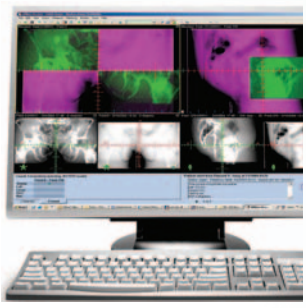
ONCOLOGY ISSUES

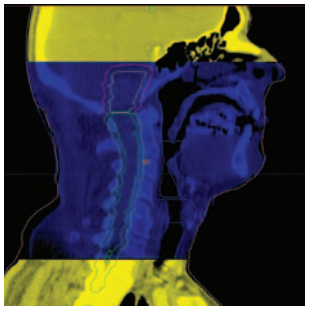
The Journal of the Association of Community Cancer Centers

July | August 2012

Putting the Pieces Together

Community & academic affiliation





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Oncology Issues
July | August 2012
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DEPARTMENTS

ACCC
Association of Community Cancer Centers

ONCOLOGY ISSUES
The Journal of the
Association of Community Cancer Centers

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

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

FROM THE EDITOR

Ready Player One

BY CHRISTIAN DOWNS, JD, MHA

Back in high school, one of my football coach's favorite methods of teaching was to gather the players in the film room and say something to the effect of:

"*Okay* (insert the name of any flower native to southwest Virginia), *today we're going to learn how to* (insert whatever the team did wrong in the previous game). *Watch this film and see how* (insert any Hall of Famer) *does it. See how easy that is? Now, do it like that* (insert the name of another flower native to southwest Virginia)."

At the time I didn't appreciate his technique, but looking back I now understand that my coach was trying to teach the team through a real-world example or experience. Now, using Hall of Famers is not always the most effective motivator. And in all fairness to my coach, he would occasionally use our team players from time to time. In fact, ol' number 64 was called out plenty of times—as an example of what ***not*** to do.

Today, I'm going to take this lesson from my former football coach and apply it to this edition of *Oncology Issues*.

We've heard from many of our readers that they value the real-world experiences of other community cancer centers. In fact, most readers have said it's these experiences—successes, challenges, triumphs, and sometimes even hardships—that they are most interested in rather than whether or not the cancer program is demographically similar.

So let's take a look at some of the "experiences" shared in this issue.

In our cover story, Cecilia Zapata and her colleague Benjamin Greer explore the hot topic of academic medical center and community cancer center affiliation. While the authors readily admit that there are no "cookie-cutter" approaches for this relationship model, they share their successful three-step affiliation process of assessments, site visits, and stakeholder reviews.

In another example of a shared experience, staff at Simmons Cancer Center writes about a programmatic evaluation that showed how they could improve care transitions across treatment settings. The solution: develop a patient and family focused transitional care program.

Finally, Aurora Health Care shares how it developed system-wide strategic planning for its multi-site robotically-assisted surgical program. The goal: to develop strategies to support adoption and growth of minimally invasive surgery while being mindful to demonstrate value, quality, and cost-effectiveness. Not doing robotic surgery? Take some of the principles and apply it to a program for genetic testing, Gamma Knife, or even molecular imaging.

If learning from shared experiences is for you, definitely check out ACCC's 2012 Innovator Awards, sponsored by GE Healthcare. In 2012, eleven ACCC member programs were selected by a panel of their peers to be recognized at the ACCC 29th National Oncology Conference in San Antonio, Tex., October 3–6, 2012. These innovators will share their forward-thinking strategic planning, creative solutions, and replicable models with meeting attendees.

So, come to San Antonio, learn from the experiences of ACCC's 2012 Innovator Award winners, and apply their lessons to your program. Who knows? Maybe next year, you'll hear:

"*ACCC is proud to announce that* (insert your cancer program here) *is a 2013 Innovator Award winner!*"

Take advantage of the early bird discount and register today! OI

PRESIDENT'S MESSAGE

Quality Cancer Care and Malpractice: The Elephant in the Room

BY GEORGE KOVACH, MD

One major concern regarding the Affordable Care Act was its failure to address malpractice reform as a means to control healthcare costs. Under the umbrella of malpractice costs lurks the slippery issue of defensive medicine (i.e., a medical practice designed to avert possible future malpractice suits).

Mello and colleagues writing on "National Costs of the Medical Liability System" in *Health Affairs* [2010;29(9)], state: "Although most scholars of malpractice agree that defensive medicine is highly prevalent, reliable estimates of its cost are notoriously difficult to obtain....." With that caveat, the authors did arrive at an estimated overall cost of defensive spending for both physicians and hospitals in 2008 of $45.6 billion.

Although a fraction of overall healthcare expenditures, defensive medicine is a pivotal reflection of a broken healthcare system. And if malpractice reform is not adequately addressed, continued liability fears will likely inhibit physicians moving toward cost-effective care delivery.

On the one hand, we have recent examples of potential cost-effective changes in care delivery, such as the recommendations by the American Board of Internal Medicine Foundation, in conjunction with nine specialty boards, toward reducing 45 tests or procedures that have limited medical value. ASCO provided five cost-effective changes (*http://choosingwisely.org*) addressing treatment of advanced refractory solid tumors, staging of prostate and breast cancers, surveillance of post-adjuvant breast cancer patients, and the use of cytokines. Recently, the United States Preventive Services Task Force (USPSTF) made its controversial recommendations regarding PSA screening. As a practicing oncologist for 35 years, I find the ASCO recommendations very appropriate. The USPSTF recommendations, I view with skepticism, an indication of the reality that these approaches will require time for universal acceptance. NCCN has provided excellent treatment guidelines as a proof of concept and such similar guidelines should be encouraged.

On the other hand, in Oct. 2011, the Washington State Supreme Court recognized "loss of chance" as a new cause of action. Just what do those words mean? The "loss of chance" doctrine was affirmed by the Ninth Circuit Court in 1972, involving "what might have been" if medical treatment occurred earlier in the diagnosis of a disease, limiting damages if there was less than a 50 percent chance of survival or improvement. More recently, however, less than 50 percent has been accepted. Liability for future potential medical problems is also gaining popularity. Therefore, failure to monitor is becoming an acceptable tort, with precedent set in Massachusetts in 2009, and now accepted in Ohio and West Virginia. How will this factor affect the new ASCO and PSA guidelines? I would expect cautious and slow acceptance of the guidelines in order to avoid liability, impeding attempts to lessen defensive medicine practices.

What's the solution? Any solution must involve discussion of tort reform along with the medical community doing a better job of defining best practices and guidelines for clinicians and educating the public on the best treatment options and outcomes. Collaboration within the oncology community can lead to rapid determination and development of evidence-based diagnostic, treatment, and survivorship guidelines. We need to address the "elephant in the room" before others do it for us. OI

Coming in Your 2012 *ONCOLOGY ISSUES*

- Cancer Management Systems
- Creating a Culture of Partnership—Taking Multidisciplinary Care Beyond Theory to Practice
- Implementing a Service Excellence Program
- 6 Critical Success Factors for Increasing Patient Throughput
- Two Model Cancer Survivorship Programs: TACTIC and THRIVE
- Adding a Dedicated FTE for Quality and Safety
- New Cancer Center Design—Non-moving Patient and LEAN Design
- Clinical Business Tools for Evaluating and Managing Radiation Oncology
- Cancer Center Registry: Employee vs. Independent Contractor
- A Day in the Life of a Patient Navigator

more online @ www.accc-cancer.org

ACCC's 2012 Innovator Award Recipients

VIDEO

Hear directly from the award recipients as they describe their innovative programs in these new videos on: *www.youtube.com/user/ACCCvision*.

Multiple Myeloma Survey

SURVEY

ACCC recognizes that treating and supporting the multiple myeloma patient presents major challenges to the healthcare team at community cancer centers. We need your help in completing this survey to identify specific ways that we can meet your needs. Take our survey by **July 27, 2012** at: *www.accc-cancer.org/multiplemyeloma*.

ACCC Member Toolkit

TOOL

The latest tools to help you and your team make the most of ACCC membership. Explore the toolkit by clicking on any image in the online toolbelt at: *www.accc-cancer.org/accessyourtools*.

The Financing of Hospital-based Chemotherapy: Implications for Drug Selection

WEBINAR

Newly-affiliated medical oncologists or those considering hospital affiliation can learn how to measure relative costs of chemotherapy in hospital IP and OP settings. Explore the basis for reimbursement for drug-based cancer care in ambulatory and IP systems and review specific cases to learn how hospital P&T committees select drugs. To participate, go to: *www.accc-cancer.org/openweb/OPENeducation-webinar-medicaloncology.asp*.

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fast

Healthcare Professionals & Social Media

- In 2011, 1 in 3 healthcare professionals surveyed cited use of social media when searching for a job, compared with 1 in 5 in 2010.
- Nearly half of all healthcare professionals surveyed said they use social media for professional networking.
- More healthcare professionals are using mobile job alerts year-over-year and success rates are up as well. Of those using job alerts, 10% received an interview, 14% received a job offer, and 8% secured a job.
- Physicians continue to be the heaviest users of mobile devices among their medical colleagues for professional reasons; 41% of physicians cited use of mobile devices or tablets for healthcare-related content or jobs in 2011.
- Facebook was once again chosen by 3 out of 4 healthcare professionals surveyed as their most favored site for career-seeking opportunities.

Source: AMN Healthcare. *http://www.amnhealthcare.com*

TOP APPS FOR DOCS

The Merck Manual

Micromedex Drug Information

VisualDx

The Oncologist

Anatomy 3D–Organs

Epic Canto

Mobile MIM

Source: *MobiHealthNews.com*

facts

Tips to Help Hospitals Thrive—Not Just Survive—on Medicare Margins

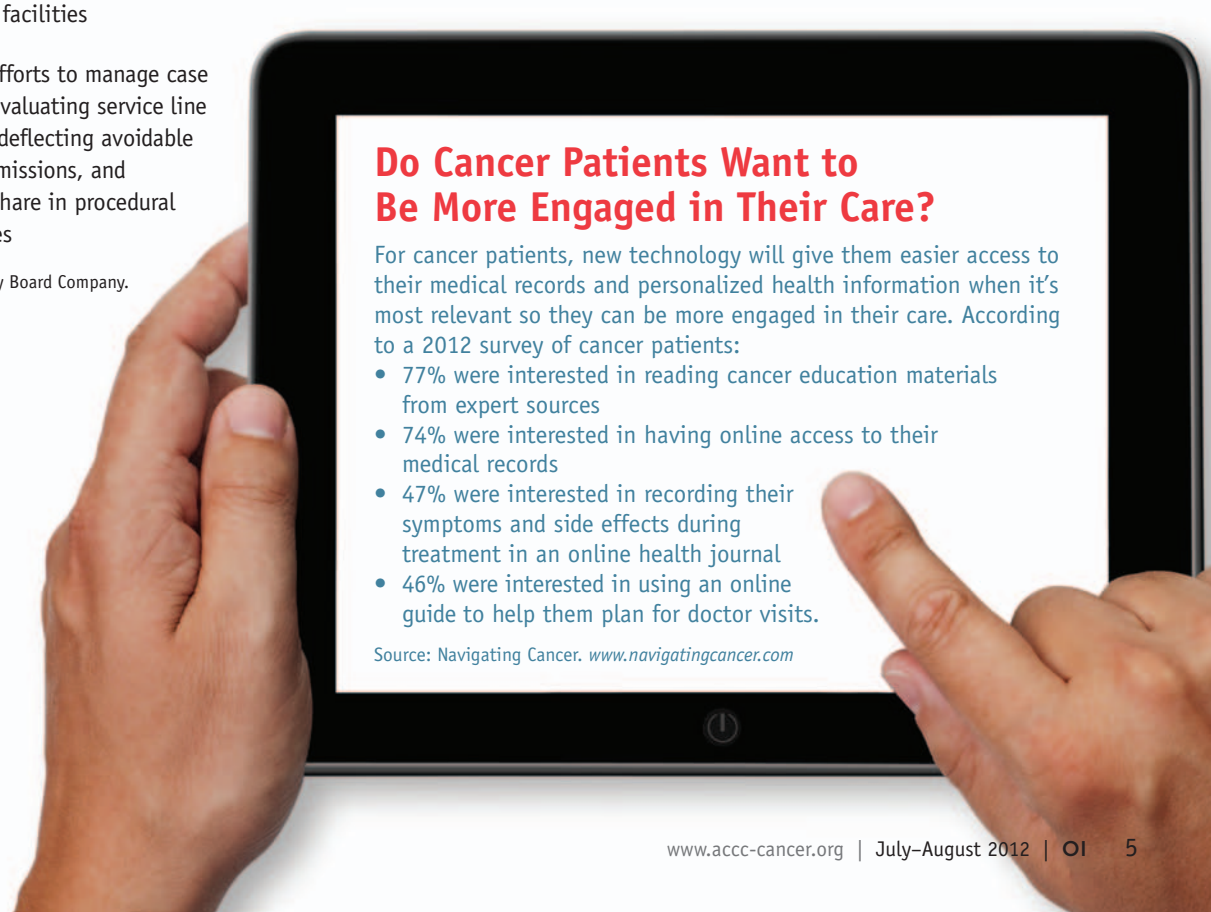
1. Sustained focus on rationalizing labor spending
2. Standardization of clinical protocols
3. Development of team-based care models
4. Best-in-class revenue cycle operations
5. Demonstrated performance on all value-based purchasing contracts
6. Gains in effective capacity by improving throughput and investing in less-costly outpatient facilities
7. Proactive efforts to manage case mix by re-evaluating service line portfolios, deflecting avoidable medical admissions, and capturing share in procedural service lines

Source: The Advisory Board Company. *www.advisory.com*

122 MILLION ADULTS COULD HAVE PRE-EXISTING CONDITIONS

Between 36 million and 122 million adults (20%–66% of adults 19 to 64 years old) have medical conditions that could result in their being denied health insurance coverage if they tried to buy it through the individual market, according to a Government Accountability Office report. Cancer was the condition with the highest average annual treatment expenditure, at about $9,000.

Source: *Health Care Daily Report,* April 27, 2012.



Do Cancer Patients Want to Be More Engaged in Their Care?

For cancer patients, new technology will give them easier access to their medical records and personalized health information when it's most relevant so they can be more engaged in their care. According to a 2012 survey of cancer patients:

- 77% were interested in reading cancer education materials from expert sources
- 74% were interested in having online access to their medical records
- 47% were interested in recording their symptoms and side effects during treatment in an online health journal
- 46% were interested in using an online guide to help them plan for doctor visits.

Source: Navigating Cancer. *www.navigatingcancer.com*

USPSTF Gives PSA Test "D" Grade

On May 21 the U.S. Preventive Services Task Force (USPSTF) gave the prostate-specific antigen (PSA) test a grade of "D," essentially saying that the test may not be appropriate as it is being used currently. This recommendation runs counter to what has become common practice in many primary care, urology, and oncology offices across the country.

After reviewing two large studies, the USPSTF panel expressed its belief that PSA tests saved the life of just one man out of 1,000. In addition, the panel believes that for every man saved by PSA testing, another one will develop a blood clot, two will have heart attacks, and another 40 will develop incontinence or impotence due to unnecessary treatments.

Will the USPSTF recommendation change how the PSA test is given and how it is paid for? The answer to the first part is that practice will likely change very little due to this recommendation. Many men currently are given the option to take the PSA test, and many will opt for it. Men with lower risk factors may delay the test, perhaps; however, it is safe to say that the PSA test is not likely to disappear any time soon.

The second half of the question is harder to answer. Most insurers will not do anything right away to change their policies. Large insurers have already said that while they will review the data from the studies, they believe that PSA testing is still an important part of prevention of prostate cancer. Payers may eventually put some limitations on the test based on risk factors or age, but doing so will take some time.

Medicare coverage is also tricky. Because of the Affordable Care Act, patients can receive preventive tests at no cost if the tests have a positive recommendation from the USPSTF. With this change, it is possible that PSA tests will not be eligible for this coverage. Medicare will still likely cover the test, but the test would fall out of the preferred category. Only time and more studies will tell if this decision has a major impact on the practice of medicine. Stay tuned to ACCC for more information.

ACCC Submits Comments on Medication Non-Adherence and EHR Meaningful Use Criteria

On May 7 ACCC submitted comments to the Office of the Surgeon General regarding the causes, impact, and potential solutions for prescription medication non-adherence, which can increase costs to the patient, health plans, and society.

ACCC members identified four potential solutions for non-adherence:

1. Physicians or other members of a patient's healthcare team should contact the patient within 72 hours after prescribing a medication to ensure that the patient fills the prescription, understands how to take the medication, and understands potential side effects.
2. Pharmacists and/or insurers should educate patients and physicians about therapeutic substitutions and how they affect the dosing regimen prescribed by the physician.
3. Policymakers should develop an "electronic pill box" that explains the differences between medications and helps patients understand when to take their medications.
4. The Centers for Medicare & Medicaid Services (CMS) and other payers should continue to implement programs that help reduce patients' out-of-pocket costs for medications, such as the provisions in the Patient Protection and Affordable Care Act that close the Medicare Part D "donut hole."

On a separate issue, ACCC submitted comments to CMS on the proposed rule specifying Stage 2 electronic health record (EHR) meaningful use criteria and related matters for eligible professionals, eligible hospitals, and critical access hospitals.

IOM's CEO Checklist for High-Value Health Care

The Institute of Medicine (IOM) has developed a checklist of procedures and organizational tools that providers can use to deliver high-quality care at lower cost. The 10-item checklist is divided into four categories: foundation elements, infrastructure fundamentals, care delivery priorities, and reliability and feedback. The checklist includes the following as essential to delivery of high-quality, lower-cost care:

- Senior leadership committed to

continued on page 12

Announcing: J-code for YERVOY™ (ipilimumab) J9228

Indication

YERVOY (ipilimumab) is indicated for the treatment of unresectable or metastatic melanoma.[1]

J-code for YERVOY[2]

HCPCS Code	Description	Effective
J9228[a]	Injection, ipilimumab, 1 mg	January 1, 2012

[a]Replaces J9999, J3490, J3590, and C9284.

Product Description	 50-mg/10 mL (5 mg/mL), single-use vial of YERVOY	 200-mg/40 mL (5 mg/mL), single-use vial of YERVOY
NDC Number		
10-digit	0003-2327-11	0003-2328-22
11-digit	00003-2327-11	00003-2328-22

*The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol-Myers Squibb and its agents **make no guarantee** regarding reimbursement for any service or item. This coding guidance is not intended to provide specific directions on requesting prior authorization or submitting claims for* YERVOY *and does not provide a guarantee of receiving prior authorization or reimbursement. Oncology practices need to make coding decisions based on the diagnosis and treatment of each patient and the specific insurer requirements.*

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Important Safety Information

WARNING: IMMUNE-MEDIATED ADVERSE REACTIONS

YERVOY can result in severe and fatal immune-mediated adverse reactions due to T-cell activation and proliferation. These immune-mediated reactions may involve any organ system; however, the most common severe immune-mediated adverse reactions are enterocolitis, hepatitis, dermatitis (including toxic epidermal necrolysis), neuropathy, and endocrinopathy. The majority of these immune-mediated reactions initially manifested during treatment; however, a minority occurred weeks to months after discontinuation of YERVOY.

Assess patients for signs and symptoms of enterocolitis, dermatitis, neuropathy, and endocrinopathy and evaluate clinical chemistries including liver function tests (LFTs) and thyroid function tests at baseline and before each dose.

Permanently discontinue YERVOY and initiate systemic high-dose corticosteroid therapy for severe immune-mediated reactions.

Please see Important Safety Information, including **Boxed WARNING regarding immune-mediated adverse reactions**, continued on the following pages.

REFERENCES **1.** YERVOY (ipilimumab) [package insert]. Princeton, NJ: Bristol-Myers Squibb; March 2011.
2. Alpha-numeric HCPCS. Centers for Medicare & Medicaid Services Web site. http://www.cms.gov/HCPCSReleaseCodeSets/Downloads/12anweb.zip. Accessed November 1, 2011.

YERVOY™ (ipilimumab)
Injection for intravenous infusion

Important Safety Information (cont)

Recommended Dose Modifications

Withhold dose for any moderate immune-mediated adverse reactions or for symptomatic endocrinopathy until return to baseline, improvement to mild severity, or complete resolution, and patient is receiving <7.5 mg prednisone or equivalent per day.

Permanently discontinue YERVOY for any of the following:

- Persistent moderate adverse reactions or inability to reduce corticosteroid dose to 7.5 mg prednisone or equivalent per day
- Failure to complete full treatment course within 16 weeks from administration of first dose
- Severe or life-threatening adverse reactions, including any of the following
  - Colitis with abdominal pain, fever, ileus, or peritoneal signs; increase in stool frequency (≥7 over baseline), stool incontinence, need for intravenous hydration for >24 hours, gastrointestinal hemorrhage, and gastrointestinal perforation
  - AST or ALT >5 × the upper limit of normal (ULN) or total bilirubin >3 × the ULN
  - Stevens-Johnson syndrome, toxic epidermal necrolysis, or rash complicated by full-thickness dermal ulceration or necrotic, bullous, or hemorrhagic manifestations
  - Severe motor or sensory neuropathy, Guillain-Barré syndrome, or myasthenia gravis
  - Severe immune-mediated reactions involving any organ system
  - Immune-mediated ocular disease which is unresponsive to topical immunosuppressive therapy

Immune-mediated Enterocolitis:

- In the pivotal Phase 3 study in YERVOY-treated patients, severe, life-threatening or fatal (diarrhea of ≥7 stools above baseline, fever, ileus, peritoneal signs; Grade 3-5) immune-mediated enterocolitis occurred in 34 (7%) and moderate (diarrhea with up to 6 stools above baseline, abdominal pain, mucus or blood in stool; Grade 2) enterocolitis occurred in 28 (5%) patients
- Across all YERVOY-treated patients (n=511), 5 (1%) developed intestinal perforation, 4 (0.8%) died as a result of complications, and 26 (5%) were hospitalized for severe enterocolitis
- Infliximab was administered to 5 of 62 (8%) patients with moderate, severe, or life-threatening immune-mediated enterocolitis following inadequate response to corticosteroids
- Monitor patients for signs and symptoms of enterocolitis (such as diarrhea, abdominal pain, mucus or blood in stool, with or without fever) and of bowel perforation (such as peritoneal signs and ileus). In symptomatic patients, rule out infectious etiologies and consider endoscopic evaluation for persistent or severe symptoms
- Permanently discontinue YERVOY in patients with severe enterocolitis and initiate systemic corticosteroids (1-2 mg/kg/day of prednisone or equivalent). Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue over at least 1 month. In clinical trials, rapid corticosteroid tapering resulted in recurrence or worsening symptoms of enterocolitis in some patients
- Withhold YERVOY for moderate enterocolitis; administer anti-diarrheal treatment and, if persistent for >1 week, initiate systemic corticosteroids (0.5 mg/kg/day prednisone or equivalent)

Immune-mediated Hepatitis:

- In the pivotal Phase 3 study in YERVOY-treated patients, severe, life-threatening, or fatal hepatotoxicity (AST or ALT elevations >5x the ULN or total bilirubin elevations >3x the ULN; Grade 3–5) occurred in 8 (2%) patients, with fatal hepatic failure in 0.2% and hospitalization in 0.4%
- 13 (2.5%) additional YERVOY-treated patients experienced moderate hepatotoxicity manifested by LFT abnormalities (AST or ALT elevations >2.5x but ≤5x the ULN or total bilirubin elevation >1.5x but ≤3x the ULN; Grade 2)
- Monitor LFTs (hepatic transaminase and bilirubin levels) and assess patients for signs and symptoms of hepatotoxicity before each dose of YERVOY. In patients with hepatotoxicity, rule out infectious or malignant causes and increase frequency of LFT monitoring until resolution
- Permanently discontinue YERVOY in patients with Grade 3-5 hepatotoxicity and administer systemic corticosteroids (1-2 mg/kg/day of prednisone or equivalent). When LFTs show sustained improvement or return to baseline, initiate corticosteroid tapering and continue over 1 month. Across the clinical development program for YERVOY, mycophenolate treatment has been administered in patients with persistent severe hepatitis despite high-dose corticosteroids
- Withhold YERVOY in patients with Grade 2 hepatotoxicity

Immune-mediated Dermatitis:

- In the pivotal Phase 3 study in YERVOY-treated patients, severe, life-threatening or fatal immune-mediated dermatitis (e.g., Stevens-Johnson syndrome, toxic epidermal necrolysis, or rash complicated by full thickness dermal ulceration, or necrotic, bullous, or hemorrhagic manifestations; Grade 3–5) occurred in 13 (2.5%) patients
  - 1 (0.2%) patient died as a result of toxic epidermal necrolysis
  - 1 additional patient required hospitalization for severe dermatitis
- There were 63 (12%) YERVOY-treated patients with moderate (Grade 2) dermatitis
- Monitor patients for signs and symptoms of dermatitis such as rash and pruritus. Unless an alternate etiology has been identified, signs or symptoms of dermatitis should be considered immune-mediated
- Permanently discontinue YERVOY in patients with severe, life-threatening, or fatal immune-mediated dermatitis (Grade 3-5). Administer systemic corticosteroids (1-2 mg/kg/day of prednisone or equivalent). When dermatitis is controlled, corticosteroid tapering should occur over a period of at least 1 month. Withhold YERVOY in patients with moderate to severe signs and symptoms

Please see brief summary of Full Prescribing Information, including **Boxed WARNING regarding immune-mediated adverse reactions**, on the following spread.

YERVOY™
(ipilimumab)
Injection for intravenous infusion

Important Safety Information (cont)

- Treat mild to moderate dermatitis (e.g., localized rash and pruritus) symptomatically. Administer topical or systemic corticosteroids if there is no improvement within 1 week

Immune-mediated Neuropathies:

- In the pivotal Phase 3 study in YERVOY-treated patients, 1 case of fatal Guillain-Barré syndrome and 1 case of severe (Grade 3) peripheral motor neuropathy were reported
- Across the clinical development program of YERVOY, myasthenia gravis and additional cases of Guillain-Barré syndrome have been reported
- Monitor for symptoms of motor or sensory neuropathy such as unilateral or bilateral weakness, sensory alterations, or paresthesia. Permanently discontinue YERVOY in patients with severe neuropathy (interfering with daily activities) such as Guillain-Barré–like syndromes
- Institute medical intervention as appropriate for management of severe neuropathy. Consider initiation of systemic corticosteroids (1-2 mg/kg/day of prednisone or equivalent) for severe neuropathies. Withhold YERVOY in patients with moderate neuropathy (not interfering with daily activities)

Immune-mediated Endocrinopathies:

- In the pivotal Phase 3 study in YERVOY-treated patients, severe to life-threatening immune-mediated endocrinopathies (requiring hospitalization, urgent medical intervention, or interfering with activities of daily living; Grade 3-4) occurred in 9 (1.8%) patients
  - All 9 patients had hypopituitarism, and some had additional concomitant endocrinopathies such as adrenal insufficiency, hypogonadism, and hypothyroidism
  - 6 of the 9 patients were hospitalized for severe endocrinopathies
- Moderate endocrinopathy (requiring hormone replacement or medical intervention; Grade 2) occurred in 12 (2.3%) YERVOY-treated patients and consisted of hypothyroidism, adrenal insufficiency, hypopituitarism, and 1 case each of hyperthyroidism and Cushing's syndrome
- Median time to onset of moderate to severe immune-mediated endocrinopathy was 11 weeks and ranged up to 19.3 weeks after the initiation of YERVOY
- Monitor patients for clinical signs and symptoms of hypophysitis, adrenal insufficiency (including adrenal crisis), and hyper- or hypothyroidism
  - Patients may present with fatigue, headache, mental status changes, abdominal pain, unusual bowel habits, and hypotension, or nonspecific symptoms which may resemble other causes such as brain metastasis or underlying disease. Unless an alternate etiology has been identified, signs or symptoms should be considered immune-mediated
  - Monitor thyroid function tests and clinical chemistries at the start of treatment, before each dose, and as clinically indicated based on symptoms. In a limited number of patients, hypophysitis was diagnosed by imaging studies through enlargement of the pituitary gland
- Withhold YERVOY in symptomatic patients. Initiate systemic corticosteroids (1-2 mg/kg/day of prednisone or equivalent) and initiate appropriate hormone replacement therapy. Long-term hormone replacement therapy may be necessary

Other Immune-mediated Adverse Reactions, Including Ocular Manifestations:

- In the pivotal Phase 3 study in YERVOY-treated patients, clinically significant immune-mediated adverse reactions seen in <1% were: nephritis, pneumonitis, meningitis, pericarditis, uveitis, iritis, and hemolytic anemia
- Across the clinical development program for YERVOY, immune-mediated adverse reactions also reported with <1% incidence were: myocarditis, angiopathy, temporal arteritis, vasculitis, polymyalgia rheumatica, conjunctivitis, blepharitis, episcleritis, scleritis, leukocytoclastic vasculitis, erythema multiforme, psoriasis, pancreatitis, arthritis, and autoimmune thyroiditis
- Permanently discontinue YERVOY for clinically significant or severe immune-mediated adverse reactions. Initiate systemic corticosteroids (1-2 mg/kg/day of prednisone or equivalent) for severe immune-mediated adverse reactions
- Administer corticosteroid eye drops for uveitis, iritis, or episcleritis. Permanently discontinue YERVOY for immune-mediated ocular disease unresponsive to local immunosuppressive therapy

Pregnancy & Nursing:

- YERVOY is classified as pregnancy category C. There are no adequate and well-controlled studies of YERVOY in pregnant women. Use YERVOY during pregnancy only if the potential benefit justifies the potential risk to the fetus
- Human IgG1 is known to cross the placental barrier and YERVOY is an IgG1; therefore, YERVOY has the potential to be transmitted from the mother to the developing fetus
- It is not known whether YERVOY is secreted in human milk. Because many drugs are secreted in human milk and because of the potential for serious adverse reactions in nursing infants from YERVOY, a decision should be made whether to discontinue nursing or to discontinue YERVOY

Common Adverse Reactions:

- The most common adverse reactions (≥5%) in patients who received YERVOY at 3 mg/kg were fatigue (41%), diarrhea (32%), pruritus (31%), rash (29%), and colitis (8%)

Please see brief summary of Full Prescribing Information, including **Boxed WARNING regarding immune-mediated adverse reactions**, on the following spread.

Bristol-Myers Squibb

731US11AB18319 01/12 Printed in USA

YERVOY™ (ipilimumab)
Injection for intravenous infusion

YERVOY™ (ipilimumab) Injection, for intravenous infusion ℞ ONLY

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

WARNING: IMMUNE-MEDIATED ADVERSE REACTIONS

YERVOY (ipilimumab) can result in severe and fatal immune-mediated adverse reactions due to T-cell activation and proliferation. These immune-mediated reactions may involve any organ system; however, the most common severe immune-mediated adverse reactions are enterocolitis, hepatitis, dermatitis (including toxic epidermal necrolysis), neuropathy, and endocrinopathy. The majority of these immune-mediated reactions initially manifested during treatment; however, a minority occurred weeks to months after discontinuation of YERVOY.

Permanently discontinue YERVOY and initiate systemic high-dose corticosteroid therapy for severe immune-mediated reactions. *[See Dosage and Administration (2.2)* in Full Prescribing Information*]*

Assess patients for signs and symptoms of enterocolitis, dermatitis, neuropathy, and endocrinopathy and evaluate clinical chemistries including liver function tests and thyroid function tests at baseline and before each dose. *[See Warnings and Precautions]*

INDICATIONS AND USAGE

YERVOY (ipilimumab) is indicated for the treatment of unresectable or metastatic melanoma.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

YERVOY can result in severe and fatal immune-mediated reactions due to T-cell activation and proliferation. *[See Boxed Warning]*

Immune-mediated Enterocolitis

In Study 1, severe, life-threatening, or fatal (diarrhea of 7 or more stools above baseline, fever, ileus, peritoneal signs; Grade 3–5) immune-mediated enterocolitis occurred in 34 (7%) YERVOY-treated patients, and moderate (diarrhea with up to 6 stools above baseline, abdominal pain, mucus or blood in stool; Grade 2) enterocolitis occurred in 28 (5%) YERVOY-treated patients. Across all YERVOY-treated patients (n=511), 5 (1%) patients developed intestinal perforation, 4 (0.8%) patients died as a result of complications, and 26 (5%) patients were hospitalized for severe enterocolitis.

The median time to onset was 7.4 weeks (range 1.6–13.4) and 6.3 weeks (range 0.3–18.9) after the initiation of YERVOY for patients with Grade 3–5 enterocolitis and with Grade 2 enterocolitis, respectively.

Twenty-nine patients (85%) with Grade 3–5 enterocolitis were treated with high-dose (≥40 mg prednisone equivalent per day) corticosteroids, with a median dose of 80 mg/day of prednisone or equivalent; the median duration of treatment was 2.3 weeks (ranging up to 13.9 weeks) followed by corticosteroid taper. Of the 28 patients with moderate enterocolitis, 46% were not treated with systemic corticosteroids, 29% were treated with <40 mg prednisone or equivalent per day for a median duration of 5.1 weeks, and 25% were treated with high-dose corticosteroids for a median duration of 10 days prior to corticosteroid taper. Infliximab was administered to 5 of the 62 patients (8%) with moderate, severe, or life-threatening immune-mediated enterocolitis following inadequate response to corticosteroids.

Of the 34 patients with Grade 3–5 enterocolitis, 74% experienced complete resolution, 3% experienced improvement to Grade 2 severity, and 24% did not improve. Among the 28 patients with Grade 2 enterocolitis, 79% experienced complete resolution, 11% improved, and 11% did not improve.

Monitor patients for signs and symptoms of enterocolitis (such as diarrhea, abdominal pain, mucus or blood in stool, with or without fever) and of bowel perforation (such as peritoneal signs and ileus). In symptomatic patients, rule out infectious etiologies and consider endoscopic evaluation for persistent or severe symptoms.

Permanently discontinue YERVOY in patients with severe enterocolitis and initiate systemic corticosteroids at a dose of 1 to 2 mg/kg/day of prednisone or equivalent. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least one month. In clinical trials, rapid corticosteroid tapering resulted in recurrence or worsening symptoms of enterocolitis in some patients.

Withhold YERVOY dosing for moderate enterocolitis; administer anti-diarrheal treatment and, if persistent for more than one week, initiate systemic corticosteroids at a dose of 0.5 mg/kg/day prednisone or equivalent. *[See Dosage and Administration (2.2)* in Full Prescribing Information*]*

Immune-mediated Hepatitis

In Study 1, severe, life-threatening, or fatal hepatotoxicity (AST or ALT elevations of more than 5 times the upper limit of normal or total bilirubin elevations more than 3 times the upper limit of normal; Grade 3–5) occurred in 8 (2%) YERVOY-treated patients, with fatal hepatic failure in 0.2% and hospitalization in 0.4% of YERVOY-treated patients. An additional 13 (2.5%) patients experienced moderate hepatotoxicity manifested by liver function test abnormalities (AST or ALT elevations of more than 2.5 times but not more than 5 times the upper limit of normal or total bilirubin elevation of more than 1.5 times but not more than 3 times the upper limit of normal; Grade 2). The underlying pathology was not ascertained in all patients but in some instances included immune-mediated hepatitis. There were insufficient numbers of patients with biopsy-proven hepatitis to characterize the clinical course of this event.

Monitor liver function tests (hepatic transaminase and bilirubin levels) and assess patients for signs and symptoms of hepatotoxicity before each dose of YERVOY. In patients with hepatotoxicity, rule out infectious or malignant causes and increase frequency of liver function test monitoring until resolution.

Permanently discontinue YERVOY in patients with Grade 3–5 hepatotoxicity and administer systemic corticosteroids at a dose of 1 to 2 mg/kg/day of prednisone or equivalent. When liver function tests show sustained improvement or return to baseline, initiate corticosteroid tapering and continue to taper over 1 month. Across the clinical development program for YERVOY, mycophenolate treatment has been administered in patients who have persistent severe hepatitis despite high-dose corticosteroids. Withhold YERVOY in patients with Grade 2 hepatotoxicity. *[See Dosage and Administration (2.2)* in Full Prescribing Information*]*

Immune-mediated Dermatitis

In Study 1, severe, life-threatening, or fatal immune-mediated dermatitis (eg, Stevens-Johnson syndrome, toxic epidermal necrolysis, or rash complicated by full thickness dermal ulceration, or necrotic, bullous, or hemorrhagic manifestations; Grade 3–5) occurred in 13 (2.5%) YERVOY-treated patients. One (0.2%) patient died as a result of toxic epidermal necrolysis and one additional patient required hospitalization for severe dermatitis. There were 63 (12%) patients with moderate (Grade 2) dermatitis.

The median time to onset of moderate, severe, or life-threatening immune-mediated dermatitis was 3.1 weeks and ranged up to 17.3 weeks from the initiation of YERVOY (ipilimumab).

Seven (54%) YERVOY-treated patients with severe dermatitis received high-dose corticosteroids (median dose 60 mg prednisone/day or equivalent) for up to 14.9 weeks followed by corticosteroid taper. Of these 7 patients, 6 had complete resolution; time to resolution ranged up to 15.6 weeks.

Of the 63 patients with moderate dermatitis, 25 (40%) were treated with systemic corticosteroids (median of 60 mg/day of prednisone or equivalent) for a median of 2.1 weeks, 7 (11%) were treated with only topical corticosteroids, and 31 (49%) did not receive systemic or topical corticosteroids. Forty-four (70%) patients with moderate dermatitis were reported to have complete resolution, 7 (11%) improved to mild (Grade 1) severity, and 12 (19%) had no reported improvement.

Monitor patients for signs and symptoms of dermatitis such as rash and pruritus. Unless an alternate etiology has been identified, signs or symptoms of dermatitis should be considered immune-mediated.

Permanently discontinue YERVOY in patients with Stevens-Johnson syndrome, toxic epidermal necrolysis, or rash complicated by full thickness dermal ulceration, or necrotic, bullous, or hemorrhagic manifestations. Administer systemic corticosteroids at a dose of 1 to 2 mg/kg/day of prednisone or equivalent. When dermatitis is controlled, corticosteroid tapering should occur over a period of at least 1 month. Withhold YERVOY dosing in patients with moderate to severe signs and symptoms. *[See Dosage and Administration (2.2)* in Full Prescribing Information*]*

For mild to moderate dermatitis, such as localized rash and pruritus, treat symptomatically. Administer topical or systemic corticosteroids if there is no improvement of symptoms within 1 week.

Immune-mediated Neuropathies

In Study 1, one case of fatal Guillain-Barré syndrome and one case of severe (Grade 3) peripheral motor neuropathy were reported. Across the clinical development program of YERVOY, myasthenia gravis and additional cases of Guillain-Barré syndrome have been reported.

Monitor for symptoms of motor or sensory neuropathy such as unilateral or bilateral weakness, sensory alterations, or paresthesia. Permanently discontinue YERVOY in patients with severe neuropathy (interfering with daily activities) such as Guillain-Barré-like syndromes. Institute medical intervention as appropriate for management of severe neuropathy. Consider initiation of systemic corticosteroids at a dose of 1 to 2 mg/kg/day prednisone or equivalent for severe neuropathies. Withhold YERVOY dosing in patients with moderate neuropathy (not interfering with daily activities). *[See Dosage and Administration (2.2)* in Full Prescribing Information*]*

Immune-mediated Endocrinopathies

In Study 1, severe to life-threatening immune-mediated endocrinopathies (requiring hospitalization, urgent medical intervention, or interfering with activities of daily living; Grade 3–4) occurred in 9 (1.8%) YERVOY-treated patients. All 9 patients had hypopituitarism and some had additional concomitant endocrinopathies such as adrenal insufficiency, hypogonadism, and hypothyroidism. Six of the 9 patients were hospitalized for severe endocrinopathies. Moderate endocrinopathy (requiring hormone replacement or medical intervention; Grade 2) occurred in 12 (2.3%) patients and consisted of hypothyroidism, adrenal insufficiency, hypopituitarism, and one case each of hyperthyroidism and Cushing's syndrome. The median time to onset of moderate to severe immune-mediated endocrinopathy was 11 weeks and ranged up to 19.3 weeks after the initiation of YERVOY.

Of the 21 patients with moderate to life-threatening endocrinopathy, 17 patients required long-term hormone replacement therapy including, most commonly, adrenal hormones (n=10) and thyroid hormones (n=13).

Monitor patients for clinical signs and symptoms of hypophysitis, adrenal insufficiency (including adrenal crisis), and hyper- or hypothyroidism. Patients may present with fatigue, headache, mental status changes, abdominal pain, unusual bowel habits, and hypotension, or nonspecific symptoms which may resemble other causes such as brain metastasis or underlying disease. Unless an alternate etiology has been identified, signs or symptoms of endocrinopathies should be considered immune-mediated.

Monitor thyroid function tests and clinical chemistries at the start of treatment, before each dose, and as clinically indicated based on symptoms. In a limited number of patients, hypophysitis was diagnosed by imaging studies through enlargement of the pituitary gland.

Withhold YERVOY dosing in symptomatic patients. Initiate systemic corticosteroids at a dose of 1 to 2 mg/kg/day of prednisone or equivalent, and initiate appropriate hormone replacement therapy. *[See Dosage and Administration (2.2)* in Full Prescribing Information*]*

Other Immune-mediated Adverse Reactions, Including Ocular Manifestations

The following clinically significant immune-mediated adverse reactions were seen in less than 1% of YERVOY-treated patients in Study 1: nephritis, pneumonitis, meningitis, pericarditis, uveitis, iritis, and hemolytic anemia.

Across the clinical development program for YERVOY, the following likely immune-mediated adverse reactions were also reported with less than 1% incidence: myocarditis, angiopathy, temporal arteritis, vasculitis, polymyalgia rheumatica, conjunctivitis, blepharitis, episcleritis, scleritis, leukocytoclastic vasculitis, erythema multiforme, psoriasis, pancreatitis, arthritis, and autoimmune thyroiditis.

Permanently discontinue YERVOY for clinically significant or severe immune-mediated adverse reactions. Initiate systemic corticosteroids at a dose of 1 to 2 mg/kg/day prednisone or equivalent for severe immune-mediated adverse reactions.

Administer corticosteroid eye drops to patients who develop uveitis, iritis, or episcleritis. Permanently discontinue YERVOY for immune-mediated ocular disease that is unresponsive to local immunosuppressive therapy. *[See Dosage and Administration (2.2)* in Full Prescribing Information*]*

ADVERSE REACTIONS

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

- Immune-mediated enterocolitis *[see Warnings and Precautions]*.
- Immune-mediated hepatitis *[see Warnings and Precautions]*.
- Immune-mediated dermatitis *[see Warnings and Precautions]*.
- Immune-mediated neuropathies *[see Warnings and Precautions]*.
- Immune-mediated endocrinopathies *[see Warnings and Precautions]*.
- Other immune-mediated adverse reactions, including ocular manifestations *[see Warnings and Precautions]*.

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed cannot be directly compared with rates in other clinical trials or experience with therapeutics in the same class and may not reflect the rates observed in clinical practice.

The clinical development program excluded patients with active autoimmune disease or those receiving systemic immunosuppression for organ transplantation. Exposure to YERVOY (ipilimumab) 3 mg/kg for four doses given by intravenous infusion in previously treated patients with unresectable or metastatic melanoma was assessed in a randomized, double-blind clinical study (Study 1). *[See Clinical Studies (14)* in Full Prescribing Information*]* One hundred thirty-one patients (median age 57 years, 60% male) received YERVOY as a single agent, 380 patients (median age 56 years, 61% male) received YERVOY with an investigational gp100 peptide vaccine (gp100), and 132 patients (median age 57 years, 54% male) received gp100 peptide vaccine alone. Patients in the study received a median of 4 doses (range 1 to 4 doses). YERVOY was discontinued for adverse reactions in 10% of patients.

The most common adverse reactions (≥5%) in patients who received YERVOY at 3 mg/kg were fatigue, diarrhea, pruritus, rash, and colitis.

Table 1 presents selected adverse reactions from Study 1, which occurred in at least 5% of patients in the YERVOY-containing arms and with at least 5% increased incidence over the control gp100 arm for all-grade events and at least 1% incidence over the control group for Grade 3–5 events.

Table 1: Selected Adverse Reactions in Study 1

	Percentage (%) of Patients[a]					
	YERVOY 3 mg/kg n=131		YERVOY 3 mg/kg+gp100 n=380		gp100 n=132	
System Organ Class/ Preferred Term	Any Grade	Grade 3–5	Any Grade	Grade 3–5	Any Grade	Grade 3–5
Gastrointestinal Disorders						
Diarrhea	32	5	37	4	20	1
Colitis	8	5	5	3	2	0
Skin and Subcutaneous Tissue Disorders						
Pruritus	31	0	21	<1	11	0
Rash	29	2	25	2	8	0
General Disorders and Administration Site Conditions						
Fatigue	41	7	34	5	31	3

[a] Incidences presented in this table are based on reports of adverse events regardless of causality.

Table 2 presents the per-patient incidence of severe, life-threatening, or fatal immune-mediated adverse reactions from Study 1.

Table 2: Severe to Fatal Immune-mediated Adverse Reactions in Study 1

	Percentage (%) of Patients	
	YERVOY 3 mg/kg n=131	YERVOY 3 mg/kg+gp100 n=380
Any Immune-mediated Adverse Reaction	15	12
Enterocolitis[a,b]	7	7
Hepatotoxicity[a]	1	2
Dermatitis[a]	2	3
Neuropathy[a]	1	<1
Endocrinopathy	4	1
Hypopituitarism	4	1
Adrenal insufficiency	0	1
Other		
Pneumonitis	0	<1
Meningitis	0	<1
Nephritis	1	0
Eosinophilia[c]	1	0
Pericarditis[a,c]	0	<1

[a] Including fatal outcome.

[b] Including intestinal perforation.

[c] Underlying etiology not established.

Across clinical studies that utilized YERVOY doses ranging from 0.3 to 10 mg/kg, the following adverse reactions were also reported (incidence less than 1% unless otherwise noted): urticaria (2%), large intestinal ulcer, esophagitis, acute respiratory distress syndrome, renal failure, and infusion reaction.

Based on the experience in the entire clinical program for melanoma, the incidence and severity of enterocolitis and hepatitis appear to be dose dependent.

Immunogenicity

In clinical studies, 1.1% of 1024 evaluable patients tested positive for binding antibodies against ipilimumab in an electrochemiluminescent (ECL) based assay. This assay has substantial limitations in detecting anti-ipilimumab antibodies in the presence of ipilimumab. Infusion-related or peri-infusional reactions consistent with hypersensitivity or anaphylaxis were not reported in these 11 patients nor were neutralizing antibodies against ipilimumab detected.

Because trough levels of ipilimumab interfere with the ECL assay results, a subset analysis was performed in the dose cohort with the lowest trough levels. In this analysis, 6.9% of 58 evaluable patients, who were treated with 0.3 mg/kg dose, tested positive for binding antibodies against ipilimumab.

Immunogenicity assay results are highly dependent on several factors including assay sensitivity and specificity, assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of incidence of antibodies to YERVOY with the incidences of antibodies to other products may be misleading.

DRUG INTERACTIONS

No formal drug-drug interaction studies have been conducted with YERVOY (ipilimumab).

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C

There are no adequate and well-controlled studies of YERVOY in pregnant women. Use YERVOY during pregnancy only if the potential benefit justifies the potential risk to the fetus.

In a combined study of embryo-fetal and peri-postnatal development, severe toxicities including increased incidences of third-trimester abortion, stillbirth, premature delivery, low birth weight, and infant mortality occurred following intravenous administration of ipilimumab to pregnant cynomolgus monkeys every 21 days from the onset of organogenesis through parturition at doses of 2.6 or 7.2 times the recommended human dose of 3 mg/kg (by AUC). *[See Nonclinical Toxicology (13.2)* in Full Prescribing Information*]*

In genetically engineered mice in which the gene for CTLA-4 has been deleted (a "knockout mouse"), offspring lacking CTLA-4 were born apparently healthy, but died within 3–4 weeks due to multi-organ infiltration and damage by lymphocytes.

Human IgG1 is known to cross the placental barrier and ipilimumab is an IgG1; therefore, ipilimumab has the potential to be transmitted from the mother to the developing fetus.

Nursing Mothers

It is not known whether ipilimumab is secreted in human milk. Because many drugs are secreted in human milk and because of the potential for serious adverse reactions in nursing infants from YERVOY, a decision should be made whether to discontinue nursing or to discontinue YERVOY, taking into account the importance of YERVOY to the mother.

Pediatric Use

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

Geriatric Use

Of the 511 patients treated with YERVOY at 3 mg/kg, 28% were 65 years and over. No overall differences in safety or efficacy were reported between the elderly patients (65 years and over) and younger patients (less than 65 years).

Renal Impairment

No formal studies of YERVOY in patients with renal impairment have been conducted. *[See Clinical Pharmacology (12.3)* in Full Prescribing Information*]*

Hepatic Impairment

No formal studies of YERVOY in patients with hepatic impairment have been conducted. *[See Clinical Pharmacology (12.3)* in Full Prescribing Information*]*

OVERDOSAGE

There is no information on overdosage with YERVOY.

PATIENT COUNSELING INFORMATION

See MEDICATION GUIDE in Full Prescribing Information.

- Inform patients of the potential risk of immune-mediated adverse reactions.
- Advise patients to read the YERVOY Medication Guide before each YERVOY infusion.
- Advise women that YERVOY may cause fetal harm.
- Advise nursing mothers not to breast-feed while taking YERVOY.

Manufactured by: Bristol-Myers Squibb Company
Princeton, NJ 08543 USA

Bristol-Myers Squibb
Princeton, NJ 08543 U.S.A.

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this goal

- Organizational culture of continuous improvement
- Comprehensive IT systems in place
- Practice of evidence-based care
- Internal transparency regarding performance, outcomes, and costs.

The checklist is available at *www.iom.edu/Global/Perspectives/2012/CEOChecklist.aspx*.

Major Health Insurers to Keep Some Health Reform Measures, Regardless of Supreme Court's Decision

On June 11 three major health insurers announced their intention to keep some provisions of the health reform law, regardless of the U.S. Supreme Court's ruling, according to *BNA Health Care Daily Report*.

UnitedHealthcare and Humana Inc., announced they will keep five health insurance reform provisions already in effect. Aetna, Inc., said it will keep at least three provisions currently in effect.

The UnitedHealthcare and Humana provisions being retained are:

- Preventive health services without copayments.
- Dependent coverage up to age 26. Coverage will be offered on parents' plans, regardless of young adults' eligibility for other insurance coverage, whether they are in school, or whether they are married.
- Elimination of lifetime coverage limits.
- No rescissions of health coverage, except for in cases of fraud or intentional misrepresentation of material facts.
- Provision of what Humana terms "a clear and simple process for appeals claims decisions," as well as the option to have cases reviewed by independent organizations.

For updates on the Supreme Court decision visit *acccbuzz.wordpress.com*.

ACCC Medical Home Survey Results

An ACCC survey of 217 administrators, oncologists and oncology nurses—63 percent of whom work in a hospital-based cancer program—showed that a majority are familiar with the medical home concept and most believe the oncology home model could work in their practice or hospital cancer service line.

In fact, the great majority of respondents believe that within five years they will be practicing as part of an ACO and/or a medical home. By 2017 only 25 percent of respondents believe their facility will keep its current staffing and billing structure. Thirty-two percent envision their practice or hospital being part of both an ACO and medical home, 26 percent believe their facility will join or become an ACO, and 18 percent anticipate becoming a medical home. Forty-six respondents said they believe a medical home could provide better-quality, collaborative care at lower costs, and they would consider applying for recognition from the National Committee for Quality Assurance (NCQA).

At the same time, the survey revealed concerns. Most respondents (more than 90 percent) say they are concerned about medical home and ACO start-up costs and payer negotiations.

Responses were mixed on whether these changes will be favorable. While 45 percent believe moving away from the buy-and-bill model will result in better patient care, 15 percent believe it won't. And 33 percent of respondents said the change will negatively impact providers.

The survey was conducted as part of the oncology medical home theme of ACCC Immediate Past-President Thomas Whittaker, MD, FACP.

PCORI Update

In a recently released preliminary draft report, the Patient-Centered Outcomes Research Institute (PCORI) indicated that it might include electronic health records in future comparative effectiveness research (CER) efforts. The draft report, generated by PCORI's Methodology Committee, is provided as a resource for use by applicants for PCORI funding announcements. The draft suggests that PCORI will eventually recommend how to use the millions of electronic medical records from doctor and hospital visits each year—that are not currently useable—for comparative effectiveness research. But first PCORI must tackle the medical, financial, and political hurdles that prevent widespread use of electronic records.

The full draft report, which sets out 60 standards to guide patient-centered outcomes research, is available at *www.pcori.org/assets/Preliminary-Draft-Methodology-Report.pdf*.

A public comment period on an updated form of the report starts in July. OI

CMS Reports Healthcare Spending Grew 3.9 Percent in 2011

According to new estimates released from CMS on June 12, healthcare spending in the U.S. grew 3.9 percent in 2011, the same rate recorded in 2010, and close to the historically low 3.8 percent growth in 2009.

Projections are for health spending to continue slow growth until 2014, when coverage expansion mandated under the ACA goes into effect.

The report, "National Health Expenditure Projections: Modest Annual Growth Until Coverage Expands and Economic Growth Accelerates," can be accessed from *Health Affairs* at *http://content.healthaffairs.org/content/early/2012/06/11/hlthaff.2012.0404*.

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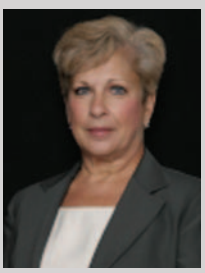
SPOTLIGHT ON OMC GROUP'S EXPERTS - SUSAN SHAFER, MT, CMM, CPC, RMC



Susan Shafer is a Senior Consultant with Oncology Management Consulting Group and brings over 25 years of experience in the healthcare field. Sue served for well over two and a half decades as practice administrator of a very active and successful oncology practice in Pennsylvania and continues to provide sales and technical support for a medical billing software program. Her responsibilities included oversight of all operations including staffing, purchasing, billing and collections, and payer contract negotiations. She also enjoys considerable experience in practice management of a free standing radiology facility as well as family practice. Susan has also specialized in instituting Physician Quality Reporting Initiative (PQRI), Quality Oncology Practice Initiative (QOPI), and E-prescribe programs into practices. Specific areas of her focus for OMC Group include billing, coding, and accounts receivable management, lost receivables and inventory management of chemotherapeutic agents to avert revenue loss.

Susan is one of the original founders and board members of the Premier Oncology Hematology Manager's Society (formerly Pennsylvania Hematology Oncology Manager's Society). She is also a former member of the Easton Hospital Office Manager's Steering Committee and since 2005 she has been a member of Amgen's Office Manager's speaker board.

Sue is a certified Medical Technologist, Certified Medical Manager with the Professional Association of Health Care Office Managers, Certified Professional Coder with the Academy of Professional Coders, and Registered Medical Coder with The American Association of Registered Health Care Professionals

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Wasted, Discarded, and Unused Drugs

BY CINDY PARMAN, CPC, CPC-H, RCC

While providers performing drug administration make every effort to ensure that all drugs are correctly delivered as required by package insert and state law and in compliance with regulatory guidelines, sometimes it is still necessary to discard the remaining drug amount in a vial or package. Billing for discarded drugs has become one of the new battle fronts in the war to reduce fraud, waste, and abuse. Accordingly, while Medicare and other insurers may reimburse for discarded drug amounts, providers must follow billing guidelines to ensure correct payment.

Drug Packaging

The United States Pharmacopeia (USP) defines multi-dose vials (MDVs) as multiple-use containers of liquid medication for parenteral administration (injection or infusion). MDVs contain more than one dose of medication and are labeled as multi-dose by the manufacturer. MDVs usually contain antimicrobial preservatives that help prevent the growth of bacteria.[1]

The Centers for Disease Control and Prevention (CDC) defines single-use vials as:[2]

> *A single-dose or single-use vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that is meant for use in a single patient for a single case/procedure/injection. Single-dose or single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative.*

Medicare Guidelines

The Medicare Claims Processing Manual, Chapter 17, Section 40 states:[3]

> *When a physician, hospital or other provider or supplier must discard the remainder of a single use vial or other single use package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label.*

And, while not required as part of national regulations, local Medicare contractors can require the use of modifier JW to report the discarded drug amount as a separate line item on the UB04 hospital claim or CMS1500 freestanding center or office claim form:

- **JW:** Drug amount discarded or not administered to any patient.

Remember, only waste from single-dose vials (SDVs) can be billed to the Medicare patient; MDVs are not subject to payment for discarded amounts of drug or biological.

While the Centers for Medicare & Medicaid Services (CMS) has published a policy regarding reimbursement for the discarded drug amount in a single-use vial, commercial and managed care payers may have to be contacted to obtain coverage information. Insurers are not *required* to reimburse for the wasted drug amount in a SDV, so obtaining this information in writing will ensure coding and billing compliance.

How Does Modifier JW Work?

When CMS implemented this modifier during calendar year 2010, the agency stated that modifier JW was required for all claims that included discarded drug amounts. However, CMS quickly revised this to state that each Medicare contractor can independently decide whether or not to require the modifier.[4]

The JW modifier is only applied to the amount of drug or biological that is discarded. Therefore, the JW modifier would not be reported when the actual dose of the drug or biological administered is less than the billing unit. For example, one billing unit for a specific drug is equal to 10 mg of the drug in a single-use vial. A 7 mg dose is administered to a patient while 3 mg of the remaining drug is discarded. The 7 mg dose is billed using one billing unit that represents 10 mg on a single line item. The single line item of 1 unit would be processed for payment of the total 10 mg of drug administered and discarded.

Billing another unit on a separate line item with the JW modifier for the discarded 3 mg of drug is not permitted because it would result in an overpayment to the provider. Therefore, when the billing unit is equal to or greater than the total actual dose and the amount discarded, the use of the JW modifier is not permitted.

For those Medicare contractors, such as CGS Medicare, that require modifier

When an individual patient is charged for the amount of drug discarded, the patient medical record must include documentation.

JW, the following is an illustration of line items submitted on the same claim:[5]

Claim Line 1:

- HCPCS code for the drug administered
- No modifier
- Number of units administered to the patient
- Calculated price for only the amount of drug administered.

Claim Line 2:

- HCPCS code for discarded drug
- Modifier JW to report wasted drug
- Number of units discarded but billed to patient
- Calculated price for only the discarded drug amount.

For example, if the patient received 316 mg of Avastin from a 400 mg single-use vial, the services would be billed as follows:

- Claim Line 1: **J9035** x 32
- Claim Line 2: **J9035**-JW x 8

The Healthcare Common Procedure Coding System (HCPCS) drug code for Avastin **(J9035)** is billed with 1 unit for every 10 mg administered; therefore, 32 units of this code are reported for the 316 mg administered to the patient. The 84 mg that is wasted is reported with 8 units, since the total number of units billed cannot exceed the 400 mg in the single-use vial. The appropriate charge amounts for the 316 mg administered and 84 mg wasted would be calculated and associated with the correct claim line item.

In addition, there is no charge for drug overfill included in a vial or package, generally to account for wastage in syringe hubs. This extra amount cannot be billed to Medicare since it does not represent an expense to the provider and exceeds the amount on the vial or package label.[6]

Keep in mind that drug waste cannot be billed if the drug was not administered, such as may occur when the patient misses an infusion appointment.

Documentation for Discarded Drugs

When an individual patient is charged for the amount of drug discarded, the patient medical record must include documentation. Documentation generally includes the date and time, amount of drug administered to the patient, amount of product wasted, and the reason for the waste. According to Novitas Solutions, a Medicare contractor, when a portion of the drug is discarded, the medical record must clearly document the amount administered and the amount wasted.[7] This medical record notation is typically performed by the nurse, pharmacist, or other individual responsible for charting.

TrailBlazer Health Enterprises requires documentation of drug waste in the patient medical record, and adds:[6]

> *Upon review, any discrepancy between amount administered to the patient and amount billed will be denied as non-rendered unless the wastage is clearly and acceptably documented.*

Some Medicare contractors, such as NHIC, state that the provider of service is expected to have the most appropriate size vial on hand to minimize the amount of discarded drugs.[8] For example, if a drug is available in 6 mg and 12 mg single-use packages and the patient requires a 6 mg injection, it would not be appropriate to purchase only the 12 mg packages and bill for 6 mgs of wasted drug for each patient that required this drug. CDC supports this position and adds:[2]

> *To prevent unnecessary waste or the temptation to use contents from single-dose or single-use vials for more than one patient, healthcare personnel should select the smallest vial necessary for their needs when making purchasing decisions.*

Multi-Dose Audits

Both the Office of the Inspector General (OIG) and certain Recovery Audit Contractors (RACs) have indicated their intent to audit chemotherapy drugs, such as Herceptin, which is available in a multi-dose vial. The Region C RAC states:[9]

> *Per its package label, Trastuzumab/ Herceptin (J9355: Injection, trastuzumab, 10 mg) is supplied from the manufacturer in a 440 mg multi-dose vial. Providers should be billing only units of J9355 associated with the amount of the drug administered to the patient. Drug waste is not paid and should not be billed for drugs supplied in multi-dose vials.*

In addition, the 2012 OIG Work Plan includes a statement of intent to review

charges for Herceptin:[10]

> *We will review payments associated with Medicare claims for the drug Herceptin to determine whether they were appropriate. For drug claims involving a single-use vial or package, if a provider must discard the remainder of a single-use vial or package after administering a dose/quantity of the drug or biological, Medicare provides payment for the amount discarded along with the amount administered, up to the amount of the drug or biological as indicated on the vial or package label. However, multiuse vials such as those used for supplying Herceptin are not subject to payment for discarded amounts of a drug or biological.*

Why Does It Matter?

If Medicare pays for the amount of the drug administered to the patient and the remaining amount of drug in a single-use package that must be discarded, why is the modifier important? In a featured article dated May 15, 2009, Report on Medicare Compliance stated:[11]

> *Billing for drug waste is emerging as a compliance and reimbursement issue for hospitals, especially in regions where the Medicare contractor requires documentation of discarded doses. Some hospitals are being audited for drug billing errors that include failure to chart wasted doses, while others sacrifice money unnecessarily by not reporting discarded drugs even though it's OK with CMS, hospital officials and consultants say.*

As a result, hospitals and freestanding infusion centers should periodically audit medical records and claim submissions to ensure that the correct drug HCPCS code, modifier JW (if required), and drug units are billed to insurance. It is also beneficial to review medical record documentation to ensure that the patient chart includes appropriate documentation of administered and wasted drug amounts.

Summary

The following is a brief summary of billing for discarded drug amounts:

- Providers may bill Medicare, and other payers with the same policy, for the amount of drug discarded from single-dose vials or single-use packages.
- Any drug amount discarded from multidose vials is not separately charged.
- The provider must make a good faith effort to schedule patients so that the use of drugs is efficient and medically appropriate.
- Any drug amount billed as discarded may not be administered to another patient.
- Coverage may not apply when the provider chooses to purchase larger packages when smaller, more appropriate packaging is available.
- The individual patient medical record must include documentation of the amount of discarded drug billed to that patient.
- Drug waste cannot be billed if none of the drug was administered, such as may occur when the patient misses an administration appointment. OI

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

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spotlight

Good Samaritan Cancer Care Center
Good Samaritan Hospital, San Jose, California

Dedicated teamwork in the delivery of quality care

Designated as a Comprehensive Community Cancer Center by the American College of Surgeons Commission on Cancer (CoC), Good Samaritan Hospital Cancer Care Center is one of only 13 facilities nationwide to receive the CoC's Outstanding Achievement Award for three consecutive surveys. "We recognize the fact that a cancer care program is the work of many, many individuals. Having that kind of distinction spurs us on to keep developing our program," said Arthur Douville, MD, Chief Medical Officer, Good Samaritan Hospital. The 422-bed, acute care hospital, a part of the HCA health system, serves San Jose—the third largest city—and Santa Clara County.

In 2010 the cancer program saw 1,079 cases, of which 899 were analytic. Leading disease sites treated are breast, prostate, lung, and colorectal cancers. Good Samaritan Cancer Care Center also sees a high number of pancreatic cancers.

Leading-Edge Care Options

Good Samaritan Cancer Care Center seeks to provide compassionate care with quality treatment and superior outcomes. A full range of leading-edge diagnostic and oncology treatment services are offered including medical oncology, radiation oncology, surgical oncology, and support services for patients and their families. "Our patients really respect and appreciate the opportunity to get leading-edge care near their own homes and in their own communities," said Dr. Douville.

Good Samaritan cancer services are provided in two convenient locations—at Good Samaritan Hospital in San Jose and at Mission Oaks—just one mile from the hospital. The BreastCare Center, radiation oncology services, and a medical oncology group are located within the Mission Oaks facility. The BreastCare Center, which is accredited by the American College of Radiology, has three digital mammography rooms, two ultrasound rooms, a prone stereotactic table, and bone densitometry. Staffed by fellowship-trained radiologists specializing in mammography, the BreastCare Center performs 20,000 exams annually (both routine and diagnostic) with digital mammography and stereotactic biopsy equipment.

Radiation therapy treatment modalities available in the Mission Oaks location include IMRT, IGRT with RapidArc, external beam radiation therapy, prostate seed implant, partial breast brachytherapy (MammoSite, Savi, and SenoRx Multi-Lumen Therapy), GYN HDR brachytherapy, and CyberKnife. DaVinci robotically-assisted surgery for prostate and gynecologic cancers is available on the hospital's main campus in San Jose. The radiation therapy program is staffed by two radiation oncologists, two oncology certified nurses, a supervisor, five radiation therapists, and certified physicists and a dosimetrist. The physicians are highly qualified in treatment planning for all the modalities offered in the radiation department, including having completed over 100 CyberKnife plans.

Diagnostic services, including PET/CT and MRI, and the inpatient oncology unit are located at Good Samaritan Hospital. Here, too, is the dedicated 18-bed oncology inpatient unit, which has all private rooms and a resource library for patients and family members. Chemotherapy infusion services are provided in a 12-chair outpatient infusion center conveniently located in the Outpatient Center on the floor just beneath the inpatient oncology unit. All of the oncology nursing staff is chemotherapy certified through ONS, and six oncology nurses hold OCN certification. "There is a multidisciplinary approach to care on the acute care unit," said Linda Ankeny, RN, MSN, OCN, nursing director of Oncology and Palliative Care. "We have team meetings weekly and make sure all

PHOTOGRAPHS COURTESY OF GOOD SAMARITAN HOSPITAL, SAN JOSE, CALIF.

Select Support Services

- Social work services
- Support Groups:
  - General Cancer
  - Breast Cancer
  - Leukemia, Lymphoma, and Multiple Myeloma
- Nutrition Services
- Physical and Occupational Therapy
- Pain Management
- Palliative Care
- Pastoral Care

the necessary disciplines are involved in the care of the patient."

Another reflection of the patient-focused, multidisciplinary care offered by Good Samaritan Cancer Care Center is the weekly Tumor Board meetings. These bring together medical oncologists, radiation oncologists, pathologists, radiologists, plastic surgeons, and other interdisciplinary team members to discuss challenging cases. A Head and Neck Tumor Board meets twice monthly, and a Cranial Spinal Tumor Board meets once a month.

Twelve board-certified medical oncologists are associated with the cancer program at Good Samaritan. Many of the physicians are multilingual, which is important in serving San Jose's diverse population. Surgical services at Good Samaritan include two general surgeons with a strong interest in GI oncology, and five surgeons with a focus on breast oncology. GI oncology support also includes a hospital-based endoscopy center with endoscopic ultrasound capability.

Good Samaritan Cancer Care Center participates in clinical research, including both university-related and pharmaceutical company-sponsored research. Clinical research currently underway includes: HIPEC (Hyperthermic Intraperitoneal Chemotherapy) trial; Breast X-pander implant system trial (a novel, patient-controlled, gas-driven system for tissue expansion as part of post-mastectomy preparation for breast reconstruction); and genomic analysis of breast tumor surgical pathology. Outpatient clinical trials are available through the medical oncology physician offices.

Support for Patients & Families

A variety of supportive care services are available to patients and families, including social work services; support groups; nutrition counseling; a lymphedema program; and more. The Good Samaritan Hospital Healing Arts program offers complimentary integrative medicine services such as guided imagery, Reiki, and massage to patients on the inpatient oncology unit.

Good Samaritan also recognizes the importance of providing support for caregivers. "The caregiver for the patient is very important in the success of the patient coping with the disease. We try to make sure they get the support they need," said Ankeny. This support includes personal touches such as the ACCESS program, which provides food to caregivers unable to leave the oncology unit, as well as transportation and housing assistance.

Now in its fourth year, Good Samaritan Hospital's palliative care program encompasses a multidisciplinary care team of social services, chaplaincy, the attending physician, hospice physicians for consultation, an advanced practice nurse, and other hospital team members who are involved in the patient's care. Recently, the hospital added the services of a full-time palliative care physician. Learn more about how Good Samaritan Hospital developed this exceptional program in *Oncology Issues* (November/December 2011).

Outreach & Education

The cancer program at Good Samaritan Hospital reaches out to area residents through a variety of educational activities including:

- Women's Health 360°, a health education forum for women of all ages
- Team Good Sam involvement in the local ACS Relay for Life
- BreastCare Center staff participation in community and corporate health fairs
- Employee "Colon Cancer Free Zone" program raising awareness among staff on the importance of screening for colon cancer.

Stepping Up

Good Samaritan Cancer Care Center is taking proactive steps toward meeting the new CoC standards. During the Cancer Committee's quarterly meetings, each of the standards and its requirements are discussed. On the horizon for the cancer program at Good Samaritan Hospital is the addition of nurse navigation services, increased involvement with HCA's Sarah Cannon Institute to further develop research efforts, and enhancing information technologies to facilitate the cancer registry efforts.

"A key is our cancer registry," said Dr. Douville. "The manager of our registry pays very close attention to the CoC standards and keeps our feet to the fire. It's a matter of team work and the dedication of many individuals to their individual work in cancer care as part of a team."

tools

Approved Drugs

• Genentech (*www.gene.com,* a member of the Roche Group) announced Food and Drug Administration (FDA) approval of **Perjeta™ (pertuzumab) injection** for use in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer (mBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

Pertuzumab is a recombinant humanized monoclonal antibody that targets the extracellular dimerization domain (Subdomain II) of HER2, and thereby blocks ligand-dependent heterodimerization of HER2 with other HER family members, including EGFR, HER3, and HER4.

This approval is based on data from a Phase III study, which showed that people with previously untreated HER2-positive mBC who received the combination of Perjeta, Herceptin, and docetaxel chemotherapy lived a median of 6.1 months longer without their cancer getting worse (progression-free survival, or PFS) compared to Herceptin plus docetaxel chemotherapy (median PFS 18.5 months vs. 12.4 months).

• The FDA approved **Votrient™ (pazopanib)** (GlaxoSmithKline, plc, *www.gsk.com*) to treat patients with advanced soft tissue sarcoma (STS) who have received prior chemotherapy. The efficacy of pazopanib for the treatment of patients with adipocytic STS or gastrointestinal stromal tumors (GIST) has not been demonstrated.

The approval is based on a randomized, double-blind, placebo-controlled, multicenter Phase III PALETTE study in patients with metastatic STS who had received prior chemotherapy, including anthracycline.

Votrient is a pill that works by interfering with angiogenesis. The recommended dose and schedule of pazopanib is 800 mg orally once daily, administered without food (at least 1 hour before or 2 hours after a meal).

Drugs in the News

• Ambit Biosciences (*www.ambitbio.com*) and Teva Pharmaceutical Industries Ltd. (*www.tevapharm.com*) announced clearance of an investigational new drug application (INDA) with the FDA for **CEP-32496**, a noval BRAF (V600E) kinase inhibitor. CEP-32496 is a small molecule kinase inhibitor of V600E mutated BRAF.

• Bayer HealthCare (*www.bayer.com*) announced submission of a new drug application (NDA) to the FDA seeking approval for the oral multi-kinase inhibitor **regorafenib** for the treatment of patients with metastatic colorectal cancer (mCRC). The submission is based on the results of the CORRECT study, an international, multicenter, randomized, double-blind, placebo-controlled Phase II study that enrolled 760 patients with mCRC whose disease had progressed during or within three months following the last administration of approved standard therapies.

Assays and Genetic Tests in the News

• Agendia (*www.agendia.com*) announced the launch of the company's **ColoPrint microarray-based 18-gene expression signature** for predicting the risk of distant recurrence for stage II colon cancer patients who have undergone surgery.

• Quest Diagnostics (*www.questdiagnostics.com*) launched the **Quest Diagnostics Thyroid Cancer Mutation Panel**, a new molecular test designed to help physicians determine if a thyroid gland is cancerous and requires surgical removal. The new panel identifies mutations of the molecular markers *BRAF, V600E, RAS, RET/PTC,* and *PAX8PPAR gamma,* which are associated with papillary and follicular thyroid cancer.

In addition the company has introduced the **Quest Diagnostics Thyroglobulin (Tg) Post-Treatment Monitoring Test** to aid in monitoring for recurrence of cancer following surgery.

Approved Devices

• Devicor® Medical Products, Inc. (*www.devicormedical.com*) announced the commercial launch of the **Mammotome® *elite* Biopsy System**, a tetherless single insertion, multiple sample,

vacuum-assisted biopsy (VAB) device featuring proprietary TruVac™ vacuum technology. Unlike devices that rely on automated syringes, *elite* provides a vacuum that achieves nearly the same suction power of the traditional Mammotome VAB system, enabling the device to capture large, high-quality tissue samples.

In March, the company received FDA 510(k) clearance for the Mammotome *elite* Biopsy System, which will be used to aid in the detection and treatment of breast cancer in ultrasound-guided breast and axillary lymph node biopsies.

- Mevion Medical Systems, Inc. (*www.mevion.com*) received FDA 510(k) clearance for the company's **MEVION S250 Proton Therapy System**. The MEVION S250 Proton Therapy System provides the same precise, non-invasive treatment advantages and capabilities of complex, large, and costly proton therapy systems but with higher patient throughput, significantly reduced footprint, improved reliability, and lower implementation and operational costs.

- Ventana Medical Systems, Inc. (*www.ventana.com*), a member of the Roche Group, received 510(k) clearance from the FDA for the **VENTANA Companion Algorithm p53 (DO-7) image analysis application** using the VENTANA iScan Coreo Au scanner and VIRTUOSO software. Ventana is currently the only company offering an FDA-cleared p53 image analysis algorithm for determining p53 expression levels in breast cancer patients. In addition, the company offers FDA-cleared algorithms for HER2 (4B5), PR (1E2), and Ki-67 (30-9).

- ViewRay Incorporated (*www.viewray.com*) has received FDA 510(k) premarket notification clearance for its MRI-guided radiation therapy system. The **ViewRay System** features a unique combination of radiotherapy delivery and simultaneous magnetic resonance imaging for the treatment of cancer. OI

Doxil C.A.R.E.S. Physician Access Program Initiates Open Enrollment

Janssen Products, LP, announced the initiation of an open enrollment process for the Doxil® C.A.R.E.S. Physician Access Program. In a May 9, 2012, letter, Rob Bazemore, President, Janssen Products, LP, announced that, "Returning a reliable supply of Doxil to the marketplace remains our top priority. We are able to re-open enrollment at this time because some physician allocation requests have changed and freed up product for reallocation. Other physicians indicated Doxil earmarked for patients in the program is no longer needed, or they opted patients out of the program. We've met the needs of all physicians who submitted enrollment forms for their patients during the recent Doxil C.A.R.E.S. Physician Access Program re-enrollment process and this latest assessment has allowed us to re-open enrollment for patients not currently enrolled." For more information, call 1.866.298.5774. Beginning July 1, providers administering Doxil and billing Medicare should begin using the temporary HCPCS code that CMS has assigned specific to Doxil (Q2048), and discontinue use of code J9001.

New Mobile Apps Launched

- Eli Lilly and Company (*www.lillyoncology.com*) has launched a searchable clinical trial mobile application for oncology healthcare professionals. The app—available for Apple iPad and iPhone, as well as RIM's BlackBerry and Google's Android platforms—allows healthcare professionals to search oncology trials that are enrolling new patients by disease state, molecule being studied, study phase, country, state, and keyword.

The mobile app provides details on all global oncology trials. The app's functionality provides a mechanism for healthcare professionals to contact Lilly Oncology for additional details on its trials, as well as a third-party contact for non-Lilly clinical trials.

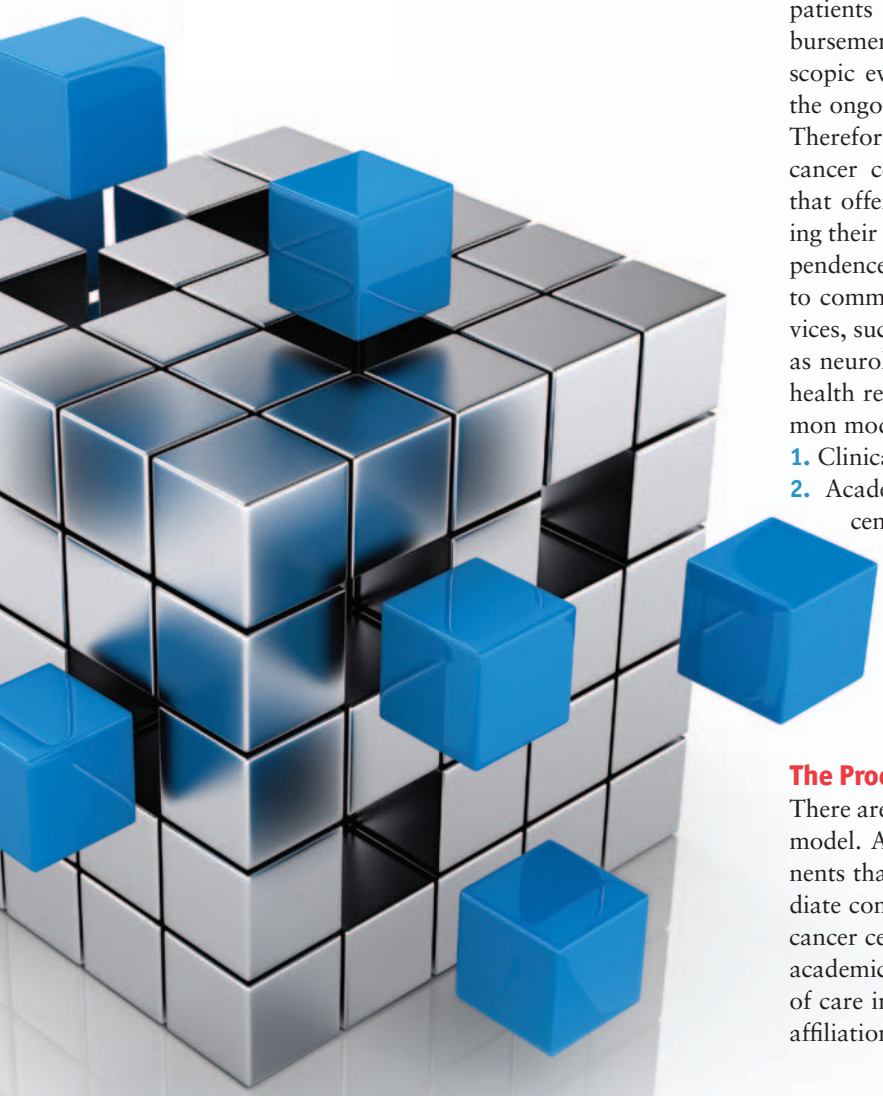
Details for downloading the clinical trial app are available on a new website, *LillyOncologyPipeline.com*.

- Velos, Inc., (*www.velos.com*) has released **Velos Aversi**, an iPad app for clinicians in oncology and bone marrow transplantation. The app is designed to record, track, and export patient adverse events and graft-versus-host-disease at point-of-care in hospital and ambulatory care settings. The app is available for download from the Apple App Store.

AMC Affiliation with a Community Cancer Center

Putting the pieces together

BY CECILIA ZAPATA, MS, AND
BENJAMIN GREER, MD



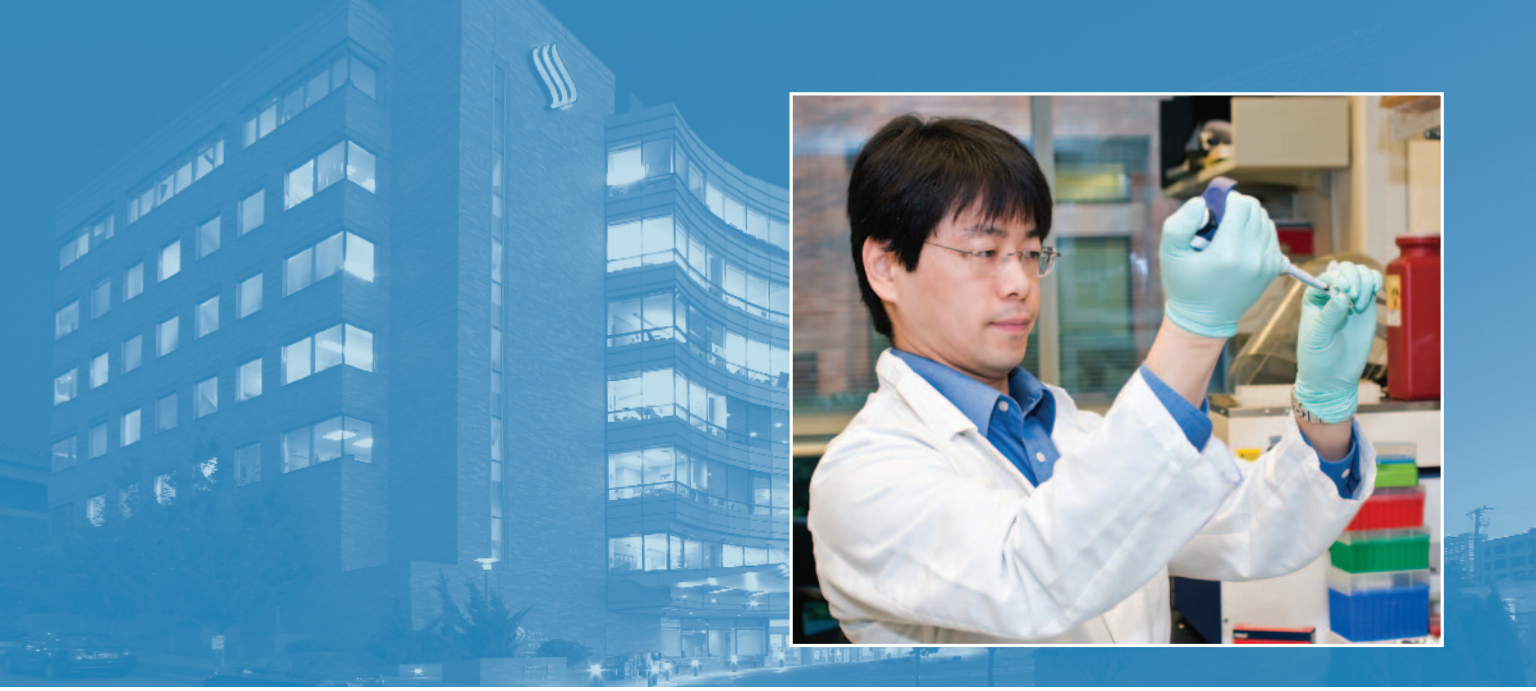
The healthcare industry is changing. Across the country, community cancer centers are examined closely for cost effectiveness, quality care, and access to treatments for patients closer to home. New requirements, reduced reimbursement, shifts in payer models or contracts, and microscopic evaluations of clinical performance are just some of the ongoing challenges community cancer centers face today. Therefore, it is no surprise that more and more community cancer centers are looking for partnerships or affiliations that offer the right balance of structure to assist in improving their oncology care delivery without sacrificing their independence. Many models exist. There are community-hospital to community-hospital affiliations that combine specific services, such as cardiology, and specialty surgical services, such as neurology. Some affiliations focus primarily on electronic health record (EHR) integration. Two of the two most common models of oncology-specific affiliations include:

1. Clinical research and pharmacy affiliations
2. Academic medical center (AMC)-to-community cancer center affiliations.

This article focuses on the latter. While the AMC affiliation model and process described here is specific to the Seattle Cancer Care Alliance affiliation program, some similarities to other academic affiliations likely exist.

The Process

There are no "cookie-cutter" approaches for this relationship model. Affiliations will vary, depending on the core components that are available and offered. The needs of the immediate community will determine the needs of the community cancer center, helping to identify what an affiliation with the academic institution might offer to help improve the quality of care in the community setting. That said, the path to any affiliation begins with three steps.



Step 1: Assessment. A full and complete assessment of the community cancer center program is key to understanding what infrastructure is in place or what infrastructure needs improvement and/or enhancement. This assessment should include a broad view of patient volumes, disease focus, staffing model, and other pertinent information critical to the overall operations of the cancer center program. The assessment provides insights on the program's experience with clinical trials, which is a priority for an academic affiliation model. This exercise benefits both the community cancer center and the academic medical center, providing a mechanism to find areas for collaboration and focus for the affiliation.

Step 2: Site Visit. This face-to-face visit is the initial step in building the relationship. Without a candid dialogue, the potential affiliation already is on softer ground. This relationship building step is the foundation for the partnership and the ongoing face-to-face interactions between the two organizations that are critical to a successful affiliation. Specifically, this interaction between the community cancer center lead clinical and administrative staff and the academic medical center's affiliation team and directors is an opportunity to meet in person, answer questions from both sides, and tour the facility first hand.

Occasionally, the academic medical center team will provide a more formal presentation to the community cancer center executive leadership, which often is indicative of overall executive leadership commitment to the affiliation. The site visit also engages all of the staff and helps alleviate any feelings of being "threatened" by a potential collaboration with an outside organization. The visit opens the door for continued dialogue and is an opportunity to evaluate cultural similarities and differences.

Step 3: Internal Stakeholder Reviews. After completing steps 1 and 2, the two organizations should independently:

- Review the potential affiliation relationship with their internal stakeholders
- Discuss any added financial commitment (for example, an affiliation membership fee)
- Assess the overall value and benefits affiliation
- Confirm leadership commitment to move forward.

Steps 1 through 3 can take up to a year to complete, but, in the end, these steps are the defining factor in moving forward with any affiliation. Only after this review and when overall agreement and consensus is reached can contract and agreement negotiations begin.

Benefits to Affiliation

When deciding to affiliate, community cancer centers should consider many factors including, overall infrastructure, quality, and culture. So what are the benefits and challenges with an AMC-community cancer center affiliation? Figure 1 (page 24) outlines some core components of an AMC-community cancer center affiliation, with Fox Chase Cancer Center Partners representing the academic medical center.[1] Although the diagram does not present a comprehensive list of benefits, it shows what community cancer centers can access when affiliating with an academic medical center and the benefits of having access to these programs.

Access to clinical research. These mostly investigator initiated trials are otherwise not available to community cancer centers. From the academic medical center's perspective, implementing trials at community sites provides access to patients eligible for enrollment on protocols that are critical to improving current standards of care. It also benefits the community cancer center, increasing patient access to a variety of trials.

Access to continued medical education and additional educational opportunities for other disciplines. These opportunities come in a variety of formats from grand rounds to shadow opportunities and actual classroom-style forums.

FIGURE 1. AFFILIATION BENEFITS BETWEEN AN ACADEMIC MEDICAL CENTER AND ITS COMMUNITY PARTNERS

CLINICAL RESEARCH
Access to an array of clinical trials
Support in developing research infrastructure
Invitations for physicians to participate in study design
Assistance streamlining and overcoming regulatory hurdles
QUALITY ASSURANCE
Assistance with clinical quality measurements
Periodic quality audits
Evaluation of clinical infrastructure
CONTINUING MEDICAL EDUCATION
Participation in grand rounds and tumor boards
Frequent educational seminars
Physician education and networking
CLINICAL OPERATIONS SUPPORT
Assistance with accreditation
Staff training in advanced techniques
Onsite second opinions at select locations
BUSINESS SUPPORT
Creation of formal program plan—both strategic and operational
Coordinated marketing and co-branding campaigns
Feasibility studies and business plans
ADVANCED SERVICES
Access to genetic counselors and other highly trained staff
Support in establishing high-risk screening programs

Source: Fox Chase Cancer Center Partners, Philadelphia, Pa.

Learning opportunities are often tailored specifically to the community cancer center's educational needs. By participating in these events, the community cancer center develops a stronger relationship with the academic providers with specialty expertise in oncology care and research. The academic medical center benefits from establishing relationships with community providers by:

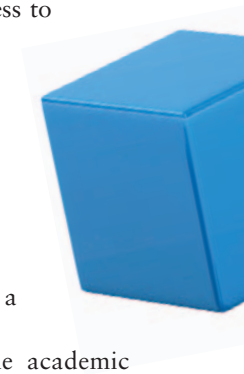
- Hearing first-hand challenges with certain patient-care issues and learning how academic providers can assist
- Improving protocol development to better fit a community cancer center setting
- Gaining opportunities for collaborating in other projects.

Access to program development expertise. This expertise can range from developing a survivorship clinic to assistance with an accreditation process or implementing various patient navigation models. The community cancer center and the academic medical center both benefit from the sharing of best practices and plans to improve the quality of care and the patient experience.

Access to quality assurance experts. This access raises the bar for improving the standards of cancer care in the community by allowing the community cancer center to participate as a part of the academic affiliation network. Most academic affiliate models have what is described as a "network" where several community cancer centers within a region are affiliate members of the academic institution. Network members benefit from other programs by leveraging each affiliate's expertise and best practices. The network relationship provides a safe environment for sharing information that would otherwise be considered competitive intelligence. And because each of the affiliates has gone through the same in-depth due diligence prior to becoming an affiliate, network affiliates already share a common culture and mission between themselves and with the academic organization. Fostering an annual event where all the affiliates can gather is one way to continuously encourage sharing and collaboration. Finally, the opportunity for program integration becomes an option.

From the academic perspective, affiliation can help realize a mission-driven effort to improve access to quality care for oncology patients.

While this list of benefits is by no means comprehensive, there are challenges related to affiliation.



Affiliation Challenges

Examples of common affiliation challenges include:

- Lack of an efficient process for referring a patient from the affiliate
- Cumbersome process for referring to the academic medical center
- Medical records are not available, thus delaying patient care
- Electronic transfer of films for a patient referred to the academic center is inefficient and often delays the patient's appointment

ALL PHOTOS COURTESY OF SEATTLE CANCER CARE ALLIANCE.

- Insurance coverage issues
- Healthcare reform issues
- Leadership and physician transitions at the community cancer center
- New "ownership" of the community cancer center
- Clinical research is not a revenue-generating program.

The good news: once challenges are identified, they often become an opportunity to improve processes for the best possible patient care delivery.

In addition to the challenges listed above, "perceptions" may exist that—left unaddressed—may turn into challenges. Usually, however, these are resolved by improving communication, fostering face-to-face interactions, and continuing education and awareness about each organization. For example:

- A "perception" that patients do not return to the community cancer center after a referral to the academic medical center. This complaint or issue between community cancer centers and academic medical centers is common. Although there may be some truth to this perception, it is an opportunity for improvement. Academic centers are large organizations with very complicated operational structures. Academic affiliation program leaders must make time to educate and communicate to their internal programs about the affiliate (the community cancer center) and its clinical staff and infrastructure. The academic medical center should provide several venues to increase interaction between its internal programs and its affiliate(s).
- A "perception" that community cancer centers are competition or lack integrity in the delivery of oncology care. This "perception" of community-based care varies, especially in the current healthcare environment where collaborations and/or affiliations seem to be the best approach to manage the changing healthcare landscape. Most, if not all, community cancer center providers have come from an academic setting; some community centers have very robust clinical and research infrastructures. Continued education and awareness about each organization and infrastructure is critical, and providers need to have plenty of opportunities for dialogue.

Leveraging Affiliation

Successful affiliation relationships do not happen overnight. Success requires champions (a director and medical director) from both the community cancer center and the academic medical center to be fully engaged, to believe in the mission and vision of the relationship, and to be the constant "face" of the relationship for the life of the affiliation. The first year of the affiliation (once all agreements are signed) is the "getting-to-know you" phase where additional introductions of programs, initiative development, and overall "learning the dance steps" occur.

The second year brings more specific program development and goals, infrastructure improvements, and training and education.

By years three through five, the community cancer center and the academic medical center are comfortable with and knowledgable about the other program. Now opportunities exist for more targeted program development, such as survivorship clinics, and new ventures for additional collaborations, such as protocol development, care pathway development, and other integrated opportunities. At this stage, within the affiliations, coordinated efforts in quality performance, strategic planning, and, sometimes, with payer negotiations, can be initiated.

Into the Future?

Affiliations, joint ventures, partnerships, and other collaborative models are here to stay. More and more, patients are demanding higher standards of care and access to experts and new treatments closer to home. Unfortunately, the number of cancer patients will rise exponentially in the next decade, and we already know that reimbursement will continue to decline, affecting how we run our business. We face additional challenges in clinical research, changes to accreditation requirements, drug shortages, and more. Affiliations and partnerships allow cancer programs to explore resources and expertise from each other. By affiliating or partnering, we can be unified in riding out the constant healthcare evolution. OI

—Cecilia Zapata, MS, is director, Regional and Global Network and Physician Education Outreach, Seattle Cancer Care Alliance. Benjamin Greer, MD, is network medical director, Seattle Cancer Care Alliance and professor of Medicine at the University of Washington.

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Patient and Family Focused Transitional Care

BY SUSAN SAYLES, MS, RN, OCN; SONYA REYES, MSW, LCSW, OSW-C; STEPHANIE CLAYTON, MHSM, CMPE; TAMMI WALLACE, BSN, RN, OCN; JEFF KENDALL, PSYD; AND HEIDI HAMANN, PHD

In 2010 and 2011, the ambulatory programs at Simmons Cancer Center, Dallas, Texas, experienced a double digit increase in new patient appointments. During the same period, the inpatient unit average daily census grew from 4 to 15+ patients. Because of this growth, Simmons Cancer Center evaluated its program and determined that it was not providing comprehensive seamless care across oncology treatment settings. These findings provided the cancer center with an opportunity to develop a transitional care program to better meet the needs of its patients and families. Coordinating care across healthcare settings involved multiple components of collaboration and communication with the goal of creating a seamless process for the patients and their families.

Gap Analysis

The process of building the transitional care team started with a gap analysis of patient hospital stays, with particular emphasis on the discharge process, care coordination, psychosocial needs, and transitions from the inpatient to outpatient care settings. The gap analysis included an assessment

of 62 patients over a three-month period.

The assessment process consisted of telephone interviews with patients after discharge from the inpatient oncology unit. An oncology-certified clinical social worker completed all interviews. The goal of the interviews was to collect data about the strengths and weaknesses of the existing model of patient care with particular attention to patient satisfaction, readiness for discharge, communication among professionals, and psychosocial needs. Through this interview methodology Simmons Cancer Center identified the following gaps in care:

- Discharge planning was reactive versus proactive.
- Supportive counseling during inpatient stay was absent.
- Referrals to oncology-specific community resources were limited.
- Education of disease process and clarification of care plan was limited.
- Communication and collaboration between care providers was inconsistent.
- Follow-up clinic appointments were inconsistently scheduled prior to discharge.
- Emotional needs were not adequately evaluated or addressed.
- Expensive discharge medication was not being preauthorized.

Simmons Cancer Center staff was informally interviewed and through this set of interviews the following additional gaps in care were identified:

- The outpatient medical teams were often unaware of the discharge plan until after it was executed and the patient showed up for his or her outpatient appointment.
- The outpatient medical team was often unaware of medical equipment that was set up, changes in the patient's status, the increased role of the patient's caregiver, or if an admission to skilled nursing facilities or rehabilitation centers occurred.
- Patients' medications were not being preauthorized, and patients often left the hospital with expensive drug prescriptions that they were unable to fill.
- The psychological and emotional needs of patients were not adequately evaluated or addressed.

Once patients and staff identified these issues, Simmons Cancer Center had the opportunity to build a transitional care team that would address these gaps in care.

Defining Transitional Care

The National Cancer Institute (NCI) defines transitional care as:[1]

> *Support given to patients when they move from one phase of treatment to another, such as from hospital care to ambulatory care. It involves helping patients and families with medical, practical, and emotional needs as they adjust to different levels and goals of care.*

The process of planning for these transitions is frequently referred to as discharge planning because it implies a release from one facility to another. To ensure successful discharges, however, transitions of care must occur through an integrated, seamless relationship between the inpatient and outpatient care teams.[2]

Transitional care planning helps the patient and family:

- Address medical, practical, and emotional issues that arise as they adjust to different levels and goals of care
- Make decisions that balance disease status and treatment options with family needs, finances, employment, spiritual or religious beliefs, and quality of life
- Identify and manage medical, practical, and emotional issues to prevent an interruption of care.

Peikes and colleagues recognized the need for a multidisciplinary team who would provide both healthcare and social support interventions.[2] This need is particularly true for oncology patients, many of whom are in the middle of treatment when admitted to the hospital. An acute episode can lead to delays or cessation of treatment, often resulting in less optimal medical outcomes, as well as emotional distress for

OUR PROGRAM AT-A-GLANCE

In 1988 Harold C. Simmons and his wife Annette, through a generous endowment, made provision for the Harold C. Simmons Cancer Center and Clinics, part of the University of Texas Southwestern (UT Southwestern) Medical Center. UT Southwestern consolidated in January 2005, and now consists of two hospitals, University Hospital Zale Lipshy, University Hospital St. Paul, and outpatient ambulatory clinics that provide comprehensive patient care to Dallas and surrounding areas. The Simmons Cancer Center sees nearly 3,000 analytic patients per year and has comprehensive cancer treatment programs in the following 10 areas: brain and spinal cord, breast, gastrointestinal, gynecological, head and neck, lung, hematological (including BMT) melanoma, sarcoma, and urologic. In addition to medical care, we offer a full complement of support services, including nutrition, clinical social work, psychology, and integrative therapies to enhance each medical treatment program. In 2010 Simmons Cancer Center was granted NCI cancer center designation; the entire program is working to achieve comprehensive cancer center designation.

both the patient and family. Building the care plan with the patient and family at the center is of upmost importance. The integration of the biopsychosocial assessment and medical assessment is necessary and must be the foundation for all successful transitional care plans.

Our Program Goals

The goal for Simmons Cancer Center's transitional care program is to implement NCI's vision for transitional care in order to reduce readmissions and expenditures, while improving quality, safety, and patient satisfaction. More specifically, Simmons Cancer Center set out to develop a transitional care program in which the patient and family would be supported regardless of location within the cancer program. The cancer center focused on four initial goals:

1. Develop a program that supports patients and their families as they transition from one treatment setting to another within the cancer program.
2. Focus on collaboration and communication across the treatment settings to create a perception of seamless transitions for patients and their families.
3. Ensure that patient data is communicated between settings in an accurate and timely manner.
4. Ensure that all of the needs of our patients and their families are addressed, including social, emotional, and spiritual needs.

Our Guiding Principle & Primary Focus

Focus on the patient and family first is the guiding principle at Simmons Cancer Center (see Figure 1, at right). Patients and their families are placed at the center of the decision-making process of the healthcare team. Regardless of the care setting, the healthcare team is responsible for:

- Supporting the patient and family as they transition from one setting to another
- Collaborating and communicating across settings
- Meeting the "whole patient" and family needs.

Simmons Cancer Center focused its transitional care program on the inpatient unit from the point of admission through a comprehensive hand-off to the next treatment setting. The transitional care team guides the patient and family through a myriad of issues, including:

- Insurance coverage
- Medication regimes
- Multiple consulting physicians
- Home health care needs
- Emotional adjustment
- Establishment of follow-up appointments prior to discharge.

In this way the team can help patients make the most informed choices possible in regard to their transitions in care and care settings.

How We Did It

Here's how Simmons Cancer Center closed the gaps in care and met the goals of its transitional care program.

The development of the program began with educating the inpatient nursing staff on the patient and family-focused model of transitional care. This education was conducted by members of the Simmons Cancer Center administration, oncology social work, and the nurse manager of the inpatient oncology unit. Transitional care planning committee members took the concept to the Unit-Based Council where we presented the gap analysis and discussed the transitional care program. Oncology staff nurses met with the oncology program's administrative leadership to provide support, feedback, guidance, and insight for each step of the process.

To put the plan in place, Simmons Cancer Center administration created a transitional care team comprised of a clinical oncology social worker and a physician assistant. This team works in partnership with the inpatient nursing team and the UT Southwestern (UTSW) inpatient nursing team, oncology residents, fellows, and attending physicians. The clinical oncology social worker, designated as the transitional care coordinator, is responsible for the biopsychosocial assessment for each oncology admission. This assessment is used to evaluate a patient's:

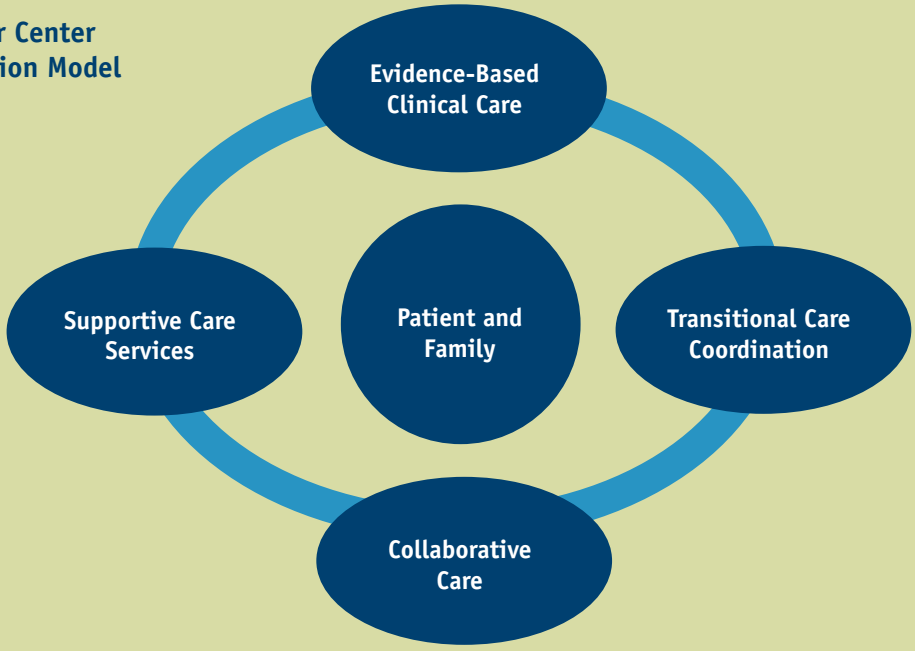
- Emotional and psychiatric distress
- Adjustment to illness, grief, and/or end-of-life concerns
- Existing support systems
- Financial issues
- Home care planning.

The transitional care coordinator also provides supportive counseling to patients and their families relevant to oncology issues.

The physician assistant works closely with both the inpatient and outpatient physician teams, acting as a liaison to ensure the comprehensive oncology treatment plan is delivered with accuracy. The physician assistant ensures that outpatient clinic appointments are made before discharge from the inpatient setting and that the family is involved in all decision making. Clinical handoff to the outpatient setting is a vital component of continuity of care and seamless transition between care settings.

The transitional care team meets with oncology residents, fellows, and attending physicians daily. During these meetings patient issues are discussed with the intent to identify and manage medical, practical, and emotional issues that may prevent or interrupt care. In addition, these meetings allow the treatment team to make decisions that balance disease status and treatment options with family needs, finances, employment, spiritual or religious beliefs, and quality of life. The oncology clinical social worker also works closely with the UTSW case management team to ensure a proactive approach to discharge planning.

Figure 1. Simmons Cancer Center Transition Care Coordination Model



Evaluating Our Program

Simmons Cancer Center used the following two Press Ganey questions to help evaluate its transitional care coordination program:

1. Overall rating of care given.
2. Staff worked together to care for you.

For question 1, the inpatient unit was given a mean score of 56.0 (n=25) for the second quarter of 2010. This mean score improved to 100.0 (n=3) in the fourth quarter of 2011. Given the low N for this mean score of 100.0, we looked at the third quarter score which was 80.6 (n=36). The general trend from second quarter 2010 to fourth quarter 2011 demonstrates an upward track in assessments of care quality.

For question 2, the inpatient unit was given a mean score of 53.8 (n=26) for the second quarter of 2010. This mean score also improved to 100.0 (n=3) in the fourth quarter of 2011. Given the low N for this mean score of 100.0, we looked at the third quarter score which was 75.0 (n=36). The general trend from second quarter 2010 to fourth quarter 2011 demonstrates an upward track in assessments of care coordination.

In the process of developing a transitional care program at Simmons Cancer Center, the team learned several lessons that could benefit community cancer centers looking to develop a similar program:

1. Development of a transitional care coordination program requires administrative support and, at Simmons Cancer Center, additional staff. The additional staff was justified in order to maintain our focus on patient- and family-centered care. In addition, the increase in staff allowed us to meet the goals of increased patient satisfaction, decreased length of stay, and cost containment. Although all transitional care services are not billable, the added attention to care coordination supports a decrease in length of stay and cost containment, which offsets the expense of additional staff.
2. Program success requires a multidisciplinary approach that includes: gap analysis, staff input, staff training, and staff support.
3. Multidisciplinary communication and the development of adequate communication systems across cancer treatment settings are primary components of success.
4. Program evaluation must include multiple assessment points and an ability to modify the program based on the assessment data. OI

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THE BIG PICTURE

System-wide strategic planning for a multi-robotic surgical program

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In Brief

In 2010 the senior leadership of Aurora Health Care launched a System Robotic Surgery Steering Committee with a goal to maintain a standard of robotic surgery practices across the health system. The Steering Committee was established with a mission to unite key stakeholders across the system to provide consistency in standards and policies that promote safe, high-quality patient care and strategic oversight for existing and future robotic surgery programs. The Steering Committee is accountable for the development and oversight of a standardized approach to training, proctoring, and credentialing of surgeons; development of a clinical outcomes database; system and site-based programs oversight; and an annual strategic evaluation and planning process.

Surgical technologies have evolved to offer patients less invasive procedures that have been shown to improve pain levels, decrease time spent in the hospital, and improve outcomes—allowing for a better patient experience. Intuitive Surgical introduced the da Vinci Surgical System (da Vinci robot) to the United States in 2000.[1] The robot provided a wide range of motion compared to laparoscopic technologies and set out to change the way surgeons operate. According to Intuitive Surgical, more than 200,000 da Vinci robotic-assisted procedures were performed in 2009 (a 51 percent increase from 2008).[1] A majority percentage of the cases were prostatectomies, with hysterectomies being the fastest growing procedure (a 130 percent increase from 2008).[1] Hospitals that purchase robotic devices may initially see growth in patient referrals due to patient demand and little diffusion of technology. However, as more facilities implement robotic surgery programs, the novelty of the technology will fade and demand will stabilize.

At the present time, the state of Wisconsin has 25 robotic surgery programs with a total of 29 robots. Aurora Health Care leads robotic surgery programs across Wisconsin and is responsible for 5 of the 25 programs with a total of 6 da Vinci robots. Aurora Health Care acquired its first da Vinci robot in 2001 primarily for cardiac surgery use. Over time, more surgical disciplines incorporated the new technology into their practices. Currently, approximately 78 percent of da Vinci procedures across Aurora Health Care are cancer related.

In an effort to develop a system-wide strategic plan versus a hospital-specific plan, Aurora Health Care senior leadership launched a System Robotic Surgery Steering Committee to strategically evaluate its current programs and develop objective criteria for future adoption in order to remain a high-quality and competitive leader in robotic surgery. The Steering Committee is charged with providing strategic oversight for Aurora's existing and future robotic surgery programs, including training and credentialing, quality outcomes tracking, and a defined process for strategic evaluation and planning.

Table 1. Training & Experience Requirements for Robotic Surgery Applicants

RESIDENCY AND FELLOWSHIP TRAINED APPLICANTS
Applicants who completed a structured curriculum in minimal-access procedures and therapeutic robotic devices during residency or fellowship will provide a case log and a letter of recommendation from the program director verifying the applicant's competence in the performance of da Vinci robotic gynecologic procedures. The case log must document the applicant's role in each robotic case (primary surgeon, assistant surgeon, and observer). A case log of between 10 and 20 cases is required. The department chief will determine if the case log is adequate or if additional cases should be performed with a preceptor before robotic surgery privileges are granted.
EXPERIENCED APPLICANT
Experienced surgeons who were not trained in da Vinci surgical robotics during their residency or fellowship but have mastered robotic procedures, and currently hold robotic surgery privileges at another hospital, will provide documentation of successful completion of a surgical robotics hands-on training practicum on robotic surgery resulting in a certificate of completion. Experienced surgeons will also submit a case log of at least 10 robotic surgery cases performed as the primary operator during the past year, and a letter of recommendation from the department chief or section chair at the hospital where the cases were performed, verifying the applicant's competence.
PRECEPTOR PATHWAY
Surgeons who wish to pursue da Vinci robotic procedures training at an Aurora Health Care hospital will do so through a formal preceptorship. Robotic surgery preceptorship proposals shall be forwarded, as applicable, to the medical director of Surgical Robotics, chair of the Site-Based Robotic Surgery Steering Committee, and/or the appropriate department chief or section chair at each Aurora Health Care hospital to which the applicant is applying.

A key to the success of the Steering Committee was the strategic invitation of key stakeholders from across the organization. Steering Committee members included:

- Aurora's chief medical officer (CMO)
- Market executive vice president (EVP)
- A system-wide clinical program representative
- A surgical specialty representative
- Site surgical services
- Site medical administrators
- Medical group leadership.

Ad hoc members included the vice president of Medical Staff Services, the director of Finance, and a Data Warehouse representative. The chief operation officers of Aurora Health Care appointed the Steering Committee Co-Chairs: the CMO and Market EVP. The health system's service line leader for cancer helped to facilitate the Steering Committee.

The co-chairs then selected the Steering Committee members to ensure equal representation from each of Aurora's site-based robotic surgery programs. Each site was required to have physician representation. The Steering Committee developed four subgroups that would focus on key initiatives for robotic surgery: Training and Credentialing, Quality, Strategic, and Communications.

Training & Credentialing

The Training and Credentialing Subgroup had two objectives: 1) to develop recommendations to Aurora Medical Staff Credentialing of criteria necessary to obtain and maintain robotic surgery privileges and 2) to develop evaluation criteria for supporting training of Aurora physicians in robotic surgery. The ultimate goal was to set standards that support safe, high-quality, cost-efficient surgical care across Aurora.

The Steering Committee developed a standardized set of guidelines for training and credentialing surgeons interested in robotic surgery based on the SAGES/MIRA recommendations and input from the Training and Credentialing Subgroup (see Table 1, above). Surgeons who are granted robotic surgery privileges are also asked to participate in the organized peer review process for robotic surgery at each hospital where robotic surgery privileges are exercised (see Table 2, at right). Renewal of robotic surgery privileges will occur at the time of biannual reappointment and will be based on unbiased, objective results of peer review and the organization's quality assurance mechanism.

Quality Metrics

The Quality Subgroup was tasked with developing metrics to ensure that the Robotic Surgery Programs delivered the highest

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Table 2. Peer Review Screening Criteria
Post-operative length of stay >3 days
Re-operation during same admission
Readmission within 30 days of surgery
Post-operative blood loss requiring transfusion
Collateral organ and tissue damage
Prolonged operating time—surgical specialty to determine definition of timeframe based on surgical procedure
Post-operative wound infection

Table 3. Prostate Measures
PREOPERATIVE MEASURES
Age
Race
BMI
Patient origin information using zip code
Robotic surgery patient's prostate volume by ultrasound
Gleason score
PSA
INTRA-OPERATIVE MEASURES
Number of nodes removed when applicable
Complications
–Bowel injury
–Rectal injury
–Ureteral injury
–Bladder injury
Conversion rate to open
Positive margins
POST-DISCHARGE MEASURES
Bleeding requiring transfusions (<30 days post)
Readmission (within 30 days)
Patient reported continence—pads per day at 1, 6, 12, 18, and 24 months (currently not inputted into database)
Patient reported potency—SHIMS, drugs used at 1, 6, 12, 18, and 24 months (currently not inputted into database)
PSA at 6, 12, 18, and 24 months and at annual follow-up

Surgeons who are granted robotic surgery privileges are also asked to participate in the organized peer review process for robotic surgery at each hospital where robotic surgery privileges are exercised.

AURORA HEALTH CARE AT-A-GLANCE

Established in 1984, Aurora Health Care is Wisconsin's largest not-for-profit healthcare organization with sites in more than 90 communities throughout eastern Wisconsin, including 15 hospitals, 155 clinics, and 82 community pharmacies. More than 3,400 physicians are affiliated with Aurora Health Care, including more than 1,100 that make up Aurora Medical Group. Aurora offers inpatient care at 14 acute-care hospitals and one psychiatric hospital. Approximately 115,000 surgeries are performed annually at Aurora hospitals.

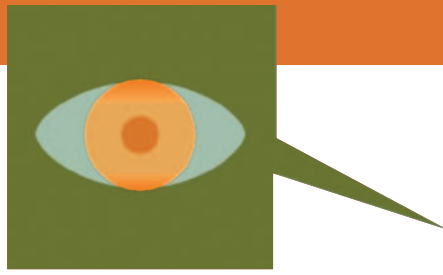
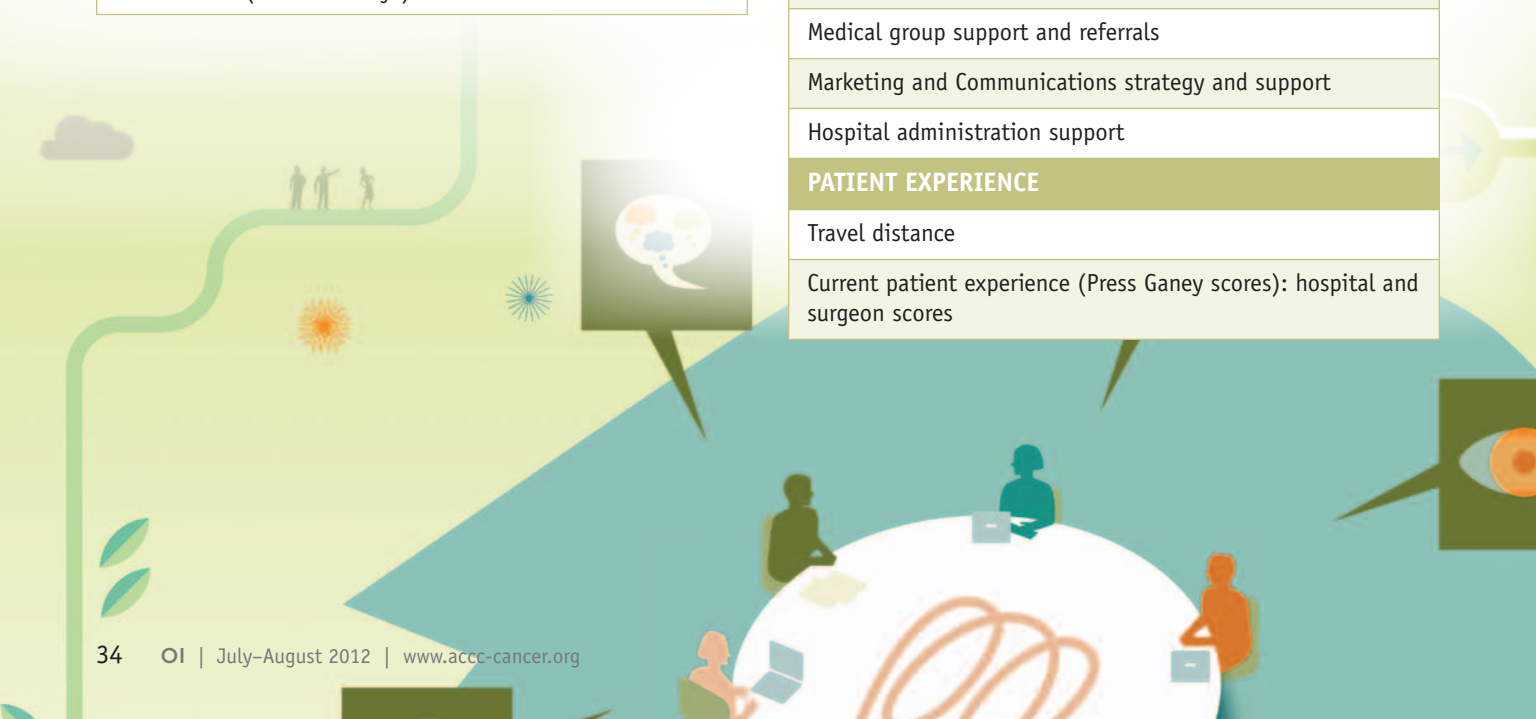


Table 4. Endometrial Measures

PREOPERATIVE MEASURES
Age
Race
BMI
Patient origin information using zip code
INTRA-OPERATIVE MEASURES
Number of nodes removed
Unilateral, bilateral, or no salpingo-oophorectomy
Complications
–Bowel injury
–Rectal injury
–Ureteral injury
–Bladder injury
Conversion rate to open
POST-OPERATIVE MEASURES
Pathologic staging
Pathologic history and pathologic grade
Positive margin rates
Bleeding requiring transfusion
Infection rate
Length of stay
POST-DISCHARGE MEASURES
Bleeding requiring transfusions (<30 days post)
Readmission (within 30 days)

Table 5. Strategic Subgroup: Objective Criteria to Guide Markets for Evaluations

MD CHAMPION
Robotic training in fellowship
Attendance in specialty courses and training
Minimally invasive surgery (MIS) experience
Strong interest
ACTUAL OR POTENTIAL VOLUME Incidence of:
Prostate
Benign GYN hysterectomies
GYN oncology
ENT diseases
Esophageal disease
General surgery procedures
Complex mitral and tricuspid valve procedures
Kidney transplant donor procedures
Kidney cancer
MARKET DYNAMICS
Population growth
Market competition
Aurora's market position
Aurora's short- and long-term market strategy
MARKET SUPPORT
Geographic draw and market buy-in
Medical group support and referrals
Marketing and Communications strategy and support
Hospital administration support
PATIENT EXPERIENCE
Travel distance
Current patient experience (Press Ganey scores): hospital and surgeon scores



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level of safety and quality of patient care. Initial responsibilities included defining, monitoring, and reporting quality standards for robotic surgery by surgical specialty, and developing a plan for a robotic surgery database and resources for ongoing maintenance of data extraction for reporting. Ultimately this group will be responsible for addressing patient outcomes and providing measures for evidence-based practices that support quality for a robotic surgery program. These data will serve as the driver for the Steering Committee's recommendations to Aurora Health Care senior leadership in guiding decisions that are supported by evidence-based data.

The decision was made to develop a system-wide robotic surgery database focusing initially on endometrial and prostate cancer. The database was supported by philanthropic funds from the Vince Lombardi Charitable Board. Data were pulled from the tumor registry, medical records, laboratory and pathology, and the cost accounting systems. Quality metrics defined include data from pre-, intra-, and post-operative measures (see Table 3, page 33 and Table 4, at left).

Strategic Planning & Communications

The Strategic Subgroup focused on developing a consistent objective evaluation of current and future robotic surgery technology across Aurora sites, including a process of ongoing evaluation and re-deployment of existing robotic surgery technology (see Table 5, at left).

With the health system's six da Vinci robots, the Strategic Subgroup worked to develop strategies to support adoption and growth of minimally invasive surgery, while being mindful to demonstrate value, quality, and cost-effectiveness. The subgroup developed criteria for evaluating robotic surgery model upgrades to provide guidance for decision-making based on volumes of actual and potential cases by type (urology, gynecologic, etc.), market support, and patient experiences.

Looking to the future, the Strategic Subgroup discussed the newest technologies in robotic surgery, which include the use of a robotic simulator to assess surgical proficiency and aid in the training process. Aurora currently does not own a simulator. Future recommendations from the Strategic Subgroup will include consideration of use and efficacy of a simulator as a tool for annually assessing the competency of surgeons who use the surgical robot.

The Communications Subgroup focused on consistent messaging through public relations and internal and external media outlets, including Aurora website pages. The future strategy of communication efforts will include transparency of our quality outcomes results on the Internet and to consumers seeking information on options through our second opinion nurse call line.

Looking Ahead

The future of Aurora's Robotic Surgery Program will focus on a system-wide approach to the decision-making process versus the original focus, which was site based with a goal to maximize the potentials of individual robotic surgery programs. The development of the system-wide Aurora Robotic Steering Committee allowed for key stakeholders to make recommendations on how robotic surgery programs would be implemented at each site safely and uniformly with high-quality patient care. OI

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Acknowledgment: **Special thanks to the Vince Lombardi Cancer Foundation for supporting the robotic-assisted surgery database project.**

Growing a

Using the NCCCP Navigation Assessment Tool

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Oncology care is complex, involving various disciplines and multiple treatment options from numerous specialists.[1] Oncology patient navigation was developed in response to this complexity. Harold P. Freeman, MD, is credited with founding and pioneering the concept of patient navigation in 1990 for the purpose of eliminating barriers to timely cancer screening, diagnosis, treatment, and supportive care.[2] Although navigation has shown efficacy as a strategy to reduce cancer mortality, increase patient satisfaction, and improve health outcomes, the healthcare community has been slow to adopt the model. However, recent developments suggest that formal patient navigation programs, particularly in oncology, improve patient outcomes, decrease patient distress, and reduce financial stress on the healthcare system.[1,3–5] Another recent development: By 2015 patient navigation will become a standard of care for all cancer programs accredited by the Commission on Cancer (CoC).[6]

Navigation Program

Given these developments, cancer programs that do not yet offer navigation services are beginning to ask: *How do we build a cancer navigation program?*

Current research has focused on explaining navigation without discussion of the "how to" aspects of developing a navigation program.[7] Thus, a standardized process by which all navigation programs may assess their developmental progress is needed. While not all navigation programs are created equal, universal consistencies exist. These "consistencies" can assist cancer centers and navigators in their program development efforts.

Navigation vs. Case Management

Community cancer centers in the initial stages of building a cancer navigation program should first understand how navigation differs from a case management model of care delivery.

Case management is a collaborative process of assessing, planning, facilitating, and advocating to meet an individual's health needs through communication and available resources, as well as promoting quality cost-effective outcomes. The main goal of case management is to maintain continuity of care through comprehensive, coordinated services, including the ability to follow a patient's changing needs over time. This follow-up is particularly crucial when the patient has a significant and chronic disability.[8] Benchmarks for case management require:[9]

- Organizational arrangements to support service delivery
- Staff trained for the approach and its application to the particular practice setting
- A strategy to ensure that the organization can respond to evidence from practice that advocates for systemic and policy change.

While these definitions and requirements can make it difficult to discern the differences between a navigator and a case manager, these roles are distinct. Navigator responsibilities include:[10]

- Conducting comprehensive assessment of a patient's holistic needs
- Providing supportive care throughout the continuum of cancer treatment
- Connecting patients to individualized information or community resources
- Facilitating discussions on the management of their cancer.

The literature identifies three different types of navigators: lay person(s), social worker(s), and nurse(s). A community cancer center must carefully assess the type of navigator that will best meet the needs of its patient population, community, and program. In these challenging economic times, cancer programs do not have the resources for trial and error, and must have a concise course of action to efficiently build an effective navigation program. The Navigation Assessment Tool discussed below offers a comprehensive pathway for community cancer centers to develop and/or grow a navigation program.

Development of the Navigation Assessment Tool

Through the National Cancer Institute Community Cancer Centers Program (NCCCP), navigators from 30 different cancer centers collaborated to delineate core measures to assess

USING THE NAVIGATION ASSESSMENT TOOL

While patient navigators are increasingly common, hospitals have yet to gain consensus on the roles and responsibilities for the position. To consistently define roles and responsibilities, infrastructure must be standardized. Nationwide, navigation programs are unique in as many ways as they are similar and must be created to meet the individual needs of a cancer program and its patient population.

The NCCCP Navigation Assessment Tool is intended to be used in assessing your navigation program. It is ***not*** designed to be a step-by-step process from one core measure to another. After all core measures are evaluated and levels defined, choose the core measures your cancer center wishes to improve on and work to increase to a different level within that core measure.

To achieve a baseline assessment, we recommend using a multidisciplinary team to ensure the most accurate rating of a new or existing navigation program. The optimal multidisciplinary team would include navigators, administrators, physicians, and any other appropriate healthcare provider connected to oncology patient care. Using the Navigation Assessment Tool, the team should review each category and refer to the definitions to accurately assess a rating—from Level 1 to Level 5—for each core measure.

While an accurate baseline assessment is crucial, determining the proper goal for your navigation program is equally essential. While most programs will seek to be a Level 5, a Level 3 or 4 may be the appropriate course of care based on the needs of the patients, clinicians, and community. Programs are not expected to achieve Level 5 status in all areas, but instead to use the tool as one way to assess a navigation program and set goals for improvement and growth. In any case, in completing this tool, your program will uncover opportunities for improvement across the continuum. Through this evaluation process, the Navigation Assessment Tool becomes a quality improvement tool, allowing implementation of interventions that can advance a program to the next level. Realistic goals, evaluated annually, will move a navigator program to the most favorable level.

progress in developing a cancer navigation program. This network of navigators led the effort to establish guidelines and consistencies in the development of a cancer navigation program at NCCCP sites.

Recognizing the important role of the nurse navigator and wanting to support the navigation programs at the 30 NCCCP sites, the NCCCP Quality of Care Subcommittee formally established a navigation networking group in 2010. In monthly networking conference calls, group members shared best practices, tools, job responsibilities, and performance improvement activities. These calls quickly revealed that while the 30 NCCCP sites were in different locations, with different patient populations, all were encountering the same concerns and barriers in establishing and growing a patient navigation program. To help define a pathway for programmatic advancement at NCCCP sites, the navigation networking group used a matrix format to develop a Navigation Assessment Tool.

The purpose of the Navigation Assessment Tool is to help cancer programs create a high-quality, patient-focused process that provides a return on investment (ROI). The tool presents the infrastructure and the basic building blocks for starting a patient navigation program. It also provides a framework for cancer programs to set goals and benchmarks and to grow their navigation services.

Core Measures

After a literature review and brainstorming sessions to find common themes for the Navigation Assessment Tool, the navigation networking group identified 16 core measures as "essential" to navigation program development:

1. Key Stakeholders
2. Community Partnerships
3. Acuity System and Risk-factor Identification
4. Quality Improvement
5. Marketing

6 Percentage of Patients Offered Navigation

7 Continuum of Care

8 Support Services

9 Reporting Tools

10 Financial Assessment

11 Focus on Disparate Population(s)

12 Navigator Responsibilities

13 Patient Identification

14 Navigator Training

15 Engagement with Clinical Trials

16 Multidisciplinary Conference Involvement

Each core measure has five levels. These identify program growth potential and allow a cancer center to set goals to advance its patient navigation program. Here is a brief look at each of these core measures.

Measure 1

Key Stakeholders

Buy-in from the healthcare providers using the navigation services is critical to the long-term success and survival of any navigation program.[11] The Navigation Assessment Tool defines the following key stakeholders as essential to a successful program:

- Navigators and cancer center staff.
- Cancer center administration. Buy-in from administration is necessary as navigation is not a direct revenue generating program.
- Physician involvement (both employed and private practice physicians). Physician support is important, particularly in specialty areas such as medical, surgical, and radiation oncology; rehabilitation; palliative care; and hospice.

A key step in implementing a navigation program is to garner institutional support for the program by building consensus with referring physicians, payers, administration, advocacy, and support networks.[12] A program champion is critical and should be knowledgeable about:[13]

- Healthcare barriers
- Navigation advocacy
- Methods to address gaps in services
- Physician and patient satisfaction
- Ways to promote the positive impact navigation has for patients and the healthcare system.

In early development (Level 1) community cancer centers garner support from an administrator committed to cancer center efforts and activities who can then act as an advocate for the navigator's role in meeting both patient and physician needs. A highly integrated program (Level 5) is reached when the navigation program receives referrals—not only from oncologists and other specialty physicians—but also from non-employed physicians, primary care physicians, and community partners.

Measure 2

Community Partnerships

The Navigation Assessment Tool defines community partnerships as those entities, within and outside of a program, that provide support for patients along the continuum of care. Patient navigators have been described as "supportive guide(s)," facilitating patient referrals to resources throughout the cancer continuum.[14]

Patients face many medical, emotional, and financial barriers, including:[15]

- Absence of payment sources
- Insufficient coverage for treatment
- Lack of affordable transportation and child care
- Cultural issues
- Language barriers
- Limited education.

To remove barriers, the oncology patient navigator must be aware of and develop relationships with a cadre of internal and external support services. The Navigation Assessment Tool outlines options from working with departments outside of the cancer center but still inside your healthcare system (Level 1) to the patient navigator joining a community organization as a committee or board member (Level 5).

Measure 3

Acuity System and Risk-factor Identification

Many patient navigation functions are consistent from one navigator to another—regardless of disease site. However, resources devoted to any particular patient depend on the individual's needs and the number of patients seen in that particular disease site. Patient needs also vary depending on stage at diagnosis, tumor site, type of treatment (single modality versus multiple modality), and the extent of the patient's support system.[16] Establishing an acuity system or patient risk-factor system of measurement is necessary to:

- Assess navigator workload
- Evaluate navigation assignments based on measured workload (rather than just navigator-to-patient ratios)
- Provide the support the navigator requires based on acuity levels.

The Navigation Assessment Tool defines risk factor as the variable increase of risk from complications with the disease and treatment of cancer. Acuity system is defined as the ability to determine the appropriate level of care or intervention based on patient need and disease process. A Level 1 program is described as having no risk factor or acuity system available—most likely to be true in newly developing navigation programs. Level 5 encompasses an integrated acuity system that would ensure quality of care by completing periodic re-evaluation throughout the patient care trajectory with the goal of addressing issues as they occur and, ideally, preventing issues from occurring. At present, an evidenced-based acuity system has not been developed or tested for navigation. Hospital- and facility-specific acuity systems and risk assessments are more common in mature navigation programs.

Measure 4

Quality Improvement

One of the primary goals of navigation is to overcome barriers to timely and quality care.[17] At least four primary measurable outcomes of navigation have been identified within this area:[18]

1. Improving the time to diagnosis
2. Reducing time to initiation of cancer treatment
3. Increasing patient satisfaction with care
4. Improving cost-effectiveness.

As nurse navigation services are not billable, community cancer centers face a growing need to identify measures of sustainability for their navigation programs. Developing quality improvement measures will document the worth of navigation by establishing outcomes in a quality improvement format.

Under Measure 4, the Navigation Assessment Tool defines a Level 1 program as having no quality improvement measures in place, which may be typical of a newly developed navigation program. Level 2 is achieved through activities such as brainstorming about metrics and reporting findings to the multidisciplinary team or cancer committee. When at least one quality improvement initiative is in place, the navigation program moves to Level 3, and so forth until Level 5, which requires demonstrated program improvement, quantifiable financial contribution to the cancer program, and identified cost savings to the organization through the navigation program.

Measure 5

Marketing

A wide range of disciplines and physicians who champion the navigation program can help ensure programmatic success. To secure champions and educate both internal and external customers, community cancer centers must effectively market their navigation program. Marketing must start at the very beginning of the navigation implementation process with the goal of garnering key physician support. Initial marketing may occur by word of mouth (Level 1). As the program matures, more formal marketing is necessary to increase utilization of navigation services. These marketing initiatives may include basic written materials (Level 2) and health fairs and cancer screening events (Level 3). Level 5 is achieved when the navigation program begins using targeted media sources to engage internal customers, other healthcare providers, patients, and the community.

Measure 6

Percentage of Patients Offered Navigation

As mentioned previously, the 2012 American College of Surgeons CoC Standard 3.1 on Patient Navigation states that a patient navigation process is to be established to address barriers to care for patients with cancer and healthcare disparities either on site or by referral.[6] With Measure 6, the Navigation Assessment Tool provides community cancer centers a means to monitor the progress being made toward meeting this CoC standard. One of the challenges in determining the percentage of patients offered navigation is determining the appropriate denominator, such as all analytical cases or total number of abnormal breast biopsies.

Measure 7

Continuum of Care

There are numerous key contact points in the patient navigation journey:[12]

- Abnormal finding to diagnosis
- Diagnosis to seeing a surgeon
- Transitions from surgeon to medical oncologist or radiation oncologist
- Changes in treatment regimens or modalities
- Transition into survivorship.

Focusing on education, logistics, and other support, a patient navigator can guide the patient through these key contact points, coordinate resources, and provide tools for coping with the high-risk phases, while allowing the physician to focus on the clinical management.[7] Thus, community cancer centers should offer navigation services to patients through, at least, these high-stress phases and into multiple settings (inpatient, outpatient, infusion clinics, radiation departments, etc.).

In the Navigation Assessment Tool, the continuum of navigation includes outreach and screening, abnormal finding to diagnosis, treatment, outpatient and/or inpatient care, and survivorship and/or end-of-life care. A navigator may have responsibility for all areas within the continuum or be designated to cover a specific area. A program may include disease-specific navigators or have multi-site navigators. The benchmark of a Level 5 program is that navigation is uninterrupted across the cancer care continuum; all functional areas of the cancer continuum have navigation.

In the tool, a program with one functional area within cancer navigation, e.g., a treatment navigator, would score at Level 1. As new functional areas, e.g., a survivorship navigator, are added to the navigation program, higher levels are reached along the matrix. Level 5 indicates that navigation occurs across all functional levels of the continuum into survivorship.

Measure 8

Support Services

For patients to be cared for appropriately, community cancer centers should ensure that support for all potential needs is available through navigator referrals. Available support that may be used by the navigation team can be identified from the inpatient care area (Level 2) or may be accessed through an outpatient setting (Level 3 or 4). While the focus of a benchmarked program is to have the services available to the patient within the cancer center, established referral patterns to community organizations may be more feasible due to limited resources. Measure 8 highlights the importance of advocacy to the navigator role, as the navigator is responsible for both assessing patient needs and making referrals to supportive services. To adequately address patient needs, navigators must connect with all members of an interdisciplinary team.

Measure 9

Reporting Tools

To evaluate the need for and the success of a navigation program, community cancer centers must develop reporting tools and/or a means of documenting navigation data.

Although electronic patient navigation software systems are now available, most institutions are reluctant to invest large sums of money in technology for budding navigation programs until the Accountable Care Organization (ACO) direction becomes more certain. Paper documentation is a cost-effective alternative that allows some flexibility for change as the navigation program grows.

Measure 9, Level 1, is defined as a program that does not offer a formal navigation report or tool but instead uses the patient's chart to describe the navigation services offered to the patient. To achieve Level 2, the cancer center must develop a simple database (e.g., in Access or Excel) to track basic statistics, such as number of patients contacted, diagnosis, and referrals. From these basic steps, hospital information technology (IT) departments can often develop high-level program-specific databases (Level 3). These data can provide valuable reports to assist with evaluation of productivity, timeliness of care, referral patterns, patient satisfaction, and the overall impact of the navigation program.

Integration of these databases into the hospital's EMR is the likely next step (Level 4), with the highest level being an electronic patient navigation system (Level 5). These systems offer documentation capabilities, as well as tracking and management tools as patients are navigated through the phases of treatment; some systems are even able to interface with the facility via EMR.

As a non-revenue producing program, patient navigation programs must provide robust outcome metrics that can be tracked and trended to ensure continued support and resource allocation.

Measure 10

Financial Assessment

Aside from the expected cost of medical care and treatment, patients often struggle with additional costs associated with the changes to their lives. For example, patients often will decline treatments, drop out of treatment, or delay appropriate follow-up and possibly jeopardize their outcomes and even survival because of the financial burdens of care. Therefore, financial assessment that gauges a patient's ability to achieve the best possible outcome with the least possible financial burden is a core component of navigation services. Measure 10 begins with Level 1: no formal financial assessment performed and progresses to Level 5: a comprehensive financial assessment with data collection completed on types of services provided and number of patients assisted.

Most institutions have inpatient financial specialists available to assist patients and families. Now cancer programs are seeing the benefit of using financial specialists to help meet the needs of the outpatient population as well. High-priced technology and treatments, complex insurance plans, and difficult economic times have made the financial specialist an integral member of the cancer treatment team. Indeed, with such a considerable impact, the financial assessment can be as important as the physical assessment. A proactive approach provides the opportunity to secure funding for diagnosis and treatment, identify services which may not be covered up front, and provide additional resources if needed. Addressing and alleviating financial difficulties helps the patient, as well as the financial viability of the healthcare organization.

Measure 11

Focus on Disparate Population(s)

A key goal of the NCCCP is to provide high-quality cancer care to disparate populations. Americans who live in poverty, as well as certain ethnic and racial groups, have higher cancer death rates than other populations.[19] Patient navigators are an important intervention against these disparities.[10]

Measure 11 depicts a cancer program's journey from identification of the underserved (Level 1) through the outreach to and integration of the defined population (Level 5). A disparate population can be the Native Americans in Montana, the Pacific Islanders in Hawaii, the rural population of Maine, the Hispanic population in Pennsylvania, the lower socio-economic status in Louisiana, or the elderly in Georgia. Each population is different and requires culturally sensitive programs and providers to gain trust and meet medical needs. To ensure that staff maintains skills and knowledge, programs should conduct a cultural sensitivity assessment and create cultural objectives, at least, on an annual basis (Level 5).

Measure 12

Navigator Responsibilities

These are as varied as the institutions in which navigators work. Often navigators are initially assigned to a disease-site-specific patient population, for example breast cancer patients. Navigators are responsible for the support and education of the patient from diagnosis through treatment (Level 1). A more integrated model has the navigator coordinating care between multiple disciplines within the cancer program. As the navigation program matures, the navigator's role may include participation in support groups, structured educational offerings, and a variety of family and patient-centered programs (Level 2). A hallmark of quality care is the offering of disease-specific multidisciplinary clinics or conferences (MDCs), and navigators should attempt to be a part of these patient services (Level 3). Navigators are able to offer insight to the MDC on patients' physical, emotional, and financial needs and concerns. Navigators may also be responsible for quality improvement projects and assist with medical audits and strategic planning (Level 5).

Whatever the navigator's level of responsibility, community cancer centers should clearly define the scope of navigator accountability to help focus efforts, as well as to resolve conflict and prevent burnout and avoid unrealistic demands on the navigator's time, attention, and resources.

Measure 13

Patient Identification

To identify patients, the navigator may review pathology reports, daily procedure schedules, or radiology reports sorting patients by diagnosis (Level 1). Patients may self refer or be referred by oncology providers who are usually early adaptors, seeing the benefits of care coordination and patient satisfaction (Level 3). As the navigation program develops and demonstrates improved patient outcomes, primary care physicians and other specialty providers will refer patients appropriately, perhaps at the first indication of a suspicious finding (Level 5).

Measure 14

Navigator Training

Staff training is essential to successful implementation of a navigation program. Despite extensive experience in clinical care, navigators will require considerable training to excel in core competencies, particularly given the broad array of patient situations likely to be encountered. To ensure effective and timely patient interventions, navigators must be trained to understand the patient experience and know when and how to engage with the patients.

In Measure 14, programs without formal staff training in place fall within Level 1. To ensure success, however, education on defined core competencies will be necessary (Level 2). As experience is gained, programs can develop in-house training and curriculum specific to navigator core competencies, allowing continued development of the navigator role (Level 3). This training should eventually become a navigation staff requirement and may be conducted in-house, locally, or through certification in oncology in their respective disciplines (Level 4). To achieve Level 5, navigators should receive formal training through a nationally recognized training program.

Measure 15

Engagement with Clinical Trials

The navigator plays a key role in educating patients about the benefits of clinical trials and helping patients take an active role in their own health. Most navigators have basic knowledge of clinical trials; more in-depth education can be obtained through the National Cancer Institute (NCI), the Oncology Nursing Society (ONS), or other oncology organizations. Navigators should share this information with patients and the community to dispel misconceptions and fear surrounding participation in clinical research. Working with the research team, navigators can identify patients for referral and assist patients in accessing new treatments. At Level 5, the navigator is working with the research team, assisting with specific trial referrals for underserved populations. These disparate populations often have limited access to or knowledge of the benefits of clinical trials. It is the navigator's responsibility to educate and support the patient and ensure access to the highest level of quality care possible.

Measure 16

Multidisciplinary Conference Involvement

According to the CoC, the multidisciplinary conference is integral to improving the care of cancer patients by contributing to the patient management process and outcomes.[6] Navigators should attend tumor conferences to: 1) share information about the patient care provided through navigation services and 2) support the discussion of the patient's case. With more experience and involvement as a member of the MDC team, the navigator will be expected to assist with case finding presentation (Level 3). The navigator can then begin to provide formal review of discussions within the MDC with the patient and family (Level 4), preferably through open communication between the patient and the care team. The most integrated level of participation occurs when the patient is informed of presentation at the MDC with a full report on the treatment planning discussion shared with the patient, referring physician, and the primary care provider (Level 5). At this point, the navigation program can conduct formal audits, track compliance, and ensure that outcome data are readily available.

Future Implications

The Navigation Assessment Tool matrix of program development is both comprehensive and logical. To date, research efforts have focused on understanding navigation program benefits for the patient and the facility or clinic. However, without standardization, the efficacy of one program may not translate to other programs. Therefore, standardization of process in navigation program development is necessary.[5]

Many new and even established navigation programs are unsure how to grow or remain relevant. With little research available to show strong evidence of navigation program growth potential, administrators will begin to question the benefit from a stagnant program. Through the use of the Navigation Assessment Tool, any program can evaluate itself against 16 core measures that are present in some part for all navigation programs. By having a tool to monitor programmatic growth (and prospects for growth), a navigator is able to demonstrate expansion opportunities and quality improvement of a program through the establishment of realistic goals. OI

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Online Content Only!

Use the NCCCP Navigation Assessment Tool to assess your navigation program and/or services. As all navigation programs are built uniquely, the authors encourage you to rate your program as you feel appropriate. The purpose of the Navigation Assessment Tool is not to gauge one program against another, but to assist cancer centers to build a stronger navigation program. This tool can be used to assess an individual tumor site or the entire navigation program. Download the NCCCP Navigation Assessment Tool online at: *www.accc-cancer.org/oi/JA2012*.

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RN Training in Cancer Survivorship Care

A PILOT STUDY

BY MARCIA GRANT, RN, DNSC, AND DENICE ECONOMOU, RN, MN, CHPN

In 2011 nursing research and education staff from City of Hope, Duarte, California, developed a two-day course on Registered Nurse (RN) training for cancer survivorship. The primary aim: to improve the quality of care and quality of life for cancer survivors by training nurses about the specific needs of cancer survivors. The course was developed as a pilot and in anticipation of receiving a National Cancer Institute (NCI) training grant. Course curriculum used adult learning principles to develop interactive and small-group educational modules. These modules were built around the Institute of Medicine (IOM) report components of care. Course content provided an overview of survivorship care nursing roles that could be integrated into individual practice.[1] See Table 1 (right) for an example of course modules.

Experts in the area of cancer survivorship care served as course faculty, including Marcia Grant, RN, DNSc, Betty Ferrell, RN, PhD, Denice Economou, RN, MN, and other City of Hope staff; Mary McCabe, RN, MN, from Memorial Sloan-Kettering Cancer Center; and Amy Jacobson, RN, NP-BC, from the University of California, Los Angeles.

Participant Characteristics

Forty-six nurses from 27 different settings participated in the pilot course, which took place May 2–3, 2011, at the City of Hope. Participants paid a moderate fee for the two-day course with additional expenses supported by the City of Hope and Cedars-Sinai Medical Center in Los Angeles.

Looking at participant characteristics, 67 percent were RNs, 26 percent were nurse practitioners (NPs), and 7 percent were clinical nurse specialists (CNSs). These nurses held a variety of positions:

- 39 percent worked in outpatient oncology units
- 20 percent worked in inpatient oncology units
- 11 percent were administrators
- 9 percent worked as nurses in private practice (physician office setting)
- 9 percent were involved in research-related activities
- The remaining 12 percent was a mix of nurse educators, navigators, and case managers.

Nearly half (48 percent) of participants reported that their programs were not currently providing any survivorship services prior to attending this course. The other half (52 percent) said their programs were providing some type of survivorship activities in their setting. One participant came from a program that was just starting a survivorship clinic.

Participants also practiced in a variety of settings:

- 43 percent were employed by academic or teaching hospitals
- 31 percent worked at community hospitals
- 15 percent were employed by a private practice (physician office setting)

PHOTOGRAPHS COURTESY OF CITY OF HOPE—DEPARTMENT OF NURSING RESEARCH AND EDUCATION

Table 1. RN Training for Cancer Survivorship Care—Examples of Program Content	
Nurses' Role in Starting a Survivorship Clinic: An Overview of Survivorship Activities for RNs	Faculty: Wendy Landier, PhD, RN, NP
Cancer and Aging: Caring for the Older Cancer Survivor	Faculty: Arti Hurria, MD
Fertility & Sexuality Issues for Cancer Survivors	Faculty: Anna Cathy Williams, RN, BSN, PHN
Institutional Change: Building Your Case	Faculty: Marcia Grant, RN, DNSc

- 7 percent worked in a research department
- 4 percent were employed by an HMO hospital.

The variety of nursing professionals and practice settings demonstrated that the desire to provide survivorship care is strong across all care settings. This need may be related to the new Commission on Cancer Standards. In 2015 Standard 3.3 will require a Survivorship Care Plan that includes a "comprehensive care summary and follow-up plan to patients with cancer who are completing cancer treatment."[2] This care plan is to be provided to patients on completion of treatment to qualify for CoC certification.

Outcomes

To help faculty understand the level of participants' survivorship knowledge prior to completing the course, attendees were given a pre- and post-test assessment. Pre-test knowledge scores averaged 86 percent, while post-test scores averaged 95 percent. At the completion of the two-day course, participants evaluated course content and faculty. Course faculty was evaluated on a scale of 0 to 5. Scores averaged: 4.84 for Clarity of Presentation; 4.86 for Quality of Content; and 4.84 for Value to a Clinician or Practitioner. Participant comments included:

- Very informative
- Very good speakers
- There was a wealth of information on survivorship
- All topics were very interesting and informative
- Excellent, knowledgeable presenters and valuable resources.

Faculty was pleased with the positive comments and curriculum insight this pilot training course provided. For instance, it was clear to faculty that: 1) concrete examples of the nurse role in survivorship care had been provided, 2) treatment summary and survivorship care plan needs were important, and 3) survivorship care was an opportunity for health promotion. Participating nurses continue to contact course faculty for information and resources to help put their new survivorship knowledge into practice. Because the course was able to improve participant knowledge of cancer survivorship care, faculty anticipates that cancer survivor needs will be met more effectively at these programs, thereby improving quality of life for cancer survivors and their families.

The need to train nurses in survivorship care remains strong. We were able to use this pilot course to refine the curriculum for the R25 educational program, *Preparing Professional Nurses for Cancer Survivorship Care,* which was funded through NCI grant R25 CA 151077.

The first of four *Preparing Professional Nurses for Cancer Survivorship Care* courses was held April 12–14, 2012, in Monrovia, California. Course two is scheduled for Tarrytown, New York, September 27-29, 2012. Participants must register by July 27, 2012.

To register for the September course or for more information go to: *www.cityofhope.org/survivorship-training.* This education will provide additional information on caring for the underserved, older, and non-English speaking cancer survivor, as well as methods of collecting data to measure outcomes of survivorship care. OI

—Marcia Grant RN, DNSc, is director and professor of the Department of Nursing Research and Education, and Denice Economou, RN, MN, CHPN, is project director and senior research specialist at the City of Hope, Duarte, Calif.

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action

ACCC EDUCATION UPDATES

Multiple Myeloma Initiative

A Small-Population Cancers Project from ACCC's Center for Provider Education

How Much Do You Know About Multiple Myeloma?

ACCC has launched a ground-breaking program to give cancer care providers the tools they need to care for and support patients with multiple myeloma. Soon, ACCC will conduct a survey of members to gauge knowledge about multiple myeloma, assess how programs integrate the latest clinical data into practice, and understand the extent of support services and program design. Look for the survey to arrive by email.

As part of its "Treating Small-Population Cancers in the Community Setting" educational project, ACCC will raise awareness about the special needs of patients with multiple myeloma and identify most effective practices in treating multiple myeloma in community programs. Among the many questions that ACCC will explore are:

1. How are cases reviewed in a multidisciplinary manner?
2. What guidelines are followed?
3. What type of monitoring takes place and which is appropriate?
4. Are clear policy and procedures in place to deal with any financial or managerial challenges?
5. How are patients transitioned between care settings?
6. How do cancer programs ensure that team members receive the most current information about managing the patient with multiple myeloma?

ACCC will compile the most effective practices and share them with cancer care providers across the country. Want to learn more? Go to: *www.accc-cancer.org/multiplemyeloma*.

Molecular Testing in the Community Oncology Setting: Understanding the Landscape and Identifying and Sharing Best Practices

An education program from ACCC's Center for Provider Education

Molecular Testing & Your Cancer Program

ACCC understands that the growth in molecular testing can present a challenge to community cancer centers. As a part of its education project, "Molecular Testing in the Community Oncology Setting: Understanding the Landscape and Identifying and Sharing Best Practices," ACCC has launched two surveys to better understand the needs of community-based cancer programs regarding molecular testing. A multidisciplinary expert ACCC Advisory Committee helped with survey design along with the consulting firm, Health Equity Associates, which will be conducting survey data analysis. Survey results and information gathered from focus group discussions will be used to help identify best practices in implementing molecular testing in the community setting.

The primary goals of this educational project are to:

- Understand from a multidisciplinary perspective the current molecular-testing landscape, including barriers to use of molecular testing in the community setting
- Identify a wide variety of community-based cancer programs that have excelled at implementing molecular testing, thereby improving patient care
- Identify key success factors and effective practices, demonstrated through case studies, to successfully implement molecular testing in the community setting.

For more on this project, visit *www.accc-cancer.org/moleculartesting*.

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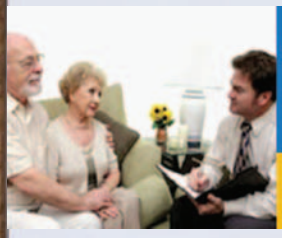

The Financial Information and Learning Network for Community-Based Cancer Programs

An educational program from ACCC's Center for Provider Education

The Financial Information and Learning Network Practical Course

This online course is focused along the continuum of "beginner" to "expert." Participants can choose to take courses in order from Course 1 to Course 10. Conversely, participants can focus solely on areas where improvements are needed. The course in its entirety can also be used to train staff new to cancer and/or financial counseling services. Free to ACCC Cancer Program Members.

- Course 1: **Archived** Understanding the Insurance Process
- Course 2: **Archived** Patient Assistance 101
- Course 3: **Archived** Patient Counseling 101
- Course 4: **June 28, 2012** Evaluating and Improving Your Revenue Cycle
- Course 5: **July 25, 2012** Financial Counseling 101
- Course 6: **August 21, 2012** Justifying a Financial Counselor Position
- Course 7: **September 19, 2012** Financial Counselors as Part of the Multidisciplinary Cancer Care Team
- Course 8: **October 25, 2012** Improving the Patient Experience
- Course 9: **November 2012** Reporting Processes and Data to Internal Stakeholders
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The Weight Gain Conundrum—When to Intervene?

BY LISA SHEPARD, RD, CSO

We are all aware of the impact that obesity has on overall health and well-being. Recently, the impact of weight gain on cancer risk, recovery, and recurrence has become a major concern. In April 2012, the American Cancer Society (ACS) released new *Nutrition and Physical Activity Guidelines* that recommend "people living with cancer maintain a healthy weight, get enough exercise, and eat a healthy diet."

As an oncology dietitian, the weight gain conundrum poses the tricky question of when to intervene. Researching the many factors that contribute to weight gain during and after cancer treatment is challenging. It involves considering many scenarios and trying to identify what may be unforeseen, incidental, associative, and preventable. In looking at the literature and listening to my patients, I'm overwhelmed at the complexity of the situation and—at the same time—aware of the importance of early intervention.

Most often, I see the weight gain conundrum in breast cancer patients. With breast cancer, it seems that obesity is an established risk factor. The risk of estrogen positive and estrogen triple negative cancer is affected by obesity, perhaps more premenopausal with triple negative and more post menopausal with estrogen positive. These findings tell us that more than estrogen is at play. For breast cancer patients, weight gain—even a 10 percent gain for a person lean at diagnosis—can increase risk for recurrence by 30 percent.

Weight gain can also occur with other cancers, particularly after chemotherapy, and especially with cancers that are hormone sensitive, such as breast, prostate, and uterine and endometrial cancers.

The dilemma we face as dietitians is multi-faceted. We really don't know what amount of weight truly poses a risk. We also sit with our patients who are articulate, educated, and committed to their health, yet we are sometimes challenged to help them with their weight gain. They tell us that they are eating less than they used to and they often are exercising to help create a deficit of calories, but they are still struggling to lose weight.

Although some of the factors contributing to the weight conundrum are not clearly identified, we do know that a "perfect storm" of events occurs.

The tumor itself may create some initial insult to the body. Stress, tumor necrosis factor, cytokines, and inflammatory hormones may begin to affect metabolism. Taste alterations can occur early on—before diagnosis—as well as during active treatment.

Steroids that are used to increase tolerance to chemotherapy can stimulate appetite, raise glucose levels, increase fat deposition, and contribute to sarcopenic obesity, a debilitating condition in which weight gain occurs as lean body mass is lost, leading to lower metabolism and impeding weight loss.

Reduced physical activity, common with cancer patients, can be exacerbated as routines are disrupted and lives are squeezed around cancer treatment. Fatigue may adversely affect food choices. Low energy combined with tight schedules may prompt the choice of more processed, less nutritious take-out meals.

Higher cortisol levels resulting from fatigue and often associated depression and stress may further present metabolic imbalances from elevated glucose, more fat deposition, and decreased immunity. Other food-related side effects created by chemotherapy include nausea, altered taste, bloating, gas, diarrhea—all of which affect eating and can result in erratic eating patterns.

Many patients believe that cancer causes weight loss and may inadvertently overeat. "Comfort" foods may become staples during treatment. Friends may bring very caloric, high-fat casseroles and high-sugar treats to make life easier. Fruits, vegetables, and whole grains—the staples of immune-enhancing nutrients—are often overlooked. With the stress and discomfort of diagnosis and treatment, many patients believe it's just too much to have to focus on "healthy" eating. It may even be what we providers believe to some extent.

This cascade of weight gain and health implications for long-term disease-free survival begs the question of timing for intervention of diet and exercise. At the time of treatment we truly have a "teachable moment" that could affect long-term outcome. We need to educate our patients early on. OI

—Lisa Shepard, RD, CSO, is oncology dietitian at the Carl & Dorothy Bennett Cancer Center, Stamford Hospital, Stamford, Conn.

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