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ONCOLOGY ISSUES

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

July | August 2015

The Cancer Program Administrator of the Future

ACCC
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GRANIX®
(TBO-FILGRASTIM)
Injection

Take a bite out of G-CSF acquisition costs

Based on wholesale acquisition cost (WAC) of all short-acting G-CSF products as of November 11, 2013. WAC represents published catalogue or list prices and may not represent actual transactional prices. Please contact your supplier for actual prices.

GRANIX® is an option in short-acting G-CSF therapy

- A 71% reduction in duration of severe neutropenia vs placebo (1.1 days vs 3.8 days, $p<0.0001$)[1]
  - Efficacy was evaluated in a multinational, multicenter, randomized, controlled, Phase III study of chemotherapy-naïve patients with high-risk breast cancer receiving doxorubicin (60 mg/m^2 IV bolus)/docetaxel (75 mg/m^2)[1]
- The safety of GRANIX was established in 3 Phase III trials, with 680 patients receiving chemotherapy for either breast cancer, lung cancer, or non-Hodgkin lymphoma (NHL)[1]
- Now offering a new presentation for self-administration

Indication

- GRANIX is a leukocyte growth factor indicated for reduction in the duration of severe neutropenia in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

Important Safety Information

- **Splenic rupture:** Splenic rupture, including fatal cases, can occur following the administration of human granulocyte colony-stimulating factors (hG-CSFs). Discontinue GRANIX and evaluate for an enlarged spleen or splenic rupture in patients who report upper abdominal or shoulder pain after receiving GRANIX.
- **Acute respiratory distress syndrome (ARDS):** ARDS can occur in patients receiving hG-CSFs. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving GRANIX, for ARDS. Discontinue GRANIX in patients with ARDS.
- **Allergic reactions:** Serious allergic reactions, including anaphylaxis, can occur in patients receiving hG-CSFs. Reactions can occur on initial exposure. Permanently discontinue GRANIX in patients with serious allergic reactions. Do not administer GRANIX to patients with a history of serious allergic reactions to filgrastim or pegfilgrastim.
- **Use in patients with sickle cell disease:** Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disease receiving hG-CSFs. Consider the potential risks and benefits prior to the administration of GRANIX in patients with sickle cell disease. Discontinue GRANIX in patients undergoing a sickle cell crisis.
- **Capillary leak syndrome (CLS):** CLS can occur in patients receiving hG-CSFs and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration. Episodes vary in frequency, severity and may be life-threatening if treatment is delayed. Patients who develop symptoms of CLS should be closely monitored and receive standard symptomatic treatment, which may include a need for intensive care.
- **Potential for tumor growth stimulatory effects on malignant cells:** The granulocyte colony-stimulating factor (G-CSF) receptor, through which GRANIX acts, has been found on tumor cell lines. The possibility that GRANIX acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which GRANIX is not approved, cannot be excluded.
- **Most common treatment-emergent adverse reaction:** The most common treatment-emergent adverse reaction that occurred in patients treated with GRANIX at the recommended dose with an incidence of at least 1% or greater and two times more frequent than in the placebo group was bone pain.

Please see brief summary of Full Prescribing Information on adjacent page.

For more information, visit GRANIXhcp.com.

Reference: 1. GRANIX® (tbo-filgrastim) Injection Prescribing Information. North Wales, PA: Teva Pharmaceuticals; 2014.

TEVA Oncology

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GRANIX®
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BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR
GRANIX® (tbo-filgrastim) injection, for subcutaneous use
SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

GRANIX is indicated to reduce the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Splenic Rupture

Splenic rupture, including fatal cases, can occur following administration of human granulocyte colony-stimulating factors. In patients who report upper abdominal or shoulder pain after receiving GRANIX, discontinue GRANIX and evaluate for an enlarged spleen or splenic rupture.

5.2 Acute Respiratory Distress Syndrome (ARDS)

Acute respiratory distress syndrome (ARDS) can occur in patients receiving human granulocyte colony-stimulating factors. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving GRANIX, for ARDS. Discontinue GRANIX in patients with ARDS.

5.3 Allergic Reactions

Serious allergic reactions including anaphylaxis can occur in patients receiving human granulocyte colony-stimulating factors. Reactions can occur on initial exposure. The administration of antihistamines, steroids, bronchodilators, and/or epinephrine may reduce the severity of the reactions. Permanently discontinue GRANIX in patients with serious allergic reactions. Do not administer GRANIX to patients with a history of serious allergic reactions to filgrastim or pegfilgrastim.

5.4 Use in Patients with Sickle Cell Disease

Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disease receiving human granulocyte colony-stimulating factors. Consider the potential risks and benefits prior to the administration of human granulocyte colony-stimulating factors in patients with sickle cell disease. Discontinue GRANIX in patients undergoing a sickle cell crisis.

5.5 Capillary Leak Syndrome

Capillary leak syndrome (CLS) can occur in patients receiving human granulocyte colony-stimulating factors and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration. Episodes vary in frequency, severity and may be life-threatening if treatment is delayed. Patients who develop symptoms of capillary leak syndrome should be closely monitored and receive standard symptomatic treatment, which may include a need for intensive care.

5.6 Potential for Tumor Growth Stimulatory Effects on Malignant Cells

The granulocyte colony-stimulating factor (G-CSF) receptor through which GRANIX acts has been found on tumor cell lines. The possibility that GRANIX acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which GRANIX is not approved, cannot be excluded.

6 ADVERSE REACTIONS

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

- Splenic Rupture [*see Warnings and Precautions (5.1)*]
- Acute Respiratory Distress Syndrome [*see Warnings and Precautions (5.2)*]
- Serious Allergic Reactions [*see Warnings and Precautions (5.3)*]
- Use in Patients with Sickle Cell Disease [*see Warnings and Precautions (5.4)*]
- Capillary Leak Syndrome *[see Warnings and Precautions (5.5)]*
- Potential for Tumor Growth Stimulatory Effects on Malignant Cells [*see Warnings and Precautions (5.6)*]

The most common treatment-emergent adverse reaction that occurred at an incidence of at least 1% or greater in patients treated with GRANIX at the recommended dose and was numerically two times more frequent than in the placebo group was bone pain.

6.1 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 clinical practice.

GRANIX clinical trials safety data are based upon the results of three randomized clinical trials in patients receiving myeloablative chemotherapy for breast cancer (N=348), lung cancer (N=240) and non-Hodgkin's lymphoma (N=92). In the breast cancer study, 99% of patients were female, the median age was 50 years, and 86% of patients were Caucasian. In the lung cancer study, 80% of patients were male, the median age was 58 years, and 95% of patients were Caucasian. In the non-Hodgkin's lymphoma study, 52% of patients were male, the median age was 55 years, and 88% of patients were Caucasian. In all three studies a placebo (Cycle 1 of the breast cancer study only) or a non-US-approved filgrastim product were used as controls. Both GRANIX and the non-US-approved filgrastim product were administered at 5 mcg/kg subcutaneously once daily beginning one day after chemotherapy for at least five days and continued to a maximum of 14 days or until an ANC of ≥10,000 x 10^6/L after nadir was reached.

Bone pain was the most frequent treatment-emergent adverse reaction that occurred in at least 1% or greater in patients treated with GRANIX at the recommended dose and was numerically two times more frequent than in the placebo group. The overall incidence of bone pain in Cycle 1 of treatment was 3.4% (3.4% GRANIX, 1.4% placebo, 7.5% non-US-approved filgrastim product).

Leukocytosis

In clinical studies, leukocytosis (WBC counts > 100,000 x 10^6/L) was observed in less than 1% patients with non-myeloid malignancies receiving GRANIX. No complications attributable to leukocytosis were reported in clinical studies.

Additional Adverse Reactions

Other adverse reactions known to occur following administration of human granulocyte colony-stimulating factors include myalgia, headache, vomiting, Sweet's syndrome (acute febrile neutrophilic dermatosis), cutaneous vasculitis and thrombocytopenia.

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The incidence of antibody development in patients receiving GRANIX has not been adequately determined.

7 DRUG INTERACTIONS

No formal drug interaction studies between GRANIX and other drugs have been performed.

Drugs which may potentiate the release of neutrophils, such as lithium, should be used with caution.

Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting bone-imaging results.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

Risk Summary

There are no adequate and well-controlled studies of GRANIX in pregnant women. In animal reproduction studies, treatment of pregnant rabbits with tbo-filgrastim resulted in increased spontaneous abortion and fetal malformations at systemic exposures substantially higher than the human exposure. GRANIX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Animal Data

In an embryofetal developmental study, pregnant rabbits were administered subcutaneous doses of tbo-filgrastim during the period of organogenesis at 1, 10 and 100 mcg/kg/day. Increased abortions were evident in rabbits treated with tbo-filgrastim at 100 mcg/kg/day. This dose was maternally toxic as demonstrated by reduced body weight. Other embryofetal findings at this dose level consisted of post-implantation loss, decrease in mean live litter size and fetal weight, and fetal malformations such as malformed hindlimbs and cleft palate. The dose of 100 mcg/kg/day corresponds to a systemic exposure (AUC) of approximately 50-90 times the exposures observed in patients treated with the clinical tbo-filgrastim dose of 5 mcg/kg/day.

8.3 Nursing Mothers

It is not known whether tbo-filgrastim is secreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when GRANIX is administered to a nursing woman. Other recombinant G-CSF products are poorly secreted in breast milk and G-CSF is not orally absorbed by neonates.

8.4 Pediatric Use

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

8.5 Geriatric Use

Among 677 cancer patients enrolled in clinical trials of GRANIX, a total of 111 patients were 65 years of age and older. No overall differences in safety or effectiveness were observed between patients age 65 and older and younger patients.

8.6 Renal Impairment

The safety and efficacy of GRANIX have not been studied in patients with moderate or severe renal impairment. No dose adjustment is recommended for patients with mild renal impairment.

8.7 Hepatic Impairment

The safety and efficacy of GRANIX have not been studied in patients with hepatic impairment.

10 OVERDOSAGE

No case of overdose has been reported.

TEVA Oncology

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GRX-40581 January 2015

This brief summary is based on TBO-004 GRANIX full Prescribing Information.

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FROM THE EDITOR

Back to the Future

BY CHRISTIAN G. DOWNS, JD, MHA

Back in 1962 the television cartoon "The Jetsons" premiered, offering viewers a glimpse of what the future might look like. (I know at least some of you will remember the cartoon's catchy theme song.) More than 50 years later, it's fun to look back and see what the show's creators actually got right! For example, the cartoon—set in the year 2062—frequently featured George video-chatting with his grumpy boss, Cosmo Spacely. Today that technology is readily available and used by millions. Astronauts even Skype from the International Space Station! The more interesting question remains: now that we have this technology, when and how do we want to use it? Does anyone really want to see my mug filling up their Galaxy Tab screen? Give me a party line and a rotary dial phone any day.

As you read this edition of *Oncology Issues*, I want you to think about the cancer program of the future. "The Jetsons" also featured pills with tiny cameras to see the insides of a person; we have that technology now too. As you envision what the cancer program of the future might look like, try and imagine what the next Skype technology or the next endoscope capsule might be.

A great place to help you get started is Brendan Fitzpatrick and Chad Schaeffer's cover article, "The Cancer Program Administrator of the Future." As cancer care and cancer treatment have become increasingly more complex, so too has the role of these leaders. The authors note that visionary administrators must be leaders with a broad and deep knowledge of the oncology service line and industry, capable of functioning seamlessly in a matrixed environment and communicating effectively with multiple stakeholders—staff, clinicians, members of the C-Suite, patients, and payers, just to name a few.

Next, check out Ryan Langdale's "Strategic Planning for the Oncology Service Line." Strategic planning is a tool we all use to plan where we want our program to be—in the short- and long-term future. This article offers tips for crafting an action-oriented strategic plan that is specific to the unique nature of cancer care, including a roadmap to get you started (or continue) on your journey.

In the "Center of It All," Amber Gregg and Karen Schmidt focus on community needs assessments. These tools not only help cancer programs identify future needs, they help them develop and implement outreach strategies and programs to meet these community needs.

Of course any look into the future should include the ACCC 32nd National Oncology Conference, October 21-23, in Portland, Oregon. I urge you not to miss the chance to hear what your peers across the country are doing *today* to prepare for the future in areas such as cancer prehabilitation, cancer survivorship, and cancer research. At this meeting, ACCC will also release a white paper from its 2015 Institute for the Future of Oncology on integrated delivery networks in cancer. There is even a 2015 ACCC Innovator Award Winner presenting on implementation of real-time location systems—a technology that sounds straight out of "The Jetsons." So remember, when you're looking with an eye to the future—whether it's as macro as new cancer delivery models or as micro as succession planning for your cancer program—ACCC has the resources and tools you need. OI

The OCM—To Participate or Not?

BY STEVEN L. D'AMATO, BSPharm, BCOP

The Oncology Care Model (OCM)—the first specialty care model implemented by the Center for Medicare & Medicaid Innovation (CMMI)—looks to transform the future of oncology care around quality and value. Starting in 2016 the OCM will seek to improve care coordination, appropriateness of care, and access to care for beneficiaries undergoing chemotherapy using a model that incorporates a care coordination fee and episode-based payments. Participating practices must meet certain requirements to both participate in the OCM and to continue to receive enhanced payments. Further, practices had to demonstrate their intent to meet the EHR standards *prior to* participation; all other requirements must be met by the end of the first quarter of the performance period to maintain eligibility to participate in the OCM. Requirements include:

- Provide and attest to 24-hour-a-day, 7-day-a-week patient access to an appropriate clinician who has real-time access to the patient record. Clinicians may be RNs, NPPs, or physicians who can access the patient record through the EHR. The goal: to potentially reduce utilization of the emergency department. Practices must attest to providing this 24-hour clinical support during the performance period.
- Attestation and use of ONC-certified EHRs. By the end of the first performance year, eligible professionals in the practice must attest to Stage 1 of Meaningful Use, with the intention of attesting to Stage 2 of Meaningful Use by the end of the third performance year.
- Utilize data for continuous quality improvement. Practices are required to collect and report data on several metrics. CMMI will leverage both claims data and data reported by the practice to provide actionable feedback in the form of regular monitoring reports. Practices are also expected to use their own data—along with the monitoring reports—to improve their performance and achieve the goals of the OCM.
- Provide core functions of patient navigation. (Practices had to provide a written description in their application for how they will meet these requirements.)
- Document a care plan that contains the 13 components in the Institute of Medicine Care Management Plan.
- Treat patients with therapies consistent with nationally-recognized clinical guidelines. Practices will report when care is either consistent with ASCO and/or NCCN clinical guidelines. When care is not in accordance with established guidelines, practices must provide explanations for their treatment decisions.

Sounds like a tremendous amount of work, right? So why participate in the OCM? Well, here's why our practice, New England Cancer Specialists, Scarborough, Maine, submitted an OCM application. From a programmatic perspective, our practice has already built the infrastructure needed to fulfill most of the OCM requirements through participation in a CMMI grant entitled COME HOME (the Community Oncology Medical Home). That said, our practice will face challenges and unknowns. What kind of reporting data will we receive back from CMMI, and how will we align it with our own data to improve processes? How will the OCM affect our payer relationships? How will benchmarking and risk adjustments be made, as we are the only private practice in our region?

In the end, maybe it all comes down to hope. Our hope that by participating in this payment reform initiative our practice will be able to affect positive change and help shape the way oncology care is reimbursed. Our hope that our patients will continue to see the benefits of improvements we have made to date, including our triage system, urgent care, and extended practice hours. Our hope that the OCM will help the entire oncology community improve upon what it does already, culminating in a sustainable payment model to take us boldly into the future. OI

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- Building Bridges, Breaking-down Barriers: One Psycho-Oncology Program's Approach to Quality Patient Centered Psychosocial Care
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INFO

ICLIO e-Newsletter

The first e-newsletter from the ACCC Institute of Clinical Immuno-Oncology offers articles such as "Assessing Immunotherapy Response—Why irRC Matters" and "Helping Your Patient Understand Immuno-Oncology." Read more at accc-ICLIO.org.

TOOL

New! Lung Screening Program Resources

Visit the just-launched ACCC website section on lung cancer focused on resources for establishing and growing a lung screening program. ACCC has partnered with the Lung Cancer Alliance (LCA) to create this information hub with sample forms, letters, useful links, and more at www.accc-cancer.org/lung.

AWARD

2015 ACCC Innovator Award Winners Announced

Six member programs will receive this award at the ACCC National Oncology Conference, Oct. 21-23, 2015, Portland, Ore. Winning programs include an oncology prehabilitation program and a family program for parents with cancer and their children. Learn more at: www.accc-cancer.org/Innovator.

TOOL

Oncology Care Model Resource Center

Want to keep current with this voluntary program? Go to www.accc-cancer.org/OCM where you will find the most recent updates from CMS, an OCM timeline, and more.

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fast

Survey Finds that Sperm Banking Increases with Counseling for Cancer Patients

- About one-quarter (**23.4%**) of the men surveyed received fertility counseling; of those, **16.7%** underwent sperm banking—compared to **6.2%** of men who did not receive counseling.
- Of those who did not receive counseling, approximately **6%** preserved their sperm before and after initiation of a nursing education program.
- After the nursing education program was implemented, **17%** of men who received counseling preserved their sperm.

Source. Survey presented at the 110th Annual Scientific Meeting of the American Urological Association (AUA). Publication Number: PD52-11. www.AUAnet.org.

Emergency room use rising—despite ACA coverage expansion.

Source. American College of Emergency Physicians. http://newsroom.acep.org/2015-05-04-ER-Visits-Continue-to-Rise-Since-Implementation-of-Affordable-Care-Act.

facts

Payer Negotiation Tips for Oncology Practices!

- Monitor and manage your payer contracts just like you would your investments.
- Involve your whole staff in preparing for contract negotiations; look at insurers who reimburse the least and start with them.
- Build relationships with your payers by asking about their concerns and partnering on programs that improve the quality of care.
- Differentiate your practice by offering patient navigation, survivorship, and other patient-centered services.
- Know if your contract has an annual renewal option with a negotiation window; if you miss that deadline, the contract is renewed automatically.
- Beware of "silent PPOs" as they can access discounted rates for services without your authorization, preventing you from billing patients for amounts above the contracted fee.

Source. Colwell J. Payer Negotiation: A Little Preparation Goes a Long Way. Physicians Practice. www.physicianspractice.com/revenue-cycle-management/payer-negotiation-little-preparation-goes-long-way.

The Power of "Clowning Around"

New study highlights role medical clowns play in reducing anxiety, pain, and medical costs of children undergoing surgery.

Source. Study presented at the 110th Annual Scientific Meeting of the American Urological Association (AUA). www.AUAnet.org

Will Patients Pay Out-of-Pocket for Genetic Tests?

A recent survey on comprehensive tumor genetic profiling (CGP) found:

- **61%** of patients were aware of CGP
- **67%** indicated they believed CGP could improve their treatment
- **79%** were interested in CGP; younger respondents and those with private health insurance showed more interest
- Patients with less than a high school education were not as likely to pay out-of-pocket for any costs beyond those covered by insurance
- Individuals with an income of more than **$50,000** AND private insurance were more likely to pay out of pocket.

Source. Fox Chase Cancer Center. ASCO 2015 Annual Meeting Abstract #1545.

Alternative Payment Models: Here to Stay?

BY LEAH RALPH

The February decision by the Center for Medicare and Medicaid Innovation (CMMI) to build its first specialty care model around oncology is an important indication of the agency's focus on how to contain costs in cancer care. The Oncology Care Model (OCM) has been a focal point for many months, as practices consider whether or not to participate and the Centers for Medicare & Medicaid Services (CMS) works to provide continuous updates and assistance as practices make their way through the application process. The OCM will provide a monthly, per-beneficiary care coordination fee to administer chemotherapy, while requiring practices to meet certain infrastructure and quality requirements. In addition, and perhaps most attractive, it allows practices the opportunity to share in any savings that materialize based on a historical spending benchmark.

Of the 443 practices who completed the first step toward OCM participation (submitting a letter of intent in early May), 106—nearly one-quarter—are ACCC members. To help our members navigate this process, ACCC launched its OCM Resource Center: a one-stop-shop for tips, tools, and real-time information from CMS. We've held webinars, gathered testimonials, and created an OCM hotline to answer your questions.

How this model plays out over the next five years and beyond will have real implications for the future of oncology payment reform. It's likely the OCM will be an iterative process. As selected practices get started in the spring of 2016, we'll see CMS make adjustments—albeit small adjustments—and work with practices to implement their programs, as we have seen with other CMMI models.

CMMI's work is part of a broader effort by the Department of Health and Human Services (HHS) to move Medicare payments away from fee-for-service towards reimbursement for quality and value. In January, HHS announced explicit goals to tie 85 percent of Medicare payments to quality programs like CMS' PQRS (Physician Quality Reporting System) or EHR Meaningful Use requirements by 2016, and 90 percent of payments by 2018. Taking it one step further, HHS also announced a goal of tying 30 percent of Medicare payments to alternative payment models (APMs), like the OCM, by 2016 and 50 percent by 2018. For context, in 2011, Medicare made almost no payments to providers through APMs, but today those payments represent approximately 20 percent.

In many ways, the long-awaited passage of a permanent fix to the sustainable growth rate (SGR) formula solidifies the future of APMs in the Medicare program and likely across the healthcare system. In April, Congress finally repealed and replaced the flawed SGR—a huge win for ACCC members after 80 plus meetings on Capitol Hill and hundreds of letters sent to legislators just as Congress was negotiating the bill. The Medicare Access and CHIP Reauthorization Act (MACRA)—the legislation that repealed the SGR—creates important relief for providers by establishing much needed predictability in payment rates. Ultimately, however, MACRA will require a shift in the way physicians are paid in Medicare. Starting in 2020, the law creates a new dual-track reimbursement system, in which future payments will be contingent on participating either in a new quality program under fee-for-service, called the Merit-Based Incentive Program (MIPS), or opting to receive a certain percentage of Medicare payments through an APM, like the OCM. While physicians may choose either track, and will be familiar with the quality requirements under MIPS, the law calls for higher updates in the APM track, creating a stronger incentive to participate in an alternative payment model.

CMS recently reinforced its commitment to developing APMs with an announcement that the agency is expanding the Pioneer Accountable Care Model (ACO) program. The agency was able to demonstrate that this early ACO program produced cost savings (more than $384 million in its first two years) without decreasing quality of care. This move is notable because it is the first time CMS has used its authority to allow CMMI to expand a demonstration project. How CMMI does this will be watched carefully, as it will set precedent for future expansions and provide insight into their approach.

While we have a way to go in the development and evaluation of appropriate, successful APMs—and even longer before providers are required to participate—these models appear to be here to stay. We encourage our members to become familiar with what it might take for your program to engage in payment reform initiatives and look to ACCC as a resource in the coming months on the OCM and other models. OI

Leah Ralph is ACCC manager of provider economics & public policy.

tools

Approved Drugs

• The U.S. Food and Drug Administration (FDA) has approved Eli Lilly and Company's (www.lilly.com) **Cyramza® (ramucirumab)** for use in combination with FOLFIRI for the treatment of patients with metastatic colorectal cancer (mCRC) whose disease has progressed on a first line bevacizumab-, oxaliplatin-, and fluoropyrimidine-containing regimen.

• Amgen (www.amgen.com) announced that the FDA has approved use of **Neupogen® (filgrastim)** to treat adult and pediatric patients acutely exposed to myelo-suppressive doses of radiation (Hemato-poietic Syndrome of Acute Radiation Syndrome, or H-ARS).

Drugs in the News

• Aptose Biosciences Inc. (www.aptose.com) announced that the FDA has granted the company orphan drug designation for **APTO-253** for the treatment of acute myeloid leukemia (AML). APTO-253, a first-in-class inducer of the KLF4 gene, is the company's lead product candidate in a Phase Ib clinical trial in patients with AML, high-risk myelodysplastic syndrome (MDS), and other hematologic malignancies in which KLF4 silencing is reported as operative.

• Novogen (www.novogen.com) announced that its subsidiary joint venture company with Yale University, CanTx, Inc., has received notification from the FDA that its chemotherapy candidate drug, **Cantrixil**, has been granted orphan drug designation for ovarian cancer.

Cantrixil is a cyclodextrin envelope containing the active ingredient, TRXE-002. It is designed as an intra-cavity chemother-apy to be injected directly into the peritoneal and pleural cavities without causing local irritation or toxicity. Its purpose is to achieve high drug levels in the environment in which the cancer is spreading through the migration of the cancer stem cell.

• Janssen Research & Development, LLC (www.janssenrnd.com) has initiated the rolling submission of its biologic license application (BLA) for **daratumumab** to the FDA for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immuno-modulatory agent (IMiD), or who are double refractory to a PI and an IMiD. Daratumumab —an investigational human anti-CD38 monoclonal antibody—received FDA breakthrough therapy designation for this set of patients in May 2013.

• The FDA has granted fast track designation for the development of Merck's (www.merck.com) **evofosfamide (previously known as TH-302)** administered in combination with gemcitabine, for the treatment of previously untreated patients with metastatic or locally advanced unresectable pancreatic cancer.

Evofosfamide is an investigational hypoxia-activated pro-drug thought to be activated under severe tumor hypoxic conditions, a feature of many solid tumors. The compound, currently in Phase III trials, is being developed in collaboration with Threshold Pharmaceuticals, Inc.

• The FDA has granted orphan drug designation to **GMI-1271** (GlycoMimetics, Inc., www.glycomimetics.com) for the treatment of patients with acute myeloid leukemia (AML). GMI-1271 is a novel and proprietary E-selectin antagonist. GlycoMi-metics is currently recruiting patients in a Phase I/II, open-label multicenter study designed to evaluate the safety, pharmaco-kinetics, and efficacy of GMI-1271 in combination with chemotherapy in adult patients with AML.

• Bristol-Myers Squibb Company (www.bms.com) announced that the FDA has accepted for filing and review the supplemental biologics license application (sBLA) for **Opdivo® (nivolumab)** for the treatment of previously untreated patients with unresectable or metastatic melanoma. The FDA also granted priority review for this application.

• The FDA has accepted Aspyrian Thera-peutics' (www.aspyriantherapeutics.com) investigational new drug (IND) application to begin clinical studies of **RM-1929** for the treatment of patients with recurrent head and neck cancer. This therapy uses an antibody conjugate to precisely target cancer cells after which it is locally activated to elicit rapid anticancer responses.

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• AbbVie (oncology.abbvie.com) announced its investigational medicine **venetoclax**, an inhibitor of the B-cell lymphoma-2 (BCL-2) protein, which is being developed in partnership with Genentech and Roche, has been granted breakthrough therapy designation by the FDA for the treatment of chronic lymphocytic leukemia (CLL) in previously treated (relapsed/refractory) patients with the 17p deletion genetic mutation.

Devices in the News

• SurgiQuest, Inc. (www.surgiquest.com) announced that its **AirSeal® System** recently received 510(k) clearance from the FDA for transanal endoscopic surgery (TES). The category of transanal endoscopic surgery includes both transanal minimally invasive surgery and transanal total mesorectal excision, a surgical technique that has been shown to significantly improve patient outcomes in colorectal cancer procedures.

Genetic Tests and Assays in the News

• Roche (www.roche.com) announced that the FDA has approved the **Cobas® KRAS Mutation Test** for diagnostic use. The real-time PCR (polymerase chain reaction) test is designed to identify KRAS mutations in tumor samples from mCRC patients and aid clinicians in determining a therapeutic path for them.

• Biodesix, Inc. (www.biodesix.com) announced that its **VeriStrat® test** received a positive coverage decision from United Healthcare. VeriStrat, included in the standard of care guidelines, is a blood-based proteomic test that provides physicians with prognostic and predictive information that helps guide treatment of advanced NSCLC.

• Personal Genome Diagnostics, Inc. (www.personalgenome.com) announced the launch of its **LungSelect™** product that identifies the most common, clinically actionable genetic alterations in the plasma of non-small cell lung cancer (NSCLC) patients. The plasma-based LungSelect test enables testing of all NSCLC patients for relevant sequence mutations, insertions and deletions, and genomic rearrangements, including those patients who may have acquired new mutations post-treatment and those with multiple tumor sites. LungSelect simultaneously identifies somatic sequence mutations and translocations that can be treated with agents already approved by the FDA or that are in clinical trials, including most defined in the NCCN Guidelines.

• NeoGenomics, Inc. (www.neogenomics.org) announced the launch of its **NeoLAB™** assays, which use next generation sequencing and other advanced molecular technologies. These 12 tests use cell-free circulating DNA and RNA found in blood plasma to identify molecular abnormalities in the bone marrow without the need for a bone marrow biopsy. Physicians can use the new liquid biopsy tests to: 1) screen patients to determine if a bone marrow biopsy is necessary, especially when myelodysplastic syndrome or acute leukemia is suspected; 2) monitor disease status, response to therapy and predict early relapse; and 3) complete testing when a bone marrow sample is inadequate or is technically difficult to obtain.

Anticoagulant Management

BY CINDY PARMAN, CPC, CPC-H, RCC

Anticoagulation therapy is widely used to prevent and treat thromboembolic disorders, and is most commonly associated with mechanical valve management, atrial fibrillation, post-cerebrovascular accident, acute myocardial infarction, pulmonary embolism, and other valvular heart diseases. Failure to receive anticoagulant drugs, when indicated, can increase a patient's risk of thrombosis and embolism. Insufficient or excessive levels of a blood thinner can increase a patient's risk of bleeding.

The goal of oral anticoagulation is to maintain levels of anticoagulation capable of preventing thromboembolic events without increasing the risk of hemorrhagic complications. The duration of anticoagulation therapy varies with the underlying indication and with the patient's response to therapy. Some conditions require anticoagulation therapy for only a few months, while other conditions require long-term and possibly life-long anticoagulation treatment.

According to the Centers for Medicare & Medicaid Services (CMS), there are at least three strategies for managing anticoagulation:

1. Physician office-based testing and management (that treat approximately 75 percent of patients)
2. Anticoagulation clinics (that treat approximately 20 percent of patients)
3. Home PT/INR (prothrombin time/international normalized ratio) monitoring with patient reporting or physician-directed self-management (less than 5 percent of patients are anticoagulated this way).

Medicare provides coverage for home PT/INR monitoring for beneficiaries who:[1]

- Require chronic oral anticoagulation with warfarin for a mechanical heart valve, chronic atrial fibrillation, or venous thromboembolism; and
- Have been anticoagulated for at least three months prior to the use of the home INR device; and
- Have undergone a face-to-face educational program on anticoagulation management and demonstrated the correct use of the device prior to its use in the home; and
- Continue to correctly use the device in the context of the management of the anticoagulation therapy following initiation of home monitoring; and
- Home-testing with the device occurs no more frequently than once a week.

Home management is typically focused on patients who require long-term or life-long anticoagulation therapy.

Management Codes

The procedure codes for anticoagulant services are intended to describe the outpatient management of warfarin therapy, including ordering, review and interpretation of INR testing, communication with patient, and dosage adjustments as appropriate.[2] It is important to note that these procedures can only be billed by the treating physician on an office or outpatient basis, including domiciliary, rest homes, or home settings. These codes would not be reported for patient care initiated or continued during patient admission to a hospital or observation unit. When this situation occurs, any anticoagulant management services provided after discharge should be reported with the subsequent outpatient management code (**99364**) and not with the initial therapy code because the initial course of therapy has already been captured as part of the inpatient services.

Last, the procedure codes listed below for anticoagulation management are not reported in connection with home INR testing for a patient with a mechanical heart valve (refer to HCPCS codes **G0248** to **G0250**) or when the services are being managed by another source (e.g., outpatient pharmacist/nurse anticoagulation clinic).

These codes were effective Jan. 1, 2007, and were created to report physician management of patients receiving long-term anticoagulant therapy:

- **99363.** Anticoagulant management for an outpatient taking warfarin, physician review and interpretation of INR testing, patient instructions, dosage adjustment (as needed), and ordering of additional tests; initial 90 days of therapy (must include a minimum of 8 INR measurements).

Management is typically significantly more intensive during the initial 90 days of service. For each prothrombin time test, a physician (and/or his or her staff) must access the patient's medical record, review the results, and determine whether any dosage adjustment and/or change in care plan is necessary. The physician may make dosage adjustments and/or care plan changes to account for acute illness and/or

possible drug interactions; diet changes affecting vitamin K intake; and/or changes to procedures that require withholding or alternative anticoagulation. The physician then must make a notation in the medical record, contact the patient to convey the results/instructions, and arrange repeat testing at the appropriate interval.

- **99364.** Each subsequent 90 days of therapy (must include a minimum of 3 INR measurements).

When the physician reports a charge for anticoagulant management, this same work cannot also be used to support a patient visit code during the same reporting period. In addition, short-term anticoagulant management of less than 60 continuous outpatient days is not reported and the codes cannot be billed if the specified number of services per reporting period is not performed. Physician-patient encounters—both non-face-to-face (e.g., telephone calls and electronic communications) and face-to-face—are captured in these codes. This means that the procedure codes for telephone management and online medical management related to anticoagulant management are not billed in addition to codes **99363** and **99364**.

Typical physician services during the patient's course of therapy include reviewing, interpreting, and ordering initial and repeat prothrombin time tests; making dosage adjustments and/or care plan changes as needed; and communicating to the patient to convey results and provide instructions. The blood draw and the prothrombin time test can be reported separately by the provider that furnishes the respective service.[3]

Medicare does not pay codes **99363** or **99364** to the hospital. The 2015 Outpatient Prospective Payment System (OPPS) payment list indicates that both of these codes are status "B," which means that neither of these codes is recognized under the OPPS for separate reimbursement. In addition, while both codes include relative value units (RVUs) on the Medicare Physician Fee, that payment under the Physician Fee schedule is bundled into the reimbursement for other services provided to the patient.

Hospital Anticoagulation Clinic

Pharmacists perform medication therapy management services (MTMS, procedure codes **99605**, **99606**, and **99607**) for patients that require multiple medications. These MTMS should not be confused with pharmacist-managed anticoagulation clinics. (For a refresher on coding for pharmacy services, see my "Compliance" column in the May-June 2012 *Oncology Issues*. It is available to ACCC members at mynetwork.accc-cancer.org.)

Prior to Jan. 1, 2014, hospitals generally reported anticoagulation clinic services performed by a pharmacist or hospital nurse with procedure code **99211**, the lowest level established patient visit code. However, effective Jan. 1, 2014, Medicare replaced all the patient visit procedure codes with one HCPCS Level II code:

- **G0463.** Hospital outpatient clinic visit for assessment and management of a patient.

In addition, CMS defined an outpatient encounter to include direct personal contact in the hospital between a patient and a physician, or other person who is authorized by state law and, if applicable, by hospital staff bylaws to order or furnish services for diagnosis or treatment of the patient. While CMS previously included Questions & Answers (Q&As) on its website relating to anticoagulation clinics, incident-to and hospital charges, these Q&As have been deleted and were not replaced with updated information at the time this article was published.

Office or Freestanding Anticoagulation Clinic

While the standard E/M codes are no longer available in the hospital outpatient department, these codes continue to be reported for office-based services. WPS Medicare provides specific information on its website regarding billing **99211** for anticoagulation management. (Remember: this guidance may not apply to any other Medicare contractor):[4]

Services billed to Medicare under CPT code **99211** must be reasonable and necessary for the diagnosis and treatment of an illness or injury. This would include appropriately performed and documented anticoagulation management.

99211 for Anticoagulation Management "Do's"

- Document the patient's indication for anticoagulant therapy, current dose, and prothrombin time and INR results

- Assess the patient in person for signs and symptoms of bleeding and/or adverse effects to anticoagulant therapy
- Assess the patient for changes in health status that may impact or account for fluctuations in lab results (for example, new or changed medications that may cause a drug interaction with the anticoagulant therapy)
- Provide medically necessary education as needed based on the patient's individual circumstances
- Document the identity of the ancillary staff performing the service "incident to" the supervising physician
- Document the identity of the billing physician who was notified of the results, gave orders, and provided direct supervision.

99211 for Anticoagulation Management "Don'ts"

Procedure code **99211** should not be billed in these circumstances:

- When the in-person encounter with the patient was only for the diagnostic test
- For telephone care, i.e., instructions on changing doses, assessment, and/or education
- When the only documentation would be vital signs, the patient's current and future dose of anticoagulant, and when the lab work is to be repeated
- When direct physician supervision is not met or is not performed by the physician treating the patient's medical problem requiring anticoagulant therapy (i.e., as seen in some Coumadin® clinics)
- Based on the delivery of repetitive education that does not serve the medical needs of the individual patient.

Additionally (not just limited to anticoagulation management), code **99211** should not be used for:

- Routine, in-person prescription renewals unless the patient's condition requires re-evaluation prior to the renewal determination
- Routine blood pressure checks that have no impact on the patient's care
- Performing diagnostic or therapeutic procedures.

WPS Medicare has also published information regarding Comprehensive Error Rate Testing (CERT) errors related to the reporting of procedure code **99211** (Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified healthcare professional. Usually the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.). The following are examples of documentation that did not meet the requirements for payment of procedure code **99211**:[5]

- Provider billed CPT **99211(25)**, established patient office visit which does not require the presence of a physician. The documentation received included the PT/INR result, result of C-Difficile Toxin. No documentation to support the service billed.
- Submitted documentation includes progress note from previous week and lab results. No medical documentation submitted to support the evaluation and management code billed.
- Missing documentation to support any evaluation and management services provided. Only documented service is a PT/INR sheet with typed vital signs, dosage and typed initials, and PT/INR results.

When procedure code **99211** is billed, medical record documentation must support a medically necessary face-to-face patient encounter that includes both evaluation and management. The evaluation portion of the encounter is supported when the individual patient medical record includes documentation of a clinically relevant and necessary exchange of information between the provider and the patient. The management portion of the visit then requires documentation of an influence on patient care.

Last, consider this example from the April 2015 issue of *Healthcare Business Monthly* (a publication of the American Academy of Professional Coders):

"A patient presents for a prothrombin time and international normalized ratio (PT/INR). A nurse performs the test, gives the results to the provider, and relays a medication change to the patient. The visit no longer meets incident-to requirements because there was a change in medication. You may not bill 99211; you may bill only the PT/INR. To bill for evaluation and management (E/M), the provider must have seen the patient."

The term "change in medication" may be interpreted differently by different payers. While some insurers may consider a change in dosage of the same medication to be acceptable for incident-to billing, other payers may consider this to be a reason for the physician to see the patient and explain the dose change. It is certain, however, that if the patient will discontinue one medication and begin a different medication for the same diagnosis, the physician must meet with the patient to explain this change in prescription.

Modifier 25

When a significant, separately identifiable patient visit occurs on the same day as another billable service, **modifier 25** can be appended to the patient visit code. The official definition of this modifier includes:

"It may be necessary to indicate that on the day a procedure or service identified by a CPT code was performed, the patient's condition required a significant, separately identifiable E/M service above and beyond the other service provided or beyond the usual pre-operative and post-operative care associated with the procedure that was performed. A significant, separately identifiable E/M service is defined or substantiated by documentation that satisfies the relevant criteria for the respective E/M service to be reported. The E/M service may be prompted by the symptom or condition for which the procedure and/or service was provided."

This means that in order to report a patient encounter, even an encounter at the lowest level of service, there must be documentation that supports patient evaluation and management that is separate from the work required to take vital signs, obtain the specimen, process the laboratory test, and communicate the test results to the patient. For example, Cahaba Medicare provides the following scenarios regarding proper use of code **99211** in the office setting:[6]

- A new anticoagulant patient where education is required regarding dietary modifications, medicine restrictions, bleeding/trauma precautions, etc. This type of education would not be medically necessary at every visit, especially if the patient has been on anticoagulant therapy for an extended time. A periodic educational update (i.e., every three to six months) may be medically necessary, for example, when a patient's therapy target has been difficult to optimize.
- A patient who presents with a history of bleeding or adverse effect from anticoagulant therapy.
- A new caregiver presents with the patient to ensure compliance and needed education as noted above.

Billing Summary

All physicians, freestanding cancer centers, and hospital outpatient departments who perform anticoagulant clinic services should verify coverage and correct code assignment with the individual insurance payer. Services considered for billing include:

1. Venipuncture (code **36415**, collection of venous blood by venipuncture) or finger-stick (code **36416**, collection of capillary blood specimen [e.g., finger, heel, ear stick]). Note: procedure code **36416** does not have a separate Medicare reimbursement; this service is considered to be bundled into laboratory tests or any other services performed on the same service date.
2. Prothrombin time (code **85610**), and append **modifier QW** (CLIA waived test) when appropriate.
3. With the creation of the new Medicare HCPCS Level II code for the hospital clinic visit, there may not be an available visit charge for anticoagulation clinic visits that do not have a physician or qualified non-physician healthcare professional component on the same service date.
4. The freestanding center or physician office may be able to report code **99211** with **modifier 25** when medical record documentation supports a medically necessary, significant, separately identifiable evaluation and management service performed under the direct supervision of a physician or qualified non-physician healthcare practitioner. (If the physician reports a charge for anticoagulant management, this same work cannot also be used to support a patient visit during the same reporting period.)
5. And remember, if the reason for the patient encounter is to monitor the effectiveness of anticoagulation medication, the primary diagnosis code for the service should be **V58.83** (Encounter for therapeutic drug monitoring) in conjunction with code **V58.61** (Long-term [current)]use of anticoagulants). Then report the underlying reason for the anticoagulant therapy as a secondary diagnosis(es).

Above all, the services performed for and billed to the patient should be medically necessary. According to the Connecticut General Assembly, *"...the term 'medical necessity' must refer to what is medically necessary for a particular patient, and hence entails individual assessment rather than a general determination of what works in the ordinary case."*[7] Medical record documentation for all patient services should clearly support the medical necessity and extent of all services performed for each patient under treatment. OI

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spotlight

Charleston Area Medical Center Cancer Center

Charleston, WV

The Charleston Area Medical Center (CAMC) Cancer Center, part of the CAMC Health System, sees more patients than any other cancer center in the state of West Virginia. The Cancer Program at CAMC has been accredited by the American College of Surgeons for more than 60 years, and received commendation in all areas this past year. The cancer center is also the only QOPI-certified center in the state. With more than 20,000 patient visits last year, providing patient-centered care is a top priority.

"The relationships that are established between the patients and the staff turn into life-long friendships. To quote a patient 'when you walk down that hall to see the physician, it's always terrifying...and when you come to chemotherapy, you would think that you would be terrified. But everyone is so welcoming and friendly that you really look forward to seeing these people,'" shared Beverly Farmer, RN, BSN, OCN, NE-BC, clinical practice administrator at CAMC Cancer Center.

A Patient-Centered Approach

This patient-centered focus—coupled with an ever-growing patient population—necessitated the building of a new comprehensive cancer center. The campaign to build the new cancer center was called "The Power of Many." Before the campaign was even launched publicly, cancer center employees and all four hospital divisions raised almost $50,000 towards the effort. Once opened up to the community, the cancer center was able to raise $15 million, with the hospital system covering the rest of the building costs. "The community has played a big role in building our cancer center. We feel like they're really a part of it," said Farmer.

Key stakeholders in the construction of the new cancer center included various staff members, hospital board members, and a patient focus group.

New Center, New Services

Cancer services will relocate from two floors of a medical office building to a three-story free-standing facility. As this article goes to press, the new cancer center will be up and running. Patients and visitors can access the new facility via a drive-up entrance with a covered awning and the option for valet parking.

The lobby area features a new Steinway player piano, which will be playing from an app during the day, but could also be used by patients. One of CAMC's physicians, Dr. Jubelirer, also plays frequently.

Staff worked with an interior designer to showcase the aesthetic theme of "West Virginia" with a palate of fall colors to represent the seasonal changing of the leaves in the state each year.

On entering the center's first floor, to the immediate left is the concierge area where a greeter's desk provides way-finding. This section of the ground floor also houses navigators, social work, psychologist, dietitian services, and pastoral care. A unique supportive care option also found on the lower level is Gigi's Room. Made possible by a donor, Gigi's Room offers psychological services for children whose parents may be diagnosed with cancer or who have passed away from cancer.

The first floor also includes a dedicated oncology retail pharmacy, a cafe, and a boutique that offers prostheses and wigs, manicures, pedicures, and massages for patients. The clinical trials department and outpatient lab round out the first floor services. CAMC's clinical cancer research activities have provided state-of-the-art cancer care opportunities for patients for more than 25 years.

Once patients check in for their appointment, they are handed a pager. This system allows patients the freedom to walk around and explore areas like the healing garden while they wait.

A grand staircase leads up to the second floor. From here, patients have access to an outdoor terrace that overlooks the cancer center's healing garden. Medical oncology offices, as well as infusion services, are located here.

The new cancer center space has allowed the infusion area to go from 23 to 32 chairs and 4 private beds. Chemotherapy suites are in pods of four. Each chair comes with a heat and massage function and also a heat panel overhead so patients can have some control over their environment of care. Within the infusion area, each patient has a television, as well as room for visitors, with an option for a private or open setting. Sliding glass panels give some privacy in addition to the curtains. A chemotherapy education program is available by patient request.

On the third floor of the new building are the Tumor Registry and the Breast Center, which includes the breast surgeons' offices. The Breast Center services include mammography, bone density scans,

ultrasound, and biopsies. Currently, some open space is available on this floor, which may be dedicated to palliative care services in the future.

Radiation oncology services will eventually be offered onsite as well; however, the vaults are still being built. This service line is currently offered via a joint venture between CAMC and Alliance Oncology, a radiation oncology practice. Tumor boards meet every Monday for a multidisciplinary approach to the individual care of the patient.

An Emphasis on Supportive Care

The current staffing of the CAMC Cancer Center includes:

- 8 board-certified oncologists
- 30 nurses
- An oncology-certified pharmacist
- 5 navigators
- A social worker
- A psychologist
- A nutritionist
- Pastoral care
- A quality coordinator.

Navigation services are offered to every cancer patient. Each new patient will see a navigator to undergo distress screening; the CAMC Cancer Center uses the NCCN Distress Scale. If needed, a navigator will follow up with patients after this assessment with a phone call and/or a face-to-face meeting. Since the new building comes with more space, the navigators have their own office for patient visits.

Financial navigation is also available to patients and families. Once the physician has prescribed chemotherapy for a patient, an order is sent to a pre-certification team. The team calculates the patient's financial responsibility, and then a financial navigator gets involved to see if she can be of any assistance. One of the financial navigators is a biller, and the other is currently training to become a social worker.

According to Farmer, one of the biggest barriers to care for CAMC Cancer Center's patient population is transportation. Since the cancer center draws from all over the state of West Virginia, many patients in their service area live in a rural setting. The cancer center partners with the American Cancer Society to help offset this barrier with gas cards, and several local church organizations also assist with transportation. The cancer center operates a satellite clinic in Teays Valley (about 20 miles away) that provides medical oncology and chemotherapy infusion services.

For the survivorship portion of care, a nurse practitioner prepares the care plan. She gives the care plan to the patient, and records a copy electronically. The electronic copy is also sent to the patient's treating primary care physician.

Other supportive care services include psychological services, smoking cessation, nutrition classes, pet therapy, and an exercise program called Healthy Steps.

Select Support Services

- Social Work
- Financial Navigation
- Psychology Services
- Pastoral Care
- Nutrition Services

Number of new analytic cases in 2014: 1,493.

BY ROSEMARIE WEISMAN AND
MEREDITH B. FEINBERG, MBA

Bedside Scheduling Improves Patient Access

Recognizing that there were both issues with and opportunities for improvement of scheduling coordination and patient flow, an integrated team of clinicians, schedulers, and administrators came together in 2012 to conceptualize a patient access initiative called "Bedside Scheduling." Fueled by a desire to provide a higher level of compassionate service to inpatients newly-diagnosed with cancer, the initiative was a significant process and culture change for the hospital and cancer program. Here's our story.

The Players

North Shore-Long Island Jewish Health System is the largest healthcare system in New York State with a service area of 8 million people in the New York metropolitan area. With more than 2,750 employed physicians and 54,000 employees, the Health System is the largest private employer in New York State. The Health System comprises 19 hospitals: 5 tertiary, 9 community, 3 specialty, and 2 affiliate. It is at one of these tertiary hospitals—North Shore University Hospital—that the Bedside Scheduling initiative was rolled out.

Monter Cancer Center, Lake Success, N.Y., is the largest of the cancer center program sites within the North Shore-Long Island Jewish Health System's North Shore-LIJ Cancer Institute. It is an 80,000-square-foot, free-standing outpatient hematology and medical oncology physician practice and ambulatory chemotherapy and transfusion treatment center. The center is staffed by 35 disease-site-specific board-certified medical oncologists and more than 270 staff. With 38 exam rooms and 64 treatment bays, our 2014 annualized volume was projected at approximately 40,000 physician visits and more than 75,000 lab and treatment visits. Our onsite services include social work, nutrition counseling, laboratory, pharmacy, clinical trials, cancer genetics, and a fellowship program with 15 fellows in training.

The inpatient setting is where the Bedside Scheduling story begins. Inpatient services for Monter Cancer Center are provided in two locations: North Shore University Hospital, Manhasset, N.Y., and Long Island Jewish Medical Center, New Hyde Park, N.Y. North Shore University Hospital has a 24-bed dedicated hematologic malignancy specialty unit, a 10-bed FACT-accredited stem cell transplant unit, and a 32-bed dedicated solid tumor oncology unit; Long Island Jewish Medical Center has a 23-bed oncology unit. Both North Shore University Hospital and Long Island Jewish Medical Center offer consult services. There were 23,000 projected annualized inpatient visits for 2014. Every weekday, seven physicians round on all services at both institutions. It is this group of patients that inspired the Bedside Scheduling initiative.

Our "Before" Process

Prior to the Bedside Scheduling initiative, when an inpatient received a new cancer diagnosis, hospital staff would contact medical oncology to consult. A medical oncologist would evaluate the patient and, if the patient required follow-up, the medical oncologist would direct the patient to call and schedule an outpatient appointment with a disease-site-specific physician. Patients were given a Monter Cancer Center business card with instructions

Inpatient consults are a major volume driver for the outpatient cancer program, and our team wanted to maximize referrals from the inpatient to the outpatient setting.

to call the office post-discharge. Since the scheduling process did not start until after discharge, the burden of responsibility for making follow-up appointments was on newly-diagnosed cancer patients. Our team resolved to remove this burden from these patients by improving our scheduling coordination and patient flow.

Drivers Behind the Process Redesign

As we began to look into our scheduling process, staff identified a number of issues. For example, when answering post-discharge

Table 1. Examples of Bedside Email Sent by Fellow to Schedulers

EXAMPLE 1

Patient Name
DOB

44-year-old female with HIV/AIDS, non-adherent with HART. Admitted with UTI, neutropenia (chronic), and iron deficiency anemia. Had bone marrow biopsy done. Inpatient needs to have outpatient follow-up appointment for bone marrow biopsy results in one week. Okay to schedule with [PHYSICIAN NAME] in clinic; follow-up one week.

Name of Inpatient Attending
Name of Fellow

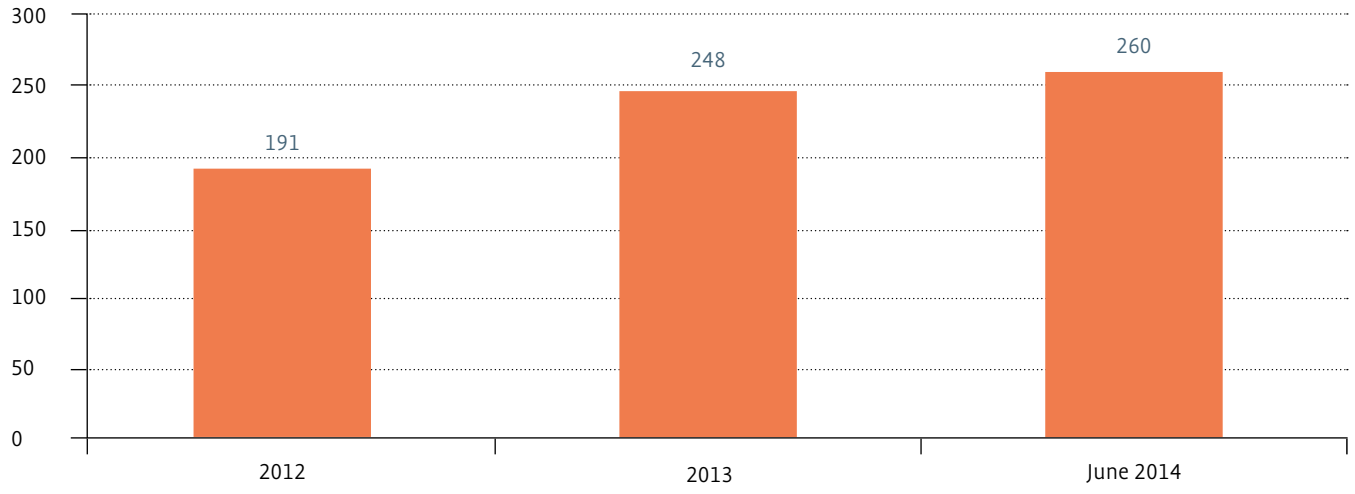
EXAMPLE 2

Patient Name
DOB

51-year-old male with possible diagnosis of multiple myeloma by [PHYSICIAN NAME] last year. Had IgGK ~ 4000 mg/dl, and presented with back pain. MRI with central epidural soft tissue abnormality (questionable etiology). Also mild anemia ~ 10. Getting RT to T7 and L2. Inpatient needs to have a multiple myeloma outpatient consult. Follow-up in one week.

Name of Inpatient Attending
Name of Fellow

Figure 1. Monter Cancer Center New Patient Hospital Consult Referrals, 2012–2014



consult appointment calls, our staff found that many patients were unclear or uncertain about their cancer diagnosis. This finding was a concern not only because our physicians are disease-site-specific, but also because it is important that patients are empowered with information about their diagnosis. These patients often did not know the name of the physician with whom to schedule an appointment, which presented the same challenges in terms of scheduling patients with the appropriate disease-site-specific team.

Often patients were calling at the last minute to schedule their appointments. Delving deeper into this particular issue, our staff found that many patients were interpreting the physician's instructions to "schedule an appointment in two weeks" as "call the office to schedule your appointment in two weeks." The end result was a growing demand to fit these visits into already full physician schedules. On several occasions, patients assumed an appointment had already been made, and just showed up at the physician office in two weeks.

Another staff concern was lack of a way to track and confirm that all patients were, in fact, calling to schedule the recommended—and potentially life-saving—follow-up care. No process was in place to let our staff know when patients were being lost to follow-up.

In addition to the process-flow challenges and clinical drivers addressed above, our staff suspected that improvements to the inpatient scheduling process might have a positive impact on our cancer program's bottom line. Inpatient consults are a major volume driver for the outpatient cancer program, and our team wanted to maximize referrals from the inpatient to the outpatient setting. With the existing process, there was simply no way to reconcile how many patients were scheduling their follow-up outpatient care with our cancer program or seeking care elsewhere.

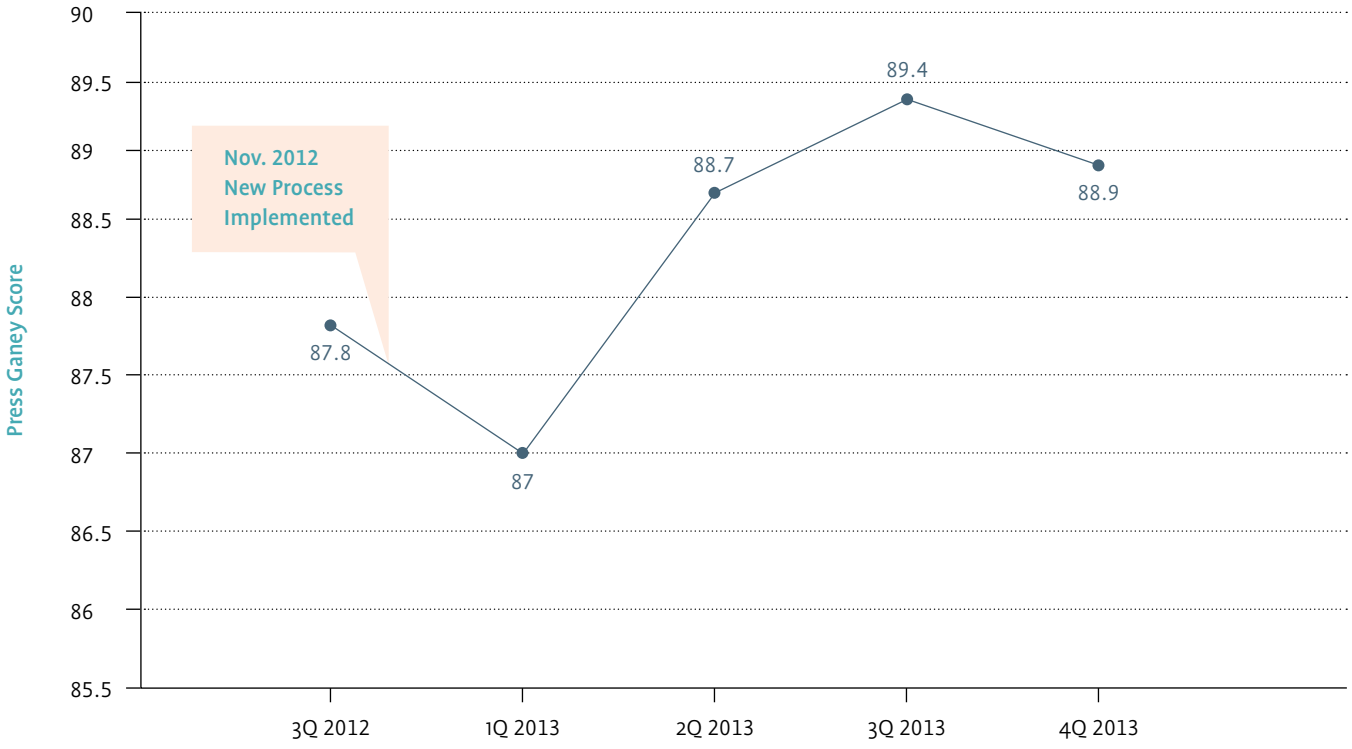
Goals & Process for Change

A small group of representatives from our leadership team met to formally review the existing scheduling process and outline all of the drivers behind the needed changes. Next, this group identified the following goals:

- Improve the outpatient scheduling process for newly-diagnosed cancer patients
- Improve the accuracy of scheduling new patient appointments
- Improve the patient experience
- Increase patient volume and decrease the outmigration of patients away from our healthcare system.

Leadership then assembled a team comprised of an attending physician, fellows, schedulers, and administrators and charged this team with implementing a solution to the scheduling process. After only two meetings, these stakeholders created a new process called "Bedside Scheduling" which:

Figure 2. Press Ganey Patient Satisfaction Score for "Scheduling Your Visit"



We no longer had issues with patients calling for last-minute appointments or, worse, showing up without a scheduled appointment.

- Moved the staff scheduling function to the patient's bedside
- Removed the scheduling burden from inpatients newly-diagnosed with cancer
- Ensured that the scheduling process for an outpatient consult for these patients occurred prior to discharge
- Improved patient access and coordination of care.

A Low Tech/No Tech Solution

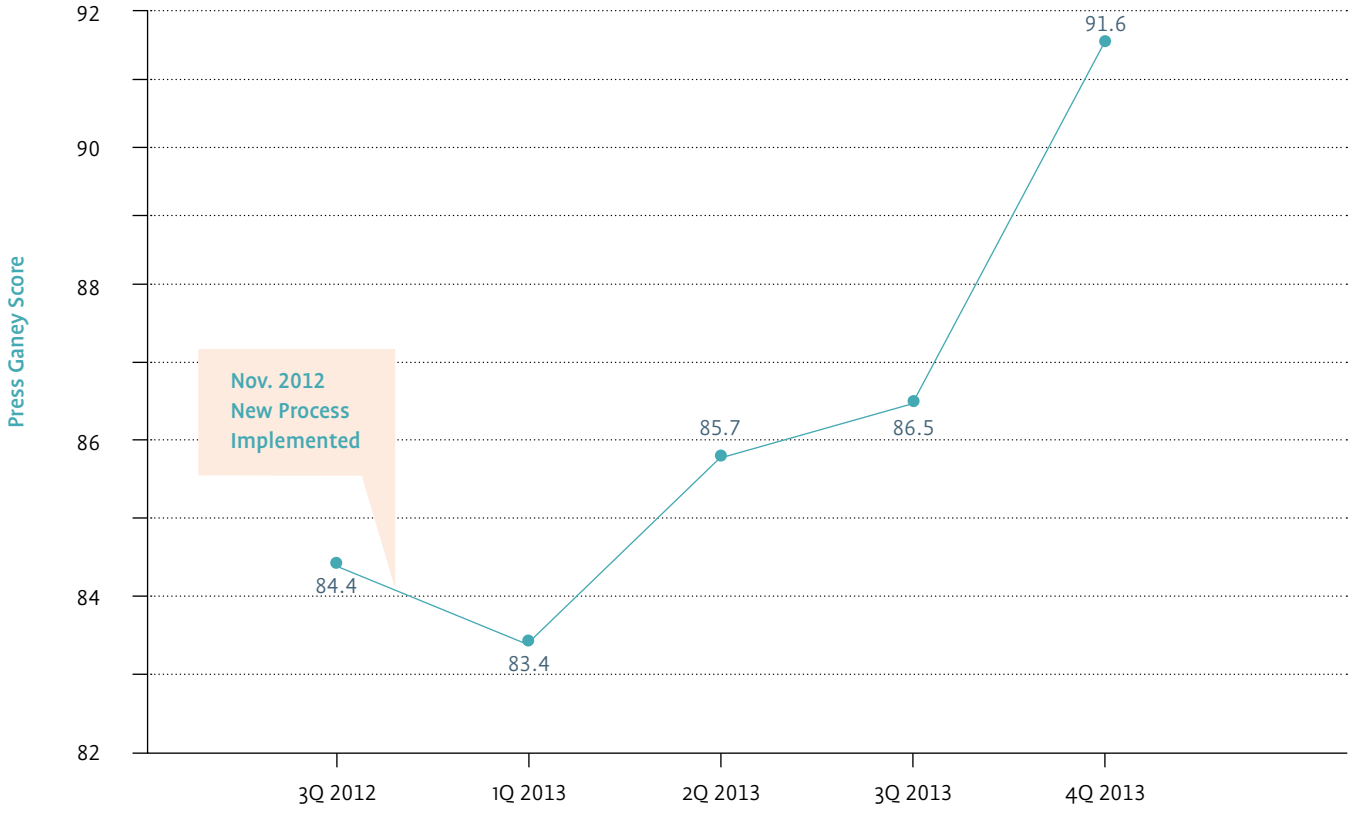
The new scheduling process is a simple, low tech solution, shifting the burden of responsibility from the patient and family to the cancer care team. Once an inpatient newly-diagnosed with cancer has been identified as someone who requires an outpatient follow-up visit, the fellow emails the following information to the schedulers:

- Patient name
- Date of birth
- Brief history and diagnosis
- Preferred contact (patient or family member)
- Preferred oncologist and/or disease-site-specific team
- When patient next needs to be seen.

Table 1, page 24, provides two examples of this type of email.

After receiving the email, the scheduler calls the patient (or the designated caregiver) while the patient is still admitted—at his or her bedside—to schedule the outpatient visit. The remain-

Figure 3. Press Ganey Patient Satisfaction Score for "Wait Time Between Calling and First Appointment Scheduled"



ing steps in Bedside Scheduling are as follows:

1. Financial counseling begins (if needed)
2. An email confirming the appointment date and time is sent back to the fellow
3. The appointment information is included in the patient's discharge form
4. An email, including all of this information, is put into the outpatient medical record for the first office visit.

Implementation Challenges

Our fellows were on board and motivated about the new Bedside Scheduling process, initiating emails the morning after roll-out. Our schedulers, on the other hand, had difficulty with the concept of Bedside Scheduling. Our scheduling staff is very amenable to and generally accepting of change; however, they are also highly-trained and sensitive to customer service expectations. The schedulers believed that it was intrusive to call patients while they were in the hospital, sharing concerns such as, "What if the patient is sleeping when I call?" or "What if the patient is out of the room having a test?" or "What if the patient has visitors?"

With persistence on the part of leadership, our schedulers were encouraged to forge ahead with the new process. Patients and their families were actually grateful to receive the call from the office coordinating their follow-up appointment, and when schedulers started to receive this positive feedback, they began to fully engage and get on board with Bedside Scheduling.

Outcomes

The entire team was quite pleased with the results of the Bedside Scheduling initiative. There was improved communication between fellows, oncologists, schedulers, and patients and their family members. Patients were now consistently being scheduled with the appropriate disease-site-specific teams. We no longer had issues with patients calling for last-minute appointments or, worse, showing up without a scheduled appointment.

We also met our goal of increasing patient volume. The medical oncology practice saw an increase in the volume of new patients referred from the inpatient setting (see Figure 1, page 25).

Finally, we experienced an increase in our Press Ganey patient satisfaction scores after Bedside Scheduling implementation (see Figures 2-4, pages 26-28). Today, inpatients who are newly-diagnosed with cancer receive their follow-up appointments with ease, allowing them the time to prepare for their outpatient visit. By removing this burden from patients, we have successfully met our most important goal: improving the patient experience. In addition, our Bedside Scheduling process has given us the opportunity to reach out to our patients and introduce ourselves and our cancer program and begin to offer our support before they even enter the building. OI

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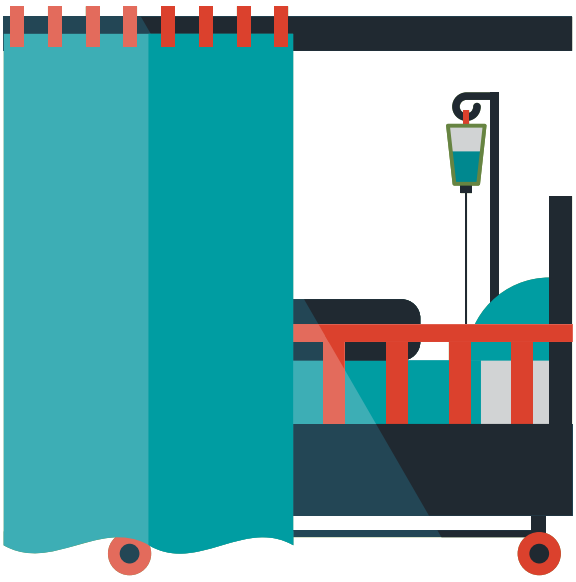
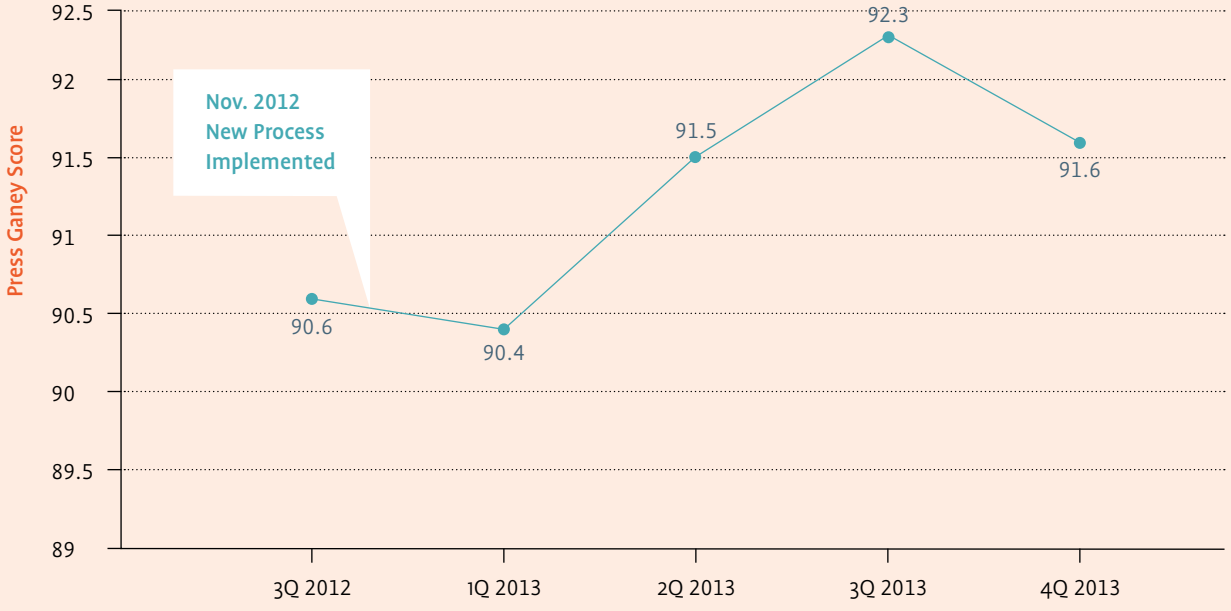


Figure 4. Press Ganey Patient Satisfaction Score for "Courtesy and Concern of the Staff Who Made Your Appointment"



Introducing the Institute for Clinical Immuno-Oncology

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A NEW ERA OF ONCOLOGY STARTS NOW.

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The Association of Community Cancer Centers (ACCC) has launched the Institute for Clinical Immuno-Oncology (ICLIO), a unique initiative that will accelerate the adoption of immunotherapy (I-O) in the community. ICLIO brings together leaders in the field to educate multidisciplinary teams to go beyond a clinical understanding of I-O and tackle real-world implementation issues. Visit us at accc-iclio.org for a wealth of resources and get involved in this transformative community.

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ICLIO is made possible by a charitable donation from Bristol-Myers Squibb.

BY BARBARA JENSEN,
RN, BSN, MBA

Treatment Room Volunteers Increase "Touch Time" for Patients

At Skagit Valley Hospital Regional Cancer Care Center, Mount Vernon, Wash., our entire cancer care team plays an important role in treatment. From our scheduling team to pharmacy, social work and support services, and radiation therapists, all staff is exposed—at some level—to the trials and challenges our patients face during their cancer journey. Our infusion nurses in particular witness daily the toll that both the disease and its treatment take on the body, mind, and spirit of the patients in their care. The therapeutic relationships that are developed with patients in active treatment often weigh heavily on the hearts and minds of the oncology nurse. The constant and repetitive exposure to the suffering of others is taxing at best, and cancer program leadership needs to make every effort to address stressors to prevent compassion fatigue and burnout in our nursing staff.

Adding to the inherent stress of caring for our patients is the fact that medical oncology continues to advance rapidly, bringing new therapeutic options to market at a very fast pace. Nurses must stay on top of these changes—both in terms of the science behind these advancements, as well as how these new treatments must be delivered to ensure that patients receive safe, timely therapy. At times, this clinical learning can overshadow the more holistic components of patient care and create competing priorities for our nurses. These competing priorities can lead to feelings of frustration as our nurses try to "be everything to everyone all the time." Often, oncology nurses spend the majority of their days safely administering and documenting the ordered treatment, as well as ensuring that patients have the physical comforts to endure long treatment days, which leaves little time to attend to the emotional, educational, and spiritual needs that go hand in hand with cancer treatment.

Nurses describe the most heart-warming and human aspects of their work as those instances when they have time to thoughtfully answer questions, provide education, interact and engage with patients and their families, or just sit silently and hold a hand.

One of my oncology nurses summed up this challenge as a lack of "touch time" between nurses and their patients. Nurses describe the most heart-warming and human aspects of their work as those instances when they have time to thoughtfully answer questions, provide education, interact and engage with patients and their families, or just sit silently and hold a hand. This same nurse said this about the challenge: "It seems that we [nurses] spend all our time involved in the 'tasks' of treatment or the 'tasks' of comfort—administering drugs, giving blood, documenting care, providing warm blankets, a pillow, offering refreshments and nourishment—that we have less and less time to meet patients where they are, to encourage, listen, educate, or to just be with them in those moments when they come face to face with the reality of their diagnosis."

How Do We Increase "Touch Time"?

Concerned about our nursing staff, their stressors, and the sometimes competing priorities, cancer program leadership began to brainstorm ways to increase the amount of "touch time" nurses experienced with their patients in our busy infusion therapy clinic. To help leadership determine where to focus its interventions, we conducted an in-depth evaluation of the time our nurses spent on clinical versus non-clinical tasks.

We then evaluated our nurse staffing model, comparing our infusion room staffing against benchmark data from other community cancer centers. Skagit Valley Hospital Regional Cancer Care Center's infusion center has an open room design with 15 treatment chairs and 2 small isolation rooms for the needs of more critical patients. We are staffed with four registered nurses during operating hours and our peak nurse-to-patient ratio averages to about four patients per nurse, with a daily visit volume ranging from seven to nine patient visits per nurse per day. Based on available comparisons, we determined that our staffing model was indeed adequate and appropriate for a center of our size and the patient mix that we treat. While recognizing how extra hands in the treatment room would lighten the load and increase job satisfaction for our nursing team, cancer program leadership concluded that adding staff was not a viable option.

> If these volunteers could provide patient comfort in the waiting room, why couldn't they do the same for patients undergoing infusion therapy?

As leadership explored other ways to increase chair-side time for our treatment room nurses, we began to notice the interaction between our front office volunteers and our patients in the waiting room. There were many volunteers who easily engaged with

patients and their families proactively, creating a warm and inviting atmosphere in a busy, sometimes hectic, environment. Our volunteer staff took the initiative to ensure the waiting room was well stocked with creature comforts and that patients' needs were addressed while they waited for their treatment. Cancer program leadership began to consider this question—if these volunteers could provide patient comfort in the waiting room, why couldn't they do the same for patients undergoing infusion therapy?

Harnessing Volunteer Power

Volunteer Services of Skagit Valley Hospital is responsible for screening, interviewing, and matching skills to assignments for more than 400 community volunteers throughout the hospital and clinics each year. This volunteer group offers a wide range of both skill sets and time availability, with a large number of retired professionals in our community looking to give back. Until 2010, all volunteers assigned to the cancer program were given only clerical or courier tasks in our front office. While this placement was appropriate for many, other volunteers were willing to make a more substantial commitment to our cancer program.

With the help of our social work team and interest from two key volunteers, cancer program leadership developed a pilot program to introduce the concept of treatment room volunteers to infusion nursing staff. An examination of the

Volunteers regularly assist our treatment room nurses with tasks that would otherwise take them away from being chair-side and available to their patients.

Treatment Room Volunteer Duties

1. Make coffee (in the treatment and waiting rooms)
2. Fill blanket warmer
3. Take and fax lunch orders
4. Assemble central line access kits
5. Stock refrigerator and snack counter
6. Run blood samples to lab (as needed)
7. Assist patients with ambulation (at nurses request)
8. Hand out lunches
9. Offer beverages and snacks (as appropriate)
10. Assist nurses with other tasks (as needed)

Thank you for giving your time and talents to help us deliver the best possible care to our patients! We appreciate you!

Treatment Room Volunteer Orientation

8:00
Welcome and Introductions
Barb Jensen, RN, BSN, MBA
Director of Oncology

8:10
Overview of Medical Oncology and Hematology Services
Kara Thomas, RN, OCN
Oncology Specialty Educator

1. Universal precautions
2. Cancer and hematology treatment
3. Supportive treatment

8:30
Overview of Social Services
Peter Wold, MSW

1. Professional boundaries, HIPPA concerns
2. Psychosocial needs of the cancer patient

9:00
Volunteer Responsibilities
Kristi Terwilliger, RN, OCN
Clinical Supervisor

1. Clinic tour
2. Treatment room tour and introductions
3. Review of treatment room duties

9:30
Review and Questions

These volunteers freed up our nurses to do more of the work they are skilled to do, and gave them time to care for the whole patient—body, mind, and spirit.

non-clinical work currently being performed by our nurses in the treatment room gave us a place to start. The tasks associated with providing for the physical comfort of our patients receiving treatment—creature comforts that our volunteers were already adept at managing—could be carved out and assigned to non-licensed, non-clinical personnel. We created a list of these tasks (see page 33), and piloted our Treatment Room Companion Program with our two interested volunteers. While the list seems short and the tasks simple, the time that these activities take away from chair-side patient care is great. The addition of extra hands to perform this work allowed us to use our nursing staff to the highest and best use of their certification. These volunteers freed up our nurses to do more of the work they are skilled to do, and gave them time to care for the whole patient—body, mind, and spirit.

Nurse Feedback

At first our nurses were leery about the Treatment Room Companion Program, raising questions regarding the appropriateness of assigning un-licensed, non-healthcare professionals to any chair-side contact with cancer patients. Concerns were raised about issues from universal precautions to patient privacy. The nurses felt that our patients were more "vulnerable" in the treatment room versus in the waiting room, and nurses expressed particular concern about volunteers using this interaction as a way to meet their own emotional needs. (Some of our volunteers have received cancer treatment at our program or have family members who have been treated for cancer.) To address these concerns, our leadership team developed two tools—a candidate screening process and a treatment room orientation—as part of our volunteer on boarding. Potential candidates are interviewed by our leadership team to ensure they will be a fit with both the nursing staff and the work specific to the treatment room. As a next step, nursing leadership staff and our social work team designed an orientation to both the infusion treatment space and the treatment room companion role, including an overview of the clinical services provided at the cancer center and a review of the psychosocial aspects of cancer treatment. A sample of this orientation agenda can be found at left.

Programmatic Benefits

Since 2010 volunteers for our Treatment Room Companion Program have spent nearly 5,000 hours helping cancer patients with a soft touch, a warm blanket, or simply a listening ear.

A warm smile always accompanies a warm blanket delivered by our volunteers.

These volunteers not only comfort the patients and families who frequent our infusion room, but they also provide willing hands to assist in many other tasks that make our nurses' load a little lighter. The program continues to recruit new volunteers to ensure that we have coverage Monday through Friday during the busiest times of the treatment day.

One previously skeptical nurse now tells everyone, "We don't know what we would do without these volunteers. They are willing to help with anything we need, always with a smile. Patients love the added attention that they receive, and we appreciate what their help does for us."

While our Treatment Room Companion Program alone cannot diminish all the stressors that this profession puts on the hearts of those who care for cancer patients, it has gone a long way to alleviate many burdens. Cancer program leadership continues to look at ways we can improve both the staff and patient experience in our program. We recognize that "the heart" of a community cancer center is truly the community we live in and serve. The need to give back, to become a part of our cancer program's success, to celebrate the healing, and mourn for the dying, are all reasons that these volunteers give of their time and talents. They inspire staff to come to work with this same intent, and we are ever grateful for their seemingly endless capacity for caring. OI

Barbara Jensen, RN, BSN, MBA, is director of Oncology, Skagit Valley Hospital Regional Cancer Care Center, Mount Vernon, Wash.

Skagit Regional Health
Skagit Valley Hospital · Skagit Regional Clinics
Regional Cancer Care Center

Our Program At-A-Glance

The Skagit Valley Hospital Regional Cancer Care Center has been providing state-of-the-art cancer care to our community for more than 30 years. Our primary location in Mount Vernon, Wash., serves Skagit and Island Counties. A second medical oncology site located within Cascade Skagit Health Alliance in Arlington, serves our patient population in North Snohomish County.

With the support of our community and the Skagit Valley Hospital Foundation, funds were raised for a major expansion in December 2006, adding radiation oncology to the medical oncology practice. This dramatically increased the breadth of therapies available to our population, and solidified the organization's commitment to providing a comprehensive approach to cancer care for the patients and families we serve.

In 2009 the Skagit Valley Hospital Foundation received a generous grant from Safeway Inc., to launch The Breast Institute at the Skagit Valley Hospital Regional Cancer Care Center. The Breast Institute was developed as our first tumor-specific program, adding patient navigation and a weekly breast cancer multidisciplinary conference to our existing services.

With more than 600 new cases diagnosed annually, Skagit Valley Hospital Regional Cancer Care Center is designated as a Comprehensive Community Cancer facility and boasts accreditations by the American College of Surgeons Commission on Cancer (CoC) and the National Accreditation Program for Breast Centers (NAPBC). Our team is dedicated to ensuring that clinically excellent care paired with a compassionate, patient-centered experience is available to the people of our community now and for future generations to come.

Onco-Contraception for Women Diagnosed with Breast Cancer

In Brief

While contraceptive counseling during breast cancer diagnosis and treatment should be an integral part of disease management, it is often overlooked by clinicians. A survey regarding reproductive health and contraception was administered to women diagnosed with breast cancer between ages 18 to 50 attending the 2011 Annual Conference for Young Women Affected by Breast Cancer. The primary objective of this study was to assess patient reporting of contraceptive counseling during breast cancer treatment and barriers to providing this type of counseling. The study's secondary objective: to identify which providers offered counseling and which contraceptive methods were recommended. Of the 111 women surveyed, only 51.4 percent indicated they had discussed contraception with a healthcare provider. This gap in the provision of onco-contraception left nearly half of surveyed women at risk of unintended pregnancy, indicating a need for contraceptive training among oncologists.

BY ERIKA K. RADEKE, MPS; ALICIA ROSTON, MPH; SHWETA BHATT, MD; ARDEN ROSTON, BA; LINDSAY ZIMMERMAN, MPH; LOUIS G. KEITH, MD, PHD; AND ASHLESHA PATEL, MD, MPH

Why Onco-Contraception?

There are nearly 3 million female breast cancer survivors in the United States,[1] and breast cancer is the most common cancer diagnosed in women who are of reproductive age.[2] In 2010 approximately 206,000 women in the U.S. were newly-diagnosed with breast cancer; 20 percent of these women were of childbearing age.[2] While younger women diagnosed with breast cancer may have more aggressive forms of cancer, five-year relative survival rates generally are 99 percent for cancer diagnosed at local stage, 84 percent for regional disease, and 23 percent for distant stage disease.[3] In this context, the quality of life (QOL) measures for breast cancer survivors are of paramount importance.

Breast cancer survivors face several reproductive health challenges associated with disease and cancer treatment. While many patients are interested in fertility preservation and future childbearing, contraception at critical points in early diagnosis and treatment is important for all patients. Treatments such as radiation, chemotherapy, and adjuvant treatment may harm a developing pregnancy and are rated as Category D or X. Category X drugs are contraindicated in women who are pregnant or may become pregnant, while Category D drugs have demonstrated risk to the fetus, but their potential benefits outweigh the risks of fetal complications.[4] Despite the contraindication and risk, one study estimated that six percent of pregnancies occur in women on Category D or X medications.[5]

The U.S. Centers for Disease Control and Prevention (CDC) recommends that women with breast cancer avoid unintended pregnancy, as it may increase risk of adverse health events.[6] Further, deferment of pregnancy for hormonally-mediated cancers is recommended for two to five years after diagnosis due to higher rates of cancer recurrence.[7] Additionally, adjuvant therapies, such as tamoxifen, have recommended duration of use of up to 10 years,[8] during which time pregnancy should be avoided.[9] Despite these recommendations, little attention is placed on the provision of contraception counseling in women diagnosed with breast cancer.[10,11] Clinicians who do not initiate this conversation with their breast cancer patients leave these women at risk for unintended pregnancy during this critical time.

A discussion between a newly-diagnosed breast cancer patient and her cancer care provider regarding onco-contraception should be an integral part of initial management.

A discussion between a newly-diagnosed breast cancer patient and her cancer care provider regarding onco-contraception should be an integral part of initial management. To date, a paucity of literature exists describing the degree to which providers discuss contraception with their cancer patients.

Survey Methods

In 2011 the Cook County Health and Hospitals System Institutional Review Board (IRB) reviewed the survey and gave it exemption status. The survey was then administered at a Teva Pharmaceutical booth in the exhibit hall of the Annual Conference for Young Women Affected by Breast Cancer held February 25-27, 2011, in Orlando, Fla. Women were eligible to take the survey if they were diagnosed with breast cancer between 18 to 50 years of age. The five-item questionnaire assessed:

1. Age and date of diagnosis and current treatment status
2. Future childbearing desires at time of diagnosis
3. Presence of contraception counseling
4. The type of healthcare professional providing counseling (if applicable)
5. Type of contraceptive recommended.

Type of healthcare professional and type of contraceptive were assessed as multiple selection questions. Response options for type of healthcare professional included oncologist, breast surgeon, obstetrician/gynecologist, primary care provider, nurse practitioner, physician assistant, or other. Response options for contraceptive method included intrauterine device, oral contraceptive pill, barrier method, and other. If "other" was selected, respondents were asked to specify type of provider or contraceptive.

Statistical analyses were performed using SAS 9.2. Descriptive statistics were used to describe this sample population. Data was stratified by those who received contraceptive counseling and those who did not. T-tests and chi-square tests compared the sample characteristics by receipt of contraceptive counseling.

> Compared to women who were interested in future childbearing, women who had completed childbearing at the time of diagnosis were 36 percent less likely to report receipt of contraceptive counseling.

Table 1. Year and Age of Diagnosis, Future Childbearing Interest, and Treatment Status by Receipt of Contraceptive Counseling*

	RECEIVED CONTRACEPTIVE COUNSELING			
	TOTAL (n=111)	YES (n=57)	NO (n=54)	p VALUE
YEAR OF DIAGNOSIS				0.046
Median	2009	2009	2008	
Interquartile Range	2007 to 2010	2008 to 2010	2006 to 2009	
AGE AT DIAGNOSIS				0.029
Mean (SD)	35.1 (5.8)	34.0 (6.0)	36.4 (5.2)	
Range	23 to 46	23 to 46	25 to 46	
COMPLETED CHILDBEARING				0.018
Yes	53	21 (39.6)	32 (60.4)	
No	58	36 (62.1)	22 (37.9)	
CURRENTLY IN TREATMENT				0.127
Yes	43	26 (60.5)	17 (39.5)	
No	68	31 (45.6)	37 (54.4)	

*Values are n (%) unless otherwise indicated. P values were derived from Wilcoxon rank sum, chi-square, and t-tests. Nine individuals were missing values for year of diagnosis; three individuals were missing values for age.

Table 2. Bivariate Prevalence Ratios of Receipt of Contraceptive Counseling by Year and Age of Diagnosis, Future Childbearing Interest, and Treatment Status*

	PREVALENCE RATIO	95% CI	p VALUE
YEAR OF DIAGNOSIS			
5 year increase in age	1.49	0.97–2.27	0.069
AGE AT DIAGNOSIS			
5 year increase in age	0.82	0.70–0.96	0.015
CHILDBEARING COMPLETE			
Yes	0.64	0.43–0.94	0.024
No	ref	—	—
CURRENTLY IN TREATMENT			
Yes	1.33	0.93–1.89	0.119
No	ref	—	—

*Measures of association were derived from bivariate log-binomial modeling. Nine individuals were missing values for year of diagnosis; three individuals were missing values for age.

Factors of interest were year and age of diagnosis, as well as completion of childbearing and treatment status. Prevalence ratios were calculated to assess differences between those who did and did not receive contraceptive counseling. Chi-square tests compared the distribution of provider type engaging in contraceptive counseling and contraceptive method recommended for future childbearing interest.

Survey Results

Of the 119 women surveyed, 8 were excluded for having undergone previous sterilization prior to diagnosis of cancer. The remaining 111 surveys were included in the analysis. Of the women included in the study, mean age at diagnosis was 35.1 years. Median year of diagnosis was 2009—within 2 years of survey administration—and 48 percent indicated they had completed childbearing at that time. At the time of survey administration, 39 percent of women were undergoing treatment. Overall, 49 percent of women reported that a healthcare provider discussed contraception with them prior to or during their cancer treatment.

Median year of diagnosis was more recent among women who received contraceptive counseling (2009) than in those who did not (2008). Younger age was also associated with reported receipt of contraceptive counseling. Mean age of women who received contraceptive counseling was 34 years compared to 36.4 years in those who did not receive counseling. Additionally, of the women who had completed childbearing, fewer reported receiving contraceptive counseling (40 percent) compared to those who had not completed childbearing (62 percent). Treatment status was not associated with receipt of counseling. See Table 1, left, for full survey results.

Bivariate prevalence ratios indicated that increased age and completion of childbearing at time of diagnosis were significantly associated with a decline in provision of contraceptive counseling (Table 2, above). A 5-year increase in age was associated with an 18 percent decrease in likelihood of receiving contraceptive counseling. Compared to women who were interested in future childbearing, women who had completed childbearing at the time of diagnosis were 36 percent less likely to report receipt of contraceptive counseling. A non-significant increase in contraceptive counseling was noted in those diagnosed more recently and in those receiving treatment at the time of survey administration.

Among women who indicated receipt of contraceptive counseling, the type of provider who engaged in counseling is listed in Table 3, page 40. Of the 56 women who specified the type of provider who discussed contraception, 73 percent indicated that their oncologists engaged in counseling and 59 percent indicated they discussed contraception with their obstetrician/gynecologist. Breast surgeons were the third most frequently mentioned provider type; 16 percent of women reported receiving

counseling from a breast surgeon. Less than 10 percent of patients who received contraceptive counseling referenced a primary care provider, nurse practitioner, or physician assistant as the provider who engaged in counseling. Of those who had completed childbearing at the time of diagnosis, 76 percent indicated an obstetrician/gynecologist provided contraceptive counseling compared to 49 percent of women who had not completed childbearing. An important, although non-statistically significant finding, was that among women who had completed childbearing, 33 percent reported an obstetrician/gynecologist was the only source of counseling compared to 17 percent of women who had not completed childbearing. Otherwise, type of provider engaging in contraceptive counseling did not differ by future childbearing interest.

Recommended methods of contraception for those who indicated having received counseling are also listed in Table 3, below. Seven women did not specify which methods of contraception were recommended. Among the remaining 50 women, barrier methods were most frequently recommended at 60 percent. Forty-six percent of participants who received counseling reported that intrauterine devices were recommended. Only 4 percent of women indicated their provider recommended oral contraceptive pills. Eighteen percent of counseled women indicated that "other" methods of contraception were recommended. Four of these women specified permanent sterilization as an "other" method of contraception. Although not statistically significant, women who had completed childbearing indicated that permanent sterilization had been recommended more frequently, 13 percent compared to 6 percent of women who had not completed childbearing.

Survey Takeaways

The ramifications of an unintended pregnancy may be more complicated for women with cancer; yet, only half of the patients in this study reported having received contraceptive counseling during this critical time. These study findings are consistent with the literature—where 67 to 85 percent of women diagnosed with cancer did not recall discussing pregnancy risk or contraception with their providers.[10, 12] Despite the fact that pregnancy is contraindicated in women with breast cancer,[6] our study demonstrates

Table 3. Reported Type of Provider Who Engaged in Contraceptive Counseling and Recommended Contraceptive Methods by Childbearing Completion Status*

	COMPLETED CHILDBEARING			
	TOTAL	YES	NO	p VALUE
TYPE OF PROVIDER				
Oncologist	41 (73.2)	14 (66.7)	27 (77.1)	0.391
Breast Surgeon	9 (16.1)	3 (14.3)	6 (17.1)	>0.999
Obstetrician/Gynecologist	33 (58.9)	16 (76.2)	17 (48.6)	0.042
Primary Care Provider	5 (8.9)	2 (9.5)	3 (8.6)	>0.999
Nurse Practitioner	4 (7.1)	1 (4.8)	3 (8.6)	>0.999
Physician Assistant	1 (1.8)	0 (0)	1 (2.9)	>0.999
Other Healthcare Provider	2 (3.6)	0 (0)	2 (5.7)	0.523
CONTRACEPTIVE METHOD				
Intrauterine Device	23 (46.0)	6 (37.5)	17 (50.0)	0.408
Oral Contraceptive Pill	2 (4.0)	1 (6.3)	1 (2.9)	0.542
Barrier Methods	30 (60.0)	10 (62.5)	20 (58.8)	0.805
Other	9 (18.0)	4 (25.0)	5 (14.7)	0.442

*Values are n (%). P values were derived from chi-square tests. Responses are not mutually exclusive, therefore percentages add to more than 100%. One individual did not specify type of provider; seven individuals did not specify type of contraception recommended.

that many clinicians have not implemented intervention to prevent pregnancy, which may negatively impact quality of life. Both prognosis and QOL issues influence oncology treatment decisions.[13, 14] QOL issues, such as psychological health, social avoidance, physical pain, fatigue, and sexual and reproductive health, should be addressed by the oncology team or through referral to other specialists.[15] Referral to a gynecologist or family medicine provider may be necessary for the management of reproductive health issues; however, the oncology team must initiate this conversation. Appropriate contraceptive care or referral should be provided expeditiously, as pregnancy soon after cancer diagnosis is not uncommon.[13, 16]

Factors associated with receipt of contraceptive counseling illustrate counterintuitive findings. We anticipated that women indicating completion of childbearing would be offered birth control more often than those interested in future childbearing. However, completion of childbearing and older age were found to significantly reduce the likelihood of counseling. Women who had completed childbearing also most frequently reported discussing contraception with an obstetrician/gynecologist. This finding may indicate that women's health providers are largely responsible for what small percentage of counseling is reported among women who had completed childbearing. Oncologists may be discussing contraception with younger patients interested in future childbearing as they may already be discussing fertility preservation with these patients.

Methods of contraception recommended did not differ significantly by future childbearing interest. There was an understandable trend in which women who had completed childbearing were more likely to report discussing sterilization as a form of permanent contraception. However, of those who indicated contraceptive counseling with a provider, six percent of women interested in future childbearing discussed permanent sterilization. Clinicians should recommend other highly effective, nonpermanent methods of contraception to these women to ensure that individual reproductive health goals may still be achieved and QOL is not negatively impacted.

Overall, the survey found that clinicians most frequently recommended barrier methods—the least effective methods of contraception. The World Health Organization classifies contraception into effectiveness categories with tier 1 methods having the highest efficacy rates and tier 4 having the lowest efficacy rates.[17] Tier 1 methods have typical-use failure rates of less than 1 percent and include male and female sterilization along with long-acting reversible options, intrauterine device and subdermal implant.[6,17] High typical-use failure rates of lower tier methods have been attributed to user compliance-based issues.[18] User compliance and subsequent unintended pregnancy have been shown to be problematic among both cancer and non-cancer patients.[5, 19-21] Tier 2 methods have typical-use failure rates of 3 to 8 percent and include injectables, pill, transdermal patch, and vaginal ring. Tier 3 methods have typical-use failure rates of 15 to 32 percent and include male/female condoms, sponge, and diaphragm. Tier 4 methods have typical-use failure rates of 27 to 29 percent and include withdrawal and spermicide.[6, 17] By recommending less effective, user-dependent methods of contraception, women who receive contraceptive counseling may still be at risk for unintended pregnancy.

According to the Society of Family Planning, the copper T intrauterine device is the optimal form of contraception for women with breast cancer due to its high effectiveness and hormone-free content.

In addition to issues with user compliance, providers must also consider the hormonal content of recommended contraceptive methods. Hormonal-based contraceptives (i.e., oral contraceptive pills, patch, ring, shot, and levonorgestrel intrauterine device) are contraindicated in women diagnosed with breast cancer.[6] However, this survey found that 4 percent of patients who discussed contraception with a provider received a recommendation of oral contraceptive pills. According to the Society of Family Planning, the copper T intrauterine device is the optimal form of contraception for women with breast cancer due to its high effectiveness and hormone-free content.[22] Two types of intrauterine contraception were FDA-approved at the time this survey was administered, the copper T and the levonorgestrel intrauterine device. While intrauterine contraception was recommended to 46 percent of survey participants, rates of counseling specifically for the copper T intrauterine device were unknown.

Other survey limitations include potential for participant selection and recall biases. The cohort of women surveyed may not fully represent the general public. We believe the women attending this type of conference may be more proactive in their cancer care and thus be more likely to have discussed contraception with their provider. These findings may therefore overestimate the proportion of women who receive contraceptive counseling and underestimate the scope of the issue. Additionally, study participants were diagnosed with cancer at a median of two years prior to survey administration, which could have impacted patient ability to recall conversations about contraception at initial diagnosis.

Still, our survey findings indicate that nearly half of all women diagnosed with breast cancer are not receiving contraceptive

counseling, leaving them at risk for unintended pregnancy. Recommendations of less effective and even contraindicated methods of contraception may further exacerbate this risk. These findings suggest that targeted onco-contraceptive training among oncologists and cancer care providers is warranted to enhance provision of appropriate counseling and referral. Establishing referral networks to obstetrician/gynecologists may facilitate contraceptive education, as well as the implementation of appropriate and effective contraceptive methods. OI

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BY BRENDAN FITZPATRICK, MBA,
AND CHAD SCHAEFFER, FACHE

The Cancer Program Administrator of the Future

Oncology care delivery is complex and involves a multitude of stakeholders and care environments. The stakes are high for both the patient and the care providers given the personal burden and high cost of cancer care. The overall healthcare landscape continues to change at an unprecedented pace. For these reasons, the future cancer program administrator must be a dynamic leader who can drive strategic direction, as well as sustain higher levels of patient-centered care in an evolving reimbursement environment.

Another Crossroads Ahead?

In January 2015, U.S. Department of Health and Human Services Secretary Sylvia M. Burwell announced plans to tie 50 percent of traditional Medicare fee-for-service payments to "quality" or "value" through alternative payment models, such as accountable care organizations (ACOs) or bundled payment arrangements by the end of 2018.[1] Then in April, the Medicare Access and CHIP Reauthorization Act (MACRA) repealed the sustainable growth rate (SGR) formula and outlined a transition for providers to dual Medicare payment systems that will emphasize value over volume. While population health initiatives with shared-risk models are shifting the focus away from payments based on volume to reimbursement for quality, value, and cost of care, the reality is that most hospitals do not have the ability to account for their true care costs or to segregate actual line-item reimbursement.

As the U.S. healthcare system undergoes transformative change, cancer programs will require a multifaceted administrative leader to ensure that the program thrives and maintains an acceptable ROI on the significant investments required to deliver quality patient-centered care (see Figure 1, page 46). Program management skills alone will likely not be sufficient to navigate these new payment models. Future cancer program administrators must have:

- Exceptional leadership abilities; they must step up as "leaders" not merely "managers"
- Strong strategic and business planning skills
- Broad and deep knowledge of the oncology service line and the industry
- Communication skills to effectively work with a variety of stakeholders, including clinicians, staff, patients, and public and private payers
- A visionary mindset.

Leaders vs. Managers

As cancer care has become increasingly complex, so has the role of the cancer program leader. Over a relatively short period of

Figure 1. The Oncology Leader of the Future "Must Haves"

time, cancer program leadership has evolved from the private practice oncologist managing his or her own business, to a dedicated practice manager, to a hospital-based administrator, to the multifaceted healthcare leader needed in today's cancer programs.

Today and for the foreseeable future, healthcare systems will function in a matrixed environment, answering to multiple system-level executive leaders and other stakeholders—particularly patients and payers. Deeper administrative specialization is occurring across health systems today with non-clinical professionals now found in departments such as Financial Decision Support, Managed Care, and Revenue Cycle. This specialization allows these operational professionals to focus on labor-intensive activities. Rather than a "manager," cancer programs today, and in the future, require a specialized administrative leader empowered to focus primarily on strategic efforts, while operational issues become the responsibility of second-level management.

That said, clinical and operational efficiencies need to interconnect seamlessly. Depending on the program size, the future cancer program administrator may be partnered with another leader with a complementary skill set.

Essential Attributes

Because the cancer service line contributes substantially to a healthcare system's bottom line, the future cancer program administrator will need to be a peer among other top C-Suite administrators so that he or she has the influence and authority needed to move the cancer program forward at the speed of medicine today. Future cancer program administrators will need to interact effectively with the healthcare system's executive administration. Requirements such as Meaningful Use and quality measures have impact across service lines and encompass both the inpatient and outpatient care setting. As such, the future cancer program administrator will need to communicate across care siloes.

This leader will be a specialized hospital administrator who serves as a champion for quality care and partners closely with the chief medical officer. As a leader, the cancer program administrator must:

- Earn and maintain the respect of co-workers
- Hold staff to established goals and objectives
- Tactfully motivate all cancer program staff to collaborate, extracting meaningful contributions from the entire team
- Build multidisciplinary teams, involving appropriate disciplines, to solve a multitude of complex issues—from marketing and strategic plans to clinical care delivery
- Communicate effectively with multiple stakeholders, including physicians and other clinicians, patients, payers, and the C-Suite
- Be accountable to upper management.

Strategic & Business Planning

Many of the changes in healthcare begin externally and take time to gain momentum. Healthcare systems are large organizations that also need time to position themselves for strategic change. Succession planning, strategic and business planning, and governance structures take time to develop, as well. The cancer program administrator must be able to forecast future needs and plan accordingly. Most often, budgets are based on historical trends, while innovative ideas need time to gain full approval and buy-in. These future leaders must anticipate and rigorously vet staffing, capital expenditures, and other programmatic requirements well in advance of actual need.

The future cancer program administrator must also understand the challenges facing the cancer program and develop viable solutions to meet these challenges. These leaders must be able to access and leverage both internal and external resources to their program's advantage. For example, some healthcare systems have patient-experience professionals and experts in Lean and Six Sigma to help with efficiency. The governance committee can also help assess progress toward programmatic change. This leader must foster buy-in by involving appropriate personnel in the process of constructing comprehensive strategic approaches.

Knowledge of the Oncology Service Line & the Industry

Oncology care is complex and a thorough understanding of its unique care delivery environment is essential for the future cancer program administrator. Cancer programs have many moving parts, including:

- Dedicated reception and registration
- Laboratory
- Medical, surgical, and radiation oncology
- Research
- Pharmacy
- Coding and billing
- Cancer registry
- Support services.

> The future cancer program administrator must also understand the challenge facing the cancer program and develop viable solutions to meet these challenges. These leaders must be able to access and leverage both internal and external resources to their program's advantage.

All of these departments have clinicians and support staff that are necessary to the delivery of quality cancer care. An essential part of patient-centered care is seamless care coordination with each patient receiving the right care at the right time. This can only happen if clinicians and support staff are in sync and working together. The cancer program administrator must be the leader who moves the team forward to realize this goal.

Future cancer program administrators must not only focus on what's going on within their program, they must also stay abreast of changes in the broader oncology community and healthcare landscape. Regulatory agencies, such as the Centers for Medicare & Medicaid Services (CMS), and credentialing bodies, such as the American College of Surgeons Commission on Cancer (CoC), propose and implement significant changes to cancer care each year. Cancer program administrators must understand these changes and their programmatic impact.

These leaders also need knowledge and understanding of:

- Local, state, and national regulations that must be met to ensure that the cancer program can keep its doors open and stay in business
- The resources and support available from various foundations, non-profits, and advocacy groups, including the opportunity to partner with these entities to improve care delivery
- Patient assistance and co-pay programs that help patients afford their cancer care and help ensure that the cancer program stays financially viable
- Disease-site-specific patient navigation to meet the unique needs of patients at different points along the cancer care continuum
- Clinical trials access onsite.

Refined Communication Skills

The future cancer program administrator must be a dynamic communicator who can effectively communicate expectations at multiple levels by:

- Commanding a room when speaking publicly
- Effectively communicating with large numbers of staff through email updates
- Using data and metrics to help communicate and support the cancer program's culture and goals
- Personally connecting one-on-one for milestone moments in their staff members' careers.

In addition, the cancer program administrator must be able to articulate the program's vision in many different settings, tailoring the message to each audience—the C-Suite, oncology clinicians, referring physicians, support staff, community leaders, patients, and payers. Through skilled communication, the administrator will work to build support for the program's vision, gather important stakeholder input, and engage staff in making improvements to the program.

Visionary Capabilities

The road ahead is complex, with promising clinical breakthroughs, ongoing regulatory changes, and operational challenges. The future cancer program administrator must solicit input and garner participation from the various vested stakeholders to create a comprehensive vision for oncology care. Quality transparency is at the forefront of healthcare reform and is being increasingly sought by patients and their families. Visionary cancer program leaders will be needed to help define quality within their cancer programs.

As a visionary leader, the future cancer program administrator will look to partner with professional organizations, such as the CoC, the American Society of Clinical Oncology (ASCO), and the American College of Radiology (ACR), to gather clinical data and organize this data in a way that makes sense to clinicians, patients, payers, and the general public.

Cost is another dynamic with increasing public visibility. And—as if quality and cost were not complicated enough issues on their own—the visionary cancer program administrator will

play an active role in helping to synthesize this quality and cost data to determine and define the cancer program's "value" to patients, payers, and society. As we all know, value-based reimbursement gained significant momentum in 2015, and it is here to stay for the foreseeable future.

Moving forward, the vision for cancer care in this country will require comprehensive local resources that are supplemented by clinical affiliations with larger entities, such as universities, NCI-designated cancer programs, and regional healthcare systems. Even geographically-isolated and rural cancer programs will be challenged to develop innovative ways to affiliate with larger entities, for example, in the form of a virtual tumor board or through a clinical research affiliation that will enable these smaller programs to offer clinical trials in their communities. And it is the future cancer program administrator who will lead these collaborative efforts.

A Bright Future Ahead

Most patients have a choice of where they will receive their cancer care. The future cancer program administrator will work to strengthen a program's reputation within its community, helping to ensure the cancer program obtains a high percentage of patients in its primary and, to a lesser degree, secondary service areas. Cancer care is about delivering the right treatment at the right time. With those words in mind, it clear that the future cancer program administrator is actually needed today. OI

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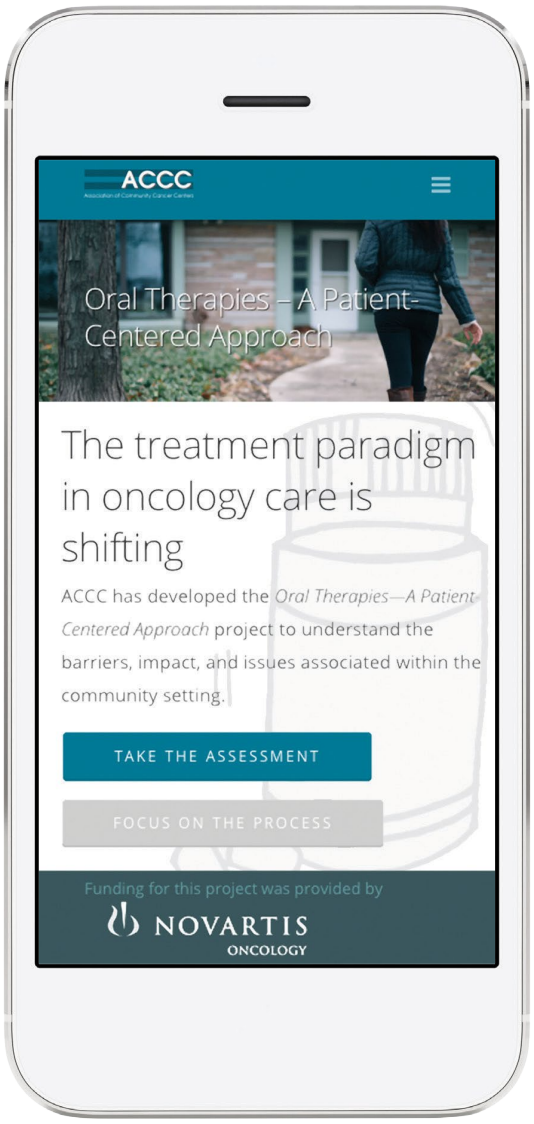

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Strategic Planning

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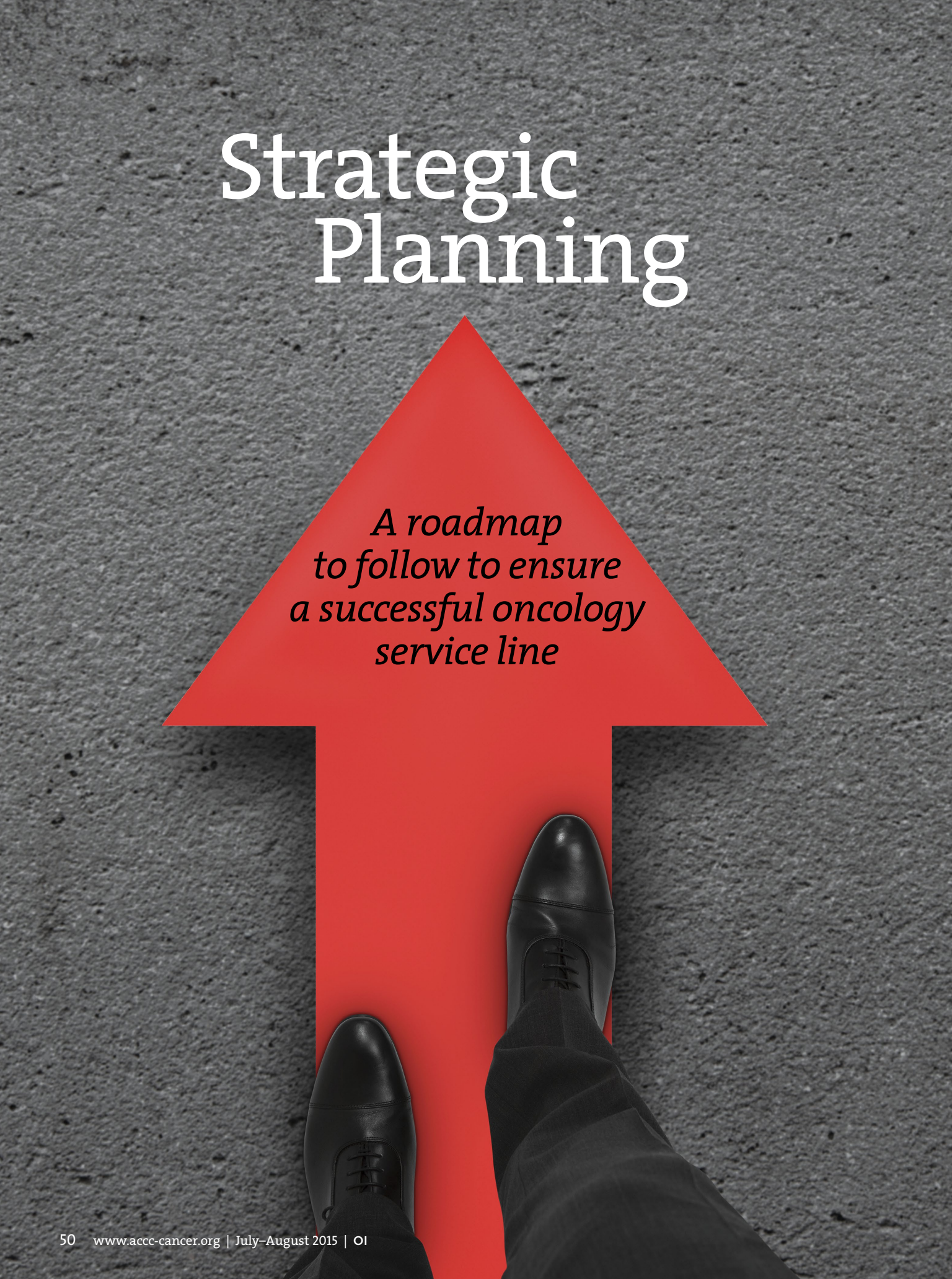


BY RYAN LANGDALE, MBA

In Brief

For many hospitals and health systems, oncology may have only recently been recognized as a "service-line," due in large part to the unique nature of cancer within the broader portfolio of hospital services. Oncology defies the norm for most hospital business—existing primarily in the outpatient setting, spanning multiple departments—and requires high capital investment, including spending for a range of supportive care services critical for its patient population. Many hospitals also find it challenging to clearly track the flow of oncology funds across multiple departments and disciplines. Yet, for successful program growth, it is important that strategic planning for oncology occur within this broader context.

This article examines the hallmark of successful oncology programs—an action-oriented strategic planning process, specific to the unique nature of cancer care—and assesses the "must haves" for cancer program planning, offering a roadmap to follow for effective oncology strategy. In making the case for oncology-specific planning, we draw on the lessons learned through our nearly 1,900 cancer planning engagements across the country over the past 42 years.

The Oncology Opportunity

In a recent strategic planning session, our team listened to a hospital CEO share a sobering assessment of his organization with the assembled leadership. He explained that fiscal year 2014 margins had been squeezed, growth opportunities were limited, and the community was rapidly losing confidence in the hospital's ability to meet its financial obligations. His message that morning was quite candid: identify novel areas for growth or face acquisition by a larger healthcare system. This mandate had brought us to the table, as the CEO believed that cancer care might be one of the few remaining opportunities for revenue growth and preservation of organizational independence.

Why was oncology viewed as such a singularly important opportunity? For this hospital, and many like it around the country, cancer care has traditionally taken a back seat in terms of institutional priority. The reasons for this are myriad, but largely boil down to competing organizational interests and a lack of knowledge specific to the economics of cancer care. Oncology is notoriously hard to pin down from a planning perspective—patients access cancer services across an array of departments, making it difficult to clearly delineate operational responsibility and identify the true financial contribution to the enterprise. For this reason, the oncology service line has not always had a strong voice in developing meaningful, specific organizational strategy.

But the needle has moved substantially in recent years. Overall population growth—coupled with an aging population—have fueled a meteoric rise in cancer diagnoses and increased visibility for oncology services. Progressive healthcare systems have invested heavily in cancer, ushering in a new age of community-based care. The rest of the country, once on the sidelines, is now rushing head-long into the business of cancer and seeking to become providers of choice in their respective regions. In this rush, we find that many organizations are failing to appreciate the complexity of the undertaking.

The planning team must appreciate that while the oncology market is growing, it is still very much a referral-driven business, and understanding those referrals today requires a global perspective.

The Market Imperative

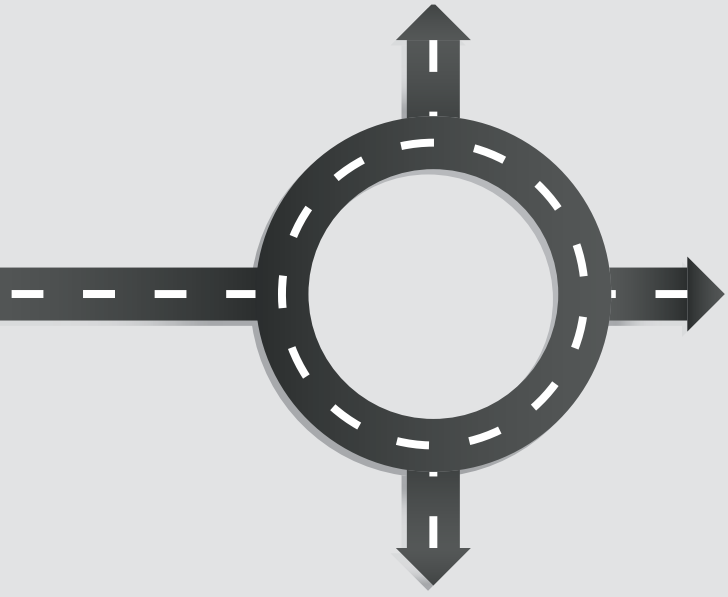
Two well-documented drivers of the increasing demand for oncology services are the growing number of cancer survivors—owing to the advances in cancer care over recent decades—and the growing, aging population in the U.S. For hospitals and health systems evaluating their institutional readiness for this surge in demand, consider the following: For every 100,000 people in your hospital service area, 500 to 600 will be diagnosed with cancer this year, and another 4,000 to 5,000 are currently living with the disease. By the year 2020, these numbers will reliably be 20 to 30 percent higher.[1]

The projected increase in demand for cancer services is both an opportunity and a challenge. Each new cancer patient uses a host of inpatient and outpatient services throughout his or her cancer journey—diagnostic, surgical, and adjuvant treatment phases. These services represent substantial opportunity in the form of program revenue contribution. At the same time, increased demand from new cancer diagnoses, newly insured patients, and expanded coverage for screening services is beginning to seriously challenge underprepared organizations.[2]

The growing market is a key factor to consider in planning strategically for the oncology service line. However, forecasting is not simply about estimating potential cancer cases and the impact on demand for downstream services. The planning team must appreciate that while the oncology market is growing, it is still very much a referral-driven business, and understanding those referrals today requires a global perspective.

The shift toward "value-based care" is rapidly realigning the shared-savings incentives of the primary care referral base. This, in turn, is rendering age-old patterns of referral inert and

CREATING AN ONCOLOGY ROADMAP



Whether your cancer program engages outside expertise or not, we suggest your organization keep the following elements central to your approach:

- ✔ A strategic plan in oncology cannot be created in isolation and cannot be a static document. The most effective plans are those developed with broad input from executive and physician leadership (at times, even those physicians who work with your competitors).
- ✔ The cancer plan should coordinate a 3- to 5-year roadmap and no further. We find that planning beyond that horizon introduces far too much uncertainty and reduces the organizational imperative to move quickly.
- ✔ The strategic plan should emanate from a broadly supported cancer program "vision statement," allowing for meaningful and measureable goals accomplished in a specific time frame.

placing a renewed emphasis on high-quality, low-cost providers. At the same time, payers are taking a more active hand in steering care to "providers of choice," making it challenging for patients to choose from a full provider menu in their narrowing networks. As this dynamic continues to evolve, hospitals will need to be cognizant of these changes and not rely on "business as usual" tactics in planning for maintenance or growth in their oncology service line.

The Business Imperative

For effective strategic planning, hospitals must also be able to quantify the true business impact of the oncology service line. In our experience, we find that the hospital C-Suite is often on unfamiliar ground with cancer. Unlike other hospital service lines, oncology services are predominantly delivered in the outpatient setting, span multiple departments, and are resistant to the categorization necessary for traditional program budgeting and contribution analysis. We commonly refer to our oncology service line financial assessments as "virtual" budgets, as they use specific ICD-9 diagnosis sets to corral all inpatient and outpatient services associated with cancer patients across the enterprise. The end result of this analysis is typically eye-opening for the C-Suite.

On average, a new cancer case in a fully-aligned healthcare system (meaning the patient stays in the system from diagnosis through, surgery, medical, and/or radiation oncology) creates $20,000 to 25,000 in contribution margin. These patients often remain in the system for follow-up care and co-morbidities as well. Many cancer programs that we have worked with have found that oncology accounts for 15 to 20 percent of total hospital net revenues, despite the fact that after surgical intervention much of outpatient cancer care is provided in the private practice setting.

While high-level analyses may serve other service lines, oncology strategic planning also requires a detailed, tumor-specific accounting of the financial contribution made by disease-site programs (e.g., breast, thoracic, colorectal). These analyses inform the strategy and tactics that allow an organization to protect access, attract patients, and provide a superior service as competitors seek to do the same.

Physician & Patient Imperatives

Oncology planning must also account for the paradigm shift underway with physician specialists. All across the country is already happening now—and is likely here to stay. Plan with the knowledge that academic medical centers are affiliating, purchasing, or otherwise aligning with programs in traditional community hospital catchment areas. Plan with an understanding that oncology is ever more an outpatient service, and that legacy acute-care strategies will not survive the next 10 years. Finally, plan with an approach that is collaborative, action-oriented, and seeks to listen first—as the alternative unilateral, top-down approach is rarely successful in the world of cancer care.

- ✔ While it is tempting to focus strategy on bricks and mortar, do not neglect medical leadership; physician alignment and transactional opportunities; distributed network strategies; risk-based contracting models; clinical and supportive care program development; or process improvement.
- ✔ The market has migrated towards tumor-specific strategy, meaning patients want their cancer treated by sub-specialists, not cancer generalists. The strategic plan should bring together multiple stakeholders in a substantive way, creating tumor-specific "centers of emphasis" that are intrinsically marketable. Explore all program elements to ensure that you are consistent with this value proposition.
- ✔ Our final advice would be to plan with the broadest context possible. Plan with the realization that cancer volumes are increasing precipitously and that oncology risk-based payment

physicians are reassessing the private practice model and evaluating meaningful alignment with hospitals. The Community Oncology Alliance reports that between 2007 and 2013, 469 medical oncology practices were aligned or purchased by hospitals.[3] For the medical oncologist, this alignment can provide financial stability in a reimbursement landscape that has been volatile in recent years. For the hospital, alignment can improve care coordination, increase patient volume, and offer the opportunity to develop an integrated IT and EHR infrastructure. In some cases, hospitals may realize a significant financial contribution from provider-based chemotherapy.

In our experience, the most successful oncology programs are built with fully aligned medical and radiation oncologists. Successful alignments are a product of proactive and carefully planned discussions between the hospital and physician practice. Those partnerships that fall short, resulting in broader "strategic" failures for the hospital, are overwhelmingly due to poor planning and a lack of oncology business understanding on the part of the hospital.

Strategic planning should also recognize that oncology referrals remain predominantly driven by primary care providers (PCPs), meaning the hospital must have a strategy for communicating a clear and consistent message about the value of their cancer program. Some of our clients have stated that their expanding medical groups will create a captive oncology referral base and reduce the need to communicate value or invest in services. In reality, this has not been the case. We've seen so-called "aligned" physicians continue to refer wherever they find the best possible value for their patients in terms of timeliness, coordination, experience, outcomes, and cost.

Perhaps the most important reason to plan with oncology specificity is the unique needs of the patient and his or her support system. Cancer is an overwhelming and terrifying diagnosis, requiring a level of care coordination unprecedented with most hospital programs. Unfortunately, this elevated level of support is quite rare, as evidenced by the Institute of Medicine's recent "Delivering High Quality Cancer Care: Charting a New Course for a System in Crisis" report.[4] As the IOM surmises, hospitals are ill-prepared to offer a "concierge" experience to patients, and the results have been dissatisfied customers, sub-par clinical outcomes, and leakage of business to academic medical centers for basic, community care. For this reason, many of the cancer programs that we have worked with recently have produced strategic visions that are focused on providing "patient-centered" care. This focus mandates attention to programmatic elements that put both physician and the patient at the center of all decision making.

The cancer programs that truly prosper in our experience are those that place strategic focus—and investment—on the resources necessary to manage the entire continuum of cancer care. This begins with the realization that today's cancer patients are savvy and demand more than just clinical excellence for their care. It further requires institutional buy-in and understanding that non-revenue producing program elements (e.g., patient navigation, survivorship, palliative care, clinical research) provide indirect financial returns. In some cases, it takes a true leap of faith when the strategic plan calls for multi-million dollar capital investments in cancer centers, linear accelerators, and the infrastructure necessary to provide comprehensive care. Our overwhelming experience is that the hospitals with a willingness to plan carefully—and invest with fortitude—enjoy substantial returns on both financial investment and goodwill and loyalty in their communities. OI

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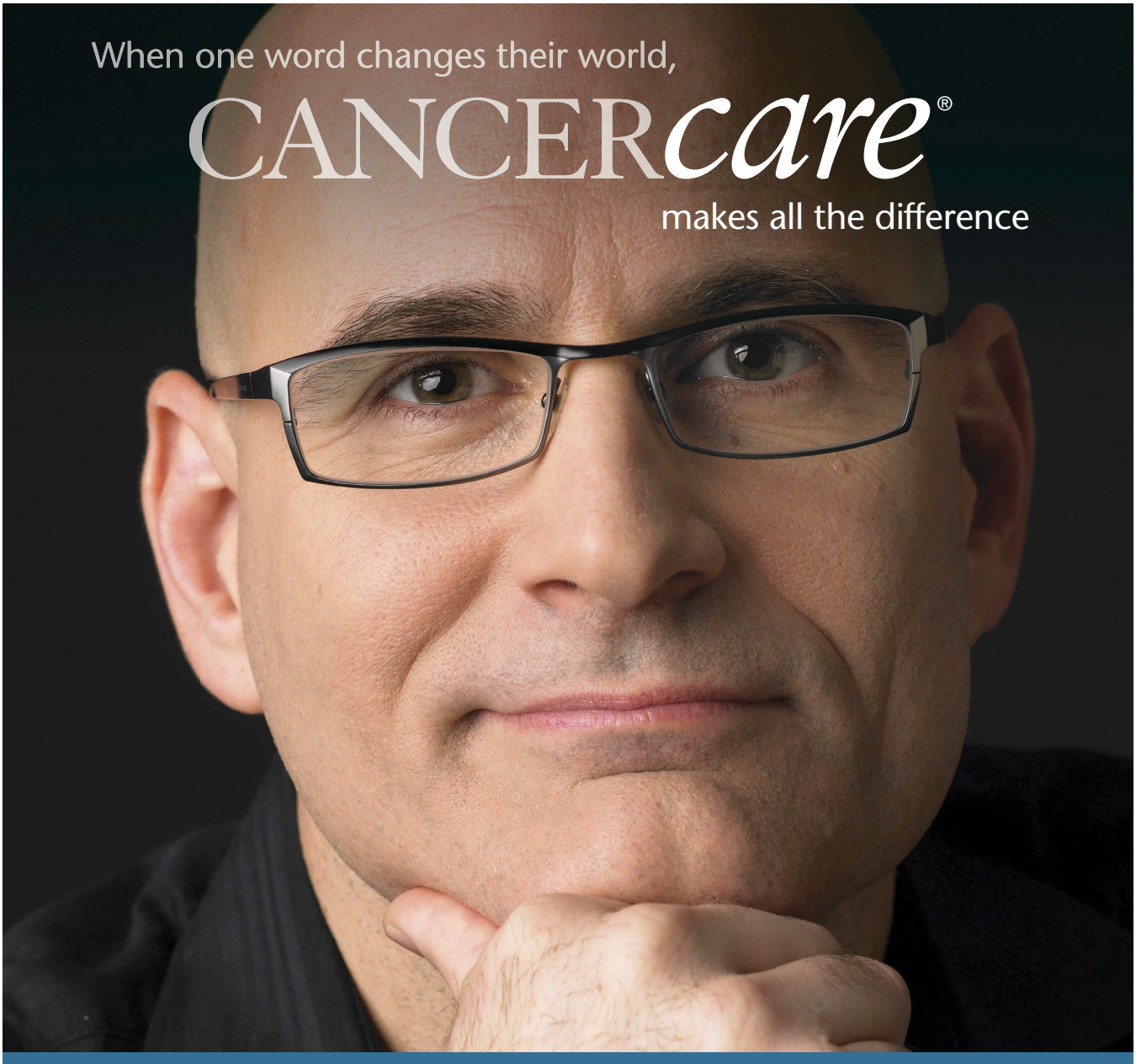

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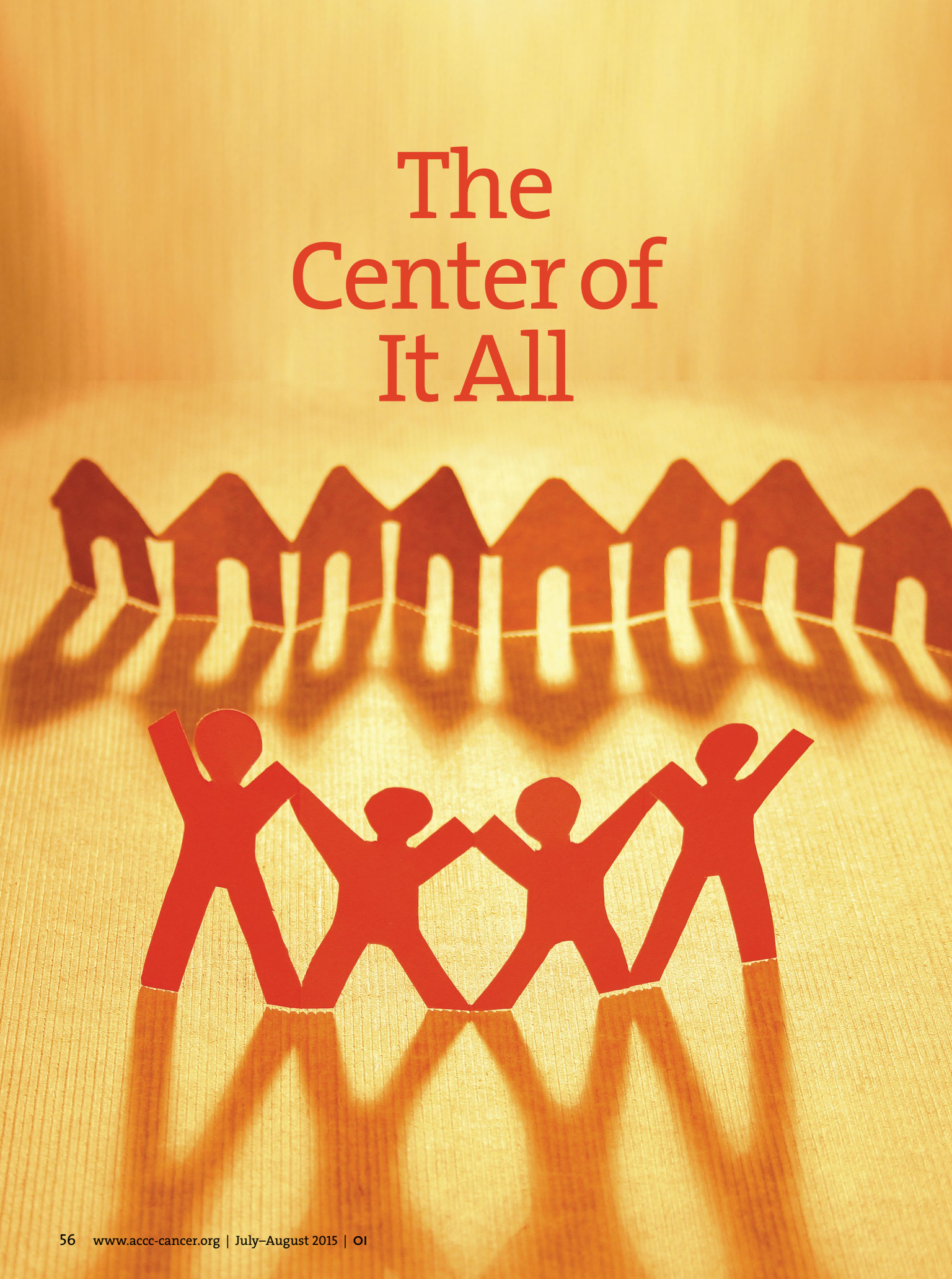


BY AMBER GREGG, MSHCPM,
AND KAREN SCHMIDT, CTR

How cancer programs are at the intersection of community needs assessments

The healthcare quality movement continues to gain traction as payers, consumers, and accrediting bodies increasingly push for greater accountability for results from providers. All aspects of the healthcare system have been impacted by the push for continuous quality improvement, including the field of cancer care.

Recent quality efforts have zeroed in on a desire to ensure that care is patient-centered and responsive to community needs—with widespread implications for cancer care providers. Pinpointing the healthcare needs of the community—and crafting effective strategies to respond to those needs—is a central theme of recent reform efforts. This article clarifies the role that community needs assessments play in helping oncology programs achieve or maintain accreditation while also creating effective programs and outreach strategies that respond to identified cancer care needs in the community.

Your Cancer Program's Role in Assessing and Responding to CHNAs

To develop the most effective programs and community outreach activities, hospitals routinely conduct community health needs assessments (CHNAs) to gain a clearer picture of the health concerns in their service areas. Though hospitals across the country have conducted these assessments for many years, the Affordable Care Act (ACA) included provisions that *mandated* CHNAs and a corresponding implementation plan to address pressing health needs at least once every three years for all non-profit hospitals.

Pinpointing the healthcare needs of the community—and crafting effective strategies to respond to those needs—is a central theme of recent reform efforts.

CHNAs provide a useful starting point for cancer programs looking to identify the demographics of their population and barriers to care. CHNAs help hospitals gain deeper insight into the greatest health problems in their communities and prioritize health needs that they are well positioned to address. For example, one hospital's CHNA might reveal that low rates of prenatal care are a central health need and hospital programs can be created or enhanced to better address this need. Another hospital's CHNA might find that cancer rates are particularly high in certain neighborhoods and preventive efforts to reverse this trend can be implemented.

CoC Cancer Program Standards and Community Needs

The American College of Surgeons Commission on Cancer (CoC) accredits cancer programs that meet comprehensive, rigorous standards focused on promoting accountable cancer care and

continuous quality improvement.[1] Almost 70 percent of recently-diagnosed cancer cases in the U.S. are treated by one of the more than 1,500 CoC-accredited cancer programs.[2] Similar yet distinct from the CHNA requirement discussed above is the community needs assessment requirement necessary for cancer programs to achieve or maintain CoC accreditation.[3]

Consistent with the overall trend in healthcare, the most recent version of the CoC standards—*Cancer Program Standards 2012, Version 1.2.1: Ensuring Patient-Centered Care*— places a heightened focus on outcomes and quality of care. The latest version of the CoC standards addresses quality and outcomes by determining if cancer programs are helping to effectively meet the needs of the communities they serve. Understanding how well cancer programs are addressing community needs is crucial given that the majority of cancer care in the U.S. is community-based.[4]

Several of the CoC cancer program standards require cancer programs to complete a community needs assessment at least once during the three-year CoC survey cycle. The community needs assessment should be designed to gain a deeper understanding of the unmet cancer care needs in the community, existing healthcare disparities related to cancer care, and available resources to address gaps in care.

Informed by the results of community needs assessments, the following CoC standards specifically require cancer programs to develop and/or modify strategies to better address these identified needs.

Cancer Program Standard 3.1: Patient Navigation Process

As cancer care has grown more complex, patients increasingly need guidance as they move along the healthcare continuum to ensure they receive timely, high-quality care. Enter patient navigation—a process to help guide patients around and through barriers to obtaining the right care at the right time in the right setting.

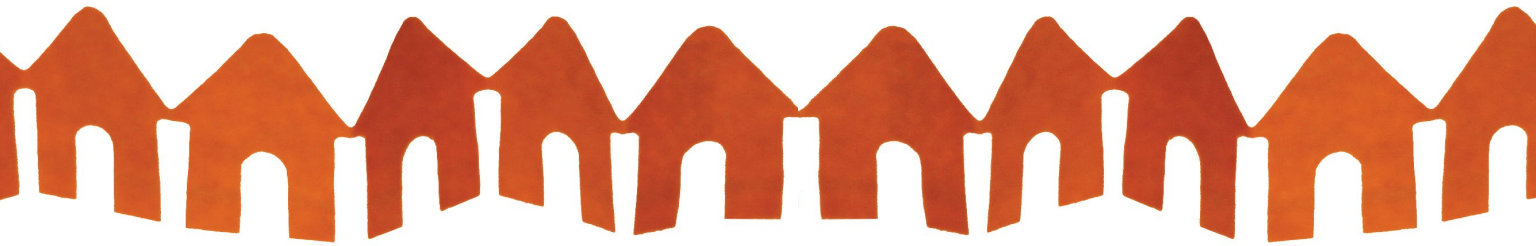
To achieve CoC accreditation, Standard 3.1 requires that cancer programs have a patient navigation process, informed by a community needs assessment, to address healthcare disparities and barriers to care. The literature is clear that certain populations, such as racial and ethnic minorities, individuals with disabilities, and residents of rural areas, are at higher risk for health disparities. Once barriers to care are identified, CoC Standard 3.1 states that resources can either be provided onsite or through referrals to community-based or national organizations. Cancer programs were required to have this standard phased in by Jan. 1, 2015.

Cancer Program Standard 4.1: Prevention Programs

Also taking into account the needs of the community as identified by the community needs assessment, Standard 4.1 requires that the cancer committee provide at least one cancer prevention program annually. This program should be designed to reduce the incidence of a specific cancer type and can be provided onsite or coordinated with other agencies and/or facilities. Furthermore, the cancer prevention program should be consistent with evidence-based national guidelines for cancer prevention. Guidance suggests that a prevention program that meets this standard encompasses more than handing out literature about cancer programs or providing a lecture. Follow-up and surveillance are integral.

Cancer Program Standard 4.2: Screening Programs

Also related to addressing community needs is Standard 4.2, which requires that the cancer committee provide at least one cancer screening program targeted to decreasing the number of patients with late-stage disease. The cancer registry is ideally suited to identify a cancer that often presents in a late stage. Mirroring the CoC's guidance related to prevention programs, screening programs should be based on community needs and be consistent with evidence-based national guidelines for cancer



prevention. The location of a screening program can be either onsite and/or coordinated with other organizations or facilities. Furthermore, the cancer program should develop a process to follow up on all positive findings.

In many communities, cancer rates are among the greatest health needs and areas of concern unveiled by CHNAs and community needs assessments. The results of each of these assessments can lead hospitals to:

- Increase cancer screenings in underserved areas
- Target educational programming aimed at increasing preventive care and decreasing rates of late-stage cancers among certain populations
- Identify groups at high-risk of certain cancers and develop programs to more closely monitor at-risk groups.

Going Forward

Effectively addressing the needs of the community cannot be achieved without high-performing cancer programs. Hospital cancer programs provide numerous benefits to the community, including:

- Screening programs and community outreach activities
- Patient support initiatives within the hospital
- Research to further establish best practices in cancer care
- Education to those who contribute to excellence in patient care.

As payers, consumers, and accrediting bodies continue to push for care that is patient-centered and responsive to community needs, cancer care providers can harness the power of community needs assessments to pinpoint where to target crucial programming.

Amber Gregg, MSHCPM, is director of Analytics and Innovation and Karen Schmidt, CTR, is a CoC-trained consultant and associate vice president, CHAMPS Oncology.

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Website: www.wheatoniowa.org

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In February, the Center for Medicare and Medicaid Innovation (CMMI) at the Centers for Medicare & Medicaid Services (CMS) announced a new, voluntary program available to physician practices that administer chemotherapy to fee-for-service (FFS) Medicare beneficiaries. The Oncology Care Model (OCM) will focus on the total cost of care for cancer patients undergoing chemotherapy during a six-month episode and tie payments to performance based on meeting certain quality metrics and practice transformation requirements. The Oncology Care Model program will last for five years and is slated to begin in Spring 2016. CMMI expects this model will produce better health outcomes, higher quality care, and lower Medicare costs for Medicare beneficiaries with cancer. Learn more about the OCM and how it may affect the oncology community at www.accc-cancer.org/OCM.

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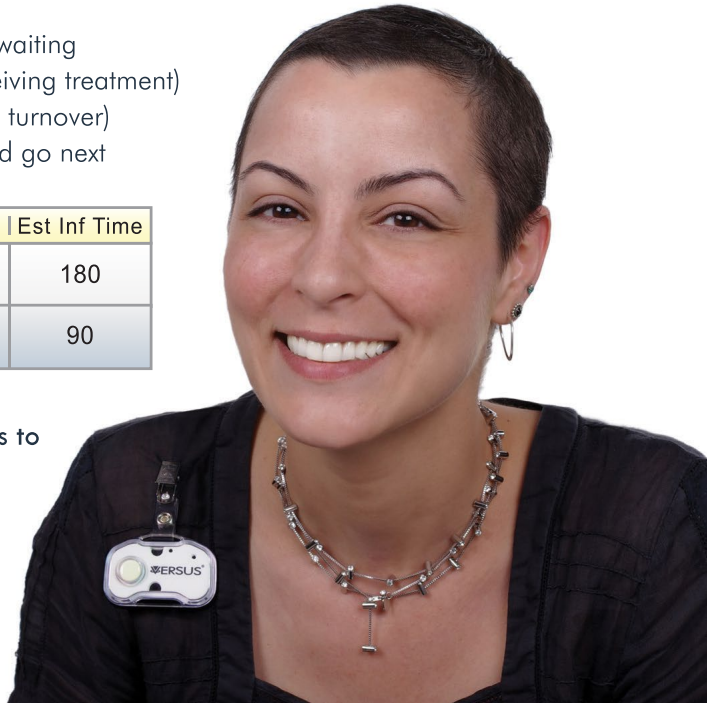
W.Carr	Inf 203B Chair	✓	✓	8:28AM	32	90



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The Importance of Being Part of ICLIO

BY TRACY VIRGILIO, RN, BSN, CCRC, OCN

Being an advocate, researcher, and an oncology nurse I felt that it was important to get involved in the Association of Community Cancer Center's (ACCC) Institute for Clinical Immuno-Oncology (ICLIO) initiative. It is a great opportunity to network with other medical oncology providers, oncology nurses, and administrators to gain knowledge from them and hear the challenges they face in immuno-oncology. Partnering together, oncology providers can prepare for the future of immuno-oncology, working with legislators to make changes that will affect the overall future in the delivery of quality oncology care.

I have been working in this field for more than 16 years now and have seen much advancement in oncology treatment. The advent of immunotherapy is completely changing the scope of oncology. Cancer treatments are becoming more individualized for each patient. With the ever-evolving oncology landscape, I believe that the science behind immunotherapy will shape the future of how we treat cancer patients. Each patient is different—different genetically and different in how the individual tolerates and responds to chemotherapy. It is only a matter of time before we see cancer providers start to design care plans tailored to specific patients.

The Hope Offered by Clinical Trials

Over the years I have been very fortunate to be involved in the clinical trial aspect of oncology. While working on the clinical trial front, I provided patients with new treatments and—most important—hope! Hope that they would get a second chance to see their children graduate, get married, and see their first grandchild being born. We offered therapies to patients who were given a three-month survival status and watched them break the mold by living for more than five years. All of these advancements were made possible by the early immuno-oncology therapies. Living past those three months was something these patients had not dreamed of at the time of diagnosis. And those trials paved the way for new ones.

I learned much from those early immuno-oncology clinical trials, including how to handle treatment-related side effects. These new therapies revealed new side effects that were not seen in early trials. New strategies were developed to manage patients based on the new information that was quickly coming out of the trials. This experience gave me the skills to:

- Educate staff on the management of these therapies
- Create new patient education materials
- Discuss and develop new pathways with the physician champion for following up with the patients in the office setting.

Next Steps

Some of the activities that we are currently doing as a practice at Associates in Hematology-Oncology in Upland, Pa., is staying abreast of the new therapies by continuing clinical trial enrollment and holding weekly nursing in-services, which include nurse educators and members of the pharmaceutical industry, as well as their reimbursement specialists.

As part of the nursing in-service, we review patient cases and discuss how we can improve patient care and manage treatment side effects in order to maximize the benefits of the immunotherapy and decrease the risks to the patient. We extend education to physicians and nurses outside of the medical oncology arena, who may come in contact with these patients. We discuss with the nurse educators what other practices are doing to manage these emerging side effects, and then learn and adapt these new techniques for our patients. We encourage patients and caregivers to ask questions so we can optimize their treatment through these open forums.

Based on discussions between nurses and the physician champion, our practice has developed and built chemotherapy templates to reflect lab studies and other critical time points indicated in the prescribing information that will affect patient outcomes. These small changes in practice and staying current on new findings, new complications, and new indications, help our staff provide the information and education our patients and their families need to make more informed decisions in their care.

Financial & Reimbursement Challenges

Recently I have become more involved with the financial and reimbursement aspect of oncology. The financial challenges new therapies create for patients make our job of providing immuno-oncology and chemotherapy medications ever more complex.

In our practice—as with many others—collaborative discussions between the financial counselor, billing department, and reimbursement specialists have become more common place. We leverage the expertise of these team members to help get therapies approved for patients and to ensure proper coding and billing practices. These discussions and meetings are quite useful as we often gain insight into challenges faced by other oncology practices, as well as payer roadblocks.

It is also important for us to know how to find funding for those patients who are in or will be in a financial crisis due to the cost of these new therapies. Having adequate funding available is especially critical to the patient and caregiver during this stressful time.

As I was finishing up this article, Twitter was all a-buzz about the new advancements—and upcoming financial challenges of immuno-oncology treatments—being discussed at this year's American Society of Clinical Oncology (ASCO) meeting in June 2015. I have to say, Dr. Leonard Saltz summed up his talk with the perfect quote from Dr. Seuss, "Unless someone like you cares a whole awful lot, nothing is going to get better. It's not." For this reason I am looking forward to partnering with ACCC and ICLIO and welcome the opportunity to bring benefit—and hope—to the oncology community and, most importantly, our patients.

Tracy Virgilio, RN, BSN, CCRC, OCN, has worked at Associates in Hematology-Oncology in Upland, Pa., for the last eight years as director of Patient Advocacy and Clinical Research. As part of her role, she acts as a clinical and financial liaison for the practice. Ms. Virgilio is also serving as an ICLIO Scholar.

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MammaPrint® provides more information about your patient's breast cancer recurrence risk with definitive, High Risk/Low Risk results. **BluePrint®** classifies Luminal-type, Basal-type and HER2-type functional molecular subtypes. Together, they reveal more clinically actionable biology:

- MammaPrint + BluePrint can reclassify up to 25% of breast cancers with potential therapeutic and prognostic implications, according to a study published in *Cancer Research.*[1]
- Most recently, NBRST, a prospective neoadjuvant study, concluded that BluePrint may be a better guide than IHC-FISH tests in making decisions about how to treat early-stage breast cancer before surgery.[2]

For more clinically actionable information, order MammaPrint + BluePrint to uncover your patient's functional molecular subtype. The difference is clear.

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1 Cristofanilli M, et al. *Cancer Res.* 2012;72(24 Suppl):Abstract nr P3-05-01.
2 Whitworth P, et al. *Ann Surg Oncol.* 2014 Aug 7.
[Epub ahead of print];doi: 10.1245/s10434-014-3908-y.

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