ONCOLOGY ISSUES

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Association of Community Cancer Centers

May | June 2016

Health Info On the Go:

Outreach at the Farmer's Market

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ACCC
Association of Community Cancer Centers

ONCOLOGY ISSUES
The Journal of the
Association of Community Cancer Centers

Oncology Issues serves the multidisciplinary specialty of oncology care and cancer program management.

Archived editions of Oncology Issues are available to members at: mynetwork.accc-cancer.org.

FROM THE EDITOR

Stories Policymakers Need to Hear

BY CHRISTIAN DOWNS, JD, MHA

At the 42nd ACCC Annual Meeting in March, Kavita Patel, MD, MS, of the Brookings Institution, told meeting attendees that providers must help policymakers understand the demanding intuitive thought process that is part of today's oncology care, as well as the tremendous amount of information that oncology providers must keep up with given the pace and variety of emerging therapies. Cancer care is complex, and if a policymaker were to read just this one edition of *Oncology Issues*, he or she would gain a better understanding of this complexity. From prevention and outreach efforts directed toward at-risk patients to provider-driven solutions to address critical workforce shortages to cutting-edge health IT technology that improves the patient experience—the breadth and scope of the issues oncology providers face on a daily basis is staggering.

Let's start with prevention, specifically provider efforts to ensure that patients have access to tools and resources to help reduce their risk of cancer. In "Health Info on the Go," Nora Katurakes and Charlene Marinelli share how Christiana Care's outreach program provides combination screenings—cancer risk assessment, cholesterol, blood sugar, and blood pressure testing—at a local farmer's market. Policymakers take note: These critical outreach and prevention services *are not reimbursed by payers*.

Our second feature article by Sandy Balentine and Valerie Quigley discusses the development of an oncology nursing fellowship program, which allowed a hospital to fill vacant positions in its busy infusion center. The looming healthcare workforce shortage, exacerbated by the aging Baby Boomer population, is doom and gloom news that policymakers have heard before. Refreshing news to their ears: The story of a proactive, low-cost, provider-driven strategy, addressing patient, health system, and community needs, developed by The Valley's Blumenthal Cancer Center!

Next, 2015 ACCC Innovator Award Winner Eastern Maine Medical Center Cancer Care shares its experience implementing a real-time location system to streamline patient flow, improve staff efficiency, reduce wait times, and enhance patient safety. A prime example of cancer care providers harnessing the power of technology to implement a cost-effective solution to real-world problems—precisely the type of forward-thinking, patient-centered strategy policymakers are seeking.

Our remaining feature articles also reflect the value that oncology providers bring to the table. In "Oncology's Value-Oriented Framework," Ryan Langdale and Kelley D. Simpson outline a strategic planning process tailored to a cancer program's individual environment and size and oriented around a program's organizational structure, resources, care delivery network, and patient population. Policymakers have mandated a shift to a value-based healthcare environment. As cancer programs make the transition, this article's takeaways offer guidance for short- and long-term strategic planning.

And finally, "ORIEN: Reshaping Cancer Research & Treatment" highlights the Oncology Research Information Exchange Network (ORIEN), a partnership of NCI-designated cancer centers and their community affiliates who share a common protocol and goal of matching cancer patients to the clinical trials that would most benefit them. Precision medicine in practice.

Circling back to Kavita Patel's call for action to educate policymakers about issues affecting the oncology community, I'd say we're on the right track. Now we just need to build on our progress by sharing these resources with our staff, patients, and community stakeholders, including our state and federal representatives. If you need help sharing *your* stories, email ACCC Director of Health Policy Leah Ralph at: lralph@accc-cancer.org. OI

Empowering Patients, Engaging Providers

BY JENNIE R. CREWS, MD, MMM, FACP

As I begin my tenure as ACCC President, I would first like to thank outgoing ACCC president, Steven L. D'Amato, BSPharm, BCOP. He has set the bar high for all ACCC presidents to come. My sincerest appreciation goes out to the ACCC Delegate Representatives for entrusting this position to me. I am honored to serve this organization.

I am also grateful to all of my predecessors for their leadership and their contributions to the Association of Community Cancer Centers. They have left a wonderful, evolving legacy of presidential themes: from our first look at the concept of the Oncology Medical Home; to providing the right care at the right time; to the importance of the multidisciplinary oncology team; to defining quality in oncology care; and, finally, revisiting the oncology medical home as it relates to integrated healthcare delivery models. I hope to add to this dynamic legacy with a presidential theme that focuses on patient-centered care:
Empowering Patients, Engaging Providers.

There will be many opportunities to explore this theme over the coming months. While we all think we understand and provide patient-centered care, in our changing healthcare environment we are being challenged to examine how we define patient-centered care—both today and tomorrow. How do we continue to provide patient-centered care as we transition to new models of cancer care delivery? How will the changing role of the patient in consumer-driven healthcare influence what we think of as patient-centered care?

In our day-to-day work, so many of the challenges we face are based in our struggle to deliver patient-centered care:

- The effort to ensure access to care—especially for patients in rural and underserved areas and for those with limited resources strained by the accelerating cost of cancer care.
- The growth of personalized medicine with expanded use of genomic analysis and molecular testing and the consequent concerns of how to use this data and how to pay for it.
- The imperative to meet accreditation requirements, such as survivorship care, and–most important–ensure that this care is relevant and valuable to our patients.
- The need to incorporate shared decision-making tools into busy programs to help patients clarify the value of outcomes, understand the financial impact of cancer treatment, and define their end-of-life wishes.
- The enhanced use of patient-reported outcomes in cancer treatment and symptom management.
- The implementation of new technologies to share data or provide telemedicine, including smart phone apps and patient portals that give patients new options in how they receive care but which will require new forms of reimbursement.

To meet all of these challenges we must first involve and empower our patients, engaging all of the multidisciplinary providers on the oncology care team with these efforts. I look forward to working with the ACCC membership this year to explore creative and practical solutions to these challenges that we all face as we strive to keep the patient at the center of everything. OI

Coming in Your 2016 *ONCOLOGY ISSUES*

- Engaging Patients & Assisting PCPs in Lung Cancer Screening
- A Family Program for Parents with Cancer & Their Children
- Fusing Clinical & Business Metrics to Improve Quality & Effect Change
- Community Collaboration Reduces Financial Distress
- Prehab Improves Outcomes for Oncology Patients
- Care Connect: Improving Care Coordination Between Oncology & Primary Care
- Training Community Nurses & Administrators to Implement Cancer Clinical Trials
- Bridging the Gap: From Inpatient to Outpatient Care
- The Evolution of Clinical Pathways and Their Role to Identify Quality and Cost Effective Care
- Community Health Needs Assessments: How Your Cancer Program Can Prepare
- Forming Partnerships to Bring Clinical Trials to the Community
- Implementing a Health Disparities and Equity Agenda

VIDEO

Oncology Value Frameworks

An expert panel discusses how these tools may improve patient care, the additional resources and education needed so that providers understand the methodology behind these tools, and the role these frameworks may play in communicating value, cost, and efficacy with the C-Suite, payers, and patients. accc-cancer.org/townhall.

SURVEY

2016 ACCC Trends in Cancer Program Survey

How does your program plan for new care delivery models; make accreditation decisions; and employ technology to remove barriers to care? Take 20 minutes to answer these and 8 more questions at: accc-cancer.org/trends2016. Your responses will help ACCC develop tools and resources to support your short- and long-term strategic planning.

BLOGS

Cost Transparency & Your Patients

An oncology financial navigator shares 6 strategies, including working with your pharmacist and chargemaster to develop price estimates for common treatments and personalizing cost of care estimates for all patients. accc-cancer.org/ACCCbuzz/financial-advocates-six-steps-cost-transparency.

INFO

Meeting the Needs of Asian American & Pacific Islander Patients

ACCC's white paper explores the unique challenges facing this growing patient population, including disparity and access issues, communication and cultural barriers, and issues related to lung cancer management and treatment. Plus, practical improvement strategies to help cancer programs meet these challenges and improve patient care. accc.cancer.org/lung.

Oncology Issues is published bimonthly at the Association of Community Cancer Centers, 11600 Nebel St., Suite 201, Rockville, MD 20852. Editorial correspondence, changes of address, manuscripts, and letters to the editor should be addressed to: Managing Editor, Oncology Issues, 11600 Nebel St., Suite 201, Rockville, MD 20852-2557. Author's instructions available at accc-cancer.org.

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Please send address changes to Association of Community Cancer Centers, 11600 Nebel St., Suite 201, Rockville, MD 20852.

4 Steps for Hosting a National Cancer Survivors Day Celebration

Sunday, June 5, is National Cancer Survivors Day, so it's time to start planning!

Step 1: Register Your Event

Register your event online at ncsd.org/registration to access a Speakers Bureau Roster with contact information for nationally-recognized celebrities and keynote speakers and other valuable resources.

Step 2: Pick a Location

While many events are held at hospitals and cancer centers, don't be afraid to get creative with your location. Think amusement park, sports venue, art museum, or a local church or synagogue.

Step 3: Choose a Theme

Plan your event around a central theme to add interest and create excitement. Need ideas? Go to: ncsd.org/choose-theme.

Step 4: Promote Your Event

Get the word out about your event through hospital newsletters, outreach to cancer patients and family members, press releases to local media, and more. Ask your mayor to sign a proclamation declaring Sunday, June 5, 2016, National Cancer Survivors Day in your city!

Source. ncsd.org. The official website of National Cancer Survivors Day.

facts

Reimbursement is the biggest problem facing health systems today, followed closely by the increasingly high cost of supplies.

Source. A 2015 national survey of hospital executives commissioned by Cardinal Health. cardinalhealth.com.

Majority of Americans Expect to See a Cure for Cancer in Their Lifetime

- Nearly **6** in **10** Americans **(57%)** expect to see a cure for cancer in their lifetime.
- This optimism is especially strong among Millennials, with nearly **3/4 (73%)** indicating the same.
- **2/3** of Americans **(68%)** don't see a cancer diagnosis as a death sentence.
- Americans whose lives have been touched by cancer are also more likely to see a cancer diagnosis as a death sentence **(35%)**, when compared to those whose lives have not been touched by cancer **(29%)**.

Source. A Harris Poll of 2,046 adults surveyed online between Jan. 20-22, 2016. theharrispoll.com/health-and-life/Majorities_Expect_Cure_for_Cancer.html.

Study finds that interruption of radiation therapy risks cancer recurrence.

Source. Ohri N, et al. Radiotherapy noncompliance and clinical outcomes in an urban academic cancer center. *International J Rad Onc.* http://dx.doi.org/10.1016/j.ijrobp.2016.01.043.

Communicating with Colleagues

Nowhere is clear communication more essential than in healthcare. One verbal blunder or electronic error can have catastrophic effects. Here are **3** suggestions to help you effectively interact with other staff.

1. Declare your preferences. Let your colleagues know how they can best connect with you.

2. Ask others how they want to correspond. Efficiency is a priority when interacting with other staff; that's why it helps to develop a "communication agreement" with your colleagues.

3. Maintain a high level of professionalism. No matter how you choose to communicate—whether it's on the phone, in an email, or via text—view every single message as a piece of formal correspondence that will live on in perpetuity.

Source. Jacques S. Communicate Effectively with Medical Colleagues. physicianspractice.com.

A Misguided Experiment?

BY LEAH RALPH

In early March, the Centers for Medicare and Medicaid Services (CMS) issued a proposal to implement a national demonstration program that would fundamentally change the way Medicare pays physicians and hospitals for Part B drugs. While CMS has broad authority to test different models to improve quality and lower costs in the Medicare program, the agency seems to be pushing the scope of its authority, breaking from past demonstration programs to propose a mandatory model in which all Part B providers–hospital outpatient departments, physician offices, and pharmacies–would be required to participate.

The proposed Part B Drug Payment Model would consist of two phases in which providers would be divided into four groups: three experimental groups and one control group over a five-year period. Phase I would be implemented as early as August 2016 and would mandate that approximately half of all Part B providers would have their reimbursement rates reduced to ASP+2.5% plus a flat fee of $16.80 per drug per day. Importantly, Congressionally-mandated sequestration will continue to apply to payments made under the model. As a result, under the proposal the experimental group's actual payment rate will be ASP+0.86% plus $16.53 per drug per day. The remaining half, the control group, would continue to be reimbursed for Part B drugs at ASP+6%.

The agency's ambitious timeline calls for Phase II to begin as early as January 2017. Phase II would further divide the control and test groups—creating a four-arm control trial—and overlay a requirement to use value-based pricing (VBP) reimbursement strategies and clinical decision support tools to produce Medicare savings. One (unlucky) group of providers will be subject to both the reduced ASP rate and the requirement to utilize VBP tools. These tools might include:

- Reference pricing: Medicare would set a standard payment for therapeutically-similar products.
- Indications-based pricing: payment would vary for a drug based on its clinical effectiveness for different indications.
- Voluntary-risk sharing agreements: CMS would enter into voluntary agreements with manufacturers to link health outcomes with payment.
- Discounting or eliminating patient coinsurance to encourage beneficiary use of high-value drugs.

Despite a preliminary list of potential tools, CMS failed to describe these VBP approaches in any meaningful detail, leaving many questions about how the agency will develop this methodology and make determinations about high-value treatments.

Perhaps most unnerving, providers would be assigned to arms of the trial at random based on their geographic location in primary care services areas. Although CMS has structured Phase I to be budget-neutral, the proposed model is designed to redistribute drug spending by increasing payments to provider specialties, such as primary care, that use relatively inexpensive drugs, and decreasing payments to hospitals and physician specialties, such as oncology and ophthalmology, that often use more costly drugs. Under the proposed model, the tipping point is $480. Drugs that cost more than $480 per day would result in lower reimbursement, whereas drugs costing less than $480 per day would receive higher payments than what is reimbursed today.

The majority of drugs–7 of 10–that would make up the largest reduction in reimbursement are used to treat cancer. Moreover, many of these drugs do not have a lower cost alternative.[1]

On both policy and process, ACCC remains deeply concerned. Rather than working with cancer care providers to build the infrastructure needed to define quality and value in their cancer programs, CMS has responded to a call for reigning in drug costs with a myopic focus on reimbursement. Our members have partnered with CMS on meaningful payment reform—including the most recent Oncology Care Model—and will soon be dedicating extensive resources to navigating a new and complex reformed physician payment system under MACRA.

Oncologists are ready for change, but CMS' proposal reaches too far, too fast, with seemingly little understanding of the devastating impact this approach will have on community cancer care and patient access. View ACCC's comment letter to CMS on the ACCC website accc-cancer.org. OI

Leah Ralph is ACCC Director of Health Policy.

References

1. Hussain F, Borden A. Proposed Medicare Part B Rule Would Reduce Payments to Hospitals and Some Specialists, While Increasing Payments to Primary Care Providers. Avalere. Available at: http://avalere.com/expertise/managed-care/insightsproposed-medicare-part-b-rule-would-reduce-payments-to-hospitals-and-some-s.

TAGRISSO™
osimertinib

A NEW TREATMENT OPTION

FOR PATIENTS WITH METASTATIC EGFR T790M MUTATION-POSITIVE NSCLC, AS DETECTED BY AN FDA-APPROVED TEST, WHO HAVE PROGRESSED ON OR AFTER EGFR TKI THERAPY

INDICATION

TAGRISSO is indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, who have progressed on or after EGFR tyrosine kinase inhibitor therapy.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

- There are no contraindications for TAGRISSO
- Interstitial Lung Disease (ILD)/Pneumonitis occurred in 3.3% and was fatal in 0.5% of 813 TAGRISSO patients. Withhold TAGRISSO and promptly investigate for ILD in any patient presenting with worsening of respiratory symptoms indicative of ILD (e.g., dyspnea, cough and fever). Permanently discontinue TAGRISSO if ILD is confirmed
- QTc interval prolongation occurred in TAGRISSO patients. Of the 411 patients in two Phase II studies, 0.2% were found to have a QTc greater than 500 msec, and 2.7% had an increase from baseline QTc greater than 60 msec. Conduct periodic monitoring with ECGs and electrolytes in patients with congenital long QTc syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval. Permanently discontinue TAGRISSO in patients who develop QTc interval prolongation with signs/symptoms of life threatening arrhythmia
- Cardiomyopathy occurred in 1.4% and was fatal in 0.2% of 813 TAGRISSO patients. Left Ventricular Ejection Fraction (LVEF) decline >10% and a drop to <50% occurred in 2.4% of (9/375) TAGRISSO patients. Assess LVEF before initiation and then at 3 month intervals of TAGRISSO treatment. Withhold TAGRISSO if ejection fraction decreases by 10% from pretreatment values and is less than 50%. For symptomatic congestive heart failure or persistent asymptomatic LV dysfunction that does not resolve within 4 weeks, permanently discontinue TAGRISSO
- Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during TAGRISSO treatment and for 6 weeks after the final dose. Advise males with female partners of reproductive potential to use effective contraception for 4 months after the final dose
- The most common adverse reactions (>20%) observed in TAGRISSO patients were diarrhea (42%), rash (41%), dry skin (31%) and nail toxicity (25%)

Please see Brief Summary of complete Prescribing Information.

Visit TAGRISSOhcp.com for more information

AstraZeneca

TAGRISSO™ (osimertinib) tablet, for oral use

Brief Summary of Prescribing Information.
For complete prescribing information consult official package insert

INDICATIONS AND USAGE

TAGRISSO is indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.

This indication is approved under accelerated approval based on tumor response rate and duration of response *[see Clinical Studies (14) in the full Prescribing Information]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

DOSAGE AND ADMINISTRATION

Patient Selection

Confirm the presence of a T790M EGFR mutation in tumor specimens prior to initiation of treatment with TAGRISSO *[see Indications and Usage (1) and Clinical Studies (14) in the full Prescribing Information]*. Information on FDA-approved tests for the detection of T790M mutations is available at http://www.fda.gov/companiondiagnostics.

Recommended Dosage Regimen

The recommended dose of TAGRISSO is 80 mg tablet once a day until disease progression or unacceptable toxicity. TAGRISSO can be taken with or without food.

If a dose of TAGRISSO is missed, do not make up the missed dose and take the next dose as scheduled.

Administration to Patients Who Have Difficulty Swallowing Solids

Disperse tablet in 4 tablespoons (approximately 50 mL) of non-carbonated water only. Stir until tablet is completely dispersed and swallow or administer through naso-gastric tube immediately. Do not crush, heat, or ultrasonicate during preparation. Rinse the container with 4 to 8 ounces of water and immediately drink or administer through the naso-gastric tube *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

Dose Modification for Adverse Reactions

Table 1 Recommended Dose Modifications for TAGRISSO

Target Organ	Adverse Reaction[a]	Dose Modification
Pulmonary	Interstitial lung disease (ILD)/Pneumonitis	Permanently discontinue TAGRISSO.
Cardiac	QTc[†] interval greater than 500 msec on at least 2 separate ECGs[b]	Withhold TAGRISSO until QTc interval is less than 481 msec or recovery to baseline if baseline QTc is greater than or equal to 481 msec, then resume at 40 mg dose.
	QTc interval prolongation with signs/ symptoms of life threatening arrhythmia	Permanently discontinue TAGRISSO.
	Asymptomatic, absolute decrease in LVEF[c] of 10% from baseline and below 50%	Withhold TAGRISSO for up to 4 weeks. • If improved to baseline LVEF, resume. • If not improved to baseline, permanently discontinue.
	Symptomatic congestive heart failure	Permanently discontinue TAGRISSO.
Other	Grade 3 or higher adverse reaction	Withhold TAGRISSO for up to 3 weeks.
	If improvement to Grade 0-2 within 3 weeks	Resume at 80 mg or 40 mg daily.
	If no improvement within 3 weeks	Permanently discontinue TAGRISSO.

[a] Adverse reactions graded by the National Cancer Institute Common Terminology Criteria for Adverse Events version 4.0 (NCI CTCAE v4.0).
[b] ECGs = Electrocardiograms
[c] LVEF = Left Ventricular Ejection Fraction
[†] QTc = QT interval corrected for heart rate

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Interstitial Lung Disease/Pneumonitis

Across clinical trials, interstitial lung disease (ILD)/pneumonitis occurred in 3.3% (n=27) of TAGRISSO treated patients (n=813); 0.5% (n=4) were fatal.

Withhold TAGRISSO and promptly investigate for ILD in any patient who presents with worsening of respiratory symptoms which may be indicative of ILD (e.g., dyspnea, cough and fever). Permanently discontinue TAGRISSO if ILD is confirmed *[see Dosage and Administration (2.4) and Adverse Reactions (6) in the full Prescribing Information]*.

QTc Interval Prolongation

The heart rate-corrected QT (QTc) interval prolongation occurs in patients treated with TAGRISSO. Of the 411 patients in Study 1 and Study 2, one patient (0.2%) was found to have a QTc greater than 500 msec, and 11 patients (2.7%) had an increase from baseline QTc greater than 60 msec *[see Clinical Pharmacology (12.2) in the full Prescribing Information]*.

In Study 1 and 2, patients with baseline QTc of 470 msec or greater were excluded. Conduct periodic monitoring with ECGs and electrolytes in patients with congenital long QTc syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval. Permanently discontinue TAGRISSO in patients who develop QTc interval prolongation with signs/symptoms of life threatening arrhythmia *[see Dosage and Administration (2.4) in the full Prescribing Information]*.

Cardiomyopathy

Across clinical trials, cardiomyopathy (defined as cardiac failure, pulmonary edema, ejection fraction decreased or stress cardiomyopathy) occurred in 1.4% (n=11) of TAGRISSO treated patients (n=813); 0.2% (n=2) were fatal.

In Study 1 and Study 2, Left Ventricular Ejection Fraction (LVEF) decline >10% and a drop to <50% occurred in 2.4% (9/375) of patients who had baseline and at least one follow up LVEF assessment. Assess LVEF by echocardiogram or multigated acquisition (MUGA) scan before initiation of TAGRISSO and then at 3 month intervals while on treatment. Withhold treatment with TAGRISSO if ejection fraction decreases by 10% from pretreatment values and is less than 50%. For symptomatic congestive heart failure or persistent, asymptomatic LV dysfunction that does not resolve within 4 weeks, permanently discontinue TAGRISSO *[see Dosage and Administration (2.4) in the full Prescribing Information]*.

Embryo-Fetal Toxicity

Based on data from animal studies and its mechanism of action, TAGRISSO can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, osimertinib caused post-implantation fetal loss when administered during early development at a dose exposure 1.5 times the exposure at the recommended human dose. When males were treated prior to mating with untreated females, there was an increase in preimplantation embryonic loss at plasma exposures of approximately 0.5-times those observed in patients at the 80 mg dose level.

Advise pregnant women of the potential risk to a fetus.

Advise females of reproductive potential to use effective contraception during treatment with TAGRISSO and for 6 weeks after the final dose. Advise males with female partners of reproductive potential to use effective contraception for 4 months after the final dose *[see Use in Specific Populations (8.1), (8.3) and Clinical Pharmacology (12.3) in the full Prescribing Information]*.

ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

Interstitial Lung Disease/Pneumonitis *[see Warnings and Precautions (5.1) in the full Prescribing Information]*

QTc Interval Prolongation *[see Warnings and Precautions (5.2) in the full Prescribing Information]*

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to TAGRISSO (80 mg daily) in 411 patients with EGFR T790M mutation-positive non-small cell lung cancer who received prior EGFR TKI therapy, in two single arm studies, Study 1 and Study 2. Patients with a past medical history of ILD or radiation pneumonitis that required steroid treatment, serious arrhythmia or baseline QTc interval greater than 470 ms were excluded from Study 1 and Study 2. Baseline patient and disease characteristics were: median age 63 years, 13% of patients were ≥75 years old, female (68%), White (36%), Asian (60%), metastatic (96%), sites of brain metastases (39%), World Health Organization (WHO) performance status of 0 (37%) or 1 (63%), 1 prior line of therapy [EGFR-TKI treatment only, second line, chemotherapy-naïve (31%)], 2 or more prior lines of therapy (69%). Of the 411 patients, 333 patients were exposed to TAGRISSO for at least 6 months; 97 patients were exposed for at least 9 months; however no patient was exposed to TAGRISSO for 12 months.

In Studies 1 and 2, the most common (>20%) adverse reactions (all grades) observed in TAGRISSO-treated patients were diarrhea (42%), rash (41%), dry skin (31%), and nail toxicity (25%). Dose reductions occurred in 4.4% of patients treated with TAGRISSO. The most frequent adverse reactions that led to dose reductions or interruptions were: electrocardiogram QTc prolonged (2.2%) and neutropenia (1.9%). Serious adverse reactions reported in 2% or more patients were pneumonia and pulmonary embolus. There were 4 patients (1%) treated with TAGRISSO who developed fatal adverse reactions of ILD/pneumonitis. Other fatal adverse reactions occurring in more than 1 patient included pneumonia (4 patients) and CVA/cerebral hemorrhage (2 patients). Discontinuation of therapy due to adverse reactions occurred in 5.6% of patients treated with TAGRISSO. The most frequent adverse reactions that led to discontinuation were ILD/pneumonitis and cerebrovascular accidents/infarctions.

Tables 2 and 3 summarize the common adverse reactions and laboratory abnormalities observed in TAGRISSO-treated patients.

Table 2 Adverse Reactions (>10% for all NCI CTCAE* Grades or >2% for Grades 3-4) in Study 1 and Study 2

Adverse Reaction	TAGRISSO N=411	
	All Grades	Grade 3-4[f]
	%	%
Gastrointestinal disorders		
Diarrhea	42	1.0
Nausea	17	0.5
Decreased appetite	16	0.7
Constipation	15	0.2
Stomatitis	12	0
Skin disorders		
Rash[a]	41	0.5
Dry skin[b]	31	0
Nail toxicity[c]	25	0
Pruritus	14	0
Eye Disorders[d]	18	0.2
Respiratory		
Cough	14	0.2
General		
Fatigue	14	0.5
Musculoskeletal		
Back pain	13	0.7
Central Nervous System		
Headache	10	0.2
Infections		
Pneumonia	4	2.2
Vascular events		
Venous thromboembolism[e]	7	2.4

* NCI CTCAE v4.0.

[a] Includes cases reported within the clustered terms for rash adverse events: Rash, rash generalized, rash erythematous, rash macular, rash maculo-papular, rash papular, rash pustular, erythema, folliculitis, acne, dermatitis and acneform dermatitis.
[b] Includes dry skin, eczema, skin fissures, xerosis.
[c] Includes nail disorders, nail bed disorders, nail bed inflammation, nail bed tenderness, nail discoloration, nail disorder, nail dystrophy, nail infection, nail ridging, onychoclasis, onycholysis, onychomadesis, paronychia.
[d] Includes dry eye, vision blurred, keratitis, cataract, eye irritation, blepharitis, eye pain, lacrimation increased, vitreous floaters. Other ocular toxicities occurred in <1% of patients.
[e] Includes deep vein thrombosis, jugular venous thrombosis, and pulmonary embolism.
[f] No grade 4 events have been reported.

Additional clinically significant adverse reactions occurring in 2% or more of patients treated with TAGRISSO included cerebrovascular accident (2.7%).

Table 3 Common Laboratory Abnormalities (≥20% for all NCI CTCAE Grades) in Study 1 and Study 2

Laboratory Abnormality	TAGRISSO N=411	
	Change from Baseline All Grades (%)	Change from Baseline to Grade 3 or Grade 4 (%)[a]
Clinical Chemistry		
Hyponatremia	26	3.4
Hypermagnesemia	20	0.7
Hematologic		
Lymphopenia	63	3.3
Thrombocytopenia	54	1.2[a]
Anemia	44	0.2
Neutropenia	33	3.4

[a] The only grade 4 laboratory abnormality was 1 patient with grade 4 thrombocytopenia.

DRUG INTERACTIONS

Drug interaction studies with inhibitors, inducers or substrates of CYP enzymes and transporters have not been conducted with TAGRISSO.

Effect of Other Drugs on Osimertinib

Strong CYP3A Inhibitors

Avoid concomitant administration of TAGRISSO with strong CYP3A inhibitors, including macrolide antibiotics (e.g., telithromycin), antifungals (e.g., itraconazole), antivirals (e.g., ritonavir), nefazodone, as concomitant use of strong CYP3A inhibitors may increase osimertinib plasma concentrations. If no other alternative exists, monitor patients more closely for adverse reactions of TAGRISSO *[see Dosage and Administrations (2.4) and Clinical Pharmacology (12.3) in the full Prescribing Information]*.

Strong CYP3A Inducers

Avoid concomitant administration of TAGRISSO with strong CYP3A inducers (e.g., phenytoin, rifampicin, carbamazepine, St. John's Wort) as strong CYP3A inducers may decrease osimertinib plasma concentrations *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

Effect of Osimertinib on Other Drugs

Avoid concomitant administration of TAGRISSO with drugs that are sensitive substrates of CYP3A, breast cancer resistance protein (BCRP), or CYP1A2 with narrow therapeutic indices, including but not limited to fentanyl, cyclosporine, quinidine, ergot alkaloids, phenytoin, carbamazepine, as osimertinib may increase or decrease plasma concentrations of these drugs *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on data from animal studies and its mechanism of action, TAGRISSO can cause fetal harm when administered to a pregnant woman. There are no available data on TAGRISSO use in pregnant women. Administration of osimertinib to pregnant rats was associated with embryolethality and reduced fetal growth at plasma exposures 1.5 times the exposure at the recommended human dose *[see Data]*. Advise pregnant women of the potential risk to a fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically-recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data

When administered to pregnant rats prior to embryonic implantation through the end of organogenesis (gestation days 2-20) at a dose of 20 mg/kg/day, which produced plasma exposures of approximately 1.5 times the clinical exposure, osimertinib caused post-implantation loss and early embryonic death. When administered to pregnant rats from implantation through the closure of the hard palate (gestation days 6 to 16) at doses of 1 mg/kg/day and above (0.1-times the AUC observed in patients at the recommended dose of 80 mg), an equivocal increase in the rate of fetal malformations and variations was observed in treated litters relative to those of concurrent controls. When administered to pregnant dams at doses of 30 mg/kg/day during organogenesis through lactation Day 6, osimertinib caused an increase in total litter loss and postnatal death. At a dose of 20 mg/kg/day, osimertinib administration during the same period resulted in increased postnatal death as well as a slight reduction in mean pup weight at birth that increased in magnitude between lactation days 4 and 6.

Lactation

Risk Summary

There are no data on the presence of osimertinib in human milk, the effects of osimertinib on the breastfed infant or on milk production. Administration to rats during gestation and early lactation was associated with adverse effects, including reduced growth rates and neonatal death *[see Use in Specific Populations (8.1) in the full Prescribing Information]*. Because of the potential for serious adverse reactions in breastfed infants from osimertinib, advise a lactating woman not to breastfeed during treatment with TAGRISSO and for 2 weeks after the final dose.

Females and Males of Reproductive Potential

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with TAGRISSO and for 6 weeks after the final dose *[see Use in Specific Populations (8.1) in the full Prescribing Information]*.

Males

Advise male patients with female partners of reproductive potential to use effective contraception during and for 4 months following the final dose of TAGRISSO *[see Nonclinical Toxicology (13.1) in the full Prescribing Information]*.

Infertility

Based on animal studies, TAGRISSO may impair fertility in females and males of reproductive potential. It is not known if the effects on fertility are reversible *[see Nonclinical Toxicology (13.1) in the full Prescribing Information]*.

Pediatric Use

The safety and effectiveness of TAGRISSO in pediatric patients have not been established.

Geriatric Use

One hundred eighty-seven (45%) of the 411 patients in clinical trials of TAGRISSO were 65 years of age and older, and 54 patients (13%) were 75 years of age and older. No overall differences in effectiveness were observed based on age. Exploratory analysis suggest a higher incidence of Grade 3 and 4 adverse reactions (32% versus 25%) and more frequent dose modifications for adverse reactions (23% versus 17%) in patients 65 years or older as compared to those younger than 65 years.

Renal Impairment

No dedicated clinical studies have been conducted to evaluate the effect of renal impairment on the pharmacokinetics of osimertinib. Based on population pharmacokinetic analysis, no dose adjustment is recommended in patients with mild [creatinine clearance (CLcr) 60-89 mL/min] or moderate (CLcr 30-59 mL/min) renal impairment. There is no recommended dose of TAGRISSO for patients with severe renal impairment (CLcr <30 mL/min) or end-stage-renal disease *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

Hepatic Impairment

No dedicated clinical studies have been conducted to evaluate the effect of hepatic impairment on the pharmacokinetics of osimertinib. Based on population pharmacokinetic (PK) analysis, no dose adjustment is recommended in patients with mild hepatic impairment [total bilirubin <upper limit of normal (ULN) and AST between 1 to 1.5 times ULN or total bilirubin between 1.0 to 1.5 times ULN and any AST]. There is no recommended dose for TAGRISSO for patients with moderate or severe hepatic impairment *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Interstitial Lung Disease/Pneumonitis

Inform patients of the risks of severe or fatal ILD, including pneumonitis. Advise patients to contact their healthcare provider immediately to report new or worsening respiratory symptoms *[see Warnings and Precautions (5.1) in the full Prescribing Information]*.

QTc Interval Prolongation

Inform patients of symptoms that may be indicative of significant QTc prolongation including dizziness, lightheadedness, and syncope. Advise patients to report these symptoms and to inform their physician about the use of any heart or blood pressure medications *[see Warnings and Precautions (5.2) in the full Prescribing Information]*.

Cardiomyopathy

- TAGRISSO can cause cardiomyopathy. Advise patients to immediately report any signs or symptoms of heart failure to their healthcare provider *[see Warnings and Precautions (5.3) in the full Prescribing Information]*.

Embryo-Fetal Toxicity

- TAGRISSO can cause fetal harm if taken during pregnancy. Advise pregnant women of the potential risk to a fetus.
- Advise females to inform their healthcare provider if they become pregnant or if pregnancy is suspected, while taking TAGRISSO *[see Warnings and Precautions (5.3) and Use in Specific Populations (8.1) in the full Prescribing Information]*.

Females and Males of Reproductive Potential

- Advise females of reproductive potential to use effective contraception during treatment with TAGRISSO and for 6 weeks after the final dose *[see Use in Specific Populations (8.3) in the full Prescribing Information]*.
- Advise males to use effective contraception during treatment and for 4 months after the final dose of TAGRISSO *[see Use in Specific Populations (8.3) in the full Prescribing Information]*.

Lactation

Advise women not to breastfeed during treatment with TAGRISSO and for 2 weeks after the final dose *[see Use in Specific Populations (8.2) in the full Prescribing Information]*.

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Choosing Wisely® Oncology Primer

BY CINDY PARMAN, CPC, CPC-H, RCC

First announced in December 2011, Choosing Wisely (ChoosingWisely.org) is part of a multi-year effort led by the ABIM (American Board of Internal Medicine) Foundation to support and engage physicians in being better stewards of healthcare resources. The overall goal is to help physicians and patients engage in conversations to reduce overuse of tests and procedures and help patients make smart and effective care choices. Participating specialty societies are working with the ABIM Foundation and *Consumer Reports* to share the lists widely with their members and convene discussions about the physician's role in helping patients make wise care choices.

However, the frequency with which physicians provide tests and procedures on the Choosing Wisely questionable list has not changed much in the years since the start of this national campaign, according to a study published in *JAMA Internal Medicine*.[1] An accompanying editorial co-authored by Cary P. Gross, MD, of Yale University School of Medicine, and David H. Howard, PhD, of Emory University in Atlanta, asserted that clinical decision-making is just one piece of the puzzle when it comes to reducing unnecessary tests or treatments, and that more targeted research, including comparative effectiveness, would help by definitely determining which treatments or services were low-value.

Following are recommendations from several specialty societies; note that even if a cancer program is focused only on one treatment modality, all recommendations should be reviewed. For example, there are more items relating to imaging of cancer patients in the ASCO recommendations than in other specialty references.

AAHPM Recommendations

The American Academy of Hospice and Palliative Medicine (AAHPM) is the professional organization for physicians specializing in hospice and palliative medicine, nurses, and other healthcare providers. The Academy's core mission is to expand patient and family access to high-quality palliative care and advance the discipline of hospice and palliative medicine through professional education and training, development of a specialist workforce, support for clinical practice standards, and research and public policy. The core purpose of the Academy is to improve the care of patients with life-threatening or serious conditions through the advancement of hospice and palliative medicine. AAHPM offers the following recommendations:[2]

1. ***Don't delay palliative care for a patient with serious illness who has physical, psychological, social, or spiritual distress because they are pursuing disease-directed treatment.***
Numerous studies, including randomized trials, demonstrate that palliative care improves pain and symptom control, improves family satisfaction with care, and reduces costs. Palliative care does not accelerate death and may prolong life in selected populations.

2. ***Don't recommend more than a single fraction of palliative radiation for an uncomplicated painful bone metastasis.***
A single fraction of radiation to a previously un-irradiated peripheral bone or vertebral metastasis provides comparable pain relief and morbidity compared to multiple-fraction regimens, while optimizing patient and caregiver convenience. Although it results in a higher incidence of later need for retreatment, the decreased patient burden usually outweighs any considerations of long-term effectiveness for those with a limited life expectancy.

3. ***Don't use topical lorazepam, diphenhydramine, or haloperidol gel for nausea.***
Topical drugs, such as topical nonsteroidal anti-inflammatory drugs for local arthritis symptoms, can be safe and effective. However, whereas topical gels are commonly prescribed in hospice practice, anti-nausea gels have not proven effective in any large, well-designed, or placebo-controlled trials. The active ingredients in the gels are not absorbed to systemic levels that could be effective; only diphenhydramine is absorbed via the skin, and then only after several hours and erratically at sub-therapeutic levels. It is therefore not appropriate for "as needed" use. The use of agents given via inappropriate routes may delay or prevent the use of more effective interventions.

ASCO Recommendations

In April 2012 the American Society of Clinical Oncology (ASCO) released its initial list of

five key opportunities to improve care and reduce cost for services that are commonly ordered but may not always be appropriate as part of the national Choosing Wisely campaign.[3] According to ASCO, these initial five practices are in common use despite the absence of evidence supporting their clinical value:[4]

1. ***Don't use cancer-directed therapy for solid tumor patients with the following characteristics: low performance status (3 or 4), no benefit from prior evidence-based interventions, not eligible for a clinical trial, and no strong evidence supporting the clinical value of further anti-cancer treatment.***
   Studies show that cancer-directed treatments are likely to be ineffective for solid tumor patients who meet the above stated criteria. Exceptions include patients with functional limitations due to other conditions resulting in a low performance status or those with disease characteristics (e.g., mutations) that suggest a likelihood of response to therapy. Implementation of this approach should be accompanied with appropriate palliative and supportive care.

2. ***Don't perform PET, CT, and radionuclide bone scans in the staging of early prostate cancer at low risk for metastasis.***
   Imaging with PET, CT, or radionuclide bone scans can be useful in the staging of specific cancer types. However, these tests are often used in the staging evaluation of low-risk cancers, despite a lack of evidence suggesting they improve detection of metastatic disease or survival. Evidence does not support the use of these scans for staging of newly diagnosed low-grade carcinoma of the prostate (Stage T1c/T2a, prostate-specific antigen [PSA] <10 ng/ml, Gleason score less than or equal to 6) with low risk of distant metastasis. Unnecessary imaging can lead to harm through unnecessary invasive procedures, over-treatment, unnecessary radiation exposure, and misdiagnosis.

3. ***Don't perform PET, CT, and radionuclide bone scans in the staging of early breast cancer at low risk for metastasis.***
   Imaging with PET, CT, or radionuclide bone scans can be useful in the staging of specific cancer types. However, these tests are often used in the staging evaluation of low-risk cancers, despite a lack of evidence suggesting they improve detection of metastatic disease or survival. In breast cancer, for example, there is a lack of evidence demonstrating a benefit for the use of PET, CT, or radionuclide bone scans in asymptomatic individuals with newly identified ductal carcinoma in situ (DCIS), or clinical stage I or stage II disease. Unnecessary imaging can lead to harm through unnecessary invasive procedures, over-treatment, unnecessary radiation exposure, and misdiagnosis.

4. ***Don't perform surveillance testing (biomarkers) or imaging (PET, CT, and radionuclide bone scans) for asymptomatic individuals who have been treated for breast cancer with curative intent.***
   Surveillance testing with serum tumor markers or imaging has been shown to have clinical value for certain cancers (e.g., colorectal). However, for breast cancer that has been treated with curative intent, several studies have shown there is no benefit from routine imaging or serial measurement of serum tumor markers in asymptomatic patients. False-positive tests can lead to harm through unnecessary invasive procedures, over-treatment, unnecessary radiation exposure, and misdiagnosis.

5. ***Don't use white cell stimulating factors for primary prevention of febrile neutropenia for patients with less than 20 percent risk for this complication.***
   ASCO guidelines recommend using white cell stimulating factors when the risk of febrile neutropenia, secondary to a recommended chemotherapy regimen, is approximately 20 percent and equally effective treatment programs that do not require white cell stimulating factors are unavailable. Exceptions should be made when using regimens that have a lower chance of causing febrile neutropenia if it is determined that the patient is at high risk for this complication (due to age, medical history, or disease characteristics).

In October 2013, ASCO announced its second list of five opportunities to improve the quality and value of cancer care. These additional recommendations include:

1. ***Don't give patients starting on a chemotherapy regimen that has a low or moderate risk of causing nausea and vomiting antiemetic drugs intended for use with a regimen that has a high risk of causing nausea and vomiting.***
   Over the past several years, a large number of effective drugs with fewer side effects have been developed to prevent nausea and vomiting from chemotherapy. When successful, these medications can help patients avoid spending time in the hospital, improve quality of life, and lead to fewer changes in the chemotherapy regimen. Oncologists customarily use different antiemetic drugs depending on the likelihood (low, moderate, or high) for a particular chemotherapy program to cause nausea and vomiting. For chemotherapy programs that are likely to produce severe and persistent nausea and vomiting, there are new agents that can prevent this side effect. However, these drugs are very expensive and not devoid of side effects. For this reason, these drugs should be used only when the chemotherapy drugs have a high likelihood of causing severe or persistent

nausea and vomiting. When using chemotherapy that is less likely to cause nausea and vomiting, there are other effective drugs available at a lower cost.

2. ***Don't use combination chemotherapy (multiple drugs) instead of chemotherapy with one drug when treating an individual for metastatic breast cancer unless the patient needs a rapid response to relieve tumor-related symptoms.***
Although chemotherapy with multiple drugs, or combination chemotherapy, for metastatic breast cancer may slow tumor growth for a somewhat longer time than occurs when treating with a single agent, use of combination chemotherapy has not been shown to increase overall survival. In fact, the trade-offs of more frequent and severe side effects may have a net effect of worsening a patient's quality of life, necessitating a reduction in the dose of chemotherapy. Combination chemotherapy may be useful and worth the risk of more side effects in situations in which the cancer burden must be reduced quickly because it is causing significant symptoms or is life threatening. As a general rule, however, giving effective drugs one at a time lowers the risk of side effects, may improve a patient's quality of life, and does not typically compromise survival.

3. ***Avoid using PET or PET-CT scanning as part of routine follow-up care to monitor for a cancer recurrence in asymptomatic patients who have finished initial treatment to eliminate the cancer unless there is high-level evidence that such imaging will change the outcome.***
PET and PET-CT are used to diagnose, stage, and monitor how well treatment is working. Available evidence from clinical studies suggests that using these tests to monitor for recurrence does not improve outcomes and therefore generally is not recommended for this purpose. False-positive tests can lead to unnecessary invasive procedures, over-treatment, unnecessary radiation exposure, and incorrect diagnoses. Until high-level evidence demonstrates that routine surveillance with PET or PET-CT scans helps prolong life or promote well-being after treatment for a specific type of cancer, this practice should not be done.

4. ***Don't perform PSA testing for prostate cancer screening in men with no symptoms of the disease when they are expected to live less than 10 years. Since PSA levels in the blood have been linked with prostate cancer, many doctors have used repeated PSA tests in the hope of finding "early" prostate cancer in men with no symptoms of the disease.***
Unfortunately, PSA is not as useful for screening as many have hoped because many men with prostate cancer do not have high PSA levels, and other conditions that are not cancer (such as benign prostate hyperplasia) can also increase PSA levels. Research has shown that men who receive PSA testing are less likely to die specifically from prostate cancer. However, when accounting for deaths from all causes, no lives are saved, meaning that men who receive PSA screening have not been shown to live longer than men who do not have PSA screening. Men with medical conditions that limit their life expectancy to less than 10 years are unlikely to benefit from PSA screening as their probability of dying from the underlying medical problem is greater than the chance of dying from asymptomatic prostate cancer.

5. ***Don't use a targeted therapy intended for use against a specific genetic aberration unless a patient's tumor cells have a specific biomarker that predicts an effective response to the targeted therapy.***
Unlike chemotherapy, targeted therapy can significantly benefit people with cancer because it can target specific gene products, i.e., proteins that cancer cells use to grow and spread, while causing little or no harm to healthy cells. Patients who are most likely to benefit from targeted therapy are those who have a specific biomarker in their tumor cells that indicates the presence or absence of a specific gene alteration that makes the tumor cells susceptible to the targeted agent. Compared to chemotherapy, the cost of targeted therapy is generally higher, as these treatments are newer, more expensive to produce, and under patent protection. In addition, like all anti-cancer therapies, there are risks to using targeted agents when there is no evidence to support their use because of the potential for serious side effects or reduced efficacy compared with other treatment options.

ASTRO Recommendations

In September 2013, the American Society for Radiation Oncology (ASTRO) released its first list of five radiation oncology-specific treatments that are commonly ordered but may not always be appropriate as part of the national Choosing Wisely campaign.[5] The list identifies five targeted treatment options that ASTRO recommends for detailed patient-physician discussion before being prescribed:

1. ***Don't initiate whole breast radiotherapy as a part of breast conservation therapy in women age ≥50 with early stage invasive breast cancer without considering shorter treatment schedules.***
Whole breast radiotherapy decreases local recurrence and improves survival of women with invasive breast cancer treated with breast conservation therapy. Most studies have utilized "conventionally fractionated" schedules that deliver therapy over 5-6 weeks, often followed by 1-2 weeks of boost therapy. Recent studies, however, have demonstrated equivalent tumor control and cosmetic

outcome in specific patient populations with shorter courses of therapy (approximately 4 weeks). Patients and their physicians should review these options to determine the most appropriate course of therapy.

2. ***Don't initiate management of low-risk prostate cancer without discussing active surveillance.***
Patients with prostate cancer have a number of reasonable management options. These include surgery and radiation, as well as conservative monitoring without therapy in appropriate patients. Shared decision-making between the patient and the physician can lead to better alignment of patient goals with treatment and more efficient care delivery. ASTRO has published patient-directed written decision aids concerning prostate cancer and numerous other types of cancer. These types of instruments can give patients confidence about their choices, improving compliance with therapy.

3. ***Don't routinely use extended fractionation schemes (>10 fractions) for palliation of bone metastases.***
Studies suggest equivalent pain relief following 30 Gy in 10 fractions, 20 Gy in 5 fractions, or a single 8 Gy fraction. A single treatment is more convenient but may be associated with a slightly higher rate of retreatment to the same site. Strong consideration should be given to a single 8 Gy fraction for patients with a limited prognosis or with transportation difficulties.

4. ***Don't routinely recommend proton beam therapy for prostate cancer outside of a prospective clinical trial or registry.***
There is no clear evidence that proton beam therapy for prostate cancer offers any clinical advantage over other forms of definitive radiation therapy. Clinical trials are necessary to establish a possible advantage of this expensive therapy.

5. ***Don't routinely use intensity modulated radiation therapy (IMRT) to deliver whole breast radiotherapy as part of breast conservation therapy.***
Clinical trials have suggested lower rates of skin toxicity after using modern 3D conformal techniques relative to older methods of 2D planning. In these trials, the term "IMRT" has generally been applied to describe methods that are more accurately defined as field-in-field 3D conformal radiotherapy. While IMRT may be of benefit in select cases where the anatomy is unusual, its routine use has not been demonstrated to provide significant clinical advantage.

In January 2014, ASTRO formed a group to develop its second Choosing Wisely list, which included representatives from health policy, government relations, and clinical affairs and quality. Based on survey results, the work group submitted a short list of eight items to the ASTRO Board of Directors, from which the Board chose the additional five items listed below:[6]

1. ***Don't recommend radiation following hysterectomy for endometrial cancer patients with low-risk disease.***
Patients with low-risk endometrial cancer, including no residual disease in hysterectomy despite positive biopsy, grade 1 or 2 with <50 percent myometrial invasion and no additional high-risk features, such as age > 60, lymphovascular space invasion or cervical involvement have a very low risk of recurrence following surgery. Meta-analysis studies of radiation therapy for low-risk endometrial cancer demonstrate increased side effects with no benefit in overall survival compared with surgery alone.

2. ***Don't routinely offer radiation therapy for patients who have resected non-small cell lung cancer (NSCLC) negative margins, No-1 disease.***
Patients with early stage NSCLC have several management options following surgery, including observation, chemotherapy, and radiotherapy. Patients with positive margins following surgery may benefit from post-operative radiotherapy to improve local control regardless of the status of their nodal disease. However, two meta-analysis studies of post-operative radiotherapy in early NSCLC with node negative or N1 disease suggest increased side effects with no benefit for disease-free survival or overall survival compared to observation.

3. ***Don't initiate non-curative radiation therapy without defining goals of treatment with the patient and considering palliative care referral.***
Well-defined goals of therapy are associated with improved quality of life and better understanding on the part of patients and their caregivers. Palliative care can be delivered concurrently with anti-cancer therapies and early palliative care intervention may improve patient outcomes, including survival.

4. ***Don't routinely recommend follow-up mammograms more often than annually for women who have had radiotherapy following breast conserving surgery.***
Studies indicate that annual mammograms are the appropriate frequency for surveillance of breast cancer patients who have had breast conserving surgery and radiation therapy with no clear advantage to shorter interval imaging. Patients should wait 6 to 12 months after the completion of radiation therapy to begin their annual mammogram surveillance. Suspicious findings on physical examination or surveillance imaging might warrant a shorter interval between mammograms.

5. ***Don't routinely add adjuvant whole brain radiation therapy to stereotactic radiosurgery for limited brain metastases.***
Randomized studies have demonstrated no overall survival benefit from the addition of adjuvant whole brain radiation therapy (WBRT) to stereotactic radiosurgery (SRS) in the management of selected patients with good performance status and brain metastases from solid tumors. The addition of WBRT to SRS is associated with diminished cognitive function and worse patient-reported fatigue and quality of life. These results are consistent with the worsened self-reported cognitive function and diminished verbal skills observed in randomized studies of prophylactic cranial irradiation for small cell or non-small cell lung cancer. Patients treated with radiosurgery for brain metastases can develop metastases elsewhere in the brain. Careful surveillance and the judicious use of salvage therapy at the time of brain relapse allow appropriate patients to enjoy the highest quality of life without a detriment in overall survival. Patients should discuss these options with their radiation oncologist.

ONS Recommendations

The American Academy of Nursing (AAN) has also engaged in the Choosing Wisely dialogue by creating "Ten Things Nurses and Patients Should Question," which is located on the AAN website.[7] While the first five recommendations may not directly impact oncology patients, the second set of five recommendations from the Oncology Nursing Society (ONS) include:

1. ***Don't use aloe vera on skin to prevent or treat radiodermatitis.***
Radiodermatitis can cause patient pain and pruritus that affect quality of life, body image, and sleep. Severe radiodermatitis can necessitate dose reductions or treatment delays that negatively impact the ability to adequately treat the cancer. The incidence of radiodermatitis can be as high as 95 percent, depending upon the population of patients receiving treatment. Studies documenting incidence have primarily occurred in women receiving treatment for breast cancer. Many Internet sites market aloe to individuals for what is commonly termed "sunburn type" reactions from radiation therapy. Research evidence shows that aloe vera is not beneficial for the prevention or treatment of radiodermatitis, and one study reported worse patient outcomes with use of aloe vera. Patients undergoing radiation therapy need to know that aloe vera should not be used to prevent or treat skin reactions from radiation therapy, since it has been shown to be ineffective and has the potential to make skin reactions worse.

2. ***Don't use L-carnitine/acetyl-L-carnitine supplements to prevent or treat symptoms of peripheral neuropathy in patients receiving chemotherapy for treatment of cancer.***
Peripheral neuropathy is a chronic side effect of some chemotherapeutic agents. This can be a significant quality of life issue for patients, affecting functional ability and comfort. In the public realm, numerous Internet sites that sell herbal and dietary supplements have specifically recommended L-carnitine/acetyl-L-carnitine for symptoms of peripheral neuropathy. This supplement is available without a physician prescription. Evidence not only has shown use of carnitine supplements to be ineffective, but research also has shown it may make symptoms worse. Current professional guidelines contain a strong recommendation against the use of L-carnitine for prevention of chemotherapy-induced peripheral neuropathy. Nurses need to educate patients not to use this dietary supplement while undergoing chemotherapy for cancer.

3. ***Don't neglect to advise patients with cancer to get physical activity and exercise during and after treatment to manage fatigue and other symptoms.***
During treatment for cancer, up to 99 percent of patients will have fatigue and many individuals continue to experience persistent fatigue for years after completion of treatment. It is the natural tendency for people to try to get more rest when feeling fatigued and healthcare providers have traditionally been educated about the importance of getting rest and avoiding strenuous activity when ill. In contrast to these traditional views, resistance and aerobic exercise have been shown to be safe, feasible, and effective in reducing symptoms of fatigue during multiple phases of cancer care. Exercise has also been shown to have a positive effect on symptoms of anxiety and depression. Current professional guidelines recommend 150 minutes of moderate-level exercise such as fast-walking, cycling, or swimming per week along with 2-3 strength training sessions per week, unless specifically contraindicated.

4. ***Don't use mixed medication mouthwash, commonly termed "magic mouthwash," to prevent or manage cancer treatment-induced oral mucositis.***
Oral mucositis is a painful and debilitating side effect of some chemotherapeutic agents and radiation therapy that includes the oral mucosa in the treatment field. Painful mucositis impairs the ability to eat and drink fluids and impacts quality of life. Oral mucositis can result in the need for hospitalization for pain control and provision of total parenteral nutrition in order to maintain adequate nutritional intake during cancer treatment. Mixed medication mouthwash, also commonly known by other names such as "magic mouthwash," "Duke's magic mouthwash," or "Mary's

magic mouthwash," is commonly used to prevent or treat oral mucositis. These are often compounded by a pharmacy, are expensive, and may not be covered by health insurance. Research has shown that magic mouthwash was reported to cause taste changes, irritating local side effects, and is no more effective than salt and baking soda (sodium bicarbonate) rinses. Instead, frequent and consistent oral hygiene and use of salt or soda mouth rinses can be used.

5. ***Don't administer supplemental oxygen to relieve dyspnea in patients with cancer who do not have hypoxia.***

Reports of the prevalence of dyspnea range from 21 percent to 90 percent overall among patients with cancer, and the prevalence and severity of dyspnea increase in the last six months of life, regardless of cancer diagnosis. Supplemental oxygen therapy is commonly prescribed to relieve dyspnea in people with advanced illness despite arterial oxygen levels within normal limits, and has been seen as standard care. Supplemental oxygen is costly and there are multiple safety risks associated with use of oxygen equipment. People also experience functional restriction and may have some distress from being attached to a device. Palliative oxygen (administration in nonhypoxic patients) has consistently been shown not to improve dyspnea in individual studies and systematic reviews. Rather than use a costly and ineffective intervention for dyspnea, care should be focused on those interventions which have demonstrated efficacy such as immediate release opioids.

Summary

The importance of reducing unneeded testing and medications can be a complicated message, especially for consumers, who have been conditioned to think that "more is better," said Lisa Letourneau, MD, MPH, executive director for Maine Quality Counts, one of the Choosing Wisely grantees.[8] She compares the "choosing wisely" message to other public health campaigns such as "don't drink and drive," but acknowledges that "choosing wisely" is more complex because it is not simply a question of convincing the public to stop a specific behavior. The message for patients should always be: "Get the care you need and not the care you don't." OI

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More about ABIM Foundation & the Choosing Wisely Campaign

The mission of the ABIM Foundation is to advance medical professionalism to improve the healthcare system (abimfoundation.org). The foundation achieves this by collaborating with physicians and physician leaders, medical trainees, healthcare delivery systems, payers, policy makers, consumer organizations, and patients to foster a shared understanding of professionalism and how they can adopt the tenets of professionalism in practice. To date, more than 80 national and state medical specialty societies, regional health collaboratives, and consumer partners have joined the Choosing Wisely campaign to promote conversations about appropriate care. In addition, the campaign will have covered more than 250 tests and procedures that the specialty society partners say are potentially overused and inappropriate, and that physicians and patients should discuss.

The campaign also continues to reach millions of consumers nationwide through a stable of consumer and advocacy partners, led by *Consumer Reports*, the world's largest independent product-testing organization, which has worked with the ABIM Foundation to distribute patient-friendly resources for consumers and physicians to engage in these important conversations.

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spotlight

Kootenai Clinic Cancer Services

Coeur d'Alene, Idaho

Kootenai Clinic Cancer Services is a community hospital-based comprehensive cancer care program. Developed in 1987, this American College of Surgeons Commission on Cancer-accredited program serves five northern counties in Idaho and Western Montana. Additionally, Kootenai's Outpatient Imaging Center is accredited through the American College of Radiology as a Breast Imaging Center of Excellence.

Kootenai provides cancer services in three locations throughout its catchment area. The largest facility is located in Coeur d'Alene, Idaho, on the Kootenai Health hospital campus. The two-story structure encompasses a 22-station infusion center (18 chairs and 4 beds) all equipped with lounge heat/massage chairs and TV/DVD players, medical oncology clinic space, and radiation oncology services. The building recently upgraded its lobby areas, clinic space, and infusion areas with new flooring, lighting, art work, and furniture.

A second location in Post Falls, Idaho, about 10 miles from the hospital campus, is the newest facility. "Our location out in Post Falls is a beautiful, new building with a lot of windows and great south-facing mountain views from the infusion room. It's a very comforting facility," said Kimberly Christen, RN, BSN, OCN, Clinical Operations Supervisor. Built in fall 2009, Kootenai Clinic Cancer Services in Post Falls also provides the same scope of comprehensive cancer care as the Coeur d'Alene location:

- Medical oncology
- Radiation oncology (in partnership with Cancer Care Northwest/Inner Pacific Alliance for Cancer Care)
- Infusion services
- Laboratory
- Pharmacy (with designated oncology pharmacy staff)
- Social worker and financial advocate
- Dietitian services
- Navigation services.

Partnering with Cancer Care Northwest and Providence Sacred Heart under the InnerPacific Alliance for Cancer Care umbrella, the radiation oncology department offers state-of-the-art technologies, such as linear accelerator-based treatments, Gamma Knife, stereotactic radiosurgery, MammaSite treatment for breast cancer patients, and brachytherapy for GYN and prostate cancer patients.

The third Kootenai Clinic Cancer Services site in Sandpoint (about 50 miles from the main hospital) operates similar to a satellite location and is adjacent to an affiliated hospital, Bonner General Hospital. Sandpoint is open three days a week and offers all the same on-site services as its sister locations, with the exception of radiation oncology.

Reaching Rural Patients

As a member of the Mayo Clinic Care Network, Kootenai Clinic Cancer Services oncologists have access to the knowledge and expertise of the Mayo Clinic in Rochester, Minnesota. This membership enables e-consultations for patients unable to travel, allowing them to receive second opinions without leaving home. Kootenai providers can send images, pathology slides, etc., to Mayo with the consult typically routed to an expert in that particular disease state. "We get a response back from them usually within a week. It's great because the patients don't need to leave home to get the expert opinion from a tertiary care center," said Kevin Mulvey, MD, medical director of Kootenai Clinic Cancer Services.

Services like these e-consultations are especially useful to a rural patient population. "The five northern counties are spread quite far and are very rural with a high number of small communities. Providing gas cards for patients who have daily radiation has been the key to getting some of the lower income, rural folks in for daily radiation," said Teresa Johnston, RN, BSN, OCN, regional manager, Cancer Services.

Kootenai Health has an independent Kootenai Health Foundation program that contributes annually to the Cancer Patient Support Fund. Funds are filtered into the Foundation via community fundraising, donations, and philanthropy. The program, which serves uninsured and underinsured patients, covers needs such as co-pay assistance, gas, groceries, and other living expenses. Kootenai also partners with the American Cancer Society's Road to Recovery for volunteer transportation services.

Kootenai brings clinical trials to their patient community via their membership in a cooperative research group. The Montana Cancer Consortium (MCC) enables access to a multitude of clinical trials through the National Community Oncology Research Program (NCORP). Comprised of 12 community oncology practices throughout Montana,

northern Idaho, and northern Wyoming, MCC maintains a robust clinical trials program through an aggressive screening process, with each new diagnosis reviewed by the research team, consisting of a research RN and a clinical research associate. To date, Kootenai Clinic Cancer Services has an accrual rate of 6 percent, the highest within the group.

Evolving Supportive Care

Kootenai Clinic Cancer Services currently employs three clinical nurse navigators, all OCNs with extensive oncology experience. The navigation program was first launched in 2011 initially with a thoracic focus and then expanded in 2012 to add a breast navigator. A third general navigator was added in fall 2014 "as we recognized the value and believed all patients should benefit from navigation," said Johnston. Navigators begin developing relationships with patients at the time of referral and serve as the primary point of contact to ensure a timely journey from treatment start to finish.

Survivorship services were recently developed in 2015 with a collaborative approach under the guidance of Kootenai's Cancer Committee. The navigators work with the physicians to develop the care plan and treatment summary. Once the summary is complete, the patient is instructed to complete a quality-of-life assessment to assist in creating the framework for the survivorship visit with an advanced practice provider. This visit may include referrals to social work, dietitian services, or other community resources.

A social worker and financial advocate work on-site in each Kootenai Clinic Cancer Services location. The dietitian coordinates with the nursing team in responding to nutritional screening consults. At the cancer clinic in Coeur d'Alene, oncology patients can also access rehabilitation services, such as a lymphedema specialist, and support groups, such as a breast cancer support group and general cancer support group. Inpatient palliative care services are available through the hospital.

Kootenai Clinic Cancer Services works to expand comprehensive care into the community via a robust outreach program under the direction of outreach coordinator Tolli Willhite. Successful past community events include:

- Spot Checks–a skin cancer screening program held at all three sites, in partnership with local dermatology clinics.
- Eat to Beat Colon Cancer–a public forum to educate on screening, early detection, prevention, and treatment.
- Pamper Me Pink–a breast cancer awareness event to educate the public regarding mammography, early detection, and treatment options.

Process Improvement

In 2011 Kootenai Clinic Cancer Services launched a thoracic working group, including an interdisciplinary thoracic-focused cancer conference held twice monthly to discuss the management of new cases. Attendees include navigation, thoracic surgeons, pulmonologists, radiation oncologists, medical oncologists, radiology, and pathology.

A twice monthly breast cancer working group was then developed in 2012. All new breast cases are reviewed by the working group, which includes navigation, general surgery, radiation oncologists, medical oncologists, reconstructive surgeons, radiology, pathology, a genetics coordinator, and a clinical research RN.

"The development of these site-specific work groups has drastically reduced our diagnosis to treatment delays," said Johnston. Since launching the thoracic group, diagnosis to treatment time was reduced by about 29 percent for this disease site.

Diagnosis to treatment time for breast patients has also been reduced by about 30 percent. These improvements were greatly impacted by the Kootenai Outpatient Imaging team who alert the navigator of all positive findings. The imaging team routinely performs same-day ultrasounds on abnormal mammograms. Kootenai Clinic Cancer Services is currently looking to develop another multidisciplinary work group for head and neck cancers. OI

Select Support Services

- Navigation
- Dietitian
- Financial advocate
- Social work
- Genetic counseling
- Lymphedema specialist

New analytic cases in 2014: 1,073
Percent of patients accrued to clinical trials in 2014: 6%

tools

Approved Drugs

• The FDA approved **everolimus** (**Afinitor**, Novartis, novartis.com) for the treatment of adult patients with progressive, well-differentiated non-functional, neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin with unresectable, locally advanced or metastatic disease.

• The FDA approved **Defitelio** (**defibrotide sodium**, Jazz Pharmaceuticals, Inc., jazzpharma.com) for the treatment of adult and pediatric patients with hepatic veno-occlusive disease (VOD), also known as sinusoidal obstructive syndrome, with renal or pulmonary dysfunction following hematopoietic stem-cell transplantation (HSCT).

• Spectrum Pharmaceuticals (sppirx.com) announced that the FDA has granted approval of **Evomela**™ (**melphalan**) **for Injection** for use in two indications: 1) use as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation (ASCT) in patients with multiple myeloma (MM), and 2) for the palliative treatment of patients with MM for whom oral therapy is not appropriate.

• AstraZeneca (astrazeneca-us.com) announced that the FDA has approved a new indication expanding the use of **Faslodex**® (**fulvestrant**) to include use in combination with **palbociclib**. The combination use is for the treatment of women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) advanced or metastatic breast cancer (MBC) whose cancer has progressed after endocrine therapy.

• The FDA approved **obinutuzumab** (**Gazyva Injection**, Genentech, Inc., gene.com) for use in combination with bendamustine followed by obinutuzumab monotherapy for the treatment of patients with follicular lymphoma (FL) who relapsed after, or are refractory to, a rituximab containing regimen. Obinutuzumab was previously approved for use in combination with chlorambucil for the treatment of patients with previously untreated chronic lymphocytic leukemia.

• Boehringer Ingelheim (us.boehringer-ingelheim.com) announced that the FDA has approved a supplemental New Drug Application (sNDA) for **Gilotrif**® (**afatinib**) **tablets** for the treatment of patients with advanced squamous cell carcinoma of the lung whose disease has progressed after treatment with platinum-based chemotherapy.

• The FDA approved **Imbruvica** (**ibrutinib**, AbbVie, abbvie.com) as a first-line treatment for patients with chronic lymphocytic leukemia (CLL).

• The FDA approved **venetoclax** (**Venclexta tablets**, AbbVie, Inc., abbvie.com, and Genentech USA, Inc., gene.com) for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA-approved test, who have received at least one prior therapy.

• The FDA approved **crizotinib capsules** (**Xalkori**, Pfizer, Inc., pfizer.com) for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive. Crizotinib was first approved in 2011 for the treatment of patients whose tumors are anaplastic lymphoma kinase (ALK)-positive.

Drugs in the News

• Genmab A/S (genmab.com) announced that a supplemental Biologics License Application (sBLA) has been submitted to the FDA for the use of **ofatumumab** (**Arzerra**®) **in combination with fludarabine and cyclophosphamide** (**FC**) for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL). The application was submitted by Novartis under the ofatumumab collaboration between Novartis and Genmab.

• Amgen (amgen.com) announced the submission of a supplemental Biologics License Application (sBLA) to the FDA for **Blincyto**® (**blinatumomab**) to include new data supporting the treatment of pediatric and adolescent patients with Philadelphia chromosome-negative (Ph-) relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). Blincyto, the first-and-only FDA-approved bispecific CD19-directed CD3 T cell engager (BiTE®) immunotherapy, is currently

available under an accelerated approval in the U.S. for the treatment of Ph- relapsed or refractory B-cell precursor ALL, a rare and rapidly progressing cancer of the blood and bone marrow impacting both adults and children.

• Actinium Pharmaceuticals, Inc. (actinium-pharma.com) announced that the FDA has granted orphan drug designation for **Iomab-B**, a radioimmunotherapeutic that conditions relapsed and refractory Acute Myeloid Leukemia (AML) patients for a hematopoietic stem cell transplant (HSCT), commonly referred to as a bone marrow transplant (BMT). Iomab-B will soon begin a 150 patient, pivotal Phase 3 multicenter trial in relapsed and refractory AML patients over the age of 55.

• Merck (merck.com) announced that the FDA has accepted for review the supplemental Biologics License Application (sBLA) for **Keytruda**® (**pembrolizumab**), the company's anti-PD-1 therapy, for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy. The application is seeking approval for Keytruda as a single agent at a dose of 200 mg administered intravenously every three weeks.

• Genentech (gene.com) announced that the FDA has accepted the company's Biologics License Application (BLA) and granted Priority Review for **atezolizumab** (**anti-PDL1; MPDL3280A**) for the treatment of people with locally advanced or metastatic urothelial carcinoma (mUC) who had disease progression during or following platinum-based chemotherapy in the metastatic setting, or whose disease worsened within 12 months of receiving platinum-based chemotherapy before surgery (neoadjuvant) or after surgery (adjuvant).

• Bristol-Myers Squibb Company (bms.com) announced that the FDA accepted a supplemental Biologics License Application (sBLA), which seeks to expand the use of **Opdivo** (**nivolumab**) to patients with classical Hodgkin lymphoma (cHL) after prior therapies.

• ProNAi Therapeutics, Inc. (pronai.com) announced that its oncology drug candidate **PNT2258** has been granted orphan drug designation by the FDA for the treatment of diffuse large B-cell lymphoma (DLBCL).

• DelMar Pharmaceuticals, Inc. (delmar-pharma.com) announced that the FDA Office of Orphan Products Development (OOPD) has granted orphan drug designation for its lead product candidate, **VAL-083**, in the treatment of medulloblastoma.

• SELLAS Life Sciences Group (sellaslife-sciences.com) announced that the FDA granted orphan drug designation for the company's **WT1 cancer vaccine** for the treatment of patients with malignant pleural mesothelioma (MPM). SELLAS recently reported positive results of a Phase 2 trial of its WT1 vaccine in MPM patients, showing that overall survival improved and progression-free survival doubled. Based on these findings, SELLAS intends to initiate a pivotal Phase 2b/3 trial of its product candidate in patients with MPM by the third quarter of 2016.

Approved Devices

• BD (Becton, Dickinson and Company, bd.com) announced it has received FDA approval for its **BD Totalys™ MultiProcessor** and **BD Totalys™ SlidePrep instruments**. Together with the BD FocalPoint™ SlideProfiler, these innovations comprise the full BD Totalys System, which further automates slide preparation, imaging and review for use in cervical cancer screening, as well as providing ancillary testing aliquot capability.

• Dignitana Inc. (dignicap.com) announced that the **DigniCap® scalp cooling system**, which was cleared by the FDA in December to effectively reduce the likelihood of chemotherapy-induced hair loss in women with breast cancer, is now available at ten cancer treatment centers across the U.S. Scalp cooling is administered alongside chemotherapy in medical infusion centers.

• Bracco Diagnostics Inc. (braccoimaging.com) announced that **Lumason** is now approved for use in ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients.

In October 2014 Lumason, known globally as SonoVue®, was approved by the FDA for use in adults with suboptimal echocardiograms, to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border in adult patients.

Devices in the News

• Royal Philips (philips.com) introduced the first commercially available MR-only simulation solution indicated for prostate cancer radiation oncology treatment planning in the U.S. Philips has achieved 510(k) clearance from the FDA for its **MRCAT** (**Magnetic Resonance for Calculating ATtenuation**) **solution** as part of its Ingenia MR-RT platform.

Indication

IRESSA is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

There's marking time...

and there's making memories

Efficacy was demonstrated in the IFUM* study

- IRESSA achieved a 50% objective response rate (ORR) (95% confidence interval [CI]: 41, 59) by blinded independent central review (BICR) and a 70% ORR (95% CI: 61, 78) by investigator assessment

Efficacy was confirmed by the IPASS† study

- 3.5-month improvement in progression-free survival (median) vs chemotherapy—10.9 months with IRESSA vs 7.4 months with carboplatin/paclitaxel (HR=0.54; 95% CI: 0.38, 0.79) by BICR

Safety was established in the ISEL‡ study

- The most frequent adverse reactions (incidence of >20% and greater than placebo) reported in IRESSA-treated patients were skin reactions (47%) and diarrhea (29%)
- ≤5.1% of IRESSA-treated patients experienced severe adverse reactions
- Approximately 5% of IRESSA-treated patients and 2.3% of placebo-treated patients discontinued treatment due to an adverse event; the most frequent adverse reactions that led to discontinuation in patients treated with IRESSA were nausea (0.5%), vomiting (0.5%) and diarrhea (0.4%)

Limitation of Use: Safety and efficacy of IRESSA have not been established in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

Important Safety Information

- There are no contraindications for IRESSA
- Interstitial Lung Disease (ILD) or ILD-like reactions (eg, lung infiltration, pneumonitis, acute respiratory distress syndrome, or pulmonary fibrosis) occurred in 1.3% of 2462 IRESSA patients; of these, 0.7% were Grade ≥3 and 3 cases were fatal. Withhold IRESSA and promptly investigate for ILD in any patient who presents with worsening of respiratory symptoms such as dyspnea, cough and fever. Permanently discontinue IRESSA if ILD is confirmed
- In patients who received IRESSA, 11.4% of patients had increased alanine aminotransferase (ALT), 7.9% of patients had increased aspartate aminotransferase (AST), and 2.7% of patients had increased bilirubin. Grade ≥3 liver test abnormalities occurred in 5.1% ALT, 3.0% AST, and 0.7% bilirubin of patients. The incidence of fatal hepatotoxicity was 0.04%. Obtain periodic liver function testing. Withhold IRESSA in patients with worsening liver function and discontinue in patients with severe hepatic impairment
- Gastrointestinal perforation occurred in three (0.1%) of 2462 IRESSA patients. Permanently discontinue IRESSA in patients who develop gastrointestinal perforation
- Grade ≥3 diarrhea occurred in 3% of 2462 IRESSA patients. Withhold IRESSA for severe or persistent (up to 14 days) diarrhea
- Ocular disorders [keratitis (0.1%), corneal erosion and aberrant eyelash growth (0.2%), conjunctivitis, blepharitis and dry eye (6.7%)] occurred in 2462 IRESSA patients. The incidence of Grade 3 ocular disorders was 0.1%. Interrupt or discontinue IRESSA for severe or worsening ocular disorders
- Bullous conditions including toxic epidermal necrolysis, Stevens Johnson syndrome and erythema multiforme have been reported from treatment with IRESSA. Erythema multiforme and dermatitis bullous have been reported in two patients (0.08%) across NSCLC trials. IRESSA treatment should be interrupted or discontinued if patients develop severe bullous, blistering or exfoliating conditions
- Based on its mechanism of action and data from animal reproduction studies IRESSA can cause fetal harm when administered to a pregnant woman. In animal reproductive studies, oral administration of gefitinib from organogenesis through weaning resulted in fetotoxicity and neonatal death at doses below the recommended human dose. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with IRESSA and for at least two weeks following completion of therapy
- Advise women to discontinue breast-feeding during treatment with IRESSA
- The most commonly reported adverse drug reactions reported in more than 20% of patients and greater than placebo, were skin reactions (47%) and diarrhea (29%)

Please see brief summary of complete Prescribing Information on adjacent pages.

*IRESSA efficacy was evaluated in a multicenter, single-arm, open-label study as a first-line treatment of 106 Caucasian patients with EGFR mutation-positive metastatic NSCLC. IFUM=IRESSA Follow-Up Measure.

†IPASS included an exploratory analysis of a subset of a randomized, multicenter, open-label trial conducted in patients with metastatic adenocarcinoma histology NSCLC receiving first-line treatment. Patients received IRESSA 250 mg orally once daily (n=88) or up to 6 cycles of carboplatin/paclitaxel (n=98). IPASS=IRESSA Pan-Asia Study.

‡Common adverse reactions were evaluated in ISEL, a randomized, multicenter, double-blind, placebo-controlled study of 1692 metastatic NSCLC patients. Patients received IRESSA 250 mg daily (n=1126) or placebo (n=562). ISEL=IRESSA Survival Evaluation in Lung Cancer. A pooled safety database from 3 randomized trials was used to evaluate for serious and uncommon adverse drug reactions.

IRESSA®
gefitinib

AstraZeneca

IRESSA® (gefitinib) tablets for oral use

Brief Summary of Prescribing Information.
For complete prescribing information consult official package insert

INDICATIONS AND USAGE
IRESSA is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test *[see Clinical Studies (14) in the full Prescribing Information]*.

Limitation of Use: Safety and efficacy of IRESSA have not been established in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations *[see Clinical Studies (14) in the full Prescribing Information]*.

DOSAGE AND ADMINISTRATION

Patient Selection
Select patients for the first-line treatment of metastatic NSCLC with IRESSA based on the presence of EGFR exon 19 deletion or exon 21 (L858R) substitution mutations in their tumor *[see Indications and Usage (1)* and *Clinical Studies (14) in the full Prescribing Information]*. Information on FDA-approved tests for the detection of EGFR mutations in NSCLC is available at: http://www.fda.gov/CompanionDiagnostics.

Recommended Dose
The recommended dose of IRESSA is 250 mg orally once daily with or without food until disease progression or unacceptable toxicity.

Do not take a missed dose within 12 hours of the next dose.

Administration to Patients Who Have Difficulty Swallowing Solids
Immerse IRESSA tablets in 4 to 8 ounces of water by dropping the tablet in water, and stir for approximately 15 minutes. Immediately drink the liquid or administer through a naso-gastric tube. Rinse the container with 4 to 8 ounces of water and immediately drink or administer through the naso-gastric tube.

Dose Modification

Dose Modifications for Adverse Drug Reactions

Withhold IRESSA (for up to 14 days) for any of the following:
- Acute onset or worsening of pulmonary symptoms (dyspnea, cough, fever) *[see Warnings and Precautions (5.1) in the full Prescribing Information]*
- NCI CTCAE Grade 2 or higher in ALT and/or AST elevations [*see Warnings and Precautions (5.2) in the full Prescribing Information*]
- NCI CTCAE Grade 3 or higher diarrhea *[see Warnings and Precautions (5.4) in the full Prescribing Information]*
- Signs and symptoms of severe or worsening ocular disorders including keratitis *[see Warnings and Precautions (5.5) in the full Prescribing Information]*
- NCI CTCAE Grade 3 or higher skin reactions *[see Warnings and Precautions (5.6) in the full Prescribing Information]*

Resume treatment with IRESSA when the adverse reaction fully resolves or improves to NCI CTCAE Grade 1.

Permanently discontinue IRESSA for:
- Confirmed interstitial lung disease (ILD) *[see Warnings and Precautions (5.1) in the full Prescribing Information]*
- Severe hepatic impairment *[see Warnings and Precautions (5.2) in the full Prescribing Information]*
- Gastrointestinal perforation *[see Warnings and Precautions (5.3) in the full Prescribing Information]*
- Persistent ulcerative keratitis *[see Warnings and Precautions (5.5) in the full Prescribing Information]*

Dose Modifications for Drug Interactions

Strong CYP3A4 Inducers
Increase IRESSA to 500 mg daily in the absence of severe adverse drug reaction, and resume IRESSA at 250 mg seven days after discontinuation of the strong CYP3A4 inducer *[see Drug Interactions (7)* and *Clinical Pharmacology (12.3) in the full Prescribing Information]*.

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS

Interstitial Lung Disease (ILD)
ILD or ILD-like adverse drug reactions (e.g., lung infiltration, pneumonitis, acute respiratory distress syndrome, or pulmonary fibrosis) occurred in 1.3% of the 2462 patients who received IRESSA across clinical trials; of these, 0.7% were Grade 3 or higher and 3 cases were fatal.

Withhold IRESSA and promptly investigate for ILD in any patient who presents with worsening of respiratory symptoms such as dyspnea, cough and fever. Permanently discontinue IRESSA if ILD is confirmed [*see Dosage and Administration (2.4) and Adverse Reactions (6.1) in the full Prescribing Information*].

Hepatotoxicity
In patients who received IRESSA across clinical trials, 11.4% of patients had increased alanine aminotransferase (ALT), 7.9% of patients had increased aspartate aminotransferase (AST), and 2.7% of patients had increased bilirubin. Grade 3 or higher liver test abnormalities occurred in 5.1% (ALT), 3.0% (AST), and 0.7% (bilirubin) of patients. The incidence of fatal hepatotoxicity was 0.04%.

Obtain periodic liver function testing. Withhold IRESSA in patients with worsening liver function and discontinue in patients with severe hepatic impairment *[see Dosage and Administration (2.4)*, *Adverse Reactions (6.1)*, and *Use in Specific Populations (8.7) in the full Prescribing Information]*.

Gastrointestinal Perforation
Gastrointestinal perforation occurred in three (0.1%) of the 2462 IRESSA-treated patients across clinical trials [*see Adverse Reactions (6.1) in the full Prescribing Information*]. Permanently discontinue IRESSA in patients who develop gastrointestinal perforation [*see Dosage and Administration (2.4) in the full Prescribing Information*].

Severe or Persistent Diarrhea
Grade 3 or 4 diarrhea occurred in 3% of 2462 IRESSA-treated patients across clinical trials. Withhold IRESSA for severe or persistent (up to 14 days) diarrhea *[see Dosage and Administration (2.4)* and *Adverse Reactions (6.1) in the full Prescribing Information]*.

Ocular Disorders including Keratitis
Ocular disorders [keratitis (0.1%), corneal erosion and aberrant eyelash growth (0.2%), conjunctivitis, blephritis and dry eye (6.7%)] occurred in the 2462 IRESSA-treated patients across clinical trials. The incidence of Grade 3 ocular disorders was 0.1% [*see Adverse Reactions (6.1) in the full Prescribing Information*]. Interrupt or discontinue IRESSA for severe, or worsening ocular disorders [*see Dosage and Administration (2.4) in the full Prescribing Information*].

Bullous and Exfoliative Skin Disorders
Bullous conditions including toxic epidermal necrolysis, Stevens Johnson syndrome and erythema multiforme have been reported from treatment with IRESSA. Erythema multiforme and dermatitis bullous have been reported in two patients (0.08%) across NSCLC trials (Study 2, Study 3 and Study 4). IRESSA treatment should be interrupted or discontinued if the patient develops severe bullous, blistering or exfoliating conditions.

Embryo-fetal Toxicity
Based on its mechanism of action and data from animal reproduction studies IRESSA can cause fetal harm when administered to a pregnant woman. In animal reproductive studies, oral administration of gefitinib from organogenesis through weaning resulted in fetotoxicity and neonatal death at doses below the recommended human dose. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with IRESSA and for at least two weeks following completion of therapy [*see Use in Specific Populations (8.1, 8.3) in the full Prescribing Information*].

ADVERSE REACTIONS
The following adverse drug reactions are discussed in more detail in other sections of the labeling:
- Interstitial Lung Disease *[see Warnings and Precautions (5.1) in the full Prescribing Information]*
- Hepatotoxicity *[see Warnings and Precautions (5.2) in the full Prescribing Information]*
- Gastrointestinal Perforation *[see Warnings and Precautions (5.3) in the full Prescribing Information]*
- Severe or Persistent Diarrhea *[see Warnings and Precautions (5.4) in the full Prescribing Information]*
- Ocular Disorders including Keratitis *[see Warnings and Precautions (5.5) in the full Prescribing Information]*
- Bullous and Exfoliative Skin Disorders *[see Warning and Precautions (5.6) in the full Prescribing Information]*

Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of IRESSA is based on the data from 2462 patients with NSCLC who received IRESSA 250 mg daily monotherapy in three randomized clinical studies (Study 2, Study 3 and Study 4). Patients with a history of interstitial lung disease, drug-induced interstitial disease, radiation pneumonitis that required steroid treatment or any evidence of clinically active interstitial lung disease were excluded from these studies.

Controlled Studies:
Study 2 was a randomized, multicenter, open-label trial in which 1217 patients were randomized to receive first-line treatment for metastatic NSCLC; 607 patients received IRESSA 250 mg daily and 589 patients received carboplatin/paclitaxel. The median duration of treatment with IRESSA was 5.9 months. The study population characteristics were: median age 57 years, age less than 65 years (73%), female (79%), Asian (100%), NSCLC adenocarcinoma histology (100%), never smoker (94%), light ex-smoker (6%), ECOG PS 0 or 1 (90%).

Study 3 was a randomized, multicenter, double-blind, placebo-controlled trial in which 1692 patients were randomized to receive second- or third-line treatment for metastatic NSCLC; of which 1126 patients received IRESSA 250 mg daily and 562 patients received placebo. The median duration of treatment with IRESSA was 2.9 months. The study population characteristics were: median age 62 years, age less than 65 years (60%), female (33%), Caucasian (75%), Asian (21%), NSCLC adenocarcinoma histology (48%), never smoker (22%), ECOG PS 0 or 1 (65%), PS 2 (29%), PS 3 (5%) and two or more prior therapies (51%).

Study 4 was a randomized, multicenter, open-label trial in which 1466 patients were randomized to receive second-line treatment for metastatic NSCLC; 729 patients received IRESSA 250 mg daily and 715 patients received docetaxel. The median duration of treatment with IRESSA was 2.4 months. The study population characteristics were: median age 61 years, age less than 65 years (61%), female (36%), Caucasian (79%), Asian (21%), NSCLC adenocarcinoma histology (54%), never smoker (20%), ECOG PS 0 or 1 (88%) and two or more prior therapies (16%).

The pooled safety database from the three randomized trials was used to evaluate for serious and uncommon adverse drug reactions. Common adverse reactions were evaluated in Study 3. The most frequent adverse reactions in Study 3 (incidence of >20% and greater than placebo) reported in IRESSA-treated patients were skin reactions (47%) and diarrhea (29%). The most frequent fatal adverse reactions in IRESSA-treated patients were respiratory failure (0.9%), pneumonia (0.8%), and pulmonary embolism (0.5%).

Approximately 5% of IRESSA-treated patients and 2.3% of placebo-treated patients discontinued treatment due to an adverse event. The most frequent adverse reactions that led to discontinuation in patients treated with IRESSA were nausea (0.5%), vomiting (0.5%) and diarrhea (0.4%).

Table 1 – Selected Adverse Drug Reactions Occurring with an Incidence Rate ≥5% and an Increase of >2% of IRESSA-treated Patients in Study 3

	Percentage (%) of patients			
	IRESSA (N=1126)		Placebo (N=562)	
Adverse Reaction	**All Grades**	**Grade 3 and 4**	**All Grades**	**Grade 3 and 4**
Skin and subcutaneous tissue disorders				
Skin reactions[1]	47%	2%	17%	0.4%
Nail disorders[2]	5%	0.1%	0.7%	0%
Gastrointestinal disorders				
Diarrhea[3]	29%	3%	10%	1%
Vomiting	14%	1.2%	10%	0.4%
Stomatitis[4]	7%	0.3%	4%	0.2%
Metabolism and nutrition disorders				
Decreased appetite	17%	2.3%	14%	2.0%

Table 1 – Selected Adverse Drug Reactions Occurring with an Incidence Rate ≥5% and an Increase of >2% of IRESSA-treated Patients in Study 3 (cont'd.)

	Percentage (%) of patients			
	IRESSA (N=1126)		Placebo (N=562)	
Adverse Reaction	**All Grades**	**Grade 3 and 4**	**All Grades**	**Grade 3 and 4**
Eye disorders				
Conjunctivitis/blepharitis/dry eye[5]	6%	0%	3.2%	0%

[1] Includes Acne, Acne pustular, Dermatitis, Dermatitis acneiform, Dermatitis exfoliative, Drug eruption, Dry skin, Erythema, Exfoliative rash, Folliculitis, Pruritus, Pruritus generalized, Rash, Rash erythematous, Rash generalized, Rash macular, Rash maculo-papular, Rash papular, Rash pruritic, Rash pustular, Rash vesicular, Skin exfoliation, Skin toxicity, Xeroderma
[2] Includes Ingrowing nail, Nail bed infection, Nail disorder, Nail infection, Onychoclasis, Onycholysis, Paronychia
[3] Includes Diarrhea, Feces soft, Frequent bowel movements
[4] Includes Aphthous stomatitis, Cheilitis, Glossodynia, Mouth ulceration, Mucosal inflammation, Oral mucosal blistering, Stomatitis, Tongue disorder, Tongue ulceration
[5] Includes Blepharitis, Conjunctival hyperemia, Conjunctivitis, Dry eye, Eye irritation, Eye pruritus, Eye swelling, Eyelid irritation, Eyelid edema, Eyelids pruritus

Table 2 – Treatment Emergent Laboratory Abnormalities Occurring More Frequently in IRESSA-Treated Patients in Study 3

	IRESSA		Placebo	
Adverse Reaction	**All Grades %**	**Grade 3 and 4 %**	**All Grades %**	**Grade 3 and 4 %**
Alanine aminotransferase increased[1]	38%[2]	2.4%	23%[2]	1.4%[4]
Aspartate aminotransferase increased[1]	40%[3]	2.0%	25%[3]	1.3%[5]
Proteinuria	35%	4.7%	31%	3.3%

[1] Patients were allowed to enter the clinical study with lab values of ALT or AST CTCAE grade 1 or 2
[2] 14% gefitinib patients and 10% placebo patients were CTC grade 1 or 2 ALT at baseline
[3] 15% gefitinib patients and 12% placebo patients were CTC grade 1 or 2 AST at baseline
[4] 0.2% of placebo patients were CTC grade 3 at baseline
[5] 0.4% of placebo patients were CTC grade 3 at baseline

The following adverse reactions have been reported with IRESSA across NSCLC trials (Study 2, Study 3 and Study 4) and are not listed elsewhere in Section 6: nausea (18%), asthenia (17%), pyrexia (9%), alopecia (4.7%), hemorrhage (including epistaxis and hematuria) (4.3%), dry mouth (2%), dehydration (1.8%), allergic reactions including angioedema and urticaria (1.1%), elevations in blood creatinine (1.5%), and pancreatitis (0.1%).

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of IRESSA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Renal and urinary disorders: cystitis, hemorrhagic cystitis

Skin and subcutaneous tissue disorders: cutaneous vasculitis

DRUG INTERACTIONS

Drugs Affecting Gefitinib Exposure

CYP3A4 Inducer

Drugs that are strong inducers of CYP3A4 increase the metabolism of gefitinib and decrease gefitinib plasma concentrations. Increase IRESSA to 500 mg daily in patients receiving a strong CYP3A4 inducer (e.g., rifampicin, phenytoin, or tricyclic antidepressant) and resume IRESSA at 250 mg 7 days after discontinuation of the strong inducer [*see Dosage and Administration (2.4)* and *Clinical Pharmacology (12.3) in the full Prescribing Information*].

CYP3A4 Inhibitor

Drugs that are strong inhibitors of CYP3A4 (e.g., ketoconazole and itraconazole) decrease gefitinib metabolism and increase gefitinib plasma concentrations. Monitor adverse reactions when administering strong CYP3A4 inhibitors with IRESSA.

Drugs Affecting Gastric pH

Drugs that elevate gastric pH (e.g., proton pump inhibitors, histamine H_2-receptor antagonists, and antacids) may reduce plasma concentrations of gefitinib. Avoid concomitant use of IRESSA with proton pump inhibitors, if possible. If treatment with a proton-pump inhibitor is required, take IRESSA 12 hours after the last dose or 12 hours before the next dose of the proton-pump inhibitor. Take IRESSA 6 hours after or 6 hours before an H_2-receptor antagonist or an antacid [*see Clinical Pharmacology (12.3) in the full Prescribing Information*].

Hemorrhage in Patients taking Warfarin

International Normalized Ratio (INR) elevations and/or hemorrhage have been reported in some patients taking warfarin while on IRESSA therapy. Patients taking warfarin should be monitored regularly for changes in prothrombin time or INR.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on its mechanism of action and animal data, IRESSA can cause fetal harm when administered to a pregnant woman. In animal reproductive studies, oral administration of gefitinib from organogenesis through weaning resulted in fetotoxicity and neonatal death at doses below the recommended human dose (*see Animal Data*). Advise pregnant women of the potential hazard to a fetus or potential risk for loss of the pregnancy.

The background risk of major birth defects and miscarriage for the indicated population is unknown; however, the background risk in the U.S. general population of major birth defects is 2-4% and miscarriage is 15-20% of clinically recognized pregnancies.

Data

Animal Data

A single dose study in rats showed that gefitinib crosses the placenta after an oral dose of 5 mg/kg (30 mg/m^2, about 0.2 times the recommended human dose on a mg/m^2 basis). When pregnant rats were treated with 5 mg/kg from the beginning of organogenesis to the end of weaning there was a reduction in the number of offspring born alive. This effect was more severe at 20 mg/kg (approximate the human clinical dose on a mg/m^2 basis) and was accompanied by high neonatal mortality soon after parturition. In rabbits, a dose of 20 mg/kg/day (240 mg/m^2, about twice the recommended dose in humans on a mg/m^2 basis) caused reduced fetal weight.

Lactation

Risk Summary

It is not known whether IRESSA is excreted in human milk. Animal studies indicate the gefitinib and its metabolites are present in rat milk at a concentration higher than those in maternal plasma. Because of the potential for serious adverse reactions in nursing infants from IRESSA, advise women to discontinue breast-feeding during treatment with IRESSA.

Data

Animal Data

Levels of gefitinib and its metabolites were 11-to-19-fold higher in milk than in blood, after oral exposure of lactating rats to a dose of 5 mg/kg.

Females and Males of Reproductive Potential

Contraception

Based on its mechanism of action and animal data, IRESSA can cause fetal harm when administered to a pregnant woman [*see Use in Specific Populations (8.1) in the full Prescribing Information*]. Advise females of reproductive potential to use effective contraception during treatment with IRESSA and for at least two weeks following completion of therapy.

Infertility

IRESSA may result in reduced fertility in females of reproductive potential [*see Nonclinical Toxicology (13.1) in the full Prescribing Information*].

Pediatric Use

The safety and effectiveness of IRESSA in pediatric patients have not been established.

Geriatric Use

Of the 823 patients enrolled in two randomized, active-controlled clinical trials 374 patients (45%) were 65 years and older, and 93 patients (11%) were 75 years and older. No overall differences in safety were observed between patients 65 years and older and those younger than 65 years. There is insufficient information to assess for differences in efficacy between older and younger patients.

Renal Impairment

Less than four percent (<4%) of gefitinib and its metabolites are excreted via the kidney. No clinical studies were conducted with IRESSA in patients with severe renal impairment.

Hepatic Impairment

The systemic exposure of gefitinib was compared in patients with mild, moderate, or severe hepatic impairment due to cirrhosis (according to Child-Pugh classification) and healthy subjects with normal hepatic function (N=10/group). The mean systemic exposure ($AUC_{0-\infty}$) was increased by 40% in patients with mild impairment, 263% in patients with moderate impairment, and 166% in patients with severe hepatic impairment. Monitor adverse reactions when IRESSA is administered to patients with moderate and severe hepatic impairment.

In a study comparing 13 patients with liver metastases and moderate hepatic impairment (addition of CTC grade of baseline AST/SGOT, ALP, and bilirubin equals 3 to 5) to 14 patients with liver metastases and normal hepatic function, the systemic exposure of gefitinib was similar [*see Warnings and Precautions (5.2) in the full Prescribing Information*].

OVERDOSAGE

Twenty three patients were treated weekly with doses from 1500 mg to 3500 mg, and IRESSA exposure did not increase with increasing dose. Adverse events were mostly mild to moderate in severity, and were consistent with the known safety profile of IRESSA. In the event of suspected overdose, interrupt IRESSA, institute supportive care, and observe until clinical stabilization. There are no specific measures/treatments that should be taken following IRESSA overdosing.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labelling (Patient Information).

Interstitial Lung Disease: Advise patients to immediately contact their healthcare provider for new onset or worsening of pulmonary symptoms such as dyspnea, cough and fever [*see Warnings and Precautions (5.1) in the full Prescribing Information*].

Hepatotoxicity: Inform patients that they will need to undergo lab tests to monitor for liver function. Advise patients to contact their healthcare provider to report any new symptoms indicating hepatic toxicity [*see Warnings and Precautions (5.2) in the full Prescribing Information*].

Gastrointestinal Perforation: Advise patients that IRESSA can increase the risk of gastrointestinal perforation and to seek immediate medical attention for severe abdominal pain [*see Warnings and Precautions (5.3) in the full Prescribing Information*].

Severe or Persistent Diarrhea: Advise patients to contact their healthcare provider for severe or persistent diarrhea [*see Warnings and Precautions (5.4) in the full Prescribing Information*].

Ocular Disorders including Keratitis: Advise patients promptly to contact their healthcare provider if they develop eye symptoms, lacrimation, light sensitivity, blurred vision, eye pain, red eye or changes in vision *[see Warnings and Precautions (5.5) in the full Prescribing Information].*

Bullous and Exfoliative Skin Disorders: Advise patients that IRESSA can increase the risk of bullous and exfoliative skin disorders and to seek immediately medical attention for severe skin reactions [*see Warnings and Precautions (5.6) in the full Prescribing Information*].

Embryo-fetal Toxicity: Advise pregnant women of the potential risk to a fetus or potential risk for loss of the pregnancy [*see Warnings and Precautions (5.7) and Use in Specific Populations (8.1) in the full Prescribing Information*]. Advise females of reproductive potential to use effective contraception during treatment with IRESSA and for at least two weeks following completion of therapy [*see Use in Specific Populations (8.3) in the full Prescribing Information*].

Lactation: Advise women to discontinue breast-feeding during treatment with IRESSA [*see Use in Specific Populations (8.2) in the full Prescribing Information].*

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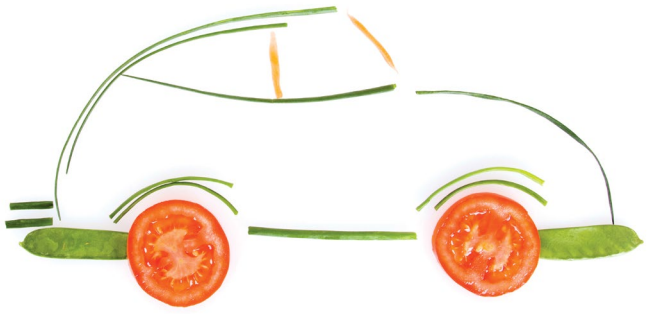
Health Info On the Go!

Community Outreach at the Farmer's Market

BY NORA KATURAKES, RN, MSN, OCN, AND
CHARLENE MARINELLI, RN, BSN, OCN



Christiana Care's Community Health Outreach and Education Program is an active community-based education awareness and screening program, serving the state of Delaware and surrounding areas for more than 15 years. The program's focus is to impact racial and ethnic minorities through awareness and to increase cancer screenings and access to local programs. Multicultural and bilingual outreach staff—certified oncology nurses, outreach workers, and advocates—provide cancer control programs to individuals, not only at the Farmer's Market featured in this article, but at faith-based communities, community centers, schools, camps, and health fairs. Patient navigation services are also provided to increase participation and cancer screenings for disparate populations. Each year Christiana Care's Community Health Outreach and Education Program reaches more than 15,000 individuals through evidence-based or best practice model programs, including:

- The Pink Ribbon Program: Delaware's Comprehensive Community Network (a navigation program)
- Avon Helping Hands for Breast Health
- A cancer screening nurse navigation program
- Promotoras de Salud
- An Asian health initiative
- The Healthy Families Program (a Latin program)
- Community-based screenings for heart disease, prostate, colon, skin, and breast cancers.[1]

Providing culturally and linguistically appropriate health information and translating education materials into the appropriate language and literacy level can ease the burden of health illiteracy and improve the patient experience.[10]

Christiana Care's *Health Info on the Go* program was designed to integrate combination screenings—cancer risk assessment, cholesterol, blood sugar, and blood pressure testing—with the delivery of health information at a non-traditional venue. This program is made possible through collaborations with state, local, and community agencies and financial support through state grants, and local and national foundations, including:

- The American Cancer Society
- The National Cancer Institute, Community Cancer Centers Program (NCCCP)
- The Arsht-Cannon Fund
- Chichester-duPont and Delaware Division of Public Health.

Outreach efforts are determined and aligned with ongoing efforts by the Delaware Cancer Consortium (dhss.delaware.gov/dph/dpc/consortium.html) and the state's health priorities, including cancer prevention, access to health services, obesity, and infant and maternal health, as identified in Delaware's 2012-2013 Community Health Needs Assessment.[2] As a state, Delaware has been able to reduce cancer disparities and improve cancer mortality, particularly for colorectal cancer patients who have benefited from the Delaware Cancer Consortium's focused, statewide outreach and patient navigation efforts. (These efforts were funded by the Delaware Cancer Treatment Program and the Screening for Life Program.[3-5])

Successful Outreach Planning

Traditionally community outreach and health promotion education is structured around community events, health fairs, or presentations about health topics, which are usually coordinated with grassroots or faith-based organizations. Meaningful or intentional outreach is planned, directed, and purposeful, utilizing evidence-based models or strategies that are proven to be successful.[6-8] Unfortunately, not all of these strategies or traditional methods have been proven to reach diverse populations, so new ideas and strategies must be tailored and tested.

Successful outreach efforts require an understanding of the health literacy and culture of the targeted audience. Recognizing and understanding the needs, cultural norms, and boundaries that support or limit participant behaviors related to screening, early detection, and prevention is vital.[9] For example, an individual with a grade school education and who does not speak English may require help with understanding information and navigating the healthcare system. Providing culturally and linguistically appropriate health information and translating education materials into the appropriate language and literacy level can ease the burden of health illiteracy and improve the patient experience.[10] Bilingual and bicultural staff help initiate crucial one-on-one conversations with participants at outreach events and build trust that the health message is relevant for these individuals. Staff who can relate to the participants' needs will further engage them and be able to assist with health needs.

The use of lay health advisers has been shown to increase breast and cervical cancer screening knowledge and practices for minority Hispanic women.[11] Interventions included one-on-one outreach to women about cervical and breast cancer screening, resulting in increased mammography self-efficacy and perceived susceptibility to cancer, and significantly increased Papanicolaou test self-efficacy. Lay health advisers working with oncology nurses and healthcare providers may help alleviate fatalistic views about cancer and promote cancer screening, ultimately improving cancer outcomes for these patient populations.[11] In addition to lay health advisors, trained medical interpreters can foster trust and engage the participants with the outreach team.

(continued on page 28)

Community outreach nurse, Renitia Pulliam, RN, (right), provides blood pressure screening at the New Castle Farmer's Market while Joceline Valentin (left) interprets in Spanish.

Health Info You Can Use!

New Castle Farmers Market

¡Información de Salud que Usted Puede Usar!

Mercado de Granjeros Locales de New Castle

Friday, October 17
National Mammography Day

- Cancer Outreach team will provide free blood pressure, diabetes and cholesterol screenings.
- Health ambassadors will be on hand to offer resources and tips on raising a healthy family.
- Christiana Care Marketplace Guides and United Healthcare Community Plan will also be available to answer your health insurance questions.

11 a.m. – 4 p.m. at the Market Stage area

Presented by: Helen F. Graham Cancer Center & Research Institute's Community Health Outreach and Education Program.

viernes 17 de octubre
Día Nacional de Mamografía

- El equipo de Alcance de Cáncer proveera examines gratuitos de la presión arterial, la diabetes y el colesterol.
- Embajadores de Salud estarán a la mano para ofrecer recursos y consejos para criar una familia saludable.
- Guias de el Mercado de Christiana Care y United Healthcare Community Plan también estarán disponible para responder a sus preguntas sobre el seguro de salud.

11 a.m. – 4 p.m. en el área del escenario del mercado

Presentado por: Programa de educación y extensión de la salud de la comunidad Centro de Oncología e Instituto de Investigación Helen F. Graham.

Stop by and let us help you schedule your mammogram!

¡Visítenos y permítanos ayudarle a programar su mamografía!

CHRISTIANA CARE HEALTH SYSTEM

Helen F. Graham Cancer Center & Research Institute

15CANC26

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Christiana Care's Outreach Efforts at the Farmer's Market

Christiana Care selected the local New Castle Farmer's Market as a non-traditional venue to offer monthly public awareness. The market has more than 75 vendors, including Asian, African-American, and Hispanic vendors. The first step was to hire diverse, bilingual outreach staff to communicate specifically with these minority communities. Christiana's goal: to engage between 75-100 shoppers per event to stop at the Farmer's Market stage and ask about monthly *Health Info on the Go* topics or participate in a screening. Individuals could access cancer experts, get connected to local resources, and learn about Christiana Care and the importance of cancer prevention screenings, all while shopping. Participants would also be able to ask outreach staff questions and take home educational brochures in both English and Spanish.

Christiana Care initially promoted the program with a monthly flyer (in English). Today, the flyer is produced quarterly in both English and Spanish, letting Farmer's Market vendors and customers know what is planned for upcoming months (see page 27). Flyers and related posters are placed at the market entrances and emailed to all market vendors. Each month the health message is posted on Christiana Care's colorful display boards, designed to engage market vendors and customers. Christiana Care created new educational materials, *Cancer News You Can Use*, for breast, colorectal, and prostate cancer in three languages: English, Spanish, and Chinese (see pages 27, 29, 31).

The program is a true joint effort between Christiana Care and the people who organize and manage the Farmer's Market. For example, the market manager champions the health and prevention messages by making announcements; providing balloons, ribbons, and refreshments at awareness events; passing out free gift certificates; and circulating information to vendors. In addition to the health information, Christiana Care outreach staff conducts screenings where they are able to initiate conversations about health risk factors. Christiana Care has developed a combination cancer screening program that includes clinical testing of blood pressure, glucose, and total cholesterol/HDL for community participants. Immediate results and recommendations are provided. Specifically, the screening nurse navigator gives instructions and, as needed, makes immediate referrals to other outreach team members to help individuals access state programs for funding cancer screenings and find healthcare providers. Participants are paired with outreach staff that can further assist, educate, and help navigate patients with recommendations from the combination screening.

The Farmer's Market venue is used to promote Christiana Care's other events and programs, including its annual Latinas

(continued on page 30)

Healthy Families program manager, Luisa Ortiz-Aponte (left), shares information about the annual free skin screening at the Helen F. Graham Cancer Center with Beatriz Velasquez.

Sea proactivo y reduzca su riesgo de padecer cáncer colorrectal [3]

Puede reducir su riesgo de padecer cáncer colorrectal haciendo las modificaciones siguientes en su estilo de vida:

- Ejercítese regularmente; por lo menos 30 minutos tres veces a la semana
- Mantenga un peso saludable
- Mantenga una alimentación saludable que incluya bastantes frutas y verduras
- Limite el consumo de grasa, especialmente de grasa saturada
- Evite fumar
- Limite el consumo de alcohol

3 *Sociedad Americana de Cáncer. www.cancer.org. Pautas sobre la nutrición y actividad física para la prevención del cáncer 2008.*

4 *Sociedad Americana de Cáncer. www.cancer.org. Detección temprana, diagnóstico y clasificación por etapa 2010.*

12CANC47

Pruebas de detección y la detección temprana [4]

No permita que el miedo o la vergüenza eviten que se haga las pruebas de detección.

En el centro de cáncer Helen F. Graham Cancer Center se recomienda que tanto hombres como mujeres, a partir de los cincuenta años, se hagan pruebas de detección según uno de los programas siguientes:

- Una prueba de sangre oculta en heces (fecal occult blood test; FOBT) o prueba inmunoquímica fecal (fecal immunochemical test, FIT) cada año
- La sigmoidoscopia flexible cada 5 años*
- FBOT o FIT anuales y la sigmoidoscopia flexible cada 5 años*
- Un enema de bario de contraste doble cada 5 años
- La colonoscopia cada 10 años
- La colonografía por TC (colonoscopia virtual) cada 5 años.

**Se prefieren las pruebas combinadas más que ya sea la FOBT o la FIT anual o la FSIG (sigmoidoscopia flexible) cada 5 años por sí sola.*

Las personas con riesgo moderado o alto de padecer cáncer colorrectal deben hablar con un médico sobre un programa de pruebas distinto.

Para obtener más información sobre el cáncer colorrectal, comuníquese con su proveedor de atención de la salud o con Helen F. Graham Cancer Center sobre cómo realizarse una prueba gratuita de detección del cáncer colorrectal.

302-623-4661

www.christianacare.org/cancerscreeningprograms

CHRISTIANA CARE HEALTH SYSTEM
Helen F. Graham Cancer Center

One of the original 14 cancer centers in the nation selected for the National Cancer Institute Community Cancer Centers Program.

NCI COMMUNITY CANCER CENTERS PROGRAM

(continued from page 28)
Conference, the Delaware Quit Line's smoking cessation program, Avon Helping Hands for Breast Health, the Pink Ribbon Program, and a Family Risk Assessment Program.

Outcomes

From January 2009 to December 2015, Christiana Care hosted 53 *Health Info on the Go* monthly events. Staff utilized these opportunities and one-on-one conversations to recruit individuals for breast screenings, colorectal cancer screenings, and skin cancer screenings. The combination screening was offered at 34 events and 1,087 individuals were screened. This type of combination screening helps initiate "cancer screening" conversations with individuals who are uninsured or otherwise would not discuss cancer screenings. Of the participants:

- 816 were minorities (46 percent Hispanic, 21 percent African American, and 7 percent Asian) and 1.5 percent other or not reported
- 34 percent were uninsured
- 24 percent had not seen a doctor in the last two years
- 21 percent required referral for cancer screenings.

Additional referrals were made to genetic counselors, primary care, and state programs, such as lung cancer screening and smoking cessation programs.

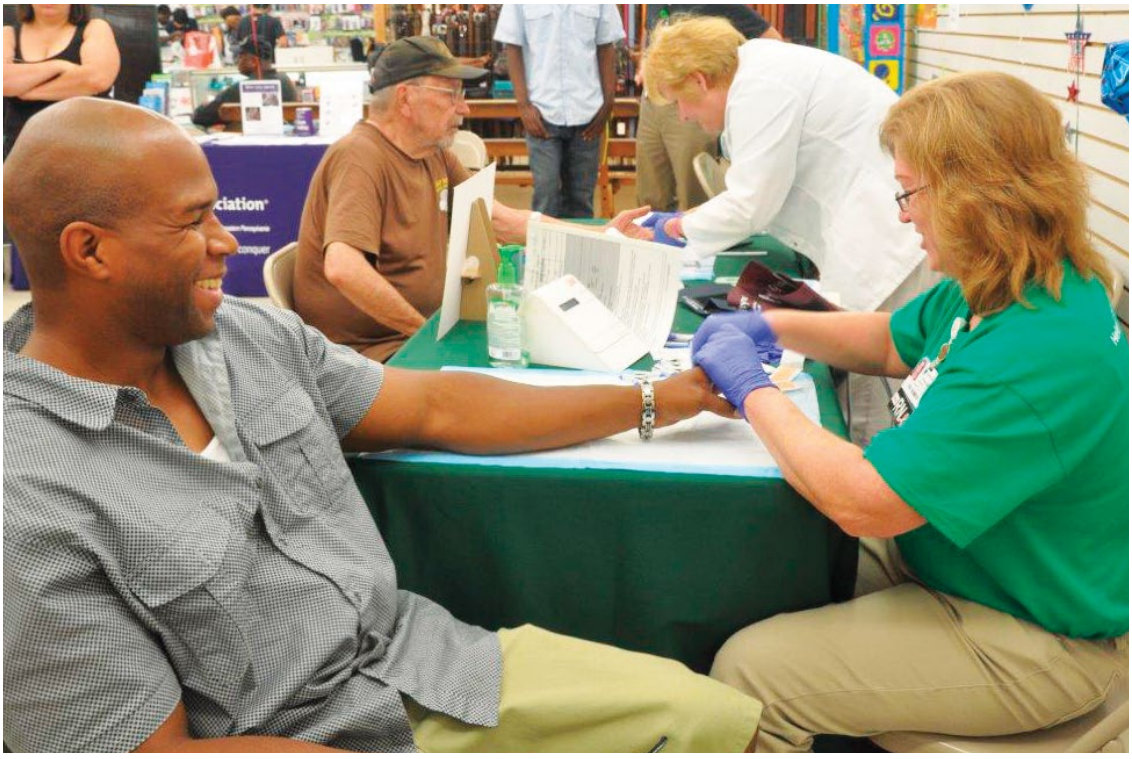
During calendar years 2014 and 2015, more than 200 (216) individuals expressed interest in having outreach staff contact them following the combination screening at the Farmer's Market. Outreach staff assisted 76 individuals, including:

- 30 individuals who needed assistance to enroll in healthcare funding programs, such as the State Screening For Life Program, programs through the Affordable Care Act, charity programs, and grant-funded Susan G Komen–Philadelphia affiliate programs.
- 26 individuals who needed help finding a primary care provider or arranging a healthcare visit to a provider.
- 20 individuals completed a cancer screening (15 mammograms, 3 pap screenings, 1 colonoscopy).
- 18 individuals enrolled in the Healthy Families Program (for Latinos).
- 2 individuals asked to join the volunteer group "Promotora," to help others connect to resources in the community.
- 4 individuals received written materials as requested.

Going Forward

One challenge for Christiana Care's *Health Info on the Go* program continues to be the large number of individuals (67 during calendar year 2014 to 2015) being lost to follow-up after the initial contact, largely due to changes in telephone numbers or addresses and individuals changing their minds and refusing help that was previously planned at the Farmer's Market. Outreach staff has also noticed that a number of patients needing assistance have listed the local federally-qualified health center as their health

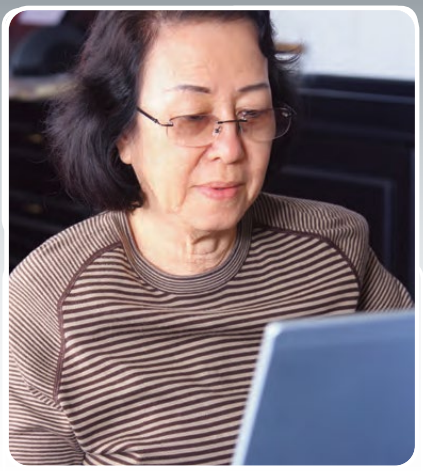
(continued on page 32)



Screening nurse navigator, Charlene Marinelli, RN, BSN, OCN, conducts a screening at the New Castle Farmers Market Farmer's Market.

实用癌症通讯

结直肠癌



可预防。可治疗。可战胜！

如果早期检出并得到治疗，90%的结直肠癌或者结肠癌是可以治愈的。从50岁起无论男女都应该开始做结直肠癌筛查。如果你有其它危险因素，如家族结直肠癌病史，应与医生或医务人员商议更频繁或提早做筛查。

什么是结直肠癌？[1]

结直肠癌包括大肠（结肠）、消化系统末端部份癌症和直肠的癌症。一开始时只是肠道内长出的一些非癌性（良性）细胞小群落，称为息肉。一段时间后，有些息肉可能会变成恶性肿瘤。

你有危险罹患结直肠癌吗？[1]

如果你有以下因素，患结直肠癌的概率更大：

- 年龄在50岁或50岁以上
- 有结直肠癌和/或息肉的家族史或个人史
- 有炎症性肠病的个人史
- 吸烟
- 肥胖或不爱运动
- 饮食中有过高的饱和脂肪和/或红肉

结直肠癌有哪些症状？[2]

无论男性或女性，青年或老人，任何人都有可能患上结直肠癌。如果你有高危因素，不要等到症状出现。结直肠癌在早期可能不会有什么症状，因此最好定期做筛查。

平时应注意观察的症状包括：

- 排便习惯不明原因的改变
- 长期腹泻或便秘
- 便血
- 粪便变窄，细如铅笔
- 大便有尚未排尽的感觉
- 持续腹痛
- 不明原因或突发性体重下降
- 长期感觉疲劳或不明原因的疲倦

CHRISTIANA CARE HEALTH SYSTEM
Helen F. Graham Cancer Center

[1]National Cancer Institute. www.cancer.gov. General Information about Colon Cancer 2009.
[2]National Cancer Institute. www.cancer.gov. Symptoms. 2006.

(continued from page 30)
home. Outreach staff is working closely with the federally-qualified health centers to reconnect these individuals to their providers for continuing care.

One of the challenges of any outreach program is to demonstrate the value it provides to the community. Through this outreach effort at the Farmer's Market, Christiana Care was able to partner with the state's Health Insurance Exchange Navigators to further improve the Asian (Mandarin speaking) community's understanding about the Affordable Care Act and the Medicaid program. This partnership helped many Asian community members connect with enrollment specialists who were able to help many of them visit a primary care provider for the first time. Christiana Care's bilingual Asian outreach coordinator continues to leverage this collaboration to facilitate appropriate cancer screenings for this patient population.

In an effort to improve referral outcomes, Christiana Care has encouraged outreach staff to verify that participants want further assistance from a navigator, and that they understand how the navigation process will work. Christiana Care has initiated a standardized process for follow-up that it is currently evaluating, which includes a community outreach tracker sheet for participants who agree to take next steps with follow-up based on recommendations. The plan is to capture and document the navigation process being used to move participants toward completion of screening and treatment recommendations. Christiana Care hopes to use this information to further report the value of patient navigation and outreach services.

Lastly, further review of the outreach education materials is underway to assure that materials are at the appropriate reading level and align with the information that is being promoted at each event. Christiana Care learned early on that having bilingual materials increased awareness and engagement of participants and that bilingual and multicultural staff and medical interpreters increased the number of people taking advantage of the free combination screening at the Farmer's Market.

Taking its outreach education and screening services directly to Delaware residents has allowed Christiana Care to connect to underserved people and minority populations. As Christiana Care continues to reach more of its community neighbors with information, the hope is that outreach staff can connect these individuals to community resources and screenings that may save lives. Program results indicate that many of these individuals did not have access to local primary care or the federally-qualified health centers, and that many lack the financial resources to return if medical care is needed. Specifically, outreach coordinators found instances of patients with diabetes who had stopped taking medications, individuals who did not understand their benefits under the Affordable Care Act, and many non–English speaking individuals who needed assistance with navigating or finding appropriate health resources. Christiana Care's *Health Info on the Go* program has helped connect individuals to insurance and Medicaid enrollment specialists. In fact, the program has become so popular that many community partners have asked to participate, including the Beautiful Gate Outreach Program (HIV), the United Healthcare Community Program, the Blood Bank of Delaware, the Alzheimer's Association, and some of the federally-qualified health centers. OI

Nora C. Katurakes, RN, MSN, OCN, is the manager of Community Health Outreach and Education, and Charlene W. Marinelli, RN, BSN, OCN, is a screening nurse navigator at the Helen F. Graham Cancer Center and Research Institute at Christiana Care Health System, Newark, Del.

Two Patient Stories

In 2014, 43-year-old A.A.B. of New Castle, Del., was screened at the Farmer's Market and learned that he was at increased risk for heart attack due to his borderline high range blood pressure. Mr. B. did not speak English, so a Christiana Care bilingual outreach coordinator helped explain the screening results and recommendations and discussed the importance of eliminating tobacco use. On that same day B.V., who recently moved to the U.S. from Columbia and worked for a vendor at the Farmer's Market, told bilingual outreach coordinators Luisa Ortiz-Aponte and Joceline Valentin that she did not have insurance coverage and was worried about how to pay for preventive screenings. Outreach staff immediately connected Ms. V. to the Christiana Care annual skin cancer screening program and made arrangements for her to receive a free mammogram at the Breast Center through a grant from Susan G. Komen–Philadelphia affiliate.

CHRISTIANA CARE HEALTH SYSTEM AT-A-GLANCE

In all that we do, Christiana Care Health System (Christiana Care) strives to serve the members of our community as respectful, expert, and caring partners in their health. We do this by creating innovative, effective, and affordable systems of care that our neighbors value. This is The Christiana Care Way: a promise to all our neighbors who trust us to care for them. We implement approaches to care that focus on the specific needs of our community. The care we provide goes well beyond treating the sick and includes health-related programs and initiatives that seek to improve the overall welfare of patients. To succeed, we must be creative, and we must be innovative. The people we serve are often, quite literally, our friends, our families, and the people who live with us in our community.

Christiana Care is one of the country's largest healthcare providers, ranking 21st in the nation for hospital admissions. Christiana Care is a private, not-for-profit, non-sectarian teaching health system and a leading provider of healthcare services to the people of Delaware and neighboring states of Pennsylvania, Maryland, and New Jersey. Christiana Care has a network of services, including the Christiana Hospital, the Helen F. Graham Cancer Center and Research Institute, and the Surgicenter, all located on the suburban campus in south Wilmington. The Helen F. Graham Cancer Center and Research Institute is one of the original 16 NCCCP sites, designated from 2007 to 2014. The Helen F. Graham Cancer Center and Research Institute includes:

- A Breast Center
- A breast surgeons practice
- Radiation therapy
- Genetic counseling
- Psychology
- Nutrition
- Survivorship
- Cancer rehabilitation
- Care management
- Community health outreach and education
- The Center for Translational Research
- The National Cancer Institute, Community Oncology Research Program (NCORP).

Until quite recently, Delaware was first in the nation in both rates of cancer incidence and mortality. Now the state is 14th for cancer mortality.[1] Many factors contributed to the progress that Delaware has made in reducing its cancer burden and some of the influences include programs designed and implemented by the Community Health Outreach and Education Program at Christiana Care's Helen F. Graham Cancer Center and Research Institute.

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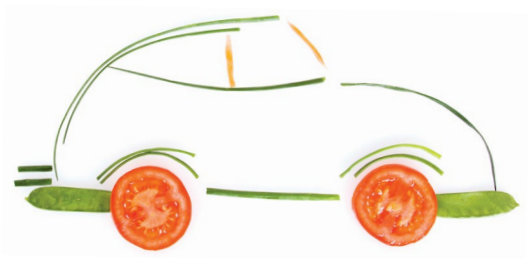
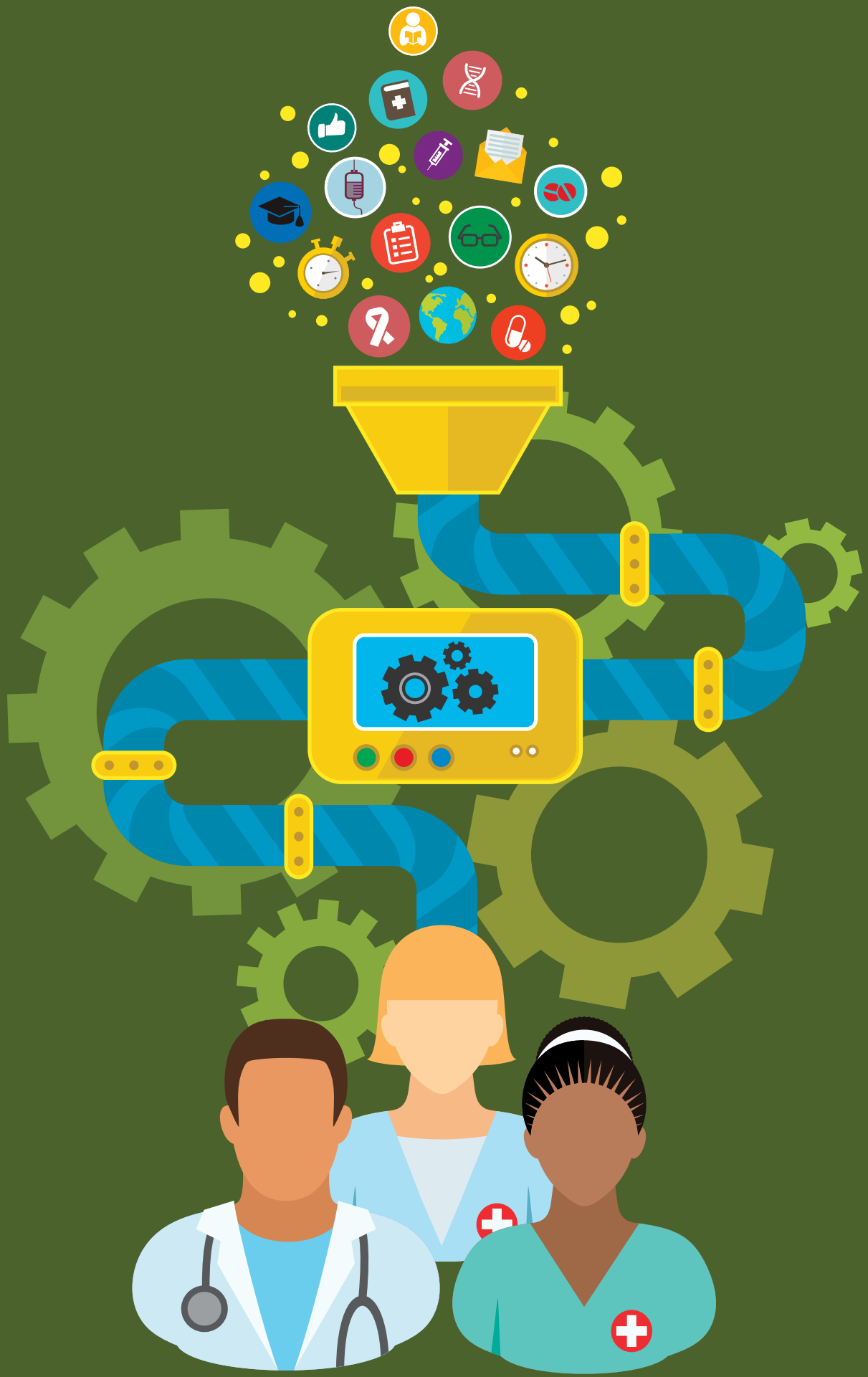




BY SANDY BALENTINE, MSN, RN, OCN, MBA
AND VALERIE QUIGLEY, BSN, RN, OCN

The Oncology Nursing Fellowship Program

A Pipeline for the Future

Productivity and staffing in an ambulatory oncology infusion center can be challenging. A shortage of skilled applicants to fill staffing needs adds further challenges. Such was the case at The Valley Hospital, a fully-accredited, acute-care, not-for-profit 451-bed hospital in northeast New Jersey.

Valley's Blumenthal Cancer Center is located three miles from the hospital in a 128,000-square-foot outpatient building. The ambulatory infusion center is located in this outpatient center and has seen tremendous growth over the last 10 years. From 2012 to 2013 alone, the infusion center experienced a more than 40 percent increase in visits (Table 1, page 36). Since more than half of all visits entail administering IV chemotherapy, this required a large increase in nursing care and, subsequently, an increase in nursing care hours.

Meeting an Urgent Need

National benchmarks for outpatient infusion staffing related to patient ratios do not exist, so measuring productivity can be a struggle for cancer programs. Given its rapid growth, the Blumenthal Cancer Center experienced this struggle firsthand. Our patient volume was increasing, and we did not have enough trained nurses to provide quality care to these very sick patients. We needed to be able to show some benchmark data that could justify a staffing increase. We took the infusion nurse-to-patient ratio reported in the ACCC 2013 *Trends in Cancer Programs* report and used it as a baseline for creating an evidence-based nursing care hour for our infusion area. (A nursing care hour is a calculation that determines the total hours of care provided to each patient. See box at right). With the support of the chief nursing officer, we presented our data to our operations committee with a request for additional staffing for our department, which was granted.

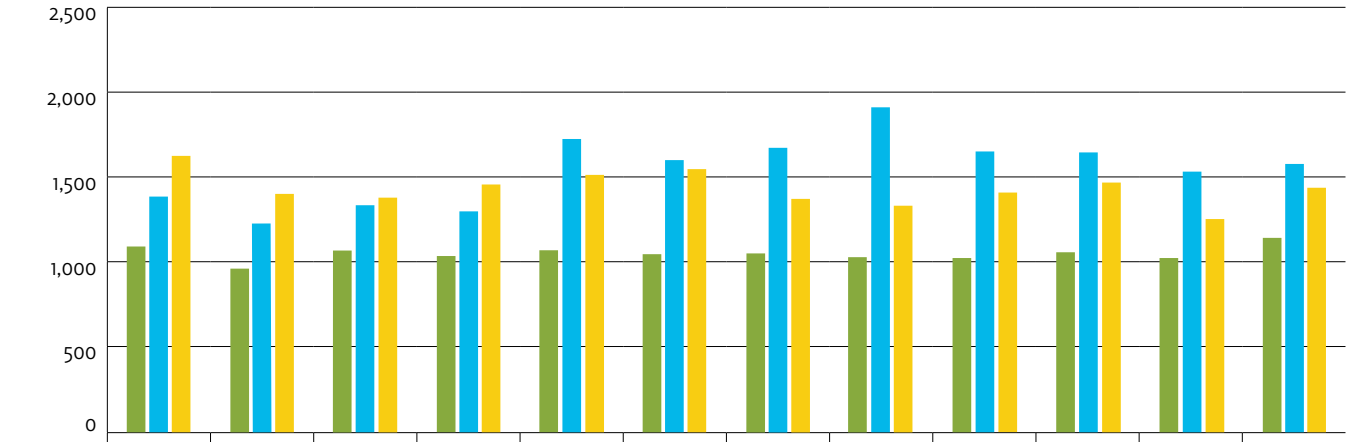
With a new nursing care hour in hand, we still were faced with the challenge of filling our vacant positions. Even prior to the approval of the new nursing care hour, we had experienced vacancies for more than six months. Although we received both internal and external applicants, we did not receive any applicants who had both the oncology and chemotherapy background that we needed in our cancer program. As a Magnet hospital, we also require that all new nursing staff have a minimum credential of a BSN. This made our staffing struggle even more difficult.

After brainstorming with our colleagues in Education and Patient Care Services, we came up with the idea of an Oncology Nursing Fellowship Program. The program would be patterned after the successful Graduate Nurse Residency Program already in place at our hospital. Unlike the Residency Program, which accepts graduate

Calculating a Nursing Care Hour

A nursing care hour is a calculation that determines the total hours of care provided to each patient. The calculation is: Nursing (staff) hours, including RNs, clinical shift supervisors, and patient care associates (similar to medical assistants), divided by the number of patients per day. This calculation typically includes only those staff positions with a patient assignment.

Table 1. Ambulatory Infusion Center Visits



	JAN	FEB	MAR	APRIL	MAY	JUNE	JULY	AUG	SEPT	OCT	NOV	DEC
2012	1,095	975	1,079	1,029	1,079	1,044	1,043	1,022	1,014	1,048	1,014	1,058
2013	1,401	1,230	1,339	1,303	1,718	1,596	1,646	1,921	1,668	1,666	1,529	1,496
2014	1,625	1,401	1,392	1,466	1,505	1,549	1,395	1,332	1,405	1,482	1,258	1,436

nurses right out of school, our Fellows would need a minimum of two years of experience as a medical, surgical, or critical care nurse to qualify. Before being accepted into the Fellowship program, fellows would need to agree to work a minimum of one year in the cancer center upon completion of the program. We developed a planning committee comprised of the Director of Clinical Oncology, the Clinical Supervisor of Infusion, staff nurses, and the education staff to begin the planning process.

Getting Started

We set a four-month time period for the program. This decision was based on the volume of education and experience we felt the Fellows needed before they would develop the skills required to care for our oncology patients. We realized that the management staff would also learn many things during the first Fellowship session that would guide us in future sessions. In designing the first class, we incorporated the flexibility to extend the Fellowship if the Fellows required additional time to fulfill the requirements, complete the chemotherapy and biotherapy course, and/or develop the comfort level needed to care for our oncology patients independently.

We developed various forms, such as, a weekly checklist (Figure 1, page 37), a summation form (Figure 2, page 39), a skills list, and a form for staff to assess their clinical experiences (Figure 3, page 41). The Fellows also received a journal and a binder of materials to use throughout the program. The binder included a "Seek-n-Find" list of items to locate on the unit, such as the AED, fire extinguishers, etc.; a schedule of their assignments for the duration of the Fellowship program; and copies of important policies related to the preparation, administration, and safety procedures of chemotherapy. View the "Seek-n-Find" exercise online at: accc-cancer.org/oncology_issues/MJ2016.asp.

A vital component of the Fellowship program was topic selection, including where the Fellows would receive their education. The course curriculum has specific sessions on new and frequently used chemotherapies, along with basics such as the pathophysiology of cancer, how we find cancer, and how we treat cancer (see Figure 4, page 43).

Planning a 360-Degree Fellowship Experience

We planned to give our Fellows the opportunity to spend time in several different oncology departments, with the goal of helping them gain a thorough understanding of oncology and disease specifics. They would spend time in radiation oncology, learning how radiation works on cancer cells, and how radiation therapy is used in conjunction with chemotherapy. The advanced practice nurses (APNs) in the medical oncology office planned to have our Fellows shadow them in their clinic area to see how they work with patients to make care decisions. Fellows would also spend time in surgical oncology, observing cancer surgery in the operating room.

On our inpatient oncology unit, Fellows could gain a better understanding of the critical interaction and communication that takes place between the inpatient and outpatient areas to provide the best possible care for patients.

The Fellows would also shadow our clinical trials nurses and learn about the importance of clinical trials for patients. We participate in clinical trials in the infusion area and are often able to offer patients new drugs that may improve their outcomes.

In addition, our Fellows would spend time with our breast

(continued on page 38)

Figure 1. Oncology Fellowship Weekly Checklist

Every Monday: Luckow Rounds, 12:00 pm-1:00 pm
Every Monday: Breast Cancer Conference
Every Thursday: Oncology Rounds, Dr. Harrison 8:00 am-9:00am

DATE	ACCOMPLISHMENT(S) FOR THE WEEK	DATE COMPLETED
Week 1	• Orient to unit and staff. • Develop rapport with preceptor and become comfortable with Fellowship plan and schedule. • Observation of preceptor in clinical setting. • Understand the registration process. • Observation of Integrative Medicine.	
Week 2	• Orient to the pharmacy. Learn additional steps involved in preparing chemotherapy. • Learn difference between chemotherapy and monoclonal antibodies. • Able to document medications on EMAR, PYXIS®. • Attend education on pathophysiology of cancer.	
Week 3	• Able to start IV's, access ports, change PICC dressings. • Learn process for chemotherapy safety and process for chemotherapy spills. • Training on coding and billing.	
Week 4	• Orient to social worker role and responsibilities. • Review proper documentation in Meditech. • Observation of oncology surgery.	
Week 5	• Able to care for and properly document on 2 non-chemotherapy patients. • Observation of NP in office setting.	
Week 6	• Able to care for and properly document on 3 non-chemotherapy patients. • Radiation Oncology: observation and education on how it works and when it is appropriate to order.	
Week 7	• Able to care for and properly document on 4 non-chemotherapy patients. • Observation and orientation to inpatient oncology unit.	
Week 8	• Able to care for and properly document on 5 non-chemotherapy patients. • Oncology course video.	
Week 9	• Complete the ONS Chemotherapy/Biotherapy Course. • Orientation to oncology clinical trials.	
Week 10	• Able to care for and properly document on 1 patient receiving chemotherapy.	
Week 11	• Able to care for and properly document on 2 patients receiving chemotherapy.	
Week 12	• Able to care for and properly document on 3 patients receiving vesicants.	
Week 13	• Able to care for and properly document on 4 patients receiving chemotherapy.	
Week 14	• Able to care for and properly document on a full assignment.	
Week 15	• Able to care for and properly document on a full assignment.	
Week 16	• Able to care for and properly document on a full assignment. • Review program. Decide if all areas are covered and identify additional needs of Fellow.	

The preceptor role is an important factor in the success of the Oncology Nursing Fellowship Program; the support and guidance provided by the Preceptor supports the Fellow throughout the program.

(continued from page 36)
navigator, learn about Gamma Knife radiosurgery, explore specifics related to colon cancer, and learn about the need for patients to go home with infusion pumps.

Recognizing the impact of social, psychological, and financial concerns on patients undergoing cancer treatment, our planning team would arrange for Fellows to spend time rounding on patients with our social worker. In this setting, they could better understand:

- The emotional distress that accompanies a cancer diagnosis
- The financial impact of cancer treatment
- Patient fears related to job security and health insurance
- The resources that social workers can provide to help patients cope with these and other challenges.

Dietitians also play a critical role in caring for patients, especially those with co-morbidities, and our nursing Fellows would be able to observe the effects of treatment on our patients' nutrition and appetites.

Finally, the Fellows would observe the activities of the oncology pharmacy—including the roles of oncology pharmacists, chemotherapy, biotherapy, the pharmacy hoods, and safety protocols—as well as the critical interaction between the nurses and pharmacists in chemotherapy administration.

Preceptors

Each nursing Fellow would be assigned a preceptor to work with during the four-month program. We consulted with staff to see who had the experience and interest in serving as a preceptor to a nursing Fellow. With the understanding that everyone learns in a different way, we wanted our preceptors to be able to adjust their teaching style as needed to help the Fellows learn. We sent our preceptors to preceptor training, which was already offered at our hospital. Here, the preceptors learned to identify how their Fellows learned, how to work with them in the clinical area, and how to be available to them.

Matching the Fellow with an appropriate preceptor was decided upon as a group, with the option to make a change if necessary. We also had to decide if the Fellows would work with the same preceptor for the entire four months or if there would be a benefit to switching the preceptors during the program. The decision was made to assign a single preceptor to each Fellow but remain open to the idea to make a change if we thought it would be beneficial to the Fellows.

Recruiting Fellows

After the planning team finished designing the program, the recruitment process began. Our planning team decided to

(continued on page 40)

Figure 2. Oncology Nursing Fellowship Weekly Summation Form

Fellow/Preceptor:

Fellow's experience this week:

Number of patients:

Diagnosis:

Admit/Discharge/Transfers:

New procedures/treatments experienced (IVs, drips, equipment, etc.):

Charting/medication administration:

Strengths and/or opportunities for improvement:

Evidence of critical thinking/time management and delegation:

Service excellence/customer service skills:

Issues addressed with Fellow or Preceptor concerns:

Plan, goal, and experience needed with:

Additional educator notes:

Fellow signature: Manager signature:

Educator signature: Preceptor signature:

Date:

(continued from page 38)
look for experienced nurses from within our hospital to join us at the infusion center as Fellows. Those nurses would already be familiar with the services at Valley Hospital and aware and accepting of our culture. We only accepted applications from internal employees with at least two years of nursing experience. The interested nurses completed an application form (Figure 5, page 44) indicating their background (or lack thereof) in oncology. The director of clinical oncology then made a phone call to each applicant before bringing them to our cancer center for an interview. The applicants were interviewed by the director and the infusion supervisor, as well as the preceptor nurses from our unit. Since the applicants were internal, the supervisor and director were also able to review their files in human resources and talk frankly with their current supervisors. We looked at previous evaluation scores, any peer reviews, and attendance records.

Our Fellowship Experience

For the first Fellowship session, we accepted two nurses as Fellows. One had worked in the ICU, and the other had worked in the hospital's outpatient surgery center. They impressed us during their interview process with their commitment to quality patient care and their interest in oncology as a specialty. We received positive reports from their supervisors and their peers; their annual evaluation scores were high; and their attendance records were good.

On their first day, the Fellows spent time meeting with their preceptors, the supervisor of the infusion center, and the education staff who outlined in detail how the following four months would proceed. They reviewed the materials in their binders and reviewed the requirements for the program. In addition, the Fellows completed their "Seek-n-Find" list, which, in addition to helping them locate important items, gave them an opportunity to meet staff who work in the oncology area.

We felt that it was very important for our Fellows to immediately feel welcome, so we held a breakfast on their first morning. Here, they had the opportunity to meet with our infusion center staff, our chief nursing officer, and other staff who would be working with them as a part of our team.

Each day, the Fellows wrote in journals to document what they learned, challenges encountered, and questions they wanted to review with their preceptors the next day. This journaling gave them an outlet to express their experiences and feelings during the Fellowship program. They reviewed the topics in their journals

(continued on page 42)

Many departments have contributed to the success of the Oncology Nursing Fellowship program, including nursing supervision and management, nursing education, oncology practice management, and supportive care services.

Figure 3. Oncology Nursing Fellowship Assessment of Clinical Experiences

Observation Area Experience

1. What did you observe today?

2. What is the role of the oncology nurse in this clinical area?

3. What kind of skills does the nurse have to master to function in the area you've observed?

4. How will this experience affect your nursing practice in your own oncology clinical area?

5. Identify the positive and negative aspects of this clinical experience.

(continued from page 40)
each day in their standing meeting with their preceptors. The Fellows also met weekly with the infusion supervisor and the staff educator. During this time, the Fellows discussed how things were going, what they had learned, and if they had met their weekly goals. If the Fellowship program needed to move at a slower pace, that adjustment would be addressed here. If a Fellow experienced a problem working with his or her preceptor, a discussion would occur at this meeting as well.

Meanwhile, the rest of the infusion team worked together to help carry the patient load. We were already in a tight staffing situation, and now we had preceptors who had lighter assignments several days a week in order to work with the nursing Fellows. As a result, we experienced days when staffing was short and nurses were working overtime. During these challenging times, we reminded everyone of our original intentions and the future gains from the Fellowship program. With the assistance of per diem staff and the teamwork of our supportive staff, we were able to provide sufficient nursing coverage to care for our patients during the four-month Fellowship program.

After three months of orientation and education with their preceptors, the nursing Fellows began to work on their Oncology Nursing Society (ONS) chemotherapy and biotherapy course. Our hospital has decided to use the newly-revised ONS course as the required course to administer chemotherapy at our facility. The course is challenging but comprehensive, and typically takes at least 16 hours to complete. It took our nursing Fellows twice as long to complete the course, but they both accomplished it with very strong scores. They had the full support of not only their preceptors but also the entire nursing staff as they studied to complete the course.

OUR PROGRAM AT-A-GLANCE

The Valley Hospital is accredited by the American College of Surgeons as a Comprehensive Cancer Center and by the National Accreditation Program for Breast Centers (NAPBC). Valley is widely known for its excellence in breast cancer diagnosis and treatment, lung cancer diagnosis and treatment, radiation oncology (including TomoTherapy), chemotherapy and infusion, GYN oncology, prostate cancer care, and other clinical and supportive care services. The Valley Hospital was the first hospital in New Jersey to receive The Joint Commission's Gold Seal of Approval for Cancer and is a three-time recipient of Magnet Designation from the American Nurses Credentialing Center (ANCC).

After completion of their chemotherapy and biotherapy certificate, the nursing Fellows continued to work closely with their preceptors. However, they were now allowed to administer chemotherapy with oversight. They continued to have daily meetings with their preceptors and weekly summations with the supervisor and educator.

The Future of Our Oncology Nursing Fellowship Program

The Fellowship program was a success, and it was extended for an additional two weeks beyond the planned four-month time period. After completion of the ONS chemotherapy and biotherapy course, the nurses and their preceptors felt an additional two weeks of reviewing and administering chemotherapy under the watchful eyes of the preceptors would be beneficial.

The Fellows have since become an integrated part of the infusion team. Their preceptors are still available to them when they have questions about a protocol or drug administration.

Based on our experience with this initial Fellowship session, we will make adjustments to future nursing Fellowship programs. We plan to continue the Fellowship program to assure adequate staffing for the future of our cancer center. We have also discussed designing a portion of the program for Fellows who have had limited oncology experience. By supplementing their knowledge and experience, we feel we can make them even stronger members of our oncology team.

The United States is projected to experience a shortage of registered nurses, which will only intensify as Baby Boomers age and the need for healthcare grows. As many as 1 million registered nurses will be nearing retirement age within the next 10 to 15 years, according to projections from the Health Resources and Services Administration.[1] Clearly, planning now for the future is critical—and having a successful Oncology Nursing Fellowship Program in place is the first step toward ensuring a skilled and educated workforce to care for our oncology patients for years to come. OI

Sandy Balentine, MSN, RN, OCN, MBA, is the director of Clinical Oncology at The Valley Hospital in Ridgewood, N.J., and a member of the Oncology Nursing Society. Valerie Quigley, BSN, RN, OCN, is currently the nursing manager for the ambulatory infusion center at The Valley Hospital in Ridgewood, N.J., and a member of the Oncology Nursing Society.

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Figure 4. Outpatient Oncology Nursing Fellowship Program Overview & Curriculum

Objective: To provide a program to train experienced nurses about oncology in order to continue to provide trained nurses in a tight market for oncology nurses. This program will incorporate education about the disease process, chemotherapy and how it works, chemotherapy administration, treatment modalities, and other factors affecting the plan of care for oncology patients in the infusion center.

Length of Fellowship Program: 4 month period

Preceptors: Maximum of 2 nurses per preceptor

Education:

1. Education in order to be prepared for chemotherapy-biotherapy test. Either a 2-day on-site program or an online course. Fellows must receive their certificate by the end of the 4-month period.
2. Attendance at the 2-day oncology seminar offered at Valley when it falls within the dates of the program. If possible, administration will request that the program be taped and offered.
3. A minimum of 3 credits of oncology CE programs that are approved by preceptor.
4. Attendance at a minimum of 4 chemotherapy drug inservices.
5. Completion of any oncology education required by the Oncology Department; these could be requirements for certification or the department.
6. Review of chemo spill safety with pharmacy-live demo.

Experiential Areas:

1. Inpatient A3
2. Pharmacy at Luckow
3. Radiation Oncology
4. Oncology Clinical Trials
5. Oncology Tumor Conference
6. Oncology Social Worker
7. Front Desk Registration
8. Nurse Practitioner in Medical Oncology Practice
9. Intraperitoneal Chemotherapy
10. PORT Insertion (observation in OR)
11. PICC Team (observe insertion)
12. Chemotherapy Experiences: IP chemo, IVP chemo, IV Infusion chemo, SQ chemo, drugs requiring a filter, access and deaccess port, Infusystem pumps.

Other Requirements:

- Journal entries on a daily basis by both nurse and preceptor. This will be a summation of the day and will be signed by both. This will be kept on the unit.
- A binder will be assigned that will be filled with materials for the program. It will also remain on the unit.
- Fellows will follow the schedule of her preceptor, including 8- or 10-hour shifts and weekends and/or holidays.
- The unit specific competency record will be completed before the completion of the program.
- Fellows will complete and pass the chemotherapy/biotherapy qualification test.

Applicants: Applicants will be nurses with a minimum of 1 year of hospital experience. They will undergo an interview with the Nurse Manager and Director for Infusion along with select nurse staff members from the infusion center.

Figure 5. Application for Participation in the Outpatient Oncology Nursing Fellowship Program

Name: _____

Best way to contact you: _____

Unit where you currently work: _____

Shift work on unit: day _____ evening _____ night _____

Hours worked per day: 8 _____ 10 _____ 12 _____

Unit Manager _____

How long have you worked as a registered nurse? _____ years

How many years have you worked at Valley? _____ years

Have you ever had any experience in an oncology area? _____ If yes, please explain.

_____

_____

_____

_____

Please give us an explanation of why you are interested in this program? Keep in mind that the program will last for 4 months and will require a minimum commitment of working in the Infusion Center for 1 year after completion of the program.

_____

_____

_____

_____

_____

_____

_____

_____

Signature Date

INNOVATE. ACHIEVE. INSPIRE.

CONGRATULATIONS

2016 ACCC INNOVATOR AWARD RECIPIENTS

ACCC is proud to recognize these Cancer Program Members for their significant achievements in enhancing oncology care.

Baton Rouge General Medical Center, Pennington Cancer Center
Baton Rouge, LA
Tele-Health Technology Connects Patients with Nutrition Services

Cone Health System, Cone Health Cancer Center
Greensboro, NC
The Study of High Cost Oncology Patients to Improve Care and Curb Costs

Fox Chase Cancer Center
Philadelphia, PA
Enhancing Survivorship through Improved Provider Communication, Care Coordination, and Professional Education

Mary Bird Perkins Cancer Center
Baton Rouge, LA
Early Detection of Cancer for the Medically Underserved

Park Nicollet HealthPartners, Frauenshuh Cancer Center
St. Louis Park, MN
Establishing Personal Pain Goals in Oncology Patients to Improve Patient Care and Decrease Costs

Sanford USD Medical Center, Sanford Cancer Center
Sioux Falls, SD
Expanding Access to Immunotherapy in the Community Setting—
ICLIO Innovator Award Winner

The Outer Banks Hospital, The Outer Banks Hospital Cancer Services
Nags Head, NC
HPV Vaccination: Engaging Community Partners for Success

University of Maryland Upper Chesapeake Health, Kaufman Cancer Center
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Building a Palliative Care Program from the Inside Out

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Visit accc-cancer.org/oncologyconference for more details.

Location Technology Improves Efficiency, Safety & the Patient Experience

BY BRENDA CLEMENTS, RN, MBA, OCN

In 2009 Eastern Maine Medical Center (EMMC) Cancer Care, opened a new, state-of-the-art, 135,000-square-foot, standalone three-story treatment facility, which employs more than 160 staff members, and provides care to between 250 to 300 patients each day. Today the Lafayette Family Cancer Center is home to radiation oncology, medical oncology, pediatric oncology, breast surgical specialists, rheumatology specialists, anemia management and blood management, behavioral health, genetics, supportive (palliative) care, clinical research, laboratory services, medical imaging services, and the only PET/CT in the region.

When planning for this new facility began in 2007, EMMC Cancer Care knew it would need some way to communicate the status of patients across this three-story building that measures longer than a football field. We selected a computerized communication tool, but unfortunately it proved non-viable for our setting. In 2008, desperate for an alternative, we found a real-time location system that promised to help us communicate the status of patients through automated electronic white boards. This kind of technology was used in hospitals for years, mainly for locating assets like IV pumps, and increasingly, this technology was being used to monitor the status of patients in ambulatory clinics, such as multi-specialty groups. EMMC Cancer Care would be the first to try the technology in an oncology program.

EMMC Cancer Care found that the real-time location system not only helped staff communicate the status of patients, it also streamlined patient flow through the facility, improving staff efficiency, reducing wait times, and enhancing patient safety—ultimately optimizing the patient experience.

We found that the real-time location system not only helped staff communicate the status of patients, it also streamlined patient flow through the facility, improving staff efficiency, reducing wait times, and enhancing patient safety.

The Technology

Our real-time location system consists of three basic components: badges, sensors, and software. Both patients and staff wear lightweight locator badges, which are picked up by sensors installed throughout the facility. Sophisticated rules-based software takes this location data and automatically updates electronic whiteboards. Once installed and set up, the system virtually runs itself—with very little interaction from staff. Just by wearing the badges, staff can see the location of all patients and staff on floor plan views (FPVs), a map of our facility that also displays the color-coded status of rooms and treatment chairs: available, occupied, or in need of turnover (see Figure 1, page 48).

The system's "list views" show information about each patient, including:

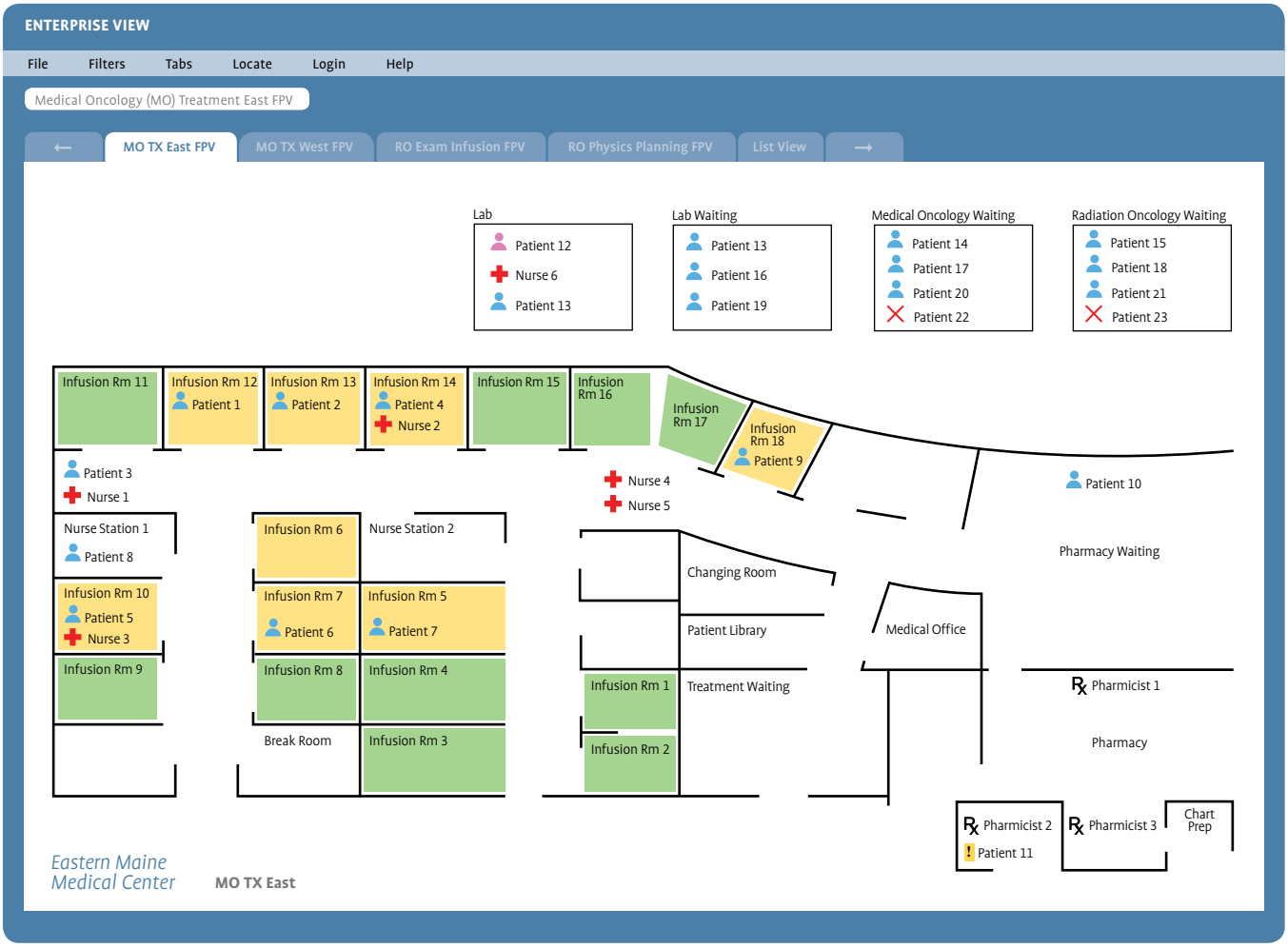
- The patient's location
- The visit type (brought in from the electronic health record [EHR])
- The physician's name (brought in from the EHR)
- Which providers have seen the patient
- The providers scheduled to see patients next
- Patients' current wait or alone time
- Patients' overall length of stay.

Because information updates automatically, the patient's entire experience is visible to everyone involved in their care (Figure 2, page 49).

Automating Patient Flow

Our first step when implementing the real-time location system was to determine the different pathways patients take through our facility. Then, the vendor programmed the software with our specific patient flow to trigger alerts on the

Figure 1. Rendering of Enterprise View Screenshot



patient's stage of care, based on their location, interaction with caregivers, and/or button pushes (explained below).

All patients receive badges when they check in for their appointment; patients then sit in the waiting room before being escorted to either an exam room or a treatment chair.

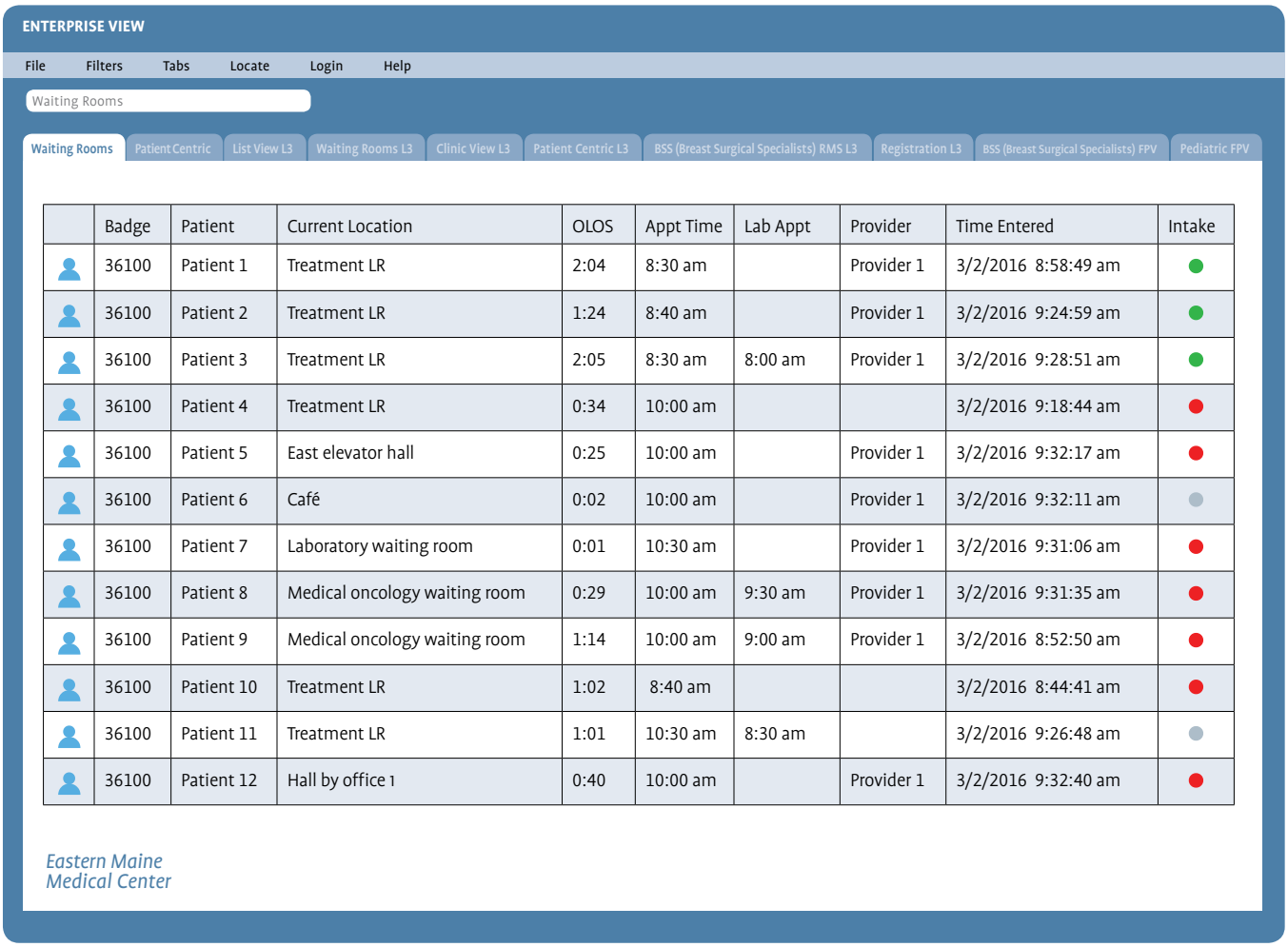
Certified medical assistants (CMAs) and treatment nurses simply glance at their monitor to see who is in the waiting room. No more walking or calling back and forth to see if patients have arrived yet for their appointment.

With a glance at the floorplan view to determine which room is clean and available, the CMA escorts patients into their treatment area. Once patients are situated, the CMA presses the button on her badge. This "button push" signals the system that patients are ready to see the provider, and the provider's name is highlighted on the list view.

All providers have a dedicated monitor in their office so they can tell at a glance when their patients are ready to be seen. When a patient's name is highlighted, providers make their way to the exam room. At first we also had the system trigger a message to the providers' pagers. However, we found this step to be unnecessary as providers preferred to use the list view only and delete extra pages that may occur during critical patient/provider conversations.

Similarly, treatment room nurses escort their patients to treatment chairs. Once they complete their assessment, establish IV access, and verify lab results, RNs press their badge buttons. We can program the "button push" to mean different things in different locations—or even based upon who's wearing the badge. In this scenario the button push signals the system that the patient is ready for treatment. On the list view, an icon appears in the chemotherapy column, alerting the pharmacist to start mixing medication.

Figure 2. Rendering of Waiting Room List View



	Badge	Patient	Current Location	OLOS	Appt Time	Lab Appt	Provider	Time Entered	Intake
	36100	Patient 1	Treatment LR	2:04	8:30 am		Provider 1	3/2/2016 8:58:49 am	
	36100	Patient 2	Treatment LR	1:24	8:40 am		Provider 1	3/2/2016 9:24:59 am	
	36100	Patient 3	Treatment LR	2:05	8:30 am	8:00 am	Provider 1	3/2/2016 9:28:51 am	
	36100	Patient 4	Treatment LR	0:34	10:00 am			3/2/2016 9:18:44 am	
	36100	Patient 5	East elevator hall	0:25	10:00 am		Provider 1	3/2/2016 9:32:17 am	
	36100	Patient 6	Café	0:02	10:00 am		Provider 1	3/2/2016 9:32:11 am	
	36100	Patient 7	Laboratory waiting room	0:01	10:30 am		Provider 1	3/2/2016 9:31:06 am	
	36100	Patient 8	Medical oncology waiting room	0:29	10:00 am	9:30 am	Provider 1	3/2/2016 9:31:35 am	
	36100	Patient 9	Medical oncology waiting room	1:14	10:00 am	9:00 am	Provider 1	3/2/2016 8:52:50 am	
	36100	Patient 10	Treatment LR	1:02	8:40 am			3/2/2016 8:44:41 am	
	36100	Patient 11	Treatment LR	1:01	10:30 am	8:30 am		3/2/2016 9:26:48 am	
	36100	Patient 12	Hall by office 1	0:40	10:00 am		Provider 1	3/2/2016 9:32:40 am	

Eastern Maine Medical Center

Improving Safety & Pharmacy Efficiency

Every time a pharmacist is interrupted during order review, the potential for error rises greatly. Yet in our previous treatment facility, pharmacists commonly experienced interruptions from nursing regarding patient arrival, need for drug, and drug readiness. These interruptions can lead to costly mistakes—both because of patient safety and the reimbursement dollars lost from mixing and preparing incorrect medications.

Our real-time location system solves this by automating communication with pharmacy. Once the pharmacist sees notification from the RN that a patient is ready for meds, a simple click on the list view changes the icon, acknowledging the order. When the meds are mixed, pharmacists click again to change the icon, alerting the RN that pre-meds or chemotherapy meds are ready (see Figure 3, page 50).

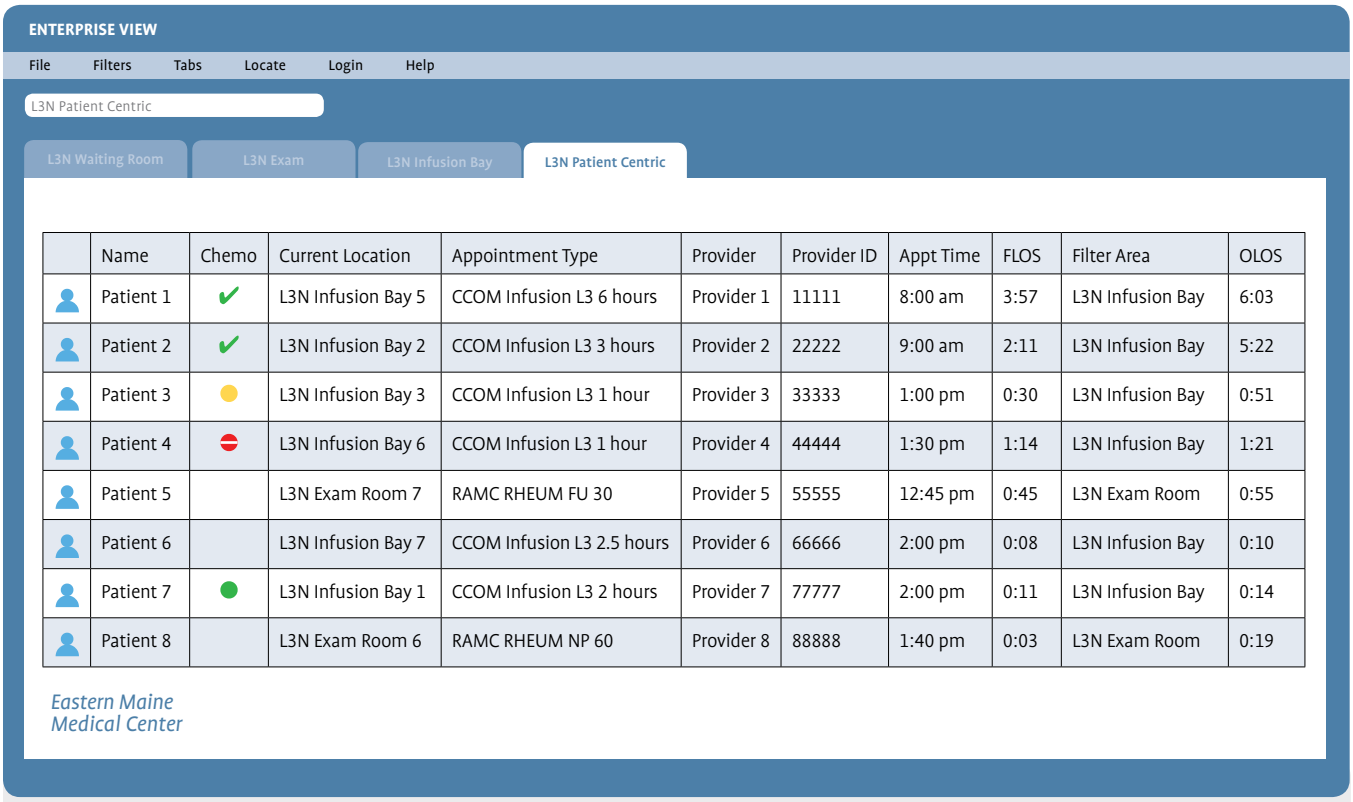
Orders are processed efficiently and without interruption, greatly improving pharmacy workflow and pharmacists' job satisfaction.

Increasing Time for Patient Care

The automated pharmacy communication is just one example of how the system optimizes nursing workflow. Prior to the integration of the real-time location system, treatment nurses would make multiple trips to the pharmacy to see if meds were ready. Now, nurses are always informed by just glancing at a monitor. This step alone has saved each treatment nurse from walking more than one mile per day.

In Medical Oncology, we used a paper trail to drive patient flow, which required CMAs to take a paper slip to the provider for each patient when he or she was ready to be seen. Now, we save time and money by not walking all this paper around.

Figure 3. Rendering of Automated Pharmacy Communication



	Name	Chemo	Current Location	Appointment Type	Provider	Provider ID	Appt Time	FLOS	Filter Area	OLOS
	Patient 1	✔	L3N Infusion Bay 5	CCOM Infusion L3 6 hours	Provider 1	11111	8:00 am	3:57	L3N Infusion Bay	6:03
	Patient 2	✔	L3N Infusion Bay 2	CCOM Infusion L3 3 hours	Provider 2	22222	9:00 am	2:11	L3N Infusion Bay	5:22
	Patient 3	●	L3N Infusion Bay 3	CCOM Infusion L3 1 hour	Provider 3	33333	1:00 pm	0:30	L3N Infusion Bay	0:51
	Patient 4	⛔	L3N Infusion Bay 6	CCOM Infusion L3 1 hour	Provider 4	44444	1:30 pm	1:14	L3N Infusion Bay	1:21
	Patient 5		L3N Exam Room 7	RAMC RHEUM FU 30	Provider 5	55555	12:45 pm	0:45	L3N Exam Room	0:55
	Patient 6		L3N Infusion Bay 7	CCOM Infusion L3 2.5 hours	Provider 6	66666	2:00 pm	0:08	L3N Infusion Bay	0:10
	Patient 7	●	L3N Infusion Bay 1	CCOM Infusion L3 2 hours	Provider 7	77777	2:00 pm	0:11	L3N Infusion Bay	0:14
	Patient 8		L3N Exam Room 6	RAMC RHEUM NP 60	Provider 8	88888	1:40 pm	0:03	L3N Exam Room	0:19

Eastern Maine Medical Center

- ● Patient in treatment chair, nursing assessment done, IV access established (if needed)
- ● Pharmacy acknowledgement that the patient is ready; pharmacy has orders and will institute processing
- ✚ Anti-emetics ready for pick-up/delivered
- ✔ Chemotherapy ready for pick-up/delivered
- ⛔ In response to a yellow dot, a negative sign means one of the following:
  1) pharmacy has not received orders, or
  2) there is a problem with the order

CMAs walk four miles less per day each, and our providers appreciate not having to wait for someone to deliver the paper, or possibly losing the paper (aka the patient) on their desk.

These wasted steps took time away from direct patient care—and not just the time it takes to go back and forth. Every time nurses step away from their work, the potential for interruption heightens, further delaying patient care.

Today our nurses not only walk a lot less, they also feel they have more time to spend with their patients, doing what they love to do—provide safe, quality patient care.

Enhancing the Patient Experience

Our patients' time is valuable. They don't want to spend it sitting in the waiting room, or waiting for their next stage of care. The real-time location system allows us to proactively monitor the time patients spend alone. If a patient has been in a location for more than 20 minutes without seeing a staff member, an alert appears on staff workstations.

The only way to clear this alert is for a staff member to physically go into the room of the waiting patient. While there, staff members let patients know how long they may expect to wait, and ask if they need anything. Patients appreciate the update and knowing that they are "not forgotten."

Because of the automated communication around the patient visit, we have drastically reduced wasted time, which means patients spend less time at the facility overall and receive higher quality care.

The system also assists EMMC Cancer Care with pediatric patients and their parents. Parents and children both receive badges, which are easily linked by pressing badge buttons

together in the registration area. We can see on our floorplan view if the parent is with the child; or if they're not, we use the locator function of the system to find the parent's location.

Parents know they can step away to take a phone call, get some coffee, or just take a walk around the facility. They can do this with peace of mind, because they know we can find them when they're needed. Thanks to this attention to patient care, our Avatar Patient Satisfaction Scores are consistently greater than 95 percent.

Finding Each Other, Finding Equipment

Beyond the sophistication of the patient flow aspects of the real-time location system, simply finding other staff members and needed equipment saves EMMC Cancer Care both time and money.

Previously, overhead paging was needed to find a provider or other staff member to ask a question about patient care; then wait and hope they would call back.

Using the "locate" feature, staff members simply enter the name of the person they're looking for and the system serves as a real-time phone directory, displaying the extension number of the closest phone. Dialing that extension allows staff members to reach each other immediately and receive answers in a timely fashion. This feature not only further expedites patient care, it also lends to a quieter environment, benefiting both patients and staff.

In the case of equipment, staff members simply attach a badge to items like a vein finder. Using the "locate" feature, a staff member types in "AccuVein" to find out where the piece of equipment is currently located. Even though the vein finder is not used very often, it's a very important piece of equipment. Traditionally EMMC Cancer Care would have purchased one for each of the three floors in the building, just so nurses would not waste time finding the piece of equipment when it was needed. The three vein viewers would then sit unused for a great portion of the day. With the real-time location system, EMMC Cancer Care is able to share one vein viewer across all floors; nurses now know its exact location when they need it. Sharing one piece of equipment instead of purchasing extras for convenience is an efficient cost saver.

Assisting with Meaningful Use

The real-time location system is so dynamic and flexible that EMMC Cancer Care is continually finding new ways to use it. Recently, we added a column to our patient "list view" that indicates which patients require Depart/Discharge paperwork. This option gives more visibility to our Meaningful Use requirements.

Decision Making & Process Improvement with Accurate Data

While the real-time location system helps us improve care delivery in real time, it is also passively recording data about our operations, much like a consultant would do by following people around with stopwatches. The data is automated and accurate, without any personal bias, allowing users to run a variety of reports on various metrics, or have them automatically emailed on a regular basis. Some of the metrics we track include:

- Room and chair utilization
- Average wait times for various stages of care
- Average length of stay in the lab, in exam, treatment, etc.
- Patient time with provider
- Patient time with nurse
- Exam-to-provider times.

These metrics help administration understand patients' overall experience and shed light on operations in various ways by:

- ***Revealing bottlenecks.*** After reviewing data from these reports, we saw that patients were waiting too long for intake and not making it to their scheduled appointments on time, putting providers behind schedule. By identifying the root cause of this issue, we realized we were not giving CMAs enough time for the intake process. With some minor tweaks to our timing and scheduling, we reduced the wait time for intake and improved patient throughput, getting providers back on schedule.
- ***Managing capacity.*** Because the real-time location system automatically monitors when rooms and chairs are occupied by patients, when they're in need of turnover, and when they are available, we can run a report to understand our room and chair utilization rates and overall capacity. We use this data to adjust patient scheduling, accommodate more patients, decrease wait times, and increase revenue.
- ***Reducing patient complaints.*** We've all been in the situation where a patient complains about how often they were checked on, or how much time their provider spent with them. In some cases, we've even had patients refuse to pay their bills. Our "alone time" alert forces patient rounding and interaction. We now know how long the provider was with the patient, or every staff member that interacted with patients during their visit. Running reports of this information—including patient wait times—has helped us improve wait times, the quality of care we provide, and patient and staff satisfaction.
- ***Managing infection control efforts.*** The real-time location system allows us to see immediately who has been exposed to an infectious patient. For example, a patient was recently diagnosed with chicken pox after a visit to our facility. Where we would normally have had to alarm upwards of 250 potentially immune-compromised patients and let them know they were possibly exposed, the location system allowed us to run a quick report and know that only 10 patients were actually in the same vicinity of the infectious patient. That meant we didn't have to call 240 patients and needlessly send them for testing or cause undue concern.

Overcoming Objections

Implementing a real-time location system is not without its challenges. The first challenge we had to overcome: funding.

EMMC Cancer Care, Bangor, Maine.

Today there is a wealth of data from various cancer programs showing how a system like this improves operations and the patient experience, but back in 2009, EMMC Cancer Care was the first health system to implement this technology. To demonstrate the need, I took executives from our health system on a tour of the new building and purposely got lost. I asked them, "How are we going to navigate this space? What happens if a patient gets lost?" It was a very effective exercise.

The next challenge, and the question we received most about the system is, "How do you get nurses and providers to wear the badge?" There are a few common objections from staff that are easily overcome with the right approach.

First, staff members may be hesitant to wear the badge because it emits signals, which they perceive could be harmful to their health. In fact, the signals are no different than what we use every day in TV remote controls (infrared light) and remote keyless entry for cars (radio frequency). Cancer program leadership explained this reasoning and led by example. Prior to opening the new building, the manager of Nursing Services wore her badge every day. Staff could see that it had no ill effects on the manager (or her clothing, as it's very lightweight).

Second, there's the "big brother" issue. Staff members are afraid administration is going to use the system to "track" them. While it's possible to use real-time location systems in this way, cancer program leadership reassured staff members that the badges would not be used for punitive action. Administration does not want to know how long breaks take, or which staff member is using the bathroom the most.

The purpose of the real-time location system is to streamline staff workflow and improve the patient experience. When presented in this light, staff members become more receptive to the idea. When you actually begin using the system (and don't use it in a punitive way), staff members quickly come to realize the benefits and embrace the efficiency it provides.

As for patients, we have found most are more than happy to wear the badge during their appointments. In fact, one patient recently told me that it takes a weight off her mind. "To know that I can't get lost in this building, that if I take a wrong turn or sit in the wrong waiting room, that you'll find me, that's just one less thing I have to worry about."

Innovating New Uses for the Technology

Because EMMC Cancer Care staff members have embraced the real-time location system, they are continuously innovating new ways to leverage it to improve the patient experience, quality, safety, and care. Many of the benefits and features noted above, such as the pharmacy communication and pediatric parent association, were actually conceived by employees and implemented in partnership with the vendor. I am most proud that the innovations in patient care made possible by EMMC Cancer Care and our real-time location system are now used nationwide by some of the top programs in cancer treatment. OI

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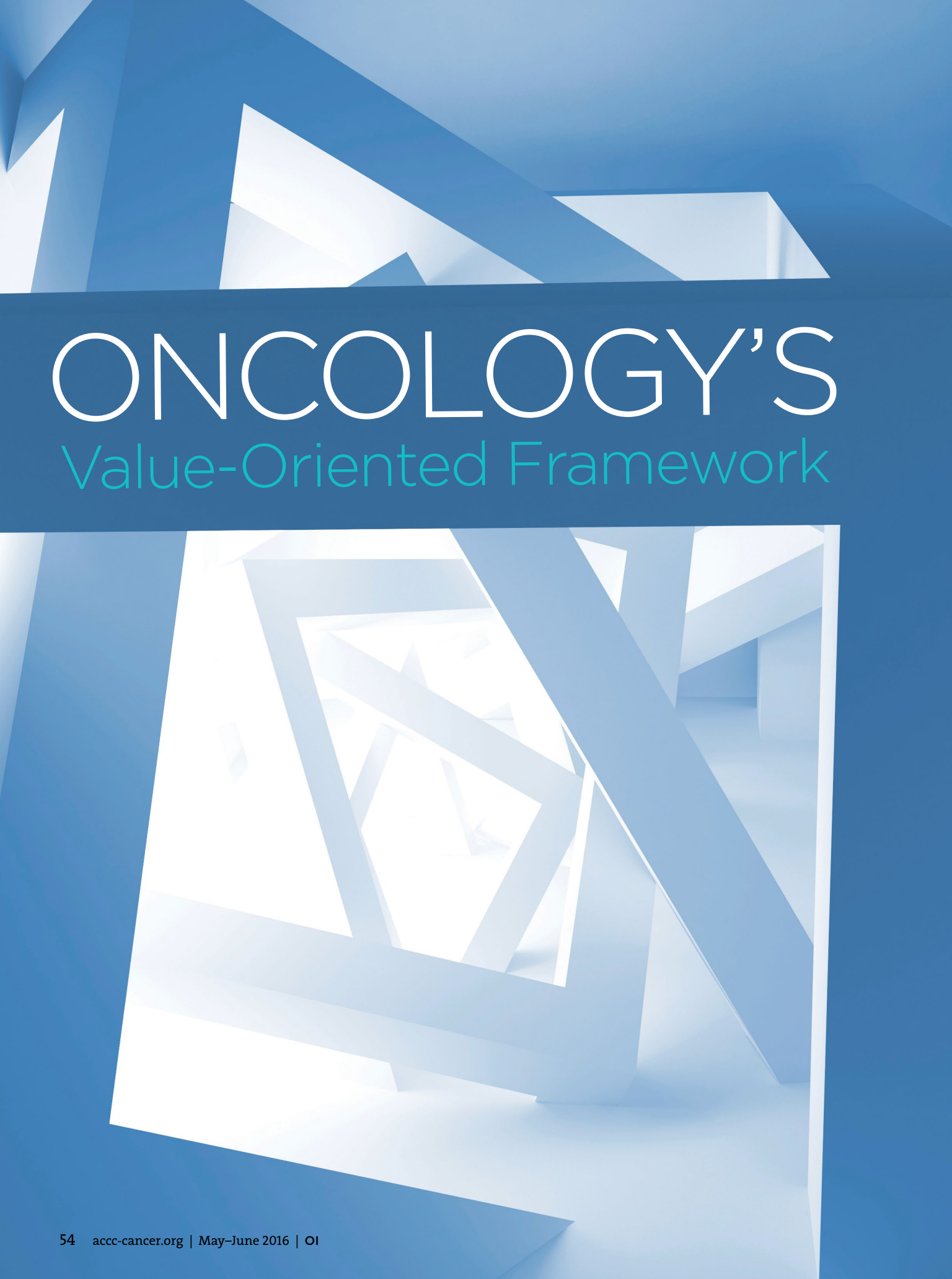


ONCOLOGY'S
Value-Oriented Framework

BY RYAN LANGDALE, MBA,
AND KELLEY D. SIMPSON

In our previous article, "Strategic Planning: A Roadmap to Follow to Ensure a Successful Oncology Service Line" (July-August 2015 *Oncology Issues*), we established a case for oncology-specific strategic planning. The discussion largely focused on the uniqueness of the cancer service line within the broader hospital portfolio, as well as some actionable tips for engaging the organization in planning. What was absent from that preliminary discussion was the framework by which hospitals can make strategic decisions in oncology and see them through to implementation. A number of excellent strategic planning tools have been published by consultancies and academia, but we have found that they often lack the necessary specificity for oncology and, more importantly, do not fully address the all-important question for healthcare organizations—how do we plan for an uncertain, value-based future? The following article addresses this question directly and advances an approach that we have found beneficial for framing the appropriate strategic questions, forecasting the impact of a value-based transition, and designing and implementing positive, future-oriented strategy for oncology service lines.

Emerging Process for Planning

The traditional model for strategic planning, as depicted in Figure 1, page 56, involves self-evaluation, articulating a vision, determining resource requirements, and then implementation. This strategic planning model is well-suited for a static environment because—absent any significant macro-level changes—most organizations are good at assessing and mitigating program gaps. However, this model begins to break down when the national, regional, and local healthcare landscape begins to shift and organizations are faced with new complexities as they evaluate their legacy planning process. With this complexity, a new step emerges in the process (Figure 2, page 57),

> The changes in the healthcare industry require a re-examination of all the beliefs, attitudes, resources, and processes that define the business of oncology and our approach to caring for patients with cancer.

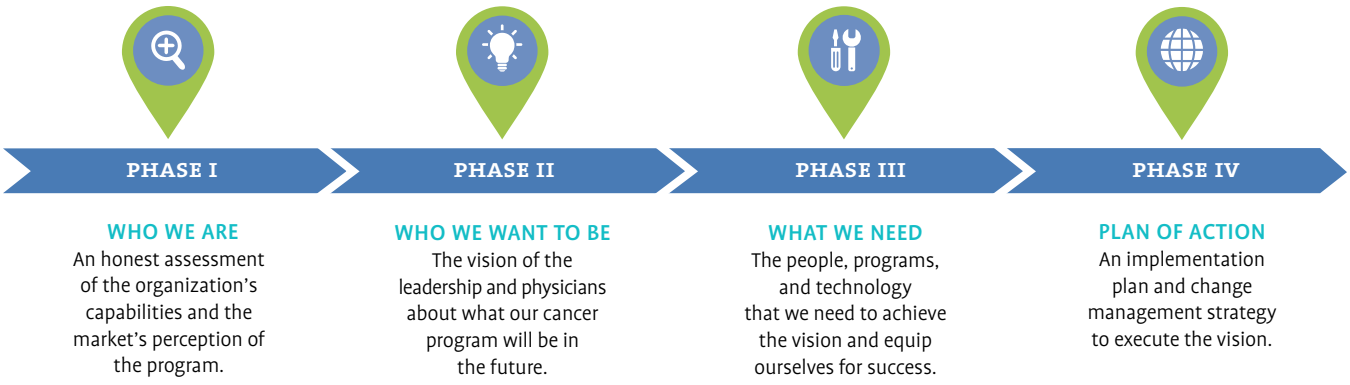
along with new questions such as:

- Are we asking the right questions of our current capabilities?
- Are we all aligned with "who we want to be" in the value-based world?
- And most importantly, what future are we planning for and how does that affect the infrastructure, human capital, technology, and services we need to succeed in cancer care?

The future-oriented process for cancer program strategy places a new lens on everything we do in planning. The questions we should be asking include:

- How does the expectation for value-based care change the way we assess our current capabilities and organizational readiness? (Phase I)
- How do we craft our vision as payers, patients, and regulatory agencies change the way we have traditionally done business? (Phase II)
- What does our oncology service line look like in a value-oriented ecosystem, and how quickly can we transition? (Phase III)
- How do we prepare for a new reality, and what tools, processes, partners, and leadership do we need to get from here to there? (Phase IV)

Figure 1. Traditional Process for Cancer Planning



- What does a value-based strategy require of us financially and operationally as we attempt to prioritize, sequence, and implement transformative changes within our cancer program? (Phase V)

What the Future Holds

Many of the cancer programs that we work with express a feeling of "paralysis" when it comes to preparing for the value-based future of healthcare. Their perception is that forecasting for this future is equivalent to "fortune-telling," and for that reason they are delaying the reimagining and redesign of their cancer programs. While this reaction to uncertainty is understandable, and prevalent, we strongly believe that delaying value-based readiness is a mistake for long-term program success. No single expert has the answer for "what the future holds," but many have expressed informed, directional opinions to support strategic planning and organizational adaptation.

The ACCC Institute for the Future of Oncology released its predictive recommendations in the fall of 2015, outlining what their forum believes to be the trends that will shape oncology. Among them were continued consolidation and integration of providers, evidence-based and patient-participatory clinical care, data-equipped multidisciplinary teams, and value-based pricing and reimbursement.[1] While this was a cancer-specific forecasting exercise, other publications like Deloitte's "Lens into the Future" support the Institute's findings with CEO commentary on the future of healthcare. Interviews with these leaders revealed unanimity on the forces that will change healthcare in coming years, among them:[2]

- Fundamental change in the way hospitals are paid
- A migration to ambulatory care
- Integrated care delivery networks
- A new mindset of "consumerism" as patients become discerning customers of the cost and quality of their healthcare product.

If the consensus of our thought leaders in the C-suite and the cancer industry is that transformational change is imminent, then the question we face is not "what does the future hold?" but rather, "how do we prepare for it?"

Planning for Value

The changes in the healthcare industry require a re-examination of all the beliefs, attitudes, resources, and processes that define the business of oncology and our approach to caring for patients with cancer. This assessment can be politically sensitive, financially burdensome, and logistically overwhelming for the physicians and administrators responsible for the continuity and success of the oncology service line. For these reasons, we believe that a framework is helpful. A value-based planning framework assists with prompting the right questions, soliciting honest reflection, and formulating strategies for the future.

Environmental Review

The value-based framework begins with an environmental review. In this phase of planning, the cancer program should capture candid feedback and all of the classic planning information, including competitive landscape, market share, organizational strengths and weaknesses, program performance—and a few novel elements, such as payer market maturity (i.e., Where are local payers with oncology-specific alternative payment models [APMs]? Are they involved in pilot projects for APMs? Do they have risk-based contracts with physicians or hospitals?), delivery network capabilities at a tumor-specific level, and technology and data sophistication.

Value-Based Strategy

The environmental review informs the beginnings of the strategic planning process, and the unifying question of "who do we want to be in the value-based world?" This question is typically expressed as a "vision statement," but in its most basic form it should be a broadly-endorsed and inspiring expression of the

Figure 2. Emerging Process for Cancer Planning

program's ambition and value proposition. The substance of a cancer program's aspirations will differ based on size, location, and community need, but the frameworks for evaluating a path forward share many commonalities.

The general value-based framework is oriented around the value-based readiness of the cancer program's Organization, Resources, Network, and Population (Figure 3, page 58).

Organization. This sphere addresses the value-based readiness and capabilities needed from the cancer program's leadership, governance structure, physician engagement and alignment, and design of collaborative culture and incentives. This category is evaluated first because without visionary leadership, an engaged medical staff, and a cultural shift in cancer care delivery, the rest of the program strategy is meaningless. Succeeding in the value-based cancer environment of 2020 will require an unprecedented leadership toolkit, organizational agility, and service-line integration. Further, it will demand that physicians are aligned under the common objectives of the program, and that incentives are aligned under a value-based framework in a manner that encourages shared success for the provider, physician, and patient.

Resources. This sphere evaluates the infrastructure, competencies, and processes that will serve as enablers for a value-based care architecture. As the organization evaluates its current program against the needs of the future, a significant amount of planning and work will need to be done with respect to care standardization and measured utilization; process optimization; multidisciplinary collaboration; patient engagement; data-integration and management; and optimized access to personalized medicine, technology, and care settings. The Resources sphere is wide-ranging, but serves to frame the distinct programmatic and capital investments that will be required to successfully transition to value-based care.

Network. This sphere assesses the care delivery structure and partnerships that characterize a cancer program that can succeed in value. It recognizes that cost and quality will reward organizations that scale services across an integrated care delivery network, leverage shared best practices, and build relationships with non-traditional stakeholders. Network planning should evaluate health system competencies, delivery network design, payer and employer engagement, affiliations, and financial ventures. Succeeding in the value-based environment will require that the strategic plan look beyond the four walls of the cancer program and engage the entire integrated delivery network in designing a transparent, synergistic, and competitive cancer program.

Population. This sphere evaluates the unique needs of cancer program constituents and the value-based products that can best manage their care. As Deloitte noted in their "consumerism" feedback, patients are increasingly sophisticated in directing their care toward a healthcare product that is centered on their needs—be they cost or outcome-focused.[2] The biggest challenge for cancer programs is determining how to invest in a value-based, patient-centric product while managing an awkward and unpredictable transition to risk-based reimbursement. The Population strategy sphere seeks to address this quandry by examining risk stratification, consumer engagement, product design and transition, high-risk patient management, and program financial planning. These elements, along with those of the Organization, Resources, and Network spheres, produce a scorecard and roadmap that inform the strategies, tactics, priorities, and investments necessary to achieve value-based program success (Figure 4, page 59).

Investment & Implementation

The final phases of value-based strategic planning involve development of the financial business case and implementation plan. As many early adopters have discovered, preparing for value-based care is a resource-intensive process that is made even more untenable as hospital margins continue to contract. Cancer program leadership is responsible for evaluating the projected impact on patient caseloads, utilization, and financial contribution emanating from the proposed strategies, and deter-

mining whether it justifies the contemplated programmatic and capital investments. This analysis is complicated by the uncertain timeline of value-based reimbursement transition, but as evidenced by CMS' proclamation earlier this year, we can expect more than 50 percent of payments to account for quality and cost by 2018.[3]

The implementation of value-based care design is the subsequent challenge once a strategic plan and business case are complete. Many sound strategies have floundered without commitment to execution and follow-through on the organizational, resource, network, and population imperatives for change. Successful implementation involves:

- Project champions
- Accountable deadlines
- Frequent engagement with patients
- Physician-led change management.

Scaling the Framework

The caveat to value-based strategy is that "one size does ***not*** fit all." Our value-based framework is flexible, and scalable, but must be tailored to the individual environment and size of the cancer program (see Figure 5, pages 60-61). Many of the value-based framework's modules produce starkly different tactics, depending on the size of the program, the market it serves, and the aspirations of the service line. In future articles we will investigate the value-based planning approach for cancer programs of varied size and scope, addressing essential elements for success. This process will cover smaller community cancer programs having new cancer caseloads of less than 500 per year, all the way through large community-academic cancer programs with 2,500+ annual cases. These articles will build upon the value-based framework and speak to the tailored, actionable steps that every cancer program—regardless of size and scope—can take towards value readiness.

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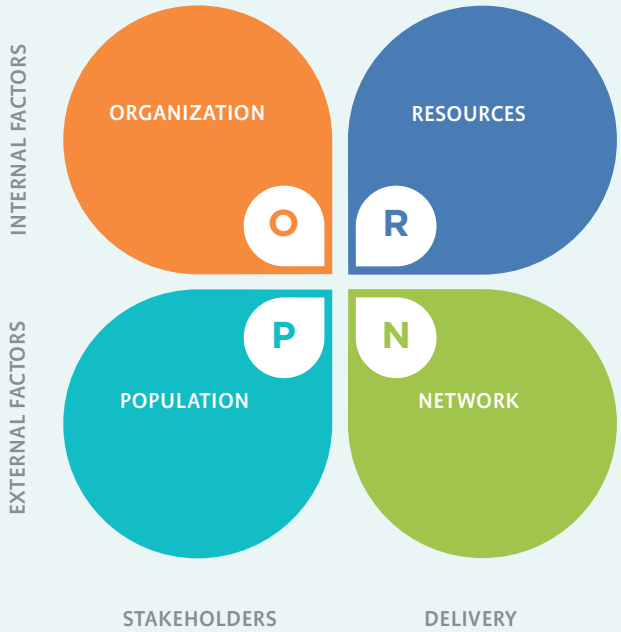
Figure 3. Value-Based Planning Framework



ORGANIZATION

- What collective vision are we working towards?
- What leadership and governance structure is necessary to lead in value?
- How are physicians engaged in the value-based goals of the enterprise?

RESOURCES

- What systems allow for visibility into cost and quality?
- How has care been standardized and navigated to improve value?
- What capital and program investment is required to succeed in the value-based model?

POPULATION

- Who is the customer in 2020 (i.e., patients, employers, payers)?
- What unique value proposition resonates with the customer?
- How do we assess and manage cancer population risk?
- What specific positioning do we adopt relative to competitors?

NETWORK

- What is the optimal level of integration in the care delivery model?
- How do we collaborate with payers to succeed in the market?
- Which partner institutions will lend us scale (i.e., the size and scope of the partner institution) and care competency?
- How are we managing specialty care with our partners?

Figure 4. Strategic & Tactical Planning

VALUE-BASED READINESS →

ORGANIZATION	BASIC	TRANSLATIONAL	MATURE	CANCER 2020 STRATEGY
Leadership		●		
Program governance	●			
Institutional commitment		●		
Physician alignment		●		
Compensation model			●	
Medical staff profile	●			
Collaborative cultural		●		
RESOURCES				
Care standardization			●	
Process optimization			●	
Personalized medicine	●			
Multidisciplinary & navigated care		●		
Disease-focal points	●			
Information technology		●		
Facilities & equipment		●		
NETWORK				
System standardization		●		
Care delivery network		●		
Payer engagement			●	
Employer engagement		●		
Care access	●			
Value-based partners		●		
Academic affiliations	●			
POPULATION				
Risk stratification	●			
Consumer engagement		●		
Product design			●	
Product transition	●			
Screening & surveillance			●	
High-risk population management			●	
Population virtual budget			●	

STRATEGIES

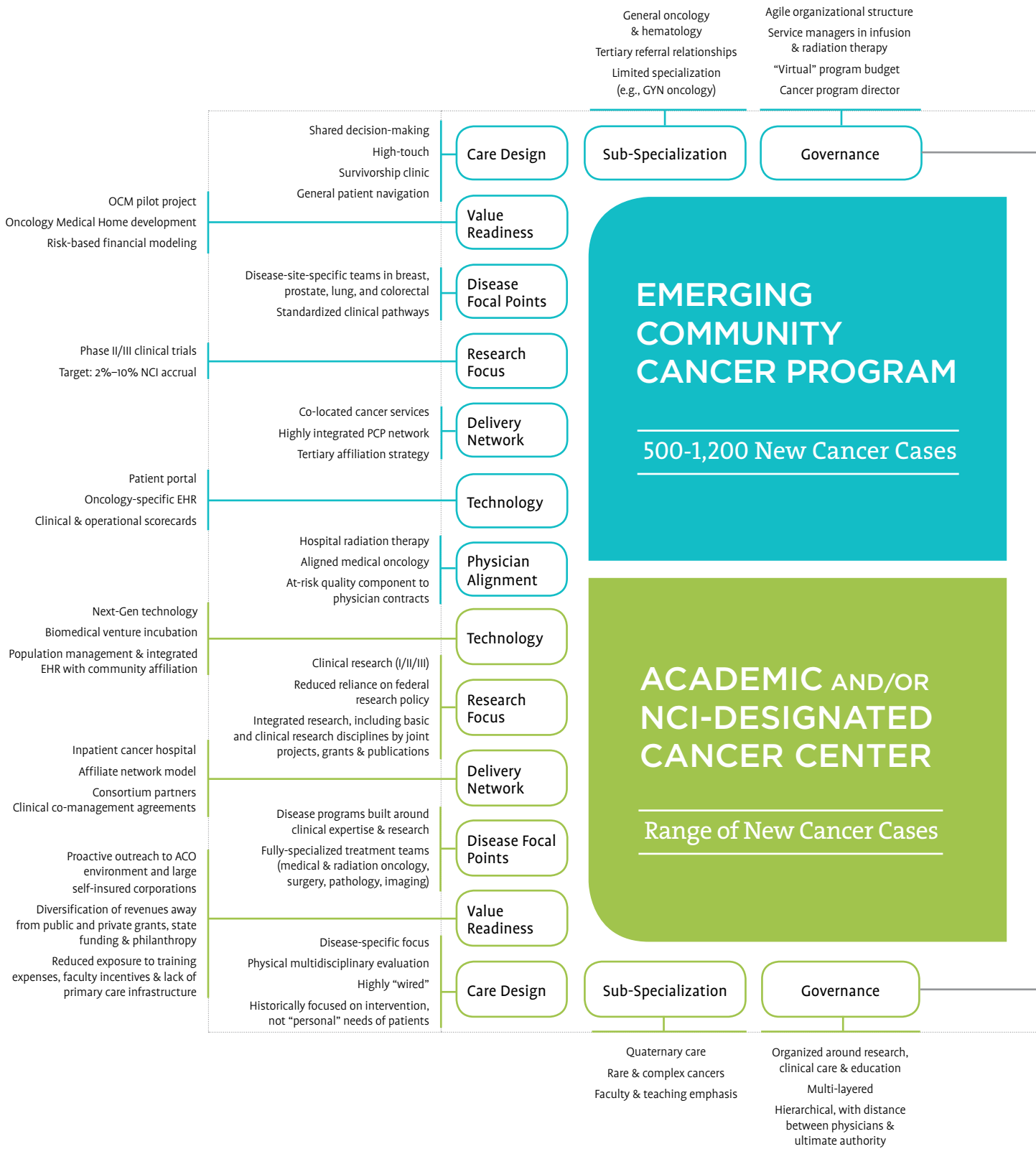
TACTICS

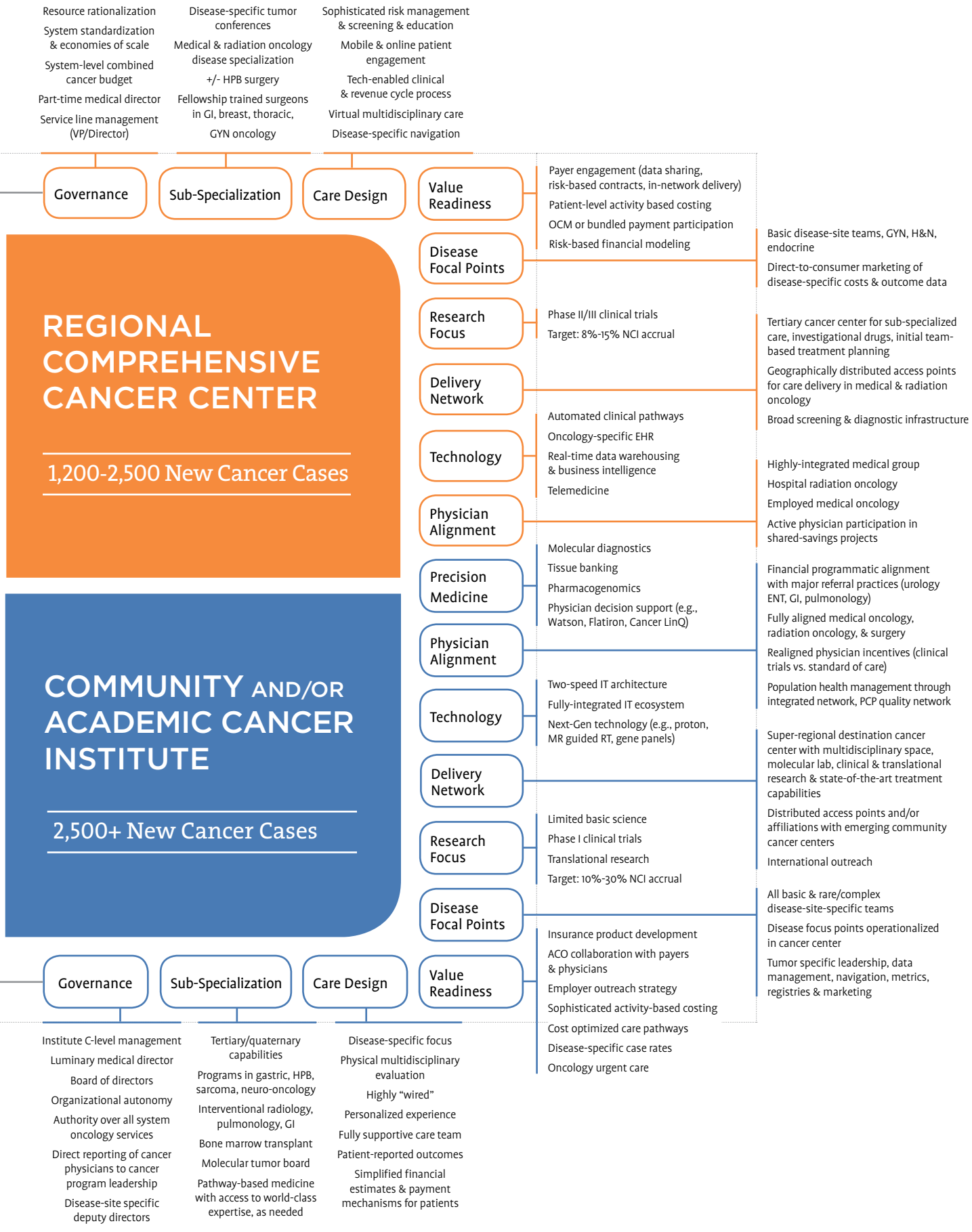
PRIORITIES

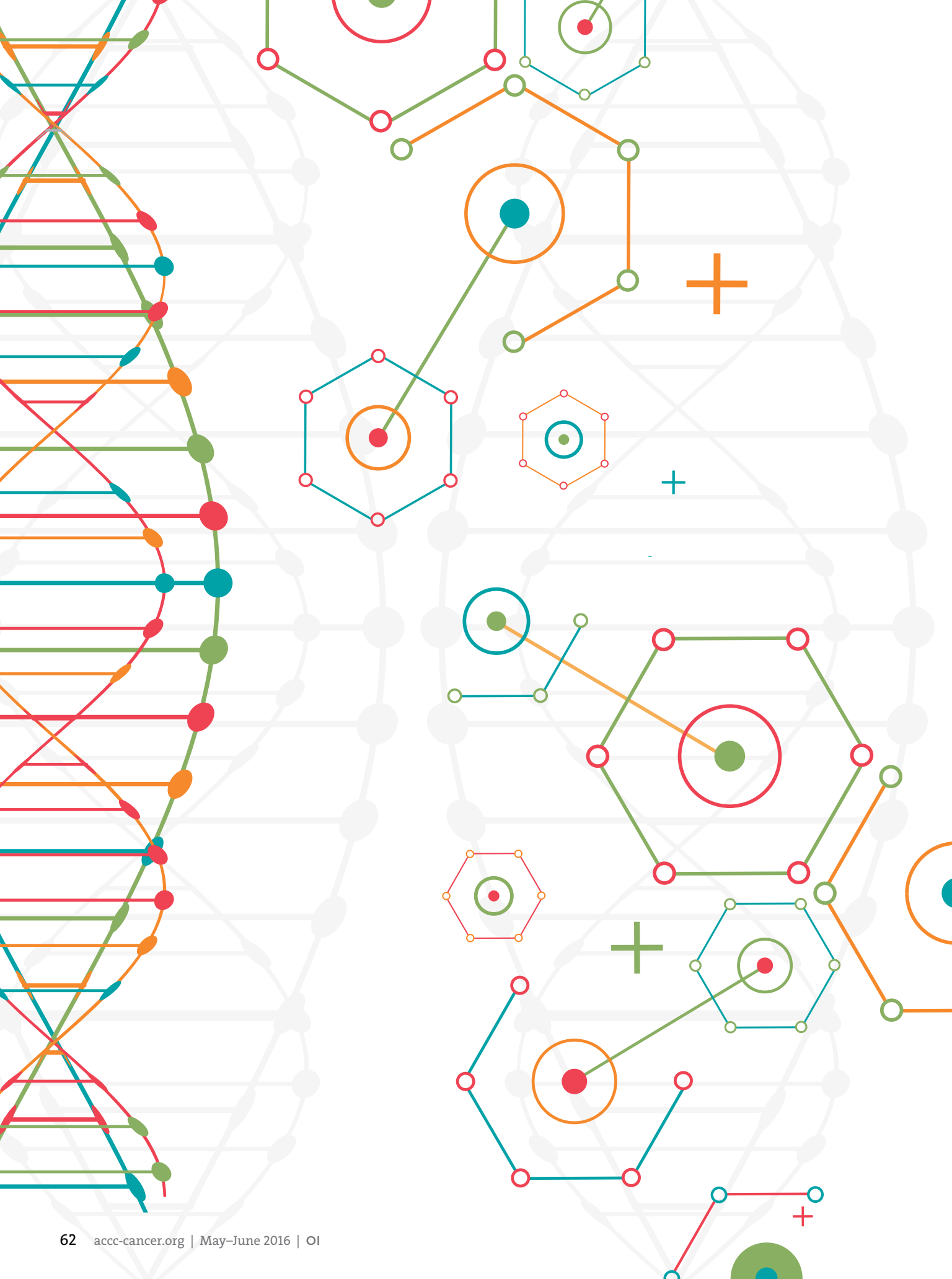
TIMELINES

INVESTMENTS

Figure 5. Value-Based Growth Matrix




Resource rationalization
System standardization & economies of scale
System-level combined cancer budget
Part-time medical director
Service line management (VP/Director)
Disease-specific tumor conferences
Medical & radiation oncology disease specialization
+/- HPB surgery
Fellowship trained surgeons in GI, breast, thoracic, GYN oncology
Sophisticated risk management & screening & education
Mobile & online patient engagement
Tech-enabled clinical & revenue cycle process
Virtual multidisciplinary care
Disease-specific navigation
Governance
Sub-Specialization
Care Design
REGIONAL COMPREHENSIVE CANCER CENTER
1,200-2,500 New Cancer Cases
COMMUNITY AND/OR ACADEMIC CANCER INSTITUTE
2,500+ New Cancer Cases
Value Readiness
Payer engagement (data sharing, risk-based contracts, in-network delivery)
Patient-level activity based costing
OCM or bundled payment participation
Risk-based financial modeling
Disease Focal Points
Basic disease-site teams, GYN, H&N, endocrine
Direct-to-consumer marketing of disease-specific costs & outcome data
Research Focus
Phase II/III clinical trials
Target: 8%-15% NCI accrual
Delivery Network
Tertiary cancer center for sub-specialized care, investigational drugs, initial team-based treatment planning
Geographically distributed access points for care delivery in medical & radiation oncology
Broad screening & diagnostic infrastructure
Technology
Automated clinical pathways
Oncology-specific EHR
Real-time data warehousing & business intelligence
Telemedicine
Physician Alignment
Highly-integrated medical group
Hospital radiation oncology
Employed medical oncology
Active physician participation in shared-savings projects
Precision Medicine
Molecular diagnostics
Tissue banking
Pharmacogenomics
Physician decision support (e.g., Watson, Flatiron, Cancer LinQ)
Physician Alignment
Financial programmatic alignment with major referral practices (urology ENT, GI, pulmonology)
Fully aligned medical oncology, radiation oncology, & surgery
Realigned physician incentives (clinical trials vs. standard of care)
Population health management through integrated network, PCP quality network
Technology
Two-speed IT architecture
Fully-integrated IT ecosystem
Next-Gen technology (e.g., proton, MR guided RT, gene panels)
Delivery Network
Super-regional destination cancer center with multidisciplinary space, molecular lab, clinical & translational research & state-of-the-art treatment capabilities
Distributed access points and/or affiliations with emerging community cancer centers
International outreach
Research Focus
Limited basic science
Phase I clinical trials
Translational research
Target: 10%-30% NCI accrual
Disease Focal Points
All basic & rare/complex disease-site-specific teams
Disease focus points operationalized in cancer center
Tumor specific leadership, data management, navigation, metrics, registries & marketing
Value Readiness
Insurance product development
ACO collaboration with payers & physicians
Employer outreach strategy
Sophisticated activity-based costing
Cost optimized care pathways
Disease-specific case rates
Oncology urgent care
Governance
Sub-Specialization
Care Design
Institute C-level management
Luminary medical director
Board of directors
Organizational autonomy
Authority over all system oncology services
Direct reporting of cancer physicians to cancer program leadership
Disease-site specific deputy directors
Tertiary/quaternary capabilities
Programs in gastric, HPB, sarcoma, neuro-oncology
Interventional radiology, pulmonology, GI
Bone marrow transplant
Molecular tumor board
Pathway-based medicine with access to world-class expertise, as needed
Disease-specific focus
Physical multidisciplinary evaluation
Highly "wired"
Personalized experience
Fully supportive care team
Patient-reported outcomes
Simplified financial estimates & payment mechanisms for patients



BY MICHAEL A. CALIGIURI, MD; WILLIAM S. DALTON, PHD, MD; LORNA RODRIGUEZ, MD, PHD; THOMAS SELLERS, PHD, MPH; AND CHERYL L. WILLMAN, MD

ORIEN

Reshaping Cancer Research & Treatment

An opportunity for a patient to enroll in a clinical trial is part of cutting-edge cancer treatment, and becomes even more critical as personalized cancer treatment leads to evidence-based clinical decisions.[1] Yet while 85 percent of cancer patients are diagnosed and receive initial treatment at a community cancer center, the majority of clinical trials are offered at academic or National Cancer Institute (NCI)-designated Cancer Centers.[2]

Community cancer programs enroll patients in clinical trials through the NCI Community Oncology Research Program (NCORP, formerly the Community Cancer Oncology Program), established by the National Cancer Institute in 1983 to facilitate Phase III clinical trials in the community practice setting.[3] A key goal of the 2003 National Institutes of Health Roadmap for Medical Research was to promote partnerships between academic-based investigators and community-based physicians to conduct clinical research on a sustained basis.[4]

Despite these efforts, many community cancer programs face barriers in enrolling patients and participating in clinical trials,[3] and more than 40 percent of programs surveyed by the Association of Community Cancer Centers (ACCC) say they are concerned about meeting the Commission on Cancer standard for clinical trial accrual.[5,6]

To date, many clinical trials of pharmaceuticals fail because physicians and drug companies are unable to find a sufficient number of patients to participate in research.[9] Identifying enough patients with rare biomarkers to test promising treatments requires collaborative partnerships among large academic and community health systems.[9]

Extending precision cancer clinical trials to community cancer programs is a primary goal of the Oncology Research Information Exchange Network (ORIEN), a partnership of some of the leading NCI-designated Cancer Centers nationwide. Founded by Moffitt Cancer Center, The Ohio State University Comprehensive Cancer Center–Arthur G. James Cancer Hospital and Richard J. Solove

Research Institute (OSUCCC–James), and M2Gen, ORIEN members use a common protocol to harness the power of big data among participating institutions. More than 10 cancer programs nationwide have joined the partnership since it formed in 2014 with the shared goals of enriching and growing the database to further promising research underway in their labs and clinics and to match their patients with clinical trials.

Community Cancer Programs Are Key

The recognition that cancers are a disease of the genome—not of a specific organ or location in the body—has given rise to precision cancer medicine. Identifying the abnormal genes that affect a relatively small group of patients creates the need for broader data sets from which to create new knowledge and a larger pool of patients for clinical trials.[7] Historically, cancer programs have conducted clinical trials and maintained their own patient data, but have not been inclined to share it with others.[8]

Keeping data in silos comes at a cost. To date, many clinical trials of pharmaceuticals fail because physicians and drug companies are unable to find a sufficient number of patients to participate in research.[9] Identifying enough patients with rare biomarkers to test promising treatments requires collaborative partnerships among large academic and community health systems.[9]

In 2006 ORIEN founder Moffitt Cancer Center created an approach to deliver personalized medicine called Total Cancer Care®, and quickly realized the scope of the project required a consortium network of cancer programs and a corporation to manage it. With funding from the state of Florida, Hillsborough County, and the city of Tampa, Moffitt leveraged a partnership with Merck Pharmaceuticals to launch M2Gen to help implement and manage the Total Cancer Care consortium. By the end of 2009 the consortium was comprised of Moffitt and 17 community cancer programs in 10 states.[10]

M2Gen's experience with Total Cancer Care and the consortium guides ORIEN members as they implement the Total Cancer Care protocol. The use of this shared research protocol gives cancer researchers access to a broader group of potential patients for personalized clinical trials.

ORIEN members are cancer programs that on some level compete with each other, and yet recognize that data sharing signals a sea change in the traditional approach to basic and clinical research. As ORIEN becomes operational, it is empowering cancer researchers like never before.

Total Cancer Care: The Common Thread

While each ORIEN member collects patient data and tissue samples and utilizes its own EHR (electronic health record), the use of Total Cancer Care gives ORIEN the ability to study all of the member cancer programs' patient data across the entire network. Total Cancer Care's patient-focused approach sets ORIEN apart:[10]

- ORIEN members prospectively consent patients to Total Cancer Care, asking them up front to donate their tissue and clinical data to advance cancer treatment and research.
- Patients give ORIEN permission to re-contact them throughout their lives, to update information.
- Patients are monitored for disease progression and eligibility for clinical trials as soon as they need one.

By consenting to Total Cancer Care, patients allow the cancer programs to store clinical data and tissue samples for molecular analysis, and give permission for cancer programs to re-contact patients throughout their lifetime. If researchers have another question or discover an appropriate clinical trial for the patient, they can get back in touch. Patients consent to provide access to their medical history, diagnosis and pathology data, treatment type, treatment response, disease progression, and other factors over time. Sources include EHRs, cancer registries, and patient self-reported information. Data collection begins when patients opt in to Total Cancer Care.

Each ORIEN member maintains its own separate, secure database, which interacts in a limited, controlled way through Total Cancer Care. As ORIEN's operations and strategy arm, M2Gen facilitates its informatics, data management, and clinical trial matching:

- All members have access to ORIEN's extensive de-identified HIPAA-compliant database.
- M2Gen analyzes data from all participating ORIEN programs to quickly connect patients with clinical trials based on their molecular profile.
- ORIEN partners seeking to test hypotheses using fuller data sets held at one or more of the other ORIEN institutions submit their proposal to M2Gen to obtain approval from the involved institutions.
- Each institution chooses whether to permit usage of its data for any specific project.
- Non-ORIEN members from academic institutions can apply to use the ORIEN database.

Nearly 135,000 patients have consented to Total Cancer Care, and the growing ORIEN database gives researchers a better chance to identify patients with a specific mutation who might benefit from a clinical trial of a targeted therapy. The diverse patient population represented by all ORIEN members allows researchers to study cancers that affect underserved minority patients and the specific genomic mutations that might be occurring among patients with different racial backgrounds. (For more on Total Cancer Care, turn to page 66.)

Patients: the Center of the ORIEN Constellation

Behind ORIEN's datasets and tissue samples are cancer patients who recognize they can help further cancer research for future generations, and perhaps for themselves. Total Cancer Care is an ambitious partnership between patients, physicians, and researchers to improve all aspects of cancer prevention and treatment. Patients participate by donating information and tissue. Researchers leverage the data to discover new pathways and better cancer therapies. Physicians use the information to educate and care for patients.

By opting in to Total Cancer Care, patients become active partners in a lifelong study of their disease. They are followed throughout their lifetime, and agree to continue to donate clinical data and tissue for research. This ongoing contact with patients provides unprecedented insight and information into the evolution of disease conditions and treatment progress and efficacy.

Patients consent to Total Cancer Care knowing that their data and tissue samples are a gift to the cancer program. Moffitt has 95 percent consent rate and at OSUCCC-James, 92 percent of patients who were asked have consented to Total Cancer Care since it was implemented in 2014. In focus groups prior to implementing Total Cancer Care at OSUCCC-James, the team learned that patients just assumed that the cancer program kept samples of their blood and tissue for research. They were disappointed it had not been done all along.

While patients are altruistic and want to "pay it forward," there's definitely something in it for them, too. By providing their data, tissue, and other information, patients give researchers and healthcare providers the opportunity to be proactive about treating their cancers. Clinicians can begin to anticipate treatment needs, including clinical trial options, specific to a patient's biological and epidemiological profile.

A significant distinction of the Total Cancer Care approach is the ability to assign patients to precise cohorts based on clinical and molecular characteristics. With the growing amount of patient data from ORIEN programs, M2Gen will divide the patient population into ever smaller groups to find genetic variants and mutations and link them to specific types of patients. ORIEN is building an informatics system that will study patterns, allowing researchers and clinicians to predict events based on aggregate assessment of information. By comparing patient populations and identifying patterns, ORIEN members can anticipate what a particular patient will need.

Total Cancer Care was developed to identify and meet needs. ORIEN's priority at the moment is to identify groups of high-risk patients—those who have stopped responding or are not responding to standard therapy—and to find a suitable clinical trial. Establishing a clinical trial in the first place depends on having a critical mass of eligible participants. As more patients are consented to Total Cancer Care, more clinical trials will become available, and more patients will be accrued to those clinical trials.

Extending Total Cancer Care to Community Cancer Programs

Delivering precision oncology treatment to patients is a paradigm shift for providers and for patients. Historically, oncologists were focused on treating cancer based on the location of the tumor; now the molecular profile of the tumor guides our decisions. This approach requires the ability to understand and interpret genomic information.

The ORIEN partnership has grown rapidly over the past year, and many members are just ramping up Total Cancer Care in their clinics. Over time, ORIEN members will extend Total Cancer Care to community hospital partners, enabling their patients and affiliated physicians to work with ORIEN to contribute to the research consortium and to learn about clinical trials for their patients.

ORIEN shares the goals of President Obama's Precision Medicine and National Cancer Moonshot initiatives—to promote a network of national databases that collect and share genetic and health outcomes data to be leveraged for use in developing new treatments. Molecularly-targeted medicine holds tremendous promise for all disease, particularly cancer, and ORIEN is a collaborative pathway to operationalize it. OI

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ROLLING OUT TOTAL CANCER CARE

ORIEN's cornerstone is the Total Cancer Care protocol, and the protocol is central to ORIEN membership. Developed at Moffitt Cancer Center in 2006, Total Cancer Care is being implemented and offered to patients across the entire alliance. With standardized data collection on hundreds of common data elements and standardized procedures for obtaining and storing bio-specimens, protocol implementation is a significant undertaking. Smooth rollout depends on effective planning and early and ongoing education of stakeholders. As a co-founder of ORIEN, OSUCCC-James was the first member outside Moffitt to implement Total Cancer Care and to offer the protocol to its patients. As new members join ORIEN and roll out Total Cancer Care, they benefit from these lessons learned by Moffitt, OSUCCC-James, and other ORIEN members:

- *Provide education to stakeholders early.* The sheer scope of the protocol is designed to consent hundreds of thousands of patients for the course of their lifetime. The sharing of data for clinical trials matching, collecting and banking of specimens, and generating of molecular data require having discussions about the purpose, benefits, and the processes in place early on with all the stakeholders, including the Institutional Review Boards charged with protecting human subject research. Internal stakeholders at the cancer program should also be made aware of the benefits to their research and patients.
- *Adapt the Total Cancer Care protocol.* Each ORIEN member will tweak the protocol slightly to fit its specific needs; however, key elements of the consent and protocol cannot be changed. The ORIEN Protocol Advisory Committee, along with M2Gen, reviews each partner's consent and protocol to ensure harmonization and inclusion of ORIEN's essential elements.
- *Embrace a change management approach.* Cancer program researchers may be accustomed to maintaining their disease-specific biobanks. Total Cancer Care changes the paradigm by creating a centralized infrastructure for the collection, banking, and storage of high-quality specimens. By making a compelling case for this change at every opportunity, cancer program leaders can help clinicians adopt the new approach and ease the transition.
- *Introduce Total Cancer Care in phases; begin with your champions to ensure early success of protocol implementation.* Dedicated Total Cancer Care consenters are incorporated into the clinic team. Collaborate with registration staff and nurse managers to establish a consent system that works for each clinic.
- *Communicate progress.* Update investigators and staff on the impact of Total Cancer Care and ORIEN, such as the number of consented patients and ORIEN projects underway.

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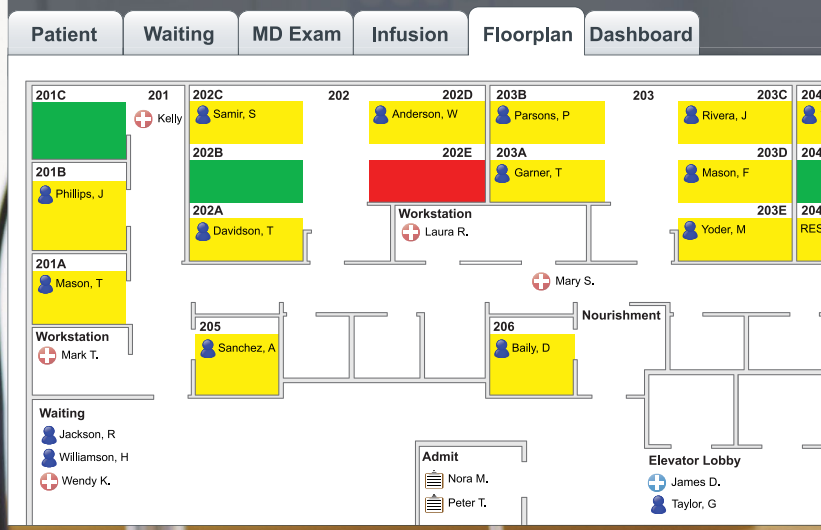

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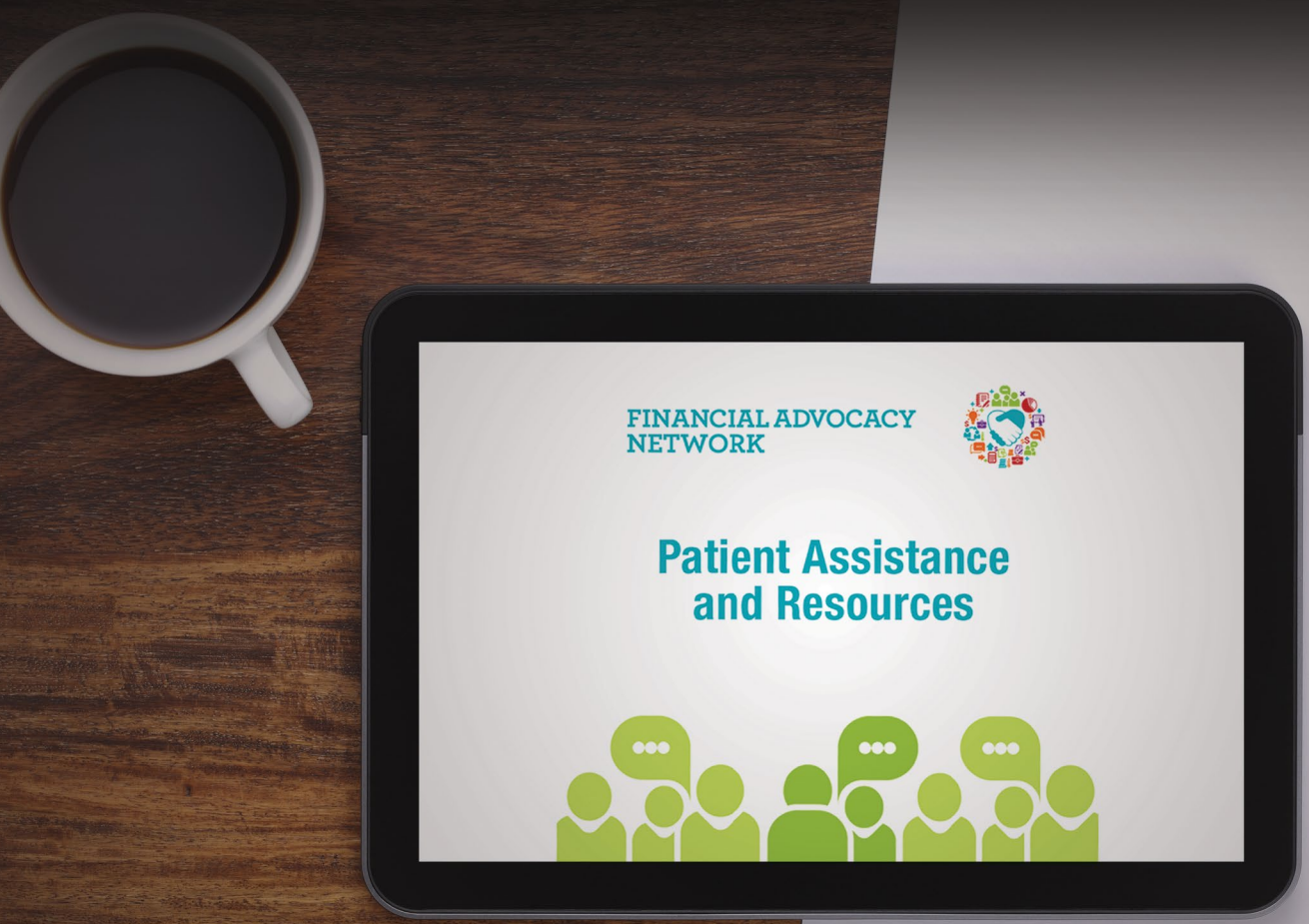

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WORKSHOP DATES & LOCATIONS

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Thursday, September 29, 2016
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DIRECTOR, CANCER CARE CENTER
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Wausau, Wisconsin

The Service Line Administrator is accountable for providing strategic leadership and direction for the Aspirus Regional Cancer Center. The scope of accountability includes overseeing and understanding all relevant dimensions of the services that are included within the defined service line. This includes a comprehensive understanding of market conditions, as well as the operational, financial, and quality components of the service line. The Service Line Administrator will work to define, develop, and implement all of the necessary structures, relationships, and resources needed to achieve the strategic goals of Aspirus, Inc., through the attainment of immediate, near-term, and long-term service line goals.

This position has direct reports, but must be comfortable and proficient working in a matrix management structure. Leads and coordinates a wide variety of administrative, fiscal, clinical, and technical activities to ensure attainment of goals and objectives.

For more information, go to aspirus.org or email Tammy.Bents@aspirus.org.

CHAIR, ONCOLOGY DIRECTOR, CANCER CENTER
Jiahui, China

Partners Healthcare International (Boston, affiliated with Massachusetts General Hospital) and private investors have a "first of its kind" hospital in China under construction, Jiahui International Hospital, a multi-site, vertically integrated "ecosystem," based on a culture of collaboration and patient and family focus. The newly created Chair, Oncology & Director, Cancer Center position will implement a consistent, evidence-based, multidisciplinary model of clinical care and research that meets international standards. This position will afford the opportunity to develop oncology care from its infancy, hire staff, and develop clinical protocols and research relationships. Ideal candidates will be board certified in medical or surgical oncology and have extensive clinical experience in a cutting-edge environment; prior work in research design and administration; a track record of research funding, and demonstrated ability to develop relationships with academic institutions and international pharmaceutical companies.

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CANCER REGISTRY SUPERVISOR
Pinehurst, North Carolina

Essential Responsibilities:

- Coordinates abstraction and coding of patient and cancer-related information, treatment, and staging at FirstHealth Moore Regional Hospital.
- Manages and analyzes registry data for the purposes of quality, education, research, outcomes, productivity, and compliance.
- Participates in the research process, including patient identification, data collection, data analysis, and reporting.
- Makes decisions regarding employment, retention, promotion, demotion, and other personnel actions.
- Coordinates cancer registry staff, assists with staffing, coordination of work schedules, annual performance reviews, training and education, and work productivity.

Essential Qualifications:
Associate's Degree required; Bachelor's Degree preferred. Certified Tumor Registrar certificate required. Applicant must have five years' CTR experience, extensive knowledge of Cancer Registry coding principles, and knowledge of NC regulations for reporting and CoC accreditation.

Apply online at firsthealth.org.

CLINICAL SPECIALIST, PRACTICE INTEGRATION & SUPPORT
Alexandria, VA

The American Society of Clinical Oncology seeks a Clinical Specialist, Practice Integration & Support to join its Quality and Guidelines Department and lead oncology practice recruitment and integration for quality assessment and reporting programs; provide knowledge and experience-based clinical/practice expertise; recruit, train, and support practices interested and engaged in programs; and oversee participant support services.

Essential Responsibilities:

- Market and recruit participants into the QOPI program; support recruitment for QOPI Certification.
- Integrate practices into the program through training, resources, and tools; manage alerts and announcements; provide relevant and useful information through the QOPI and/or Quality website.
- Oversee and manage the staffing of the QOPI Help Desk.
- Respond to inquiries regarding quality content collected—often clinical—and work with Clinical Data Specialist to prepare abstractor guides.
- Liaise with the State Affiliate Council and others looking to integrate QOPI and QCP.

Essential Qualifications:

- Minimum 5 to 8 years experience
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- Proficient skills in Microsoft Office and Adobe Suite
- Strong customer service skills
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The ideal candidate will also possess:
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DIRECTOR OF CLINICAL OPERATIONS
Dana-Farber Community Cancer Care
Quincy, Massachusetts

Minimum Job Qualifications:

- Clinical education & experience
- Required: Masters in Nursing (MSN) required or Bachelor's in Nursing with Masters in Business (BSN) or Masters in Healthcare Administration (MHA).
- Clinical oncology experience
- Pharmacy knowledge preferred
- Knowledge of Physician Practice operations, compliance, and clinical care
- Proficiency with IT platforms, specifically EMRs
- Ability to independently interact with staff across multiple disciplines to accomplish goals; effectively link into a collaborative, matrixed organization.

Duties & Responsibilities:

- Supports Executive Medical Director in determining clinical alignment and operational capacity to support initiatives for growth
- Teams with Nursing Leadership to implement short- and long-term strategic nursing goals
- Supports strategies to promote and manage growth in patient activity in collaboration with other Senior Leaders.

Supervisory Responsibilities:

- Oversees Project Leader EMR, Clinical Operations Administrator, Director of Nursing, and Nurse Practitioners
- Collaborates closely to support Laboratory, Compliance/Quality, and Pharmacy.

Apply online at Click2Apply.net/44z3657cwm. EOE.

42nd ACCC Annual Meeting, CANCERSCAPE

1. Nearly 500 oncology professionals gathered in Washington, D.C., March 2-4, 2016, for sessions centered on policy, value, and quality. Attendees heard a recurrent message: Their experience, perspective, and input on the issues of value-based care, quality measures, and outcomes are essential as the healthcare system and oncology transition to the new world of alternative payment models and value-based care.

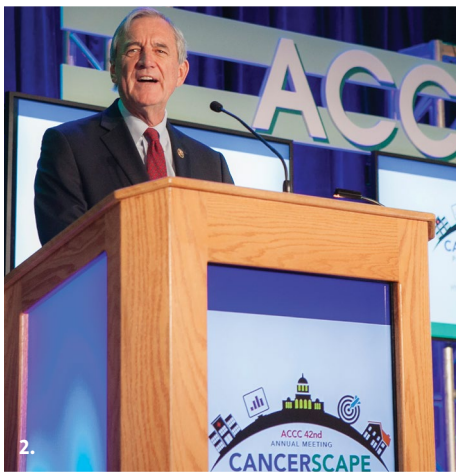
2. In CANCERSCAPE's opening session, **Congressman Rick Nolan** (MN-D) called out the vital role ACCC members can play in helping educate legislators and policymakers, "No one can articulate need, challenges, and the potential to ultimately cure cancer [better] than the people in this room today," he said.

3. Lindsay Conway of The Advisory Board Company updated attendees on Medicare payments and what to expect in 2016. Two examples of the forward momentum in quality this year will be "testing" new oncology quality measures through PCHQR Quality Reporting Measures and CAHPS for Cancer Care (cahps.ahrq.gov).

4. Kavita Patel, MD, MS, of the Brookings Institution told attendees that communicating about the oncology care process so that policymakers understand real-world cancer care delivery is imperative. Part of that conversation should aim to help policymakers understand the demanding intuitive thought process that is part of today's oncology care, along with the tremendous amount of information cancer care providers must keep up with given the pace and variety of emerging therapies, she said.

5. During the 2016 ACCC Capitol Hill Day, members representing 27 states held more than 84 meetings with legislators. At a lunch address, **Representative Lois Capps (CA-D)**, co-sponsor of the PACT Act, spoke about the critical role care planning and coordination play in supporting patients throughout their treatment. (Rep. Capps pictured here with **ACCC Board Member Randal A. Oyer, MD**.)


1.



2.


3.


4.


5.

ACCC Welcomes its Newest Members

Clearview Cancer Institute
Huntsville, Ala.
Delegate Rep: Michelle Brown, MSN, CRNP
Website: clearviewcancer.com

Memorial Healthcare
Owosso, Mich.
Delegate Rep: Jaime Ritter, RN, BSN, OCN
Website: memorialhealthcare.org

Moncrief Cancer Center
Fort Worth, Tex.
Delegate Rep: Emily Berry, MSPH
Website: moncrief.com

The Outer Banks Hospital Cancer Services
Nags Head, N.C.
Delegate Rep: Robin Hearne, RN, MS
Website: theouterbankshospital.com

SCL Health Cancer Centers of Colorado
Lafayette, Colo.
Delegate Rep: Karen Irish, MBA
Website: goodsamaritancolorado.org

FREE! One-Day Financial Advocacy Workshops

Learn innovative solutions to strengthen your financial assistance program and grow services. These case-based workshops are framed around 4 key areas: Communicating with the Patient and Care Team, Maximizing External Assistance, Optimizing Patient Coverage, and Improving Patient Collections.

Dallas, Texas
Wednesday, August 17, 2016
Omni Dallas Hotel at Park West

Philadelphia, Pennsylvania
Thursday, September 29, 2016
Sonesta Philadelphia Downtown

For more information and to register go to: accc-cancer.org/FAN.

FREE! ACCC Oncology Reimbursement Meetings

A 360° look at oncology reimbursement issues, tools to strengthen your program, and information to help you weather market changes. Gain a full-spectrum perspective in just one day of sessions:

- Hear the latest trends in oncology coding and billing, navigate new regulations in 2016, and gain strategies to overcome reimbursement obstacles
- Learn how recent shifts from volume-based payment to reimbursement based on quality will impact providers
- Gain practical how-to's for increasing efficiency through the proper management of financial data
- Hear strategies for the practical application of radiation oncology CPT codes in physician office and hospital settings.

FREE to ACCC members; non-members are invited to join us at the low registration rate of $69.

August 25, 2016 | Denver, Colorado
Grand Hyatt Denver

November 17, 2016 | Baltimore, Maryland
Hyatt Regency Baltimore Inner Harbor

December 13, 2016 | Costa Mesa, California
Hilton Orange County/Costa Mesa

Register online at: accc-cancer.org/reimbursementmeeting

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- Publications with strategies to improve payer, provider, and patient communication on immuno-oncology value, methods of action, and coverage.
- ACCC Learning Portal, an online education platform will offer on-demand module courses focused on administrative and operational issues.
- Webinars led by experts specializing in real-world implementation strategies.
- Podcast commentary from tumor-specific collaborative working groups to help identify and outline best practices and strategies.
- ICLIO National Conference addresses challenges and opportunities in treatment and delivery.

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Patients Rising

BY TERRY WILCOX

Patients Rising (patientsrising.org) has a very specific mission: to fight for access to vital therapies and services for patients with life-threatening and chronic diseases. If patients need specific treatments to survive and live a more productive, better quality life, we believe that access to those treatments and creating a balanced dialogue in the national conversation around these issues is essential. Through our programming: *The Daily Rise; Voices of Value; Right Patient, Right Treatment, Right Time; Patients Rising University*; and other commentary, we educate, advocate, and communicate on the importance of patient access to essential treatments and diagnostics. We focus on ensuring that the patients' voice is heard, access to new therapies is paramount, and the pipeline of progress is not threatened.

Patients with cancer often feel as though the onslaught of stress, bills, and concerns is endless. That's why we founded our partner organization, Patients Rising NOW (patientsrisingnow.org). Too many cancer patients face overwhelming challenges with their health insurance, while simultaneously battling a life-changing disease. Together, we're working to effect positive change.

Merriam-Webster defines "insurance" as: "A means of guaranteeing protection of safety." It is not unreasonable, therefore, for patients with cancer to expect "protection" from the many unknown costs that arise during their cancer treatment. These patients assume that dealing with their health insurer will be a helpful process—not one that often tranfers them from one representative to the next, with little hope or no end in sight.

That's one of the reasons we put forward a Patient Declaration, which clearly outlines what patients should know about and expect from all those helping them through their illness and disease. More than 11,000 patients have already signed this declaration, and our hope is that it will help ensure that "having health coverage means having access to healthcare." Specifically, our Patient Declaration advances these five principles:

1. ***As a patient, I expect to be able to access the healthcare services I need.***
   Health insurance should mean that, as a patient, I can gain affordable access to choices for primary care doctors, specialists, and hospitals in my community. I should know that I can receive care at any hospital in case of emergency.

2. ***As a patient, healthcare decisions must remain between me and my doctor.***
   Having health insurance should not mean my insurance company making medical decisions for me. As a patient, I put a lot of time and careful consideration into finding the best physician and discussing the best treatment course for my particular disease. When health insurers interrupt that process, dictating what treatments they will and will not cover, lives can be changed for the worse.

Take, for example, Janet, who was on a traditional chemotherapy combination for her first phase of anti-cancer therapy. Each treatment cost upwards of $40,000. When Janet switched to an oral medication, her insurer denied payment—despite the fact that the cost was basically the same as her original regimen. This is why federal oral parity legislation is needed. (Learn more at: http://www.accc-cancer.org/advocacy/LegislativeAction.asp.)

Yes, these newer treatments are expensive—the entire healthcare system is expensive—but if you look at healthcare costs like a pie, treatment of patients with targeted cancer drugs represent just a sliver of the healthcare cost pie. Patients Rising advocates for a realistic conversation about our healthcare system—including, but not limited to, cost.

3. ***As a patient, I will have access to my personal health information, and my health insurance company will be clear and transparent with me about their practices.***
   Navigating the healthcare system is complicated enough; having health insurance shouldn't add further complications. And yet that is what happened to Amy Thomson who shared her story with NPR.[1] Amy Thomson's infant daughter needed to be transported to a hospital 600 miles away from their home in Butte, Montana, which required air transportation. Imagine the family's shock when they were left with a $56,000 bill for that air ambulance. The family was able to fight and win their appeal, but the process was anything but simple. According to NPR, Thomson believes that there is something ethically wrong with companies profiteering off of people's

tragedies.[1] To help avoid what the Thomson family endured, patients should have a clear understanding of what their health insurance does and does not cover.

4. ***As a patient, additional healthcare costs will be limited by my health insurance company.***
   Ask most people, and they will tell you that they believe this to be the purpose of health insurance. Unfortunately, a recent new Kaiser Family Foundation/*New York Times* poll instead found, "Among the insured with medical bill problems, 63 percent report using up most or all their savings and 42 percent took on an extra job or worked more hours."[2] That startling statistic shows that for too many patients, health insurance is failing to deliver on its core promise.

5. ***As a patient, I expect my healthcare coverage will treat me as an individual, not a policy number.***
   Having health insurance does not change the fact that we are individual patients who need personalized care and who face unique challenges. Our health insurance should provide this personalized care and individual support. Ask any physician or scientist: every patient and every person's physical makeup is different. We need to be treated that way.

It's time for policymakers to introduce new ideas and challenge the status quo of the healthcare and insurance industries. Patients Rising is committed to engaging patients, caregivers, physicians, the media, health policy experts, and industry executives to elicit realistic, solution-oriented discussions around the issues patients face. Working together, we can amplify our collective voice and create lasting impact on the future of cancer care in the United States. OI

> Too many cancer patients face overwhelming challenges with their health insurance, while simultaneously battling a life-changing disease.

Terry Wilcox is the Co-Founder and Executive Director of Patients Rising and Patients Rising NOW. She is the former Executive and Creative Director of Vital Options International and the creator of the web series Understanding Cancer. Her passion is challenging the entire healthcare system to think broadly about the system challenges while always remaining focused on patients and the sanctity of their relationship with their doctor.

References

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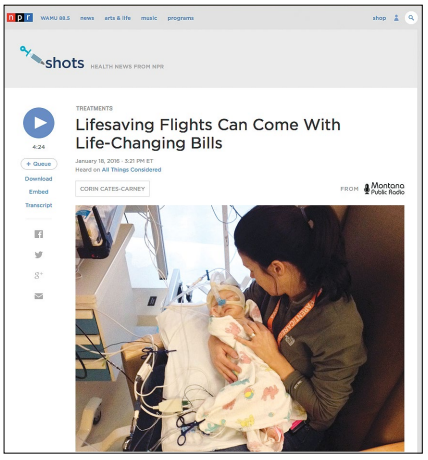
2. Kaiser Family Foundation. New Kaiser/New York Times Survey Finds One in Five Working-Age Americans With Health Insurance Report Problems Paying Medical Bills. Available online at: kff.org/health-costs/press-release/new-kaisernew-york-times-survey-finds-one-in-five-working-age-americans-with-health-insurance-report-problems-paying-medical-bills. Last accessed March 14, 2016.



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