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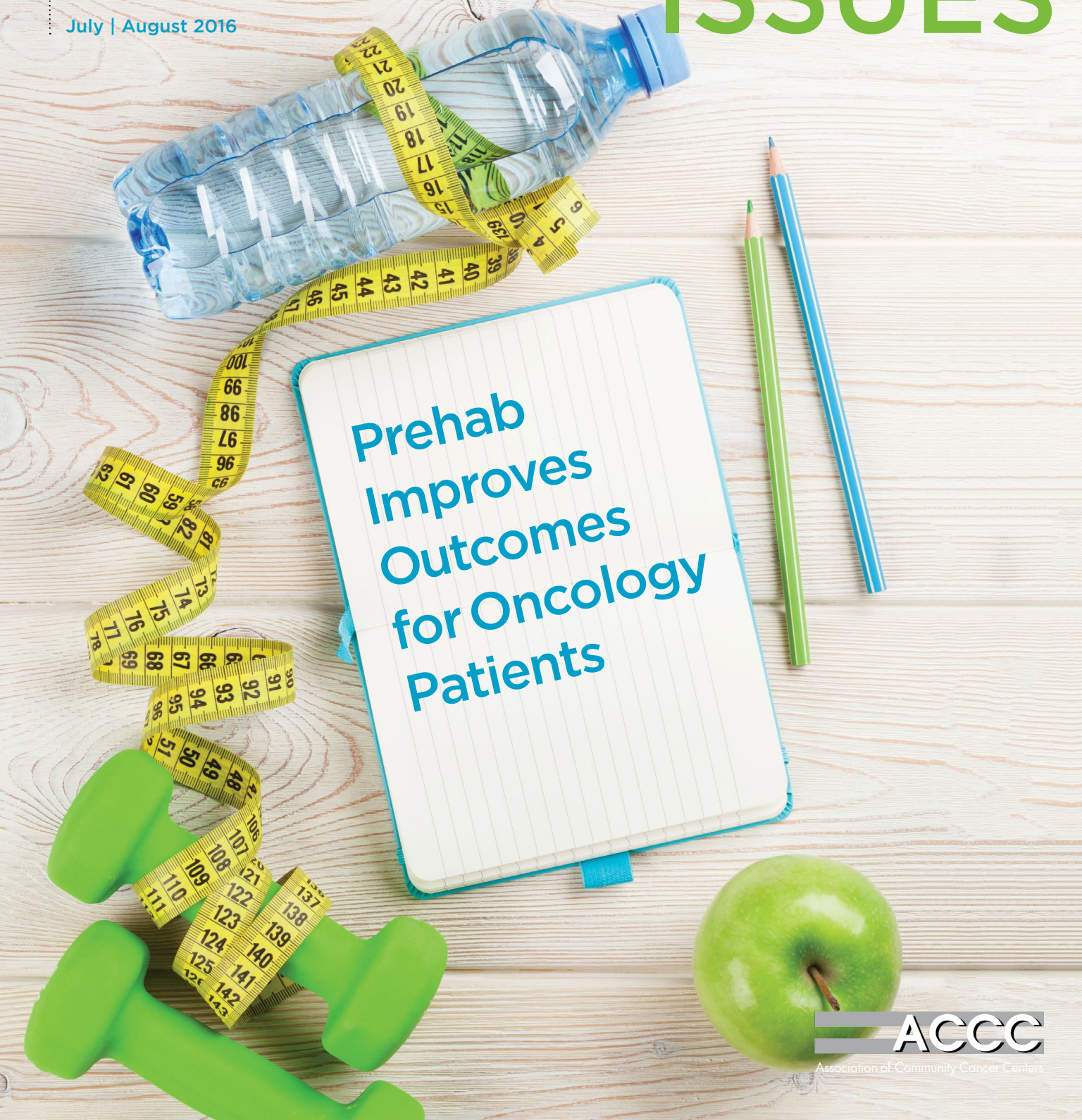
ONCOLOGY ISSUES

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

July | August 2016



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FROM THE EDITOR

A Changing Community

BY CHRISTIAN DOWNS, JD, MHA

I was recently asked how community oncology had changed over the last 20 years. As you can imagine, the never-ending wave of clinical, economic, and programmatic shifts that continue to reshape the oncology landscape make this question nearly impossible to answer. That said, I think it's important to reflect on the meaning of the words "community oncology" in today's healthcare environment.

Back in 1995, the phrase "community oncology" likely brought to mind an image of a solo medical oncologist, in a small practice, treating patients with a limited number of therapies. Today, that snapshot of "community oncology" looks more like an IMAX movie—featuring large, multidisciplinary care teams with highly-trained nurses and pharmacists, along with medical and radiation oncologists, surgeons, specialists, and even primary care providers. Many once-solo oncology practices are now enterprise-level operations with hundreds of physicians, representing multiple specialties and subspecialties. Academic programs have adapted as well, opening up satellite locations and partnering with "community programs" to bring research and specialized services to patients where they live. Those words bear repeating—providing cancer care to patients in the communities where they live—because for many of us, those words truly define how we think of "community oncology" today.

ACCC has worked hard to keep members abreast of the rapid changes in the oncology marketplace and provide practical support as our membership embraces innovative ways of delivering care to patients *in the communities where they live.* This edition of *Oncology Issues,* which highlights the 2015 ACCC Innovator Award winners, is a clear indication of just how far our members have come.

Messina Corder and Kathryn Duval's article on cancer prehabilitation (or prehab) describes a program that offers rehabilitation services to patients prior to treatment. Mary Washington Hospital's prehab program couples physical therapy with nutritional support, stress reduction strategies, and nurse navigator intervention, improving patient outcomes post-surgery.

Our next 2015 ACCC Innovator Award winner, PIH Health Hospital, Whittier, Calif., was recognized for its nurse practitioner-run lung cancer screening program, a true partnership with primary care practitioners in the community, who refer to the program with the goals of increasing early detection, improving the quality and timeliness of care, and enhancing communication among the multidisciplinary treatment team.

Then read how ACCC Board Member and social worker extraordinaire Krista Nelson (and her colleagues) saw the struggles patients faced communicating to family members—especially children—about their cancer diagnosis and treatment, and responded by creating the Providence Family Program. The program delivers early intervention and ongoing support throughout the cancer care journey—to families in the community, not just to those who have received care at Providence Cancer Center, Providence, Ore.

Continue on to read about our last two 2015 ACCC Innovator Award winners. One program was recognized for a QI initiative that streamlined workflow, improved patient throughput, and enhanced collaborative decision making between providers in a multi-site radiosurgery program, while the other received an award for a unique cancer patient support fund driven solely by community philanthropy. Both programs—through different innovative approaches—working to improve access to care for patients in their communities.

So, yes, we've come a long way in the last 20 years. And while the definition of "community oncology" has changed with the oncology landscape, the commitment of ACCC and its membership to ensure *patients' access to care in the communities where they live* has remained a constant. OI

Acting Our Way Into New Thinking

BY JENNIE R. CREWS, MD, MMM, FACP

Value-based payment reform is fast becoming a reality for cancer programs and oncology practices. Whether by participating in the Centers for Medicare & Medicaid Services' Oncology Care Model or through implementation of MACRA (Medicare Access and CHIP Reauthorization Act of 2015) and its Merit-Based Incentive Payment System (MIPS), ACCC members are in the midst of defining value in cancer care and transforming practice patterns to improve care delivery, meet quality metrics, and contain costs. These efforts can seem daunting. One of the greatest challenges is effecting cultural change to transition to value-based care.

The cultural shift in value-based care requires us to think differently—not only about how care is given, but also about who delivers that care. It may mean flexible staff scheduling to accommodate extended hours. It may require the expanded use of advanced practice clinicians or novel partnerships with primary care providers (PCPs). It may require new technologies, algorithms, and decision-making tools. It may mean that work traditionally performed by physicians be shared with other members of the health-care team.

In his article "Changing the Way We Change," Richard Pascale notes, "The problem is that the whole burden of change typically rests on so few people." Pascale makes the case that we must engage all stakeholders to address challenges, maintain involvement in change processes, and sustain new behaviors in order to "act our way into a new way of thinking rather than think our way into a new way of acting." In other words, the actions of the team can change the thinking (culture) of the team.

And cancer care teams can do this! Oncology has a strong tradition of collaboration among the many disciplines that provide cancer care. Moreover, ACCC has a strong tradition of sharing best practices, providing education, and promoting dialogue between all members of the multidisciplinary team. The Association's online forum ACCCExchange, the Financial Advocacy Network (FAN), the Institute for Clinical Immuno-Oncology (ICLIO), and National Oncology Conference are just a few examples of the robust foundational resources ACCC offers its members for peer-to-peer learning.

The recently launched ACCC OCM Collaborative (accc-cancer.org/OCM) will do the same for practices participating in the CMS Oncology Care Model. Learn more about this new initiative on page 6.

Another new ACCC education project—Achieving Excellence in Patient-Centered Care—dovetails nicely with my President's Theme: "Empowering Patients, Engaging Providers" and looks to help cancer programs and oncology practices focus on patients' perspectives of value.

With these resources, ACCC is actively supporting the oncology community as we "act our way into the new thinking" of value-based care. OI

Coming in Your 2016 *ONCOLOGY ISSUES*

- Beyond Breast Conservation: Oncoplastic Surgery in the Community Cancer Center
- Implementation of a Health Disparities & Equity Program at the Duke Cancer Institute
- Piloting a Model for Delivery of Pharmacogenetic Testing in Community Cancer Centers
- Care Connect: Improving Care Coordination Between Oncology & Primary Care
- The Evolution of Clinical Pathways and Their Role to Identify Quality and Cost Effective Care
- High Intensity Focused Ultrasound (HIFU) Treatment for Prostate Cancer
- Training Community Nurses & Administrators to Implement Cancer Clinical Trials
- Bridging the Gap: From Inpatient to Outpatient Care
- Community Health Needs Assessments: How Your Cancer Program Can Prepare
- Forming Partnerships to Bring Clinical Trials to the Community

more online @ accc-cancer.org

INFO

Optimal Care Coordination Model for Lung Cancer Patients on Medicaid—First Steps

ACCC has begun a three-year effort to develop an optimal care coordination model for this vulnerable patient population. First steps included completing an environmental scan. Among the key findings is the need to 1) increase patient engagement to improve outcomes, 2) integrate patient navigators into care teams to promote Medicaid beneficiaries' access to timely, high-quality care, and 3) ensure Medicaid beneficiaries timely access to supportive services, including attention to psychosocial needs, palliative care needs, hospice services and end-of-life care, and survivorship issues. Read an executive summary of the scan and learn more at: accc-cancer.org/carecoordination.

RESOURCE

Immunotherapy Payment Methods

Available through the ACCC eLearning Portal, accc-cancer.org/elearning, *Immerse Yourself in Immuno-Oncology Implementation* shares operational approaches for the effective integration of immunotherapy into your cancer care program. Also available: modules that explore "real-world" clinical practice issues related to immunotherapy, including solutions to optimize patient care and immuno-oncology coverage and reimbursement, including strategies to overcome access challenges.

BLOG

A Snapshot of a Case-Based Financial Advocacy Network Workshop

This workshop revealed several key themes, including the need to educate providers and patients about the complexity of Medicare and the different options available during open enrollment; the need to improve communication about patients' financial concerns across all members of the cancer care team; and the importance of tracking ROI and savings. accc-cancer.org/ACCCbuzz/snapshot-case-based-financial-advocacy-network-workshop.

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fast

The number of uninsured continues to decline. In 2015, 28.6 million persons of all ages (9.1%) were uninsured—7.4 million fewer persons than in 2014.

Source. U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. National Center for Health Statistics. www.cdc.gov/nchs/data/nhis/earlyrelease/insur201605.pdf.

Key Drivers & Challenges in Adoption of Virtual Care

Drivers

- Increase patient volumes & loyalty (**29%**)
- Care coordination of high-risk patients (**17%**)
- Reduce costs for access to medical specialists (**17%**)
- Meaningful use & payer incentives for adoption (**13%**)
- Patient requests & consumer demand (**13%**)

Challenges

- Too many other technological priorities (**19%**)
- Maintaining a sustainable business model (**18%**)
- Organizational readiness to implement new services & technology (**18%**)
- Regulatory compliance & risk concerns (**15%**)

Source. A poll conducted by KPMG LLP, the U.S. audit, tax, and advisory firm. kpmg.com/us.

facts

What Do the Experts Think About Sunscreens?

- **99%** of dermatologists agree that regular use of sunscreens lowers skin cancer risk.
- Nearly all (**96%**) consider FDA-approved sunscreens currently available in the U.S. to be safe.
- Virtually all (**99%**) recommend their family and friends use sunscreen to help protect their skin.
- Dermatologists cite SPF levels as one of the main criteria that they regularly use to recommend a sunscreen. Overall, **92%** are comfortable recommending sunscreens with an **SPF 50** or higher.

Source. An April 2016 survey by the National Society for Cutaneous Medicine. soccutmed.org.

More patients will die from pancreatic cancer than breast cancer this year, moving pancreatic cancer from the 4th to the 3rd leading cause of cancer-related death.

Source. Siegel RL, et al. Cancer statistics, 2016. *CA: A Cancer Journal for Clinicians*. Jan. 2016. http://onlinelibrary.wiley.com/enhanced/doi/10.3322/caac.21332/.

Financial Distress: What Our Patients are Telling Us

- Only about **1/2** of patients understand their health insurance coverage for their cancer care "completely" or "very well."
- **25%** of patients between the age of 25 and 64 stopped working during active treatment; **13%** switched from full- to part-time; only **1/3** continued working full-time after their diagnosis.
- Despite **58%** of patients reporting being distressed about their finances during treatment, **25%** of those younger than age 64 said their care team never considered their financial situation during treatment planning; **34%** said it was only "sometimes" considered.
- **29%** of patients skipped doctors' appointments; **38%** postponed or did not fill drug prescriptions; **34%** skipped doses; **30%** ordered medications online from sources outside the U.S.; and **31%** cut oral medications in half.
- **1/3** of patients ages 25 to 54 reported cutting back on groceries and transportation.
- **21%** missed a utility bill payment; **17%** missed a rent or mortgage payment.

Source. 2016 CancerCare Patient Access and Engagement Report. cancercare.org/accessengagementreport.

Survey Finds Strong Support for Moonshot Initiative

- **82%** of Americans want the next U.S. president to continue to invest in the program.
- A large majority of Democrats (**90%**), Republicans (**73%**), and Independents (**77%**) support extending the Moonshot program into the next presidency.
- **44%** say the $1 billion the government invested is the right amount; **42%** think more funding is necessary.

Source. The Leukemia & Lymphoma Society. Finding Cancer Cures. An online survey conducted by Russell Research, April 22-April 25, 2016.

And They're Off!

BY LEAH RALPH

Last month, practices participating in the Center for Medicare & Medicaid Innovation (CMMI) Oncology Care Model (OCM) finally made it to the finish line—or, more accurately, to the starting line. On June 10, nearly a year after the application deadline, practices signed contracts with CMS, officially signaling whether they were in or out of CMMI's flagship oncology-specific alternative payment model.

Getting there was no easy feat; OCM practices spent months producing implementation and financial plans, conducting extensive self-assessments, and hiring consultants and vendors to help them achieve infrastructure requirements, and—up until the final hour—negotiating with CMS on specific contracting arrangements and what these meant for OCM eligibility. Respite for these practices is brief: the program is scheduled to begin July 1, 2016, with any initial Part B administration claim or Part D chemotherapy claim and ICD-10 code for cancer diagnosis triggering a 6-month episode of care under the OCM.

As with any new payment model, several aspects of the OCM are proving to be operationally complex. CMS has specified a number of issues that were unclear in the original request for applications (RFA), including a methodology for patient attribution, the initial set of quality measures, additional detail on the performance-based payment methodology, and a "novel therapies" adjustment to account for newer therapies under an approach that benchmarks providers' performance against historical spend.

Practices are also facing requirements to provide their quality measure data through an OCM registry that is still being built, leaving big questions about compatibility with existing EHR systems. Bigger hurdles may prove to be CMS' ability to provide timely data to allow for improvements or course corrections within an episode, or achieving true cultural buy-in among providers and staff in OCM practices to work longer hours and transform the way they deliver care.

Over the past several months, ACCC has worked closely with OCM practices to troubleshoot barriers, clarify CMS requirements, and get answers from the agency on individual circumstances. We have built a network of support for practices that includes webinars, access to OCM experts, and education opportunities to share experiences among OCM peers.

In early June, ACCC launched an online forum, the Oncology Care Model (OCM) Collaborative, exclusively for providers to share tips, tools, and resources as they troubleshoot OCM onboarding and implementation challenges. The group also serves as a liaison to CMS, identifying trending issues and facilitating calls on critical topics. To receive updates and access the ACCC OCM Collaborative, visit ocmcollaborative.org and sign up today.

Most practices see the OCM as a strategic opportunity to work with new data sets, build infrastructure, and learn how to operate under a risk-based arrangement with Medicare. Even if your cancer program is not participating in this new model, the successes and failures of the OCM will permeate future oncology payment reform efforts, both public and private. Particularly with the passage of the Medicare Access and CHIP Reauthorization Act (MACRA) and CMS's recently proposed Quality Payment Program, providers will be increasingly required to test the waters of alternative payment models. Look to the OCM quality measures and "practice transformation" requirements as a preview of what CMS believes cancer care providers should be able to do—and how you should be structured—in the coming years. OI

Leah Ralph is ACCC Director of Health Policy.

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TAGRISSO:

BREAK THROUGH

THE T790M RESISTANCE BARRIER

in patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, at progression on or after EGFR TKI therapy

- Proven efficacy in two separate, global, Phase II, single-arm, open-label clinical trials in patients with metastatic EGFR T790M mutation-positive NSCLC who had progressed on or after EGFR TKI therapy[1]
  - A 59% objective response rate (95% CI: 54–64) in patients who progressed with previous EGFR TKI therapy
- In a separate dose-finding part of AURA, 63 patients with centrally confirmed EGFR T790M positive NSCLC who progressed on prior systemic therapy, including an EGFR TKI, were administered TAGRISSO 80 mg[1]:
  - 51% (32/63) of patients in the 80-mg cohort had a confirmed response by BICR
  - The median DoR was 12.4 months
- Grade 3/4 adverse events occurred at <3.5%[1]
- <6% of patients in a pooled analysis (N=411) had either dose reductions or discontinuations due to adverse events[1]
- 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[1]
- The most common adverse events in a pooled analysis of TAGRISSO patients (N=411) were diarrhea (42%), rash (41%), dry skin (31%), and nail toxicity (25%)[1]

Visit **TAGRISSOhcp.com** for more information

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%)

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.

Please see Brief Summary of complete Prescribing Information.

Reference: 1. TAGRISSO [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2015.

AstraZeneca

TAGRISSO™
osimertinib

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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Advance Care Planning: Coding & Reimbursement

BY CINDY PARMAN, CPC, CPC-H, RCC

Advance care planning is designed to help anyone—healthy or sick—communicate his or her wishes for medical treatment. The voluntary process involves educating patients on the types of medical decisions that may be required, encouraging advance consideration of those decisions, and letting family, caregivers, and/or surrogate decision makers know about the decisions made. Advance care planning allows patients to make decisions for care they want to receive if they are ever unable to speak for themselves. According to Joanne Lynn, MD, a geriatrician and hospice physician who heads the Center on Elder Care and Advanced Illness for the Altarum Institute, "Advance care planning is about planning for the 'what if's' that may occur across the entire lifespan."[1]

Healthcare leaders and providers must become comfortable talking about end-of-life care and death with patients, as the discussion is more important now than ever before, according to a recent report from the Institute of Medicine (IOM).[2] The report, *Dying in America*, found that end-of-life care is fragmented, which can lead to preventable hospitalizations. Creating a clear, holistic approach to integrating the clinical and social aspects of truly innovative end-of-life support into the conventional, well-established standard of care still eludes many well-intentioned stakeholders looking to bring much needed innovations into practice.[3]

For example, the Centers for Disease Control and Prevention (CDC) states that most people would prefer to die at home, yet only about one-third of adults have an advance directive expressing their wishes for end-of-life care.[1] In addition, between 65 percent and 76 percent of physicians whose patients had an advance directive were not aware that it existed. These gaps must be bridged so that patient preferences on end-of-life care are communicated before they lose the capacity to make those decisions themselves.

Understanding Advance Care Planning

Advance directives only work if the individual understands the document, his or her surrogate understands the individual's wishes, the physician is aware of the document's existence, the physician complies with the surrogate's instructions, and the document is revised as an individual's condition and goals change. Advance care planning documents include, but may not be limited to:

- Living will
- Durable power of attorney for healthcare
- Physician orders for life-sustaining treatment (POLST)
- Medical orders for life-sustaining treatment (MOLST)
- Healthcare proxy
- Do not resuscitate orders
- Organ or tissue donation.

There are a number of perceived barriers to advance care planning, including lack of patient awareness regarding the process, patient denial of death or inability to make his or her own decisions, concerns that patients may view the process as surrendering control, and lack of physician skill in initiating a discussion of end-of-life care and death. According to general practitioners, cancer patients are more involved in the process of advance care planning than non-cancer patients. Because patients with cancer often have a more predictable disease course, defining the right moment to initiate advance care planning may be easier among this patient population.[4] A 2000 survey by Steinhauser and colleagues of more than 1,400 patients, family members, or professionals involved with end-of-life care revealed that patients' most important goals are:[1]

- Pain and symptom management
- Preparation for death
- Achieving a sense of completion
- Decisions about treatment preferences
- Being treated as a "whole person."

In addition, patients strongly rated the importance of being mentally aware, understanding the course and prognosis of their disease process, the possibility of stopping treatments, options for palliative care, having funeral arrangements made, helping others, coming to peace with God or other spiritual issues, and not being a burden. Participants ranked freedom from pain as most important and dying at home as least important among criteria. In contrast to this finding, a report from the National Hospice and Palliative Medicine Organization found that the median length of time Medicare patients spent in hospice care in 2012 was only 19 days.[5]

Procedure Codes

Effective Jan. 1, 2015, clinicians can use two procedure codes for Advance Care Planning:

- **99497**. Advance care planning, including the explanation and discussion of advance directives, such as standard forms (with completion of such forms, when performed), by the physician or other qualified healthcare professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate.
- **+99498**. Each additional 30 minutes. (List separately in addition to code for primary procedure.)

According to the *CPT® Manual*, a "physician or other qualified healthcare professional" is an individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who performs a professional service within his or her scope of practice and independently reports that professional service.

This means that, unless there are insurer guidelines to the contrary, the individual who performs the advance care planning must be able to do so based on scope of practice and privileging, and also must bill for the service in his or her name and provider number. Additional authoritative coding guidance included in *CPT® Changes: An Insider's View 2015* states that the following elements of advance care planning must be performed and documented:

1. The performing provider performs a cognitive evaluation to determine the patient's capacity to understand risks, benefits, and alternatives to advance care planning choices.
2. The performing provider discusses the various advance care planning tools, such as living will, durable power of attorney, etc.
3. The performing provider reviews blank advance directive and orders for life-sustaining treatment forms with those present.
4. The performing provider reviews the patient's values and overall goals for treatment (e.g., the types of treatment the patient does or does not want), which may include a review of the types of life-sustaining treatments available.
5. The performing provider discusses the patient's diagnosis, prognosis, palliative care options, and procedures for avoiding hospital admission (or readmission).
6. The performing provider shares the patient's personal values and decisions and reviews the role of a designated agent as a substitute decision maker if the patient loses decisional capacity.
7. The performing provider answers all questions from the patient, family members, or surrogates.

CPT® Assistant, December 2014, provides still more information on the use of these codes. This coding reference states that the patient must have an understanding of his or her current medical condition, potential complications, and expectations of the current plan of care. This information is generally communicated using disease-specific scenarios that describe real clinical situations the patient may experience. Last, clinicians may find it necessary to periodically assess the patient's physical, emotional, social, and spiritual well-being, with regular revision of the care plan based on the changing needs of the patient and family.

The Advance Care Planning codes are time-based; therefore, the medical record must accurately identify the amount of time spent in discussion with the patient. During the time Advance Care Planning is billed, there is no active management of the patient's disease process or other services performed.

Some payers may require the following HCPCS Level II code in place of the CPT procedure codes:

- **S0257**. Counseling and discussion regarding advance directives or end-of-life care planning and decisions, with patient and/or surrogate. (List separately in addition to code for appropriate evaluation and management service.)

Medicare Coverage

Effective Jan. 1, 2016, the Centers for Medicare & Medicaid Services (CMS) established coverage and reimbursement for Advance Care Planning. The patient is responsible for coinsurance and deductible for this service, unless it is performed as part of an annual wellness visit.[6] Advance care planning services furnished on the same day, by the same provider and billed on the same claim as an annual wellness visit, are considered to be a preventive service. In order to ensure that the deductible and coinsurance are waived for the advance care planning, the procedure code(s) must

include modifier 33 (preventive services).

According to the CMS 2016 Medicare Physician Fee Schedule Final Rule:[7]

1. Advance care planning will be paid when the described service is reasonable and necessary for the diagnosis or treatment of illness or injury.
2. Since the services are by definition voluntary, Medicare beneficiaries may decline to receive them.
3. If advance care planning services are performed outside an annual wellness visit, the performing practitioner is encouraged to notify the beneficiary that Part B cost sharing will apply as it does for other physician services (e.g., coinsurance and deductible).
4. CMS plans to monitor utilization of the advance care planning codes over time to ensure that they are used appropriately.
5. When adopting CPT codes for payment, CMS generally also adopts CPT coding guidance.
6. In an exception to CPT guidelines, CMS stated, "We note that the CPT code descriptors describe the services as furnished by physicians or other qualified health professionals, which for Medicare purposes is consistent with allowing these codes to be billed by the physicians and NPPs whose scope of practice and Medicare benefit category include the services described by the CPT codes and who are authorized to independently bill Medicare for those services. Therefore only these practitioners may report CPT codes **99497** or **99498**."

   However, the agency recognized that there may be elements of the advance care planning service that are performed by qualified clinical staff under the supervision of the physician. "Accordingly, we [CMS] expect the billing physician or NPP to manage, participate and meaningfully contribute to the provision of the services, in addition to providing a minimum of direct supervision."

Although only the supervising physician or non-physician practitioner (NPP) can bill for advance care planning, the billing provider must personally document his or her meaningful contribution to the discussion and any other staff member performing services must separately document their participation.

While Medicare guidelines state that advance care planning can be charged on the same day as an annual wellness visit or other patient encounter, bundling edits prevent separate payment of advance care planning when it is performed on the same day as therapeutic treatment or other procedures. For example, advance care planning is bundled and will not be paid separately on the same day as:

- Radiation treatment management
- Clinical treatment planning
- Special treatment procedure
- Simulation
- Computer planning, including calculations and treatment devices
- Physics services
- Treatment delivery, including IMRT, SRS, SBRT, and proton therapy
- Hyperthermia
- Brachytherapy
- Hydration
- Therapeutic drug administration
- Chemotherapy treatment.

Other Payers & Regulations

Near the end of calendar year 2014, Massachusetts became the first state to require doctors, hospitals, nursing homes, and other health providers to offer end-of-life counseling to terminally ill patients.[8] The state has a sample brochure to help initiate the discussion, and there was widespread agreement in Massachusetts that more end-of-life planning is a good idea.

It is important to review individual payer policies because insurance policy requirements take precedence over other coding guidance. For example, BlueCross BlueShield of North Carolina includes the following in a Corporate Reimbursement Policy:[9]

"Care management services, which include chronic care management (**99490**), complex chronic care management (**99487**, **99489**), transitional care management (**99495, 99496**), and advance care planning (**99497, 99498, S0257**) are considered incidental to other evaluation and management services and not eligible for separate reimbursement."

Anthem in Virginia states that there is no separate payment for advance care planning, but these services are considered to be an integral component of Anthem's value-based payment innovation programs.[10]

However, PriorityHealth states that payment for advance care planning is considered preventive and not subject to co-pays, deductibles, or coinsurance.[11]

Coding Scenario 1

The physician completes all elements of advance care planning and documents that the discussion required 36 minutes. Code assignment would include only code **99497**; an additional 30-minute time increment cannot be charged unless the "midpoint" has been passed. This means that add-on code **+99498** for each additional 30 minutes would not be reported unless there was a total documented time of at least 46 minutes (30 minutes for code **99497** and at least 16 minutes for add-on code **99498**).

Coding Scenario 2

The non-physician practitioner spends 15 minutes completing the advance care planning discussion. The patient was well-versed on the topic and did not require an extensive dialogue. This service would not be separately coded and billed. In order to bill procedure code **99497** (30 minutes of discussion time), the time midpoint must be passed. This means that unless there is at least 16 minutes of documented advance care planning counseling time, there is no billable service to charge.

Coding Scenario 3

The patient presents for an established patient visit and advance care planning. The

physician documents a Level 3 established patient visit and 25 minutes of advance care planning. Codes for this encounter include **99213-25** (Level 3 established patient visit) and **99497** (first 30 minutes of advance care planning). **Modifier 25** reports that the patient visit is significant and separately identifiable from the advance care planning service. This means that medical record documentation must clearly support two separate services: the established patient visit and the advance care planning.

Coding Scenario 4

The patient presents for a subsequent Medicare annual wellness visit and advanced care planning that required 54 minutes. The physician separately documents the elements of the annual wellness visit and advanced care planning discussion. Codes for this encounter include:

- **G0439**. Annual wellness visit, includes a personalized prevention plan of service (PPS), subsequent visit.
- **99497-33**. Advanced care planning, first 30 minutes; preventive service.
- **+99498-33**. Advanced care planning, each additional 30 minutes; preventive service.

Closing Thoughts

End-of-life care decisions are deeply personal, and are based on individual patient values and beliefs. Death is both a human and a medical event, and patients vary greatly in what they want at the end of their lives. Some people want to continue aggressive treatment up to the time of death; these individuals are willing to endure treatment side effects and hospitalization in the hope of gaining weeks or months of additional life. Others prefer to focus on their quality of life, and may choose to concentrate on closure and comfort care in familiar surroundings, including pain control and relief from uncomfortable disease symptoms while retaining their dignity.

Most Americans living today will cope with one or more chronic conditions for an extended period of time, spend some years living with disabilities (functional and/or cognitive impairment) at the end of life, and face decisions that will affect the timing and quality of death. Public policy and healthcare systems will continue to develop more effective ways to ensure that advance care planning is routine for all adults, address the various communication styles of individuals, and ensure that patients' goals and wishes are reflected in treatment plans.[1]

In a perfect world, patients with advance directives would be confident that their healthcare providers know their end-of-life wishes. Good advance planning for healthcare decisions is, in reality, a continuing conversation about values, priorities, and the meaning and quality of one's life. Healthcare professionals, payers, and policy makers have a responsibility to ensure that end-of-life care is compassionate, affordable, sustainable, and of the best quality possible. Advance care planning is about quality of care; it is about helping people to live the way they want to at the end of their lives. OI

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spotlight

Samaritan Pastega Regional Cancer Center

Corvallis, Oregon

The Samaritan Pastega Regional Cancer Center in Corvallis, Oregon, is a comprehensive community cancer program providing oncology care at both the regional and community levels. The cancer program (as part of Samaritan Health Services Cancer Program) has been accredited by the American College of Surgeons Commission on Cancer since 2011.

Today, cancer services are provided in the brand new cancer center building that sits on a hilltop rise, greeting patients entering the Good Samaritan Regional Medical Center campus. The new facility, which opened in late 2015, serves as the hub of the cancer program. Satellite services also operate in four additional locations across three counties, covering almost 100 miles.

The new cancer center took more than 12 years to come to fruition. After some key donors committed to seeing the new center built and a successful community fundraising campaign, the facility opened in December 2015, creating a single, consolidated location for outpatient cancer care services.

Previously, cancer services were spread throughout several buildings across the medical campus. To access care, patients had to either drive or walk across campus to different sites of care, and for patients fatigued by cancer treatment, this was burdensome.

Consolidated Cancer Care

The glass-fronted atrium serves as the focal point of the building, with the stonework on the exterior echoed on interior finishes. The design incorporates natural light and art, creating a calm, healing environment. "The change of venue in terms of the openness of our new center has been a real positive for patients. Our prior location was certainly functional, but it wasn't as open or light as the place we have now," said David Hufnagel, DO, medical director for Samaritan Cancer Program's medical oncology and hematology services.

Cancer patients receiving treatment at the new center appreciate the convenience of having services all in one location. "The patient response we hear in clinic has all been very positive. After seeing us in clinic, patients used to have to cross the street to get their labs done, or a port flush done and infusion. Now they're able to do all that in one place," said Dr. Hufnagel.

The Samaritan Pastega Regional Cancer Center has three floors containing a range of oncology services including medical oncology (with eight medical oncologists on staff), infusion, clinical trials, resource center, lymphedema therapy, social work, financial counseling, laboratory, PET-CT, a café, and a concierge. Patient navigation is currently available for breast and head and neck cancer patients.

A benefit of the new facility is the significant increase in the number of infusion chairs. "That was a big issue before we moved, and now we have a lot more infusion space. It was always very difficult to get extra patients into infusion. Now we don't have that difficulty," said Dr. Hufnagel.

The infusion center is located on the third floor, with 8 open bay infusion chairs, 10 private infusion rooms, plus one room with a bed. Large windows provide scenic views of the valley. "Having infusion in the same building as the clinic is important because if a patient is having a complication during clinic hours, it's more than likely that their doctor is just right downstairs," said Dr. Hufnagel.

New services also include three multi-purpose meeting rooms equipped with teleconferencing equipment. The cancer center's teleconferencing capabilities are primarily used to communicate with Samaritan's satellite sites and for tumor boards. The cancer center intends to expand the use of this technology to perform telemedicine in the future; the center is affiliated with Stanford Health Care and their Stanford Cancer Center, in a developing relationship to provide telemedicine.

The new cancer center is connected by a covered walkway to the building that formerly served as the cancer center, which now is dedicated to radiation oncology services. Expanding the existing center was not an option due to construction regulations. The solution was to build the new center directly in front of the existing location, then join the two buildings by way of landscaping and a short, covered pathway.

The radiation oncology unit—with a staff of three radiation oncologists—includes a new Varian VitalBeam linear accelerator, and radiation services, including cone-beam 3D CT imaging, IMRT, IGRT, and electronic brachytherapy.

Medical oncology and chemotherapy services are offered within the cancer center and at all satellite locations. Radiation therapy services are available only within the regional cancer center in Corvallis.

The Mario Pastega House

For some of the rural outlying communities within Samaritan's catchment area, transportation to appointments can be a barrier. While many of these patients can be seen at the satellite locations, those requiring radiation therapy may have to drive up to an hour, depending on where they live.

To help alleviate this travel burden, the Mario Pastega House was founded in 2004. The house is a 6,500-square-foot overnight residence located on the hospital campus with

- 12 guest suites
- A chapel
- An outdoor patio and garden
- A children's play structure
- A central kitchen and dining area
- Living and recreation areas
- On-site laundry facilities.

Lodging at the Mario Pastega House is available to patients who are coming from more than 25 miles away and who have a referral from a medical provider or hospital staff member. A nominal donation is suggested, but no one is ever turned away for financial reasons.

Unique Community Support Programs

Community outreach is driven by a full-time (FTE) staff member with the help of more than 100 community volunteers spreading the message about the value of early cancer detection.

That's My Farmer is a collaborative program between Samaritan's cancer resource centers and local farmers markets. Dietitians lead a six-week-long series for cancer survivors about the health value of eating fresh, local produce. Survivors receive a cookbook and cooking tips, and meet weekly with the dietitian to discuss food prep and healthy eating. The program operates on grant funding, allowing the cancer center to distribute vouchers to each survivor participant for their local farmer's market.

The donor-funded SurvivorFit program provides cancer survivors with free, three-month memberships to local fitness centers. A trainer with specific education related to oncology provides one-on-one fitness consultations.

Samaritan also offers numerous services to patients and families at no charge through their two Samaritan Cancer Resource Centers located in Albany, Oregon, and at the Samaritan Pastega Regional Cancer Center. Services include massages, wig fittings, support groups, art therapy, and more. OI

Select Support Services

- Dietitians
- Navigation
- Social work
- Financial counseling
- Cancer resource centers
- That's My Farmer
- SurvivorFit

New analytic cases in 2014: 1,446
Percent of patients accrued to clinical trials: 8 percent

tools

Approved Drugs

- The Food and Drug Administration (FDA) has approved Exelixis, Inc.'s (exelixis.com) **Cabometyx™ (cabozantinib)** for the treatment of advanced renal cell carcinoma in patients who have received prior anti-angiogenic therapy.

- Eisai Inc. (eisai.com) announced that the FDA has approved **Lenvima® (lenvatinib) in combination with everolimus** for the treatment of patients with advanced renal cell carcinoma who were previously treated with an anti-angiogenic therapy.

- The FDA granted accelerated approval to Bristol-Myers Squibb's (bms.com) **Opdivo® (nivolumab)** for the treatment of patients with classical Hodgkin lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation and post-transplantation Adcetris® (brentuximab vedotin).

- Genentech Inc., (gene.com) announced that the FDA has granted accelerated approval to **Tecentriq (atezolizumab injection)** for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neo-adjuvant or adjuvant treatment with platinum containing chemotherapy.

Drugs in the News

- Amgen (amgen.com) announced that the FDA has accepted for priority review the supplemental biologics license application (sBLA) for **Blincyto® (blinatumomab)** to include new data supporting the treatment of pediatric and adolescent patients with Philadelphia chromosome negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia.

- The FDA has granted priority review for Eli Lilly and Company's (lillyoncology.com) biologics license application (BLA) for **olaratumab**, a PDGFRα antagonist, in combination with doxorubicin, for the potential treatment of people with advanced soft tissue sarcoma not amenable to curative treatment with radiotherapy or surgery.

- Bristol-Myers Squibb Company (bms.com) announced that the FDA has granted breakthrough therapy designation to **Opdivo (nivolumab)** for the potential indication of recurrent or metastatic squamous cell carcinoma of the head and neck after platinum-based therapy.

Approved Devices

- Hologic, Inc. (hologic.com) announced FDA clearance and commercial launch of the **Affirm™ prone biopsy system**, the first dedicated prone biopsy system to offer both 2D and 3D imaging-guided breast biopsies.

- The FDA has approved **Axumin** (Blue Earth Diagnostics, blueearthdiagnostics.com), a radioactive diagnostic agent for injection. Axumin is indicated for PET imaging in men with suspected prostate cancer recurrence based on PSA levels following prior treatment.

- Royal Philips (Philips.com) announced that the **Philips' suite of computed tomography (CT) solutions** has achieved 510(k) clearance from the FDA for low-dose lung cancer screening.

Genetic Tests & Assays in the News

- Roche (roche.com) announced the FDA approval of the first cytomegalovirus (CMV) test for use in hematopoietic stem cell transplant recipients. With this approval, the **Cobas® AmpliPrep/Cobas® TaqMan® CMV Test** is available for monitoring CMV treatment in all types of transplant patients in the U.S.

- The FDA has approved the **cobas EGFR Mutation Test v2** (Roche, roche.com), a blood-based companion diagnostic for the cancer drug Tarceva® (erlotinib). This is the first FDA-approved, blood-based genetic test that can detect epidermal growth factor receptor (EGFR) gene mutations in NSLC patients.

- The FDA has approved Roche's (roche.com) **Ventana PD-L1 (SP142) Assay** as a complementary diagnostic to provide PD-L1 status on patients who are considering treatment with the FDA-approved Roche immunotherapy Tecentriq™ (atezolizumab) for metastatic urothelial cancer.

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*NINLARO 1Point does not file claims or appeal claims for callers. It cannot guarantee success in overturning payer denials.

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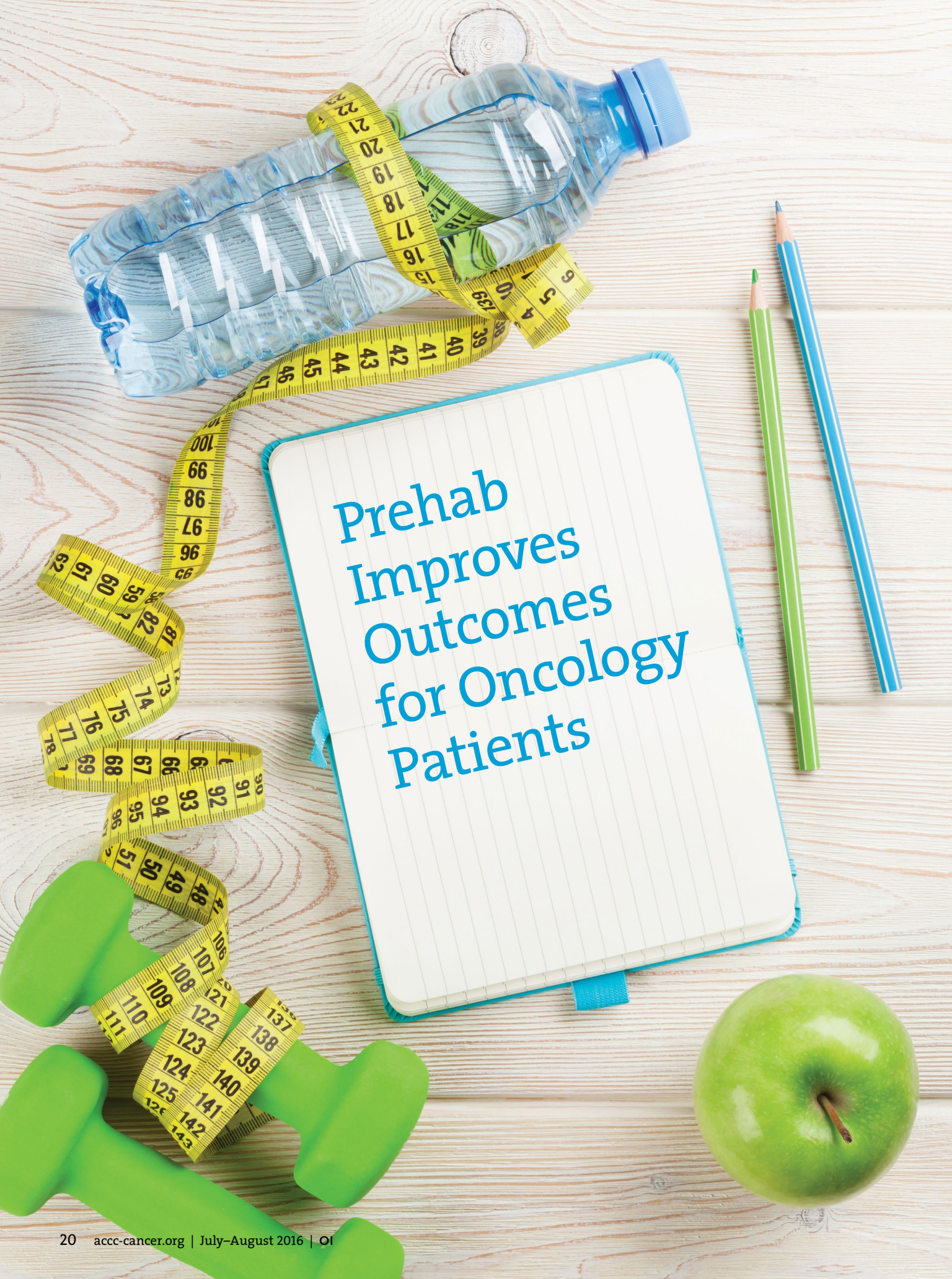

Prehab Improves Outcomes for Oncology Patients

BY MESSINA CORDER, MBA, BSN, RN, AND
KATHRYN DUVAL, MS, CCC-SLP

For some newly-diagnosed cancer patients, decreased functional status and comorbidities can impact treatment options. A focused prehabilitation (prehab) program couples physical therapy with holistic care that includes nutritional support, stress reduction strategies, and nurse navigator intervention. Integrating prehabilitation can not only improve patient outcomes post-surgery, it can also decrease hospital length of stay (LOS).

Physical Impairment & Cancer Patients

According to the literature, about 65 to 90 percent of cancer patients have a physical or functional impairment.[1-5] These impairments include difficulty walking, difficulty swallowing, immobility in a limb, or muscle weakness. One 2015 study looked at 529 older adults with cancer and found that 65 percent had a potentially modifiable deficit and needed physical therapy (PT), occupational therapy (OT), or a speech consult, but only 9 percent received these treatments.[4] Another study looked at 163 women with metastatic breast cancer, finding that 92 percent of those women had some type of modifiable impairment.[1] The study also found that 530 of the impairments were documented in the patient chart, but less than 2 percent of patients received treatment for the impairment.[1]

With so many of our cancer patients living with functional impairments, early recognition and intervention can have a positive impact on their overall health outcome.

As providers, we know the treatments and potential side effects of cancer, so we can often predict the types of impairments our patients may develop. Mary Washington Hospital, Fredericksburg, Va., looked to prehabilitation to prevent or reduce the severity of these physical impairments.

Why Prehab?

Cancer prehabilitation is a part of rehabilitation medical care. Prehab is not merely handing out exercises or information on how to stay healthy, but rather an intervention-based program to improve certain outcomes. For patients with cancer, prehab occurs in the time between diagnosis and the start of treatment. At a prehab appointment, patients undergo a physical and a psychological assessment to determine their baseline function level and to identify any issues upfront. Armed with the patients' baseline information, providers assess how patients are deviating from that baseline and intervene if they start to develop impairment(s) during treatment. This assessment is also an opportunity to address any psychological or psychosocial issues and connect patients to the appropriate supportive services upfront.

> We believed that adding prehab services would allow us the opportunity to educate patients immediately after diagnosis—before they even begin treatment—to obtain their baseline assessments, and start the necessary interventions.

By narrowing the focus on specific outcomes, prehab allows clinicians to intervene earlier—sometimes before the physical impairments manifest—and also monitor patients throughout the cancer treatment process. This type of care may:

- Improve health outcomes
- Reduce patient rehab visits after cancer treatment
- Decrease hospital LOS
- Decrease costs
- Improve patient quality of life (QOL).

Getting Started

The first step in our prehab implementation process was to look at our own patients. In 2014, we conducted a functional impairment survey of approximately 100 cancer patients, and found that 79 percent of these patients did indeed have some type of functional or physical impairment. Our team went a step further and looked at how many of these 100 patients underwent physical therapy, occupational therapy, or a speech therapy consult. Only 12 percent had received these supportive care services, so imme-

diately we recognized an opportunity to intervene and improve our patient outcomes.

During patient encounters, our patients were telling us about their cancer-specific side effects. Among the issues raised by patients were lack of ability to focus at work, trouble swallowing, difficulty gaining weight, experiencing "chemo-brain," etc. While these were familiar stories, we realized we had a new opportunity to identify these issues early on. We incorporated physical functioning in our distress screening tool so that our nurse navigators could screen patients for psychosocial needs, psychological issues, and physical functioning. We believed that adding prehab services would allow us the opportunity to educate patients immediately after diagnosis—before they begin treatment—to obtain their baseline assessments, and start the necessary interventions.

From Rehab to Prehab

Mary Washington Regional Cancer Center launched a cancer-focused rehabilitation program in 2013, finding a physician champion in thoracic surgeon J. Timothy Sherwood, MD. Dr. Sherwood soon approached our rehabilitation team about the possibility of treating his lung cancer patients prior to surgery. He said that by the time lung cancer patients reached the surgery stage, many were experiencing debilitating functional issues to the point that they were not good surgical candidates. Their impairments made them a high-risk population for complications, and most would need to go to a nursing facility post-treatment. For these reasons, the decision was made to pilot the prehab program with our lung cancer patients. (Our cancer center sees between 250 to 275 lung cancer cases per year.)

Our cancer center used the Survivorship Training and Rehabilitation (STAR) Program (starprogramoncologyrehab.com) to develop our prehabilitation services. STAR Certification for rehabilitation requires cancer centers to implement a prehab protocol consisting of five components:

1. General and targeted therapies with a PT, OT, or speech therapist
2. Smoking cessation
3. Nutrition and dietitian services
4. Stress reduction therapies via navigation
5. Integrated medicine program for complementary therapies.

We worked with the STAR program and Dr. Sherwood to develop a prehab protocol and pathway for our lung cancer patients, and identify outcome measures. We would use a movement assessment log; patients with higher baseline numbers had more physical or functional impairments. After prehab, patients would be measured again to see if they improved in the following areas:

- Distance walked
- Time to up-and-go, which is their sitting to standing time
- Ability to climb steps
- Their score on a FACT-G quality of life (QOL) questionnaire, which measures a patient's overall physical and emotional well-being.

Oncology-trained therapists conduct baseline physical and psychological assessments prior to treatment and provide targeted interventions personalized for each patient to reduce incidence and severity of current and future impairments.

The Pilot Program

By October 2013, our first patients were moving through the prehab program. Dr. Sherwood began screening all of our lung cancer patients after diagnosis, assessing their functional level and identifying any physical limitations or severe deconditioning that would put them at increased risk for surgery. Dr. Sherwood referred these at-risk patients to the lung prehab program, which was tailored to meet individual patient needs. Most patients were seen two to three times per week for three to four weeks; some only needed to come in once or twice a week. After prehab, Dr. Sherwood re-assessed patients and, if they showed improvement, scheduled the procedure.

After surgery, patients had an average hospital length-of-stay of three days, and were discharged home with rehabilitation. Patients generally returned for rehab about three times a week for three to four weeks—again the rehab was tailored to the patients' individual needs. As our pilot project progressed, we found that some of our lung cancer patients were doing so well they did not have to return for rehabilitation services.

One of the questions we are often asked about the prehab program is, "Are you concerned with the delays in surgery due to prehab?" Dr. Sherwood's answer is an emphatic "No." The prehab program works to improve patients' chances of being good surgical candidates, while also increasing their chance of better post-operative outcomes. This, in turn, can reduce the cost of care post-treatment.

The normal schedule from diagnosis to surgery at Mary Washington is two weeks, but with the addition of prehab, this time frame is now six to eight weeks from diagnosis to surgery. When discussing treatment options with patients, staff educates patients about the value and medical reasoning behind prehabilitation.

Pilot Program: A Case Study

Our very first lung cancer prehab patient, Ms. A, had stage IA lung cancer. She came to us with quite a few co-morbidities: osteoarthritis, limited mobility, and dyspnea. She'd had previous surgeries for knee and back pain and was deconditioned. Dr. Sherwood assessed Ms. A, concluding that she would likely experience poor outcomes from surgery and would probably need to go to a nursing facility post-procedure. After hearing about the possibility of a stay at a nursing facility, Ms. A agreed to go to prehab. After six weeks of balance training, body and function strengthening, and aerobic endurance, Ms. A returned to Dr. Sherwood to be re-assessed for surgery. Based on the outcomes measures discussed previously, Dr. Sherwood deemed the patient fit for surgery.

After her lung resection, Ms. A returned home after only three days in the hospital. She received four weeks of physical therapy before transitioning to her local YMCA exercise program.

In the words of Ms. A, "*I felt very secure in Dr. Sherwood sending me to the STAR Program, and I tried to do everything they told me to do. I wasn't worried about the delay in surgery, because I was in the best hands. I just wanted to stay out of that nursing home. Dr. Sherwood picked the right words to motivate me!*"

Ms. A's baseline movement assessment score was 91; after prehab, she saw a 53 percent decrease in her functional impairment. Specifically, Ms. A improved her walking distance and her dyspnea had resolved. Generally cancer patients are healthy at diagnosis and then their health declines due to cancer treatment. It was shocking to see the opposite effect in Ms. A—all due to prehab. The team felt it had truly demonstrated that prehab can have a positive impact on patients' health status by decreasing their surgical risks and hospital length of stay.

Key to the success of our pilot prehab program: physician engagement and an experienced physical therapy team, plus a physician champion spearheading the effort, who could explain the benefits to other physicians.

Patient Outcomes & Reimbursement

During our pilot project, 12 patients were referred to prehab over a 17-month period, with 6 patients completing the full program. Pilot program outcomes included:

- A 21 percent improvement in patients' ability to walk, or the distance they were able to walk.
- A 40 percent decrease in patients' hospital LOS. (Looking at 2009-2012 registry data, our lung patients who had surgical resection had an average post-op LOS of five days; the average LOS for patients in the prehab pilot was three days.)

Through our prehab pilot program, we've been able to reduce the number of rehabilitation visits needed post-treatment. Interestingly, during the pilot program, we were also able to reduce the number of prehab visits needed. At the start of the pilot program, patients had about 13 prehab visits; by 2015, processes and efficiency improved to the point that most patients now had only 9 sessions. This metric was particularly important, as payers—including Medicare—will only reimburse for a certain number of rehabilitation visits.

Left: Physician champion in thoracic surgery, J. Timothy Sherwood, MD. Right: The STAR Program requires an interdisciplinary team—physicians, nurses, therapists, nutritionists, and more—from both the inpatient and outpatient setting to develop and execute protocols that are specific for cancer diagnoses.

With regards to reimbursement, there is no order for prehab. Instead cancer programs must focus on the specific issues being treated, ensuring appropriate documentation for payers. In other words, reimbursement is linked to the use of ICD-10 codes for treatment of muscle weakness, lumbago, difficulty walking, difficulty swallowing, pain in limb, etc. Bottom line: prehab is treating the same conditions that are treated in rehabilitation, but earlier in the care trajectory so that we can decrease—or possibly even prevent—physical impairments post-treatment.

Measuring Programmatic Success

Mary Washington Healthcare has identified five pillars of excellence as indicators to measure the success of the organization. Looking at these pillars specific to our prehab program we found:

- ***Pillar 1. Quality.*** We showed that prehab services improve patient outcomes.
- ***Pillar 2. Safety.*** We showed that prehab improved functionality for the patients.
- ***Pillar 3. Service.*** Adding prehab services improved the patient experience by preventing and/or reducing the severity of physical impairments in an efficient and effective manner.
- ***Pillar 4. Growth.*** More cancer patients were referred to prehab, increasing access to these services.
- ***Pillar 5. Finance.*** We showed that prehab could help reduce the cost of care by decreasing hospital LOS.

Prehab provides clinicians the opportunity to help patients make a lifestyle change, reinforcing the value of being healthy and continuing to exercise. Moreover, cancer patients often must take time off from work and cut back or stop other activities. When cancer treatment is complete, these patients want to get back to their "norm," and prehab can help them do so sooner.

Messina Corder, MBA, BSN, RN, is manager for regional cancer center administration and Kathryn Duval, MS, CCC-SLP, is administrative director of Clinical Operations at Mary Washington Regional Cancer Center, Fredericksburg, Va.

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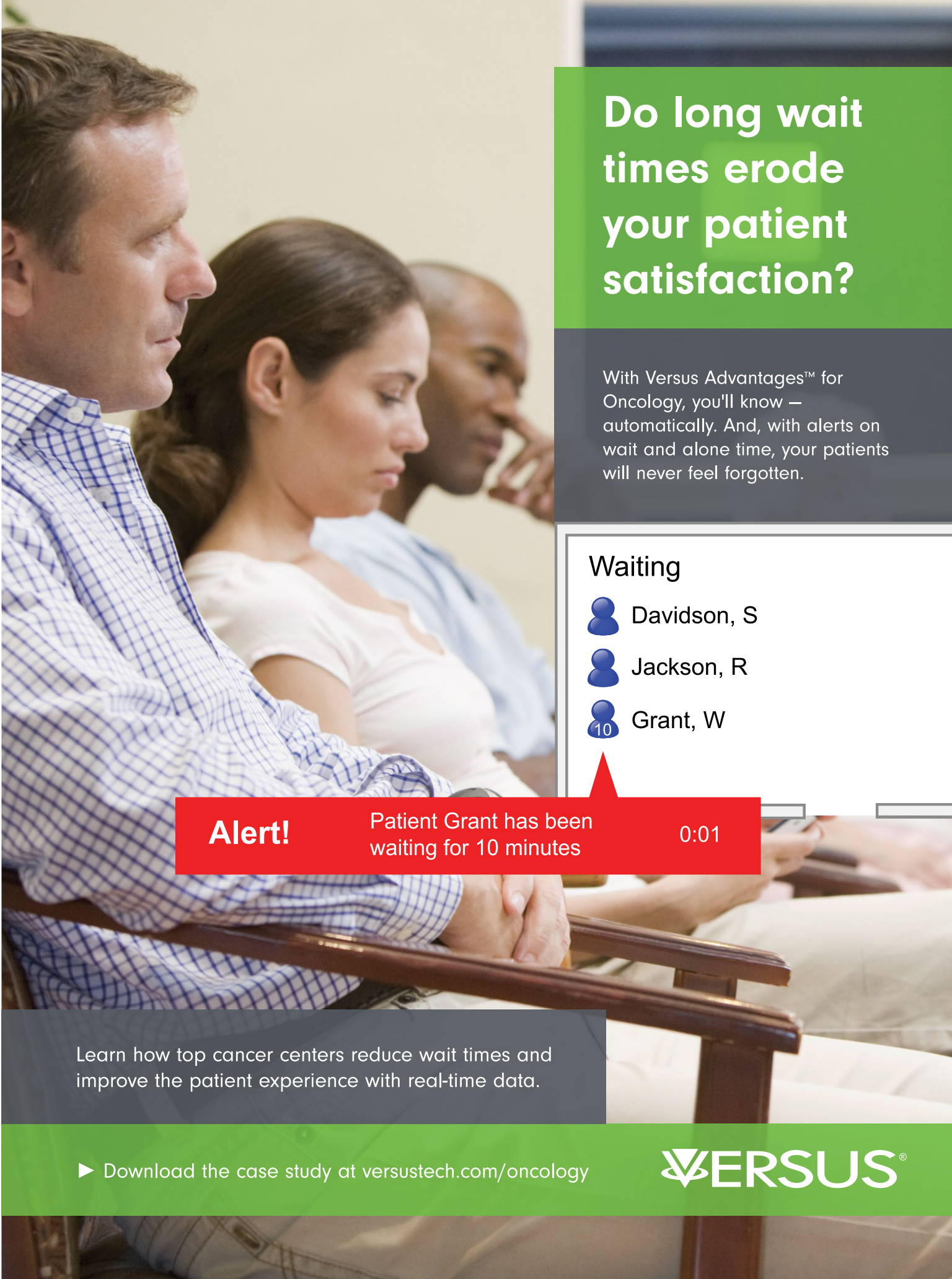
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Indication

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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Engaging Patients & Assisting Primary Care Physicians in Lung Cancer Screening

In 2014 PIH Health Hospital, Whittier, Calif., initiated a lung cancer screening program with the goal of early detection, improving the quality and timeliness of lung cancer care, and refining communication among the multidisciplinary treatment team. This nurse practitioner-run program uses an enrollment method—primary care practitioners can refer or patients can self-refer. Features of the lung cancer screening program include:

- Streamlined scheduling process
- Shared decision-making and counseling
- Ongoing follow-up that relieves the pressure on busy primary care offices.

With reallocation of current support resources and minimal investment, the cancer program achieved return on investment in its lung cancer screening program in the form of an increased number of procedures and referrals. The program is also on its way to realizing a long-term goal of seeing a decrease in diagnosis of late-stage lung cancer for a high-risk patient population. The lung cancer screening program focuses on empowering patients to be advocates for their own health by being involved in screening, follow-up, and smoking cessation.

Our Program At-a-Glance

PIH Health Hospital Whittier is a 548-bed community hospital and is a Commission on Cancer-accredited Community Cancer Center. Located in south Los Angeles County in Whittier, Calif., the cancer program covers a primary service area of 2.1 million people across three counties. PIH Health Hospital includes an associated physician group with 49 primary care practitioners and 94 specialists.

In the primary and secondary service areas there are 17 hospitals with 4 (including PIH Health) offering lung cancer screening services. PIH Health is an American College of Radiology Designated Lung Cancer Screening Center and a Lung Cancer Alliance Screening Center of Excellence

The creation of a lung cancer screening program was fundamental in the formation of a thoracic oncology team. While all the pieces of a strong thoracic oncology team existed, there was no formal lung tumor board or consistent way in which patients were being navigated through the specialties. As a result the two programs were developed simultaneously.

Finding a Model that Works

When the United States Preventive Services Task Force (USPSTF) published its lung cancer screening recommendations in 2013, PIH Health's cancer center became interested in developing a lung cancer screening program. There was strong administrative support and engagement of a physician champion, Daniel Saket, MD, Director of Radiology, from the start. Dr. Saket was instrumental in finding a model that would best serve the patient population in the community.

After evaluating many models used across the United States, he selected the model used by Yale Cancer Center, New Haven, Conn. This model employs an enrollment process with the use of a nurse practitioner (NP). Before launching the lung cancer screening program, conference calls were held with Yale's pulmonologist and cardio-thoracic surgeon to learn more about the logistics of their program.

A top priority for the new lung cancer screening program was to assist primary care physicians (PCPs). Due to the shortage of

PCPs and the aging population, it can be difficult to make a separate appointment to discuss screening in a shared decision-making manner. To make lung cancer screening easy and efficient for both patients and their providers, the goal was to develop a simple process that could be conducted in one visit with the lung cancer screening program's NP.

Developing a Screening Process

With the new and evolving nature of lung cancer screening, there were many different recommendations and the PIH Health Lung Cancer Screening Program felt it was important to clearly state whom it would screen. An enrollment form was created both on paper and in our electronic health record (EHR) that reflected the screening population and could be used to help identify those patients who qualified. View this enrollment form online at: accc-cancer.org/oncology_issues/JA2016. There were two stratifications for those eligible for screening, and all criteria must be met in order for the patient to qualify:

- Age 55 to 80
- Current or former smoker who has quit within the last 15 years
- 30 pack a year or greater smoking history

OR

- Age 50 (no upper age limit)
- Current or former smoker (no limit to time since quit)
- 20 pack a year or greater smoking history
- Additional risk factor: Occupational exposure to asbestos, silica, arsenic, soot, diesel fumes, nickel, etc. (second-hand smoke is not considered an additional risk factor).

At the time these program criteria were developed the secondary screening criteria was a National Comprehensive Cancer Network (NCCN) 2B recommendation. It was felt that these patients could still benefit from screening based on preliminary research, and so it was offered with education going out to both the referring physicians and patients that this screening would not be covered by the insurance as a preventive service and the patient would be responsible for any co-pays or deductibles. With the release of the 2016 NCCN Lung Cancer Screening Guidelines, the situation changed and it now has the same level of recommendation as the first category—though payers are still not paying for it as a preventive service.

Once these referrals are received via fax or through the EHR, the patient is contacted by the centralized scheduling department to verify the information. This step became necessary because 90 percent of the time the forms were incompletely or incorrectly filled out. The information on the enrollment is linked to payment, so it is essential to ensure that patients meet all the criteria prior to scheduling. If there are any questions about a patient qualifying, the NP is notified and speaks with the patient directly. Once a patient is verified as being a screening candidate, the NP places an order for the low-dose computed tomography (LDCT) exam. The patient is scheduled for a shared decision-making education session and LDCT scan on the same day, and any necessary insurance authorization is obtained.

The Lung Cancer Screening Program is responsible for:

- Receiving enrollment forms and fielding patient self-referral calls
- Pre-screening patients
- Verifying insurance and obtaining authorization
- After confirming patients have met the screening criteria, placing the order for the LDCT scan and scheduling the patient.

Patients are allowed to self-refer to the lung cancer screening program, and this can be a controversial topic at some facilities. However, this program has found that patients who self-refer are taking initiative with their own healthcare, and they should be

The Lung Cancer Screening Program strives to put patients first by providing a personal and hands-on approach to care.

PIH Health Hospital Whittier is a community cancer center serving three California counties.

empowered and not made to jump through hoops. Self-referring patients are required to have a physician to whom results can be sent, but the patient does not need to see the physician first to obtain a referral or order.

Leveraging Existing Resources

Initially, the NP was responsible for all of the tasks listed above, but as the lung cancer screening program grew, it was no longer feasible for one person to handle everything. In lieu of hiring additional staff, the centralized radiology scheduling department began to support the lung cancer screening program. By drawing on processes already in place, this department took over the pre-screening verifications and appointment scheduling. Any clinical questions, concerns, or patient education needs are escalated to the NP—thus improving resource utilization within designated scopes of practice. If patients do not meet the screening criteria the NP is notified, communicates back to the referring physician, and provides any patient education regarding why they do not qualify.

Marketing and business development were additional existing resources that were leveraged. These departments already had a relationship with community providers and knew our target audience. By providing them with a fact sheet and enrollment forms they were able to get the word out to the community providers about this new guideline and the service provided at PIH Health. View this fact sheet online at: accc-thecancer.org/oncology_issues/JA2016.

Putting Patients First

In alignment with PIH Health's directive of "patients first" a primary goal was to make the lung cancer screening process as easy as possible for patients.

On the day of the scheduled low-dose CT, patients are asked to arrive 30 to 45 minutes prior to their radiology appointment. This allows time for the patient to be checked in and have a 15 minute shared decision-making meeting with the NP prior to the exam. This implementation of a shared decision-making and education session from the inception of the program—before it was mandated by the Centers for Medicare & Medicaid Services (CMS)—has been one of the biggest keys to success. It sets the stage for ongoing follow-up, compliance, and making sure patients understand the risks and benefits of the lung cancer screening.

Shared decision-making is about empowering patients. Patients are made aware of the risks of developing lung cancer and how screening can help with early detection. Patients are encouraged to quit smoking (if they have not already), and they receive information on the different options available to help them quit. Educated patients are empowered patients and for many smokers or former smokers it is a way for them to take back control of their health.

The shared decision-making session always starts with finding out the patient's knowledge level as it relates to lung cancer screening. Patients are asked: "What did the doctor tell you about this test you are having today?" The most common answer is: "My doctor says I need to have it because I smoke/smoked." Physicians have a lot of information to cover with patients, who often have many co-morbidities, and they do not have the time to provide them with extensive education about lung cancer screening or smoking cessation. Having the lung cancer screening program's NP meet with patients allows time to thoroughly explain screening and answer any questions. Some of the main points covered include:

- A brief history of lung cancer screening
- The benefits and risks of screening, the mortality decrease, the use of the low-dose technology, and how this type of screening differs from a typical chest X-ray
- Smoking cessation advice.

In addition to these basics, each patient receives a copy of the Lung Cancer Alliance's brochure called "Lung Nodules." View this brochure online at: accc-cancer.org/oncology_issues/JA2016. This brochure educates patients on what nodules are and how different sizes will affect follow-up. This information helps prepare patients for the results and instills in them that this is not a one-time exam. Spending the time discussing the follow-up care upfront along with the program tracking has helped to improve compliance in follow-up because the patients know what to expect from the beginning.

The shared decision-making session is a vital part of patient empowerment. The lung cancer screening program encourages patients to commit to ongoing screening by undergoing the scan every year, as they may be at risk for developing a lung cancer in the future.

Once patients have had their shared decision-making session, they receive their low-dose CT exam. Once the scan is complete, patients are told that they will receive a call from the NP within 48 hours and are provided with her contact information in case they have any questions. From start to finish, patients have personal contact with someone whom they know they can call. Currently, the imaging center blocks one CT scanner for two 15-minute time slots a day for lung cancer screening.

Patients are anxious to receive their test results, so all attempts are made to notify patients within two business days via telephone. A letter with a copy of the report is also sent to the referring physician. If there is a suspicious finding that may require additional imaging or a biopsy, the NP reaches out to the referring physician. A discussion occurs about who will inform the patient of the results and a follow-up plan is put into place. This conversation is also an opportunity to discuss a pulmonary referral since input from the referring physician will be important if a biopsy is necessary. The goal is to have the patient seen by a pulmonologist and have any additional workup and biopsies within two weeks.

For patients who require interval or ongoing annual follow-up (Lung-RADS™ 1-3), the lung cancer screening program tracks and contacts patients when they are due for follow-up. When patients are due to be screened, the radiology scheduling department reaches out to them and obtains any insurance authorizations. Then, the NP provides an order, schedules the patient, and sends the referring provider a letter and radiology report once it is complete.

Table 1. Lung Cancer Patients Diagnosed & Treated, 2013-2015

STAGE	2013 (Baseline)	2014 (Screening initiated 6/2014)	2015
0	0	2	1
I	25	31	32
II	4	11	10
III	15	16	16
IV	52	47	51
Unknown	1	3	1
TOTAL	97	110	111

Below is a snapshot of the PIH Health Lung Cancer Screening Program to date:

- Total patients screened: 424
- Cancers detected: 12
- Suspicious in progress (being worked up): 5
- False positives (negative biopsies): 3
- Screening follow-up rate: 96 percent.

A Brief History of Lung Cancer Screening

Lung cancer is the leading cause of cancer-related mortality for both men and women. It kills more people every year than colon, pancreatic, breast, and prostate cancers combined.[1] Viewed as a women's health issue, it kills more women than breast, uterine, and ovarian cancer combined.[2] Lung cancer remains a serious problem; however, early detection through advances in lung cancer screening is bringing earlier diagnosis and treatment to more patients.

In 2013 the National Lung Screening Trial (NLST) results were published. This major, multi-site study covered more than 50,000 people from across the nation, and showed a 20 percent decrease in mortality rate with the use of low-dose CT scans for the high-risk population (people between the ages of 55 to 74, current smokers or former-smokers that quit within the last 15 years, and who had a minimum of a 30-pack year history).[3]

In December 2013, the United States Preventive Services Task Force (USPSTF) published its recommendations making lung cancer screening a grade B recommendation. The significance of this recommendation is that under the Affordable Care Act, all grade B recommendation preventive services must be covered by insurers with no cost-sharing to the patient—meaning no co-pays and no deductibles. This recommendation took effect in January 2015 and was a big win for lung cancer care.

Additionally, the USPSTF recommendations raised the qualifying age to 80 years old. The NLST trial results looked at patients up to age 74 (50% of lung cancers). By raising the age to 80, it is possible to potentially capture the additional 20% typically found in that age range.

In February 2015, the Centers for Medicare & Medicaid Services (CMS) issued a decision memo for screening for lung cancer with low-dose computed tomograpy (CAG-00439N) covering this exam, including these additional stipulations:

- Screening programs must report to a national registry.
- Shared decision-making/counseling sessions must be provided to the patients before their first exam.
- Standardization in reporting through the Lung-RADS system.
- The upper age limit for participants was lowered to 77.

Percentages of Initial Screening by Lung-RADS Classification:

- Lung-RADS 1: 36 percent
- Lung-RADS 2: 41 percent
- Lung-RADS 3: 18 percent
- Lung-RADS 4A: 3 percent
- Lung-RADS 4B: 2 percent

A True Team Effort

Lung cancer screening is a great tool for early detection, but it is only one small component of a successful lung cancer program. PIH Health employs an excellent team of physicians, and it was apparent early on that a mechanism for communication amongst these specialists was needed. This realization led to the development and implementation of our Multidisciplinary Lung Cancer Conference. The multidisciplinary team includes the following: radiologist, interventional radiologist, pulmonologist, cardiothoracic surgeon, oncologist, radiation oncologist, pathologist, and the lung cancer screening program NP. Prior to this conference, a patient diagnosed with lung cancer could be referred to a pulmonologist, cardiothoracic surgeon, or oncologist, depending on where their primary provider sent them. Patients would often get one or two tests done and then get referred to the next specialist for one or two more tests while weeks went by. The multidisciplinary team agreed that this scenario was problematic and created an agreed-upon patient flow, beginning with the pulmonologists, with the goal of having the patient staged and ready to start treatment within two weeks of diagnosis.

There was much variation in practice with different specialties following different guidelines, so standardized treatment pathways were created based on the NCCN guidelines. It was the task of the NP navigator to create algorithms for the treatment of each stage. These were then presented at the multidisciplinary conference, adjustments were made and put into place once all of the physicians were in agreement. This process has helped to streamline the work up of lung cancer patients and to provide consistent high-quality care.

PIH Health began offering lung cancer screening in June 2014. The Multidisciplinary Lung Cancer Conference began bimonthly in July 2014 and by 2015 became a weekly occurrence. In 2013 there were 97 lung cancer patients diagnosed and treated at PIH Health. In 2014 the number increased to 110, and in 2015 the number held steady at 111. Since the screening program began, there has been an increase in diagnosis of early-stage lung cancer. While the stage IV diagnosis rate has remained high over the last two years, the hope is that it will decrease as screening becomes a standard of care. The data collected reflects lung cancer patients that were diagnosed and treated at PIH Health. With the availability of many new lung cancer treatment options for late-stage lung cancers, many more patients are opting for treatment when previously they would go on hospice and not receive treatment. This could be an explanation for the increase in stage IV lung cancer in our data. Table 1, page 34, shows the number of lung cancer patients diagnosed and treated at PIH Health Hospital Whittier in 2013-2015.

The Multidisciplinary Lung Cancer Conference is key to the success of the lung cancer screening program. Left to right, back: Lisa Wang, MD (Oncology); Jessica Peckham, NP-C (Navigator); Daniel Saket, MD (Radiology); Dustin Stevenson, DO (Oncology); Nannette Kovash, MD (Radiology); Nathan Honda, MD (Pathology); front: Daniel Akhavan, MD (Pulmonary); Eduardo Tovar, MD (Cardiothoracic Surgery); Nadeem Chishti, MD (Pulmonary); Kuimars Saketkhoo, MD (Pulmonary).

Lessons Learned

The success of the PIH Health lung cancer screening program can be attributed to tremendous administrative support and a strong physician champion from the beginning. Improved communication and utilization of the multidisciplinary team has been vital to the success of the program. Many of the physician practices are seeing more lung cancer patients than ever before.

Critical to the program's success was the ability to leverage existing resources. Initially, the NP navigator position was the only position created for the formation of this program. The additional support provided by marketing, radiology centralized scheduling, and the cancer program helped to get the lung cancer program up and running quickly, resulting in positive patient outcomes.

The multidisciplinary approach to care, especially through the formation of pathways, has helped to streamline the lung cancer screening experience for patients. With ongoing data collection and tracking, there is room to build on our current success and search for quality improvement opportunities. OI

Jessica Peckham, MSN, RN, NP-C, PHN, OCN, is a pulmonary oncology nurse navigator with PIH Health Hospital, Whittier, Calif.

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BY KRISTA NELSON, MSW, LCSW, OSW-C

Bridging the Gap

A Family Program for Parents with Cancer and their Children

In 2004 oncology social worker Krista Nelson, MSW, LCSW, OSW-C, and several supportive care colleagues at Providence Cancer Center, Portland, Ore., saw that patients with children were struggling to communicate with their families about their illness and realized that there was no real support available to this hidden population. In response to this patient need, these clinicians developed the Providence Family Program, which uses a group model to deliver early and ongoing intervention and support throughout the cancer care journey. Creating a framework to talk about the impact of cancer on the family, the Providence Family Program offers effective communication techniques and coping strategies, as well as practical tips to help families adjust to their "new normal."

> The Providence Family Program educates parents on how to use developmentally and age-specific information about cancer when talking to their children.

Communication is Key

According to the Institute of Medicine (IOM), 24 percent of parents undergoing cancer treatment have a child 18 years of age or younger at home.[1] Recently, the IOM released a workgroup report about families touched by cancer, and though it focused heavily on pediatric oncology, the report also highlighted the importance of treating the whole family.[2] Research and experience tells us that parents want support and information on how to talk to their family about a diagnosis of cancer.

For example, one day during clinic, as the oncology social worker, I was seeing a patient who'd just found out she had metastatic breast cancer. I asked her to tell me about her treatment plan. The patient replied, "You know what? I actually did not hear any of that. All I could think about was my kids, how I was going to tell them, and if they were going to remember me."

Another patient that I saw was a head and neck cancer patient who was going to have a significant surgery in addition to chemotherapy and radiation, and she wanted advice on how to talk about this treatment regimen with her family.

Some of the most important education we can share with patients diagnosed with cancer is how to talk to their children. I remind these parents that they know their children much better than the treatment team does, offering reassurance that the dread of this conversation is often worse than the actual conversation

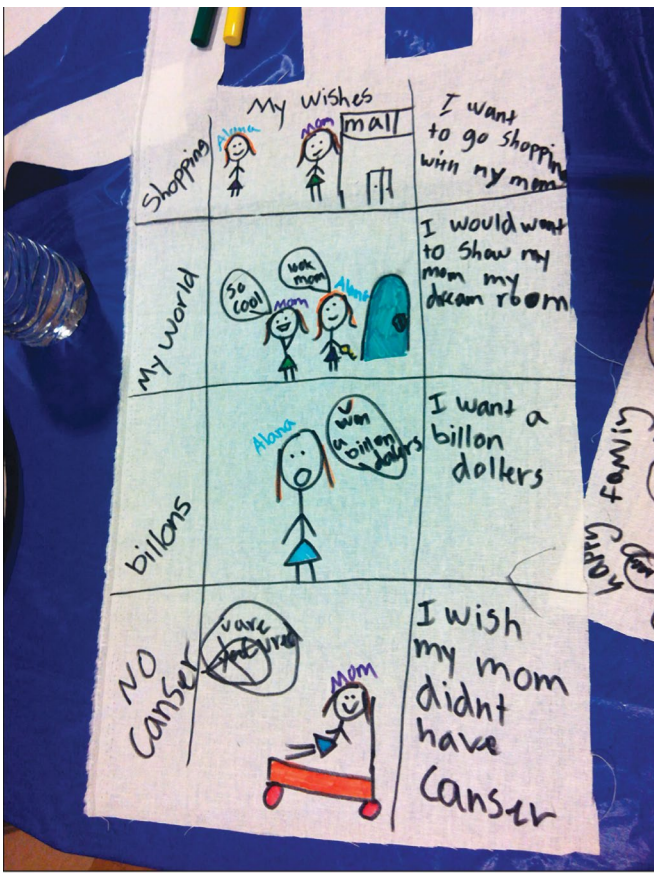
itself. Perhaps the most important message for these parents to hear is that their cancer will most likely not have any long-term negative impact on their child's functioning.

The Providence Family Program educates parents on how to use developmentally and age-specific information about cancer when talking to their children. Our experience has been that parents coming to the hospital with an older child want them to spend less time in the hospital. Younger kids will sit and play at the bottom of the hospital bed all day, but parents tell us they want a "sense of normalcy" for their teenagers.

Many cancer patients tell me that they worry about their children asking if they are going to die. Conversations around mortality are very emotional, and patients express uncertainty about how to answer that question. I advise patients to tell their children what they know, framing the conversation so the children understand that, for example, while the physicians do not think the parent will die right now, they will let the children know if the situation changes. I urge parents to create a legacy of truth with the information they share with their children, encouraging parents to use real words—like cancer and chemotherapy—and to explain what these words mean so that their children understand.

As an oncology social worker, I am just one member of the multidisciplinary cancer care team, and it does not fall to only one staff member to have this conversation. Our supportive care staff reminds other cancer care team members that we *all* support our patients and their families and, as such, any one of us can provide needed resources. Speaking with families in our Providence Family Program, I've heard stories about how children found out about their parent's illness from a third party—sometimes overhearing phone calls or conversations among adults. That is not the optimal way for children to learn this news. Bottom line: as healthcare professionals, we should reach out early and often to our patients about any issues with their children and other family members.

After dream room meditation that focused on creating a safe place, an eight-year-old girl made this flag; her mom has stage IV breast cancer.



Treating the Whole Family

A 2014 literature review article identified three common themes among cancer patients who expressed concerns about the best ways to talk with their children:[3]

1. Parents try hard to maintain normalcy in their children's lives.
2. Parents strive to be good parents and parenting became a priority.
3. Parents are concerned about the emotional impact their cancer has on their children.

The article also states that it is imperative that the cancer care team provide parents with the support and resources they need to feel confident in preparing their children for this change. While we all do our best to provide great care for our patients and families, this literature review article highlighted an opportunity for clinicians to think outside of the box in terms of the services and resources we provide.

So what exactly can members of the cancer care team do? First, identify the patients in your program or practice who have children at home. If you're seeing a patient under the age of 50, you may want to proactively ask about his or her family life. If you don't have the opportunity to speak personally with patients about their children, at least provide patients with community resources and help educate other staff on ways to talk about this topic with patients. Patients and families who seem to be doing well also want support about how to parent through this challenging time. In other words, do not simply focus on your highly-distressed patients; this type of education and support is beneficial to all patients with children still at home. The Providence Family Program supports families as a unit, with the understanding that cancer does not just affect the patient. By supporting the entire family, we hopefully can improve their everyday life.

A photo of Portland's Hawthorne Bridge taken by the author.

Building the Bridge

Today, the Providence Family Program:

- Is free to patients and families in our community
- Accommodates different learning styles and needs
- Uses evidence-based interventions
- Offers peer support
- Includes support around parenting with cancer
- Incorporates art as a modality to communicate about cancer.

The staff that manages and runs the Providence Family Program is a combination of hospital employees and volunteers; it requires about 10 to 11 people to host this monthly event. Most staff are social workers, and volunteers are required to take specialized training. Clinical staff pre-screens all participating families so that we are prepared to support each family and child's needs. If a patient is near death, it may not be appropriate for the family to attend the program, as we do not want to introduce another loss to group members. For these families, our supportive care staff offers monthly telephone support and support groups, which are open and ongoing—anyone can come and go at any time. Each month about 30 percent of Providence Family Program participants are new to the program.

To educate staff about the Providence Family Program, our supportive care team put together a one-page glossy handout, containing tips and education on talking to kids about cancer. View this handout online at: accc-cancer.org/oncology_issues/JA2016. This free handout is available in the hospital and at all clinic locations. We also share it with other healthcare professionals in the community.

One of our challenges is finding space for the program. Currently, the Providence Family Program requires seven different spaces for activities. However, because the hospital is less busy at night, we can use hallways for high-energy play with the younger kids.

About a week before every meeting of the Providence Family Program, we mail out the planned curriculum—including the research that supports the curriculum—to our volunteers. Today the Providence Family Program meets monthly, with anywhere between 20 to 60 attendees. Hosting this group is similar to throwing a big party. We provide dinner (usually pizza) in a family setting, so families can come together and share a meal. Some of our families come from two hours away to participate in the program. After dinner, we divide the participants into three main groups: children, teenagers, and parents. Sometimes we may have two parent groups, depending on the number of attendees. Each group has at least one masters-level trained social worker to lead the group.

Group Structure & Activities

Families are invited to participate in a free meal 30 minutes prior to group, and the group runs about 90 minutes. After a welcome and the meal, we split into age-specific groups. Typically, the children's group begins with a check-in. We sit together on the floor and have each child say who in their family has cancer, what kind of cancer they have, and how they might be feeling. We end

with an ice-breaker. In every group, we try to add a mindfulness piece for the kids, and meditation is a popular activity. After we introduce the themed activity for the night, the children are able to process their feelings and thoughts in the group setting. When the time of sharing is over, we transition to a different room set up with supplies for the designated art project, which connects with the theme (i.e., worry boxes, journals, fear collages).

After the art session, we transform the room into a giant playroom, and it can become chaotic. Many of these children have parents that may die of cancer, so after discussing their fears, they often bring big energy into the playroom. While we have high-energy games, such as dodge ball, we also have areas set up for quiet play.

After playtime, staff leads a calming activity, such as centering of breath or meditation exercises. Our closing ritual in each age-specific group room is that participants receive a ceramic heart, which they use to make a wish (either aloud or to themselves) for the month.

The Providence Family Program's group structure is not conducive for children under five years of age. Based on past experience, we have found that, in order for children to participate in a meaningful way, they must be able to sit in a circle without their parent. We support our families with younger children by referring them to therapists in the community.

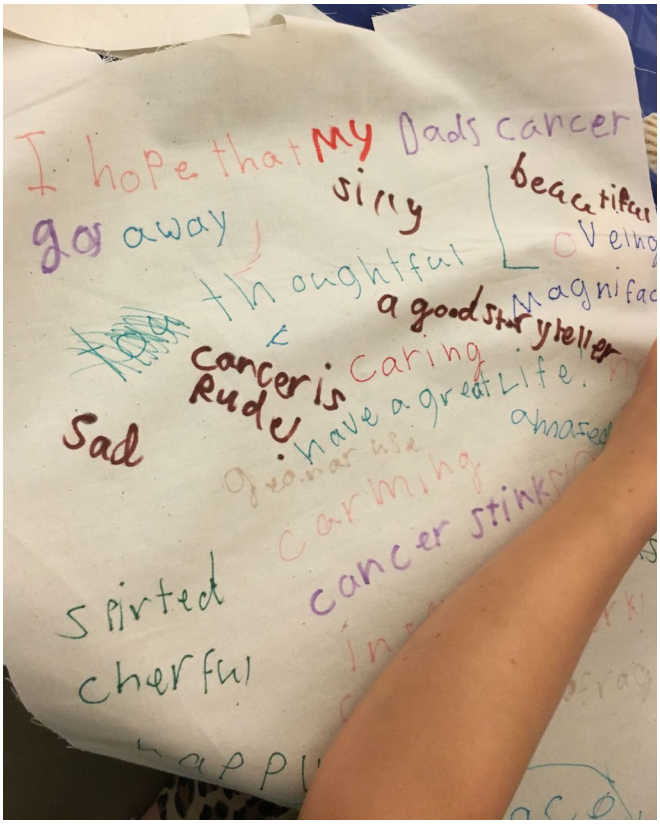
The teenage group focuses on the same themes and activities, but the environment is such that they can listen to music, talk to each other and group leaders, and enjoy extra pizza.

While the adult group follows a similar structure as far as activities, it is very different because—although this group can become like a support group—we make a concerted effort to keep the focus on the children. Some of the topics discussed include:

- How can the cancer program support your kids?
- How do you parent with cancer?
- What are some of your children's strengths and weaknesses?
- What issues are you struggling with as a parent with cancer?

There is ritual built into the monthly meetings of the Providence Family Program. At the end of the group, we bring the families together around a central fountain in our cancer center. Using art as the identifier, we ask the kids to share what they made, what they were feeling as they worked, and how these feelings relate to their parents' cancer. We end the night with a "secret squeeze," which is the participants and staff holding hands and passing a hand squeeze around the fountain. One of the children is chosen to be the "secret squeezer," and we all cheer when the squeeze makes it around the circle.

A seven-year-old child decorated this flag while attending the Providence Family Program with a dad who has stage IV colon cancer.



Communicating Through Art

Art is the bridge that connects the families with their feelings, opens lines of communication, encourages coping, and helps participants share with one another and within their family. The monthly Providence Family Program meeting may be the only opportunity these families have to talk about their feelings. Many parents have told us, "The only time we talk about cancer is on the way to family group and on the way home from family group when we are sharing our art projects."

Although the Providence Family Program does not have art therapists, we did consult an art therapist during program development. Our oncology social workers have found that the art projects help them communicate to the kids, which in turn helps the children to communicate with their parents. Art projects, such as masks, fear collages, and plates, are taken home by families at the conclusion of each meeting.

We sometimes tailor art projects to the different seasons. For example, in October, we typically make paper mache masks, asking children and parents to paint the inside with their feelings about cancer, how they cope with cancer, and what emotions they keep bottled inside. Participants decorate the outside of the mask based on how they perceive cancer in their world and how they are coping with the world at large.

Within our community, hospice social worker colleagues have shared stories of going into the homes of parents near the end of their life and seeing art from the Providence Family Program displayed on shelves and walls. Families often talk about how meaningful this art is to them and how it bridges communication.

A mom with stage IV colon cancer creates a flag that communicates her hopes for herself and her family.

The Nuts & Bolts of the Program

The Providence Family Program is free to our community; participants do not have to receive treatment at Providence Cancer Center. The program receives referrals from physicians, nurses, other social workers in the community, or families who know someone with cancer. For our team, the question: "How do I tell my children that I have cancer?" triggers a referral to the Providence Family Program. We have a conversation with the patient about how to talk about death and perform an assessment to learn more about their children. We ask, "Is there anything you think I should know about your child that would help them succeed or be more comfortable in our group?" The first time the family attends the program, we have them complete a consent form.

We know that children do better, in general, if they have some rituals in their life, such as sharing a meal with family. Accordingly, one of our art projects was for children to use a non-toxic paint to decorate the back of a plate with an activity they hoped to do with their parents or a favorite celebration. The bridging activity comes when children then take the plate home and use it during a shared meal.

It is important to have a variety of play available for the younger children. For example, we have a quiet space, dollhouses, board games, art supplies, and dress-up materials.

Two or three times a year, we keep the family together as a unit and do an activity together. Some past family activities have been a drum circle, memory books, candles, wish flags, or making a coat of arms around a family picture taken that evening.

One year we provided "coping backpacks" before the school year started. Our staff filled the backpacks with iTunes gift cards, stress balls, journals, activity books, tissues, and healthy snacks. The kids decorated the outside of the backpacks and encouraged parents to write letters to their children to include inside.

Fear collages are always a powerful activity. The kids populate collages with moving images that represent their fears about cancer. While this activity can be difficult and emotional for parents to hear, these fears may not have been discussed before, and this activity creates an opportunity for children to share.

The annual budget for the Providence Family Program is modest. Food costs for the program range between $200 to $300 a month; art supplies generally run about $300 a month. Not including staff time, the Providence Family Program costs between $6,000 and $7,500 annually. Our medical foundation has helped us partner with community groups to help fund and support this program. We've even had children who've known someone who has been a part of the group raise money for the Providence Family Program because they understood how important the group was to their friend.

The Providence Family Program is available year round. Since the program has grown in popularity, we've made the informal

decision that families no longer dealing with cancer (about two years post-treatment) would no longer benefit from the program. The majority of families opt out of the program on their own. In the rare occurrence when a family is still attending two years post-treatment, we suggest other activities, such as volunteering in the community.

Patient Feedback

Since launching the program in 2004, we have collected some quality outcomes research. Almost all (95 percent) of our families felt their children benefited from being around another child who had a parent with cancer. Other questions we asked Providence Family Program participants:

- Do you feel the art activities we do in the Providence Family Program help your family talk about their feelings about cancer? (84 percent answered yes; 5 percent were unsure.)
- Do you feel like participating in the Providence Family Program increased your family's communication about cancer? (68 percent answered yes; 20 percent were unsure.)
- Has the Providence Family Program changed the way you communicate as a family? (68 percent answered yes; 20 percent were unsure.)
- Has the Providence Family Program reduced your children's anxiety about the cancer? (68 percent answered yes; 20 percent were unsure.)

Overall, 63 percent of respondents felt that participating in the Providence Family Program helped bring them closer together as a family. The box at right showcases first-person testimonials about the program.

Going Forward

For the past 11 years, the Providence Family Program's main themes have been communication, feelings, and coping. As we begin to expand and update our meeting curriculum, we frame those themes into our discussions:

- What are we trying to be thoughtful about?
- What does the research tell us about how kids cope?
- How can we support these children and families?
- How can we integrate the use of creative modalities into our support?

When first developing the program, we assumed most of our parents would be women with early-stage breast cancer; however, about 70 percent of the parents that attend the Providence Family Program have advanced cancer. Since the majority of participants are patients with advanced-stage cancer, many do die. After a parent dies, the family does not come back to the Providence Family Program. Instead, we refer these families to bereavement support services in the community. That said, the Providence Family Program does honor the children of deceased parents by asking the participants in the next group to make wishes on a ceramic heart. This heart is then mailed with a bereavement packet to the families, which includes literature on how to support children when a parent dies, community bereavement resources for children and adults, and a note from the team.

Today, with the emphasis on patient-centered care, some cancer centers are looking to develop these types of programs and services. The model we used to develop the Providence Family Program is easily replicable and is, in fact, featured in the *Handbook of Oncology Social Work: Psychosocial Care for People with Cancer*, a compilation of successful evidence-based interventions.[4] OI

Krista Nelson, MSW, LCSW, OSW-C, is an oncology social worker and program manager of quality and research, cancer support services, Providence Cancer Center, Portland, Ore.

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In Their Own Words

"It [the Providence Family Program] is such an incredible and helpful place to be. Cancer is so confusing, as are all the repercussions of cancer on the family. The support and love we receive in this group allows us to find safety and love in very challenging times."

"There is a grief in not being able to control cancer, and the damage it does to everyone. You guys give us renewed hope in this group. Thank you from the bottom of our hearts."

"We were hesitant to come [to the Providence Family Program], but it was the best place for my kids. They loved seeing other kids their age going through the same thing."

"The only thing that would make the group [the Providence Family Program] better is if the group was to meet more often."

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Start Small, Think Big!

Fusing Clinical & Business Metrics to Improve Quality & Effect Change

BY MELISSA CRONN AND LORRI SMITH, RN, BSN

Words such as "tranquility," "serenity," and "calm" are not often associated with our current healthcare environment. In reality, we work in a complex, multi-faceted, and constantly changing oncology landscape. Providers face new challenges to treating patients every day. Further, we must constantly take a hard look at the business of providing care and—using the data we collect on a daily basis—identify how we can improve to deliver better care to our patients. In 2010 Alliance Oncology, the managing member of Austin CyberKnife, initiated a process improvement project to better leverage data collection and improve care delivery.

As the healthcare payment landscape shifts from volume-based to value-based reimbursement, healthcare facilities need to look inward at their business performance to understand how to improve and adapt to this change.

Mining Your Data

Part of the Seton Healthcare Family of Hospitals in Texas, Austin CyberKnife at University Medical Center Brackenridge is a radiosurgery program that partners with Alliance Oncology at Seton Healthcare on its operations and management. Austin CyberKnife is based in Austin, Tex., and provides radiation services to a large catchment area in the state.

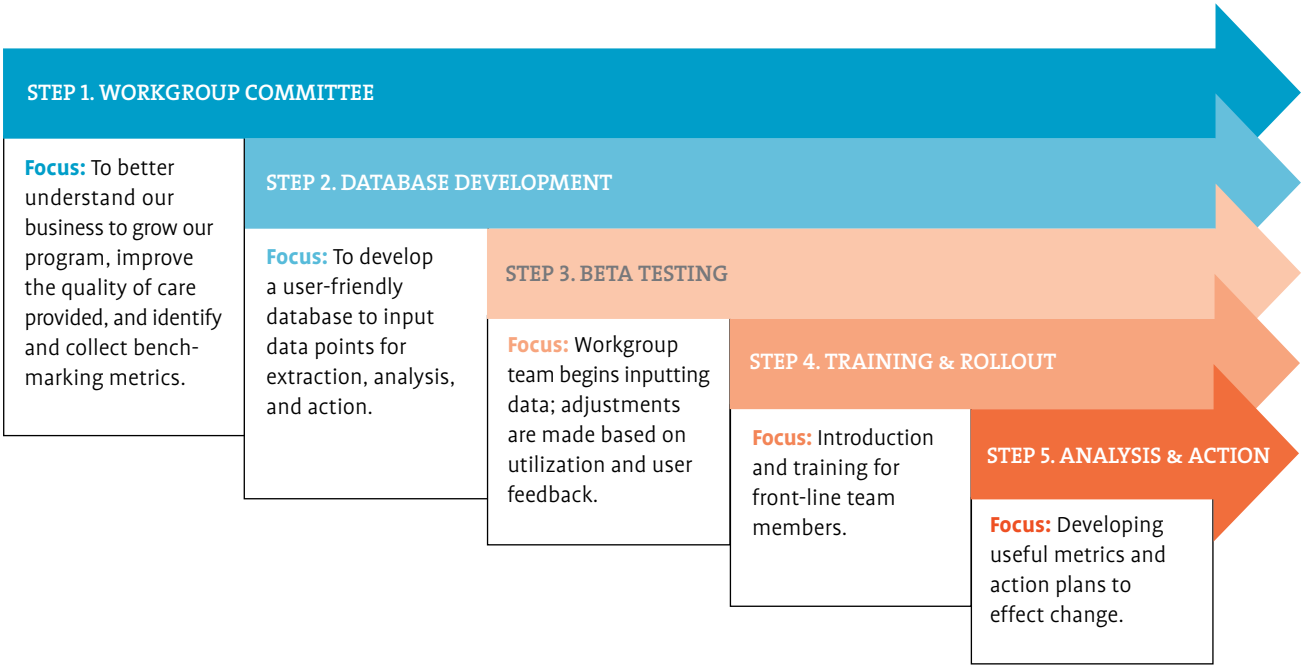
When healthcare facilities set out to better understand their business of providing patient care, they look to their data. At Austin CyberKnife, we knew we had a trove of information in our data, but how could we use it to improve patient care? We began by taking a step back to understand where our data comes from.

Similar to many other healthcare facilities, our data and metrics come from a variety of sources, including multiple EHRs (electronic health records) and paper chart data that comes in from some of our smaller referring clinics. We had to learn how to take data from these disparate systems, aggregate, and mold it to ensure a true "apples to apples" comparison as we began our performance improvement project.

Next we had to identify the quality improvement benchmarks that would most benefit our patients. On the clinical side, we looked to streamline workflow and improve patient throughput. Decreasing wait time between simulation and first treatment, for example, would not only lead to improved outcomes but also help ease the anxiety of our radiation oncology patients.

We were also looking to enhance collaboration and communication among the cancer care team. For example, while our

Figure 1. Our Performance Improvement Planning Process



radiosurgery program is based in Austin, some of our patients travel for several hours to receive treatment at our program. So how do we ensure good communication and collaborative decision making with the other providers caring for these patients?

In addition to our efforts to improve patient care, we also wanted to use our data to better understand our business practices. As the healthcare payment landscape shifts from volume-based to value-based reimbursement, healthcare facilities need to look inward at their business performance to understand how to improve and adapt to this change.

Getting Started

Our process improvement initiative began with the creation of a workgroup to help develop a single repository for the data coming in from the different EHRs and paper charts. Since data affects the work of every staff member, we included stakeholders from each practice area in this workgroup: business development staff, clinical staff, physician services representatives, and IT support. A variety of perspectives is essential since each team has a different way of viewing and using data.

In addition to housing patient information, we wanted a database that could be used:

- By the marketing team in community outreach efforts
- By our physicians to connect with other members of the cancer care team and referring physicians
- To manage incoming referrals
- To track patients treated and then be able to feed back outcomes data to treating and referring physicians.

During the initial brainstorming sessions, some key questions helped guide our discussions:

- What did we want to know from our data?
- What would help us do our jobs better?
- What would help us provide better care to our patients?
- What would help us communicate better with our patients' different care teams?

Workgroup members took these core questions back to their teams; their answers served as our starting point for our process improvement efforts.

Speaking the Same Language

Once the technical framework for the database was completed, we needed to beta test our database. We started at one Alliance

Oncology site and then began rolling out the test to other Alliance Oncology sites, including Austin CyberKnife. At each site, we noted how patient throughput differed, and how those differences affected the way the database was used, how information was coming into the database, and ultimately, how information was coming out of the database.

As with EHRs, the information you put into a database affects what you are able to retrieve from the database. To ensure correct input of data at the front end, the workgroup established common definitions. During this process, we realized that the same language was not always being spoken between different departments and sites of service—and sometimes even within clinical teams. For example, the time frame for treatment plan approval varied by site. One Alliance Oncology site marked a treatment plan as approved when the surgeon signed off; others defined the treatment plan as approved when the radiation oncologist signed off. In the end, the workgroup established a specific definition and benchmark for each piece of data. While this process can be painstaking, developing common definitions across your database can help eliminate confusion across clinical, billing, and marketing teams.

Narrowing Our Focus

Another obstacle our workgroup faced was the massive amount of data available. After narrowing our definitions to retrieve accurate metrics, the workgroup had to decide how to most effectively focus the data to effect improvement. The workgroup began by identifying the metrics that were most important for our program to measure. When we started, the workgroup wanted *everything*. Starting so big and then having to narrow our focus meant that it took a longer time to get our database into shape. Once the workgroup focused on one or two improvements, it began to make real progress.

And these successes highlighted the value that comes from data measurement. For example, when we were able to decrease time from simulation to treatment from 10 days to 6 days, we saw a corresponding increase in patient satisfaction. Staff members were motivated because they contributed to streamlining patient throughput.

This type of benchmarking can also result in business growth and long-term value. As our program anticipates more clinical benchmarking and a pay-for-performance shift, we can use our data to evolve and meet these changes.

Another initiative identified by the workgroup during its data mining was improving physician outreach to the community. Prior to this process improvement initiative, we tracked incoming referrals by noting the location of the referring physician's primary practice. We did not look at where our patients were coming from, and in a state like Texas you have patients living in very rural areas.

Based on 2013 data, the majority of our patients lived within a 25-mile radius. Accordingly, we saw an opportunity to grow our market share. Working with our physicians and our physician service representatives, we developed a strategic plan. Our physicians went out into the surrounding rural communities to attend community events and describe the care services and treatment options we offered. Measuring our results over 2014, we saw a 12 percent revenue growth in our market share, and a 55 percent increase in patients coming from 50 miles or more for our program. While this improvement was exciting from a revenue standpoint, the enhanced teamwork between our physicians and our physician service representatives was also beneficial.

> Staff recognition that their actions could improve the effectiveness of how the physician works was probably the number one factor that improved our simulation-to-first-treatment time.

Improving Time from Simulation to Treatment

From a clinical standpoint, one of the main goals of our performance improvement project was to decrease the time from simulation to first treatment. The top Alliance Oncology outlier site, Austin CyberKnife took, 12 days from simulation to treatment, so our Austin CyberKnife team set a goal to decrease this time by 20 percent.

Administration motivated the care team by showing them the data. When some providers questioned the data, we showed them how we retrieved it and where it came from. This team of caregivers wanted to provide high quality care, and when staff saw data that revealed their site was the outlier, they were not happy. Each member of the team looked at this metric and asked, "What can I do individually to help improve the time to treatment?"

Our group works with almost every neurosurgeon in Austin, and these physicians are spread across the entire county. Accordingly, the surgeons do a lot of remote planning of their patients—from their offices 50 miles away—and then go back and forth on their renditions. To help these surgeons expedite their work, we developed a tool that addressed common process questions. This tool most benefited our physicists who fielded the majority of surgeon phone calls regarding process questions.

Scheduling strategy was another important piece to streamlining patient throughput. Our physicians rotate through our practice—one radiation oncologist on Monday, another one on Tuesday, and so on—so we had to take that information into account when scheduling patients for simulation consults. In other words, staff had to complete their tasks before the physician came in on his or her scheduled day to see patients or a patient would have to wait a full week for the next appointment. Staff recognition that their actions could improve the effectiveness of how the physician works was probably the number one factor that improved our simulation-to-first-treatment time.

Culture change was also key to the performance improvement initiative. It can be easy to write off a longer simulation to treatment time by saying, "It's just the way my doctors work." But physicians and nurses are scientists, and when we showed them the science behind reducing our simulation to treatment time, buy-in was obtained fairly quickly.

Even with the improvements achieved, we are constantly tweaking our process. For example, two physicists voiced concerns about the beginning point of the simulation to treatment metric. The physicists felt they did not have control from the beginning of the simulation because patients may need additional imaging. They requested the measurement begin from the time all necessary treatment planning imaging is complete to first treatment because it was a more realistic measurable time frame.

Six months into this performance improvement initiative, we were able to decrease time from simulation to first treatment by 29.9 percent at Austin CyberKnife.

Lessons Learned

Our advice to other cancer programs looking to conduct similar process improvements project is to start small and empower your staff because they're the ones that touch the patients every day. Challenges may arise, but they can often be overcome if you document and share the improvements realized with your busy staff.

We get so caught up by excessive—and often overly burdensome—healthcare documentation, writing it down and making certain it is done and done right, that sometimes we have to stop, step back, and say, "What was the simple process I was trying to do, and how can I help the patient through the process?" Using your data, plan for attainable goals that will help you grow your program and improve your patient care. Start small, but think big! OI

Melissa Cronn is administrator, Seton Cancer Program, Seton Healthcare Family of Hospitals, and Lorri Smith, RN, BSN, is director, Clinical Services, Alliance Oncology, Austin, Tex.

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BY PATRICIA INAMA RODA, MSN, BS, RN,
AND JAIME FRITCHMAN, BS

A Community Comes Together to Help Patients with Cancer

A cancer diagnosis is a life-altering event that can result in significant financial hardship. Patients are often underinsured, uninsured, have high deductibles, or are unable to work during treatment. For clinicians, financial challenges are understandably an area of distress that we want to minimize for our patients. In 2009 the Ann B. Barshinger Cancer Institute, Lancaster, Pa., part of the Lancaster General Health system, partnered with the Lancaster General Health Foundation to launch a fund to provide financial support for needy patients. The funding program has evolved over the past four years to include other revenue sources and guidelines to ensure consistent execution and evaluation.

The Lancaster General Health Foundation

The Lancaster General Health Foundation is a private, non-profit foundation dedicated to supporting excellence in patient care across the Lancaster General Health system. It has raised more than $80 million to support health system priorities, including $25.2 million for the campaign to build the Cancer Institute. Fundraising for the oncology service line that supports patient care, equipment and technology needs, staff education, and research remains a continued priority for the Foundation.

The Foundation, working with the oncology leadership, develops donor opportunities to support patients receiving care. In addition to providing patient financial support, program development for survivorship services is seen as an opportunity for growth and development for the Institute. The community has responded generously. The Foundation has one fund that is devoted solely to supporting the financial needs of patients receiving treatment at the Cancer Institute: the Cancer Patient Support Fund.

> Staff listens for key words or comments, such as concern about being able to work during treatment, fear of losing insurance, concerns about the cost of drugs, and questions about what services are covered by insurance, and we often uncover financial problems after treatment begins.

Wraparound Services

As the Ann B. Barshinger Cancer Institute prepared for the opening of its new facility in 2013, leadership felt that a plan for wraparound services was imperative. Specifically, cancer program

leadership outlined the support services necessary to assist patients throughout the disease trajectory. Social work, genetic and behavioral counseling, nurse navigation, and financial counseling were identified as needs, and a staffing plan was developed. By opening day, the oncology financial counselor was ready to provide comprehensive assistance to patients. Over the past two years supportive service positions grew to match our growing patient volume; with this growth came additional patients who needed financial assistance.

From the day the Cancer Institute opened, leadership recognized that the two biggest barriers facing our patients were emotional distress and financial concerns. Thus, many of our patients receive referrals to the oncology financial counselor. Patients who may benefit from such a referral are identified at several touch points, including:

- Upon entry to our healthcare system during distress screenings
- From conversations with patients at the registration desk
- By providers during office visits.

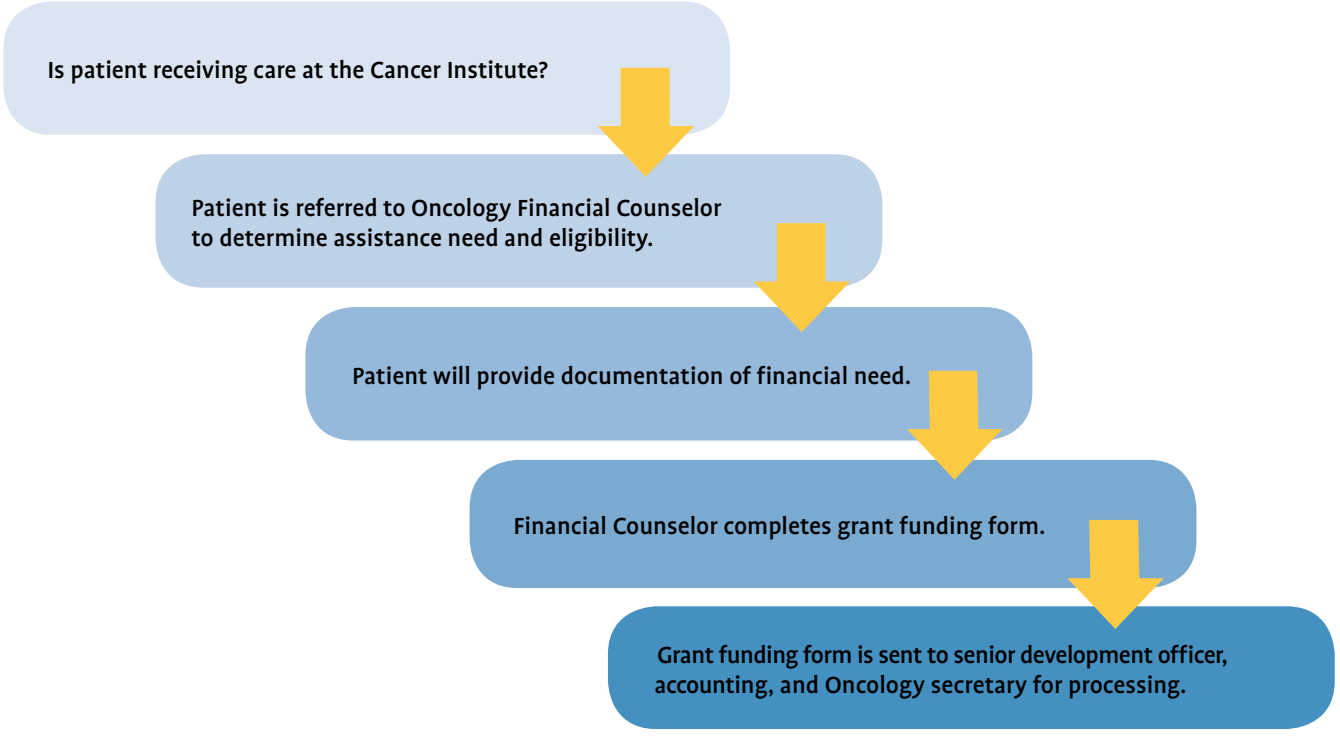
Staff listens for key words or comments, such as concern about being able to work during treatment, fear of losing insurance, cost of drugs, and questions about what services are covered by insurance, and we often uncover financial problems after treatment begins. At every encounter, staff goes out of its way to treat patients with great sensitivity and respect—we've found that many of these individuals have never previously had to ask for financial assistance.

The Importance of the Oncology Financial Counselor

Daily, these professionals counsel patients experiencing financial distress and personal hardship as a result of the cost of their cancer treatment, including challenges paying for everyday necessities. Some patients even file for bankruptcy or are at constant risk of losing their home due to medical debt. According to the Fred Hutchinson Cancer Research Center, patients with cancer are 2.5 times more likely to declare bankruptcy than people without cancer.[1]

At the Ann B. Barshinger Cancer Institute, we provide one-on-one financial counseling to patients, addressing their financial concerns and helping them complete applications for assistance programs. The oncology financial counselor also manages and screens patients for the multiple grants provided by the Lancaster General Health Foundation's Cancer Patient Support Fund. These grants help patients with gap funding, disease screening costs, and/or assistance with over-the-counter medications. Funds are distributed to patients who are deemed low income and who meet our medical and financial guidelines.

Figure 1. Grant Process



Cancer Patient Support Guidelines & Application Process

To ensure a consistent application process for the Cancer Patient Support Fund, the Cancer Institute developed and implemented guidelines for cancer patients. To be eligible for a grant, patients must:

- Have a cancer diagnosis
- Be under the care of a Cancer Institute provider
- Comply with treatment plan and appointments
- Have an annual income within 250 percent of the federal poverty guidelines.

When patients apply for a grant, they must submit a bill for payment; the oncology financial counselor then completes the needed forms: a funding request form and a check request. On average, the check request process takes two weeks.

To avoid fraud, checks are made out directly to the vendor of service. Once these forms are completed, they are submitted to the Foundation for an approval signature. After securing necessary signatures, the form is sent to the accounting department for processing. A tracking spreadsheet documents the date, patient information, bill amount, and type of bill paid. To ensure data accuracy and privacy, this spreadsheet is accessible by only a few employees.

A color coding process helps signal if patients are approaching the annual maximum dollar amount for assistance, which is $500 per fund. Currently the Cancer Patient Support Fund has seven separate funds, some targeted for a specific disease site, such as breast cancer. In individual cases, additional funds can be allocated by the financial counselor with supervisory approval. These steps make the application process smooth, concise, equitable, and error proof (Figure 1, left).

After the patient's bill is submitted for processing, the oncology financial counselor sends patients a letter and a card that identifies the fund that paid their bill. A cover letter is included along with the card. This is done because many patients thought that the hospital provided the financial support, and it was important for them to know that their generous community provided the funding dollars.

Building Community Awareness & Relationships

Due to ever-increasing funding needs, it is vital to maintain the donor revenue stream, which is accomplished in many ways. Within our community, the Cancer Institute works to build relationships and heighten the awareness of community stakeholders. Donations can be big or small—all are welcome. Frequently, patients and/or families want to give back to the Cancer Institute, or pay it forward. Here is a list of activities that we engage in to build and increase awareness:

- ***Building tours,*** which highlight the Cancer Institute's unique design and care delivery model.
- ***Formal funding check presentations,*** which recognize group or individual donors. We take pictures and post them on the Foundation website.
- ***Presentation of "Mission Moments"*** where meaningful stories are shared at various meetings to reinforce the significant financial needs of patients.
- ***Development Committee activities.*** The purpose of this com-

THE ANN B. BARSHINGER CANCER INSTITUTE AT-A-GLANCE

Opened in July 2013, the Ann B. Barshinger Cancer Institute was built to serve its community—specifically, so families did not have to travel outside of their community to receive oncology care. The Cancer Institute provides access to advanced medical treatments, the newest technologies, and a multispecialty network of clinicians who work together to ensure that patients receive the most effective treatment plan for the best possible outcome. The state-of-the-art facility offers its community skilled and compassionate treatment teams who coordinate care and support recovery, including one convenient location for medical care, support services, and wellness and survivorship programs. Personalized care is focused on the mind, body, and spiritual well-being of our patients; the environment is designed around patient comfort. The Cancer Institute's mission: to reduce the burden of suffering due to cancer in the communities we serve.

Our top cancer sites are breast, lung, and colon, with 2,047 analytic cases for 2014. We serve the Lancaster County community—a population of 529,000 and the city of Lancaster with approximately 60,000 residents. Both have very diverse needs; a thriving city surrounded by a more traditional farming community, including a large Amish population. The city of Lancaster is located in southeastern section of Pennsylvania, approximately 90 minutes west of Philadelphia.

mittee is to advance the fundraising priorities at the Cancer Institute. The committee works closely with the Lancaster General Health Foundation staff and Board of Trustees and Cancer Institute leadership to build sustainable fundraising programs for the oncology service line.

- ***Sharing patient feedback with donors.*** Emails and letters of thanks from patients are shared with donors. Some patients attend donor events and provide a short explanation of how money from the Cancer Patient Support Fund helped them during their treatment. When patients are willing to do this, it reinforces the importance of continued fundraising.
- ***Hosting survivorship activities.*** Patients feel strongly about the impact these programs have to help them transition back to a new norm after treatment.
- ***Attending local community events.*** Staff provides support at local events to highlight awareness and fundraising for donor events, serving at registration or participating in fundraising events.
- ***Recognizing "Healthcare Heroes."*** This method for recognizing providers or staff comes in the form of a card, which is filled out by patients; patients can also make a donation. The staff or provider receives a healthcare hero pin and a copy of the card.
- ***Sending thank you notes.*** These personal handwritten notes are sent to donors, thanking them for their donation(s).

Making a Difference

Over the past three years, the Cancer Institute has built a successful financial assistance program in terms of dollars raised and the number of patients served. Yet, we continue to identify additional funding opportunities to deliver ongoing financial assistance.

In the last three years, the Cancer Patient Support Fund has paid out nearly $85,000 in funds to more than 200 cancer patients.

During FY 2015 the Cancer Institute held an inaugural event, The Gingham Gala, to raise funds specifically for the Cancer Patient Support Fund. This money is for any cancer patient and is not disease-site specific. The gala raised more than $82,000. This event was so successful that the Cancer Institute hosted it again this year on May 21, raising $112,000 for the fund.

Patient & Family Satisfaction

The Cancer Institute's Cancer Patient Support Fund is a financial safety net for many patients, and patients and families express tremendous appreciation for this support through heartfelt letters, words of thanks, and by giving back once they are able.

In the words of one of our patients, "What a gift for so many people that traveling to other cities is no longer necessary. What a gift for so many people to be able to stay at home around family and friends. What a gift for so many of us to be able to conserve our energy to improve our treatments and health by being treated at the Cancer Institute. If it were not for the community who has given so generously to support patients and programs, there would be many people who would struggle. The Cancer Institute is a magnificent facility with the most caring and devoted people I have ever met." OI

Patricia Inama Roda, MSN, BS, RN, oncology clinical support manager, and Jaime Fritchman, BS, oncology business office manager at the Ann B. Barshinger Cancer Institute, Lancaster, Pa.

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2015 FAN Learning Labs

Practical strategies for improving your financial advocacy services

FINANCIAL ADVOCACY NETWORK (FAN)

Resources & Tools for the Multidisciplinary Team

Cancer patients frequently experience financial burden and distress because of the high out-of-pocket costs associated with their treatments, the indirect and non-medical costs related to medical care, and the potential for lost income or employment while undergoing treatment. Studies have demonstrated that one out of every six cancer patients with high out-of-pocket costs will abandon their medication.[1] The cutoff for "high" appears to be approximately $200; patients with an out-of-pocket cost greater than $200 are at least three times more likely to not refill prescriptions than those with out-of-pocket costs of $100 or less. Cancer patients are also at greater risk for bankruptcy, especially given that cancer is the highest costing medical diagnosis with mean out-of-pocket costs exceeding $35,000.[2] Moreover, financial distress directly impacts overall suffering and quality of life among patients with advanced cancer.[3]

BY JOSEPH KIM, MD, MPH

The ACCC Financial Advocacy Network

ACCC established the Financial Advocacy Network (FAN) in 2011 to help community cancer programs implement and grow their financial advocacy and financial navigation services. To do so, FAN developed a robust array of tools, resources, and networking opportunities. In 2015 ACCC conducted a membership survey to better understand the needs around financial advocacy in the community setting. Based on these survey results, ACCC hosted a series of FAN regional case-based workshops and conducted several on-site FAN Learning Labs for Process Improvements at member cancer programs. Here are the results of those learning labs.

FAN Learning Labs for Process Improvements

Drawing on findings from the membership survey, the FAN Advisory Committee identified three ACCC-member programs to participate in a two-hour on-site learning lab with their financial advocate team to discuss their current financial navigation processes and key opportunities for improvement. Workshop participants included cancer program administrators, senior executive leaders, nurses, patient navigators, financial advocates, social workers, and other members of the multidisciplinary cancer care team. The goal of the workshop: to help these programs develop improvement plans to address identified gaps and barriers and implement meaningful changes that will lead to measurable quality and process improvements in the delivery of their financial navigation services. The 2015 FAN Learning Lab participants were:

- AnMed Health Cancer Center, Anderson, S.C.
- Eastern Maine Medical Center Cancer Care, Brewer, Maine
- Virginia Cancer Institute, Henrico, Va.

During the workshop, attendees received practical education intervention, reviewed real-world case studies, shared effective practices and identified opportunities for ideas for process improvements, and explored how to proceed with implementing some of those changes. Learning lab attendees were also introduced to the Plan–Do–Study–Act (PDSA) cycle for improvement. At the conclusion of each workshop, attendees were asked to schedule a follow-up meeting to discuss and prioritize areas for improvements and corresponding action items. Accordingly, each cancer program held a follow-up meeting to outline two to three improvement plans. Programs then applied the PDSA cycle for improvement to develop specific action items, agree on progress metrics, and document the changes over a six-month period. Below are strategies from these improvement plans, including practical suggestions for cancer programs looking to grow their financial advocacy and financial navigation services. Access the PDSA Worksheet and user instructions online at: ihi.org/resources/pages/tools/plandostudyactworksheet.aspx.

Strategy 1. Proactively Identify Underinsured New Patients

Many cancer patients have health insurance, but they may be underinsured based on their financial circumstances and the types of services and care they will need. Some cancer programs lack an efficient process for identifying underinsured patients who may be eligible to optimize their insurance coverage and avoid significant financial distress.

The FAN Learning Lab participants agreed that they needed to be more proactive in identifying all underinsured cancer patients. Many cancer programs do not have a comprehensive, structured process to assess whether new patients are underinsured. Learning Lab participants agreed that they wanted to build an effective process to screen 100 percent of all new patients. Some even committed to performing the necessary calculations based on the Commonwealth Fund definition (see box on page 60) in order to accurately identify patients who meet the criteria for being underinsured. Those programs that developed education resources for patients used these tools to explain the rationale and benefit of modifying insurance coverage or purchasing supplemental coverage.

Practical Suggestions for Improvement

- Assign an individual to review information on all new patients who lack any form of secondary insurance or supplemental coverage. Patients who meet that initial criteria

can be assigned to a financial advocate who reviews the patient's chart and discusses optimal health insurance coverage options with the patient. Financial advocates may also identify documentation errors (outdated or inaccurate insurance information) and use these opportunities to update or correct the patient's insurance information.

- Assign an individual to review information on all patients who have a diagnosis of metastatic disease and are actively working. Patients with advanced cancer may lose their ability to work and some may have unrealistic expectations about their ability to work while undergoing cancer treatment. These patients may not be aware of the different types of resources available to assist them under these circumstances; financial advocates must be prepared to guide patients through the process of finding these resources and filling out the necessary applications.

Strategy 2. Conduct Ongoing Screening for Financial Toxicity

Cancer patients receiving chemotherapy are routinely monitored for signs and symptoms of treatment-related toxicities. However, cancer patients are often not continuously screened for financial toxicity. "Financial toxicity" is a relatively new term in oncology, but due to the economic burden of cancer, the phrase is gaining widespread recognition. Researchers have found that cancer patients often experience major financial fallout primarily driven by medical bills and high out-of-pocket treatment costs. Identifying patients who are at high-risk for financial toxicity can be accomplished through continuous screening processes, but many cancer programs only assess patients at the start of treatment and not throughout the continuum of care.

One cancer program that participated in the Learning Labs agreed that it would be important to incorporate ongoing screening "checkpoints" for patients who are receiving active treatment. Financial advocates can schedule follow-up meetings by reviewing patient appointments and making time for periodic assessments. An electronic patient scheduling tool can send reminders to financial advocates about patient appointments and a tracking tool can help financial advocates monitor how often they meet with each patient.

Another Learning Lab participant discovered an opportunity to engage with breast cancer patients at a weekly consortium meeting. This cancer program was able to have conversations with patients who were in different stages of their treatment plans, which often included surgery, radiation, and chemotherapy. Financial advocates identified one to two patients each week from this meeting and spent time with these patients assessing financial distress and discussing possible resources and assistance programs.

Practical Suggestions for Improvement

- Re-assess how often patients are being screened for financial toxicity. Starting with an initial financial screening assessment at the first visit provides some baseline information about the patient. Then, repeat screening after the patient has been receiving treatment for two to three months. Some financial advocates schedule the first follow-up phone call when patients receive their first medical bill.
- Optimally, financial toxicity screening should be ongoing as patients continue to receive care.
- If paper-based screening forms are used, consider ways of incorporating the information into the electronic health record (EHR).
- Consider developing or modifying the financial (or psychosocial) screening forms to include questions beyond simple yes/no questions. For example, asking, "Do you need financial assistance?" may not be sensitive enough to identify patients who are experiencing mild financial toxicity. Consider changing yes/no responses to a five-point rating scale.
- Researchers at the University of Chicago have developed a financial toxicity patient-reported outcome tool called the comprehensive score for financial toxicity (COST) measure. This 11-part questionnaire is designed to assess the risk for financial distress due to the high cost of treatment. Patients are asked to indicate their agreement with a statement like, "I worry about the financial problems I will have in the future as a result of my illness or treatment" using a five-point rating scale: not at all, a little bit, somewhat, quite a bit, and very much. Learn more and download the COST tool online at: accc-cancer.org/oncology_issues/JA2016.

Strategy 3. Reassign Roles & Responsibilities

The evolving role of financial advocates is driving cancer programs to reassess titles, roles, and responsibilities across members of their financial advocacy team. Some cancer programs use titles like financial navigator, financial counselor, or financial advocate. Other cancer programs may have dedicated financial consultants or financial specialists who work closely with social workers and billing specialists. Given the lack of uniformity of titles and team structures across various cancer programs, it remains important to clearly outline and define the roles and responsibilities that will be assigned to each member of the financial advocacy team.

One of the cancer programs that participated in the FAN Learning Labs had been discussing ways to reassign certain roles among their team of financial counselors to maximize efficiencies across the various tasks that are being performed. Prior to the

Learning Lab, this program had a team of patient financial counselors who were each responsible for:

1. Insurance benefit verification
2. Pre-authorizations
3. Meeting with patients to identify assistance programs
4. Filling out applications for assistance programs.

Each financial counselor was spending time across all four areas and these individuals worked in multiple locations. The cancer program decided to pilot the idea of reassigning the four key duties listed above. One group of financial counselors only performed benefit verification and pre- authorizations; the second group of financial counselors focused on spending time with patients to identify assistance programs and filling out the necessary applications. After making this change, financial counselors were more effective and efficient in their respective areas of expertise. This model also allowed their financial counselors to more accurately track the number of patients who were enrolled in assistance programs. Moreover, this cancer program found that more patients were successfully enrolling in assistance programs, so it expanded this team model across more locations and added staff to their financial advocacy team.

Practical Suggestions for Improvement

- Re-assess how members of the financial advocacy team currently divide their roles and responsibilities. If the team is large enough, consider allowing certain individuals to focus on becoming highly specialized in specific areas to maximize efficiencies. Look at the amount of time each person spends on certain tasks and explore whether it may be beneficial to allow staff members to focus on fewer tasks and become more specialized.
- Consider whether new job titles will need to be used to more accurately link staff members with their specific roles and responsibilities.
- Identify ways to accurately track and measure the success of these types of changes across the different roles and responsibilities.

Strategy 4. Broaden the Scope of Financial Advocacy Services

Cancer programs have a tremendous opportunity to broaden the types of financial advocacy services they currently offer their patients. By providing formal training and education to staff members, the financial advocacy team may be able to provide greater benefit to patients who are referred for assistance.

One of the FAN Learning Lab participants invested in a formal education and training program for their financial advocacy staff. The trainer met with financial advocates and improved their ability to provide additional services. Financial advocates learned how to optimize insurance coverage for each patient and became more proficient at navigating the health insurance marketplace. They also discovered ways to identify additional resources for Medicaid patients, and they were more effective when guiding patients who qualified for disability benefits. Through formal education and training, this cancer program was able to track their savings associated with the broader services offered by their financial advocates. Among the measurable results achieved during the first quarter after training, financial advocates:

- Helped two cancer patients save a total of $16,000 in out-of-pocket costs by improving health coverage through the health insurance marketplace.
- Effectively guided patients applying for Medicaid and had four patients approved for coverage (with an estimated savings of $32,000).
- Found external assistance programs for patients totaling $84,000.
- Worked with their pharmacy department to help 18 patients obtain free drugs and save $146,000 in infusion drug costs.

Practical Suggestions for Improvement

- Consider investing in formal training and education for members of the financial advocacy team. By increasing the skills of each team member, the cancer program can offer a broader range of services to patients. Cancer programs may also identify opportunities to cross-train certain members of the team so that crucial roles are still covered when staff go on vacation.
- Implement effective ways to measure and track financial savings over time. This information can be used to expand the team and justify ongoing education and training.
- Tap into ACCC FAN resources or attend a live meeting. Learn more at accc-cancer.org/FAN.

Strategy 5. Improve Patient Communication & Education

Patients who have limited literacy or understanding about their health insurance may not comprehend terminology like co-pay, co-insurance, deductible, or maximum out-of-pocket. They may also not understand what types of medical services are covered by their insurance plan. Furthermore, racial and ethnic minority patients are most vulnerable to financial decline attributable to cancer, so providers need to know how to effectively communicate with patients about financial distress.

After the FAN Learning Lab, one cancer program decided to improve how it educated patients about out-of-pocket treatment costs. The cancer program assembled a team to identify ways to

help patients receive more education about health insurance and financial navigation. It proactively identified common questions that patients are likely to ask about health insurance benefits in their local region and assigned financial advocates to become experts in navigating the online health insurance marketplace. Prior to the open enrollment periods for Medicare and the marketplace, the cancer program posted informational signs in their offices about health insurance education sessions it was providing. During these education sessions, financial advocates explained the differences across standard Medicare, Medicare Advantage, and Medicare Supplemental Insurance (Medigap). As a result of these education sessions, some patients made decisions to improve their insurance coverage before they started treatments.

Another Learning Lab participant assigned a financial advocate to meet with all cancer patients in the infusion room prior to treatment. It developed a pricing tool to provide estimates for out-of-pocket treatment costs when patients who required infusion therapy asked about cost. Discussions about treatment costs led to communication about financial assistance opportunities, and this program tracked improved savings in co-pay assistance programs. Over a four-month period, it received $344,500 in co-pay assistance by working with 49 patients and helping them apply for assistance programs. The same cancer program also applied for drug replacement and received $975,764 in gross charges for uninsured patients. By improving communication with patients and family members, this cancer program saw the patient satisfaction scores regarding billing increase from 80 percent in October 2015 to 92.5 percent in January and February 2016.

Practical Suggestions for Improvement

- Assess how financial advocates are currently explaining health insurance to patients. Identify ways that this information may be presented more effectively. Consider the use of printed forms and brochures that include visual aids. Look at opportunities to provide patient education in group settings, especially before open enrollment periods.
- Identify common questions and misconceptions that patients are likely to have. Although patients may not always verbalize these thoughts, financial advocates can proactively address them and guide patients to make more informed decisions. For example, many patients may not understand the difference between Medicare Advantage and Medicare Supplemental Insurance.
- Utilize tools like the Health Literacy Tool Shed at: healthliteracy.bu.edu, an online database of health literacy measures funded by the U.S. National Libraries, or download a glossary of health coverage and medical terms at: accc-cancer.org/oncology_issues/JA2016.
- By making greater efforts to improve communication with patients, financial advocates may find more opportunities to identify and apply for assistance programs. Be sure to track the savings associated with these programs.

Looking Ahead

As the landscape of cancer care continues to evolve, cancer programs will need to look for ways to strengthen the financial advocacy services they provide to their patients. By adopting a culture of continuous process improvement, financial advocacy teams can find ways to make incremental improvements and pilot new ways of delivering services to meet the growing needs of their patients. ACCC remains committed to sharing effective practices and providing ongoing education and resources for cancer programs that are looking for ways to develop and strengthen their financial advocacy services. ACCC is holding additional FAN Regional Workshops and Learning Labs in 2016. Further, in January 2017, ACCC will be rolling out a certificate program for financial advocates. This comprehensive on-demand certificate program will give financial advocates the key knowledge and skills necessary to succeed in the field of financial advocacy, as well as offer supplemental tools and strategies to enhance the learning experience. OI

Joseph Kim, MD, MPH, is president of Qsynthesis, a healthcare quality improvement consultancy.

Defining the Term "Underinsured"

In the 2014 Commonwealth Fund Biennial Health Insurance Survey, 51 percent of underinsured adults reported problems with medical bills or debt and 44 percent reported not getting needed care because of cost.4 The Commonwealth Fund defines someone as "underinsured" if: [4]

- Out-of-pocket costs, excluding premiums, over the prior 12 months are equal to 10 percent or more of household income; or
- Out-of-pocket costs, excluding premiums, are equal to 5 percent or more of household income if income is under 200 percent of the Federal Poverty Level; or
- Deductible is 5 percent or more of household income.

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Thursday, September 29, 2016
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AN APP FOR YOU!

Access patient assistance and reimbursement programs from your desktop, tablet, or mobile device.

Find resources by Foundations and Co-Pay Assistance Programs, Drug Name (brand or generic), and Manufacturer Name. Access drug assistance information from the ACCC *Patient Assistance and Reimbursement Guide* and link directly to the ACCC Oncology Drug Database.

The Financial Advocacy Network (FAN) app is available at accc-fan-app.org.

ACCC
Association of Community Cancer Centers

This program is a benefit of membership.
Association of Community Cancer Centers

Don't Get Left Behind!

Recognizing value and return on investment that comes with membership to the leading education and advocacy organization for the multidisciplinary cancer care team, many of your peers across the U.S. have already renewed their 2016-2017 ACCC Cancer Program Membership. Renew today so that your team doesn't miss out on resources, including:

- *Oncology Issues*, ACCC's award-winning journal. Upcoming articles include pharmacogenetic testing in the community setting, clinical pathways and their role in identifying quality and cost-effective care, training nurses and administrators to implement clinical trials, and more.
- ACCCExchange, the Association's listserv is where your peers are talking about "hot topic" issues related to revenue cycle specialists, oncology NP productivity measurement tools, benchmarks for oncology dietitian services, and more.
- ACCC education programs and resources. New programs are coming soon related to metastatic breast cancer, oral oncolytics, and patient-centered care.

Invoice renewals went out to Delegate Representatives in May; second reminders went out in June. Be sure and check with your Delegate Rep to make sure your cancer program has renewed!

A Reminder from ACCC's Bylaws Committee

Dec. 1, 2016, is the deadline for submission of any proposed amendments to the ACCC Bylaws. Proposed recommendations should be sent to Betsy Spruill at bspruill@accc-cancer.org.

ACCC's Bylaws are available online at: accc-cancer.org/about/pdf/Bylaws-2016.pdf.

If you don't know who your Delegate Rep is, or if you're the person who should be receiving this important reminder, contact the membership department at: membership@accc-cancer.org today. OI

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. If you deal with oncology business and reimbursement, this meeting is for you. Free to ACCC members; non-members are invited to join us at the low registration rate of $69.

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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

3 ACCC Member Programs Selected for 2016 FAN Learning Labs

Experiential multidisciplinary learning labs for process improvements with a focus on financial advocacy services will be held onsite at the following ACCC member programs.

- Cancer Center at Ohio Valley Medical Center, Wheeling, W. Va.
- New York Presbyterian, Weill Cornell Medical Center, New York, N.Y.
- St Luke's University and Health Network, St. Luke's Cancer Center, Bethlehem, Pa.

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careers

VICE PRESIDENT, ONCOLOGY SERVICES
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Lee Memorial Health System (LMHS) includes the Regional Cancer Center, diagnostic/ambulatory services, a multispecialty group practice with almost 300 physicians and 150 mid-level practitioners, and a large GPO.

Role and Responsibilities:
The Vice President of Oncology Services is responsible for the executive-level strategic and business planning; clinical program implementation and oversight; management and evaluation of all oncology programs; and operating initiatives—outpatient and inpatient.

Reporting to the Chief Medical Officer, the Vice President is responsible for the CoC-accredited oncology service line's day-to-day operations, including growth in programs and market share; financial results; clinical outcomes and patient satisfaction; quality initiatives; and, staff performance measurement and evaluation.

Candidate Requirements:
We seek individuals adept at managing daily and financial operations; short- and long-term planning and program development; physician collaboration, partnership and relationship development; cancer committee facilitation and leadership; staff recruitment, retention, mentoring and training; marketing and branding; and, facility development. Candidates should have a graduate degree (preferably), meaningful leadership experience in healthcare management or consulting with a significant portion having been in oncology services; business acumen; team orientation and a high EQ; comfort leading a major clinical service line; and the ability to be the thought leader for oncology for the System.

For more information email Arnie Kuypers at: akuypers@thekuyperscompany.com.

HEMATOLOGY/ONCOLOGISTS
Shreveport, Louisiana

LSUHSC-Shreveport in the Section of Hematology-Oncology, Feist-Weiller Cancer Center is seeking full-time physicians at the Assistant Professor level. Practice includes all facets of the Department of Medicine and the Feist-Weiller Cancer Center; serve as an attending faculty on the clinical services staffed by the Section of Feist-Weiller Cancer Center. In addition, expected to participate in overall faculty activities, including medical student, house staff, and fellow teaching responsibilities; conduct research and publish findings in journals and make presentations at medical conferences; MD or equivalent. Applicants must qualify for a Louisiana license. BE/BC necessary. Opportunities available now; positions will remain open until filled.

LSUHSC-Shreveport is an equal opportunity employer, and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability status, protected veteran status, or any other characteristic protected by law.

Candidates should send CV and 3 letters of reference to Glen Mills, MD at: gmills@lsuhsc.edu.

DIRECTOR OF ONCOLOGY SERVICES
Columbus, Georgia

The Director of Oncology Services provides managerial leadership and administrative direction for the Oncology service line of Columbus Regional Healthcare System. Responsible for the daily management and oversight of the John B. Amos Outpatient Cancer Center, IP Oncology unit, Breast Center, and all oncology-related clinical services. The ideal candidate is responsible for human resources functions, including hiring, evaluating employee performance, counseling, and termination of staff. Responsible for ensuring delivery of quality care and ensures full compliance with TJC and other regulatory agencies.

Qualifications:
- Master's Degree in Allied Health, Business Administration, Healthcare Administration, or Nursing required.
- 3 to 5 years experience in a hospital or health system; previous experience at the Director level is required.
- GA RN license if a Registered Nurse.
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Why *Skinny On Skin*?

ROBIN TRAVERS, MD

As a dermatologist, one of my most common responsibilities is to perform skin cancer screenings for my patients. I often begin by asking, "What brought you in to the office today? Have you noticed anything new or changing on your skin?" It may come as a surprise to learn how often patients will tell me that their hair stylist noticed an unusual mole on their scalp and suggested that they visit a dermatologist. Or that a massage therapist noticed a strange growth on their back and referred them to a dermatologist for evaluation.

A Unique Opportunity

Estheticians and other salon professionals are in a unique position to take note of unusual growths on their client's skin and initiate an important conversation that may ultimately save a patient's life! Dr. Neville Davis, an Australian dermatologist wrote, "Melanoma writes its own message in the skin with its own ink, and it is there for all of us to see." This is a really important message: you DON'T have to go to medical school to know how to spot the warning signs of skin cancer. These warning signs sit right on the skin's surface, and using a few simple rules, a beauty professional is in a terrific position to be able to recognize them and save a life.

Skin cancer is by far the most common type of cancer around the world. Most (but not all) skin cancers are related to exposure to ultraviolet (UV) light from the sun or from artificial light sources like tanning beds. There are three major types of skin cancer: basal cell carcinoma, squamous cell carcinoma, and melanoma. Estheticians, hair stylists, nail technicians, and massage therapists can play an important role in recognizing all three types of skin cancer. Which is why the Melanoma Foundation of New England's *Skinny On Skin* program is a critical education tool for beauty industry professionals.

The *Skinny on Skin* program is offered as an on-site educational session to groups of salon professionals who take advantage of the MFNE's commitment to free professional skin cancer education. New England-based hair stylists are invited to register for local *Skinny on Skin* training events online. In addition, *Skinny on Skin* has developed a web-based training platform, allowing salon professionals across the United States to take advantage of this proven educational program without geographic, time, or financial barriers.

The Basics

Basal cell carcinoma is the most common form of skin cancer. These often arise on sun-exposed areas of the body. The face, ears, scalp, and the back of the neck are common locations. Basal cell carcinomas show up as pearly or translucent pink bumps on the surface of the skin. They bleed very easy and do not heal well. When clients tell their hairdressers that they bumped their head three months ago but the site never seemed to heal, it can prompt a salon professional to look more closely. Basal cell carcinomas are curable by surgical removal, but the results can be disfiguring.

Squamous cell carcinomas are often scalier and crustier bumps that also show up on sun exposed areas of the body. These itchy bumps may crack and bleed easily and commonly appear on the head and neck, ears, forearms, and hands. People may report that they have an itchy, tender bump on their scalp and ask that their hair stylist be careful around the site to avoid irritating it further. With a quick look, a salon professional can confirm the presence of a suspicious spot, open up a conversation with the client, and refer them to a doctor for more precise diagnosis.

Melanoma is less common than basal cell carcinoma or squamous cell carcinoma, but it is potentially deadly if not caught early. Melanoma can occur at any age, but it is becoming more and more common among young women as a result of tanning bed use. Even a single episode of sunburn, especially before the age of 18-years-old, can cause damage to the skin that will later show up as melanoma. Melanomas on the scalp can be among the most deadly form of skin cancer, and hair professionals can play a crucial role in recognizing them early.

If caught in its early stages, melanoma is highly curable. This finding highlights the importance of early skin cancer detection, and salon professionals can play an important role in making this a reality. Hair stylists and other beauty professionals often see their clients on a regular basis and spend much of their visit looking at precisely the areas that are at risk for melanoma. The comfortable, friendly relationship a salon professional frequently has with a client offers the perfect setting for an alert esthetician or massage therapist to encourage the client to seek further medical attention for a potentially deadly skin cancer.

In fact, a 2011 study published in *JAMA Dermatology*[1], showed that, even though very few hair professionals had received any formal skin cancer education, many stylists already informally examine the skin of the head and neck and offer skin care advice as part of their profession. This study showed that salon professionals could be armed with confidence from a skin cancer educational session. Supplement this knowledge with customer information cards that can be offered to clients, and suddenly hair stylists and estheticians are in a terrific position to become health advisors for skin cancer prevention and early detection.

The ABCDEs

Knowing a few simple warning signs of melanoma allows salon professionals to be instrumental in finding early skin cancers and helping clients get help early. The *Skinny on Skin* program asks salon professionals to look for these "ABCDEs" of melanoma.

A. **Asymmetry.** Benign, normal moles should be symmetric. Your attention may be drawn to moles where one half looks very different from the other half. If you mentally draw a line through the middle of a mole, the two sides should match. If they do not, this asymmetry may be an early warning sign for melanoma.

B. **Border irregularity.** Benign moles have a smooth, even border. Your attention might be drawn to a mole with a jagged border. A notched, irregular, blurred or scalloped edge should alert you to the possibility of an early melanoma.

C. **Color.** There is no single color that is worrisome. Some patients have very deeply pigmented moles, while others might be a light reddish brown. The key is that a mole should be evenly colored throughout. A single mole that has multiple colors within it may be a signal for an early melanoma.

D. **Diameter.** Benign moles are usually less than 6 mm in size. Moles that are larger moles than a pencil eraser size are thought to be more worrisome for melanoma. Spotting a large mole may alert salon professional to the presence of an early melanoma.

E. **Evolution.** Benign moles tend to look the same over time. If a mole starts to evolve or change in size, shape, symptoms, color, or elevation, this may be an early sign of melanoma. Estheticians who see clients on a regular basis are in an excellent position to notice a changing mole that may be an early melanoma.

Far more people visit their estheticians, hair stylists, and other salon professionals on a regular basis than their dermatologist. Salon professionals see their clients every few months and build a trusting relationship over time. This puts them in a unique position to save their client's life by spotting any unusual spots on their skin that may be early skin cancers and directing them to the appropriate professional for treatment. As part of their community outreach and prevention efforts, cancer programs may want to consider reaching out to salon professionals in their community with education similar to what the Melanoma Foundation of New England has done with its *Skinny on the Skin* program. Learn more at: mfne.org/prevent-melanoma/the-skinny-on-skin. OI

Dr. Robin Travers is a dermatologist at SkinCare Physicians in the Boston, Mass area. She writes a monthly column in the JAMA Dermatology *summarizing the most relevant and exciting recent dermatology research. Dr. Travers serves on the Medical Advisory Board of the MFNE and coaches MFNE's Marathon Team for the Boston Marathon every year.*

References

1. Bailey EE, Marghoob AA, Orengo IF, Testa MA, White VR, Geller AC. Skin cancer knowledge, attitudes, and behaviors in the salon: a survey of working hair professionals in Houston, Texas. *Arch Dermatol*. 2011;147(10):1159-1165.

Xtandi® (enzalutamide) 40 mg capsules

XTANDI® (enzalutamide) capsules for oral use
Initial U.S. Approval: 2012
BRIEF SUMMARY OF PRESCRIBING INFORMATION

The following is a brief summary. Please see the package insert for full prescribing information.

INDICATIONS AND USAGE

XTANDI is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

CONTRAINDICATIONS

Pregnancy

XTANDI can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings in animals. XTANDI is not indicated for use in women. XTANDI is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus and the potential risk for pregnancy loss.

WARNINGS AND PRECAUTIONS

Seizure

In Study 1, which enrolled patients who previously received docetaxel, 7 of 800 (0.9%) patients treated with XTANDI experienced a seizure and no patients treated with placebo experienced a seizure. Seizure occurred from 31 to 603 days after initiation of XTANDI. In Study 2, 1 of 871 (0.1%) chemotherapy-naive patients treated with XTANDI and 1 of 844 (0.1%) patients treated with placebo experienced a seizure. Patients experiencing seizure were permanently discontinued from therapy and all seizure events resolved. There is no clinical trial experience re-administering XTANDI to patients who experienced seizure.

Limited safety data are available in patients with predisposing factors for seizure because these patients were generally excluded from the trials. These exclusion criteria included a history of seizure, underlying brain injury with loss of consciousness, transient ischemic attack within the past 12 months, cerebral vascular accident, brain metastases, and brain arteriovenous malformation. Study 1 excluded the use of concomitant medications that may lower the seizure threshold, whereas Study 2 permitted the use of these medications.

Because of the risk of seizure associated with XTANDI use, patients should be advised of the risk of engaging in any activity where sudden loss of consciousness could cause serious harm to themselves or others. Permanently discontinue XTANDI in patients who develop a seizure during treatment.

Posterior Reversible Encephalopathy Syndrome (PRES)

There have been reports of posterior reversible encephalopathy syndrome (PRES) in patients receiving XTANDI. PRES is a neurological disorder which can present with rapidly evolving symptoms including seizure, headache, lethargy, confusion, blindness, and other visual and neurological disturbances, with or without associated hypertension. A diagnosis of PRES requires confirmation by brain imaging, preferably magnetic resonance imaging (MRI). Discontinue XTANDI in patients who develop PRES.

ADVERSE REACTIONS

Clinical Trial 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.

Two randomized clinical trials enrolled patients with metastatic prostate cancer that has progressed on androgen deprivation therapy (GnRH therapy or bilateral orchiectomy), a disease setting that is also defined as metastatic CRPC. In both studies, patients received XTANDI 160 mg orally once daily in the active treatment arm or placebo in the control arm. All patients continued androgen deprivation therapy. Patients were allowed, but not required, to take glucocorticoids.

The most common adverse reactions (≥ 10%) that occurred more commonly (≥ 2% over placebo) in the XTANDI-treated patients from the two randomized clinical trials were asthenia/fatigue, back pain, decreased appetite, constipation, arthralgia, diarrhea, hot flush, upper respiratory tract infection, peripheral edema, dyspnea, musculoskeletal pain, weight decreased, headache, hypertension, and dizziness/vertigo.

Study 1: Metastatic Castration-Resistant Prostate Cancer Following Chemotherapy

Study 1 enrolled 1199 patients with metastatic CRPC who had previously received docetaxel. The median duration of treatment was 8.3 months with XTANDI and 3.0 months with placebo. During the trial, 48% of patients on the XTANDI arm and 46% of patients on the placebo arm received glucocorticoids.

Grade 3 and higher adverse reactions were reported among 47% of XTANDI-treated patients and 53% of placebo-treated patients. Discontinuations due to adverse events were reported for 16% of XTANDI-treated patients and 18% of placebo-treated patients. The most common adverse reaction leading to treatment discontinuation was seizure, which occurred in 0.9% of the XTANDI-treated patients compared to none (0%) of the placebo-treated patients. Table 1 shows adverse reactions reported in Study 1 that occurred at a ≥ 2% higher frequency in the XTANDI arm compared to the placebo arm.

Table 1. Adverse Reactions in Study 1

	XTANDI N = 800		Placebo N = 399	
	Grade 1-4[a] (%)	Grade 3-4 (%)	Grade 1-4 (%)	Grade 3-4 (%)
General Disorders				
Asthenic Conditions[b]	50.6	9.0	44.4	9.3
Peripheral Edema	15.4	1.0	13.3	0.8
Musculoskeletal And Connective Tissue Disorders				
Back Pain	26.4	5.3	24.3	4.0
Arthralgia	20.5	2.5	17.3	1.8
Musculoskeletal Pain	15.0	1.3	11.5	0.3
Muscular Weakness	9.8	1.5	6.8	1.8
Musculoskeletal Stiffness	2.6	0.3	0.3	0.0
Gastrointestinal Disorders				
Diarrhea	21.8	1.1	17.5	0.3
Vascular Disorders				
Hot Flush	20.3	0.0	10.3	0.0
Hypertension	6.4	2.1	2.8	1.3
Nervous System Disorders				
Headache	12.1	0.9	5.5	0.0
Dizziness[c]	9.5	0.5	7.5	0.5
Spinal Cord Compression and Cauda Equina Syndrome	7.4	6.6	4.5	3.8
Paresthesia	6.6	0.0	4.5	0.0
Mental Impairment Disorders[d]	4.3	0.3	1.8	0.0
Hypoesthesia	4.0	0.3	1.8	0.0
Infections And Infestations				
Upper Respiratory Tract Infection[e]	10.9	0.0	6.5	0.3
Lower Respiratory Tract And Lung Infection[f]	8.5	2.4	4.8	1.3
Psychiatric Disorders				
Insomnia	8.8	0.0	6.0	0.5
Anxiety	6.5	0.3	4.0	0.0
Renal And Urinary Disorders				
Hematuria	6.9	1.8	4.5	1.0
Pollakiuria	4.8	0.0	2.5	0.0
Injury, Poisoning And Procedural Complications				
Fall	4.6	0.3	1.3	0.0
Non-pathologic Fractures	4.0	1.4	0.8	0.3
Skin And Subcutaneous Tissue Disorders				
Pruritus	3.8	0.0	1.3	0.0
Dry Skin	3.5	0.0	1.3	0.0
Respiratory Disorders				
Epistaxis	3.3	0.1	1.3	0.3

a CTCAE v4
b Includes asthenia and fatigue.
c Includes dizziness and vertigo.
d Includes amnesia, memory impairment, cognitive disorder, and disturbance in attention.
e Includes nasopharyngitis, upper respiratory tract infection, sinusitis, rhinitis, pharyngitis, and laryngitis.
f Includes pneumonia, lower respiratory tract infection, bronchitis, and lung infection.

Study 2: Chemotherapy-naive Metastatic Castration-Resistant Prostate Cancer

Study 2 enrolled 1717 patients with metastatic CRPC who had not received prior cytotoxic chemotherapy, of whom 1715 received at least one dose of study drug. The median duration of treatment was 17.5 months with XTANDI and 4.6 months with placebo. Grade 3-4 adverse reactions were reported in 44% of XTANDI-treated patients and 37% of placebo-treated patients. Discontinuations due to adverse events were reported for 6% of XTANDI-treated patients and 6% of placebo-treated patients. The most common adverse reaction leading to treatment discontinuation was fatigue/asthenia, which occurred in 1% of patients on each treatment arm. Table 2 includes adverse reactions reported in Study 2 that occurred at a ≥ 2% higher frequency in the XTANDI arm compared to the placebo arm.

Table 2. Adverse Reactions in Study 2

	XTANDI N = 871		Placebo N = 844	
	Grade 1-4[a] (%)	Grade 3-4 (%)	Grade 1-4 (%)	Grade 3-4 (%)
General Disorders				
Asthenic Conditions[b]	46.9	3.4	33.0	2.8
Peripheral Edema	11.5	0.2	8.2	0.4
Musculoskeletal And Connective Tissue Disorders				
Back Pain	28.6	2.5	22.4	3.0
Arthralgia	21.4	1.6	16.1	1.1
Gastrointestinal Disorders				
Constipation	23.2	0.7	17.3	0.4
Diarrhea	16.8	0.3	14.3	0.4
Vascular Disorders				
Hot Flush	18.0	0.1	7.8	0.0
Hypertension	14.2	7.2	4.1	2.3
Nervous System Disorders				
Dizziness[c]	11.3	0.3	7.1	0.0
Headache	11.0	0.2	7.0	0.4
Dysgeusia	7.6	0.1	3.7	0.0
Mental Impairment Disorders[d]	5.7	0.0	1.3	0.1
Restless Legs Syndrome	2.1	0.1	0.4	0.0
Respiratory Disorders				
Dyspnea[e]	11.0	0.6	8.5	0.6
Infections And Infestations				
Upper Respiratory Tract Infection[f]	16.4	0.0	10.5	0.0
Lower Respiratory Tract And Lung Infection[g]	7.9	1.5	4.7	1.1
Psychiatric Disorders				
Insomnia	8.2	0.1	5.7	0.0
Renal And Urinary Disorders				
Hematuria	8.8	1.3	5.8	1.3
Injury, Poisoning And Procedural Complications				
Fall	12.7	1.6	5.3	0.7
Non-Pathological Fracture	8.8	2.1	3.0	1.1
Metabolism and Nutrition Disorders				
Decreased Appetite	18.9	0.3	16.4	0.7
Investigations				
Weight Decreased	12.4	0.8	8.5	0.2
Reproductive System and Breast Disorders				
Gynecomastia	3.4	0.0	1.4	0.0

Table 2. Adverse Reactions in Study 2 (cont.)

a	CTCAE v4
b	Includes asthenia and fatigue.
c	Includes dizziness and vertigo.
d	Includes amnesia, memory impairment, cognitive disorder, and disturbance in attention.
e	Includes dyspnea, exertional dyspnea, and dyspnea at rest.
f	Includes nasopharyngitis, upper respiratory tract infection, sinusitis, rhinitis, pharyngitis, and laryngitis.
g	Includes pneumonia, lower respiratory tract infection, bronchitis, and lung infection.

Laboratory Abnormalities

In the two randomized clinical trials, Grade 1-4 neutropenia occurred in 15% of patients treated with XTANDI (1% Grade 3-4) and in 6% of patients treated with placebo (0.5% Grade 3-4). The incidence of Grade 1-4 thrombocytopenia was 6% of patients treated with XTANDI (0.3% Grade 3-4) and 5% of patients treated with placebo (0.5% Grade 3-4). Grade 1-4 elevations in ALT occurred in 10% of patients treated with XTANDI (0.2% Grade 3-4) and 16% of patients treated with placebo (0.2% Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of patients treated with XTANDI (0.1% Grade 3-4) and 2% of patients treated with placebo (no Grade 3-4).

Infections

In Study 1, 1% of patients treated with XTANDI compared to 0.3% of patients treated with placebo died from infections or sepsis. In Study 2, 1 patient in each treatment group (0.1%) had an infection resulting in death.

Falls and Fall-related Injuries

In the two randomized clinical trials, falls including fall-related injuries, occurred in 9% of patients treated with XTANDI compared to 4% of patients treated with placebo. Falls were not associated with loss of consciousness or seizure. Fall-related injuries were more severe in patients treated with XTANDI and included non-pathologic fractures, joint injuries, and hematomas.

Hypertension

In the two randomized trials, hypertension was reported in 11% of patients receiving XTANDI and 4% of patients receiving placebo. No patients experienced hypertensive crisis. Medical history of hypertension was balanced between arms. Hypertension led to study discontinuation in < 1% of patients in each arm.

Post-Marketing Experience

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

Neurological Disorders: posterior reversible encephalopathy syndrome (PRES)

DRUG INTERACTIONS

Drugs that Inhibit CYP2C8

Co-administration of a strong CYP2C8 inhibitor (gemfibrozil) increased the composite area under the plasma concentration-time curve (AUC) of enzalutamide plus N-desmethyl enzalutamide by 2.2-fold. Co-administration of XTANDI with strong CYP2C8 inhibitors should be avoided if possible. If co-administration of XTANDI with a strong CYP2C8 inhibitor cannot be avoided, reduce the dose of XTANDI.

Drugs that Induce CYP3A4

Co-administration of rifampin (strong CYP3A4 inducer and moderate CYP2C8 inducer) decreased the composite AUC of enzalutamide plus N-desmethyl enzalutamide by 37%. Co-administration of strong CYP3A4 inducers (e.g., carbamazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine) with XTANDI should be avoided if possible. St John's wort may decrease enzalutamide exposure and should be avoided. If co-administration of a strong CYP3A4 inducer with XTANDI cannot be avoided, increase the dose of XTANDI.

Effect of XTANDI on Drug Metabolizing Enzymes

Enzalutamide is a strong CYP3A4 inducer and a moderate CYP2C9 and CYP2C19 inducer in humans. At steady state, XTANDI reduced the plasma exposure to midazolam (CYP3A4 substrate), warfarin (CYP2C9 substrate), and omeprazole (CYP2C19 substrate). Concomitant use of XTANDI with narrow therapeutic index drugs that are metabolized by CYP3A4 (e.g., alfentanil, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus and tacrolimus), CYP2C9 (e.g., phenytoin, warfarin) and CYP2C19 (e.g., S-mephenytoin) should be avoided, as enzalutamide may decrease their exposure. If co-administration with warfarin cannot be avoided, conduct additional INR monitoring.

USE IN SPECIFIC POPULATIONS

Pregnancy– Pregnancy Category X.

Risk Summary

XTANDI can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings in animals. While there are no human data on the use of XTANDI in pregnancy and XTANDI is not indicated for use in women, it is important to know that maternal use of an androgen receptor inhibitor could affect development of the fetus. Enzalutamide caused embryo-fetal toxicity in mice at exposures that were lower than in patients receiving the recommended dose. XTANDI is contraindicated in women who are or may become pregnant while receiving the drug. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus and the potential risk for pregnancy loss. Advise females of reproductive potential to avoid becoming pregnant during treatment with XTANDI.

Animal Data

In an embryo-fetal developmental toxicity study in mice, enzalutamide caused developmental toxicity when administered at oral doses of 10 or 30 mg/kg/day throughout the period of organogenesis (gestational days 6-15). Findings included embryo-fetal lethality (increased post-implantation loss and resorptions) and decreased anogenital distance at ≥ 10 mg/kg/day, and cleft palate and absent palatine bone at 30 mg/kg/day. Doses of 30 mg/kg/day caused maternal toxicity. The doses tested in mice (1, 10 and 30 mg/kg/day) resulted in systemic exposures (AUC) approximately 0.04, 0.4 and 1.1 times, respectively, the exposures in patients. Enzalutamide did not cause developmental toxicity in rabbits when administered throughout the period of organogenesis (gestational days 6-18) at dose levels up to 10 mg/kg/day (approximately 0.4 times the exposures in patients based on AUC).

Nursing Mothers

XTANDI is not indicated for use in women. It is not known if enzalutamide is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from XTANDI, a decision should be made to either discontinue nursing, or discontinue the drug taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness of XTANDI in pediatric patients have not been established.

Geriatric Use

Of 1671 patients who received XTANDI in the two randomized clinical trials, 75% were 65 and over, while 31% were 75 and over. No overall differences in safety or effectiveness were observed between these patients and younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Patients with Renal Impairment

A dedicated renal impairment trial for XTANDI has not been conducted. Based on the population pharmacokinetic analysis using data from clinical trials in patients with metastatic CRPC and healthy volunteers, no significant difference in enzalutamide clearance was observed in patients with pre-existing mild to moderate renal impairment (30 mL/min ≤ creatinine clearance [CrCL] ≤ 89 mL/min) compared to patients and volunteers with baseline normal renal function (CrCL ≥ 90 mL/min). No initial dosage adjustment is necessary for patients with mild to moderate renal impairment. Severe renal impairment (CrCL < 30 mL/min) and end-stage renal disease have not been assessed.

Patients with Hepatic Impairment

Dedicated hepatic impairment trials compared the composite systemic exposure of enzalutamide plus N-desmethyl enzalutamide in volunteers with baseline mild, moderate, or severe hepatic impairment (Child-Pugh Class A, B, or C, respectively) versus healthy controls with normal hepatic function. The composite AUC of enzalutamide plus N-desmethyl enzalutamide was similar in volunteers with mild, moderate, or severe baseline hepatic impairment compared to volunteers with normal hepatic function. No initial dosage adjustment is necessary for patients with baseline mild, moderate, or severe hepatic impairment.

OVERDOSAGE

In the event of an overdose, stop treatment with XTANDI and initiate general supportive measures taking into consideration the half-life of 5.8 days. In a dose escalation study, no seizures were reported at ≤ 240 mg daily, whereas 3 seizures were reported, 1 each at 360 mg, 480 mg, and 600 mg daily. Patients may be at increased risk of seizure following an overdose.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been conducted to evaluate the carcinogenic potential of enzalutamide.

Enzalutamide did not induce mutations in the bacterial reverse mutation (Ames) assay and was not genotoxic in either the *in vitro* mouse lymphoma thymidine kinase (Tk) gene mutation assay or the *in vivo* mouse micronucleus assay.

Based on nonclinical findings in repeat-dose toxicology studies, which were consistent with the pharmacological activity of enzalutamide, male fertility may be impaired by treatment with XTANDI. In a 26-week study in rats, atrophy of the prostate and seminal vesicles was observed at ≥ 30 mg/kg/day (equal to the human exposure based on AUC). In 4-, 13-, and 39-week studies in dogs, hypospermatogenesis and atrophy of the prostate and epididymides were observed at ≥ 4 mg/kg/day (0.3 times the human exposure based on AUC).

Manufactured by: Catalent Pharma Solutions, LLC, St. Petersburg, FL 33716

Manufactured for and Distributed by: Astellas Pharma US, Inc., Northbrook, IL 60062

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Rx Only

astellas MEDIVATION

076-1200-PM

Xtandi® (enzalutamide) 40 mg capsules

XTANDI (enzalutamide) capsules is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

Important Safety Information

Contraindications

XTANDI is not indicated for women and is contraindicated in women who are or may become pregnant. XTANDI can cause fetal harm when administered to a pregnant woman.

Warnings and Precautions

Seizure In Study 1, conducted in patients with metastatic castration-resistant prostate cancer (CRPC) who previously received docetaxel, seizure occurred in 0.9% of XTANDI patients and 0% of placebo patients. In Study 2, conducted in patients with chemotherapy-naive metastatic CRPC, seizure occurred in 0.1% of XTANDI patients and 0.1% of placebo patients. There is no clinical trial experience re-administering XTANDI to patients who experienced a seizure, and limited safety data are available in patients with predisposing factors for seizure. Study 1 excluded the use of concomitant medications that may lower threshold; Study 2 permitted the use of these medications. Because of the risk of seizure associated with XTANDI use, patients should be advised of the risk of engaging in any activity during which sudden loss of consciousness could cause serious harm to themselves or others. Permanently discontinue XTANDI in patients who develop a seizure during treatment.

Posterior Reversible Encephalopathy Syndrome (PRES) In post approval use, there have been reports of PRES in patients receiving XTANDI. PRES is a neurological disorder which can present with rapidly evolving symptoms including seizure, headache, lethargy, confusion, blindness, and other visual and neurological disturbances, with or without associated hypertension. A diagnosis of PRES requires confirmation by brain imaging, preferably MRI. Discontinue XTANDI in patients who develop PRES.

Adverse Reactions

The most common adverse reactions (≥ 10%) reported from two combined clinical studies that occurred more commonly (≥ 2% over placebo) in XTANDI patients were asthenia/fatigue, back pain, decreased appetite, constipation, arthralgia, diarrhea, hot flush, upper respiratory tract infection, peripheral edema, dyspnea, musculoskeletal pain, weight decreased, headache, hypertension, and dizziness/vertigo.

In Study 1, Grade 3 and higher adverse reactions were reported among 47% of XTANDI patients and 53% of placebo patients. Discontinuations due to adverse events were reported for 16% of XTANDI patients and 18% of placebo patients. In Study 2, Grade 3-4 adverse reactions were reported in 44% of XTANDI patients and 37% of placebo patients. Discontinuations due to adverse events were reported for 6% of both study groups.

- Lab Abnormalities: Grade 1-4 neutropenia occurred in 15% of XTANDI patients (1% Grade 3-4) and 6% of placebo patients (0.5% Grade 3-4). Grade 1-4 thrombocytopenia occurred in 6% of XTANDI patients (0.3% Grade 3-4) and 5% of placebo patients (0.5% Grade 3-4). Grade 1-4 elevations in ALT occurred in 10% of XTANDI patients (0.2% Grade 3-4) and 16% of placebo patients (0.2% Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of XTANDI patients (0.1% Grade 3-4) and 2% of placebo patients (no Grade 3-4).
- Infections: In Study 1, 1% of XTANDI patients compared to 0.3% of placebo patients died from infections or sepsis. In Study 2, 1 patient in each treatment group (0.1%) had an infection resulting in death.
- Falls (including fall-related injuries), occurred in 9% of XTANDI patients and 4% of placebo patients. Falls were not associated with loss of consciousness or seizure. Fall-related injuries were more severe in XTANDI patients, and included non-pathologic fractures, joint injuries, and hematomas.
- Hypertension occurred in 11% of XTANDI patients and 4% of placebo patients. No patients experienced hypertensive crisis. Medical history of hypertension was balanced between arms. Hypertension led to study discontinuation in < 1% of all patients.

Drug Interactions

Effect of Other Drugs on XTANDI Avoid strong CYP2C8 inhibitors, as they can increase the plasma exposure to XTANDI. If co-administration is necessary, reduce the dose of XTANDI.

Avoid strong CYP3A4 inducers as they can decrease the plasma exposure to XTANDI. If co-administration is necessary, increase the dose of XTANDI.

Effect of XTANDI on Other Drugs Avoid CYP3A4, CYP2C9, and CYP2C19 substrates with a narrow therapeutic index, as XTANDI may decrease the plasma exposures of these drugs. If XTANDI is co-administered with warfarin (CYP2C9 substrate), conduct additional INR monitoring.

Please see adjacent pages for Brief Summary of Full Prescribing Information.

astellas MEDIVATION

94% of insured patient lives are covered for XTANDI*[2]

*As of February 2015. A product's placement on a plan formulary involves a variety of factors known only to the plan and is subject to eligibility.

To learn more, please visit **XtandiHCP.com**

Xtandi® (enzalutamide) 40 mg capsules

XTANDI (enzalutamide) capsules is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

Rx

Start XTANDI at disease progression to metastatic CRPC for your patients on GnRH therapy*[1]

*Or after bilateral orchiectomy.[1]

94% of insured patient lives are covered for XTANDI†[2]

†As of February 2015. A product's placement on a plan formulary involves a variety of factors known only to the plan and is subject to eligibility.

To learn more, please visit **XtandiHCP.com**

Select Safety Information

XTANDI is not indicated for use in women. XTANDI is contraindicated in women who are or may become pregnant.

Seizure occurred in 0.9% of patients receiving XTANDI who previously received docetaxel and in 0.1% of patients who were chemotherapy-naive. Permanently discontinue XTANDI in patients who develop a seizure during treatment.

There have been post approval reports of **posterior reversible encephalopathy syndrome** (PRES), a neurological disorder which can present with rapidly evolving symptoms and requires confirmation by brain imaging. Discontinue XTANDI in patients who develop PRES.

References: 1. XTANDI [package insert]. Northbrook, IL: Astellas Pharma US, Inc. **2.** Data on file, Medivation, Inc.

Please see inside page for additional Important Safety Information.
Please see adjacent pages for Brief Summary of Full Prescribing Information.