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ONCOLOGY ISSUES

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

May | June 2017

Fox Chase Cancer Center
Care Connect



*Improving
Collaboration
Between
Oncology &
Primary Care*

TAGRISSO[®] (osimertinib): 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

A targeted therapy researched in two clinical trials

- Effective 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 therapy¹
 - 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 mg¹:
 - 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 events¹
- 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 confirmed¹
- 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

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

Visit **TAGRISSOhcp.com** for more information

R
1
6
0

kV 120
mA 150

Shoulder L
10.00mm/1.5:1
Tilt: 0.0
1.0s /HE
13:48:58/05.33

1: m 33.14, sd 7.52, a 33.47mm2

L
1
9
2

IMPORTANT SAFETY INFORMATION (cont.)

- 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.



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TAGRISSO™ (osimertinib) tablets, 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 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 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 60 mL (2 ounces) of non-carbonated water only. Stir until tablet is dispersed into small pieces (the tablet will not completely dissolve) and swallow immediately. Do not crush, heat, or ultrasonicate during preparation. Rinse the container with 120 mL to 240 mL (4 to 8 ounces of) water and immediately drink.

If administration via naso-gastric tube is required, disperse the tablet as above in 15 mL of noncarbonated water, and then use an additional 15 mL of water to transfer any residues to the syringe. The resulting 30 mL liquid should be administered as per the nasogastric tube instructions with appropriate water flushes (approximately 30 mL).

Dosage Modification

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

Drug Interactions

Strong CYP3A4 Inducers

If concurrent use is unavoidable, increase TAGRISSO dosage to 160 mg daily when coadministering with a strong CYP3A4 inducer. Resume TAGRISSO at 80 mg 3 weeks after discontinuation of the strong CYP3A4 inducer [see *Drug Interactions (7)*, and *Clinical Pharmacology (12.3) in full Prescribing Information*].

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 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 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 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 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 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 full Prescribing Information*]

QTc Interval Prolongation [see *Warnings and Precautions (5.2) in 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 acneiform 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, onychoclasia, 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 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****Effect of Other Drugs on Osimertinib****Strong CYP3A Inducers**

Coadministering TAGRISSO with a strong CYP3A4 inducer decreased the exposure of osimertinib compared to administering TAGRISSO alone [see *Clinical Pharmacology* (12.3) in full Prescribing Information]. Decreased osimertinib exposure may lead to reduced efficacy.

Avoid coadministering TAGRISSO with strong CYP3A inducers (e.g., phenytoin, rifampin, carbamazepine, St. John's Wort) [note: effect of St. John's Wort varies widely and is preparation-dependent]. Increase the TAGRISSO dosage when coadministering with a strong CYP3A4 inducer if concurrent use is unavoidable [see *Dosage and Administration* (2.4) in full Prescribing Information]. No dose adjustments are required when TAGRISSO is used with moderate and/or weak CYP3A inducers.

Effect of Osimertinib on Other Drugs

Coadministering TAGRISSO with a BCRP substrate increased the exposure of the BCRP substrate compared to administering the BCRP substrate alone [see *Clinical Pharmacology*

(12.3) in full Prescribing Information]. Increased BCRP substrate exposure may increase the risk of exposure-related toxicity.

Monitor for adverse reactions of the BCRP substrate (e.g., rosuvastatin, sulfasalazine, topotecan), unless otherwise instructed in its approved labeling, when coadministered with TAGRISSO.

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 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 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 full Prescribing Information].

Infertility

Based on animal studies, TAGRISSO may impair fertility in females and males of reproductive potential. The effects on female fertility showed a trend toward reversibility. It is not known whether the effects on male fertility are reversible [see *Nonclinical Toxicology* (13.1) in 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 suggests 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 dose adjustment is recommended in patients with mild [creatinine clearance (CL_{Cr}) 60-89 mL/min, as estimated by the Cockcroft Gault method (C-G)] or moderate (CL_{Cr} 30-59 mL/min, as estimated by C-G) renal impairment. There is no recommended dose of TAGRISSO for patients with severe renal impairment (CL_{Cr} <30 mL/min) or end-stage renal disease [see *Clinical Pharmacology* (12.3) in full Prescribing Information].

Hepatic Impairment

No dose adjustment is recommended in patients with mild hepatic impairment [total bilirubin less than or equal to upper limit of normal (ULN) and AST greater than 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 full Prescribing Information].

Distributed by:

AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850

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Iss. 08/16 3281701 09/16

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Oncology Issues

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Park Nicollet Oncology Research and HealthPartners Institute, Minneapolis, Minn., implemented a QI initiative aimed at collecting personalized pain goals for patients; decreasing patients' financial toxicity by reducing the number of high-cost, long-acting opioids prescribed; and reducing staff time spent on prior-authorizations and pre-approvals.

by Dylan Zylla

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Learn how Moses Cone Health System, Greensboro, N.C., identified its high-cost patients, or "hot-spotters," and put processes and systems in place to not only improve care for these patients but also reduce costs.

by Matthew A. Manning

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This research-based nutrition and wellness program educates cancer survivors through hands-on learning about anti-inflammatory nutrition, healthy food shopping and preparation, the benefits of eating local fresh fruits and vegetables, and the positive impact these foods can have for patients recovering from cancer.

By Abigail Muniz, Athena Nofziger, Jean E. Schumer, and Maisa Athamneh

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Fox Chase Cancer Center *Care Connect*

Recognizing both the impact of the growing survivor population and the existence of gaps in care coordination between oncology and primary care, Fox Chase Cancer Center, Philadelphia, Pa., developed a program to improve communication and education between the two care settings, and improve overall survivorship care.

by Kelly Filchner and Alan Howald

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Association of Community Cancer Centers

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The Journal of the
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FROM THE EDITOR.....

Cancer (and Lawn) Care

BY CHRISTIAN J. DOWNS, JD, MHA



When I write about an ACCC meeting it's usually to encourage you to attend an upcoming conference. This time around I'm taking a look back

at the ACCC 43rd Annual Meeting held in Washington D.C., at the end of March. One of ACCC's greatest strengths is the willingness—even eagerness—of our members to share their experiences and successes. And this meeting was no exception, exceeding all expectations for collaboration and networking on every front. Some of the energy and urgency we saw at this year's meeting may be attributed to the uncertain political and reimbursement landscape, yet most of the positive energy came directly from our members and their willingness to share how they are adapting and improving the services they provide to patients. Simply put, ACCC members left this meeting re-energized, ready to embrace whatever challenges arise and to excel.

This edition of *Oncology Issues* builds on these collegial themes: networking, collaborating, and sharing “how we did it” solutions to challenges.

In “Fox Chase Cancer Center *Care Connect*,” authors Kelly Filchner and Alan Howald detail how this ACCC member program recognized gaps in care coordination between oncology and primary care and developed a program to improve communication and education between the two care settings. For its efforts, Fox Chase received a 2016 ACCC Innovator Award.

Next, we hear from another 2016 ACCC Innovator Award winner, Moses Cone Health System, as author Matthew Manning shows how this ACCC member identified its high-cost patients, or “hot-spotters,” and put processes and systems in place to not only improve care for these patients but also reduce system costs. When payers cut costs, Manning writes, it's often like “mowing the grass.” The high-cost items (like the tallest

blades of grass) are the first to be cut down. By mining and analyzing claims data, his program was able to show that, in fact, the tallest blades were not high-cost drugs or new technologies, but “hot-spotter” patients. His article explores how ACCC members can take steps to reduce costs (“mow their own grass”) by improving management of these high-cost patients.

Author Dylan Zylla's article, “Improving Pain Management in Patients with Cancer,” showcases our final 2016 ACCC Innovator Award winning program, Park Nicollet Oncology Research and HealthPartners Institute, and its quality improvement initiative to collect personalized pain goals for patients. In addition to improving pain management in cancer patients, this initiative decreased financial toxicity—by reducing the number of high-cost, long-acting opioids prescribed—and staff time spent on prior authorizations and pre-approvals.

In our final feature article, “That's My Farmer,” ACCC member, Samaritan Cancer Program, shares the evolution of its research-based nutrition and wellness program, which educates cancer survivors through hands-on learning about nutrition, healthy food shopping and preparation, and the benefits of eating local fresh fruits and vegetables. Key to success: the collaborative relationships built between healthcare providers, educational institutions, local businesses, and area farmers.

While it's always beneficial to look back and recognize what we've learned from the past, we must use this knowledge to guide future efforts. So, let me conclude by talking up a meeting that you simply cannot afford to miss—the ACCC 34th National Oncology Conference, Oct. 18-20, 2017, in Nashville, Tenn. This premier “How To” meeting for the multidisciplinary cancer care team will showcase the 2017 ACCC Innovator Award winners and other ACCC member programs willing—and eager—to share effective, replicable strategies and best practices to improve your cancer service line. I look forward to seeing you there! 

Envisioning Next Gen Multidisciplinary Cancer Care

BY MARK S. SOBERMAN, MD, MBA, FACS



I often introduce myself as a recovering thoracic surgeon. Some might find that an unusual thing to say, but I truly believe that unlearning many of the things I was

taught during my surgical training has enabled me to become an effective physician executive. I've been in recovery since 2007, when I entered the MBA for Executives program at the University of Virginia's Darden School of Business. My wife and I often joke that going to graduate business school at the age of 49 was my midlife crisis. At Darden, I acquired new skills in strategy, finance, operations management, and marketing and acquired a new lens through which to view healthcare.

Traditionally, in surgical training, we are taught that the surgeon is the only thing standing between the patient and certain disaster. Leadership training taught me how to listen and to value and seek out dissenting points of view. As ACCC President, my theme will be "Envisioning Next Gen Multidisciplinary Cancer Care." Oncology is most definitely a team effort, and the team is growing as we increase collaboration amongst disciplines.

Traditionally, this collaboration has included surgery, medical oncology, radiation oncology, nursing, administration, social work, pharmacy, and the cancer registry. But, as cancer treatment evolves with more targeted and immune-based therapies, next generation multidisciplinary cancer care refers to the growing need to also include navigation, pathology, genetics, pulmonology, primary care, as well as those outside of our brick-and-mortar programs, including specialty pharmacy and third-party labs.

Several months ago, I met a patient diagnosed with a lung mass that turned out to be a rare sarcoma. Unfortunately, after surgery and chemotherapy, his disease progressed further and he was hospitalized with severe back pain due to progression of his spinal metastases.

After the patient was admitted, the medical oncology team told him he needed chemotherapy and radiation. A short while later, the neurosurgery team told him he needed immediate surgery. At this point, I received a somewhat frantic call from him. He had absolutely no idea what to do. It was obvious to me that the oncologists and neurosurgeons weren't talking to one another. The patient was stuck in the middle, completely unsure of what he should do.

I told him to *demand* that his doctors meet to discuss his plan of care and come together with a unified recommendation. It was unreasonable to expect that this frightened patient could decide between two completely different treatments. The good news is that the two teams met and reached consensus that the best option was urgent surgery.

I share this story because cancer care today is still too often siloed by specialty and organized around us, the care providers, rather than our patients' medical conditions. Patients come to us with a diagnosis of lung cancer or breast cancer. They don't come to us with a diagnosis of medical oncology or radiation oncology.

In our vision for next generation multidisciplinary care, I believe we must strengthen connections—and break down siloes—with the goal of improved communication and collaboration to move forward in the value-based healthcare environment.

To achieve the triple aim of improving the patient experience, improving population health, and reducing cost—we must ask ourselves, what new care connections are needed? This new environment demands a new vision for the multidisciplinary cancer care team.

We are fortunate to have ACCC, with its multidisciplinary "how to" focus, as we prepare today for the Next Gen Team of Tomorrow. I look forward to working with all of you this year. 

Coming in Your 2017 ONCOLOGY ISSUES

- ▶ Enhancing Survivorship through Improved Provider Communication, Care Coordination & Professional Education
- ▶ Developing a Nurse Practitioner Productivity Measurement Tool
- ▶ A Rural Chemotherapy Student Volunteer Support Program
- ▶ The Defeat GBM Collaborative: A Team-Based Approach to Researching Brain Cancer
- ▶ Foundation for Hospital Art—Painting a Brighter World in Cancer Care
- ▶ Setting up a Co-pay Card and Foundation Billing Process
- ▶ A Cognitive Approach to Cancer Treatment
- ▶ Moonshot Ready—The Cancer Biobank at St. Joseph Hospital
- ▶ Normalizing Feelings of Grief and Loss in Oncology Nurses
- ▶ Life with Cancer: A Comprehensive, Holistic, Patient-Centered Approach to Cancer Management
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Recognize Your Colleagues!

ACCC is accepting nominations for its Annual Achievement Award, Clinical Research Award, and the David King Community Clinical Scientist Award. Details for each award, as well as the nomination form can be found at accc-cancer.org/awards. To make a nomination, complete the form and email it to [Betsy Spruill at: awards@accc-cancer.org](mailto:awards@accc-cancer.org) or fax it to 301.770.1949 by June 28.



PUBLICATION

ACCC 2016-2017 Annual Report

Achievements in education and advocacy over the past 12 months; new member programs and member demographics; recent media coverage of ACCC; and the Treasurer's Report. Download today at: accc-cancer.org/about/pdf/annualReport-2017.pdf.



PUBLICATION

Updated! 2017 ACCC Patient Assistance & Reimbursement Guide

New programs and updated links. Download the revised PDF today and link directly to applications and enrollment portals. accc-cancer.org/PatientAssistanceGuide.

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fast

More on the Cost of Anti-Cancer Drugs

The National Health Interview Survey from 2011 to 2014 revealed that:

- **31.6%** of adults recently diagnosed with cancer and **27.9%** previously diagnosed with cancer in the last 2 years changed their prescription drug use due to financial reasons.

- **1/3** of non-elderly cancer survivors with high-deductible health insurance plans requested lower-cost medications from their doctors.

Source: Zheng Z, et al. Do cancer survivors change their prescription drug use for financial reasons? Findings from a nationally representative sample in the United States. *Cancer*. doi: 10.1002/cncr.30560.



Stressed Out?

A recent study finds that oncologists are suffering from burnout and stress:

- **42%** to **69%** reported feeling stressed at work.
- Nearly a third (**32%**) reported high burnout or emotional exhaustion.
- Many suffer from sleep deprivation, up to **30%** drink alcohol in a problematic way.
- More than a quarter (**27%**) have some kind of psychiatric morbidity.
- Up to **20%** of junior oncologists use hypnotic drugs.
- More than **12%** of screened positive for depression.

Source: Medisauskaitė A, Kamau C. Prevalence of oncologists in distress: systematic review and meta-analysis. *Psycho-Oncol*. 2017. doi.org/10.1002/pon.4382.



facts



Healthcare Attitudes—A Generational Comparison

Doctor-Patient Style

Boomers: Healthy skeptics

Gen X: Medical misanthropes

Millenials: Healthcare idealists

Communication Style

Boomers: Open and honest; agreeable when doc takes a team approach

Gen X: Guarded in conversation; may not be as open as necessary

Millenials: Open, but may overshare opinion; may challenge a doctor's diagnosis

How They Find a Doctor

Boomers: Ask a friend or family member for a recommendation

Gen X: Combination approach between asking people they know first and confirming online

Millenials: Look at online reviews and awards

Doctor-Patient Relationship

Boomers: **83%** have a PCP and want doctors to decide treatment options with them

Gen X: **64%** have a PCP and **1 in 4** has lost trust in a doctor or medical facility (last 2 years)

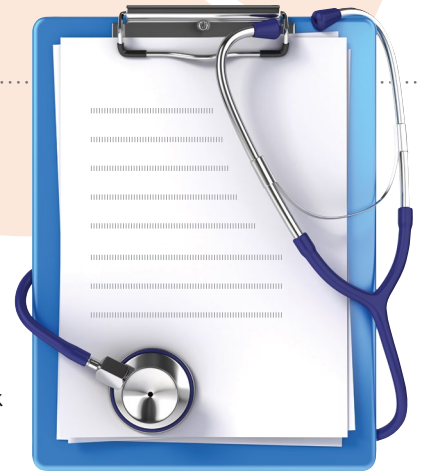
Millenials: **35%** have a PCP and choose alternate care facilities, like urgent care, in large numbers

Source: <http://www.vitals.com/about/posts/press-center/press-releases/vitals-index-study-reveals-stark-generational-differences-comes-attitudes-health-care>.

Survey Says...

- Supply chain tasks impact clinicians. Physicians and nurses spend, on average, nearly **20%** of their workweek on supply chain and inventory management. If they could reallocate this time, more than half said that they would spend this time with patients, while others would focus on research and education or training new staff.
- Nearly **1/3** of respondents haven't implemented a new inventory management system in at least **6** years.
- **78%** are manually counting inventory in some parts of their supply chain; only **17%** have an automated technology system to track products and inventory in real time.

Source: The Cardinal Health Hospital Supply Chain Survey. cardinalhealth.com/en/essential-insights/the-biggest-untapped-resource-at-your-hospital--your-supply-chain.html.



Reduction in Radiation Therapy Leads to Decline of Second Cancers in Childhood Cancer Survivors

Childhood cancer survivors are living longer. New research shows they are also less likely to develop second cancers while still young. The decline followed a sharp drop in the use of radiation therapy for treatment of childhood cancers. Between the 1970s and the 1990s, the percentage of pediatric cancer patients treated with radiation fell from **77%** to **33%**. The average radiation dose also dropped. Their chance of having second cancers within 15 years of the first cancer fell as well.

Source: Turcotte LM, et al. Temporal trends in treatment and subsequent neoplasm risk Among 5-year survivors of childhood cancer, 1970-2015. *JAMA*. 2017;317(8):814-824.



Overheard at the ACCC OCM Workshop

BY LEAH RALPH



Last month, at the ACCC 43rd Annual Meeting, Oncology Care Model (OCM) practices came together at an OCM Workshop to share updates, pain points and successes, and to collaborate on innovative approaches to meeting OCM requirements.

Participation in the OCM has been likened to “training for a marathon,” requiring cancer programs to do an honest self-assessment of their financial and operational capabilities, and double down on their investment in workflows, staffing, and data collection—all while trying to reduce costs and meet a number of beneficiary-level reporting requirements. EHRs (electronic health records) play a critical role in these efforts, and practices are finding that much of the quality and clinical data CMS is asking for is not readily accessible, requiring time-consuming chart abstraction and manual reporting. In addition to data analytics, other major challenges include staffing, investment in IT systems, and clinician education and engagement. Some practices have hired full-time patient care coordinators—similar to a research coordinator for a clinical trial—to manage OCM requirements, including identifying and tracking patients, coordinating episodes and required measures, and billing the monthly enhanced oncology services (MEOS) payments.

While the OCM’s policy goals—improving care quality and reducing costs—are the right ones, operationalizing the program has proven to be far more complex than originally anticipated, even by CMS. And, like

all major payment reform initiatives, course corrections will be needed along the way.

But despite challenges, ACCC OCM Workshop participants are also finding that the “practice transformation” requirements are strengthening their programs. Many have taken a “good, hard look” at palliative care and pain documentation, care coordination, and end-of-life conversations. Others have implemented social work and dietitian services that were not previously available to patients. While many cancer programs were doing these activities in some form before the OCM, this demonstration program has made these components robust and consistent, improving patient care. One practice called it an “awesome byproduct” of the program.

Another byproduct? Practices are also finding that the OCM is creating an imperative for the C-suite to make certain investments and providing leverage with EHR vendors; requests that were previously considered optimization items are now considered “must haves” to meet OCM requirements.

In March 2017 OCM practices faced their first big data reporting deadline, and later in the month received their first feedback reports following the first episode of care, breaking out cost per episode and comparing performance to other OCM practices. The data came in a format that was not easy to interpret, and required several practices to outsource the data analysis and interpretation. With the feedback reports practices are seeing their spending on OCM patients, and

getting a sense of how they may fare with performance-based payments down the road, but practices won’t see reconciliations against target prices until early 2018.

Where OCM practices succeed and struggle carry important implications for all cancer programs and the movement to value-based care. One practice called the OCM “the pebble in the pond for us.” We should all be watching closely. And taking notes.

For more information, visit ACCC’s OCM Collaborative at accc-cancer.org/OCM. All OCM participating programs are invited to join our online community at ocmcollaborative.org to hear what else your colleagues are saying. 

Leah Ralph is ACCC Director of Health Policy.

tools



Approved Drugs

- The U.S. Food and Drug Administration (FDA) granted accelerated approval to **Bavencio® (avelumab)** (EMD Serono, Inc., emdserono.com) for the treatment of patients 12 years and older with metastatic Merkel cell carcinoma. Avelumab is a programmed death-ligand 1 (PD-L1) blocking human IgG1 lambda monoclonal antibody. This is the first FDA-approved product to treat this type of cancer.

- Pfizer Inc. (Pfizer.com) announced that the FDA has approved a supplemental new drug application (NDA) for its first-in-class cyclin dependent kinase 4/6 (CDK 4/6) inhibitor, **Ibrance® (palbociclib)**. Ibrance now is indicated in combination with an aromatase inhibitor, expanding on its earlier indication in combination with letrozole, as initial endocrine based therapy in postmenopausal women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer.

- The FDA approved **Keytruda® (pembrolizumab)** (Merck, merck.com), an anti-PD-1 therapy, for the treatment of adult and pediatric patients with refractory classical Hodgkin lymphoma, or who have relapsed after three or more prior lines of therapy.

- Novartis (novartis.com) announced that the FDA approved **Kisqali® (ribociclib, formerly known as LEE011)** in combination with an aromatase inhibitor as initial

endocrine-based therapy for treatment of postmenopausal women with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer.

- The FDA expanded the approved use of **Stivarga® (regorafenib)** to include treatment of patients with hepatocellular carcinoma (liver cancer) who have been previously treated with the drug sorafenib. This is the first FDA-approved treatment for a liver cancer in almost a decade.

- The FDA granted regular approval to **Tagrisso (osimertinib)** (AstraZeneca Pharmaceuticals, LP, astrazeneca-us.com) 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, whose disease has progressed on or after EGFR tyrosine kinase inhibitor therapy.

- Genentech (gene.com) announced that the FDA granted accelerated approval to **Tecentriq® (atezolizumab)** for the treatment of people with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin chemotherapy.

- The FDA has approved Lexicon Pharmaceuticals' (lexpharma.com) **Xermelo™ (telotristat ethyl)** for treatment for diarrhea caused by carcinoid syndrome.

- Silvergate Pharmaceuticals, Inc. (silvergatepharma.com) announced that the FDA

approved **Xatemp™ (methotrexate) Oral Solution**, the first and only FDA-approved methotrexate oral solution. Xatemp is indicated for the treatment of acute lymphoblastic leukemia (ALL) and polyarticular juvenile idiopathic arthritis in pediatric patients.

- Tesaro, Inc. (tesarobio.com) announced that the FDA approved **Zejula™ (niraparib)**, a poly ADP-ribose polymerase (PARP) inhibitor, for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy.

Approved Devices

- Lifetrack Medical Systems Inc. (lifetrackmed.com) announced FDA approval of its **Lifesys™ PACS**, featuring patented RadNav™ technology, which serves as a guidance system to radiologists through its integrated decision support system and active templates.

- iCAD (icadmed.com) announced that the **PowerLook® Tomo Detection** received premarket approval from the FDA. This concurrent-read computer-aided detection solution for digital breast 3D tomosynthesis and is the latest innovation available on the PowerLook® Breast Health Solutions platform. 

compliance

When *NOT* to Collect from the Patient

BY CINDY PARMAN, CPC, CPC-H, RCC

As reimbursement continues to shrink through bundling, packaging, service consolidation, and other changes to insurance payment systems, many providers are training staff to collect coinsurance, deductibles, co-payments, and other patient cost-shares at the time of service. In addition, patients today are often responsible for a more sizeable portion of their medical bills, which means that the patient's financial responsibility is the largest it has been since the implementation of healthcare coverage. For the purposes of this article, deductible is defined as the amount an insured individual is responsible for payment, generally on an annual basis, prior to receiving most medical services. Co-payment is defined as the set dollar amount paid by a patient—regardless of whether or not the deductible has been met; coinsurance is defined as the amount the patient pays for each service performed after the deductible is met, generally a percentage of the insurance payment amount.

Healthcare providers could lose significant income if patients are billed after treatment has been performed.¹ Specifically, asking patients for payment after treatment has been provided may result in additional staff time, postage, and printing costs. Collecting the patient payment amount at the time of service—while the patient is still in the office—is efficient and ensures that the total charge for the service or procedure is received.

But what if the patient is a qualified Medicare beneficiary? In 2014 there were 53.8 million Medicare beneficiaries,² with

approximately 7 million of this total population enrolled in the Qualified Medicare Beneficiary program. (See Table 1, right, for the Qualified Medicare Beneficiary eligibility and benefits.) The 2017 Medicare Physician Fee Schedule (PFS) Final Rule published by the Centers for Medicare & Medicaid Services (CMS) provided a reminder related to this specific beneficiary group:³

Although we [CMS] did not solicit comments on this statement of current law and policy, we appreciate the comments received, which included comments from national beneficiary advocacy organizations, and professional, insurance, and medical billing associations.

Comment: Commenters concurred that confusion and improper QMB [Qualified Medicare Beneficiary] billing problems remain pervasive and affirmed their negative toll on beneficiaries. Commenters were supportive of CMS's expanded efforts to educate providers regarding QMB billing rules to reduce the incidence of improper QMB billing. Some commenters also noted that Medicare providers encounter difficulties discerning which patients are QMBs and advised CMS to adopt strategies to help providers ascertain this information. Additionally, one commenter noted that the variation in state policies to pay providers for Medicare cost-sharing fuels confusion, frustration and compliance problems.

Response: We continue to pursue opportunities to educate providers and welcome partnering with commenters and others in these efforts. Currently, Medicare providers must determine a

patient's QMB status through information from State Medicaid agencies, including online eligibility systems and beneficiary identification cards. We are actively exploring additional mechanisms for Medicare providers to readily identify the QMB status of patients.

We are restating information to inform providers to take steps to educate themselves and their staff about QMB billing prohibitions and to exempt QMB individuals from Medicare cost-sharing billing and related collection efforts.

Qualified Medicare Beneficiaries

According to MLN Matters SE1128, revised January 12, 2017,⁴ the Qualified Medicare Beneficiary program is a state Medicaid benefit that covers Medicare deductibles, coinsurance, and co-payments, subject to state payment limits. This program was designed to ensure full access to the Medicare benefit for the lowest income enrollees by covering the deductible and other cost-sharing. Qualified Medicare Beneficiary enrollees are the largest eligibility group within the Medicare-Medicaid enrollee population. Qualified Medicare Beneficiary enrollees apply for this benefit with their state's Medicaid program, and eligibility is re-determined annually.

Section 1902(n)(3)(B) of the Social Security Act, as modified by Section 4714 of the Balanced Budget Act of 1997⁵ defines reimbursement and balance-billing for the Qualified Medicare Beneficiary program. This legislation clarified that a state is not

obligated to pay providers up to the full amount of Medicare cost-sharing if the total payment (including both the Medicare portion and the state's portion) would exceed the state's Medicaid rate for the service.

The vast majority of states limit Medicare cost-sharing payment levels for Qualified Medicare Beneficiary enrollees and other full-benefit dual-eligible beneficiaries at their Medicaid rates. And Medicare providers must accept assignment of the Medicare payment and Medicaid payment (if any) as payment in full for services rendered to a Qualified Medicare Beneficiary enrollee.

As a result, Medicare providers may not balance bill Qualified Medicare Beneficiary individuals for Medicare cost-sharing, regardless of whether the state reimburses providers for the full Medicare

cost-share amounts. All original Medicare and Medicare Advantage providers (not only those who accept Medicaid) are required to follow these guidelines.

According to CMS, Qualified Medicare Beneficiary individuals retain their protection from balance billing when they cross state lines to receive care. In other words, providers cannot charge these individuals even if the patient's Qualified Medicare Beneficiary benefit is provided by a different state than the state in which the care is rendered. In addition, enrollees in the Qualified Medicare Beneficiary program cannot choose to "waive" their Qualified Medicare Beneficiary status and pay Medicare cost-share amounts. This means that providers may not accept these patients as self-pay in order to bill the patient directly; providers must accept Medicare

assignment for all Medicaid patients, including those in the Qualified Medicare Beneficiary program.

NO Balance Billing

The CMS publication, "Access to Care Issues Among Qualified Medicare Beneficiaries (QMB)," dated July 2015⁶ includes two studies, one of which evaluates whether Qualified Medicare Beneficiary enrollees are inappropriately balance billed. Findings that resulted from the interviews performed by the Lewin Group include:⁶

1. Providers incorrectly balance billed participants for Medicare cost-sharing; most participants paid these bills and unpaid bills were incorrectly submitted to collection agencies.
2. Participants and providers found billing processes confusing or complex.

Table 1. Qualified Medicare Beneficiary Eligibility & Benefits		
DUAL ELIGIBILITY	ELIGIBILITY CRITERIA	BENEFITS
Qualified Medicare Beneficiary	- Resources cannot exceed \$7,280 for a single individual or \$10,930 in 2015 for an individual living with a spouse and no other dependents. - Income cannot exceed 100% of the Federal Poverty Level (FPL) +\$20 (\$1,001/month, Individual or \$1,348/month, Couple in 2015). NOTE: These guidelines are a federal floor. Under Section 1902(r)(2) of the Social Security Act, states can effectively raise these limits above these baseline federal standards.	Medicaid pays Medicare Part A and B premiums, deductibles, coinsurance, and copays to the extent required by the state Medicaid Plan. - Exempts beneficiaries from Medicare cost-sharing charges. - The state may choose to pay the Medicare Advantage (Part C) premium.
Qualified Medicare Beneficiary Plus	Meets all of the standards for Qualified Medicare Beneficiary eligibility as described above, but also meets the financial criteria for full Medicaid coverage.	Provides all benefits available to Qualified Medicare Beneficiary enrollees, as well as all benefits available under the state plan to a fully eligible Medicaid recipient.

Overall, the study found that in spite of laws aimed at protecting beneficiaries from being billed the Medicare cost-share, this practice is still in effect. In addition, in states that adopted this “lesser-of” policy, providers ultimately may not be reimbursed the full amount for their services to Qualified Medicare Beneficiary enrollees. According to the CMS publication, “Dual Eligible Beneficiaries Under the Medicare and Medicaid Programs,” Medicare-covered services also covered by Medicaid are paid first by Medicare because Medicaid is generally the payer of last resort.⁷ In general, Part B providers—including physicians and hospitals—are paid 80 percent of a service’s Medicare rate by the federal program. A non-Qualified Medicare Beneficiary beneficiary would receive the bill for the 20 percent balance. However, since Qualified Medicare Beneficiary enrollees cannot be balance-billed, the provider would instead bill the balance to the state Medicaid program, which is only required by federal statute to cover a service up to its Medicaid rate. This means that when the Medicare payment exceeds the Medicaid rate, states have no obligation to pay any additional amount.

For example, if the Medicare allowable for a service is \$100, and the beneficiary cost-share is 20 percent, Medicare would pay \$80 and the beneficiary would pay \$20. If the patient has Qualified Medicare Beneficiary status, and the state Medicaid allowed \$78 for the same service, there would be no additional payment to the provider and the patient could not be balance-billed for any cost-share.

Recommendations

CMS recommends that providers and their billing staff be aware of the federal balance billing law and policies regarding Qualified Medicare Beneficiary individuals. Start by contacting the Medicaid Agency in the state(s) where Medicare beneficiaries live to learn about ways to identify Qualified Medicare Beneficiary patients. Determine

what identification cards are issued to Qualified Medicare Beneficiary individuals and verify which patients have them. Find out if state systems can be queried to verify Qualified Medicare Beneficiary enrollment for the local patient population. Contact Medicare Advantage plans directly to determine how to identify the plan’s Qualified Medicare Beneficiary enrollees.

All Medicare providers should ensure that their billing software and administrative staff exempt Qualified Medicare Beneficiary individuals from Medicare cost-sharing billing and related collection efforts. For example, if a claim is automatically crossed over to another payer, such as Medicaid, it is generally noted on the Medicare Remittance Advice.

On Feb. 3, 2017, CMS released *MLN Matters MM9911* stating that effective for claims processed on or after Oct. 2, 2017, a Qualified Medicare Beneficiary indicator will be included on the Provider Remittance Advice and to beneficiaries on their Medicare Summary Notice to reflect that the beneficiary is enrolled in the Qualified Medicare Beneficiary program and has no Medicare cost-sharing liability.⁸ One or more of the following Remittance Advice Remark Codes will be included:

- **N781:** No deductible may be collected as patient is a Medicaid/Qualified Medicare Beneficiary. Review your records for any wrongfully collected coinsurance, deductible, or co-payments.
- **N782:** No coinsurance may be collected as patient is a Medicaid/Qualified Medicare Beneficiary. Review your records for any wrongfully collected coinsurance, deductible, or co-payments.
- **N783:** No co-payment may be collected as patient is a Medicaid/Qualified Medicare Beneficiary. Review your records for any wrongfully collected coinsurance, deductible, or co-payments.

In addition, the Medicare Administrative Contractors (MACs) will include a Claim Adjustment Reason Code of **209**:

Per regulatory or other agreement. The provider cannot collect this amount from the patient. Refund to patient if collected.

Last, the Medicare Summary Notice will be modified to inform beneficiaries that if they are enrolled in the Qualified Medicare Beneficiary program they cannot be billed for Medicare cost-sharing for covered items and services.

Provider Penalties

According to CMS, providers who inappropriately balance bill Qualified Medicare Beneficiary individuals are violating their Medicare Provider Agreement and may be subject to sanctions, such as development of a corrective action plan, monetary sanctions, and increased reporting requirements. While a provider may eventually be excluded from the federal healthcare program, exclusion is relatively rare and only occurs if the provider fails to become substantially compliant during the corrective period.⁹

These days, more insured patients owe higher deductibles, co-payments, and coinsurance amounts. In addition, it is important to make sure these patients pay their cost-share amount before walking out the door after a visit or treatment. Administrative costs and low collection rates make after-the-fact collections a losing proposition for many healthcare entities. Effective collection keeps providers in business, allows the hire of quality employees, and enables the provision of exceptional, quality-focused patient care.

However, despite federal law, CMS continues to be concerned that erroneous balance billing of Qualified Medicare Beneficiary individuals persists. Many beneficiaries are unaware of the billing restrictions, or may be concerned about undermining the provider relationship if they refuse to pay the requested amount. Others may experience undue stress

when unpaid bills are referred to collection agencies.

In addition to reviewing national CMS guidelines, providers should review local Medicare contractor information. For example, Noridian Healthcare Solutions includes not only basic information on Qualified Medicare Beneficiary individuals, but also sample beneficiary and provider compliance letters relating to balance-billing these enrollees.¹⁰

Cindy Parman, CPC, CPC-H, RCC, is a principal at Coding Strategies, Inc., in Powder Springs, Ga.

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spotlight

Virginia Mason Memorial, North Star Lodge Cancer Center Yakima, Washington



Visitors and patients to North Star Lodge Cancer Center in Yakima, Wash., may do a double-take when approaching the facility for the first time. Part of Virginia Mason Memorial, the cancer center is located in the foothills of the Cascade Mountains and resembles a mountain lodge.

Senior director of the Oncology Service Line, Carol Vanevenhoven, PharmD, MBA, explains how this unusual design came about: “We had a physician with a vision to remove environmental stress from the equation of cancer care. The community really got behind the idea and with the help of The Memorial Foundation, and with many generous donors, we made it a reality.”

Built in 1999, the interior of North Star also mimics the aesthetics of a mountain lodge. The high, vaulted ceilings feature large exposed log beams. There are river rock fireplaces and large windows that allow for the maximum amount of natural light. Almost every corner of the building provides a view of either nature or a water feature that creates a calming sound as patients and visitors move throughout the building.

“You would not recognize this as a medical facility from the entry points into the clinical areas. It is designed to meet all the medical and licensure standards but in a way that sets patients and their families at ease,” says the executive director of North Star, Merle Wolf, FACHE, SPHR, SHRM-SCP.

Comprehensive Oncology Services

Virginia Mason Memorial has been continuously accredited by the American College of

Surgeons Commission on Cancer (CoC) since 1981. North Star Lodge is also accredited by The Joint Commission as part of the hospital.

The comprehensive cancer center houses medical oncology (staffed by six medical oncologists and two mid-levels), radiation oncology (staffed by three radiation oncologists), on-site laboratory services, pharmacy, and infusion on the first floor of the building. Radiation oncology services include two Varian TruBeam linear accelerators and on-site CT imaging. This allows radiation oncologists to do all aspects of treatment planning without patients needing to leave the building.

The coordination between radiation and medical oncology teams is important to patients and providers. Radiation oncologist Ellis Ziel, MD, says, “I can walk right across the building to meet with other medical experts regarding treatment coordination and care instead of calling or emailing another facility for information. This is patient centered care at its best.”

The lower level of North Star contains integrative services: genetic counselors, dietitians, the clinical trials department, cancer registry, financial advocates, social workers, navigation, support group space, and a patient library.

Medical oncologist Thomas Giever, DO, MBA, said he came to North Star Lodge because he wanted “to be part of a team that delivers state-of-the-art therapy and also participates in clinical research trials providing novel treatment options. The supportive care services at North Star allow us to help the whole person and not just treat a disease.”

Vanevenhoven says the on-site pharmacy services are a great convenience for patients. “They are able to dispense the majority of oral chemotherapy agents. So many of our patients can get their prescription dispensed here at the center, talk to a pharmacist if they’re having any challenges, and have someone proactively checking up with them about how they’re tolerating their oral agents and compliance.”

The Oncology Care Model

North Star Lodge is one of only three practices in Washington state participating in the Centers for Medicare and Medicaid Innovation (CMMI) Oncology Care Model (OCM).

The cancer center hopes that participation in this demonstration project will result in positive changes in cancer-care delivery. “We see this project as a way to be innovative and ensure that our care delivery model is patient focused and cost effective while delivering the best possible advanced care,” said Wolf.

The cancer center embarked on its OCM journey in July 2016. Since then, one of the areas of focus has been patient navigation. While the cancer center historically has always offered some form of navigation, four nurses are now solely dedicated to patient navigation and work closely with the social work department. As part of the OCM, staff implemented a new type of weekly complex case review that heavily leverages the skills of navigators and social workers. This case review focuses on the social determinants of a patient’s health-care, rather than the clinical focus of the



cancer center's multidisciplinary disease site-specific tumor boards.

Cost of Care Conversations

According to Vanevenhoven, social determinants of health play a big role in the care of patients. In Yakima, 20.5 percent of the population lives below the federal poverty level. Overall health literacy is low too, with nearly 25 percent having less than basic understanding of health-related issues.

At North Star, when social work staff administered distress screening with patients, the results showed a high number of patients who were worried about the financial piece. A process change was implemented: staff began proactively having conversations with patients about costs of care and financial assistance resources. The result was a correlation between adding proactive cost-of-care discussions and a decrease in the amount of financial distress seen in patients upon initial screening. “We now have data to demonstrate that our financial counseling is truly making a difference above and beyond anecdotal stories of patients,” said Vanevenhoven.

The financial counselors at the cancer center are not licensed social workers.

Rather, they have a different specialized skill set to check benefits and meet with patients to specifically talk about financial resources, allowing the social workers time to have different types of conversations with patients about other barriers to care, such as transportation.

One of the challenges often seen is transportation—about one-third of the cancer center's patients travel between 25 to 50 miles for treatment. “Since we don't have a great public transportation system in our community, we must leverage other resources, whether it's working with community partners like People for People or working with the Memorial Foundation to purchase gas cards for patients,” said Vanevenhoven.

Because the cancer center serves a broad geographical area, it operates two satellite clinics to make access to care easier for the geographically isolated. One clinic is located 30 miles north in Ellensburg, Wash., and the other is 30 miles south in Sunnyside, Wash. The Ellensburg clinic operates five times per month and Sunnyside is open every other week. Both clinics offer medical oncology and chemotherapy services.

North Star Lodge Cancer Center also serves a significant number of people

within the community for whom English is not their first language. “Our population is about 46 percent Caucasian and 46 percent Latino, so we have several bilingual staff here. Not only nurses and physicians but also support staff such as financial counselors,” said Wolf. 

Select Supportive Care Services

- Dietitian
- Financial counseling
- Support groups
- Genetic counseling
- Oncology physical therapy and exercise program

Number of new analytic cases seen in 2016: 853

Upon progression on
GnRH therapy* in mCRPC¹

START
Xtandi®

TO EXTEND SURVIVAL¹

23% reduction in risk of death with XTANDI + GnRH therapy vs placebo + GnRH therapy in PREVAIL¹

- Co-primary endpoint, OS: (HR = 0.77 [95% CI, 0.67-0.88])¹
- Median OS was 35.3 months (95% CI, 32.2-NR) with XTANDI vs 31.3 months (95% CI, 28.8-34.2) with placebo¹

Co-primary endpoint, rPFS²:

(HR = 0.17 [95% CI, 0.14-0.21]; $P < 0.0001$)¹

*Or after bilateral orchiectomy.¹

CI, confidence interval; HR, hazard ratio; mCRPC, metastatic castration-resistant prostate cancer; NR, not reached; OS, overall survival; rPFS, radiographic progression-free survival.

Indication

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. XTANDI can cause fetal harm and potential loss of pregnancy.

Warnings and Precautions

Seizure occurred in 0.5% of patients receiving XTANDI in clinical studies. In placebo-controlled studies, 8 of 1671 (0.5%) patients treated with XTANDI and 1 of 1243 (0.1%) patients treated with placebo experienced a seizure. In 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. In a placebo-controlled study in chemotherapy-naïve patients, 1 of 871 (0.1%) patients treated with XTANDI and 1 of 844 (0.1%) patients treated with placebo experienced a seizure. In bicalutamide-controlled studies conducted in chemotherapy-naïve patients, 3 of 380 (0.8%) patients treated with XTANDI and 1 of 387 (0.3%) patients treated with bicalutamide experienced a seizure. 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 ($\geq 10\%$) that occurred more commonly ($\geq 2\%$ over placebo) in the XTANDI patients from the two placebo-controlled 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. In the bicalutamide-controlled study of chemotherapy-naïve patients, the most common adverse reactions ($\geq 10\%$) reported in XTANDI patients were asthenia/fatigue, back pain, musculoskeletal pain, hot flush, hypertension, nausea, constipation, upper respiratory tract infection, diarrhea, and weight loss.

In the study of patients taking XTANDI who previously received docetaxel, 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 the placebo-controlled study of chemotherapy-naïve patients, 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. In the bicalutamide-controlled study of chemotherapy-naïve patients, Grade 3-4 adverse reactions were reported in 38.8% of XTANDI patients and 37.6% of bicalutamide patients. Discontinuations due to adverse events were reported for 7.6% of XTANDI patients and 6.3% of bicalutamide patients.

Lab Abnormalities: In the two placebo-controlled trials, 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).

Data vs bicalutamide

Median rPFS[§] was 19.5 months (95% CI, 11.8-NR) for patients receiving XTANDI + GnRH therapy* vs 13.4 months (95% CI, 8.2-16.4) for patients receiving bicalutamide + GnRH therapy* (HR = 0.60 [95% CI, 0.43-0.83])^{||¶1}

CONVENIENT DOSING¹

Administer XTANDI as 160 mg (four 40 mg capsules) orally, once daily

Each capsule should be swallowed whole and should not be chewed, dissolved, or opened. If a patient experiences a $\geq$ Grade 3 toxicity or an intolerable side effect, withhold dosing for one week or until symptoms improve to $\leq$ Grade 2, then resume at the same or a reduced dose (120 mg or 80 mg), if warranted. For additional dosing information, see Drug Interactions and Full Prescribing Information.

Learn more about XTANDI at StartXtandi.com

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 a study of patients taking XTANDI who previously received docetaxel, 1% of XTANDI patients compared to 0.3% of placebo patients died from infections or sepsis. In the placebo-controlled study of chemotherapy-naïve patients, 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 in the two placebo-controlled trials. 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 in the two placebo-controlled trials. 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.

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.

[†]As seen in the PREVAIL trial (Study 2): a multinational, double-blind, randomized, phase 3 trial that enrolled 1717 patients with metastatic CRPC who progressed on GnRH therapy, or after bilateral orchiectomy, and who had not received prior cytotoxic chemotherapy. All patients continued on GnRH therapy.^{1,2}

[‡]An updated survival analysis was conducted when 784 deaths were observed. The median follow-up time was 31 months. Results from this analysis were consistent with those from the prespecified interim analysis.¹

[§]Radiographic progression-free survival was defined as the time from randomization until first objective evidence of radiographic disease progression based on the assessments by Independent Central Review (ICR) or death, whichever occurred first.¹

^{||}As seen in the TERRAIN trial (Study 3): an additional trial in metastatic CRPC. TERRAIN was a multinational, double-blind, randomized trial that enrolled 375 patients and compared XTANDI + GnRH therapy, or after bilateral orchiectomy with bicalutamide + GnRH therapy, or after bilateral orchiectomy in patients who were asymptomatic or mildly symptomatic.^{1,3}

^{¶1}Radiographic disease progression was assessed by ICR using the Prostate Cancer Clinical Trials Working Group 2 (PCWG2) criteria and/or Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 criteria for progression of soft tissue lesions.¹

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 **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 and potential loss of pregnancy

WARNINGS AND PRECAUTIONS

Seizure

Seizure occurred in 0.5% of patients receiving XTANDI in clinical studies. In placebo-controlled studies, 8 of 1671 (0.5%) patients treated with XTANDI and 1 of 1243 (0.1%) patients treated with placebo experienced a seizure. In 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 a placebo-controlled study in chemotherapy-naïve patients, 1 of 871 (0.1%) treated with XTANDI and 1 of 844 (0.1%) patients treated with placebo experienced a seizure. In bicalutamide-controlled studies conducted in chemotherapy-naïve patients, 3 of 380 (0.8%) patients treated with XTANDI and 1 of 387 (0.3%) patients treated with bicalutamide 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.

Three 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. Two trials were placebo-controlled (Studies 1 and 2), and one trial was bicalutamide-controlled (Study 3). In Studies 1 and 2, patients received XTANDI 160 mg or placebo orally once daily. In Study 3, patients received XTANDI 160 mg or bicalutamide 50 mg orally once daily. All patients continued androgen deprivation therapy. Patients were allowed, but not required, to take glucocorticoids.

The most common adverse reactions ($\geq 10\%$) that occurred more commonly ($\geq 2\%$ over placebo) in the XTANDI-treated patients from the two randomized placebo-controlled 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: XTANDI versus Placebo in Metastatic CRPC 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 $\geq 2\%$ 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: XTANDI versus Placebo in Chemotherapy-naïve Metastatic CRPC

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 $\geq 2\%$ 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

^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.

Study 3: XTANDI versus Bicalutamide in Chemotherapy-naïve Metastatic CRPC

Study 3 enrolled 375 patients with metastatic CRPC who had not received prior cytotoxic chemotherapy, of whom 372 received at least one dose of study drug. The median duration of treatment was 11.6 months with XTANDI and

5.8 months with bicalutamide. Discontinuations with an adverse event as the primary reason were reported for 7.6% of XTANDI-treated patients and 6.3% of bicalutamide-treated patients. The most common adverse reactions leading to treatment discontinuation were back pain and pathological fracture, which occurred in 3.8% of XTANDI-treated patients for each event and in 2.1% and 1.6% of bicalutamide-treated patients, respectively. Table 3 shows overall and common adverse reactions ($\geq 10\%$) in XTANDI-treated patients.

Table 3. Adverse Reactions in Study 3

	XTANDI N = 183		Bicalutamide N = 189	
	Grade 1-4 ^a (%)	Grade 3-4 (%)	Grade 1-4 ^a (%)	Grade 3-4 (%)
Overall	94.0	38.8	94.2	37.6
General Disorders				
Asthenic Conditions ^b	31.7	1.6	22.8	1.1
Musculoskeletal And Connective Tissue Disorders				
Back Pain	19.1	2.7	18.0	1.6
Musculoskeletal Pain ^c	16.4	1.1	14.3	0.5
Vascular Disorders				
Hot Flush	14.8	0.0	11.1	0.0
Hypertension	14.2	7.1	7.4	4.2
Gastrointestinal Disorders				
Nausea	14.2	0.0	17.5	0.0
Constipation	12.6	1.1	13.2	0.5
Diarrhea	11.5	0.0	9.0	1.1
Infections And Infestations				
Upper Respiratory Tract Infection ^d	12.0	0.0	6.3	0.5
Investigational				
Weight Loss	10.9	0.5	7.9	0.5

a CTCAE v 4.

b Including asthenia and fatigue.

c Including musculoskeletal pain and pain in extremity.

d Including nasopharyngitis, upper respiratory tract infection, sinusitis, rhinitis, pharyngitis, and laryngitis.

Laboratory Abnormalities

In the two randomized placebo-controlled 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 placebo-controlled 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 placebo-controlled 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

Risk Summary

XTANDI is contraindicated for use in pregnant women because the drug can cause fetal harm and potential loss of pregnancy. XTANDI is not indicated for use in females. There are no human data on the use of XTANDI in pregnant women. In animal reproduction studies, oral administration of enzalutamide in pregnant mice during organogenesis caused adverse developmental effects at doses lower than the maximum recommended human dose.

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).

Lactation

Risk Summary

XTANDI is not indicated for use in females. There is no information available on the presence of XTANDI in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production.

Females and Males of Reproductive Potential

Contraception

Males

Based on findings in animal reproduction studies, advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the final dose of XTANDI.

Infertility

Based on animal studies, XTANDI may impair fertility in males of reproductive potential.

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 placebo-controlled 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 hepatic 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 $\leq$ creatinine clearance [CrCL] $\leq$ 89 mL/min) compared to patients and volunteers with baseline normal renal function (CrCL $\geq$ 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).

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Marketed by:

Astellas Pharma US, Inc., Northbrook, IL 60062
Medivation, Inc., San Francisco, CA 94105

Revised: October 2016

151074-XTA

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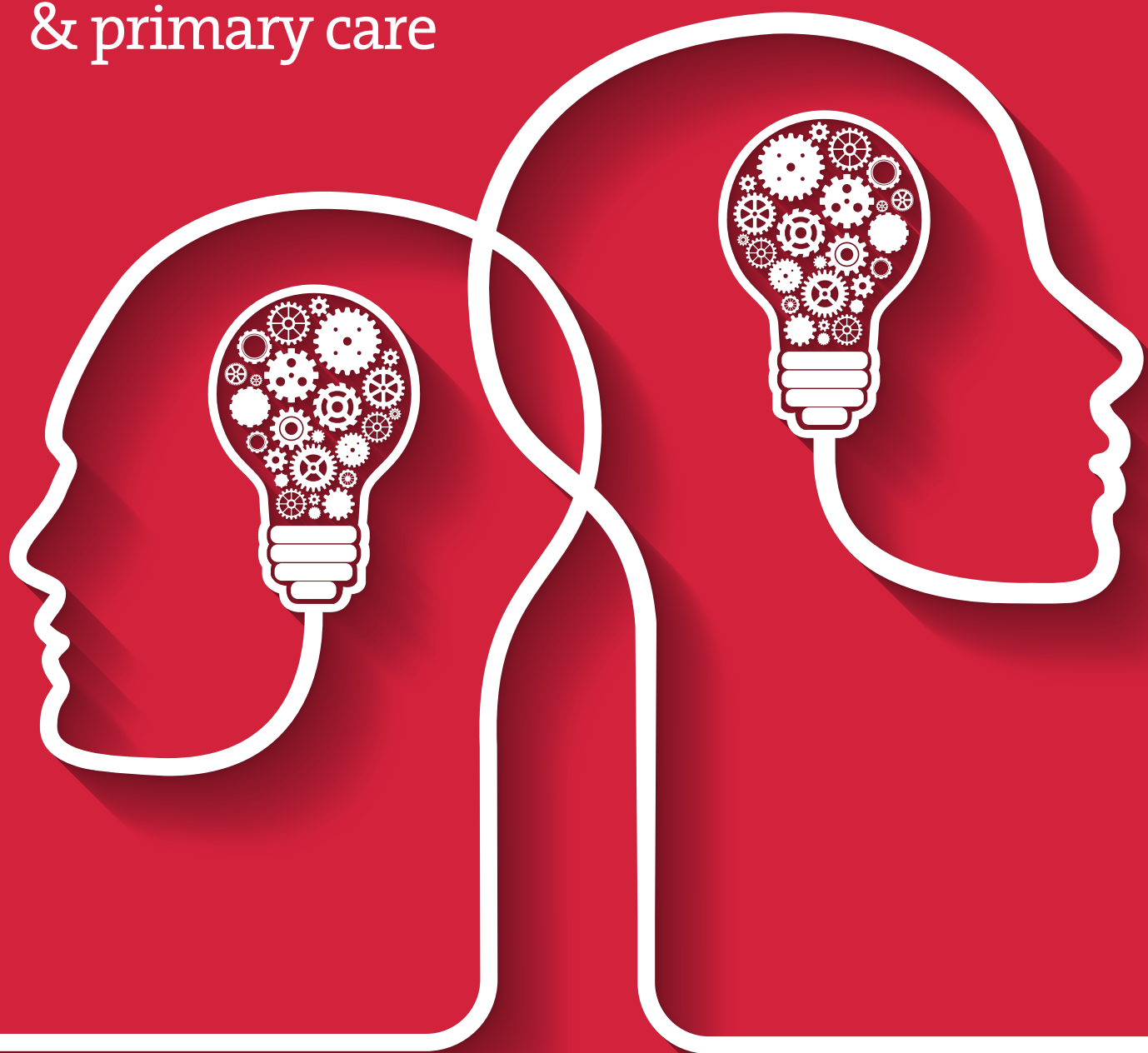
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076-1883-PM

Fox Chase Cancer Center *Care Connect*

Improving collaboration
between oncology
& primary care





When the Institute of Medicine (IOM) released its 2016 report, *From Cancer Patient to Cancer Survivor: Lost in Transition*, there were an estimated 10 million cancer survivors in the United States.¹ Currently, this estimate stands at 15.5 million and is expected to reach 20.3 million by 2026.² In its report, the IOM identified four essential elements of survivorship care: 1) prevention of recurrent and new cancers, 2) surveillance for cancer recurrence, 3) intervention for consequences of cancer and its treatment, and 4) coordination between specialists and primary care providers (PCPs). Despite this last recommendation, many PCPs do not consider themselves prepared to deal with common survivorship issues in the cancer patients they see due to a lack of adequate training.³ Specifically, PCPs identified a need for further education on topics such as:⁴

- Surveillance modalities, intervals, and duration, as well as screening for other cancers.
- Management of treatment-related morbidity.
- Prevention and risk-modifying strategies, such as diet and exercise.
- Psychosocial effects of cancer and its treatment.
- Coordination of care—with whom and when.

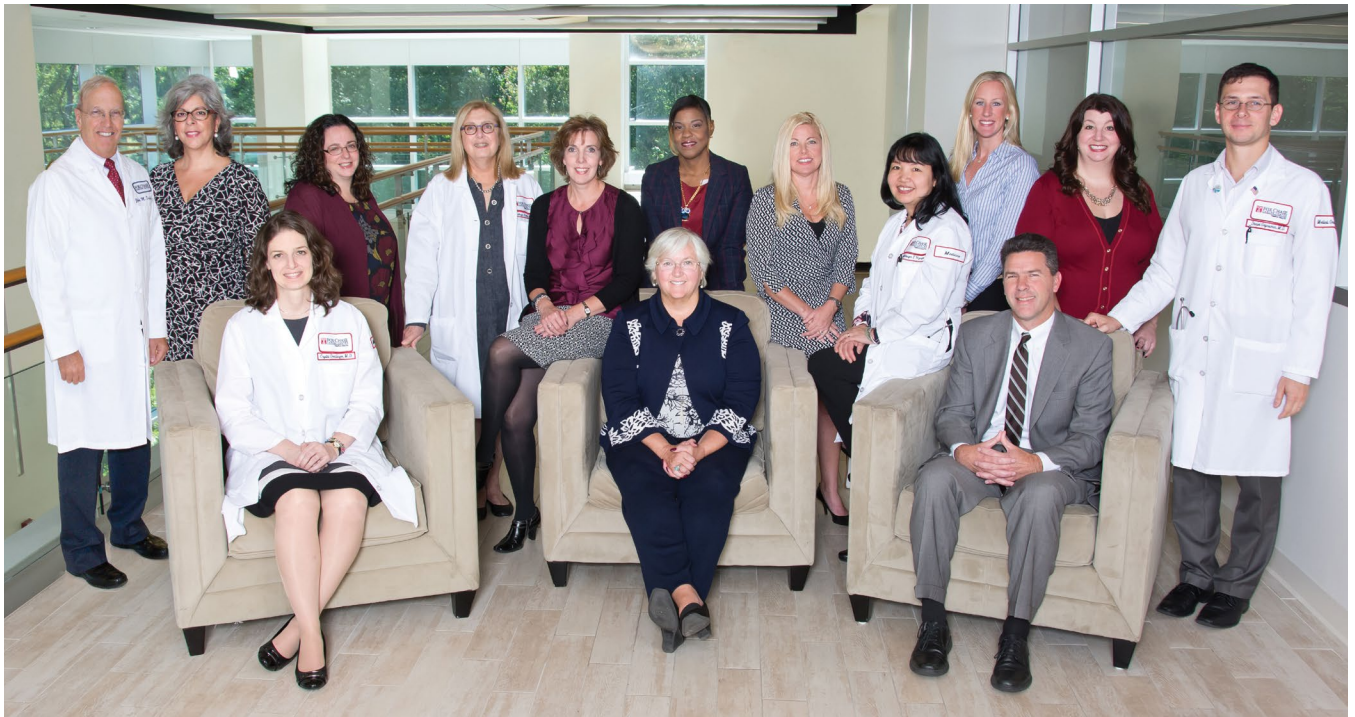
Recognizing both the impact of the growing survivor population and the existence of gaps in care coordination between oncology and primary care, senior administrative and clinical leadership at Fox Chase Cancer Center, Philadelphia, Pa., committed resources to develop a program to improve communication and education between the two settings of care, and improve overall survivorship care.

Establishing a Working Group

The first step in the process was the creation of a working group, which was tasked with identifying programmatic solutions to

Education is a key component to improving the connectivity and smooth transition of care between the oncology and primary care setting. As part of the *Care Connect* program, we established a clinical advisory team to help guide education events, patient education, and any other programming that would impact clinical care.

address three overarching questions: How are we going to handle the projected increase in cancer survivors? How can we effectively and appropriately transition survivors to primary care? How can we quell the common fear that survivors have when they no longer need to see their oncology provider? The working group was comprised of stakeholders from across Fox Chase Cancer Center and included physicians, nursing, administration, clinical program leadership, community outreach, marketing, and business development staff. As a member organization of the Temple University Health System, Fox Chase engaged physician and administrative leadership from Temple Physicians, Inc., a community-based physician network that supports primary care for patients served by the Temple Health System, to participate in the working group. Representing the view of community-based primary care physicians, their input was invaluable in helping construct the Fox Chase Cancer Center *Care Connect* program.



Fox Chase Cancer Center *Care Connect* staff members.

For three months in 2015, the working group met weekly to develop a value proposition, a framework, and program requirements that would bring value to all stakeholders—survivors, primary care physicians, and specialty oncologists. Incrementally, the working group:

- Created value propositions for Fox Chase Cancer Center and its *Care Connect* partners.
- Developed physician member participation criteria.
- Outlined a platform for provider education.
- Implemented a process to recruit primary care physicians.
- Created marketing and branding standards.

Creating a Value Proposition

The overall goal of the *Care Connect* program was to create an engagement strategy with PCPs to improve coordination of patient care. During the planning phase, the working group identified several key objectives as the core of the program:

- Improve interactions and enhance communication between PCPs and Fox Chase physicians.
- Increase collaboration to effectively transition cancer survivors back into the community when appropriate.
- Develop a network of primary care physicians to whom Fox Chase faculty could direct patients who seek those services.
- Improve care by providing education in cancer prevention and screening guidelines to community physicians.

Based on these objectives, the working group developed the following value propositions as ones that are important to *Care Connect* members:

- Effective access and communication with Fox Chase Cancer Center.
- Opportunity to improve Quality Physician Measure (QPM) scoring. (These quality measures are required by one of the main insurers in the Philadelphia area).
- Brand identity for practices.
- Education to improve core competencies.
- Shared collaboration in support of a growing cancer survivor population.

Value propositions for Fox Chase Cancer Center included:

- A process to improve transition of survivorship care back into the community.
- Opportunity to provide screening, risk, and diagnostic services.
- Ability to dispel the notion that Fox Chase Cancer Center is only a place for cancer treatment.
- Ability to leverage an organized group of PCPs for patients who need these services.

Rolling out the Pilot Program

After establishing the value framework and requirements of the *Care Connect* program, the working group initiated a limited pilot program to a select group of PCP practices that had collaborated with Fox Chase on mutual patient care in the past. While a subset of those were primary care practices in Temple Physicians, Inc., we felt it was important to include both practices within our own health system and independent primary care physicians to

(continued on page 26)

Figure 1. Quality Performance Measures Sample Report⁵

Provider ID:

Specialty:

QPM Tier _____ QPM Percentile Rank _____

PERFORMANCE MEASURES		Members Eligible for Services [*]	Members Who Received Services [†]	Percent Received Services	
				Your Results	Peer Average
Childhood Immunizations	DTaP				
	MMR				
	IPV				
	HIB				
	Rotavirus				
Adolescent Immunization	Meningococcal Vaccine				
	Tdap or Td				
Well-Care Visits	1st 15 months of life				
	3rd, 4th, 5th, and 6th years of life				
	Adolescent well-care visits				
Appropriate testing for children with pharyngitis					
Appropriate treatment for children with upper respiratory infection					
Cancer Screening	Breast cancer screening				
	Cervical cancer screening				
	Colorectal cancer screening				
Persistent asthma care					
Diabetic Care	HbA1c testing				
	HbA1c result				
	Retinal exam				
	Nephropathy screening				
Use of spirometry testing in the assessment and diagnosis of COPD					
Disease-modifying anti-rheumatic drug therapy for rheumatoid arthritis					
Persistence of beta-blocker treatment after heart attack					
Osteoporosis management in women who had a fracture					
Avoidance of antibiotic treatment in adults with acute bronchitis					
Total Score[‡]					

Note: Measures left blank are not applicable to your specialty.

^{*} Members eligible for services were enrolled in the practice from January 2014–December 2014 and qualified for inclusion in the population for a specific performance measure. If an individual member qualified for more than one performance measure, the member is counted separately for each one.

[†] Members receiving services were identified using Independence Blue Cross administrative data. Only members receiving services within the time frames and specifications of the quality performance measures are counted. Please refer to your QIPS Program Manual for a description of individual measures.

[‡] Total score is calculated using sum of all members eligible for an individual measure who are reported to have received the service in calendar year 2014.

(continued from page 24)

gain perspectives from each stakeholder group. This decision increased our understanding about how to communicate with practices using a common electronic health record (EHR) and how to communicate with practices across different EHR platforms. The three-month pilot launched in April 2015 with five practices. During the pilot program, Fox Chase:

- Hosted an initial education session at the cancer center, which was attended by PCPs participating in the pilot program.
- Provided orientation to the pilot practices.
- Provided orientation and training to internal staff about the *Care Connect* program.
- Supported facilitation of appropriate referrals to participating *Care Connect* pilot practices for survivorship care transition.
- Established processes to identify current cancer patients at Fox Chase Cancer Center that either did not have a primary care physician or were seeking a new primary care physician; 13 patients were provided a new PCP.

The pilot program allowed us to refine the processes previously developed to improve communication and patient flow, and by the end of June 2015, *Care Connect* transitioned from a pilot program to a fully functional program. *Care Connect* officially launched on July 1, 2015.

Developing PCP Requirements

As stated above, the working group developed requirements for PCP practices to participate in the *Care Connect* program. Since education is one of the most important criteria for measurement of programmatic success, PCPs are required to attend at least two of four educational programs developed by Fox Chase Cancer Center faculty (see “Clinical Advisory Team” described below). Educational sessions cover such topics as early diagnosis, cancer prevention, and common survivorship issues seen in the primary care setting. In addition to the opportunity to attend a “live” event, the *Care Connect* team developed online versions of all

Table 1. Email Blast Results

#	YOUR RESULTS	DATE SENT	TIME	NUMBER SENT	NUMBER OPENED	OPEN RATE	CLICK THROUGH
1	Fall CME 11/4/15	10/27/2015	3 pm	34	24	71%	1
2	ACS New Breast Cancer Screening Guidelines	11/20/2015	10 am	128	67	54%	0
3	Prostate	12/17/2015	2 pm	143	75	53%	0
4	Cervical	1/22/2016	10 am	142	73	53%	0
5	Spring 2016 CME	2/21/2016	10 am	507	267	53%	0
6	<i>Care Connect</i> at ASCO Cancer Survivorship Symposium	2/25/2016	10 am	142	76	56%	1
7	Spring 2016 CME	3/10/2016	10 am	506	295	59%	0
8	Colon Cancer	3/15/2016	11 am	507	278	55%	0
9	Head and Neck Cancers (early results)	3/23/2016	10 am	506	181	36%	3
10	Protect Their Skin from Sun Damage	5/18/2016	10:30 am	499	333	67%	1
11	Cancer Moonshot	7/26/2016	12:45 pm	495	317	64%	1
12	Aspirin for Colorectal Cancer Prevention?	9/21/2016	10:35 am	495	287	58%	0

educational programs to allow on-demand access to information if in-person attendance was not feasible. While either method of participation is acceptable, we highly encourage PCP attendance at in-person events so that they can connect directly with oncology providers. Direct connectivity is believed to enhance the relationships that ultimately impact care coordination.

Quality measurements are a mainstay of today's healthcare environment, and many insurers now collect metrics against which primary care physicians are evaluated. As part of the *Care Connect* program, PCPs are asked to submit quality measures from one of the main insurers in the Philadelphia region (Figure 1, page 25).⁵ The reports include measurements of screenings for breast, cervical, and colon cancer. These measures will be tracked on an annual basis and used for quality or performance improvement projects within the *Care Connect* program.

The third requirement is support and education regarding clinical trials within the scope of primary care. Research is an integral part of the mission at Fox Chase Cancer Center. Every healthcare provider involved in the care of cancer patients needs to be supportive when patients are making difficult decisions regarding clinical trial participation, and we leverage the *Care Connect* program to educate PCPs about clinical trial options for cancer patients and survivors.

Establishing a Clinical Advisory Team

Education is a key component to improving the connectivity and smooth transition of care between the oncology and primary care setting. As part of the *Care Connect* program, we established a clinical advisory team to help guide education events, patient education, and any other programming that would impact clinical care. This team is comprised of seven physician members from Fox Chase Cancer Center, as well as clinical administrative members. The physician members represent the departments of hematology, medical oncology, gynecological surgery, diagnostic imaging, pulmonology, and gastroenterology. Administrators represent clinical areas, outreach, and navigation. The team meets as needed to plan educational events. The email announcements or "eblasts" are also approved by this group prior to sending to *Care Connect* members.

Hosting Live Educational Events

Based on a literature search and needs assessment data, the clinical advisory team, in conjunction with Temple Health's CME committee, developed overarching program objectives for these live events. We are able to add specific programming objectives as each event is planned. Six educational events have been conducted to date. In addition, a *Care Connect* physician spoke at an event provided to faculty at Fox Chase Cancer Center. The topics include:

- Cancer Diagnosis & Prevention (breast, prostate, colon, lung)
- Treatment of Breast, GI, GU, & Lung Cancers

Figure 2. Sample Email Blast on New Breast Screening Guidelines



Care Connect

News Blast

EDUCATION & UPDATES FOR CARE CONNECT PHYSICIANS

The Fox Chase Cancer Center Care Connect News Blast is a resource for our members to keep you informed of our latest happenings. Here you can find timely and pertinent information, including upcoming CMEs and changes in national cancer screening guidelines.

American Cancer Society Announces New Breast Cancer Screening Guidelines

The American Cancer Society (ACS) recently released new guidelines for breast cancer screening. Among the changes, the new recommendations state that women at an average risk for breast cancer should begin having annual mammograms starting at age 45, and women aged 45 to 54 should be screened annually. Women ages 55 and older should transition to being screened every other year or have the opportunity to be screened annually. The ACS does not recommend clinical breast examination for breast cancer screening among average-risk women at any age. Women who are at high risk for breast cancer - because of family history, a breast condition or another reason - must begin screening earlier and/or more often. These women should follow the advice of their physician.

The above guidelines, published on October 20 in the *Journal of the American Medical Association*, have created some confusion among healthcare professionals. Fox Chase Cancer Center continues to follow the guidelines set forth by the American College of Radiologists and American College of Surgeons, which both recommend that women begin having annual mammograms beginning at age 40.

Some of our Fox Chase Cancer Center physicians have provided interviews on this topic. Click below to hear their perspectives on the new ACS guidelines.

[Dr. Bleicher Talks New ACS Guidelines on Fox29](#)
[Dr. Bleicher Speaks About Screening Guidelines on KYW](#)
Richard J. Bleicher, MD, FACS
Associate Professor, Department of Surgical Oncology
Director, Breast Fellowship Training Program
Fox Chase Cancer Center

If you have any questions regarding content, please feel free to contact Dr. Bleicher.
Richard.Bleicher@fcc.edu
215-728-2596

[Dr. Catherine Tuite on Good Day Philadelphia](#)
Catherine Tuite, MD
Staff Radiologist, Department of Radiology
Fox Chase Cancer Center

If you have any questions regarding content, please feel free to contact Dr. Tuite.
Catherine.Tuite@fcc.edu
215-728-3024

- Survivorship Issues with Interactive Case Review
- Lung Cancer Screening—A Comprehensive Review
- Geriatric Oncology: Treatment Management of the Older Adult with Cancer
- Management of Incidental Adrenal Nodules: Everything a Primary Care Physician Needs to Know
- The Patient-Centered Medical Home (*Care Connect* physician presentation).

Evaluations have been overwhelmingly positive with more than 80 percent of participants reporting changes in clinical practice as a result of these sessions. Interestingly, participants report that the greatest barriers to care are insurance and financial issues, as well as patient adherence.

With the understanding that some *Care Connect* providers may find it challenging to attend “live” events on a regular basis, all educational events are taped and then released as individual sessions by speaker, allowing *Care Connect* physicians to view the programming based on their own time and educational needs. The clinical advisory team created a separate CME plan and objectives for physicians who choose this option to meet the education requirements of the *Care Connect* program. Online

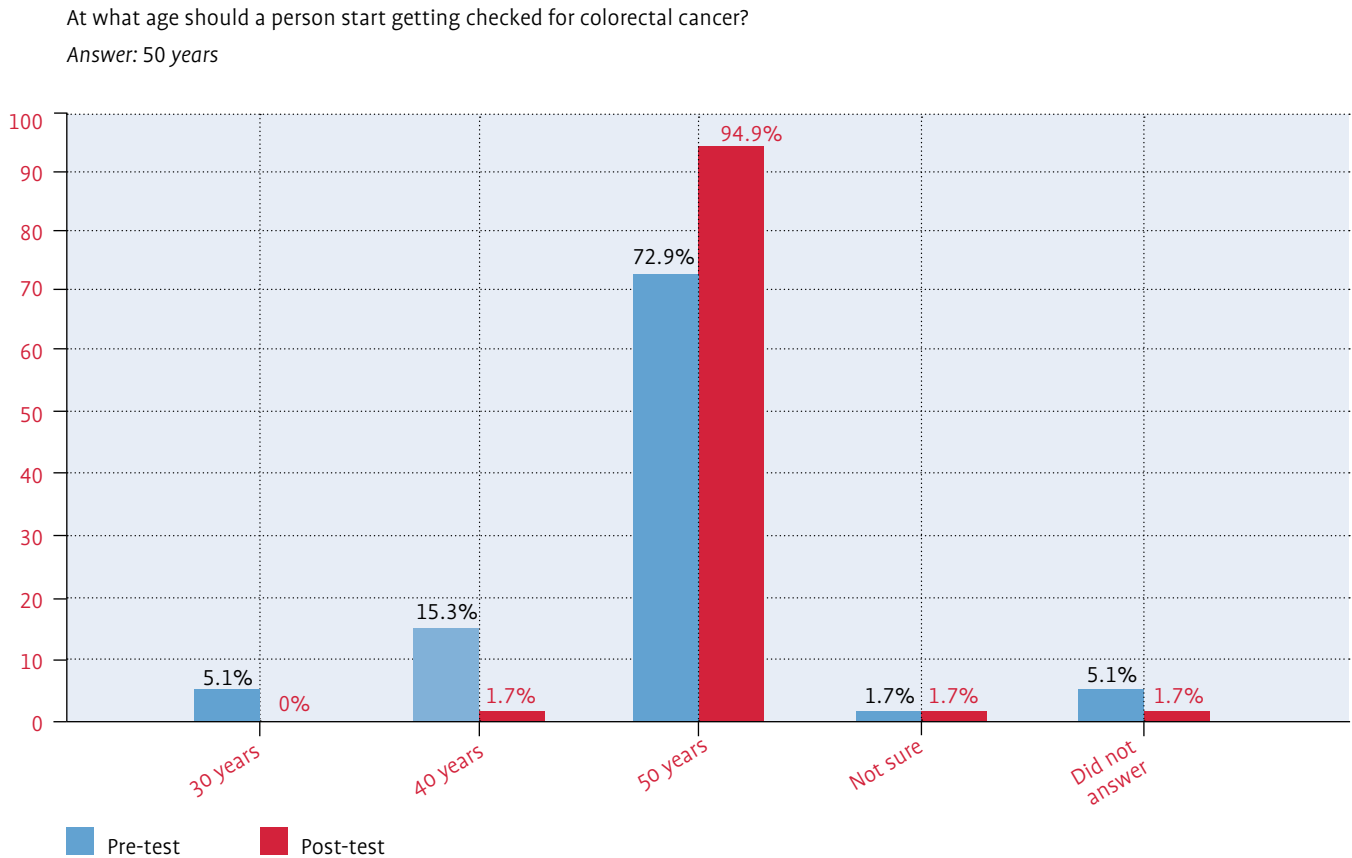
programming went live in November 2016, and the clinical advisory team disseminated instructions for accessing this educational content to each *Care Connect* practice.

Identifying Additional Education Opportunities

As the *Care Connect* program grew, we believed that there were additional opportunities to make connections with the *Care Connect* member practices. Change occurs often in the field of oncology—some of which impacts primary care delivery—so we developed a method to relay this information in a timely manner. Today an email “blast” system pushes out to *Care Connect* member practices important changes in screening and prevention practices. Figure 2, page 27, is an email about changes to the American Cancer Society mammography guidelines. Fox Chase physicians were asked to provide feedback regarding the changes and to make themselves available by phone for any *Care Connect* member that had specific questions. Other examples of email blasts include information on cancer awareness months, specific programs being held at Fox Chase Cancer Center that may be of interest to PCPs, relevant news stories impacting cancer patients, and upcoming educational programming.

Through this system, the *Care Connect* team tracks the

Figure 3. Staff Education Results: Colon Cancer



“open” rate, as well as the “click through” rate for these eblasts. Since implementation, open rates (the number of recipients who opened the email) have been consistently above 50 percent, which is outstanding for this type of communication. The average open rate for health and social services communications is 20.74 percent.⁶ The click through rates (the number of recipients who clicked through additional links embedded within the email) are much lower. Overall, the email blast system has been a successful approach to relay important information to a large group of participants with minimal workload impact (Table 1, page 26).

Staff Education

Celeste-Harris and Maryniuk describe a diabetes program where provision of educational materials and training the office staff of PCPs resulted in improved patient outcomes.⁷ Working under that premise, if every member of the primary care team is aware and educated about common health problems, patient care can be improved.⁸ Accordingly, the majority of *Care Connect* member practices have mandates regarding staff education. The aim of the *Care Connect* initiative was to add information about common cancers to the education rotation, including prevention and screening practices. *Care Connect* team members believe that primary care office staff play a vital role in improving patient care as they are the front-line individuals collecting information from patients and caregivers. In the future, the *Care Connect* program looks to develop data-driven outcomes measurements.

The *Care Connect* team worked with the members of the Office of Community Outreach at Fox Chase Cancer Center to deploy this staff education, which provided about 30 minutes of content at each practice site in a “Lunch & Learn” format. Programming was provided at a lay person-knowledge level. Staff education was piloted at a limited number of practices to determine feasibility and obtain participant feedback on the value of the educational programs. Pre- and post-tests were given to the attendees; feedback was overwhelmingly positive and demonstrated change in knowledge (see Figure 3, left). Currently, there are plans to deploy this staff education at every *Care Connect* practice. Topics to date include colon cancer, skin cancer, and basics of clinical trials. The next planned program topic is breast cancer.

Patient Education

Patient-directed education is a well-established need for most practices. As an additional benefit for our *Care Connect* members, Fox Chase’s Community Outreach department developed patient education brochures for lung, breast, ovarian, colon, skin, and prostate cancers. Materials are written at a lay person level and provide an outline of questions that patients can pose to their provider(s) when discussing prevention and screening for these six common cancers. This type of education allows patients to become more engaged participants in their care rather than just reading about a particular topic. There is support in the literature that this approach helps develop self-management and problem-solving by the patient.⁹ Patient education materials also include

a brief description of the *Care Connect* program with links to the Fox Chase Cancer Center’s website for additional information. Patient education brochures are also available in Spanish.

Marketing Efforts

Marketing of the *Care Connect* program required a multi-pronged approach. In addition to providing access to common marketing tools for the *Care Connect* members, we needed a specific plan to “market” the program internally to staff and providers.

We developed and implemented a *Care Connect* member enrollment process, and a member of the *Care Connect* team visited each primary care practice that expressed interest in joining. Physician-directed brochures were developed specifically for this process. Potential *Care Connect* members were also required to complete an application, which included basic demographic information about the practice. Once the application process was completed, Fox Chase Cancer Center marketing staff, ambulatory care leaders, and other appropriate internal departments were notified to add the practice to the Fox Chase Cancer Center’s website and other applicable *Care Connect* print materials and messaging.

We developed a *Care Connect* member marketing package (see Figure 4, pages 30-31) that included the following items:

- Brand guidelines
- *Care Connect* member logo
- Framed certificate of membership
- Template announcement ad and press release
- Patient brochure.

In addition, primary care practices have access to patient education materials developed for the *Care Connect* program. These pieces include information for top cancer disease sites (see Figure 5, page 32).

Internal efforts to market the *Care Connect* program included development of written materials, such as brochures, flyers, and posters, that were placed in key work areas, clinic space, and patient waiting areas. *Care Connect* team members presented an overview of the program at all departmental and faculty meetings. While the focus was on the provider and clinic staff, other ancillary departments were also educated—for example, telephone operators, intake staff, social work, and the resource education center. Walking rounds were completed on the inpatient units. Today *Care Connect* team members routinely attend department meetings to provide updates and to collect valuable feedback from providers. We created a map with information about the *Care Connect* members, storing it on our internal portal so staff can easily access the information for patient referrals (Figure 6, pages 34-35). When new *Care Connect* practices are added, a message goes out via Fox Chase’s daily enewsletter to alert providers and staff (Figure 7, page 36). Messaging about the *Care Connect* program has also been added to our phone system for on-hold scenarios.

The Importance of Care Coordination

Care coordination is a key component to ensure the success of the *Care Connect* program. Through this care coordination, the

Figure 4. Marketing Packet Samples



Care Connect program looks to improve patient care and the patient experience within our healthcare system. With the number of cancer survivors continuing to grow, it becomes increasingly important to oncologists and PCPs to participate in patient care models that include open and clear lines of communication as well as data sharing capabilities.¹⁰

The Care Connect program identifies patients and generates referrals through several methods, including EHR-generated

orders, email, phone calls, and patient self-referrals. A member of the Care Connect team responds to the referral, connects with the PCP office, and facilitates services for the patient. This provider also follows up with the patient to ensure his or her needs are met, and to provide further assistance to the Care Connect practice if needed. We track basic referral information including the number of days from referral to appointment. Through the Care Connect program, the mean number of days from request for

Whether you need cancer screening, currently have cancer, or are a cancer survivor, you can be sure that Fox Chase Cancer Center Care Connect physicians are experienced in providing the services you need.



WHAT IS CARE CONNECT?

Care Connect is a program between Fox Chase Cancer Center and select community physicians. Primary care and internal medicine physicians and gynecologists in communities throughout the region are working with Fox Chase in programs that focus on cancer prevention education, screening, treatment and survivorship care.

The result is a seamless coordination of care for patients.

THE CARE CONNECT DISTINCTION

Fox Chase Cancer Center has earned the highest designation from the National Cancer Institute (NCI) as a Comprehensive Cancer Center. We are extremely proud of this achievement and select Care Connect physician members who share our commitment to providing the highest standards of care.



BENEFITS TO PATIENTS

The Care Connect Program offers key benefits to patients:

- **Knowledge.** High-quality educational programming through Fox Chase means Care Connect doctors stay current on the latest developments in cancer care.
- **Support.** Through required ongoing courses at Fox Chase Cancer Center, Care Connect physicians stay up-to-date on cancer screening guidelines and can provide you direction on cancer prevention screening, survivorship, genetics and clinical trials.
- **Coordination.** The Care Connect Program helps to locate an experienced provider in your area who can meet your specific cancer-care needs.
- **Access.** Being a patient of a Care Connect physician provides you access to nurse navigators at Fox Chase Cancer Center who can help coordinate your care. These clinically-trained individuals are responsible for helping you understand your diagnosis from the very first call. They are here to answer your questions and guide you throughout the rest of your treatment.



To find a Care Connect physician in your community, call 215-728-4772 or visit FoxChase.org/careconnect.

appointment to actual patient appointment is 16 days—24 percent below the regional average of 21 days.¹¹ Collecting and tracking these metrics also allows the *Care Connect* team to report on data to stakeholders and leverage patterns for programmatic improvements and/or development.

In January 2016, we launched a pilot program to raise internal awareness of the *Care Connect* program within the Fox Chase Cancer Center New Patient Office to proactively identify patients

in need of a PCP. Patients were asked upon arrival to the cancer center about their PCP status. If a patient did not have a PCP, or if there was a need to change the PCP, the patient chart was flagged using a simple sticker (in this instance, new patients still have a paper initiation chart which then converts to EHR). The sticker alerted the clinic team and physician to have a discussion regarding the *Care Connect* program. If the patient wished to

(continued on page 33)

Figure 5. Sample of Patient Education Brochure



Lung Cancer

☒ **Know the Facts...**



My Action Plan

- ☐ I will not smoke
- ☐ I will avoid the smoke from other people smoking
- ☐ I will make my home and car smoke-free
- ☐ I will get my home tested for radon gas
- ☐ I will avoid cancer-causing agents
- ☐ As a smoker or former smoker, I will ask my doctor if lung cancer screening is the right choice for me

Are there any factors that protect me from Lung Cancer?

If you're a smoker, stop smoking. Quitting is the best way to protect yourself and others from lung cancer. If you don't smoke, don't start. Smoking causes about 90% of lung cancer deaths in men and about 80% in women. Avoid being around smoke and other cancer causing agents at home and at work.

To get help to quit smoking call us at 215-214-1618 or call the PA Quitline at 1-800-QUIT-NOW (1-800-784-8669).



Care Connect

Fox Chase Cancer Center Care Connect is a program linking Fox Chase Cancer Center and community physicians. Primary care physicians, internal medicine physicians and gynecologists throughout the region are working with Fox Chase in programs that focus on:

- Cancer Prevention
- Education
- Screening
- Treatment
- Survivorship Care

As a Fox Chase Cancer Center Care Connect member, your physician is committed to providing you with a seamless coordination of care.

Learn more about the Care Connect program at foxchase.org/careconnect.

Am I at risk for Lung Cancer?

There is no way to know for sure if you are going to get lung cancer. Certain things raise your chances of getting it. These are called risk factors. Check your risk factors below for lung cancer:

- ☐ I am a smoker
- ☐ I used to smoke
- ☐ I am around other people that smoke
- ☐ I am around radon, a radioactive gas that has no smell and comes from the ground
- ☐ I am around asbestos
- ☐ I am around other cancer-causing agents such as uranium, arsenic, and diesel exhaust
- ☐ I have a family history of lung cancer
- ☐ I have had radiation therapy to my chest
- ☐ I have another lung disease (such as COPD, emphysema, chronic bronchitis, or pneumonia)

If you checked any of these risk factors, you may be at risk for lung cancer.

What are the symptoms of Lung Cancer?

Lung cancer often has mild or no symptoms in the early stages. But as the cancer grows, symptoms may include:

- A cough that does not go away or gets worse
- Chest pain that is often worse with deep breathing, coughing, or laughing
- Hoarseness
- Weight loss or loss of appetite
- Coughing up blood or rust-colored sputum (spit or phlegm)
- Shortness of breath
- Feeling tired or weak
- Infections such as bronchitis and pneumonia that don't go away or keep coming back
- New onset of wheezing

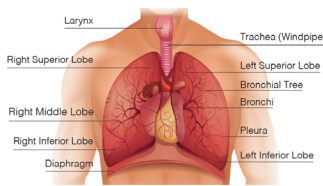
What are the screening tests for Lung Cancer?

Low-dose CT scan

A CT scan of the chest uses x-rays to create a detailed image of your lungs. Your doctor will use the image to look for signs of lung cancer. During the scan, you lie on a table that slides into the donut-shaped scanner.

If you can check **every** box below, you may want to talk with your doctor about your need for a lung screening test, or call us to make an appointment at 888-FOX-CHASE.

- ☐ You are a current smoker or have quit within the last 15 years
- ☐ You are 55-77 years old
- ☐ You have a smoking history of 30 pack-years or more. A "pack-year" means that you have smoked an average of 1 pack of cigarettes per day for a year
- ☐ Your health is good enough to consider lung cancer treatment if cancer is found



Anatomy of the respiratory system

Table 2. Patient Referrals to *Care Connect* Program: Before, During & After Pilot Program

	PRE-PILOT (9 MONTHS) APRIL 2015–DEC 2015	PILOT (6 MONTHS) JAN 2016–JUNE 2016	TOTAL (15 MONTHS) APRIL 2015–JUNE 2016
Total Patients Referred	48.0	43.0	91.0
Average Referrals Per Month	5.3	7.2	6.1

(continued from page 31)

proceed, the *Care Connect* team was notified via one of the methods described above. As a result of this pilot program, referrals increased from an average of 5.3 per month to 7.2 per month during the pilot period (see Table 2, above, and Figure 8, page 36). There are plans to expand this pilot program to include all service points of entry, for example follow-up clinics and infusion areas, to continue to identify additional patients in need of a PCP.

Current State of the Program

The *Care Connect* program has grown from a pilot program of 5 practices to a current membership of 27 primary care and 3 gynecology practices, representing 46 physician providers. A number of practices also employ advanced practice clinicians (nurse practitioners or physician assistants). We are conducting constant outreach to new practices, with 5 new practices currently being vetted at the time of this publication.

A few key initiatives are planned for the continued growth of the program, and the *Care Connect* team recently held a retreat with key stakeholders—from both Fox Chase Cancer Center and primary care practices—to aid in strategic planning. Three main components were addressed:

1. **Expansion of members.** Expanding the geographic footprint of *Care Connect* membership so that we can help additional patients find primary care coordination close to home; continue to add sub-specialty practices of relevance, such as gynecology.
2. **Improvement to the communications and connectivity between oncology and PCP providers.** Add PCPs to clinical advisory team; increase one-to-one interactions between oncology and PCP providers at educational offerings.
3. **Patient outcomes.** How can we start using the data collected to design programs or studies to show improvement in patient outcomes—both oncology and non-oncology.

In addition, plans are underway to conduct a formal physician survey to aid in future program development and to address unmet needs.

As you can see, a program that creates a formal relationship between PCPs and oncologists is an effective strategy to improve communication between the provider groups and increases the ability to coordinate care. We have learned throughout the process

Acknowledgements

The authors would like to make a special acknowledgement to the *Care Connect* team members:

Judith Bachman, Dr. John Daly, Dr. Crystal Denlinger, Dr. Kathryn Evers, Dr. Daniel Geynisman, Dr. Minhhuynh Nguyen, Dr. Stefan Barta, Dr. Cynthia Bergman, Dr. Rohit Kumar, Mary Sonke, Evelyn Gonzalez, Diane Brown, Patrick O'Brien, Leanne Lyons, Amanda Schlueter, Melissa Schrier, Jeremy Moore, Jennifer Seggev, Maureen McDade, Tricia Lewis-Scott, and Laura Higdon.

that engagement of all stakeholders is critical to the success of the *Care Connect* program. The opportunity to get busy providers together to engage in discussions about how best to improve patient outcomes and the patient experience is the engine that has driven the *Care Connect* program forward. 

Kelly Filchner, MSN, RN, OCN, CCRC, is director, Clinical Operations, Fox Chase Cancer Center Partners Cheltenham, Pa. Alan Howald, BS, is associate vice-president, Network & Business Development, Temple University Health System, Philadelphia, Pa.

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(continued on page 36)

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This map illustrates the Philadelphia area, highlighting the Fox Chase Cancer Center and its proximity to various landmarks and transportation routes. The center is marked with a red star and labeled in red text. The map includes major highways such as I-76, I-95, and I-676, as well as local roads like Cheltenham Ave. and Frankford Ave. The Delaware River is shown flowing through the region, with bridges like the Betsy Ross Bridge and Ben Franklin Bridge. Surrounding areas like Jenkintown, Cheltenham, and Camden are also labeled. A compass rose in the bottom left corner indicates the cardinal directions (N, S, E, W).

FOX CHASE
CANCER CENTER | **Care Connect**

12/2016

FOX CHASE CANCER CENTER CARE CONNECT*

PRACTICE LOCATIONS

Care Connect is a program between Fox Chase Cancer Center and primary care/internal medicine physicians in communities throughout the region. We offer support for primary care physicians in the areas of cancer prevention education, screening, treatment, and survivorship care plans. **The result is a seamless coordination of care for patients.**

ASK YOUR FOX CHASE DOCTOR FOR A REFERRAL TO ONE OF THE FOLLOWING CARE CONNECT PRACTICES OR CALL 215-728-3536.

1
Broderman Internal Medicine Associates
Susan J. Broderman, MD
2325 Heritage Center Dr., Suite 116
Furlong, PA 18925

2
Charles Bolno, DO
404 Huntingdon Pike #B
Jenkintown, PA 19046

3
Family Practice Center of Newtown
Catherine Spratt-Turner, DO
638 Newtown-Yardley Rd., Suite 2E
Newtown, PA 18940

4
Fred A. Stutman, MD
3501 Newberry Rd.
Philadelphia, PA 19154

5
Jeanes Family Medicine
Mitchell J. Marder, DO
9331 Old Bustleton Ave., Suite 100
Philadelphia, PA 19115

6
Jeanes GYN Associates – Elkins Park
Debra Somers, MD
Gail Sullivan, MD
8380 Old York Rd., Suite 100
Elkins Park, PA 19027

5
Jeanes GYN Associates – Northeast
Debra Somers, MD
Gail Sullivan, MD
9331 Old Bustleton Ave., Suite 202 & 203
Philadelphia, PA 19115

7
Jeanes GYN Associates – Staple Hall
Robert Auerbach, DO
7602 Central Ave., Suite 201
Philadelphia, PA 19111

8
MCL Primary Care
Michael Luciano, DO
882 Jacksonville Rd., Suite 204
Ivyland, PA 18974

9
Mercado Medical Practice
Max Mercado, MD
Jose A. Bossbaly, MD
7500 Central Ave., Suite 203
Philadelphia, PA 19111

10
Michael Palazzolo, MD
821 Huntingdon Pike, Suite 205
Huntingdon Valley, PA 19006

11
Port Richmond Family Practice
John Lozowski, DO
2923-25 E. Thompson St.
Philadelphia, PA 19134

6
Temple Family Medicine at Elkins Park
Pamneit Bhogal, MD
Peter Giammanco, DO
Jeffrey Mazure, DO
Matthew J. Shore, DO
8380 Old York Rd., Suite 100
Elkins Park, PA 19027

12
Temple Family Medicine at Fort Washington
Mark F. Obenrader, DO
Jason J. Sanderson, DO
515 Pennsylvania Ave.
Fort Washington, PA 19034

5
Temple Family Medicine – Old Bustleton
Carla Cuoci-Malin, DO
9331 Old Bustleton Ave., Suite 100
Philadelphia, PA 19115

9
Temple Internal Medicine Burholme
Rohit Desai, MD
7500 Central Ave., Suite 202
Philadelphia, PA 19111

5
Temple Internal Medicine – Old Bustleton
Steven Wolf, DO
9331 Old Bustleton Ave., Suite 202
Philadelphia, PA 19115

5
Temple Northeast Family Medicine
Saira Bano, MD
Roseanne Farber, DO
Larry Kramer, DO
9331 Old Bustleton Ave., Suite 201
Philadelphia, PA 19115

14
Temple Physicians at Feltonville
Gary LaNoce, DO
4857 C St.
Philadelphia, PA 19120

15
Temple Physicians at Hunting Park
Elizabeth Carazo, MD
Nuria Lopez-Pajares, MD
133 W. Hunting Park Ave.
Philadelphia, PA 19140

16
Temple Physicians at Liberty Square Adult Medicine
Ronald Cowen, DO
Delia Meltonate, MD
Anthony Luistro, MD
1300 W. Lehigh Ave., Suite 110
Philadelphia, PA 19115

17
Temple Physicians at Nicetown
Delana Wardlaw, MD
4350 Germantown Ave.
Philadelphia, PA 19140

18
Temple Physicians at Palmer Park
Kyle Montgomery, MD
Cyriac Thatchet, MD
Melanie Williams, DO
Kem Yenai, MD
1741 Frankford Ave., Suite 100
Philadelphia, PA 19125

19
Temple Physicians at Rising Sun
Jeffrey Mazure, DO
6410 Rising Sun Ave., Suite A
Philadelphia, PA 19111

20
Temple Physicians at Rockledge
Charles H. Korman, DO
Jay R. Moore, MD
Hong T. Tran, MD
8 Huntingdon Pike
Rockledge, PA 19046

21
Temple Physicians at Roosevelt Plaza
Michael P. Glowacki, MD
Stephen Sturtz, DO
6557 Roosevelt Blvd.
Philadelphia, PA 19149

22
Temple Physicians at Somerton
Pamneit Bhogal, MD
12000 Bustleton Ave.
Philadelphia, PA 19116

23
Temple Physicians at Wyndmoor
Simeon Bardin, MD
8200 Flourtown Ave., Suite 5
Wyndmoor, PA 19038

Please visit FoxChase.org/careconnect for the most up-to-date listing of Care Connect members.

*Each Care Connect Program physician is responsible for his/her own medical judgment and the patient care services provided. Fox Chase Cancer Center does not directly or indirectly assume responsibility for the medical judgment and patient care services provided by Care Connect Program physicians.

Learn more about Care Connect:

215-728-3536 | FoxChase.org/careconnect

FOX CHASE
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Care Connect

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Figure 7. Daily eNewsletter

Enews
DAILY

**Your First Look
at What's Happening
Around Fox Chase
& Jeanes Hospital**

FRIDAY, OCTOBER 30, 2015

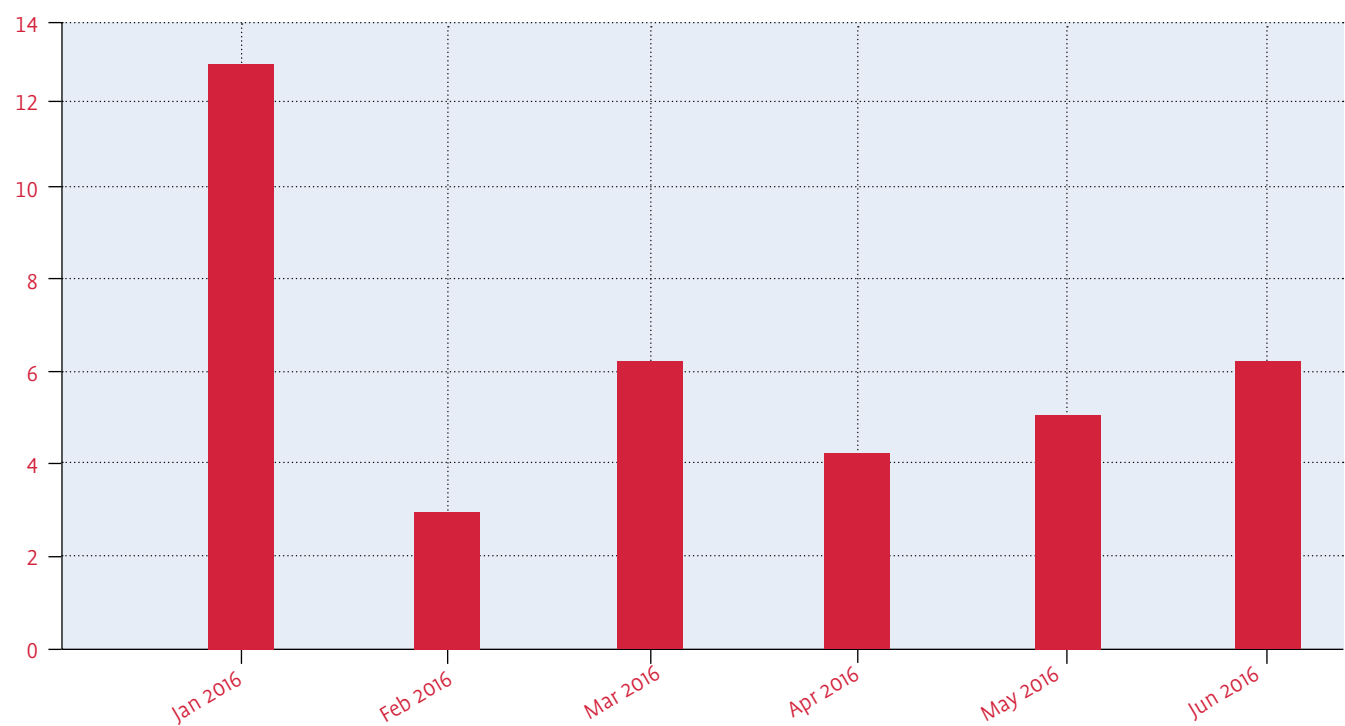
CME Event Offered for Faculty and Community Physicians

Care Connect

Current treatments for breast, lung, gastrointestinal, and genitourinary cancers will be the focus of the next [educational session](#) of the Fox Chase Cancer Center Care Connect Program—a collaborative initiative between Fox Chase and select primary care practices in the Greater Philadelphia region. Presented by Fox Chase faculty members, the event will take place on Wednesday, November 4, from 6-8 p.m. in the Reimann Auditorium. Continuing medical education (CME) credit will be offered, and dinner will be provided. Fox Chase and Jeanes Hospital faculty and staff are invited to attend along with guests from the Fox Chase Cancer Center Care Connect practices.

Launched earlier this spring, Care Connect is designed to provide a seamless continuum of care for cancer patients, enhance communication among providers at Fox Chase and in the community, and provide expertise in cancer prevention and screening guidelines to community physicians. Ongoing professional education serves as a key component of the program. Attendees can register for the November 4 session by calling Fox Chase's Care Connect line at 215-728-3536. For more details, see the [event flyer](#).

Figure 8. Patient Referrals to Care Connect Program During 6-Month Pilot Program





INNOVATE. ACHIEVE. INSPIRE.

CONGRATULATIONS

2017 ACCC INNOVATOR AWARD RECIPIENTS

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

**Aurora Health Care, Aurora
Cancer Care**

Milwaukee, Wisconsin
*Now Playing! Drug-Specific Videos
Improve Chemotherapy Patient
Education*

**Carolinas Health System, Levine
Cancer Institute**

Charlotte, North Carolina
*Wheels Up—Bringing Lung Cancer
Education & Screening to Rural
Patients*

Duke Cancer Institute

Durham, North Carolina
*Come Together: A Health Disparities
& Equity Cancer Program Built on
Community Collaboration*

**Loma Linda University Health,
Loma Linda University Cancer
Center**

Loma Linda, California
*A Perfect Fit: Mentoring Experienced
RNs to Meet Oncology Clinic Demand*

**Northwest Medical Specialties,
PLLC**

Tacoma, Washington
*Designed for Success: A Research-
Based Approach to Meet OCM
Requirements*

Oncology Specialists, SC

Park Ridge, Illinois
*Turning on the Light Switch: A Model
Immunotherapy Program at an
Oncology Practice
(ICLIO Innovator Award Winner)*

**Penn Medicine Virtua Cancer
Program**

Voorhees, New Jersey
*Beyond the Classroom: Students
Improve Access to Supportive Care
Services*

**University of Alabama at
Birmingham Comprehensive
Cancer Center**

Birmingham, Alabama
*Patient Care Connect—Lay Navigators
Improve Quality & Reduce Cost
of Care*

**University of South Alabama,
Mitchell Cancer Institute**

Mobile, Alabama
*An Acuity Tool to Optimize Nurse
Navigation Caseloads*



Association of Community Cancer Centers

The Innovator Award recipients will present their creative, replicable programs at the ACCC 34th National Oncology Conference, October 18–20, 2017, in Nashville, TN.

For details, please visit acc-cancer.org/oncologyconference.

Improving Pain Management in Patients with Cancer





In June 2014 Park Nicollet Oncology Research and Health-Partners Institute, Minneapolis, Minn., implemented a quality improvement (QI) initiative aimed at improving pain management in patients with cancer. In addition to the multidisciplinary team members identified in Table 1, page 41, a number of nursing staff was also involved in the QI initiative.

Patients with Cancer Hurt

Cancer pain is very common, having a negative impact on a patient's quality of life (QOL) and often requiring opioids for control. Controlling cancer pain is critical because the pain is prevalent throughout a patient's treatment course—from diagnosis, through active treatment, during palliative care, and at hospice and end of life (EOL). A 2007 study by van den Beuken and colleagues looked at the prevalence of pain in patients with cancer over the last 40 years and found that two-thirds of patients with advanced and metastatic cancer will experience some type of pain.¹ More importantly, the study found that almost half of those patients at times experienced moderate or severe levels of pain.¹ Another meta-analysis looked at QOL as a prognostic indicator of survival, finding that patients who report no pain have markedly better survival than patients reporting higher pain-tiered scores.²

Several years ago, the *Journal of Clinical Oncology* published a series of articles on pain management, including a landmark study about personalized pain goals in oncology, or the pain value that a patient identifies as one they consider comfortable or acceptable.³ Personalized pain goals go beyond simply reporting a patient's pain score. Instead clinicians ask, "What level do you want your pain to be at?" or "What level of pain can you accept

The mission of our QI initiative soon became clear: to improve patient quality of life by achieving better pain control with fewer side effects, and using the most cost-effective medications.

and feel comfortable with?" and then document that goal in the patient's medical record. Most cancer patients treated at Park Nicollet communicate personal pain goals between a level 3 and 4.

Getting Started

Prior to 2014, clinic-wide patient satisfaction surveys revealed that Park Nicollet was scoring low on two key questions: "How often does staff do everything they can to help you with your pain or discomfort?" and "How often is your pain or discomfort well-controlled?" (Nationally 50 percent was the benchmark, but Park Nicollet's score was about half of that or 25 percent). As our team began to look at ways we could improve those scores, we realized that there was not much research or data specifically on pain medications that cancer patients are prescribed and how their pain is controlled.

Opioids have been making headlines in national news for some time now. Certainly one area we wanted to look at when developing this QI initiative was the cost of opioids—specifically high-dollar drugs that were costing our patients hundreds of



Exterior view of Park Nicollet Oncology Research and HealthPartners Institute, Fraumshuh Cancer Center, Minneapolis, Minn.

dollars out-of-pocket each month. Our hospital pharmacy data showed that morphine, for example, may only cost a \$100/month, but long-acting oxycodone had a price tag three times that amount. In addition to high out-of-pocket costs for patients, this pricing discrepancy was creating downstream issues, for example an increased workload on our nursing staff to obtain pre-approvals or prior-authorizations and delays in patients receiving their medication as we waited to hear back from payers.

The mission of our QI initiative soon became clear: to improve patient quality of life by achieving better pain control with fewer side effects and using the most cost-effective medications. To fulfill this mission, we would:

- Determine if rollout of an opioid and constipation patient information sheet, along with a 24-hour call-in request, would improve patient satisfaction and overall pain control.
- Analyze trends in pain management of cancer patients, opioid utilization patterns, and survey data to help create a pain protocol.
- Determine if physician education on opioid cost data would lead to a change in prescribing patterns, decreasing out-of-pocket costs for patients and nurse time spent on obtaining pre-authorizations.

Next the team developed an aim statement or goals for the QI initiative:

- To increase the percentage of patients with a documented personalized pain goal.
- To increase the percentage of patients achieving their personalized pain goal.
- To decrease cost of care by reducing the use of high-cost, long-acting opioids.

A series of actionable interventions was identified, including:

- Developing a patient education piece.
- Implementing a 24-hour call-back process for critical symptoms.
- Adding a validated symptom assessment tool into our EHR (Epic).
- Developing a process where clinicians would be alerted for critical symptoms.
- Creating Pain Protocol/Epic Smartsets.
- Conducting physician education on the cost of opioids.

Educating Patients & Providers

Park Nicollet created a patient information sheet on opioid use (Figure 1, page 42). The tool is highly utilized in clinic, and we've found the information on constipation management (constipation

Table 1. Multidisciplinary Team Involved in the QI Initiative to Improve Pain Management in Patients with Cancer

TEAM MEMBER	DEPARTMENT	ROLE/RESPONSIBILITY
Dylan Zylla, MD	Oncology	Team Leader
Sarah Van Peurse, RN	Oncology	Nursing Supervisor
Lisa Illig, MD	Palliative Care	Pain & Symptom Expert
Adina Peck, DNP	Oncology	Nurse Practitioner
Pam Pawloski, PharmD	Health Partners Institute	Pharmacist/Researcher
Jim Fulbright, MS/MBA	IT—Business Intelligence	Epic Report Developer
Sara Richter, MS	Park Nicollet Institute	Statistician
Gladys Chuy, MHA	Park Nicollet Health Services	QI Leader
Amber Larson, MHA	Park Nicollet Health Services	QI Leader

being a side effect of opioid use) the most helpful to patients. Interestingly, we found that many cancer patients were fearful of opioid use—likely due to the extensive news coverage on the opioid epidemic in this country. With this tool we now had the opportunity to discuss opioid addiction. Clinicians were able to explain, “I’m prescribing this medication to help control your pain. I think it is safe and that you are not likely to become addicted in this setting.” We also found that a number of patients did not know the difference between short-acting and long-acting narcotics—specifically, what these differences mean and how to take them. So clinicians used the patient information sheet to help ensure that patients were taking their medications appropriately.

Next, we implemented a nursing protocol for documenting personalized pain goals. Specifically, we revised our rooming and check-in process so that nurses asked patients: “What is your pain goal?” or “What pain level do you want to be at?” and documented the information in the EHR to capture that data.

Finally, our palliative care physician presented pain management cases at one of our staff meetings, discussing pain control and sharing pharmacy data about the cost of different opioids. Anecdotally, we received feedback from physicians and nurse practitioners that this single education session helped jump-start conversations about drug costs and prescribing patterns, both of which are discussed later in this article.

Pulling the Data on Personalized Pain Goals

We analyzed 18 months of data on reported pain levels in our cancer patients (Figure 2, page 43), finding that 13 to 15 percent of the cancer patients seen at our clinic every month reported moderate or severe pain. When we zeroed in on patients taking opioids that number increased to between 20 to 25 percent.

Next, we pulled data on personalized pain goals from our EHR, specifically how often a personalized pain goal was obtained and how often a personalized pain goal was achieved (Figure 3, page 44). Prior to our QI initiative, which was implemented in June 2014, data showed that we had collected personalized patient goals for between 15 and 30 percent of patients. (We later learned that these were new-start chemotherapy patients.) After roll-out of the patient education piece and the nursing protocol, the percentage of personalized pain goals obtained increased dramatically. As the data in Figure 3 shows, we were able to increase collection and documentation of personalized pain goals from 16 percent to 71 percent in one year. We did not see much change in the percentage of patients who had achieved their personalized pain goal in that same time period. Today, about 85 percent of our patients report that they have achieved their pain goal.

(continued on page 43)

Figure 1. Patient Education & Information Worksheet

PAIN CONTROL USING OPIOIDS

Controlling your pain when you have cancer

At Frauenshuh Cancer Center, we care about your pain control. Pain from cancer cannot always be controlled completely, but we try to make it tolerable for you. You have been prescribed an opioid prescription pain medication to help control your pain. If you have pain that is not well managed by your opioid prescription within the next 24 hours, call Frauenshuh Cancer Center.

HOW DO I TAKE THIS MEDICATION SAFELY?

- Take your medicines as prescribed.
- Do not adjust the dose without talking to your care team.
- Do not drive or operate machinery until the medicine effects are gone and you can think clearly.
- Do not break, crush, or chew a pill unless your oncologist told you to.
- Do not drink alcohol or take illegal drugs.
- Keep your medicine in a safe and secure place away from children and pets.

Unless your care team tells you, do not take other over-the-counter medications that have acetaminophen (Tylenol) if you are taking an opiate combined with acetaminophen, including:

- Norco (hydrocodone and acetaminophen)
- Vicodin (hydrocodone and bitartrate and acetaminophen)
- Percocet (oxycodone and acetaminophen)

WHAT CAN I DO TO MANAGE CONSTIPATION FROM PAIN MEDICINE?

- Treat constipation with a laxative. Follow the guidelines below to treat your constipation.
 - ◆ Start with 1 to 2 tablets of over-the-counter senna at bedtime.
 - ◆ If you do not have a bowel movement, start taking 2 tablets of senna 2 times a day.
 - ◆ If you are still constipated after taking 2 tablets 2 times a day, add 1 capful of over-the-counter polyethylene glycol (Miralax) in the morning.
 - ◆ If you are still constipated, take 4 tablets of senna 2 times a day and polyethylene glycol (Miralax) 2 times a day.
- Drink plenty of water each day.
- Eat foods high in fiber, such as fruits, vegetables, beans, and whole-grain cereals and breads (if your diet allows.)
 - ◆ Prunes, raisins, and dried apricots may also be helpful.
- Exercise regularly by walking and moving around as much as you are able.

If you have not had a bowel movement for 3 days or have constipation with vomiting or abdominal pain, call Frauenshuh Cancer Center.

WHAT IS THE DIFFERENCE BETWEEN SHORT-ACTING AND LONG-ACTING PAIN MEDICATION?

- Short-acting medications—used for fast pain relief. You take these on an as-needed basis.

- Long-acting medications—used for continuous pain control. You must take these on a schedule to control severe pain. Long-acting medications are not used for fast pain relief, so staying on a schedule is very important to keep your pain under control.

WHAT ARE THE POSSIBLE SIDE EFFECTS?

- Constipation—Most people who take opioid pain medications develop constipation and need laxatives to have regular bowel movements. See left for recommendations.
- Nausea, vomiting, or itchiness—Take your medication with food to help prevent these symptoms. Usually, these symptoms improve over the first week. If the symptoms do not improve or are severe, call Frauenshuh Cancer Center.
- Dry mouth.
- Dizziness and drowsiness.
- Blurred vision.

WHAT ABOUT ADDICTION?

Usually, patients with cancer who take prescription opioids to manage pain or other symptoms do not become addicted.

But, people who have a history of drug or alcohol abuse may become addicted to opioids. Tell your care team if you have a current or past problem with drugs or alcohol. We can help safely manage your cancer symptoms and pain.

WHEN DO I CALL 911?

Call 911 if you have:

- Trouble breathing
- Swelling of your face, lips, tongue, or throat
- Signs of overdose, including:
 - ◆ Confusion or severe sleepiness
 - ◆ Severe nervousness or restlessness
 - ◆ Slow breathing
 - ◆ Seizures.

TELEPHONE NUMBER

If you have questions call: 952.993.0000

Frauenshuh Cancer Center

Weekdays, 8:00 am-5:00 pm

Your call is directed to a nurse.

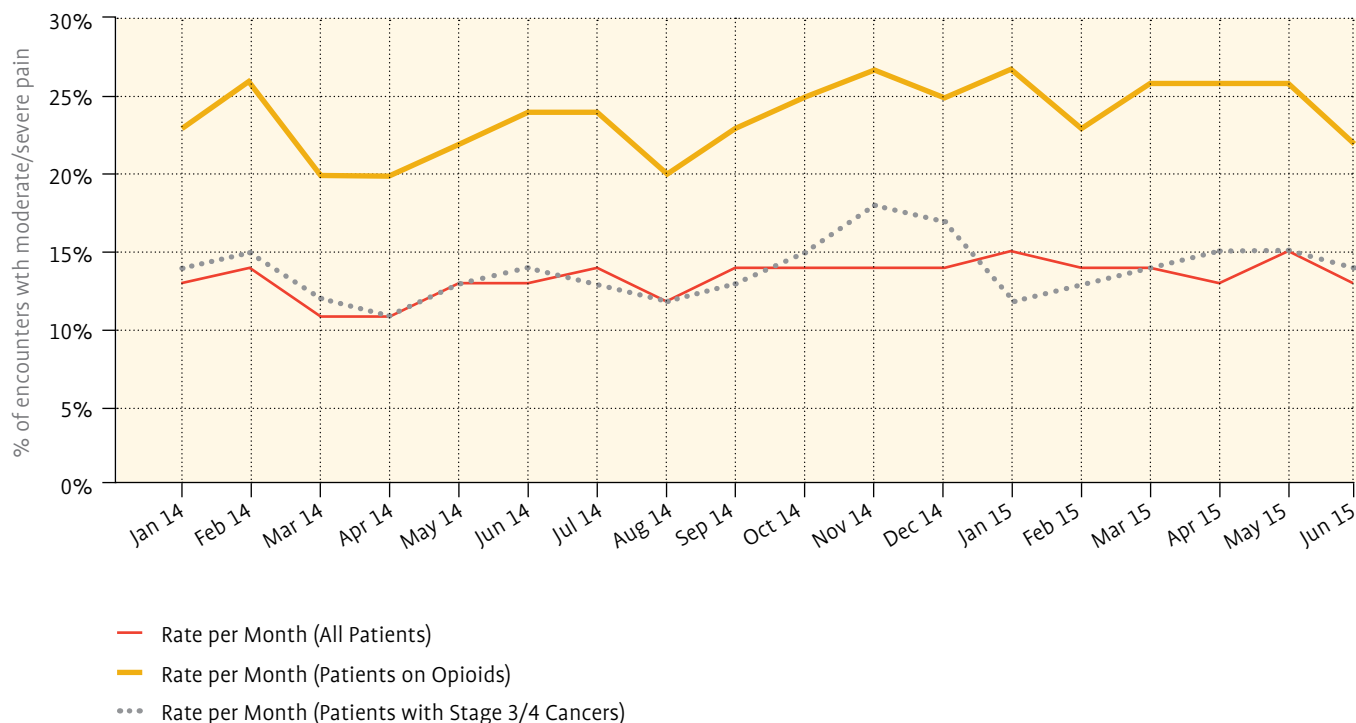
HealthPartners CareLineSM

Weekdays, 5:00 pm-8:00 am

Weekends and holidays, 24 hours

Your call is directed to a nurse line for medical advice.

Figure 2. Percentage of Patients with Moderate to Severe Pain (≥ 4)



(continued from page 41)

Pulling the Data on Prescribing Patterns

We then looked at our prescribing patterns. We pulled data on the medications our physicians were prescribing and how many new prescriptions were generated, zeroing in on the more expensive agents (Figure 4, page 45). The low-cost agents would be considered methadone and the long-acting morphine. The high-cost agents would be fentanyl and oxycodone long-acting. Prior to the implementation of our QI initiative, prescriptions were split fairly equally between low- and high-cost agents. After June 2014, when providers were educated about these cost differences and the effect this has on a patient's out-of-pocket costs and the time nurses spend to obtain pre-authorizations, we started to see a change in prescribing habits. After a few months where the percentages stayed relatively stagnant, we saw an even more dramatic change; one year later, in June 2015, the number of unique prescriptions for low-cost opioids had more than doubled the number of prescriptions for high-cost opioids.

Going Forward

We have written a grant to use validated tools to track patient-reported outcomes related to pain, including a process for importing them directly into the EHR. Specifically, we are trying to use the "My Chart" functionality in Epic to generate reports on a regular basis. Our goal: to be able to generate automatic triggers based on the patients' personalized pain goals so that clinicians receive automatic alerts when patients are a certain number of points above their personalized pain goal. Eventually, we'd like to incorporate NCCN Guidelines related to pain management. For example, NCCN Guidelines to manage pain in stage IV lung cancer patients exist, but we suspect that our clinicians may not always be leveraging these tools. Finally, as stated above, we may look into why some of our patients are still being prescribed (or are still on) the high-cost medications. Obviously some have contraindications or allergies to certain medications, but we may look to see if we can make additional QI improvements in this area.

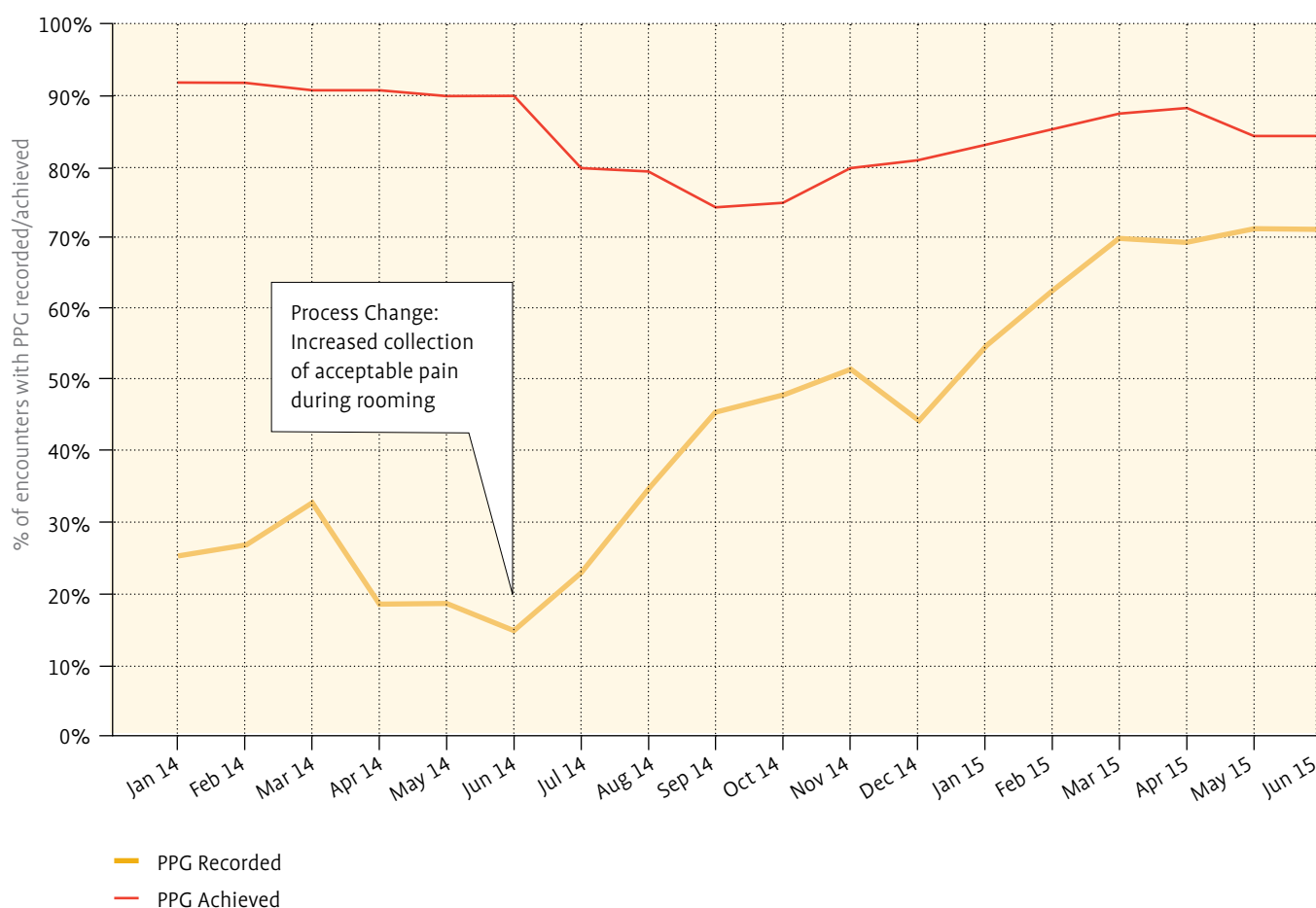
Lessons Learned

There were some limitations to our QI initiative. As stated previously, the data showed that we didn't realize much improvement in overall pain levels reported by patients. If we were to take a deeper dive into the data, we suspect that there was some improvement in high-pain patients (those on opioids), and we plan to look at this in the future. We also did not measure physician compliance related to opioid prescribing patterns, and this is another area we may look into in the future.

Improving pain in cancer patients is important and achievable. What we took from our experience is that even a fairly simple QI initiative can be very effective at hitting the IOM's Triple Aim of improving quality of care, increasing patient satisfaction, and

decreasing costs. Most important, our team was able to make these system and work flow changes without undue burden on staff. In fact, in addition to improved pain management through a process for collecting personalized pain goals for every cancer patient and decreasing financial toxicity by reducing the number of high-cost, long-acting opioids prescribed, we were actually able to reduce staff time spent on paperwork for prior-authorizations and pre-approvals for these medications. Finally, with any QI initiative that your cancer program implements you have to accept that it's not going to be perfect. And while you may not get the results you want right out of the gate, practice improvement and quality improvement is all about continuing to try. 

Figure 3. Percentage of Patient Encounters Where Personalized Pain Goals Were Recorded and Achieved



Dylan Zylla, MD, is a medical oncologist at Park Nicollet Oncology Research, Health Partners Institute, Frauenthub Cancer Center, Minneapolis, Minn.

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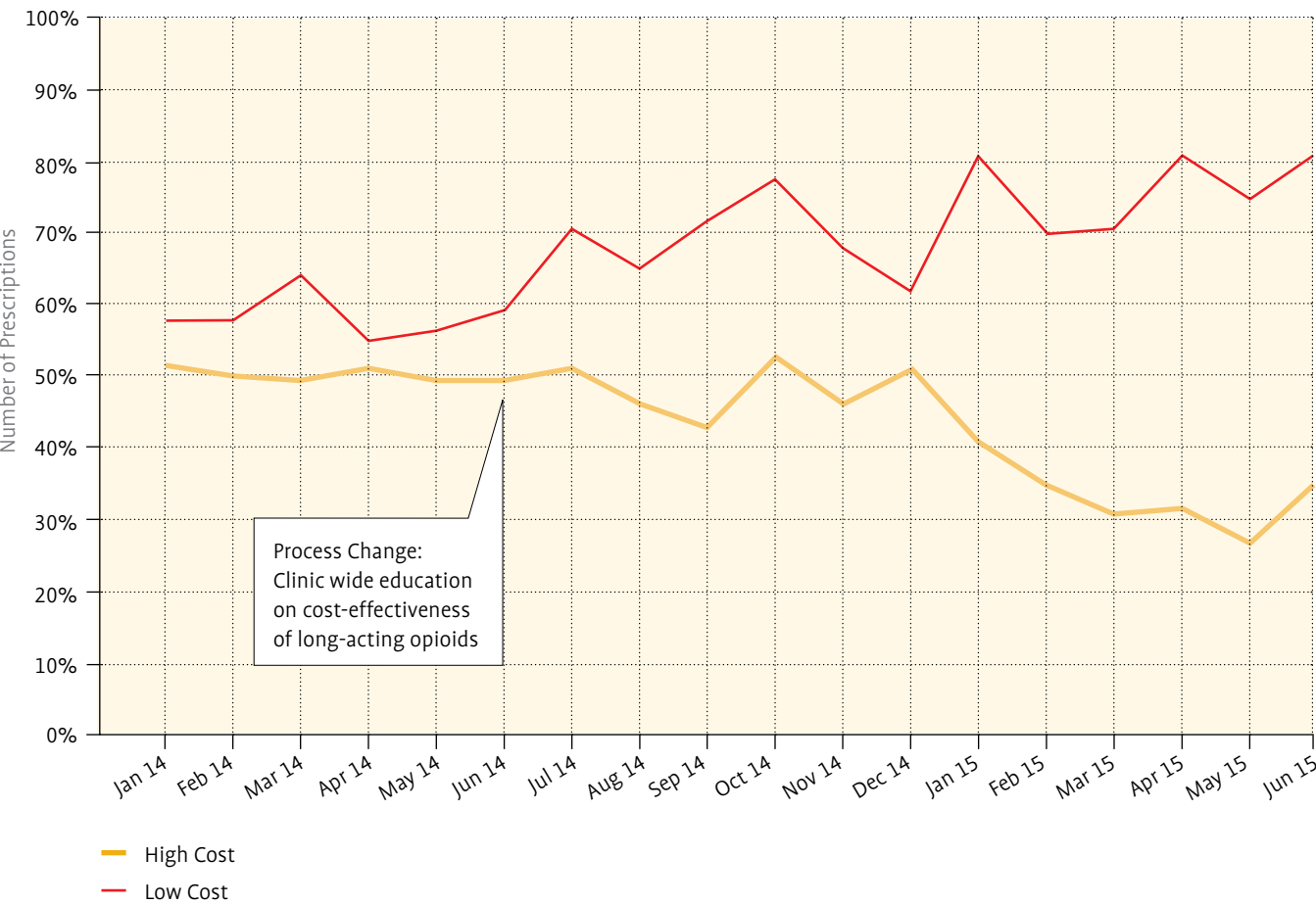
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Author’s Note

For more on this quality improvement initiative, the author would like to direct readers to a 2017 article published in the *Journal of Oncology Practice*: Zylla D, Larson A, Chuy G, Illig L, et al. Establishment of personalized pain goals in oncology patients to improve care and decrease cost. *J Oncol Pract.* 2017;13(3) e266-e272.

Figure 4. Comparison of High- and Low-Cost Long-Acting Opioids



The Study of High-Cost Oncology Patients to Improve Care & Curb Costs





Costs are rising in oncology. When you look at why health-care costs are rising, 91 percent is due to the increased price of drugs, medical devices, and hospital care.¹ These costs can be divided into three general categories for all of health-care: 1) a growing population, 2) changing thresholds, and 3) innovation. Specific to oncology, our increasing patient population is primarily the elderly. An example of our changing thresholds is the use of *Oncotype DX* testing to inform treatment decision-making for women who are node-negative. Innovation encompasses everything from oral oncolytics and targeted therapy to improvements in radiation oncology technology and equipment. Bottom line: when it comes to rising costs in healthcare, oncology is in the crosshairs.

Rise of the ACOs

Signed into law in 2010, the Affordable Care Act looked to control these rising costs with the creation of Accountable Care Organizations (ACOs) where physicians, hospitals, and payers work together to provide coordinated, high-quality care. The goal of coordinated care is to ensure that patients, especially the chronically ill, get the right care at the right time, while avoiding duplication of services and preventing medical errors. When an ACO succeeds—both in delivering high-quality care and spending healthcare dollars more wisely—it will share the savings it achieves among participants (at least initially). ACOs were designed to use the financial benefit realized from cost-savings to both empower providers and to help them improve their clinical knowledge so that they can help restructure the delivery of care to reduce redundancy. How? The ACO allows providers and hospitals to mine data, including Medicare claims data, and employ analytics to study their specific patient populations and marketplace factors to identify both intuitive—and non-intuitive—opportunities to save.

While there are many assumptions about who comprises the most expensive patients, at Cone Health we defined our “hot-spotters” as the highest spending 5% because—across healthcare—the top 5% of patients spend over 50% of healthcare dollars.²

In 2012, Cone Health System, Greensboro, N.C., helped develop Triad Healthcare Network, a provider-led collaborative ACO between community physicians and the healthcare system aimed at improving the care delivered to our patient population. Our ACO participated in the Medicare Shared Savings Program in 2014 and 2015. In our first year, the ACO saved \$21.5 million. It was in the top percentile, receiving a \$10.5 million bonus. In 2015, Triad Healthcare Network was named 5th in the nation for quality in the Medicare Shared Savings Program. In 2016, Cone Health participated in the next generation ACO model.

As part of an ACO, Cone Health has access to Medicare claims data on patients—not just the fees generated in the cancer center. As such, we learned about spending in oncology, and we are now leveraging these findings to help reduce costs. This article shares how we identified our high-cost patients or “hot-spotters” and put processes and systems in place to not only improve care for these patients but also reduce costs.

Defining the Term “Hot-Spotter”

Our ACO has more than 30,000 Medicare beneficiaries, so we knew immediately we could not study and reduce costs on every one of those patients. We understood that we needed to focus on a smaller sub-group. The question became: How do we pick the right patient sub-population? We could study just oncology patients. We could study patients with advanced disease. In the end we decided it was as simple as starting with the patients who spend the most healthcare dollars.

The concept of “hot-spotters” started in 2007 when Jeffrey Brenner, MD, a public health family practitioner working in Camden, N.J., started treating chronically sick patients who accounted for a significant percentage of the healthcare costs in his area. He operated under a hypothesis that people who had the highest costs in the healthcare system were also receiving the worst care. By helping this specific patient population, Dr. Brenner believed he could improve care and lower healthcare costs—and not just for these patients, but for the entire city. Dr. Brenner’s approach was to apply law enforcement models of assigning more resources to high-incident areas. For example, he suggested placing an outpatient clinic in a public housing building that had a high rate of ED (emergency department) utilization and hospital inpatient admissions. After three years under Dr. Brenner’s model, patients who averaged 62 hospital and ER visits per month dropped by 40 percent. Their hospital bills decreased from \$1.2 million per month to just over half a million—a 56 percent reduction. By focusing attention on the high-cost patients, i.e., “hot-spotters,” Dr. Brenner was able to make drastic changes to overall healthcare costs and improve the quality of the care through earlier interventions and improved access.

Identifying Our “Hot-Spotters”

While there are many assumptions about who comprises the most expensive patients, at Cone Health we defined our “hot-spotters” as the highest spending 5 percent because—across healthcare—the top 5 percent of patients spend over 50 percent of healthcare dollars.²

As part of our ACO efforts, Cone Health established several service line clinical practice committees to study costs and look for cost-saving opportunities. As you might imagine, our providers’ reflex reaction to cost-cutting was defensive, with many wanting to protect or exempt specific patient populations from any cost-cutting efforts. For example, our breast oncologist requested to exclude breast cancer patients and two specific drugs. Our radiation oncologists (including me) wanted to exclude stereotactic radiosurgery, citing that while these procedures are high-cost, they are low-risk and highly effective. In the end, our providers agreed to let go of all clinical assumptions and biases, and instead take a deep dive into our data.

Table 1. Total Cost of Care for “Hot-Spotters”

	Total Group
Minimum	\$ 50,053
Maximum	\$ 471,905
Mean	\$ 79,882
Median	\$ 69,435
Total	\$ 17,254,595

We started by looking at one year of claims data (2014) for more than 31,000 Medicare beneficiaries. Of these, 3,942 had a cancer diagnosis in their CMS Hierarchical Condition Categories (HCC), and from these we formed three cohorts. The low-cost cohort (55 percent of the patients) had annual claims totaling less than the ACO mean for cost of care. Our intermediate-cost patients (29 percent) incurred claims exceeding the ACO mean for cost, and our “hot-spotters,” the top five percent, incurred claims that totaled more than \$50,000 per patient.

We soon found out that our data had some limitations. We identified 216 “hot-spotters” with a cancer diagnosis in their HCC list, and we had a lot of information about their Medicare claims, but the picture was blurry. For example, while we knew the HCCs and the cost of care, we didn’t really know why the costs were incurred or how we could influence them. To learn more about our “hot-spotters” we had to move from data mining to data collection. We arranged for a pre-med student to perform chart reviews to learn more about these patients, specifically cancer type, cancer stage, treating oncologist, and treatment details to build a clear profile of our “hot-spotter” population. Here’s what we found.

Some patients had a cancer diagnosis; but, not all were active oncology patients. This was one of the limitations of the data. Cancer diagnoses can stay on patient records long after the cancer is gone. For example, one patient was a Stage I breast cancer patient treated with lumpectomy and radiation 15 years ago. However, the patient underwent left ventricular assist device (LVAD) placement during the year we were pulling Medicare claims data, which put her into the “hot-spotter” category. We went back and filtered our 216 “hot-spotters” to only include patients with three cancer center visits during the study period, which left us with 70 patients. In other words, these 70 patients were followed up more than every six months. At the end of

2014, 90 percent of the patients were still alive and 11 percent had died. In terms of costs, the minimum cost spent in the “hot-spotter” group was \$50,000 and the maximum was \$472,000 (Table 1, left). Total cost of care for these 70 “hot-spotters” was \$17 million.

Identifying “Hot-Spotter Trends”

We looked at the detailed medical characteristics of these 70 patients and recorded the data in a chart audit. Data points included:

- Number of medical oncology visits
- Plan provider
- Body mass index
- Histology
- Diagnosis date
- Stage
- Lymph node involvement
- Metastases of the brain, bone, lung, liver, or muscle
- Type of surgery (if any)
- Type of radiation (if any)
- Type of chemotherapy (if any)
- Type of immunotherapy (if any)
- Complications
- Date of final treatment.

Here’s what the data revealed.

Our “hot-spotters” had a variety of diagnoses, not really predominated by any one diagnosis. Although there were more blood and lymphatic malignancies and lung cancers, we found a relatively even distribution of presenting cancer types (Figure 1, right). We also found that all stages were represented. Stage IV was the most common at 33 percent, and we also had a high percentage of un-staged patients, which indicates blood and lymphatic malignancies (Table 2, page 50). These data alleviated some concerns from medical oncology that their personal subset of patients would represent a large percentage of the “hot-spotters.” Across physicians there was a relatively even distribution of “hot-spotters,” which aligned closely with physician office productivity. With no predominant physician or sub-specialty treating these 70 patients, data showed that the type of cancer or the treating physician were not driving the high costs of our “hot-spotters.”

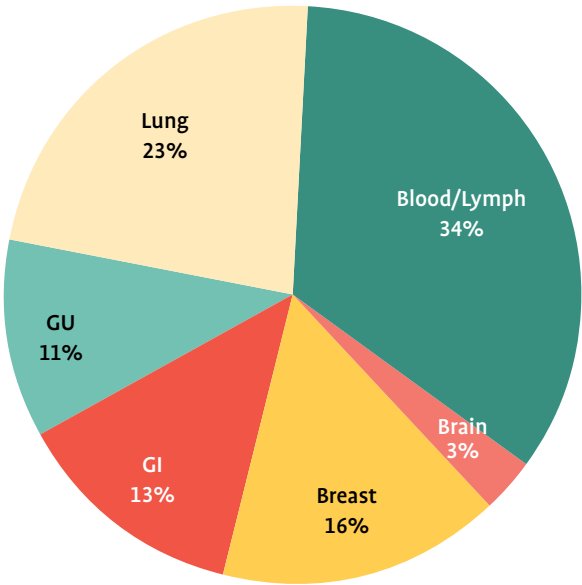
2014 data on our “hot-spotters” revealed that these patients had received a variety of treatment modalities:

- Chemotherapy: 87 percent
- Immunotherapy: 56 percent
- Radiation treatment: 45 percent
- Surgery: 44 percent.

When we compared our “hot-spotter” data against our cancer registry we found that blood and bone marrow malignancy

Figure 1. “Hot-Spotters” by Diagnosis

Primary Tumor Site



patients were 9.41 times as likely to be a “hot-spotter” (Figure 2, page 51). Breast cancer patients were half as likely to be “hot-spotters,” and that was statistically significant. Respiratory cancer patients were more likely to be “hot-spotters,” but that was not statistically significant.

When we compared “hot-spotter” data against our tumor registry for tumor stage (Figure 3, page 52), Stage I patients were 20 percent more likely to be “hot-spotters,” and that was significant. Stage IV patients were almost twice as likely to be “hot-spotters,” and unknown stage patients were also twice as likely to be “hot-spotters,” also significant.

Going into the study, I had suspicions about the role body mass index (BMI) might play, noting that patients with a high BMI sometimes have increased complications with treatment. However, 60 percent of our “hot-spotters” were overweight and 31 percent were obese. When we compared these percentages to the population of North Carolina, at 64.9 percent overweight and 27 percent obese, we found no significant relationship between BMI and cost of care in this population of active oncology patients.

How & Why Our “Hot-Spotters” Spent Money

Data revealed that 90 percent of our “hot-spotter” patients had ED visits—a median of 4.5 ED visits and a maximum of 20 ED visits during the study year (2014). Sixty percent of the 70 “hot-

Table 2. “Hot-Spotters” by Stage

Stage	Number	Percentage
I	5	7%
II	10	14%
III	12	17%
IV	23	33%
No Stage	20	29%

spotters” were hospitalized, with a median of one hospitalization and a maximum of nine hospitalizations.

Our next step was to identify why our “hot-spotters” were going to the ED and being admitted to the hospital. We found that our oncology “hot-spotters” were patients with multiple medical co-morbidities (Table 3, page 53). Thirty-eight percent had renal failure. A similarly high percentage had congestive heart failure (33 percent) and chronic obstructive pulmonary disease (32 percent). Bottom line: these medical co-morbidities were driving up the cost of care as much as the cancer diagnosis itself. Table 4, page 53, shows the top five costs by category. While chemotherapy was the top cost, it only represented one-third of the overall charges for our “hot-spotter” patients. In other words, two-thirds of the costs for these “hot-spotters” were unrelated to chemotherapy.

Interestingly, as we were compiling the results of our “hot-spotter” study, another study was published in the *British Medical Journal*, looking at the U.S. Veterans Affairs (VA) healthcare system.³ Study researchers also looked at the five percent highest-cost patients in the VA, and found that they accounted for 47 percent of total VA costs. Similar to our “hot-spotters” study, this study found that two-thirds of these patients had chronic conditions affecting three or more body systems. In conclusion, researchers suggested patients with multi-morbidity need interventions that coordinate and maximize efficiency across multiple conditions.

Identifying Opportunities for Cost-Savings

So, how do we use all of these “hot-spotter” data to help reduce costs? Are there ways to identify “hot-spotters” in advance—to profile future “hot-spotters?” For example, by focusing on patients with three or more significant co-morbidities and developing a co-morbidity scoring system, perhaps weighting congestive heart failure more highly than others. While this may work, the meth-

odology is not validated and will need to be studied. We could target individual “hot-spotters” prospectively, or develop systems to target the areas that lead to high “hot-spotter” spending, and some of those ideas are detailed below.

At Cone Health, our first step was to pull data on how some of these costs were generated, focusing on processes and/or programs already in place and processes and/or programs that could be developed to improve care and reduce costs at our cancer center.

Breast Cancer & Congestive Heart Failure

A patient receiving chemotherapy for breast cancer and who is at-risk for developing congestive heart failure may require the services of cardiology. Specifically, women receiving Herceptin are at high-risk for developing congestive heart failure; if these patients also receive Adriamycin, the risk may be as high as 30 percent. Unless there is a seamless transition of care from oncology to cardiology, these patients may be at-risk of ending up in the ED or the hospital with congestive heart failure. At Cone Health, a Breast Cancer Heart Failure Clinic existed prior to this “hot-spotter” study—and our study helped support the existence of these cross-departmental clinics and/or programs. Cone Health had developed this clinic after a few patients receiving systemic therapy for breast cancer developed full-blown congestive heart failure. Now patients receiving Herceptin are prospectively referred to cardiology, and screened for cardiovascular risk factors to assess for left ventricular ejection fraction dysfunction. The clinic has seen more than 200 women and offers screening and echocardiograms. While these services are expensive, patients who experience worsening ejection fraction can be told to stop or reduce Herceptin. At Cone Health, for all patients who received this intervention and got dose reductions, normal cardiac function returned.

The High Cost of Death

Our data revealed that one of the high-cost items was the cost of death. Eleven percent of “hot-spotters” died during the study year (2014), and 34 percent died in the subsequent year (2015). The patients who died were twice as likely to have an ED visit. The year after their “hot-spotter” year, in 2015, overall costs went down, but 42 percent stayed “hot-spotters.” So the data showed that these patients had chronic issues over multiple years. In 2015, 24 percent of these “hot-spotter” patients transitioned to intermediate- or low-cost care, suggesting that these patients had had a health crisis in 2014, but then may have recovered from it.

Looking at these data, we asked ourselves: how could we reduce the cost of death? Certainly patients without goals of care, and without hospice support, go to the ED, and all too often die in the ICU. Patients without DNR (do not resuscitate) orders may spend their final days and weeks on a ventilator. Studies have found that each patient enrolled in hospice will save \$19,000

in their final year of life,⁴ and each patient seen by palliative care specialists can reduce hospital costs by \$7,000.⁵ Based on these data, in 2015 we launched a pilot study integrating palliative care into our brain and spine oncology clinic. During the six-month study, a nurse practitioner (NP) joined the clinic one morning a week (0.1 FTE). The study period included 14 clinics with 180 patients. Of these, 24 were referred to the NP, and goals of care were established and advanced directive discussions were documented in 100 percent of those referrals. Do not resuscitate orders were activated in 37.5 percent and documented in 54 percent. Medical orders for scope of treatment forms were introduced in 87.5 percent and completed in 25 percent. In terms of change of therapy, 33 percent of patients enrolled—or seen by palliative care—were enrolled in hospice. So, extrapolating from the previous figures, adding 0.1 FTE to our brain and spine oncology clinic led to a cost savings of \$364,000 over six months.

ED Visits & Hospital Admissions

We then looked at opportunities to realize cost-savings around

ED visits and hospital admissions, or at least reducing the incidence of ED visits hospital admissions. Here’s what we found.

Our cancer patients have problems at inconvenient times. It may be during the day, when the oncologists’ clinic schedules are full, and they are not able (or amenable) to adding on patients. In the past, many of these patients were advised to go to the ED for more timely attention to their complaints. We also found that a large number of our patients relied on the ED for pain management. In the year we pulled data for our “hot-spotter” study, 961 cancer patients had 1,448 ED visits, and 23 percent of these visits were related to pain management.

We addressed these issues with a two-pronged approach: 1) creation of a standardized triage phone assessment and 2) implementation of a symptom management clinic. In an effort to reduce ED utilization and reduce admissions, we created and staffed a new advanced practice provider position. The advanced practice provider saw patients at the clinic and, under the supervision of medical oncology, managed pain and other symptoms of their disease and side effects of treatment. The clinic is available

Figure 2. “Hot-Spotter” Data Compared to Registry Data by Diagnosis

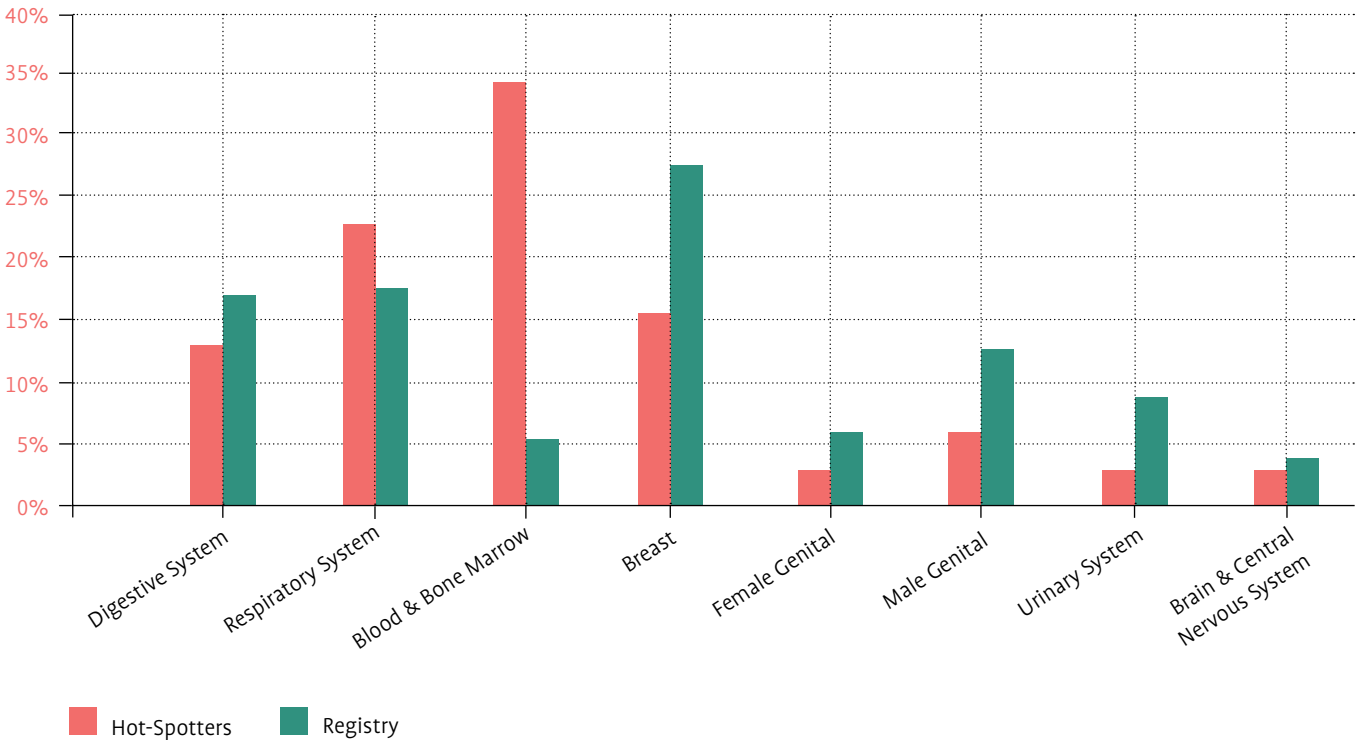
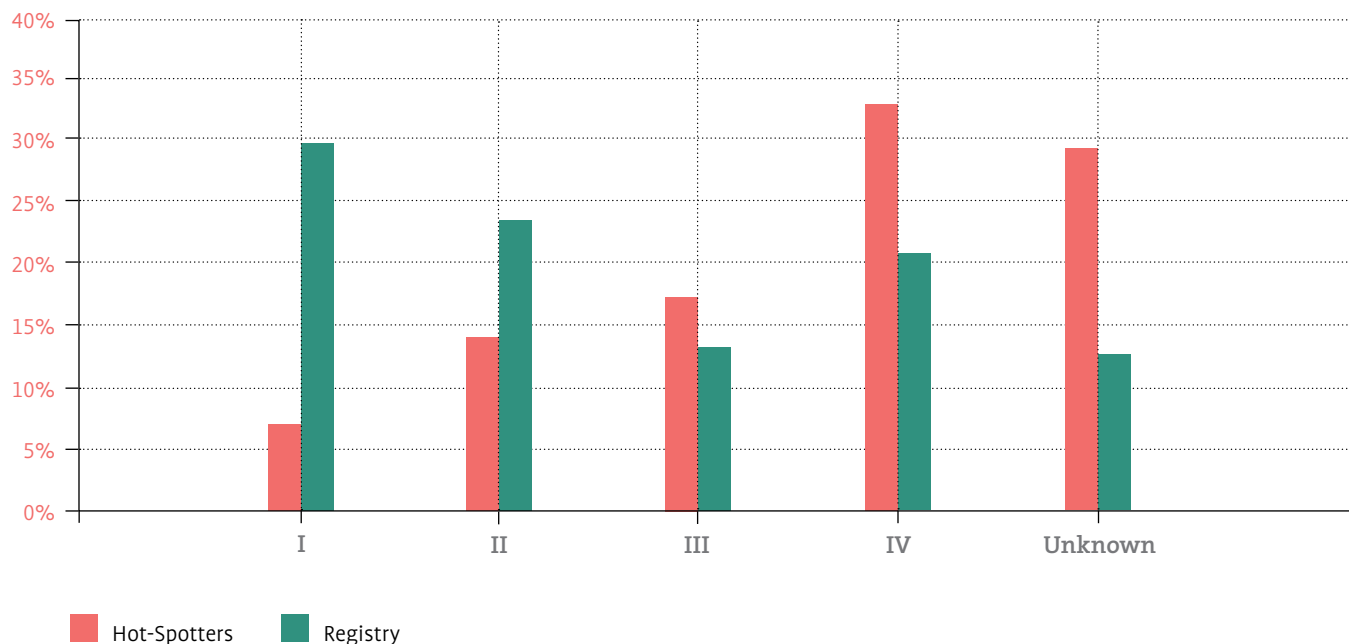


Figure 3. “Hot-Spotter” Data Compared to Registry Data by Stage



to treat most symptoms associated with cancer treatment. The top 10 conditions include anemia, nausea, dehydration, neutropenia, diarrhea, pain, vomiting, pneumonia, fever, and sepsis—all significant conditions, but not emergencies. The symptom management clinic is not used to treat patients presenting with active chest pain, acute respiratory distress, GI bleeds, stroke, or serious trauma, and the clinic does not accept patients brought in via EMS (emergency medical services). While not the first cancer center to implement a symptom management clinic, Cone Health has realized significant cost-savings and improved patient care. In the symptom management clinic’s first year, ED visits by cancer patients decreased 24.5 percent. This improvement is important because the hospital outpatient quality reporting program measure, OP35, looks at admissions and ED visits for patients receiving outpatient chemotherapy, and findings will affect future revenue.

Blood & Bone Marrow Patients

There are many reasons why these patients are more likely to be “hot-spotters.” The drugs used to treat myeloma, leukemia, and lymphoma are expensive. In addition, Cone Health does not have a bone marrow transplant unit, so when acute blood cancer patients and potential bone marrow transplant patients are diagnosed, their care is transferred out of our network to any of three nearby academic medical centers. Once that occurs, our providers have limited control over any factors affecting their quality or cost of care. The “hot-spotter” study raised the possibility of Cone Health entering into an agreement with a

bone marrow transplant partner where we would ask for collaborative management—and potentially negotiated rates—in exchange for providing patient volumes for research, tissue banking, and fee-for-service revenue from the patients referred.

Low-Cost Does Not Mean Low-Tech

Based on this study, Cone Health is comfortable making the statement that oncology providers should continue to promote high-tech treatments. Our “hot-spotter” data suggests that it is not just the advanced technology that is driving our rising health-care costs, but also the way we, as clinicians, are managing our patients. Based on these data, we believe that we can make process changes and improvements at Cone Health that will realize major cost-savings—without cutting patient access to high-tech treatments. For example, when you look at colostomy rates with IMRT versus conventional radiation for prostate cancer, the colostomy rates and all complication rates are lower, rectal bleeding rates are also lower with prostate IMRT. In another example, neutropenic fever admissions with targeted therapy are lower than they were with chemotherapy. As Cone Health turns its focus on developing a quality, integrated network of care, our plans include developing robust dashboards to track admissions and other key data and building multi-silo care teams—including primary care physicians—to collaborate on complex patients.

Our cancer patients cannot afford to lose the progress achieved from advances in technology. However, if the oncology community does not control its own spending, someone else will. As an

Table 3. “Hot-Spotters” with Co-Morbidities

Oncology Data: Hot-Spotters Co-Morbid Conditions	
CHF	33%
COPD	32%
Dialysis, Renal failure	38%
Septicemia	19%
Protein-calorie malnutrition	19%
Disorders of immunity	17%
Coag defect	23%
Feeding tube	12%

Table 4. “Hot-Spotter” Co-Morbidities by Cost

Original	
Category	% of total
Chemotherapy	33%
Inpatient Admissions	19%
Observation	13%
Surgical	9%
Dialysis	3%

example, you need look no further than 2015 when CMS cut reimbursement for stereotactic radiation by seven percent. When payers cut spending, an appropriate metaphor would be like someone “mowing the grass,” and the tallest blade of grass is the first to be cut down. When payers look at the oncology landscape, these tall blades of grass are the more expensive drugs, the more advanced radiation oncology treatments, and immunotherapy. Recognizing that our “hot-spotters” are really the tall blades of grass, I suggest providers mow their own grass by improving their management of these high-cost patients. Remember: when patients under your care are spending money in the ED and in the hospital, your cancer center is responsible for those costs—and you’re not receiving any revenue from these services. Study your own “hot-spotters” and look for ways to control their costs. Build multidisciplinary safety nets. Be ready for unanticipated sick patients during office hours and after-hours. Start mowing your own grass. 

Matthew A. Manning, MD, is a radiation oncologist at Cone Health Cancer Center, Greensboro, N.C.

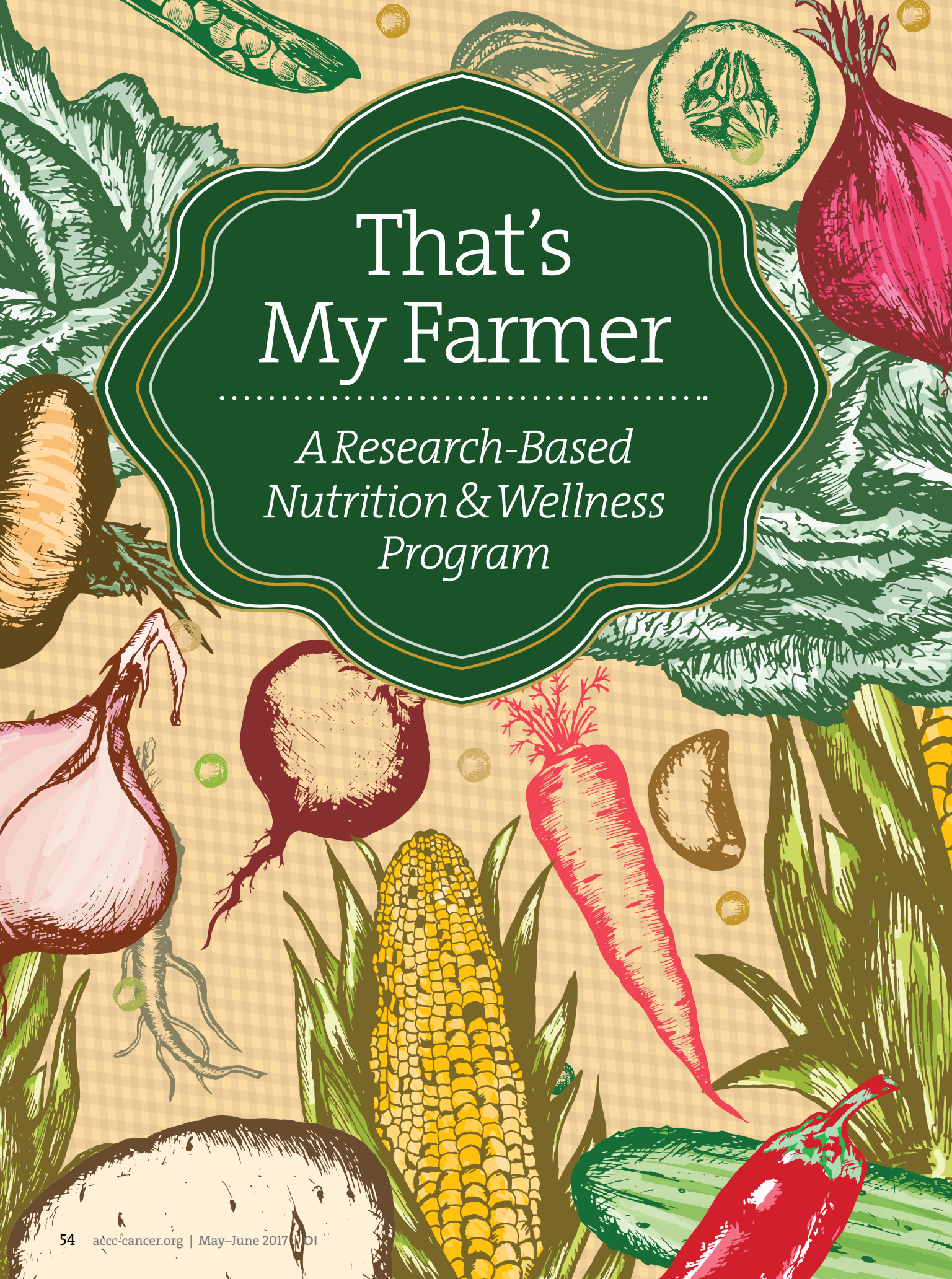
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OUR PROGRAM AT-A-GLANCE

Cone Health is located in Greensboro, in the center of North Carolina. It is an integrated not-for-profit network of healthcare providers serving multiple counties with 11,000 employees and 1,300 physicians. We have 100 locations, including 6 hospitals, 3 ambulatory care centers, 3 outpatient surgery centers, 4 urgent care centers, a retirement community, and more than 100 physician practice sites. Cone Health hospitals sit in the middle of an academic triangle, bordered by Wake Forest, Duke,

and UNC Chapel Hill. So, our health system is under some geographic pressure to offer high-quality care. Cone Health Cancer Center is accredited by the American College of Surgeons with multiple commendations. We have several multidisciplinary clinics. Eighteen medical oncologists and six radiation oncologists see more than 3,000 new patients annually. We offer state-of-the-art radiation oncology technology, including TomoTherapy, radiosurgery, and brachytherapy.



That's My Farmer

.....
*A Research-Based
Nutrition & Wellness
Program*

That's My Farmer is a research-based nutrition and wellness program designed to educate cancer survivors through hands-on learning. The multi-week program combines education on anti-inflammatory nutrition, healthy food shopping and preparation, and the benefits of eating local fresh fruits and vegetables with emphasis on the positive impact that wholesome foods can have for patients recovering from cancer. Through Samaritan Health Services—a five-hospital system in Oregon—the educational series takes place at affiliated locations and local farmers' markets in the region's mid-Willamette Valley. Registered dietitians from the Samaritan Cancer Program deliver weekly educational modules to enrolled participants using research-based nutrition guidelines. Participants also receive vouchers to aid in purchasing fresh produce.

In the Beginning

Initially, the 2013 pilot program of *That's My Farmer* focused on the diabetic community. A collaborative project between a local free medical clinic and a regional local farmers' network provided accessible and convenient diabetes education. Through this partnership, patients suffering from diet-related illnesses were referred to *That's My Farmer* to receive individualized nutrition education and farmers' market vouchers. A local physician and a provider working in the free medical clinic coordinated the pilot program, while a certified diabetes educator was contracted to provide patients with nutrition education specific to participants' needs.

Participants in the 2013 pilot received education on the proper use of glucometers and glucose testing, pertinent information about diabetes, portion sizes of foods, and the importance of exercise and activity in managing blood sugar levels and diabetes. The benefits of counting carbohydrates and keeping daily logs of food intake and blood sugar levels were also addressed with participants. In total, 114 individualized

Samaritan Cancer Resource Center leadership championed the program, successfully engaging other organizations and support throughout the Samaritan Health Services system to modify *That's My Farmer* and provide local cancer survivors with research-based information to help improve their overall well-being.

appointments were provided to 44 patients with uncontrolled type II diabetes. This program fulfilled an unmet need for low-income diabetics by providing valuable skills and education to change lives for the better.

Identifying a Need

One tool used to obtain pertinent information regarding the needs and health-associated risk behaviors of local cancer patients is the Community Cancer Needs Assessment. This survey was conducted in 2014 in collaboration with local health departments in Oregon's Benton, Lincoln, and Linn counties, which comprise the geographic area served by the Samaritan Health Services system. Cancer Needs Assessment survey data from the community is an important identifier of health risks. Table 1, page 57, shows the percentage of adults in Oregon who engage in selected risk



Cancer survivors Loren and Connie Smith of Albany, Ore., attended *That's My Farmer* together. "We learned how to shop and what questions to ask about the food we buy," said Connie. "It's made me more aware of how to take care of my own health." The couple also enjoyed learning what's seasonal in Oregon. Pictured here in 2014, the couple shops at Albany Oregon Farmers' Market.

behaviors. Data revealed that in all counties, an average of less than 1 in 4 individuals were eating 5 or more fruit or vegetables per day. This is an important area for improvement, and adapting the *That's My Farmer* program for cancer patients would help meet this need.

Adapting the Program for Cancer Survivors

Building on the success of the diabetic pilot program, in 2014 the Samaritan Cancer Resource Center, the local free medical clinic, and Samaritan Health Services' dietitians collaborated to pilot a *That's My Farmer* program specifically for cancer survivors. Samaritan Cancer Resource Center leadership championed the program, successfully engaging other organizations and support throughout the Samaritan Health Services system to modify *That's My Farmer* and provide local cancer survivors with research-based information to help improve their overall well-being. Cancer survivors (participants) were invited to bring their spouse or caregiver with them to weekly classes and trips to local farmers' markets.

The first *That's My Farmer* for cancer survivors took in place in 2014 in Albany, Ore. Sixteen participants registered for the program, receiving 12 weeks of nutrition education and vouchers to be used for purchasing unprocessed fruits, vegetables, beans, and grains. These participants were identified by oncology dietitians and invited from various cancer support groups. Of the 16 original participants, 12 completed the program; drop-outs were due to illness and/or fatigue. Educational modules included:

- Research-based nutrition guidelines.
- Advice on eating locally and seasonally available food.
- Recommendations for physical activity.

- Information on nutritional supplements.
- Exploration of the relationship between cancer and sugar.
- Information on meditation, affirmations and positive thinking, and discussion of emotions around food.

The *That's My Farmer* program also fostered meaningful relationships and friendships by connecting individuals whose lives had been touched by cancer with others on the same or similar journey. Each participant received a canvas shopping bag to take to the farmers' market along with a recipe card holder, dried beans and polenta, a crock pot, a jar of honey, and herbs and spices.

Participants met at a nearby farmers' market and were given vouchers to purchase fresh produce. These vouchers offered participants a weekly opportunity to use their in-class knowledge and purchase fresh produce. With operational funds provided by the Albany General Hospital Foundation, by the conclusion of the program each participant had received \$150 to \$200 in vouchers. The weekly voucher amount depended on the number of enrollees (i.e., more enrollees equaled a lower dollar amount). Vouchers were only permitted to be used toward the purchase of unprocessed fruits, vegetables, beans, and grains.

Participants were encouraged to fill out a survey on personal eating habits and to give feedback on the program. These surveys provided important data that was used to improve the *That's My Farmer* program and ultimately support expansion to other nearby cities.

Reshaping the Program

In 2015 *That's My Farmer* expanded to include the nearby communities of Lebanon and Corvallis in addition to Albany. Based

Table 1. Select Results of the Cancer Needs Assessment

CANCER NEEDS ASSESSMENT	BENTON COUNTY	LINCOLN COUNTY	LINN COUNTY	OREGON
Consumed 7 or more sugar-sweetened beverages per week	7.2%	20.0%	15.9%	13.3%
Consumed 5 or more fruits and vegetables per day	21.7%	23.9%	19.2%	21.9%
Current smoker	14.3%	33.1%	20.5%	19.0%
Obese	21.2%	30.3%	33.2%	25.9%
No physical activity in past month	12.9%	16.1%	21.5%	18.0%
Binge drinking the past month	17.2%	16.2%	21.9%	17.7%

on survey feedback from prior years, the series was shortened from 12 to 8 weeks. Information included in the 2015 *That's My Farmer* program was similar to the content in previous years, but it was expanded based on participant requests. In addition to the weekly class sessions, participants continued to meet at local farmers' markets to use their vouchers. Topics addressed in the 2015 sessions included:

- Research-based nutrition guidelines specific to cancer prevention.
- Recommendations for fitness and physical activity.
- Self-care and mindfulness.
- Use and safety of nutritional supplements.
- The relationship between sugar and cancer.

Similar to the prior year, 2015 participants at the three sites received a canvas shopping bag, a cookbook, a calendar, recipe cards, dried beans, grains, and herbs and spices. Instead of crockpots for each participant, weekly prizes were awarded after participants answered knowledge-based questions. Local businesses donated these weekly prizes to aid in the preparation of nutritious foods, improve self-care practices, and promote physical activity.

During the farmers' market meetings, local student volunteers assisted participants. Specifically, students from the dietetics program at Oregon State University and medical students from the nearby College of Osteopathic Medicine of the Pacific-Northwest developed and disseminated seasonal "Pick of the Week" flyers to participants. These educational flyers provided nutrition information about a fruit or a vegetable, as well as selection and storage information. Participants were asked to spend a portion of their vouchers on the "Pick of the Week"

items and spend the remaining vouchers on produce of their choice. These student volunteers decided on the "Pick of the Week" before participants arrived at the market, based on the produce available at the market that day. With the addition of the "Pick of the Week" component, many participants tried several fruits and vegetables for the first time. One participant shared, "I really liked being exposed to fruits and veggies that I don't normally use."

The team leading the 2015-16 *That's My Farmer* program consisted of three registered dietitians, staff from the Samaritan Cancer Resource Center, and student leaders. Along with the registered dietitians who facilitate the weekly classes and food demonstrations, the program brings in other healthcare providers, such as:

- Certified diabetes educators to talk about insulin resistance.
- Social workers to address mindfulness, self-care, and stress management.
- Certified personal trainers, some with cancer-specific training, to provide information on physical activity recommendations and appropriate modifications for participants.

In 2015 and 2016, the combined total used to purchase fresh fruits and vegetables through vouchers reached more than \$10,000. This money goes directly to local farmers, thus, strengthening the local economy as well.

At the end of 2016, participant feedback led to further refinements to the program. Generally speaking, participants highly valued the weekly vouchers, liked the cookbook above other incentives (shopping bag, spices, etc.), preferred more

(continued on page 59)

Figure 1. Samaritan Health Services *That's My Farmer* Pre-Survey



PARTICIPANT ID: _____

WEEK #: _____

Thank you for taking the time to fill out this intake survey.

What resources have you utilized in the past year? (Please circle all that apply):

☐ Cancer Resource Center ☐ Dietitian ☐ Social worker

☐ Support groups (i.e., art therapy, SurvivorFit, Living Well). Please list:

☐ Other support(s). Please list:

What other specific information or resources are you looking to learn? What do you hope to gain from this program?

Is there anything you would like the group leaders to know about you or your needs?

**Thank you for taking this survey to help us improve the TMF program. We will keep your answers confidential.
Please ask your lead dietitian or volunteer if you have any questions and/or concerns about this survey.**

1. Over the past 7 days, how often did you eat vegetables?	Never ☐	1 time per day ☐	2 times per day ☐	3 times per day ☐	4 times per day ☐	5 or more times per day ☐
2. When you ate vegetables, how much did you usually eat per day?	N/A ☐	Less than 1/2 cup ☐	1 cup ☐	2 cups ☐	More than 2 cups ☐	More than 3 cups ☐
3. Over the past 7 days, how often did you eat fruit?	Never ☐	1 time per day ☐	2 times per day ☐	3 times per day ☐	4 times per day ☐	5 or more times per day ☐
4. When you ate fruit, how much did you usually eat per day?	N/A ☐	Less than 1/2 cup ☐	1 cup ☐	2 cups ☐	More than 2 cups ☐	More than 3 cups ☐
5. How confident are you with the following?	Extremely confident (I'm a pro) Neutral (I'm ok) Not confident (I need help) I'm not sure					
Selecting fresh vegetables and fruit	☐	☐	☐	☐	☐	☐
Storing fresh vegetables and fruit	☐	☐	☐	☐	☐	☐
Preparing healthy meals	☐	☐	☐	☐	☐	☐
Trying new things in the kitchen	☐	☐	☐	☐	☐	☐
Eating healthy on a budget	☐	☐	☐	☐	☐	☐

(continued from page 57)

interaction during class and less didactic delivery of information via PowerPoint, and suggested changes to the program length and times offered. These changes were incorporated into the current version of *That's My Farmer*. This participant feedback has been key to programmatic success. Not only does constructive criticism and advice improve the program content and structure, it also creates a connection between the *That's My Farmer* team, the Samaritan Cancer Program, community partners, and local cancer survivor participants.

Tracking & Changing Behavior

While data from the Cancer Needs Assessment, and enrollment, attendance, and feedback in *That's My Farmer* highlight the immediate need and impact of the educational program, long-lasting impact is imperative to improved health outcomes. To extend learning beyond *That's My Farmer*, each participant receives a cookbook to use during the program and afterwards. The 2013 *Farm-Fresh and Fast* cookbook by Fairshare CSA Coalition features practical recipes using fruits and vegetables. Cooking demonstrations, using recipes from the *Farm-Fresh and Fast* cookbook, were provided to participants during *That's My Farmer* class sessions. "Pick of the Week" flyers included page numbers for recipes calling for the highlighted fruit or vegetable. This connection between the cookbook and the farmers' market led participants to try new foods and recipes and share their experiences with each other. During the following class sessions, participants would discuss their "Pick of the Week" and how they prepared it. This opportunity allowed participants to share information, build relationships, and encourage each other to continue making healthy choices.

Discussions between the dietitians and participants provided informal feedback on intake, experiences, and opportunities for growth. The relaxed atmosphere allowed participants the opportunity to share what they were gaining from the program and ask questions as they arose. Questions were recorded, either by the dietitian or lead volunteer, and followed up on as needed. These informal notes and, more importantly, pre- and post-surveys, provide valuable information on the needs of this population.

Registered dietitians use pre- and post-surveys to track participants' fruit and vegetable intake, knowledge of the information presented, and confidence in adopting healthy eating habits. Surveys are administered during the first and last week of the program. The pre- and post-surveys measure portion sizes of fruits and vegetables and intake. They also measure confidence regarding selection, storage, and preparation of fruits and vegetables. The pre-survey (Figure 1, left) touches on the various resources the participants have used within the Samaritan Cancer Program, resources or information they would like provided to them, and if there are any needs the group leaders should be aware of.

The post-survey (Figure 2, pages 60-61) asks questions about the program itself, including level of satisfaction, knowledge level of presenters, usefulness and relevance of program content, and whether participants would recommend *That's My Farmer* to others. The post-survey also includes open-ended questions about

(continued on page 62)

What Participants Had to Say...

"I really enjoyed this program. As a patient with cancer, diabetes, and a heart condition, the program has restarted my eating right."

"That's My Farmer sparked my interest in learning more about healthy eating and to implement changes not only for myself but for my family too."

"I learned something valuable from each class. My habits have changed in some areas, and I'm working on more."

"I enjoyed the 'Pick of the Week.' I really liked being exposed to fruits and veggies that I don't normally use."

"I changed what I eat right from the start of the program. The information I have now should impact the way I eat for months to come as I get more into a routine of healthy living."

"The course content covered many aspects of cancer survival, including a focus on healthier nutrition; the companionship of others dealing with cancer has been of lasting value."

Figure 2. Samaritan Health Services *That's My Farmer* Post-Survey



PARTICIPANT ID: _____

WEEK #: _____

Thank you for taking this survey to help us improve the <i>That's My Farmer</i> program. We will keep your answers confidential. Please ask your lead dietitian or volunteer if you have any questions and/or concerns about this survey.						
1. Over the past 7 days, how often did you eat vegetables?	Never ☐	1 time per day ☐	2 times per day ☐	3 times per day ☐	4 times per day ☐	5 or more times per day ☐
2. When you ate vegetables, how much did you usually eat per day?	N/A ☐	Less than 1/2 cup ☐	1 cup ☐	2 cups ☐	More than 2 cups ☐	More than 3 cups ☐
3. Over the past 7 days, how often did you eat fruit?	Never ☐	1 time per day ☐	2 times per day ☐	3 times per day ☐	4 times per day ☐	5 or more times per day ☐
4. When you ate fruit, how much did you usually eat per day?	N/A ☐	Less than 1/2 cup ☐	1 cup ☐	2 cups ☐	More than 2 cups ☐	More than 3 cups ☐
5. How confident are you with the following?		Extremely confident (I'm a pro)	Neutral (I'm ok)	Not confident (I need help)	I'm not sure	
Selecting fresh vegetables and fruit		☐	☐	☐	☐	
Storing fresh vegetables and fruit		☐	☐	☐	☐	
Preparing healthy meals		☐	☐	☐	☐	
Trying new things in the kitchen		☐	☐	☐	☐	
Eating healthy on a budget		☐	☐	☐	☐	
6. How satisfied were you overall with <i>That's My Farmer's</i> ?		Very Satisfied ☐	Somewhat Satisfied ☐	Neither Satisfied nor Dissatisfied ☐	Very Dissatisfied ☐	
7. To what extent do you agree with each of the following statements about this program?		Strongly Agree	Agree	Disagree	Strongly Disagree	
The presenters were knowledgeable		☐	☐	☐	☐	
The program materials were useful		☐	☐	☐	☐	
The right amount of information was provided		☐	☐	☐	☐	
I would recommend this program		☐	☐	☐	☐	

Figure 2. Samaritan Health Services *That's My Farmer* Post-Survey (continued)



Your opinions matter to us. Please use the space below to explain any of your answers above. We also welcome your overall comments about this program. Thank you
8. What did you enjoy the most about the program?
9. What are the pros and cons of the program?
10. How has this program impacted you?



The donor-funded Samaritan Pastega Regional Cancer Center in Corvallis, Ore., serves as the hub for the Samaritan Cancer Program, which offers satellite cancer care in four more locations across three counties.

(continued from page 59)

the pros and cons of the program and the impact on participants. Surveys from 2015 were administered more often and included questions on specific topics addressed in the educational modules. In 2016, surveys were reduced to the pre- and post-surveys and did not include the specific knowledge-based questions; this change was based on participant feedback.

Data shows that *That's My Farmer* has improved the nutrition and wellness of the cancer survivors in the community. Each year we seek feedback from participants and use this information to improve the program.

The 2016 survey data showed an increase in cancer survivors' confidence in eating healthy on a budget, preparing healthy meals, storing and selecting fruits and vegetables, and trying new things in the kitchen. The "extremely confident" option was the highest level of confidence on the survey (see Figure 3, right).

Confidence in selecting fresh produce in all three sites increased by 229 percent, storing fresh produce increased by 300 percent, preparing healthy meals by 200 percent, trying new things by 200 percent, and eating healthy on a budget increased by 260 percent. Overall this confidence increase is a positive change in the lives of local cancer survivors.

Program participants also increased their daily consumption of fruit. Figure 4, right, shows 2016 survey data on average fruit servings per day.

That's My Farmer also improved the average serving size of fruit and vegetables in all three locations. In all three cities combined, the average serving of fruit increased 124 percent, and the average serving of vegetables increased by 141 percent from the beginning of the program to the end.

The Future of the Program

As more cancer survivors participate in *That's My Farmer*, more patients are being referred from oncology providers. Participants not only want the summer series but have expressed a desire for a winter series as well. They have enjoyed the cooking demonstrations and want more hands-on experience. Post-survey data shows that participants are highly satisfied with *That's My Farmer* and would recommend the program to other cancer survivors (see Figure 5, page 64). The majority of participants strongly agreed that the program provided the right amount of information for each class; the participant who disagreed with the statement said the information was too broad. The participants all agreed that the program materials were useful and the presenters were knowledgeable.

From the provider perspective, the three annual *That's My Farmer* sessions provide valuable opportunities for growth within the program and for the Samaritan Cancer Program as a whole. Not only does the *That's My Farmer* program have the full support of Samaritan Health Services and its providers and staff, the program has the support of local farmers and businesses in the surrounding community. Peoria Gardens, a local farm, provides each cancer survivor with plant starts that have included cucum-

(continued on page 64)

Figure 3. 2016 Survey Data on the Number of Participants “Extremely Confident” in these Areas

Extremely Confident (I’m a Pro)

All Sites Combined

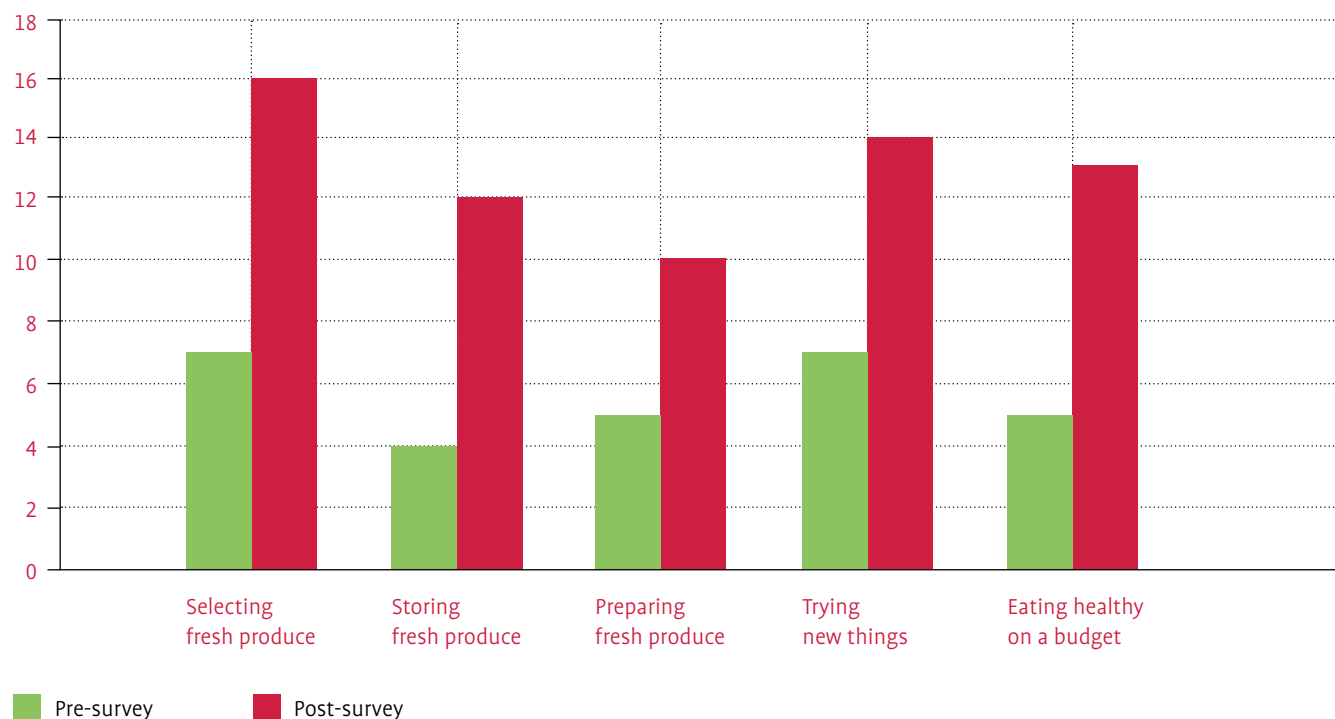


Figure 4. 2016 Survey Data on Average Fruit Servings Per Day

Average Fruit Servings Per Day

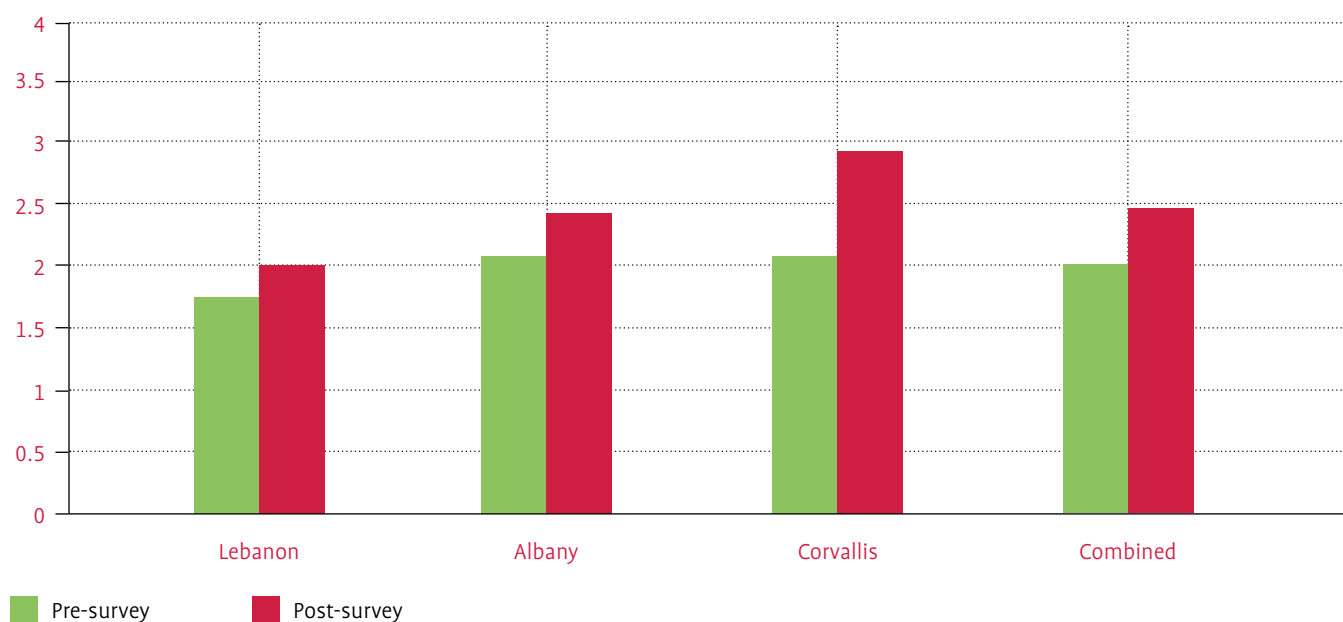
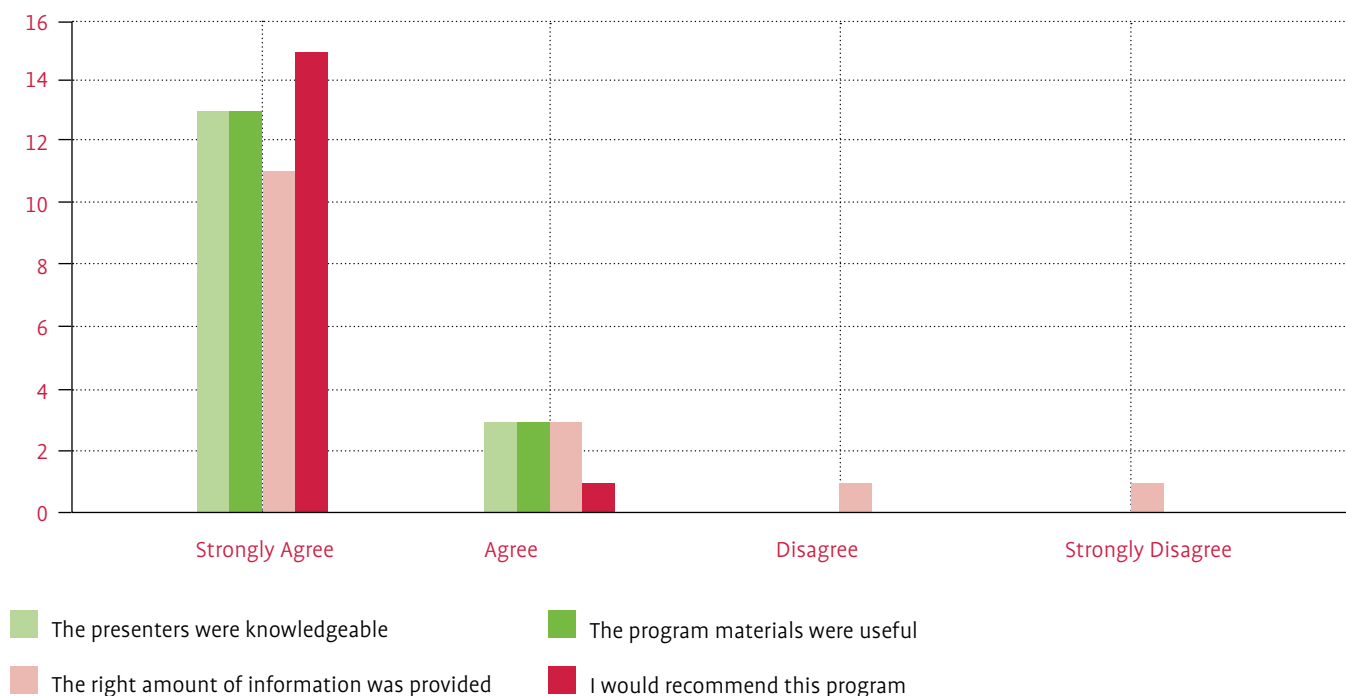


Figure 5. 2016 *That's My Farmer* Post-Survey Data

To what extent do you agree with each of the following statements about this program?



(continued from page 62)

bers, tomatoes, zucchini, squash, peas, and others. Oregon State University (OSU) has been an advocate for the program. OSU Extension Service Master Gardner program, OSU Food Hero program, and The Moore Family Center for Whole Grain Foods, Nutrition and Preventive Health, have provided the participants with educational materials, recipes, and demos on canning and gardening at the farmers' markets. Bob's Red Mill and The Moore Family Center for Whole Grain Foods, Nutrition and Preventive Health donated grain samples to participants. Collaborative relationships have been a successful highlight of the team efforts especially between healthcare providers (e.g., registered dietitians, medical social workers, etc.), educational institutions, local businesses, and area farmers.

Data shows that *That's My Farmer* has improved the nutrition and wellness of the cancer survivors in the community. Each year we seek feedback from participants and use this information to improve the program. According to the most recent 2016 surveys, the ideal program would be conducted over eight weeks, comprised of a mix of didactic teaching and group interaction, along with experiential learning on the part of participants.

Based on participant requests for follow-up, the 2016 *That's My Farmer* team is working towards a two-week refresher series for 2016 past participants. The first week of the refresher series

will be feedback on the program and whether or not participants were able to keep up with the information obtained when they were enrolled in the longer class. This feedback will provide an opportunity to assess the impact of the program and to provide necessary encouragement to continue with healthy changes. The second week will be a food demonstration for a healthy holiday meal. The objective is to provide participants with time to reflect on the program and to share their *That's My Farmer* experiences. The series would also include the same survey format given during the program; questions would be adjusted to account for the time spent away from the program.

Another area for growth is to expand the program to other locations within the Samaritan Cancer Program. We hope to expand to cancer programs located in our more geographically distant locations in 2017 so that cancer patients there may also benefit from *That's My Farmer's* life-changing education and support. 

Abigail Muniz, RDN, LD, is a clinical dietitian; Athena Nofziger, RDN, LD, CHC, is a clinical dietitian; and Jean Schumer, PhD, LCSW, is a social worker for the Samaritan Cancer Program in Oregon. Maisa Athamneh is a master's student at the University of Haifa International School in Israel. She served as a coordinator for the Samaritan Cancer Resource Centers in Oregon from 2015 to 2016.

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Rockville, Md.
Delegate Rep: Dominique Hayes,
MHA, BSN
Website: adventistsgmc.com

Carolina Blood and Cancer Care

Rock Hill, S.C.
Delegate Rep: Kashyap Patel, MD
Website: cbcca.net

CHI Health St. Francis, Cancer Treatment Center

Grand Island, Nebr.
Delegate Rep: Max Norvell, PharmD
Website: chihealthstfrancis.org

Illinois Cancer Specialists

Schaumburg, Ill.
Delegate Rep: Puneeth Indurlal, MBBS, MD
Website: illinoiscancerspecialists.com

Northwest Medical Specialties, PLLC

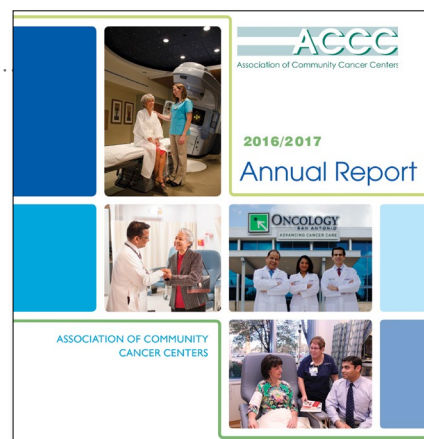
Tacoma, Wash.
Delegate Rep: Jeff Hunnicutt, BS, CSE
Website: nwmsonline.com

Sutter Coast Hospital Sutter Coast Infusion Center

Crescent City, Calif.
Delegate Rep: Roberta Rehsinschild, RN
Website: suttercoast.org

Vanderbilt Ingram Cancer Center

Nashville, Tenn.
Delegate Rep: Anna Liza Rodriguez, MSN, MHA
Website: vanderbilt.edu



ACCC 2016-2017 Annual Report

The annual report was released at the recent 2017 House of Delegates Meeting at the ACCC 43rd Annual Meeting, CANCERSCAPE. The report highlights ACCC's achievements in education and advocacy over the past year, recognizes new member programs, breaks down membership demographics, lists recent media coverage of ACCC, and includes the Treasurer's Report. Download today at: accc-cancer.org/about/pdf/annualreport-2017.pdf. 



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- The Future of Molecular Testing: Optimizing Efficiency Under Increasing Expectations
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- The Role of Genetics Professionals in a Community Cancer Program
- Virtual Molecular Tumor Board: Breast Cancer Case Studies



Association of Community Cancer Centers
These programs are a benefit of membership.

How Infusion Scheduling is Like a Game of Tetris

BY MOHAN GIRIDHARADAS



If you're of a certain age, you remember Tetris, a tile-matching puzzle video game originally designed and programmed by Russian game designer Alexey Pajitnov. Back in 1984—before “going viral” was a term—millions of people became obsessed (some might even say addicted) to this simple game, which challenged players to stack blocks of different shapes and sizes as efficiently as possible. Stacked improperly, the blocks would reach to the top of the screen—game over. Stacked optimally, the game could go on for hours.

Tetris & Infusion Scheduling

It turns out scheduling patients with varying treatment lengths is a lot like Tetris, only the odds of winning are stacked much more against you for a variety of reasons, including:

- Most infusion centers schedule patients on a first-come, first-served basis without an understanding of the overall “portfolio of patients who will be in adjacent chairs” at the time of the proposed appointment slot being planned.
- Between the randomized arrangement of appointments, late arrivals, delays in the lab and/or pharmacy, patients who experience an adverse reaction, nurses calling in sick, and the clinics running late, it is almost inevitable that there is a mid-day “crunch” sometime between 10:00 am and 2:00 pm when all of the chairs are full with numerous people in the waiting room.
- Simple spreadsheets or traditional EHR (electronic health record) approaches are not designed to create an optimal solution for scheduling infusion appointments.

By the Numbers

The complexity of the math required to create an optimized daily schedule is daunting. As an example:

- Take a 35-chair infusion center that operates from 7:00 am until 7:00 pm each day treating five types of appointments: 1 hour, 2 hours, 3-5 hours, 6-8 hours, or 9 or more hours.
- Assume that there is a sufficient number of nurses available in order to simultaneously seat 4 patients at a time to start their treatment at 10-minute intervals. That's 256 possible start times or “slots” per day (64 start times 7:00 am, 7:10 am, 7:20 am etc., until 5:30 pm multiplied by 4 patients at each start time, or $64 \times 4 = 256$)
- The number of possible ways these patient appointments can be arranged is a number with more than 100 zeros behind it. To put such a gigantic number into perspective, if we were to put all of the water in all of the oceans into gallon jugs, the number of jugs needed would be a number with only 40 zeroes behind it.

So, if the numbers are stacked against cancer center schedulers, how can they possibly arrange the roster of appointments—not just for today, but for every day for the next several weeks—in a way that allows the cancer program to keep up with increasing patient volumes, prevent excessive wait times, and keep operational costs down?

The schedule must also deal with multiple operational constraints, including the number of nurses, the number of chairs, the hours of operation, and constraints



imposed by related services, such as the lab or the pharmacy—the list goes on.

As if that scenario isn't sufficiently challenging, infusion centers have to deal with the consequences of expected and unexpected variability—very few appointments in an infusion center will start and end exactly at the planned time. Therefore, any schedule has to be resilient to the inevitable shocks that will occur.

Making the Numbers Work for You

To end up with an answer that works efficiently across multiple constrained resources, you need to start with a sophisticated prediction model to accurately estimate the total number of patients for each day of the week and to have a realistic assessment of the mix of treatment durations (i.e., how many 1-hour, 2-hour, 3-hour appointments are likely on a Monday or a Tuesday).

Armed with an accurate prediction, the next step is to optimize the scheduling template based on the multiple operational constraints that are relevant for the specific center. Unfortunately, in a problem with multiple resource constraints, most solutions are suboptimal and are likely to introduce major bottlenecks at different times of the day. Building a schedule that balances the workload (acuity, number of patients supported, etc.) across nurses may work well for the nurses but may create situations where the center runs out of chairs in which to seat patients. Similarly, attempting to schedule to available chairs makes it likely that the bottleneck will be created as a consequence of not having enough nurses to treat patients at certain times of the day.

And what about pods? Splitting the problem into pods makes it easier to conceptualize the demand on multiple resources, but creating smaller groupings of nurse and chair resources limits the overall efficiency, and locks you into patterns that may not work once the variability of the day hits—with some patients arriving late, others who have a bad reaction to a drug and need to stay in a chair longer than planned, and still others who need to be urgently added to the schedule.



The key ingredient, of course, is data, more specifically EHR data. Inspired by the likes of Toyota and just-in-time Lean manufacturing practices, data science and mathematics are changing the face of healthcare scheduling, making it possible to optimize healthcare operations in ways that have not been done before. For example, LeanTaaS data scientists mine scheduling patterns and create optimal templates that are customized to an infusion center and automatically eliminate the mid-day peak by flattening the chair utilization profile throughout the day on every single day. These templates then incorporate machine learning algorithms to continuously improve thereby adapting to the changing volumes, mix and provider patterns.

This mathematical approach to infusion center scheduling is already delivering impressive results. Providers like Stanford Health Care, UCHealth, NewYork-Presbyterian, the UCSF Helen Diller Family Comprehensive Cancer Center, the Huntsman Cancer Institute, Memorial Sloan Kettering, and many others are accommodating a 15 percent average increase in volume, seeing wait times decreased by as much as 55 percent during peak hours, and reducing overtime hours by as much as 74 percent.

Put that in real-world terms: A one-hour wait becomes 27 minutes. Who wouldn't want a half-hour of waiting room time back? Time enough to even squeeze in one more game of Tetris. 

Mohan Giridharadas is the founder and CEO of LeanTaaS, a Lean and predictive analytics company, Santa Clara, Calif.

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