and served as editor/author of 40 books and as a journal editor. He raised more than $100 million for causes and organizations, some through grant and contract writing, some through project development and corporate financing. Legislation on off-label drug availability for cancer treatment developed by Dr. Mortenson was adopted by more than 38 states and the U.S. Congress.

ASSOCIATION OF COMMUNITY CANCER CENTERS

DELIVERING EFFECTIVE MULTIPLE MYELOMA CARE

The **Multidisciplinary Multiple Myeloma Care** project delivers effective practices and vetted resources to support the cancer care team in the diagnosis, treatment, and management of multiple myeloma patients.



Models of Effective Care Delivery

This new publication offers a convenient summary of recent updates in the management of this heterogeneous disease, including:

- Diagnostic Criteria by the International Myeloma Working Group
- Revised International Staging System
- ASCO Clinical Practice Guideline Update: Role of Bone-Modifying Agents in Multiple Myeloma

Plus, read how three cancer programs—a community-based comprehensive program, an academic medical center, and an NCI-designated program—are delivering multidisciplinary care to this patient population.

Online Resource Center

Access a robust resource compendium comprised of multifaceted information to support your role in caring for patients with multiple myeloma.

Regional Lecture Series

View on-demand webinars that outline how to effectively manage patients with high-risk profiles and the need for a team-based approach to care.

Access at accc-cancer.org/multiple-myeloma-care

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Graphic Medicine

Navigating the waters as a cancer survivor for the last decade

BY CHRISTIAN "PATCH" PATCHELL

At work in my studio. Photo by Concetta Barbera @concettamariabarbera.

Navigation served as my inspiration for this article. When I finished treatment for my cancer, it was suggested that I join a support group—something to help me with the "after" of cancer. I opted to go to a meeting entitled "Navigating the New Normal." My first thought was, "That's a pretty goofy name!" My second thought: "Navigating is pretty cool, though." Like an explorer chronicling his latest expedition, I chose to document my journey through dates, times, and experiences. My "captain's log" paints the picture of an artist and educator coping, learning, and growing as a survivor.

The Expedition

April 2007: I notice a bump on the left side of my tongue. It starts to get in the way of eating. I like to eat, so I get crabby a *lot*. During one of my crabbiest episodes, my girlfriend, Melissa, suggests that I see a doctor. We argue—we never argue. In order to win said argument, I make an appointment with a doctor.

May 2007: I am diagnosed with squamous cell carcinoma of the lateral tongue, stage IV. The recommended treatment is lymph node removal and concurrent chemoradiation. The doctors keep telling me that I'm young and healthy, which is weird to hear. Melissa won the argument. I ask her if she'd like to "take a break" while I go away to Camp Cancer for nine months. She says no.

June 2007: Waiting for a PET (positron emission tomography) scan, I sketch. I begin treatments and make a pact with myself. For every day of treatment, I will draw for an hour. I won't let cancer take that away. I draw the things I've drawn all my life—the stuff I drew when I was a kid. My sketchbook becomes filled with monsters and heroes. I worry that I will lose the ability to speak—that I will lose my voice.

August to October 2007: I finish treatment, but not without highs (my sketchbook, love and support, ice cream sandwiches) and lows (hospitalization, the last week of radiation, my white blood cell count). I begin to take small steps toward returning to work and my "normal" life while I wait to see if there is any activity in my scans.

This is when I first meet with depression. My body and mind have changed, and I'm unsure of my future. Hanging out with my best friend Kyle, I break down. He takes his hand, puts it on my shaved head, and tells me to stay strong. We decide to go see *I Am Legend*, a movie in which—spoiler alert—the monsters are created as the result of a search for a cure to cancer. Kyle asks me if I'd like to leave the theater. I say no.

November 2007: No activity in my scans. I know what I'm thankful for this Thanksgiving. Melissa asks me if I want to take a break and re-experience life with her. I say yes.

January 2008: I turn 34, my happiest birthday ever. I also decide to return to teaching, my best decision ever. I apply for two grants to print the sketchbook I kept while undergoing treatments; I receive both. After showing the sketches to a former instructor, I decide to write about my

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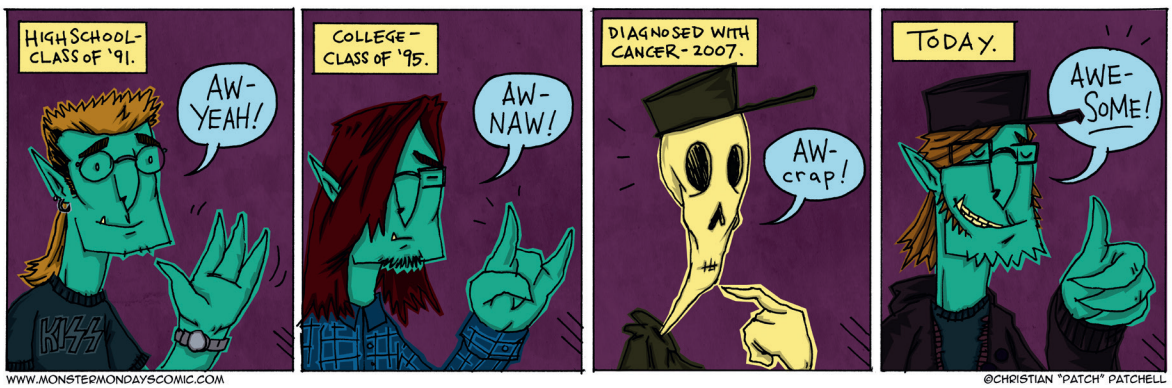

Excerpt from my online comic strip "Monster Mondays."

Access this free webinar series at
accc-cancer.org/resources/virtual-tumor-boards.asp

Molecular Testing: Resources and Tools for the Multidisciplinary Cancer Team

Given the rapidly expanding and increasingly complex molecular testing landscape, the Association of Community Cancer Centers (ACCC) partnered with the Association for Molecular Pathology (AMP) to develop a webinar series to educate the multidisciplinary team on opportunities for collaboration to improve patient care. The 12-webinar series features case studies and robust discussions on molecular testing for breast and lung cancer, various tumor board models, and effective practices.

Virtual Molecular Tumor Boards:

An Educational Series

View these on-demand webinar recordings:

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- Virtual Molecular Tumor Board: Breast Cancer Case Studies
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- The Role of Genetics Professionals in a Community Cancer Program
- Clinical Genetics vs. Tumor Genomic Profiling: Relevance in Cancer Care
- The New Age of Molecular Testing and Targeted Therapies for Lung Cancer
- Engaging Multidisciplinary Clinicians in Genomic Tumor Boards
- Challenging Issues in Breast Cancer Management
- Real-World Considerations When Implementing a Genomic Tumor Board Program
- Key Concepts and Future Directions in Molecular Testing and Care Delivery

ACCC Association of Community Cancer Centers

AMP Association for Molecular Pathology

This project is supported by Genentech, A Member of the Roche Group

(continued from page 86)

experience. Flipping through my sketchbook is like looking at a scrapbook or photo album. I start what would become *I Put the Can in Cancer: A Journey Through Pictures*.

March 2008: I mention my book-in-progress to the class I'm teaching. One of my students asks, "Are you ready to do that?" I thought I was. As I am designing page 18 of my book—a page filled with scans of the notes I wrote while I had a trach in—I have to stop. I realize two things: that I'm not over dealing with this disease and that my students are smart.

Fall 2011: My book is finished and about to be printed. It took two years to write and design; treatment only took nine months. We decide to hold a book release party at a local gallery. I have a case of 60 books shipped to the gallery early. Nearly 200 people attend. I read from my book and get choked up when I look out at the sea of faces—family, friends, students, faculty, fellow survivors. That moment stays with me to this day.

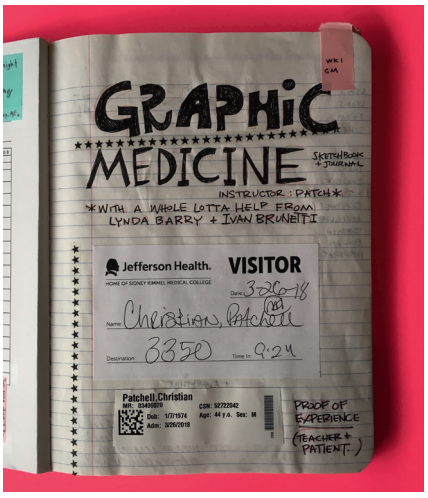
December 2013: Now five years cancer-free, I decide to propose to Melissa. I drive down to North Carolina on Christmas Day to do it. The entire way down I rehearse what I am going to say, like a kid rehearsing lines for the school play. I surprise her and say my lines (almost) perfectly. She says yes.

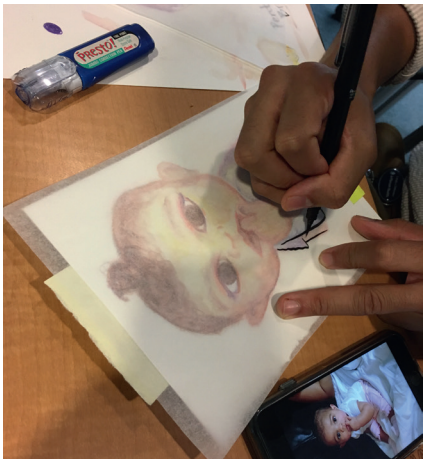
October 2015: Melissa and I wed. The room is filled with family and friends. They all know our story. It's the greatest day of my life.

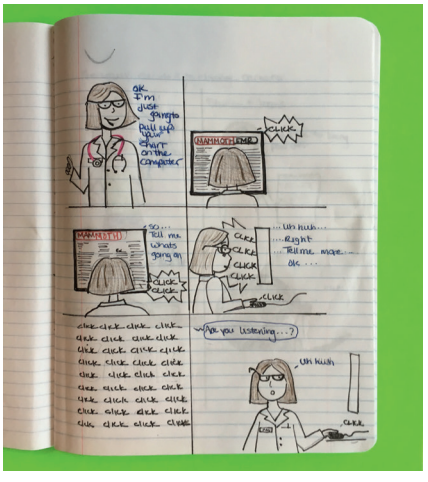
For the last decade, I have shared my book and my experiences in the classroom, at charity events, and during lectures and talks. When I share it with artists and creatives, I talk about communicating a personal experience through art. When discussing my experience with people in the dental and medical profession, I share the healing power of art and creativity. And when sharing my experience with patients, caregivers, and survivors, it's about holding on to and claiming something as your own—something that disease cannot take away.

The Here and Now

Spring 2018: I begin discussing a course to be taught at Jefferson University through the Continuing Education Program at the University of the Arts in Philadelphia. The idea is to teach observation through the arts. It is my hope to give medical students a place to feel creative and to make mistakes. I tell Melissa I fear that the students will not see me as an equal. She reminds me that I know best what I am teaching.







(Above) My wife and I. (Top right) The front page of my "Graphic Medicine" sketchbook from the course at Jefferson University. (Center right) Portrait created by student, Bruce Reaves, in the Graphic Medicine course at Jefferson University. (Below right) Comic strip created by student, Laura Ayd, in the Graphic Medicine course at Jefferson University.

Summer 2018: I begin teaching Graphic Medicine. We discuss personal stories and how to share them through drawing and writing. I am impressed with the students' writing and their interest in being creative; they come to each class invested, make art, and tell stories. I am caught off-guard by the fact that they tell personal narratives, tales about what inspired them to enter their fields—the same as me. My misconceptions of why people study medicine are erased by my first class.

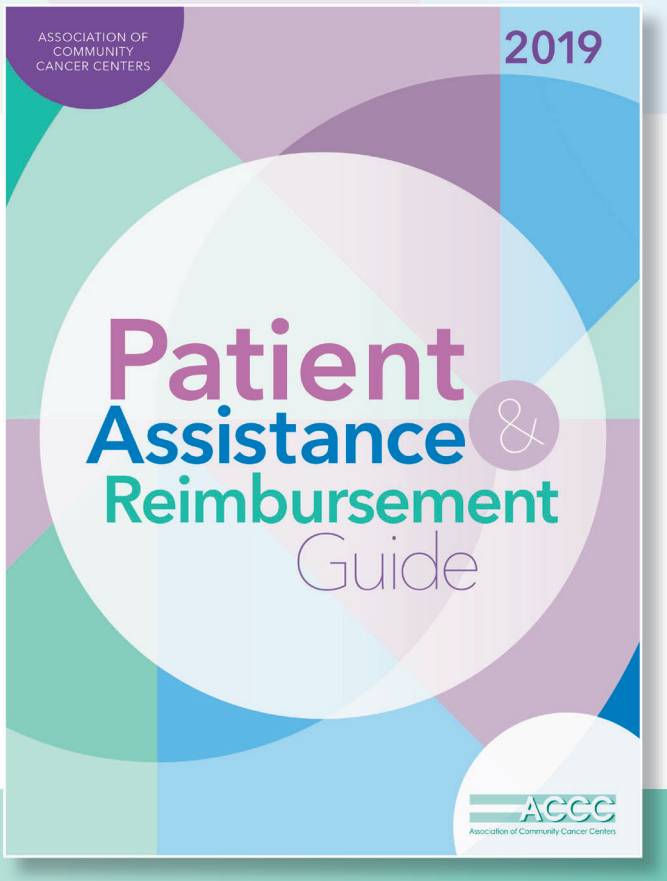
At the mid-semester point, I share my story. At first, they ask what they are trained to ask, questions about profiles and medical history. Eventually they turn to questions about my experience, questions about my artwork. I think the class is working.

October 2018: At the end of one of my classes, I tell my students about this article. I ask them what they would want to know about someone like me who is 10 years cancer-free. One of my students mentions that I should tell them how I won't draw cartoon characters smoking anymore.

Today: You're reading my story; I never lost my voice. I think I finally found out how to *navigate the new normal*. As an artist, I don't think I'll ever really warm up to the word *normal*, but as a cancer survivor, I really like that word *new*. *New* is filled with possibility and potential. *New* is where I am today.

Christian "Patch" Patchell is an artist, educator, and cancer survivor. He is also the author of I Put the Can in Cancer: A Journey Through Pictures. *You can see more of his art and writing at artbypatch.com.*

Help patients find the financial assistance they need.



Updated four times each year, the **ACCC Patient Assistance & Reimbursement Guide** provides direct access to the latest pharmaceutical and foundation patient assistance and co-pay program information.

Download the most up-to-date version at accc-cancer.org/PatientAssistanceGuide

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