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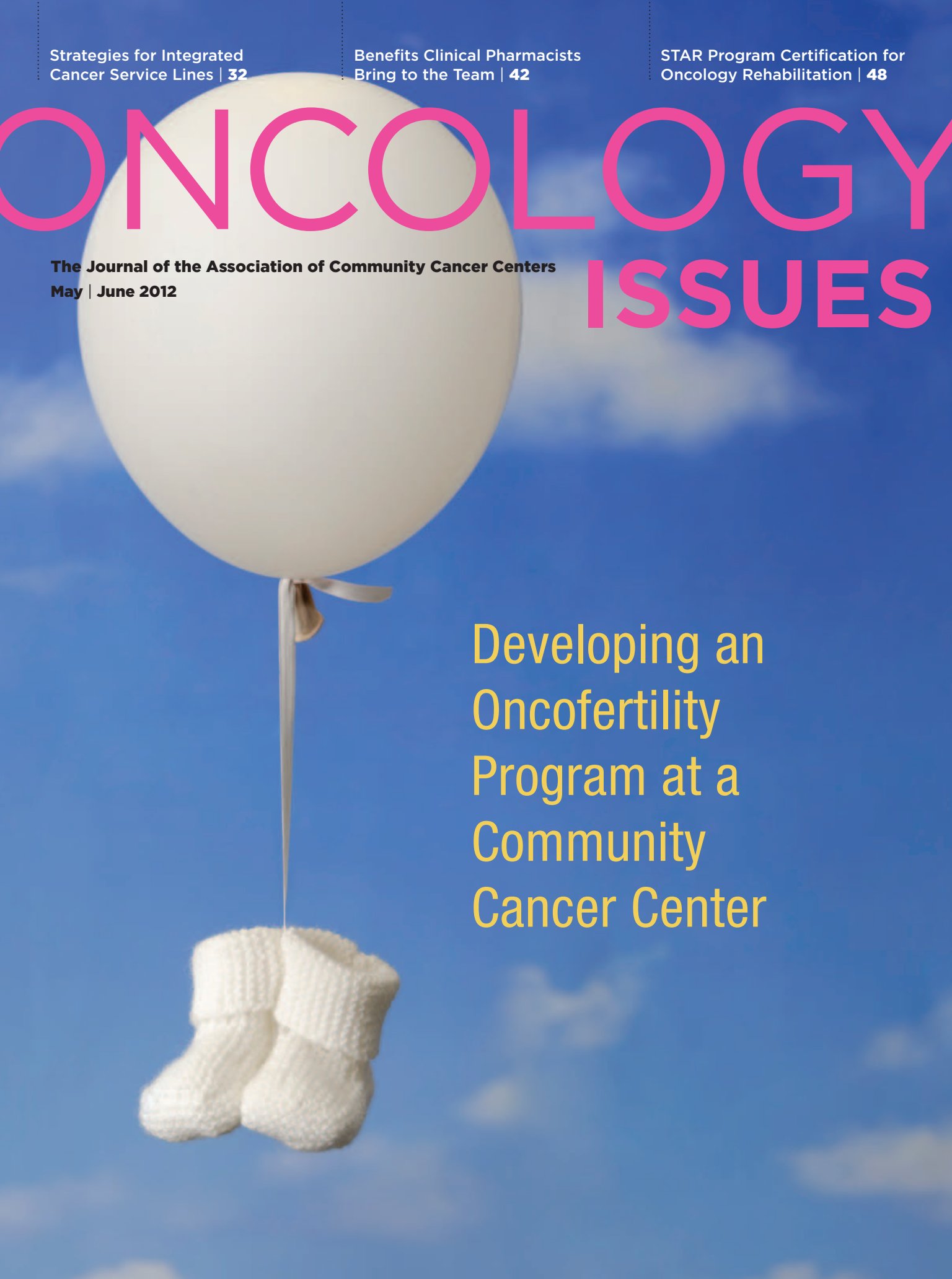
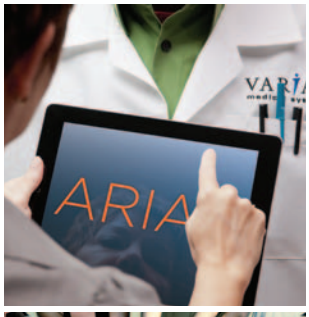
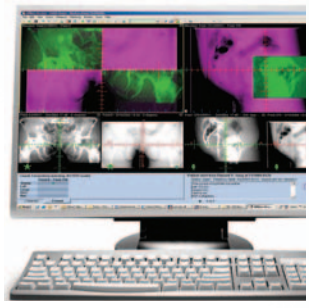
ONCOLOGY ISSUES

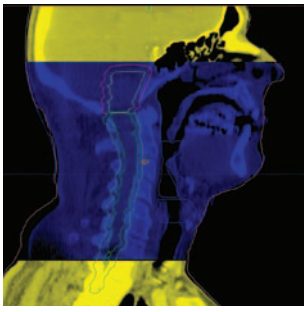
The Journal of the Association of Community Cancer Centers
May | June 2012



Developing an Oncofertility Program at a Community Cancer Center







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Oncology Issues
May | June 2012
Vol. 27 | No. 3

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

Walking a Mile in Their Shoes

BY CHRISTIAN DOWNS, JD, MHA

I want to bring your attention to an article that I read in a recent issue of *Health Affairs*. Now it might seem a bit odd that the editor of one publication would refer readers to an article in another publication—but that's how we bounce at ACCC. We have a vested interest in ensuring that our members receive useful, credible information. We care a little less about where you get it from.

The article is by Amy Berman, and it's titled "Living Life in My Own Way—And Dying That Way as Well." It is a moving piece about Ms. Berman's terminal cancer, her personal interactions with our healthcare delivery system, and the power of taking control and direction of your own care.

After reading the article, I started thinking about how we look at the "whole patient." Are we doing everything to treat the *patient* with the disease, rather than just the disease? How are *you* helping your patients live while they are being treated?

This edition of ACCC's journal addresses several of these "whole patient" issues head on.

First, newly elected ACCC Board Member, Faye Flemming, shares how she developed an innovative oncofertility program after seeing firsthand what happened to her young niece when she was diagnosed with cancer and her fertility needs went unmet by her clinicians. Flemming writes about the importance of timely assessment of fertility needs, education about fertility risks and options, counseling, quick referrals, and ongoing follow-up. And, as we always try to do in *Oncology Issues,* we include practical tools that you can adapt and use at *your* cancer program.

Next, ACCC's associate editor, Amanda Patton, interviews the co-chairs of the Alliance for Fertility Preservation: John Mulhall, MD, and Zev Rosenwaks, MD. In brief, the interview talks about what this fledgling organization hopes to do to help ensure that the fertility needs of cancer patients are met—after diagnosis, during treatment, and into survivorship.

Lastly, on the "whole patient" theme, check out the article on STAR Program Certification at Jupiter Medical Center in Florida. Implementing this cancer rehabilitation program required a three-phase process: training staff, developing and putting into place protocols, and tracking patient outcomes.

And we cannot talk about the "whole patient" without looking at how care is delivered. In this issue we highlight the importance of clinical pharmacists to patient care. Author Annie Lambert shows how clinical pharmacists are a crucial component of a system of double-checks that ensure safe care, optimal charge capture, and compliance with both external and internal guidelines.

Then, Matthew Sturm and Jessica Turgon write about bringing hospitals and physicians together in an integrated service line. The authors draw on years of experience working with hospitals and physicians to provide several critical strategies to ensure successful outcomes.

But let me close by going back to Amy Berman and her moving article in *Health Affairs*. Right now, this article is open access and available for all to read at: *http://content.healthaffairs.org/content/31/4/871.full.* For me, sharing in this patient's experiences is a great reminder of why we all need to read *Oncology Issues*. OI

PRESIDENT'S MESSAGE

Healthcare Reform, Quality Care, and Value

BY GEORGE KOVACH, MD

Healthcare reform continues to take center stage this year. And although cost, quality, and value are the common buzzwords of healthcare reform, the definitions of these terms continue to engender debate. Providers are getting better at defining quality care, but objective criteria for determining the value that patients receive from treatment, for example, are lacking. If we do not understand the metrics of value, better define the forces driving cost, and educate providers about clinical guidelines that incorporate cost-effectiveness information, we are doomed to err in our attempts to control the spiraling costs of healthcare.

To rein in the high costs, tough questions require closer attention and more objective answers. When is a high-cost treatment "worth" the expense in terms of delivering better health to patients? How much benefit, in additional months of life expectancy, would a new drug need to provide to justify its cost and warrant its use in an individual patient?

Writing in the April 2012 issue of *Health Affairs,* Peter A. Ubel and colleagues surveyed oncologists in the U.S. and Canada to find an answer. The majority of oncologists agreed that a new cancer treatment that might add a year to a patient's life would be worthwhile if the cost was less than $100,000. But when given a hypothetical individual patient case to review, the oncologists also endorsed a hypothetical drug whose cost might be as high as $250,000 per life-year gained.

The authors went on to say that expensive new cancer treatments that can extend life raise questions about whether physicians are prepared to make "value for money" trade-offs when treating patients.

We know that multiple influences drive cancer care costs, including new technologies and pharmaceuticals, regulation, and the growing numbers of patients as the population ages and we benefit from more effective treatments for disease. Attempting to control costs by decreasing payments to providers is, however, clearly a no-win proposition for either the provider or the patient.

Consider the SGR, for example. Each year the sustainable growth rate (SGR) formula compares the cost of healthcare relative to the Gross Domestic Product (GDP) and determines a reimbursement adjustment, positive or negative, to be applied the following year. The current adjustment is estimated at negative 35 percent on January 1, 2013, and the cost to fix this flawed system is now over $300 billion. Each year, Congress has had to step in with a legislative "fix" to prevent these physician reimbursement cuts. And yet the relationship between GDP and healthcare costs is obscure at best. Case in point—if the GDP underperforms, is healthcare at fault?

Even as we await the U.S. Supreme Court's decisions on the constitutionality of the Affordable Care Act, healthcare reform in some shape is inevitable. New payment models, growing attention to evidence-based medicine, and increased consolidation are already underway and unstoppable.

On a positive note, many aspects of the Affordable Care Act, such as the CMS Innovation Center, are tasked with providing more detailed reporting on healthcare costs, access, and quality. These data may afford the oncology community an opportunity to educate policymakers in Washington, D.C., and at CMS.

The Association of Community Cancer Centers has a key role to play. We must remain a strong national advocate with a voice in both helping to define quality cancer care as well as shape policy—rather than react to it. OI

Coming in Your 2012 *ONCOLOGY ISSUES*

- Cancer Management Systems
- Implementing a Service Excellence Program
- A Model for Patient and Family-Focused Transitional Care
- Robotic Surgery Programs at an Integrated Health System
- Training Nurses for Survivorship Care
- Two Model Cancer Survivorship Programs: TACTIC and THRIVE
- Academic Medical Center Affiliation with a Community Cancer Center
- 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
- A Navigation Assessment Tool—The Cornerstone of a Process to Build a Navigation Program
- A Day in the Life of a Patient Navigator

more online @ www.accc-cancer.org

Understanding the Insurance Process

WEBINAR

A representative from the Patient Advocate Foundation and a practice manager share their combined knowledge at: *www.accc-cancer.org/filn*.

ACCC's 2012 Annual Meeting on Demand

VIDEO

Watch videos and power point presentations of key sessions at: *www.accc-cancer.org/annualmeeting*.

ACCCBuzz

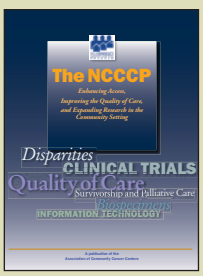
BLOGS

ACCC Executive Director, Christian Downs, mentioned nurse, blogger, and breast cancer survivor Amy Berman in his column this month. Learn more at: *http://acccbuzz.wordpress.com/2012/04/16/*.

Molecular Testing & Your Cancer Program

We'd like to hear about your experiences—successes and challenges—in implementing molecular testing. Share at: *www.accc-cancer.org/moleculartesting*.

NCI NCCCP Digital Monograph



"The NCCCP—Enhancing Access, Improving Quality of Care, and Expanding Research in the Community Setting" is available online at: *www.accc-cancer.org/NCCCP*.

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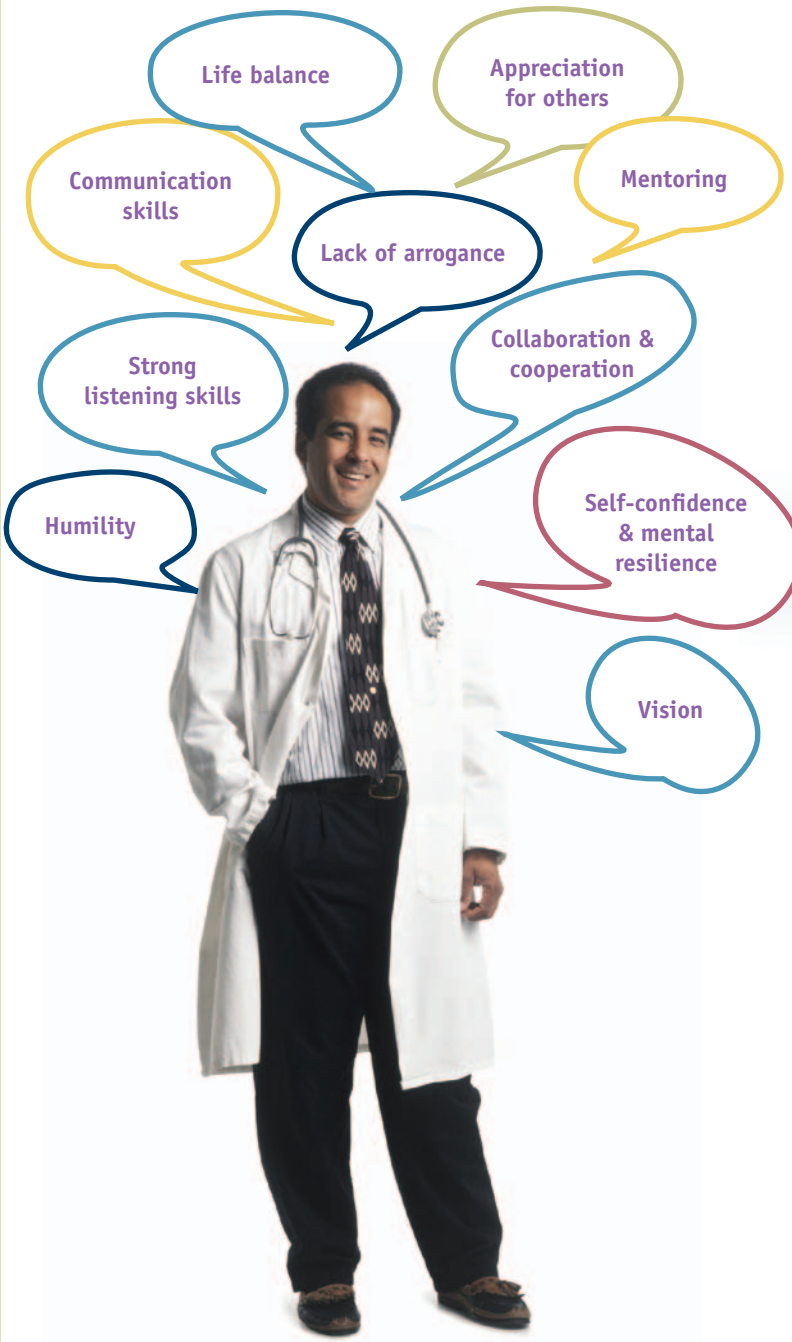
10 Skills & Characteristics of New Physician Leaders



Source: The Camden Group. www.thecamdengroup.com/top-ten/2162012.php.

facts

Top 2012 Predictions in Healthcare Data

- Mobile will explode in healthcare.
- Hospitals may be at risk to data breach risks caused by the spread of mobile devices in the workforce.
- Class-action litigation firestorms are imminent.
- Social media risks in healthcare will grow.
- Technology is outpacing security, creating unprecedented liability risks.
- Growing reliance on business associates will create new risks.
- Privacy and security training will be an annual requirement.
- Healthcare organizations will turn to cyber liability insurance.

Source: The Ponemon Institute. http://*www2.idexpertscorp.com/ponemon-study-2011/*.

Fertility & Cancer Treatments

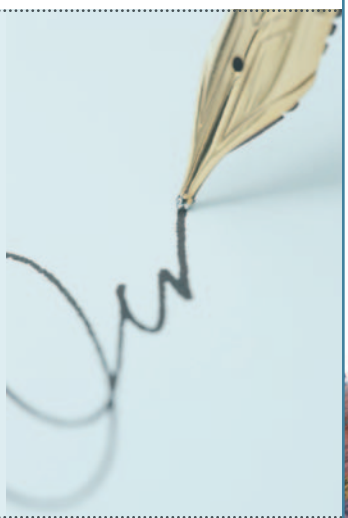
A new study found that while 61% of women received counseling on the risks of cancer treatment to their fertility, only 4% pursued fertility preservation. Still rates are increasing over time—from 1% in 1993. Women who are childless, younger, Caucasian, heterosexual, and college graduates are more likely to be counseled about the risks of cancer treatment to fertility or to preserve fertility before cancer treatment.

Source: Racial, Socioeconomic, and Demographic Disparities in Access to Fertility Preservation in Young Women Diagnosed With Cancer. Joseph M. Letourneau, et al. *CANCER;* Published Online: March 26, 2012 (DOI: 10.1002/cncr.26649).

How Much is a Physician's Signature Worth?

Celebrities are not the only ones paid a handsome sum of money for an autograph. Physicians are often paid for their signature too—if the physicians are putting their signature on an employment contract. Last year, 88% of physicians were paid an average of more than $20,000 to sign on the dotted line. The signing bonus is paid in addition to full reimbursement for the physician's relocation costs.

Source: The Medicus Firm, Dallas, Tex. *www.TheMedicusFirm.com.*



What Do We Spend on Anti-cancer Drugs?

Predictions are that the world market for cancer-treating drugs will reach $75 billion for 2012.

Source: visiongain. *www.visiongain.com/Report/770/Leading-Anti-Cancer-Drugs-and-Associated-Market-2012-2022.*

5 Commonly-used Oncology Procedures That May Not Be Necessary

On April 4, the American Society of Clinical Oncology (ASCO) issued a "Top Five" list of common, costly procedures in oncology that are not supported by evidence and that should be questioned. The list was released at a press conference hosted by the American Board of Internal Medicine Foundation (ABIM) as part if its *Choosing Wisely*® campaign. ASCO is one of nine participating physician specialty societies asked to provide specific, evidence-based recommendations physicians and patients should discuss to help make wise decisions about the most appropriate care based on their individual situation. In brief, here is ASCO's Top Five list:

1. For patients with advanced solid-tumor cancers who are unlikely to benefit, do not provide unnecessary anticancer therapy, such as chemotherapy, but instead focus on symptom relief and palliative care. (The Top Five list notes important exceptions to this recommendation based on patient circumstances—including patients who have disease characteristics, such as specific genetic mutations—for which further therapy could be beneficial.)
2. Do not use PET, CT, and radionuclide bone scans in the staging of early prostate cancer at low risk for metastasis.
3. Do not use PET, CT, and radionuclide bone scans in the staging of early breast cancer at low risk for metastasis.
4. For individuals who have completed curative breast cancer treatment and have no physical symptoms of cancer recurrence, routine blood tests for biomarkers and advanced imaging tests should not be used to screen for cancer recurrences.
5. Avoid administering colony stimulating factors (CSFs) to patients undergoing chemotherapy.

ASCO's Top Five list for oncology not only highlights a set of specific practices that should be questioned, but also—and perhaps more importantly—provides an opportunity to emphasize the importance of using evidence-based medicine to arrive at clinical decisions. Over the coming months, ASCO will continue to educate both physicians and patients about the effort and provide tools and resources providers need to consider the issues fully and make wise choices. For more information, on the Top Five list and the *Choosing Wisely* campaign, visit: *www.asco.org/topfive*.

A full manuscript detailing the background, methods, and results of ASCO's efforts was published in the *Journal of Clinical Oncology*.

ACCC Comments on PCORI Priorities & Research Agenda

Mar. 15, ACCC submitted comments to the Patient-Centered Outcomes Research Institute's (PCORI's) Draft National Priorities and Research Agenda. ACCC strongly supports PCORI's mission "to fund research that offers patients and caregivers the information they need to make important healthcare decisions."

In its comments, ACCC noted that high-quality cancer care involves "not only appropriate use of drugs, devices, and medical procedures, but also effective coordination among caregivers. Prevention and screening are vital to sparing patients the pain of cancer or allowing treatment at earlier stages of the disease. Further research into all of these aspects of cancer and its diagnosis and treatment is essential to improving patients' outcomes."

The Draft National Priorities and Research Agenda has the potential to promote important research that could change the lives of cancer patients. PCORI proposes five broad priority areas of research:

1. Assessment of Prevention, Diagnosis, and Treatment Options
2. Improving Healthcare Systems
3. Communication and Dissemination
4. Addressing Disparities
5. Accelerating Patient-Centered and Methodological Research.

ACCC's comment letter is available online at: *www.accc-cancer.org/advocacy/pdf/2012PCORIcomments.pdf*.

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.

YERVOY™ (ipilimumab)
Injection for intravenous infusion

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/HCPCSReleaseCodeSetsDownloads/12anweb.zip. Accessed November 1, 2011.

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

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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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ACCC Urges Faster Congressional Action on Drug Shortage Crisis

Mar. 16, ACCC joined 31 other medical organizations in urging House Energy and Commerce Committee Chairman Fred Upton (R-MI) to move forward with legislation to combat the drug shortage crisis. While acknowledging that drug shortages cannot be solved by Congressional action alone, ACCC and the other organizations urged Representative Upton in a letter to take action:

"Look no further than the recent methotrexate shortage as evidence that this issue can no longer be ignored, as children with otherwise treatable cancer face being without treatment options… the time to take action is now as our patients simply cannot wait any longer."

The letter requested that the Committee move forward with legislation that includes:

- Developing an early warning system for production disruption or discontinuation
- Requiring manufacturers to have contingency plans for raw materials suppliers
- Encouraging redundancies in manufacturing
- Requiring collaboration between the Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA) to offer flexibility for product development and raw material quotas and establishing incentives for manufacturers.

In addition to ACCC, the American College of Surgeons, the American Hospital Association, the American Medical Association, the American Society of Clinical Oncology, and the American Academy of Pediatrics, among others, were all signatories to the letter.

On April 5, ACCC again joined with other stakeholder to provide comments to the Senate bipartisan working group's discussion draft addressing drug shortages.

USPSTF Issues Recommendation Statement on Cervical Cancer Screening

The U.S. Preventive Services Task Force (Task Force) final recommendation statement on cervical cancer screening was published Mar. 15 online in the *Annals of Internal Medicine*. After systematic review of the available evidence, posting a draft recommendation statement for public comment, and considering the comments it received, the Task Force concluded:

- Women aged 21 to 65 should be screened with cytology (commonly known as Pap smear) every three years. As an alternative, women aged 30 to 65 who want to be screened less frequently may choose the combination of cytology and human papillomavirus (HPV) testing every five years, which offers similar benefits to cytology-only. This is an A recommendation.
- The Task Force recommends against screening women who have had a hysterectomy with removal of the cervix, women younger than 21, or women older than 65 who previously have been adequately screened. These are D recommendations. Evidence showed that the expected harms (such as, unnecessary procedures, false positives, and possible problems with future pregnancies) of screening these populations outweighed the potential benefits.
- The Task Force also recommends against cervical cancer screening using HPV testing in women younger than 30. This is a D recommendation. Evidence showed that the expected harms (such as, unnecessary procedures, false positives, and possible problems with future pregnancies) of this screening in this group outweighed the potential benefits.

These recommendations apply to women, regardless of sexual history, who have a cervix and show no signs or symptoms of cervical cancer. These recommendations do not apply to women who are already at a very high risk for cancer, such as those who have been diagnosed with a high-grade precancerous cervical lesion or who have weakened immune systems.

Since the implementation of widespread cervical cancer screening, there has been a dramatic reduction in cervical cancer deaths in the United States. "About half of women diagnosed with this disease have never had a Pap smear or have not been adequately screened. Therefore, it is important for clinicians and healthcare systems, to get women into screenings who have never been screened, or who have not been screened in the last five years," said Task Force member Wanda Nicholson, MD, MPH, MBA.

The recommendations are available on the USPSTF website at: *www.uspreventiveservicestaskforce.org/recommendations.htm*.

ICD-10 Compliance Date Moved to 2014?

On April 9, the Centers for Medicare & Medicaid Services announced a proposed rule that would delay the compliance date for the *International Classification of Diseases, 10th Revision* (ICD-10) code set from Oct. 1, 2013, until Oct. 1, 2014, as reported in the April 10 *BNA Health Care Daily Report*.

The proposed rule (CMS-0040-P) also included a requirement for health plans to adopt a unique health plan identifier for all Health Insurance Portability and Accountability Act (HIPAA) transactions. Health plans currently use several different identifiers that vary in format. The proposed rule was published in the April 17 *Federal Register*. Comments were due by May 17.

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SPOTLIGHT ON OMC GROUP'S EXPERTS - TERI U. GUIDI, MBA, FAAMA

Teri Guidi is the President and CEO of Oncology Management Consulting Group and founded the company in 2001. With more than 30 years of experience in oncology management, Teri is expert in the areas of strategic planning, financial analysis, reimbursement, program development, and market assessment. She has worked with health networks, hospitals, private practices, and the pharmaceutical industry. Recent projects have included strategic and business planning, joint venture development, hospital/physician alignment, physician compensation, new center planning, demand/feasibility analyses, educational programs, and program assessments. She has held positions at institutions ranging from NCI-designated comprehensive cancer centers to large teaching hospitals in integrated health systems to small community hospitals. She has served as Executive Director and System Vice President of cancer service lines, and as Vice President of health system owned medical oncology, gynecologic oncology and surgical oncology practices. Teri's experience spans all areas of outpatient oncology including infusion services, radiation oncology, clinical trials, and tumor registry. Among her major areas of interest are financial analysis and profitability reporting.

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Coding for Pharmacy Services

BY CINDY PARMAN, CPC, CPC-H, RCC

While insurance payers generally permit a mid-level provider to bill for services performed in his or her name and National Provider Identifier (NPI), pharmacists are not typically included. According to the Centers for Medicare & Medicaid Services (CMS) in the Medicare Claims Processing Manual:[1]

Advise physicians to use CPT codes (level 1 of HCPCS) to code physician services, including evaluation and management services. Medicare will pay for E/M services for specific non-physician practitioners [i.e., nurse practitioner (NP), clinical nurse specialist (CNS) and certified nurse midwife (CNM]) whose Medicare benefit permits them to bill these services. A physician assistant (PA) may also provide a physician service, however, the physician collaboration and general supervision rules as well as all billing rules apply to all the above non-physician practitioners. The service provided must be medically necessary and the service must be within the scope of practice for a non-physician practitioner in the State in which he or she practices.

The Medicare Payment Advisory Commission (MedPAC) addressed the involvement of clinical pharmacists in managing drug treatment in a June 2002 report, both in view of cost reductions and improvement in the quality of care.[2] This report adds that while individuals 65 and older represent only 13 percent of the total healthcare population, they consume 35 percent of all prescription medications in the United States. Pharmacist participation in a multidisciplinary patient care team may improve clinical outcomes.[3]

Pharmacists may also play a valuable role in reinforcing drug dosing schedules and educating patients about their medications. As a result, patient compliance with complicated drug regimens and follow-up visits may improve—potentially leading to better treatment outcomes.

Drug management has the potential to improve the quality of care for Medicare patients by:

- Reducing the incidence of adverse drug effects
- Improving patient outcomes
- Improving patient compliance with drug therapy.

Conversely, adverse drug events can increase patient morbidity or mortality, increase the length of hospital stays, or lead to increased emergency room visits.

Medication Therapy Management

Drug management is an evolving approach to care in which the drug therapy decisions are coordinated collaboratively by physicians, pharmacists, and other healthcare professionals together with the patient.

Medication therapy management services (MTMS) are patient-specific clinical evaluations, recommendations, and interventions directed toward clinically complex patients. MTMS go above and beyond the standard activities of product preparation and dispensing.[4] MTMS codes are not used to describe the provision of product-specific information or any other routine dispensing activity. Medication therapy management services describe:

- Face-to-face patient assessment
- Intervention as appropriate
- Performed by a licensed pharmacist.

MTMS are provided to optimize the response to medications or to manage treatment-related medication interactions or complications. As part of MTMS, pharmacists will:

- Review pertinent patient history
- Complete a medication profile (prescription and non-prescription)
- Provide specific recommendations for improving health outcomes and treatment compliance.

The above elements must be documented and may include education and training, monitoring medication compliance, modifying therapy, formulating a treatment and/or follow-up plan, management of medication problems or complications, providing recommendations for disease prevention, and/or evaluating the patient's knowledge of medication(s) and willingness to comply with medication requirements. The procedure codes for these services are:

- **99605:** Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, new patient.
- **99606:** Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, established patient.

- **+99607:** Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; each additional 15 minutes.

The Medicare Modernization Act (MMA) has defined targeted beneficiaries as individuals who have multiple chronic diseases (such as diabetes, asthma, hypertension, and/or congestive heart failure), are taking multiple covered drugs, and will incur high annual medication costs. MTMS are initiated at the request of the patient and describe services that are out of the ordinary. Remember: these codes are *not* reported to describe a counter discussion regarding dispensed medications.[5]

The good news is that there are specific procedure codes to report MTMS, but the bad news is that these services may not be reimbursed separately by insurers. For example, Medicare does not provide reimbursement in the hospital outpatient department for MTMS under the Outpatient Prospective Payment System (OPPS). According to CMS:[6]

Under the OPPS, we have no need to distinguish medical therapy management services provided by a pharmacist in a hospital from medication therapy management services provided by other hospital staff, as the OPPS only makes payments for services provided incident to physicians' services.

With regard to physician office or freestanding centers, the Medicare Physician Fee Schedule (MPFS) assigns MTMS services status indicator "X," indicating these codes represent an item or service that is not within the statutory definition of "physicians' services" for MPFS payment purposes.

Although Medicare does not pay separately for MTMS services, other non-governmental payers may include these codes on their payment schedules. However, there may be certain restrictions, such as allowing payment for each of these codes only once in a 365-day period.

Drug Supply Codes

According to CMS, pharmacies may bill the Durable Medical Equipment Regional Contractor (DMERC) for certain classes of drugs, including oral antiemetic and oral anticancer drugs. In addition to the codes for the drugs themselves, there are also HCPCS Level II codes for the dispensing of oral medications:

- **Q0511:** Pharmacy supply fee for oral anticancer, oral antiemetic, or immunosuppressive drug(s); first prescription in a 30-day period.
- **Q0512:** Pharmacy supply fee for oral anticancer, oral antiemetic, or immunosuppressive drug(s); subsequent prescription in a 30-day period.

Beginning January 1, 2006, and continuing through the present, Medicare pays a supply fee of $24 for the first prescription of an oral antiemetic or oral anticancer drug in a 30-day period and $16 for each subsequent prescription.[7] There are different allowances for the dispensing of immunosuppressive drugs after a transplant and dispensing inhalation drugs delivered via durable medical equipment.

The supply fee codes must be billed on the same claim form as the HCPCS Level II code for the oral drug, and each supplier will be limited to 12 supply fees (represented by code **Q0511**) per beneficiary per calendar year. In addition, Medicare will downcode **Q0511** to **Q0512** if more than one claim for **Q0511** is received from the supplier for a beneficiary during the 30-day period (with the exception of allowing for a refill within seven days of the end of the 30-day period).

Additional information on these pharmacy supply codes is provided in Chapter 17 of the Medicare Claims Processing Manual, including the requirement that suppliers that bill the DMERC for drug supply must have a pharmacy license to dispense drugs.[8]

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

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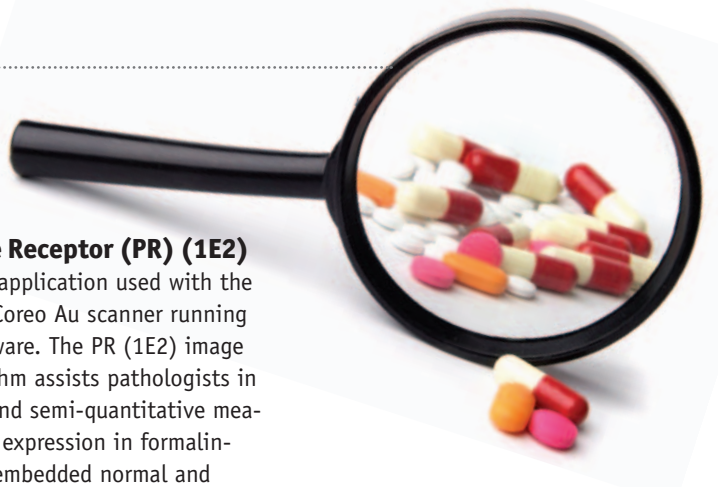
tools



Drugs in the News

- Coronado Biosciences, Inc. *(www.coronadobiosciences.com)* announced submission of an investigational new drug application (INDA) to the Food and Drug Administration (FDA) for **CNDO-109**, a novel biologic that primes natural killer cells without the need for cytokines (IL-2), and is being studied for the treatment of patients with high-risk acute myeloid leukemia (AML) in first complete remission. CNDO-109 activated NK cells have shown early efficacy in an investigator-initiated Phase I clinical trial in patients with AML, and demonstrated pre-clinical activity in multiple myeloma, breast cancer, prostate cancer, and ovarian cancer.

- Marshall Edwards, Inc. *(www.marshalledwardsinc.com)* announced submission of an INDA to the FDA to initiate clinical testing for oncology drug candidate **ME-344**, a mitochondrial inhibitor and an active metabolite of NV-128, a first-generation compound.

Assays, Genetic Tests & Vaccines in the News

- Ventana Medical Systems, Inc. *(www.ventanamed.com),* a member of the Roche Group, announced that the FDA approved the application of its **INFORM HER2 Dual ISH DNA Probe** cocktail assay **(HER2 Dual ISH)** on the Ventana BenchMark ULTRA automated slide staining platform for commercialization in the U.S. The HER2 Dual ISH assay is intended for use in the determination of HER2 gene status in breast cancer tissue as an aid in the assessment of patients that may be considered for treatment with Herceptin (trastuzumab). The HER2 Dual ISH assay detects both HER2 and chromosome 17 on a single slide using a standard light microscope.

  Ventana also received 510(k) clearance from the FDA for the **Ventana Companion Algorithm Progesterone Receptor (PR) (1E2)** image analysis application used with the Ventana iScan Coreo Au scanner running VIRTUOSO software. The PR (1E2) image analysis algorithm assists pathologists in the detection and semi-quantitative measurement of PR expression in formalin-fixed, paraffin-embedded normal and neoplastic breast tissue. This application aids the pathologist in achieving consistency and objectivity in PR interpretation for breast cancer patients.

- The FDA approved Gen-Probe's *(www.gen-probe.com)* **PROGENSA® PCA3 (Prostate Cancer gene 3) assay**, the first molecular test to help determine the need for repeat prostate biopsies in men who have had a previous negative biopsy. The PROGENSA PCA3 assay is indicated for use in conjunction with other patient information to aid in the decision for repeat biopsy in men 50 years of age or older who have had one or more previous negative prostate biopsies and for whom a repeat biopsy would be recommended by a urologist based on the current standard of care, before consideration of PROGENSA PCA3 assay results. A negative PROGENSA PCA3 assay result is associated with a decreased likelihood of a positive biopsy.

- CK Life Sciences International *(www.ck-lifesciences.com)* announced that the FDA has granted clearance for its subsidiary Polynoma LLC *(www.polynoma.com)* to proceed with Phase III clinical testing of its **melanoma vaccine**. Using a combination of antigens from three proprietary melanoma cell lines, Polynoma's melanoma vaccine is intended to stimulate the body's immune system to fight the cancer.

Devices in the News

- Kinoca Minolta *(www.konicaminolta.com/medicalusa/)* announced FDA clearance for the **Aero DR Wireless 17x17 inch Flat Panel Detector (FPD).** It is the first wireless 17x17 inch FPD weighing only 7.92 pounds. The increased imaging area of the 17x17 inch Aero DR FPD improves clinical workflow and patient care by offering users more versatility in positioning patients and allowing for more clinical data on every exposure, which may decrease the number of exposures needed for studies that require imaging a larger region of interest.

- Varian Medical Systems *(www.varian.com)* received FDA 510(k) clearance for a surface beacon transponder to be used with the Varian Calypso system as a real-time tracking device capable of monitoring motion during radiotherapy treatment for indications anywhere in the body. The **Surface Beacon Transponder®** is placed temporarily on the skin for real-time tracking of respiratory and other patient motion during radiotherapy, thereby greatly expanding the number of cancer sites for which the Calypso technology can be used.

- Hospira, Inc. *(www.hospira.com)* announced that the FDA has granted regulatory clearance for the company's **Symbiq™ 3.13 infusion device**, the enhanced version of the company's advanced infusion system platform. The clearance was granted through the new draft FDA regulatory guidance for 510(k) infusion pump submissions. Hospira plans to start working with current customers to upgrade to the enhanced Symbiq device in the first quarter, and expects to begin shipments to previously contracted customers in the second quarter. OI

2012 ACCC Innovator Awards

Sponsored by GE Healthcare

Congratulations to the 2012 ACCC Innovator Award Recipients.

Abbott Northwestern Hospital, Virginia Piper Cancer Institute, Minneapolis, MN

Mercy & Unity Virginia Piper Cancer Institute, Unity Hospital, Fridley, MN

United Hospital, Cancer Care, St. Paul, MN

How to Develop a Breast Cancer Program Across a Large Health System

Akron General Medical Center, McDowell Cancer Center, Akron, OH

Bridging the Psychosocial and Financial Needs of Oncology Patients

Anne Arundel Medical Center, DeCesaris Cancer Institute, Annapolis, MD

Rapid Access Chest and Lung Assessment Program

Dorcy Cancer Center at St. Mary-Corwin Medical Center, Pueblo, CO

A Comprehensive Team Approach for Patients with Head and Neck Cancer

Fox Chase Cancer Center, Philadelphia, PA

New Approaches to Maximize Patient Flow and Reduce Inpatient Hospital Length of Stay

Grant Medical Center, Grant Cancer Care, Columbus, OH

A Unique Screening Outreach Program: ConvenientCare Mammography

Mountain States Tumor Institute, St. Luke's Regional Medical Center, Boise, ID

A Multidisciplinary Supportive Oncology Clinic with Integrated Medication Therapy Management

Southwest Cancer Center, UMC Health System Lubbock,TX

Process Improvement Through Patient and Employee Feedback

ACCC
Association of Community Cancer Centers

GE Healthcare

2012 Innovator Award winners will share their innovations at the

ACCC 29TH NATIONAL ONCOLOGY CONFERENCE

October 3–6, 2012

Grand Hyatt San Antonio ✷ San Antonio, Texas

Details at www.accc-cancer.org/oncologyconference

spotlight

Memorial Hermann Cancer Center—Texas Medical Center, Houston, Texas

Committed to patient-centered, personalized care

March 2012 marked the opening of a new, state-of-the-art cancer center at Memorial Hermann—Texas Medical Center, a teaching hospital for The University of Texas Health Science Center at Houston (UTHealth) Medical School. The new cancer center, located within the 30-story Memorial Hermann Medical Plaza in the Texas Medical Center, is part of Memorial Hermann Healthcare System, the largest not-for-profit healthcare system in Texas. The healthcare system includes seven comprehensive cancer centers, each with "a distinct footprint in its community," said Jeannie Keith, RN, MSN, AOCN, NEA-BC, administrative director, outpatient cancer services. The health system's cancer programs are now under one ACoS accreditation as an Integrated Network Cancer Program. What distinguishes the Texas Medical Center's cancer center is its academic affiliation with UTHealth and its resources to treat all types of cancer.

The Memorial Hermann Cancer Center—TMC not only encompasses beautiful, state-of-the-art facilities, but it reflects the ongoing commitment to and growth of an academic oncology program within the health system. The collaboration between UTHealth and Memorial Hermann is helping to realize the vision of growing an academic oncology program to allow patients from Houston and beyond an opportunity at another opinion.

"We recognize that people have a choice for cancer treatment, and we are proud to be leaders in providing superior, comprehensive and accessible patient-centered care to the Houston community," said oncologist Robert J. Amato, DO, medical director of the Memorial Hermann Cancer Center—TMC and the director of the Division of Oncology at UTHealth.

Nearly all of the cancer center's physicians—surgeons, radiation oncologists, medical oncologists, diagnostic and interventional radiologists—are UTHealth oncology physicians. The new cancer center will enhance collaborative efforts in developing research tracks. The cancer center's physicians comprise a tumor-specific faculty, which also sets the program apart from the other cancer centers within the healthcare system. The cancer center has been actively recruiting faculty—nearly doubling in size over the past year—to continue efforts in tumor-specific programs, as well as the implementation of a developmental therapeutics program that will include a Phase I clinic, which is slated to open this summer.

The leading cancer sites treated are prostate, kidney, lung, brain, breast, and liver. The cancer program sees about 1,300 new analytic cases each year.

New Cancer Center Streamlines Services

Prior to the opening of the new cancer center, oncology services were spread out in multiple locations. "We had a clinic that was separate from infusion," said Dr. Amato, "research was in another location, as was academic medicine." Today, the entire clinical operation is located within the new cancer center, which occupies three floors. This consolidation of services helps to streamline the care process for patients and providers.

"Everything the patient needs during their visit can be done right on site, so it's more expeditious and efficient," said Dr. Amato. "Patients can come in, get their blood drawn, see the physician, and the pharmacist is [located] right across from the clinical setting. It's much more user friendly."

While the planning process for the new cancer center design took several years, construction was completed in approximately 12 months. Now the entire 29th floor is dedicated to the beautiful 21,000-square-foot cancer center suite. An additional 6,500 feet of shell space will allow for future expansion.

As patients exit the elevator and enter the cancer center suite, they are welcomed by a greeter who logs them in. Design elements and artwork throughout the new space incorporate natural materials and calming colors. Among the unique features integrated into the design are divider panels with encased bamboo that provide privacy between infusion bays while creating a sense of openness, nature, and warmth. Similar materials are incorporated within the gentle curve of the front reception desk.

One side of the suite overlooks downtown Houston and Rice University offering stunning views of the Houston skyline. Patients can receive chemotherapy treatment in one of the 16 open infusion pods or in a private infusion room. On the other side of the clinic are

▲ The reception area features aesthetic elements that integrate nature into the cancer center's design.

◀ The new infusion area offers patients a beautiful view of the Houston skyline.

▼ The cancer center's new Trilogy linear accelerator.

16 exam rooms. Three nursing pods are included in the suite. Offices, the nurse navigator's area, the resource library, and a conference room are housed along the central corridor. Six oncology nurses staff the infusion center, and each physician works with a clinic nurse and a medical assistant. The cancer center staff includes an FTE oncology dietitian and an FTE social worker.

An exceptional feature of the new cancer center is its state-of-the-art, dedicated oncology pharmacy. The new pharmacy area, which has three hoods for mixing, "surpasses many hospital-sized pharmacies," said Keith. The pharmacy is staffed by a clinical PharmD, supporting the clinic and physician office visits, and a staff pharmacist who oversees mixing and performs double checks. Two pharmacy technicians also mix in conjunction with the pharmacist.

Multidisciplinary Disease-site Specific Clinics

The cancer center currently offers disease-site-specific multidisciplinary clinics for lung cancer, breast cancer, and gynecologic cancer, with the addition of a lung nodule clinic being planned. A full-time dedicated master's-prepared nurse navigator helps coordinate the multidisciplinary clinics.

In developing the new cancer center, consideration was given to streamlining the care process from the patient's perspective with a goal of making the patient's visit as efficient as possible. Patient care rounds—conducted before the patient visit—help center staff plan the patient's visit to ideally minimize the need for multiple trips into the cancer center—which can be taxing for patients who are not feeling well. In attendance for the patient care rounds are the social worker, the PharmD, research coordinators, nurses, the nurse navigator, the infusion charge nurse, radiation therapy (if the patient will be receiving treatment), and physicians.

Cutting-Edge Radiation Therapy Services

The new cancer center also improves patient access to care with the addition of radiation oncology services on site. Previously, radiation therapy was not available in this location. The new two-story radiation therapy service area is the result of some "pretty phenomenal architecture," Keith said. The entrance to radiation services is located on the second floor of the Medical Plaza, adjacent to retail space. The program's new Varian Trilogy linear accelerator and treatment rooms are located on the first floor. Treatment modalities offered include high dose rate brachytherapy and stereotactic radiosurgery. Radiation oncology services are staffed by one radiation oncologist and three RTs. Physics services are provided under a contract that covers all seven of Memorial Hermann's cancer centers. Future goals include applying for NCI-funded Radiation Therapy Oncology Group status to offer clinical trials to patients.

"We want to establish ourselves not as competitors in the oncology market here, but as offering patients the opportunity of getting another opinion, more academic focused and personalized therapy," said Dr. Amato. OI

Additional Resources

- Hospital bed size: **466**
- Dedicated inpatient oncology beds: **17**
- Number of new analytic cases seen in 2010: **1,300**

Select Support Services

- Social work services
- Nutritional counseling
- Support Groups
- Cancer Resource Library
- Genetic Counseling
- Pastoral Care

PHOTOGRAPHS COURTESY OF MEMORIAL HERMANN CANCER CENTER

Developing a Community Oncofertility Program

BY FAYE FLEMMING, RN, BSN, OCN

Most academic and larger oncology facilities have fertility specialists and resources on site or easily accessible, increasing the likelihood that these programs will have a formal oncofertility program. In the community-based setting, it is more challenging to meet the fertility needs of cancer patients. While development of a quality oncofertility program will likely require time and effort, community cancer centers can and should still offer these services to their patients. In 2011 Southside Regional Medical Center won an ACCC Innovator Award for its oncofertility program. Here are innovative tools and resources developed as part of *Nicole's Oncofertility Toolkit*—named in honor of the author's niece.

Oncofertility is a somewhat new term that is used to describe cancer-related fertility issues. Unfortunately, it is a cancer care domain that is often avoided or forgotten by clinicians. However, when cancer programs do not include oncofertility in assessment and treatment planning for childbearing-age patients, they run the risk of increasing patient distress and decreasing quality of life. Instead, cancer programs should espouse the idea that oncofertility is every cancer patient's right and ensure that they offer these types of fertility-related services, including:

- Timely assessment of fertility needs and desires
- Education about fertility risks and options
- Financial and mental health counseling
- Quick referrals and care
- Ongoing and constant follow-up.

Many cancer patients experience unnecessary emotional turmoil due to a lack of attention, knowledge, support, resources, planning, and preparation related to oncofertility issues. Providers and payers share the blame. Without timely fertility support from their oncology providers, patients can quickly become depressed and helpless. No patient should be distraught because cancer programs are not meeting their fertility needs. There are many options available to cancer patients today. See page 25 for a list of these.

Oncofertility Challenges

Cancer programs developing an oncofertility program face many challenges. Time is one of the biggest hurdles. Oncofertility assessments, education, counseling, referrals, and fertility care must be completed very quickly—often *before* cancer treatment starts. Accordingly, cancer programs must include fertility-related support and care in the treatment planning process and plan of care. That said, fertility procedures, especially for women,

often require weeks to complete. Delaying the start of cancer treatment could be detrimental to patients. To ensure timely oncofertility care without unnecessary treatment delays, cancer programs should develop a formalized oncofertility process that includes continual coordination and monitoring of cancer and fertility treatment planning and care.

Fertility costs are another challenge for patients with oncofertility needs. Fertility-related care and procedures can cost thousands of dollars. Health insurance plans usually do not cover these services. Therefore, patients with oncofertility needs will likely require timely referrals to a financial specialist or resources to help:

- Assess insurance benefits
- Estimate the costs of fertility care
- Evaluate the patient's financial situation
- Connect with local and national resources
- Contact referrals
- Apply for financial assistance, disability, or other benefits
- Help the patient meet other financial needs.

Assisting patients and families with distress management during what is likely one of the most stressful times in the cancer care continuum is another challenge for providers. Patients have usually just received their diagnosis and are in the process of completing more diagnostic tests, obtaining results, and being educated on their treatment plan. Suddenly the patient is told that his or her fertility may be affected. Besides worrying about their life, health, family, work, pain, finances, and future, patients now need to worry about their fertility. To help patients and families cope with this added stress, cancer programs should ensure that distress management is a core component of their oncofertility program.

To overcome these and other challenges (see box below), successful oncofertility programs have a defined process for oncofertility care that includes up-to-date policies and procedures, tools, and resources. Further these programs ensure that staff and providers are educated about oncofertility and the oncofertility program or process.

Developing an Oncofertility Program

The first step in developing an oncofertility program is to complete a fertility-related assessment of your program, community, and patients (see page 27). As part of this assessment, answer the following questions:

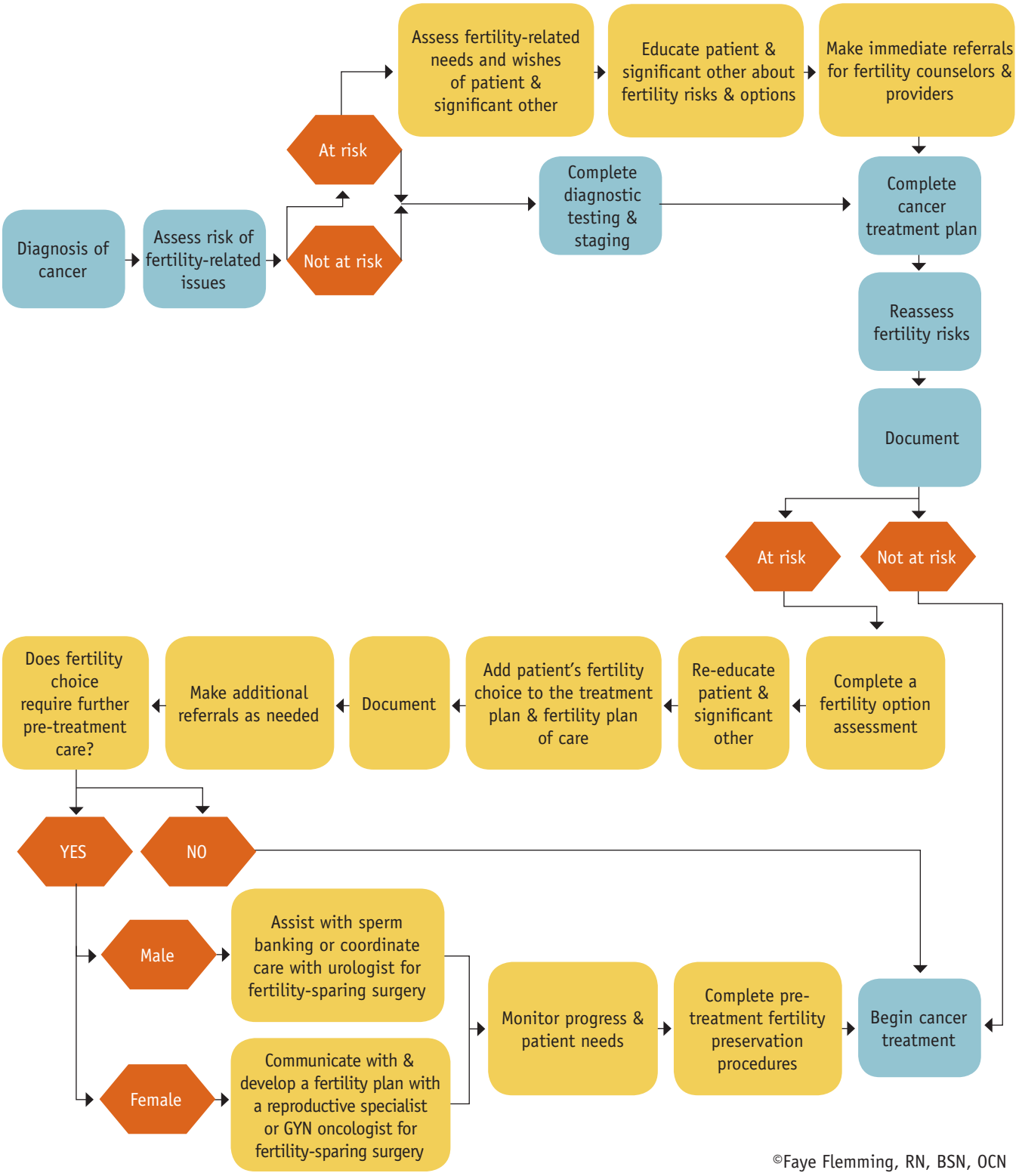
- Which oncology diseases do you see and which treatment choices are available?
- What are your patient demographics?
- Are there specific cultural, community, geographic, or other needs that should be addressed?
- What fertility assessments, policies, tools, providers, and resources does your cancer program presently use?
- Which administrators, physicians, non-physicians, community agencies, or others support a formalized oncofertility program or process?

continued on page 26

ONCOFERTILITY CHALLENGES

- Fast-growing cancers where time is of the essence for beginning treatment(s).
- Advanced cancers where patients are too ill and there are concerns about the patient's prognosis.
- Costs of fertility-related care.
- Lack of coverage by insurance:
  - Only 15 states have any type of mandatory coverage for fertility treatments (AR, CA, CT, HI, IL, LA, MD, MA, MT, NJ, NY, OH, RI, TX, WV).
  - No state mandates oncofertility preservation coverage.
- Timing of fertility care to not delay cancer treatment:
  - Timely referrals and counseling to assist patients to make informed decisions relating to fertility.
  - Timely completion of all procedures required before beginning cancer treatment.
  - Coordinating fertility care and cancer care to meet all patient needs.
- Assuring that all providers include fertility-related assessments, support, and care in their cancer treatment planning.
- Assisting patients and family with distress management during this time of additional stress.

NICOLE'S ONCOFERTILITY PRESERVATION ALGORITHM TOOL



ONCOFERTILITY TEAM ROLES

Patient
- √ Be aware of their patient rights and ask providers all the questions they have.
- √ Answer provider questions honestly, letting providers know when they do not understand.
- √ Must understand all information and options.

Significant Other
- √ Be present to offer support, discuss options with patient, ask questions, and assist with decision making.

Oncologist
- √ Be knowledgeable about the actual and/or or potential effects of recommended cancer treatments on their patient's fertility.
- √ Be knowledgeable about basic reproductive options for male and female cancer patients.
- √ Have a process in place that is used for all childbearing-age cancer patients to assure they all receive timely information, support, referrals, and follow-up for fertility-related needs.
- √ Have information and contacts for local referral sources for fertility-related needs, such as financial and psychosocial care.
- √ Develop a referral system for consults with endocrinologists and reproductive health specialists that includes sharing of information, treatment plan, timing, and monitoring of progress.
- √ Answer basic questions and provide basic information about fertility options.
- √ Obtain informed consent, which includes education about fertility-related risks for recommended treatments as early as possible in the diagnosis and treatment planning phase.

Oncology Nurse
- √ Assist oncologists and oncology team in providing education, care, assessment, distress management, referrals, support, navigation, and coordination of care.

Primary Care Physician
- √ Have a long-term relationship with the patient and generally know the patient best.
- √ Help support, educate, and guide the patient.

Social Worker & Mental Health Counselor
- √ Provide needs assessments, distress management, emotional support, counseling, psychosocial support and referrals, and mental health support and referrals.
- √ Assist with meeting cultural, ethical, and spiritual needs.

Nurse Navigator & Case Manager
- √ Provide needs assessments.
- √ Assist with access and help navigate the healthcare system and providers.
- √ Provide communication support, education, distress management, and referrals.

Financial Specialist
- √ Provide timely financial needs assessments.
- √ Assist with financial, insurance, and related support, information, and referrals.

Pastoral Care & Clergy
- √ Offer spiritual, psychosocial, and emotional support to assist patients with decision-making and support.

Pharmacist
- √ Assist with understanding cancer and fertility-related drugs.

Genetics Counselor
- √ Counsel, inform, test, and support patients that are high risk for genetic abnormalities.
- √ Counsel, inform, test, and support patients that are high risk for having offspring with possible genetic cancer risks.

Gynecologist
- √ May be the physician diagnosing female cancers.
- √ Often have a long-standing relationship with their patients.
- √ Help to prepare and guide patients in addressing fertility needs.

Oncologic Gynecologist
- √ Often the surgeon providing fertility-sparing female surgery.

Urologist
- √ May be the physician diagnosing some cancers.
- √ Help prepare and guide their patients in addressing their fertility-related issues.
- √ May be the surgeon providing fertility-sparing surgery.

Endocrinologist & Reproductive Specialist
- √ Offer expertise in fertility preservation methods.
- √ Conduct a timely consult that can help patients make better informed decisions about their future fertility.
- √ Explain options, procedures, costs, timing, success rates, and available support.
- √ Carry out any fertility-preserving procedures if chosen as the option.

Family-planning Specialist
- √ Help better educate patient and family about parenting options.

Adoption Professional
- √ Conduct timely consults that can help patients make a better informed decision about having non-biologically related offspring.
- √ Explain the criteria, timing, cost, process, and availability of adoption and answer any questions. OI

KNOW YOUR OPTIONS

Oncofertility Options for Women*

- ◯ Choose to have no children.
- ◯ Do nothing and take a chance on having children naturally after treatment is completed and the physician has given approval.
- ◯ Do nothing until after treatment is completed and then assess fertility. If patient decides she wants to have children, choose from post-treatment options.
- ◯ Radiation shielding. Use of shields for reproductive areas during radiation treatment, if this does not affect the required treatment field.
- ◯ Fertility-sparing surgery, if it will not affect outcome of cancer treatment.
- ◯ Adoption. Approximate cost: $2,500 to $50,000 or more. Cost is very dependent on the agency and country.
- ◯ Foster parenting. Approximate cost paid by agency: $500 to $900/month, depending on location and age. Note: these funds are to be used for care and supplies for the child—not compensation.
- ◯ Embryo freezing. Requires in vitro fertilization of egg and sperm and then freezing of the embryo. Approximate cost: $12,000 to $40,000 or more, plus storage fees.
- ◯ Donor egg(s). Approximate cost: $17,000 to $35,000 or more for one cycle.
- ◯ Donor embryo(s). Approximate cost: $17,000 to $25,000 or more for one cycle.
- ◯ Surrogacy. Use of another woman to implant the pregnancy into her womb and have her carry it through birth.
  - – Traditional. Uses surrogate's egg and male sperm from the couple trying to conceive. Approximate cost: $12,000 to $15,000 or more for one cycle if IVF used.
  - – Gestational. Uses embryo of cancer patient and spouse. Approximate cost: $12,000 to $15,000 or more for one cycle, plus $10,000 to $100,000 or more for compensation to the woman if she is expecting to be paid for being a surrogate.
- ◯ Experimental options. Should be done for research only:
  - – Egg freezing banking. Freeze eggs prior to fertilization. Approximate cost: $12,000 to $35,000 for one cycle, plus storage fees.
  - – Ovarian suppression. Uses gonadotropin-releasing hormone (GnRH) analogs or antagonists to suppress ovaries during chemotherapy. Approximate cost: $400 to $600/month.
  - – Ovarian tissue freezing. Freezes tissue from the ovaries and tissue is re-implanted after treatment is completed. Approximate cost: $17,000 or more, plus storage fees.

*Approximate costs are provided, but can vary greatly and/or include additional costs, such as normal pregnancy costs.

Oncofertility Options for Men*

- ◯ Choose to have no children.
- ◯ Do nothing and take a chance on having children naturally after treatment is completed and the physician has given approval.
- ◯ Do nothing until after treatment is completed and then assess fertility. If decides he wants to have children, choose from post-treatment options.
- ◯ Radiation shielding. Use of shields for reproductive areas during radiation treatment, if this does not affect the required treatment field.
- ◯ Fertility-sparing surgery, if it will not affect the cancer treatment outcome.
- ◯ Adoption. Approximate cost: $2,500 to $50,000 or more. Cost is very dependent on the agency and country.
- ◯ Foster parenting. Approximate cost paid by agency: $500 to $900/month, depending on location and age. Note: these funds are to be used for care and supplies for the child—not compensation.
- ◯ Sperm banking. Approximate cost: $675 to $2,000, plus $350 to $750/year in storage fees. (Under the "Live On" program, qualified applicants pay a total of $675 for one.)
- ◯ Donor:
  - – Sperm. Approximate cost(s): $200 to $1,500, plus artificial insemination or IVF costs.
  - – Embryo. Approximate cost(s): $12,000 to $15,000/cycle, plus pregnancy costs of between $5,000 to $10,000.
- ◯ Experimental options (should be done for research only):
  - – Testicular sperm extraction (TESE): cost varies.
  - – Epididymal sperm aspiration: cost varies. OI

U.S. Cancer Incidence Rates Age at Diagnosis 15 to 44†

AGE	COUNT
15–19 years	4,325
20–24 years	6,902
25–29 years	10,766
30–34 years	16,185
35–39 years	27,669
40–44 years	51,220
Total	**117,067**

Source: 1999–2006 (CDC WONDER online). Rates are per 100,000 and are age-adjusted to the 2000 U.S. Std. Population.
†These individuals are women and men of childbearing age.

continued from page 22

- Is there any opposition or unusual obstacles to developing an oncofertility program or process? If so, who, what, and why? Obstacles and opposition should be addressed prior to development of the program or process.

Once you have completed the fertility-related assessment, the next step is to develop a multidisciplinary oncofertility team. This team should consist of any local, state, and national healthcare providers, facilities, and organizations that can work together to best meet the fertility needs of your cancer patients. Choose team members that meet the specific needs of your patient population. Oncofertility team members typically include:

- Primary care physicians
- Oncology specialists
- Fertility specialists
- Gynecologists
- Urologists
- Financial specialists
- Nurses
- Social workers and/or mental health providers
- Nurse and/or lay navigators
- Case managers
- Pastoral care
- Genetics counselors
- Pharmacists
- Adoption specialists.

Once team members are identified, define the role each staff member will have in the oncofertility program or process. Communication, coordination, and care provided (the three "C's") should be addressed in every role definition. Be sure to include patient and family roles in this process. (See "Oncofertility Team Roles," page 24 for more.)

With your team in place, it is time to define your oncofertility process. Consider developing an algorithm first that will illustrate patient flow through the oncofertility program or process (see page 23). Define each step of the algorithm and all related responsibilities and resources. This process will be the center of your oncofertility program, ensuring that all of the oncofertility needs of your patients are assessed and addressed. (See patient assessment tool on page 28.) Process components should include:

- Assessment of fertility risks, desires, and needs
- Patient and staff education
- Distress management
- Referrals
- Counseling
- Informed consent
- Documentation
- Development, monitoring, and coordination of a fertility plan of care
- Follow-up and survivorship care and support
- Quality assurance and monitoring.

Additional Online Content

Nicole's Oncofertility Toolkit is available online at: *www.accc-cancer.org/oi/MJ2012*. Download the kit today and start using it at your cancer program. Questions? Email Faye Flemming at: *oncofertility@hotmail.com*.

An Oncofertility Toolkit

The last step will be to create or adapt tools and lists of resources to assist your team in meeting the oncofertility needs of your patients. These tools need to be as simple as possible and require the minimum amount of time and documentation to ensure the needed results. Develop and package these tools and resources so that providers have easy, one-stop access to everything they need to care for the fertility need of their patients.

I have created *Nicole's Oncofertility Toolkit* to assist cancer programs to more easily develop a formal oncofertility program. This toolkit is dedicated to my brave 28-year-old niece who recently suffered severely after her oncology providers failed to address her oncofertility needs. Nicole had requested fertility help from her healthcare providers from the moment she was told she had "some type of lymphoma." It was not until months later, after her family was able to help Nicole find the "right" fertility specialist and the "right" oncology provider that Nicole began to regain some of the hope and optimism she had lost. No patient should ever have to go through this level of distress. Nicole was an educated and engaged patient. What happens to the many cancer patients who do not know to ask for help or who do not have loved ones who have the skills to assist them?

If your cancer program does not already have an oncofertility program in place, I challenge you to create one for your patients. Simply put: it's the right thing to do. Together we can all make a difference and improve the lives of our oncology patients. OI

—Faye Flemming, RN, BSN, OCN, is oncology service line director, Southside Regional Medical Center, Petersburg, Va. She is also a member of ACCC's Board of Trustees.

NICOLE'S ONCOFERTILITY PROGRAM NEEDS ASSESSMENT

DOES YOUR ONCOLOGY PROGRAM HAVE A:

- ☐ Complete and timely* fertility risk assessment that is given to all patients?
- ☐ Complete and timely* fertility-related needs assessment that is given to all childbearing-age patients who will receive a treatment that has the potential to cause fertility-related issues?
- ☐ Timely* referral process for all patients with needs to:
  - ☐ Board-certified reproductive specialists
  - ☐ Certified reproduction center or clinic
  - ☐ Genetic counseling
  - ☐ Adoption professional(s)
  - ☐ Support groups
  - ☐ Fertile Hope
  - ☐ Nurse navigator
  - ☐ Spiritual counseling
  - ☐ Financial assistance
  - ☐ Other support services
- ☐ Process that includes cultural and ethical needs in your fertility assessment and planning?
- ☐ Verbal and written education about fertility-related items available to at-risk patients?
- ☐ Counseling to assist with decision making for all at-risk patients?
- ☐ Process for coordinating fertility care, communicating with other providers, identifying referral sources, and monitoring patients?
- ☐ Written informed consent, including fertility risks obtained prior to the start of any treatment?
- ☐ Process to ensure documentation of all of the above?
- ☐ Process and program(s) to ensure that patients with oncofertility needs are assisted with post-treatment care, outcomes assessment, completion of follow-up care, and to ensure that all fertility-related needs were met?
- ☐ Survivorship program that includes fertility needs?
- ☐ Quality monitoring program that includes fertility-related issues?
- ☐ Written process and/or policy to address oncofertility needs?

**"Timely" refers to completion as close to diagnosis and before start of treatment date as possible.*

NICOLE'S ONCOFERTILITY PATIENT ASSESSMENT TOOL

Ages of present children: _____ Stepchildren: _____ Adopted children: _____

Desire future children? ☐ YES ☐ NO Comment: _____

SECTION 1: Fertility Assessment (Complete if patient desires future children.)

Estimated latest recommended treatment start date: _____

Is hormonal therapy contraindicated for any reason (females)? ☐ YES ☐ NO
Would patient and family consider partially or non-genetically related children? ☐ YES ☐ NO
Would patient and family consider someone else carrying their child? ☐ YES ☐ NO
Does patient and family have insurance and fertility-related coverage? ☐ YES ☐ NO
What is the patient's and family's financial status and what resources are available to meet their fertility needs?

_____

_____

What is the patient's and family's emotional status and present distress level (use NCCN Distress Management Tool).
Score: _____ Comment: _____

What support systems are available? _____

Are there any co-existing challenges or support needs? _____

Does the patient or family have any religious, cultural, or other preferences and/or needs? ☐ YES ☐ NO
If yes, explain: _____

SECTION 2: Fertility Plan of Care & Monitoring

Preferred choice for reproductive-risk reduction: _____

Reproductive and support referrals needed: _____

Pre-treatment fertility procedures required? ☐ YES ☐ NO

All referrals completed? ☐ YES ☐ NO

All pre-treatment fertility interventions completed? ☐ YES ☐ NO

Reproductive needs met? ☐ YES ☐ NO
Outcome: _____

Ready to begin cancer treatment?
☐ YES ☐ NO

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.

Questions? Email: bguardado@accc-cancer.org

- Course 1: **Archived** Understanding the Insurance Process
- Course 2: **Archived** Patient Assistance 101
- Course 3: **May 8, 2012** 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 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
- Course 10: **December 2012** Financial Counseling: Tools You Can Use

For more information
www.accc-cancer.org/filn

ACCC Association of Community Cancer Centers

Education

This project is sponsored by Teva Oncology, Genentech, Lilly Oncology, and Novartis Oncology

The Alliance for Fertility Preservation

BY AMANDA PATTON

Launched in late 2011, the Alliance for Fertility Preservation is a coalition of experts in reproductive endocrinology, urology, and oncology. Building on the American Society of Clinical Oncology (ASCO) 2006 fertility guidelines, the Alliance aims to educate and empower patients with cancer to make the best decisions about fertility preservation prior to treatment or about infertility management after treatment with a goal of promoting dialogue between patients and clinicians to help optimize both expectations and care.

The Alliance is co-chaired by John Mulhall, MD, director of the Male Sexual and Reproductive Medicine Program at Memorial Sloan-Kettering Cancer Center; Zev Rosenwaks, MD, director and physician-in-chief, of the Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine at Weill Cornell Medical College and New York Presbyterian Hospital; and Glenn Schattman, MD, of Weill Cornell Medical College, and is supported by Ferring Pharmaceuticals, Inc. *Oncology Issues* spoke with Dr. Mulhall and Dr. Rosenwaks about the newly formed Alliance for Fertility Preservation.

OI. ***What was the impetus behind the formation of the Alliance for Fertility Preservation?***

DR. MULHALL. Despite the fact the ASCO guidelines suggest that patients have discussions about fertility preservation prior to treatment, indications are that a minority of clinicians are adhering to these guidelines. The Alliance for Fertility Preservation will focus on developing a rational, comprehensive clinical care pathway for patients, to increase patient awareness, and to encourage clinicians to have a dialogue with patients.

The primary impetus behind the formation of the Alliance is to increase awareness in terms of developing educational materials to empower patients to advocate for themselves. Unfortunately, what happens in some circumstances is that physicians are making the decision for the patient. The best decisions are made when patients are in complete receipt of information. For example, a patient 25 years of age with a poor prognosis, we [physicians] may think we will just skip the fertility discussion, when in fact for that patient that fertility discussion may be hugely important. It may be the means by which they can hold on to hope going through their cancer care. What we are really trying to do is put the patients in control of their own destiny.

Although the Alliance is in the "embryonic stages" of development, future goals may include the development of a website and toolkits for clinicians.

OI. ***What's the take-home message for community cancer centers?***

DR. MULHALL. If you look at the literature, 50 percent of patients who go through cancer therapy want to have or increase the size of their family. If you look at the patients who don't have children already going into cancer therapy, 75 percent of them want to have a family or extend their family. So there is a definite need to discuss these issues with patients. There are strategies in place for helping the man and the woman with cancer—before therapy—realize their fertility potential.

So number one, there is a need. Number two, there are specialists who can help. We are very interested going forward in engaging with physicians in figuring out what it is they need.

OI. ***What are the current barriers to better patient access to information on fertility preservation?***

DR. MULHALL. The number one barrier would be time in practice. This is a complicated discussion. Rather than saying, "I don't have time to do this," maybe physicians should say, "This is not my area of expertise, Mr. or Miss Jones, and by the way, we have this physician locally and this is his or her area. We'd like you to see them to have this discussion. We don't have a lot of time to do that. You might have 48 hours. But we have a relationship with Dr. X, and he or she is going to squeeze you in to have this discussion."

OI. ***Is this need becoming more critical given the increased numbers of cancer survivors coupled with advances in the fertility field?***

DR. MULHALL. The need is becoming more critical among adolescent and young adult cancer survivors. They are not in the pediatric group where there's a lot of focus on survivorship, and they are not in the adult group. They are in the middle. They tend to have reduced access to care and less insurance. So there is a large number of adolescent and young adult patients who have testis cancer or lymphoma or leukemia, who are candidates for this discussion.

The second barrier besides time is a discomfort level. For example, we did a needs assessment at Memorial Sloan-Kettering where we surveyed cancer clinicians and asked, "Do you think this [fertility preservation] is important?" The overwhelming majority said it's hugely important. But when we asked them who would they like to give this discussion, the overwhelming majority said, "Someone else." Because they don't know what the options are—it's just a different discussion.

[The goal is that] the patient is making a rational decision based on receiving comprehensive information. I think that if you look at the bigger picture of survivorship, we're not just here to cure cancer; we're here to cure the effects of the diagnosis and the treatment of cancer. That's really the survivorship credo. Talk to the patients about options and let them make the best decision for themselves.

OI. ***Dr. Rosenwaks, what do you see as the Alliance's primary mission?***

DR. ROSENWAKS. I believe that the Alliance's most important mission is to educate oncologists and patients about the available fertility options for both males and females who face the challenges of cancer therapy. While these issues are quite familiar to reproductive endocrinologists and reproductive urologists, and in spite of the fact that these issues have been discussed and presented at ASCO and other organizations, many couples do not get this information from their oncologists.

Although most oncologists are familiar with the general field of fertility preservation, also called oncofertility, the information they have may not be as comprehensive as it needs to be. Because the Alliance is made up of a broad group of experts involved in oncology and oncofertility, namely reproductive endocrinologists, reproductive urologists, oncologists, psychologists, and patient advocates, it can develop a program that will be coordinated and useful for all the parties involved. We have an opportunity to develop educational tools that will be helpful to the oncologists, their patients, the oncology programs, and the nursing and support staff, as well as reproductive specialists.

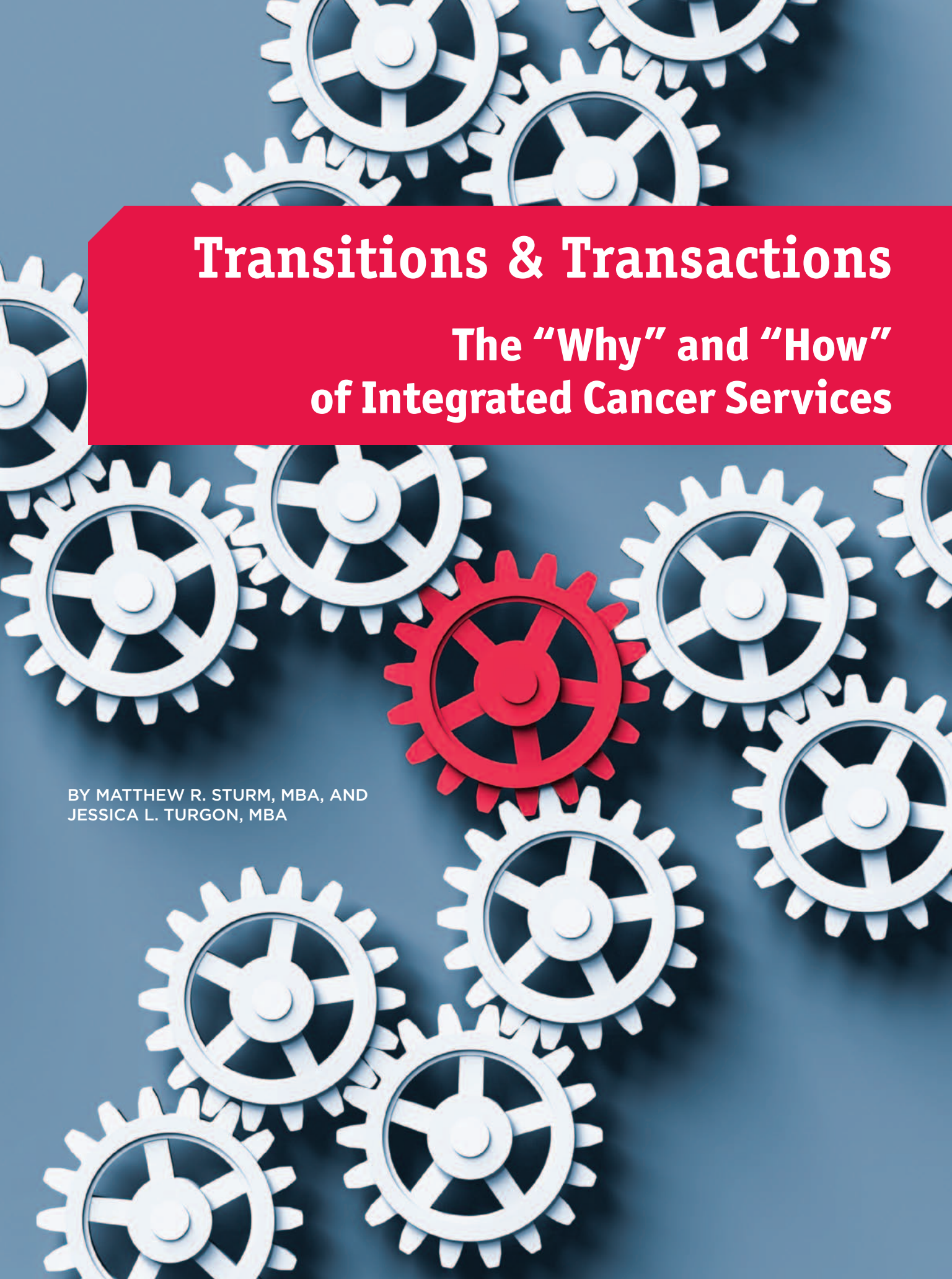
The Alliance is being created to promote collaboration between the professional groups involved in cancer therapy and the reproductive specialists who will take care of the fertility consequences of cancer therapy. It will promote a multidisciplinary approach to fertility preservation by educating reproductive endocrinologists and oncologists about available, contemporary fertility preservation options.

OI. ***How might the Alliance for Fertility Preservation benefit community-based cancer care programs?***

DR. ROSENWAKS. We hopefully will provide these centers with up-to-date, contemporary, cutting-edge information regarding the impact of various cancer treatments on fertility and, more importantly, the options available for both male and female patients who are facing cancer treatment—whether it's radiation or chemotherapy.

An example of how I envision it working is the following. Clinical oncologists and researchers will share information on the available protocols that are more protective (fertility sparing) in terms of loss of fertility and loss of germ cells, both in the male and female. As this group will include all the parties involved, oncologists, reproductive endocrinologists, reproductive urologists, radiotherapists, patient advocates, and psychologists, it will provide [community cancer] centers with a comprehensive overview and contemporary approaches to fertility preservation. We will make all the information in this critical area of oncofertility available to community cancer centers so that they can provide their patients with appropriate treatment options. OI

—Amanda Patton is associate editor for the Association of Community Cancer Centers in Rockville, Md.



Transitions & Transactions

The "Why" and "How" of Integrated Cancer Services

BY MATTHEW R. STURM, MBA, AND
JESSICA L. TURGON, MBA

In Brief

Cancer care providers, both in the hospital and practice setting, are in the midst of uncharted and stormy waters. Few would disagree about the need for the strategic alignment of hospitals, physicians, and related cancer services. Although most understand that the next five years will see industry-wide transitions to new cancer care delivery models, there is much debate on how best to achieve strategic, economic, and operational integration across multiple providers and sites of care. And since each market has different characteristics, one size does *not* fit all. The good news is that many options are available. The caveat: an effective integration strategy may entail changes in the structure and culture of the oncology community. This article discusses options for closer alignment between physicians and hospitals and describes the required steps for a successful transaction.

Over the past few years, *consolidation*, *integration*, and *clinical* coordination have achieved buzzword status. While undoubtedly overused and often ill-defined, these concepts are central to the delivery of cancer care in the next decade. As a starting point for discussion, here are definitions for these key terms:

- ***Consolidation*—**Bringing cancer physicians together under a single tax ID number.
- ***Integration*—**A hospital or health system employing providers and buying their practices.
- ***Clinical Coordination*—**Management of patient care across conditions, providers, settings, and time with a focus on care that is effective, efficient, and patient-centered. Often, clinical coordination is organized and expressed through a cancer service line.

Developing a cancer service line strategy and a model to create the right physician and hospital alignment requires an understanding of where oncology is headed in the next five years and beyond. New requirements for clinical integration between and among hospitals and physicians are very likely to include:

- A high degree of interdependence between providers and hospitals.
- Full-panel oncology providers with required in-network referrals.
- Integrated information technology (EHRs) and robust reporting capabilities.
- Basic competence in population health management.
- Defined clinical protocols and pathways across a broad spectrum of diagnoses and procedures.
- Sophisticated revenue distribution and compensation methodologies to align incentives.
- Noncompliance sanctions for both physicians and institutions.

While it takes years to reach fully developed coordinated care, hospitals should begin by considering potential partners and possible relationships in terms of how each choice promotes or prevents achievement of meaningful care coordination care across the cancer service line.

Why Oncology Providers Need Each Other

In the near term, providers must face the difficult question—*Why does anything need to change?* For some physician practices, "staying the course" may be an attractive option; however, even these groups need to understand that catalysts for change are many and varied. For hospitals and oncology practices, drivers of change include:

- A large and growing demand for services, making oncology a priority.
- Dominant volumes in ambulatory services, pointing to physician practice acquisitions as a logical expansion strategy.
- Payment reform initiatives, including value-based and bundled payments, as well as significant incentives to provide integrated oncology services.
- The need to attract and retain a dedicated group of oncology providers or risk losing them to a rival hospital or system.
- Major opportunities for hospitals to increase cancer service line reimbursement and profitability.
- An evolving competitive landscape that demands greater clinical coordination among the various oncology service providers.
- Increased competition for lucrative ambulatory services,

Table 1. Hematology and Oncology Collections for Professional Charges, 2008 to 2010

YEAR	MEDIAN	PERCENTAGE CHANGE FROM PREVIOUS YEAR
2010	$486,293	-9.0%
2009	$534,573	-22.8%
2008	$692,879	N/A

Source: 2008 to 2010 MGMA *Physician Compensation* and Production Surveys, Table 5.6, Physician Collections for Professional Charges (TC/NPP Excluded) by Hospital Ownership—Hematology/Oncology.

Table 2. Hematology and Oncology Physician Compensation, 2008 to 2010

	HOSPITAL-OWNED		NOT HOSPITAL-OWNED	
YEAR	MEDIAN	PERCENTAGE CHANGE FROM PREVIOUS YEAR	MEDIAN	PERCENTAGE CHANGE FROM PREVIOUS YEAR
2010	$375,000	18.1%	$404,412	0.8%
2009	$317,543	-6.3%	$401, 125	2.5%
2008	$338,854	N/A		

Source: 2008 to 2010 MGMA Physician *Compensation and Production Surveys,* Table 1.6, Physician Compensation (More Than 1 Year in Specialty) by Hospital Ownership – Hematology/Oncology.

such as imaging and radiation oncology.
- Growing demands for cost containment and value-based healthcare.

For oncologists, in addition to the concern for improving quality of care, interest in consolidation or integration is most often centered on a combination of compensation and lifestyle considerations. Simply put—*What do I need to do to maximize my income over time while maintaining an acceptable work schedule?*

Consider the data points in Tables 1 and 2 above. On the revenue side, over the past several years, reductions in Medicare payments for both professional services and infusion drugs have taken a big bite out of medical oncologists' revenue. Between 2008 and 2010, the median oncologist collections for professional charges declined 30 percent. In response to this loss of revenue, most practices have increased efficiency in efforts to avoid declining income. While independent oncologists have managed to eke out small increases in pay over the past two years, compensation for hospital-employed medical oncologists increased by more than 12 percent. (Note that although median compensation levels remain slightly lower for employed oncologists, the gap is narrowing quickly.)

As drug reimbursement and professional fees continue to experience downward pressure from Medicare, oncologists will find it increasingly difficult to maintain historic income levels. Hospitals are often able (and willing) to pay physicians more because of the practice's value to the cancer service line and a more favorable reimbursement model. When hospitals are able to provide attractive compensation and stability, oncologists in private practice view the integration option quite favorably and often seek out employment offers.

The message is that most hospitals and oncologists have very good reasons for considering integration. And the pressure for economic alignment is likely to remain high for the foreseeable future. While many organizations have chosen to adopt a "watchful waiting"approach to integration, this stance offers a number of risks that must be carefully evaluated, including:
- In a rapidly consolidating market, your competitors may be busy forming an integrated cancer program or service line that could significantly alter the available options in a year or two.
- While the provision of healthcare services is highly localized, the competition for providers is occurring on a national scale. Programs that seek to preserve the status quo

may quickly find themselves at a competitive disadvantage in recruiting and retaining providers.

- Responding to new payment models (e.g., ACOs, bundled payments) will require a high degree of integration and coordination. Organizations that focus on integration and coordination *prior to* seeking to participate in new payment models will have a competitive advantage.
- Oncologists must carefully consider the timing of integration with the hospital. The economic terms of integration are often a function of the practice's current performance and industry-wide trends. It is advantageous for groups to integrate *before* their financial performance declines further.

With this understanding of why hospitals and physicians are logical partners in an integrated cancer care line in mind, the next question is how to achieve such a partnership. The basic models for hospitals and oncologists to work together are illustrated in Figure 1 below. The traditional models, including medical staff affiliation, recruitment support, and joint ventures, may be useful in some instances, but do little to address the issues of clinical and economic integration. Models that include the elements of true integration are discussed below.

Co-management Arrangements

Under a co-management arrangement, oncologists and the hospital form a joint venture management company for the purpose of providing management services for the cancer service line or specific elements of the service line, such as the infusion center. The management company works with hospital administration to lead the service line and implement strategies. The management company, through its designated physician leaders, provides administrative, medical director, and quality improvement services, as negotiated by the management company. Ownership of the management company and distributions are based on the capital contributed to the venture. Figure 2, page 36, shows a sample co-management model structure.

The major benefit of co-management is that physicians become partners with the hospital in driving programmatic development. Also, in this structure, physician managers are in a strong position to enhance coordination of care. A great deal of control is ceded to the management company, giving it the ability to make significant positive changes. Financially, physicians can benefit if they are able to achieve performance goals set by the management company. Physicians often find this model attractive because they are able to remain independent of the hospital; however, co-management relationships

Figure 1. Range of Affiliation Models

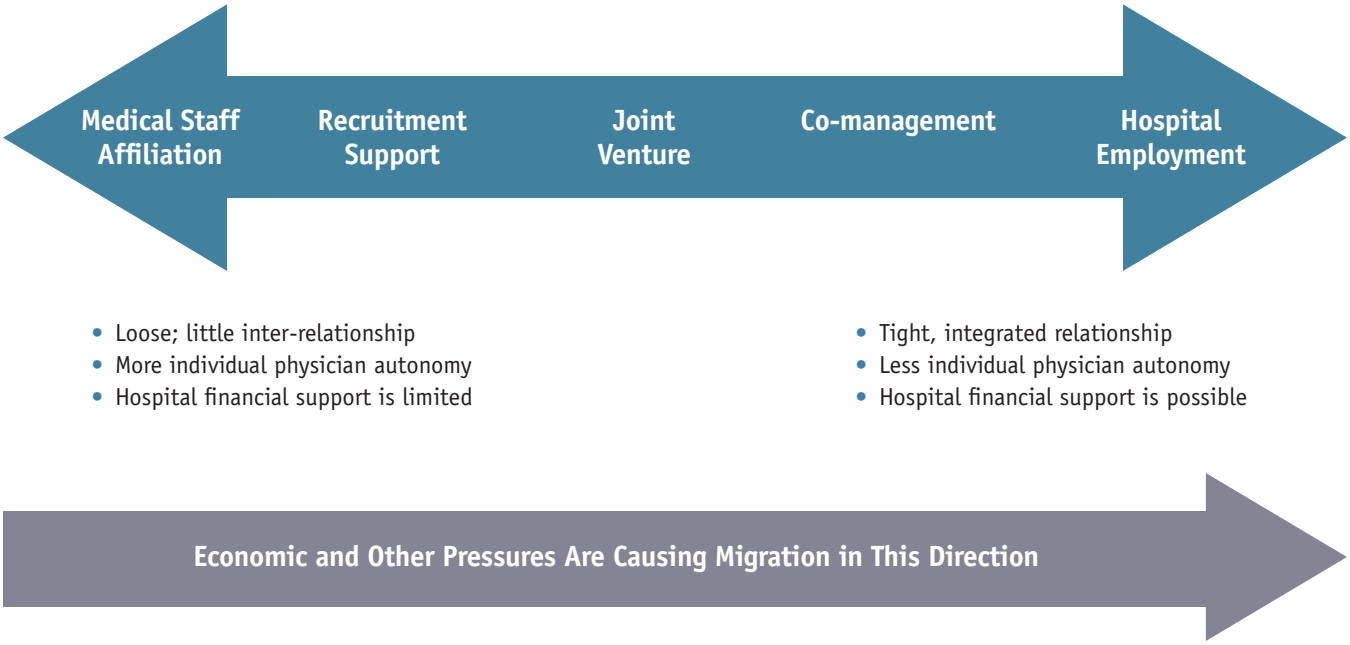
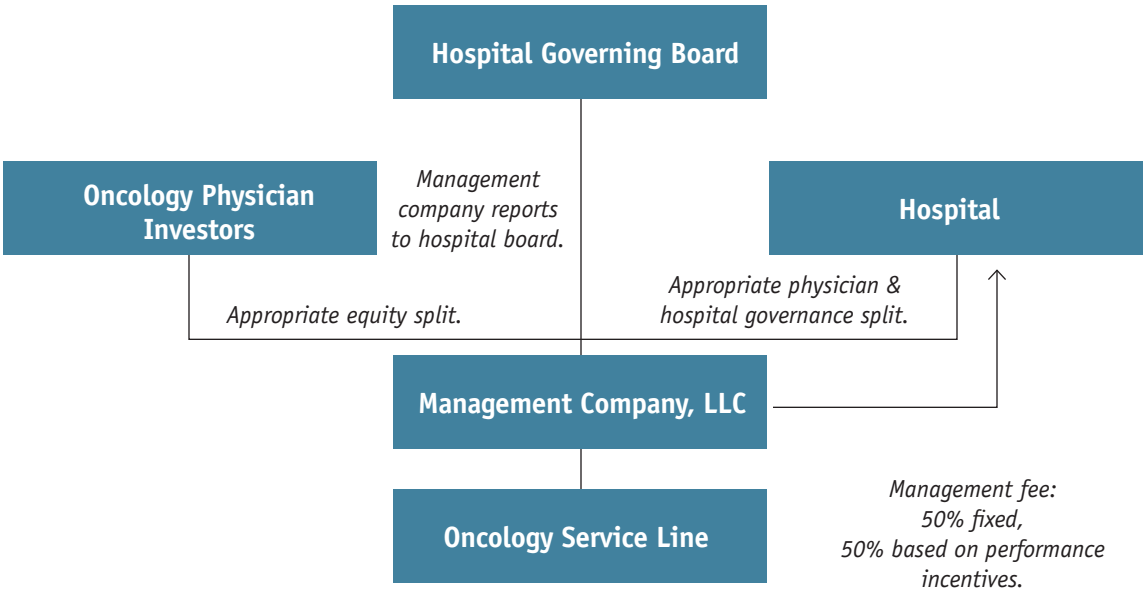


Figure 2. Example of a Co-management Model Structure



frequently involve diverse physician interests, which complicate reaching an agreement.

Employment Structures

Employment structures offer varying degrees of integration both among the oncologists and between the hospital and the physicians.

One basic employment structure is *service line employment*. In this model, oncologists are employed through the service line or cancer center of the hospital. Typically, these models include distinct employment arrangements, dedicated oversight, and decentralized support services from other physician practices employed by the hospital or health system. Commonly, governance functions for these groups are integrated with service line governance.

Another model is an *employed multispecialty group* structure. In this model, the oncologists join the physician organization of the hospital or health system. The model is characterized by a single, integrated structure with unified governance, as well as common policies and support infrastructure for all physicians.

Professional Services Agreements

PSAs are an alternative to physician employment. In the PSA model, a group(s) of oncologists is linked to a separately incorporated hospital through a professional services agreement. The hospital generally employs all staff, provides all support services, and negotiates managed care contracts. The basic arrangement is depicted in Figure 3, page 37.

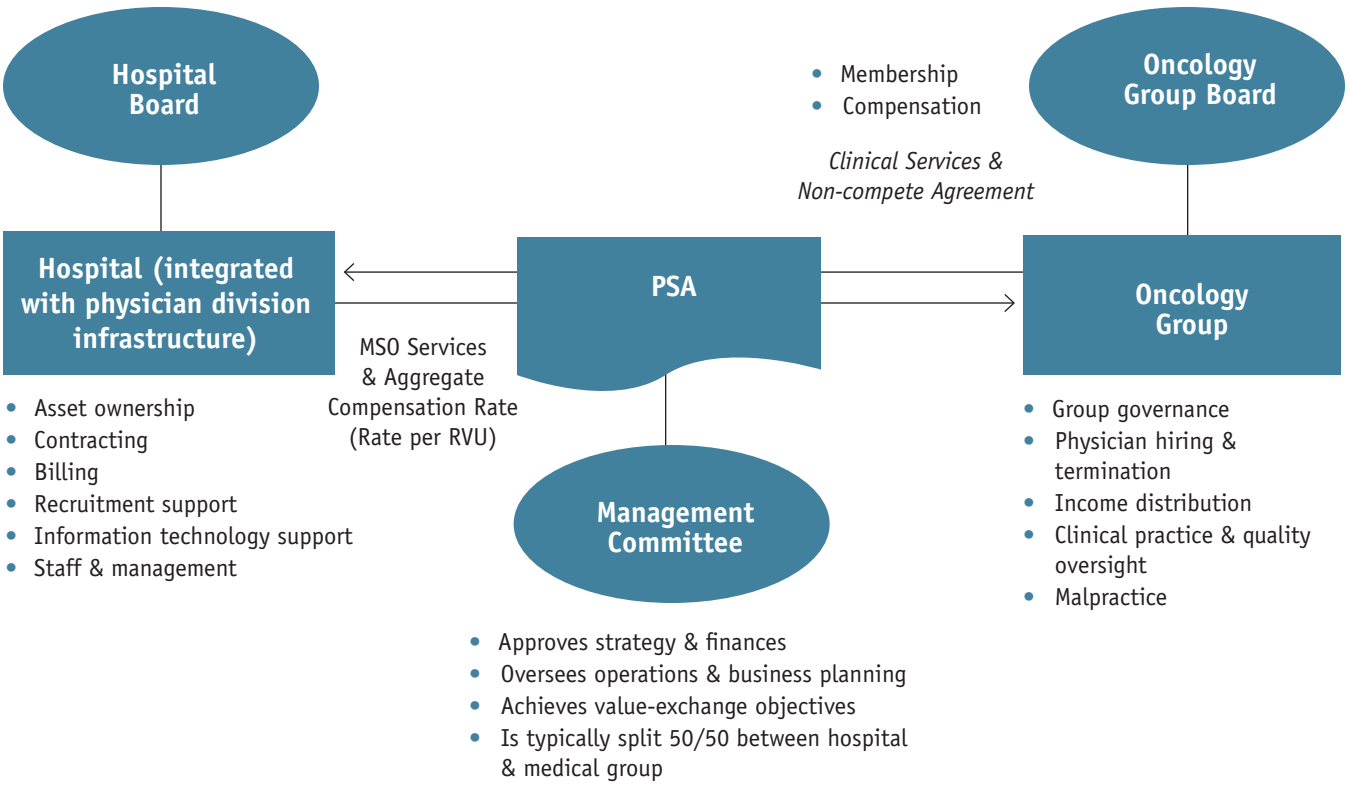
Professional services agreements are attractive because they create strong, coordinated relationships, yet allow physicians to remain relatively independent. PSAs are also flexible in that the services covered and the terms involved can be tailored to fit the circumstances. Often hospitals and health systems choose this type of arrangement because the organization is willing to invest in a tightly integrated oncology group, but faces physician resistance to employment. To ensure successful integration, the PSA should be tailored to not only create aligned incentives, but also to promote physician leadership through joint service line management and/or governance.

Service Line or Medical Group Employment

Often, acquired practices are fearful that they will be controlled or have their control diluted by other physicians, regardless of specialty. In other words, physician resistance is likely to be high if there is a perception that oncologists are being forced into a larger physician structure.

While integrated physician organizations have many benefits for hospitals and health systems in terms of standardizing the governance and operations of the physician practice,

Figure 3. Sample PSA Structure



integrated physician organizations may or may not be the appropriate solution for employed oncologists. Determine the appropriate structure for physician employment based on a careful assessment of the following variables for the employed physician organization versus the cancer service line:

- Size and sophistication
- Strategic direction
- Ability to integrate oncologists with other cancer care providers and/or referring physicians
- Other organizational demands and political realities.

While employing physicians through the service line will likely create certain inefficiencies, many organizations have found that this employment approach: 1) provides greater flexibility in responding to the unique needs of oncologists and 2) fosters the development of the service line through tighter integration and alignment with the oncologists.

Infusion Services

Careful planning is needed to decide if infusion services should be under the umbrella of the physicians or the hospital. Given typical hospital payer and purchasing contracts—including potential access to the 340B Drug Pricing Program—it is usually advantageous to transition infusion services to provider-based (i.e., hospital-based). The associated changes to policies, procedures, and operations within the oncology practice must be clearly communicated to the physicians. Significant changes are required, including:

√ To meet purchasing and payer requirements, the costs associated with infusion and pharmacy must be tied directly to the hospital's cost report and tax ID number. Carefully consider the operational and financial structures that need to be implemented to support these requirements.

√ Most notably, pharmacy and infusion suite operations must comply with hospital outpatient regulations. The feasibility process should include a review of current workflow(s) to evaluate the implications of converting services to hospital-based billing.

√ With a conversion to hospital-based billing, the revenue cycle for an outpatient department must now be run through the hospital. For example, registration and billing systems must be implemented to bill infusion administration and drug charges on a UB-04 instead of a CMS-1500.

Physician compensation is more complex in a provider-based environment where infusion therapy services are rendered by the hospital and not the physicians. When infusion services are under the umbrella of the hospital, chemotherapy is recognized as a designated health service under the Stark law and physicians cannot receive wRVU (work relative value

units) credits for chemotherapy administration. This means that even though physicians still provide supervision for chemotherapy administration, they do not earn wRVUs for this activity. To account for the virtual loss of production, organizations are increasingly adopting a model that provides a fixed base salary or wRVU credit for the historical income generated from the infusion administration services. For a more detailed description of compensation models for employed physicians, refer to "Physician Compensation: Designing the 'Best-Fit' Plan" in the March/April 2012 *Oncology Issues*.

Practice Management

Hospitals are unfamiliar with operating medical oncology practices, and careful planning should be done before transitioning an oncology practice into existing hospital systems. Hospitals that take into account and fully understand oncology-specific revenue cycle practices, EHR systems, and infusion treatment protocols can often develop interface solutions rather than replace physician office systems with hospital systems. A detailed discussion of practice management of employed physician practices is beyond the scope of this article. For additional information, go to the Meeting OnDemand broadcast of "Financial Optimization of Employed Physician Practices" from the ACCC 2012 Annual National Meeting. The broadcast is available at: *http://accc-cancer.org/meetings/meetings-AM2012-highlights.asp*.

Key Transaction Documents

It is important to understand the key documents that will be part of any integration initiative. These documents should not be viewed as something for attorneys and financial experts to work out. Because they summarize all of the critical elements of the future relationship, it is critical that both senior hospital administrators and physician leaders are fully involved in the development of these documents. The following is a summary of the documents required to complete each step. (Note: the traditional caveat that we, the authors, are healthcare consultants, not attorneys, applies. Hospitals and physicians will need to coordinate closely with a legal adviser experienced in group acquisitions and mergers.)

Confidentiality Agreement & Nondisclosure Agreement

The parties agree not to disclose information that may be acquired during the discussion and negotiation process, and they can also agree not to reveal even the existence of a potential acquisition. This initial step is generally completed *before* any substantive discussion occurs.

Confidentiality agreements may also include "standstill" and/or "no-shop" requirements. Standstill simply means that the practice cannot make material changes, such as new capital commitments, sale of assets, or modification of the compensation system while in negotiations. Hospital standstill requirements are usually limited to those actions that could affect the subject acquisition, such as new affiliations with other medical groups or the purchase of ancillary services that may impact the practice.

No-shop provisions, sometimes referred to as Exclusivity Agreements, are becoming more common. Such provisions prohibit the practice from talking to other hospitals about being acquired; these provisions can also prohibit the hospital from discussing a merger or affiliation with other practices prior to the conclusion of current negotiations. While practices and hospitals sometimes resist such restrictions, in our view, these provisions can be critical to ensure that both parties are serious about, and committed to, the proposed relationship.

Letter of Intent or Term Sheet

The Letter of Intent (LOI), sometimes referred to as a term sheet, presents the basic terms and conditions under which further discussion and planning regarding the proposed affiliation will occur. This document is the most important one in the entire process in that it defines, as completely as possible, how the parties want to structure the deal and operate jointly after completing the transaction.

The acquisition of an oncology group often requires the establishment of work groups composed of representatives of both the hospital and the oncology practice. The work groups conduct the necessary analysis and provide recommendations to a steering committee that decides the contents of the LOI. After the LOI has been agreed on by leadership, legal counsel will guide the development of the definitive agreements. A term sheet skips most of the formalities and lists deal terms in outline or bullet-point format.

Creating the LOI or term sheet encompasses at least 80 percent of the time and energy that the transaction demands. Legal advice is required to resolve some of the issues, but LOI content should be directed by the principals of the practice and the hospital. Both entities should be closely involved in the process at all times. A summary of the key elements that should be addressed can be found in Table 3 on page 39.

Budgets or financial forecasts are not included as part of the LOI content. The process for developing and approving budgets should be addressed, but financial projections themselves are not generally included in the legal documents. That said, financial projections are an important part of the planning process and should involve both hospital and oncology practice representatives to ensure that the financial *pro forma* is realistic and attainable.

continued on page 40

Table 3. Key Elements in a Letter of Intent

Determine the employment model to be used.
Define physician employment specifics such as:
Compensation, including initial methodology and process to revise methodology.
Other Employment Issues, such as benefits, vesting period, handling of past deferred compensation (tax implications), PTO policies, etc.
Term and Termination Provisions, including potential sanctions and dismissal.
Non-compete Clauses, which go into effect after termination of employment.
Document the future governance structure. Define the authority of the hospital, oncology practice, and any board, operating committee, advisory council, or similar structure formed as part of the transaction. Outline the rights and obligations of each entity to:
Be informed of decisions of management or other governance bodies.
Advise decision makers prior to final decisions.
Approve specific policy or operational decisions.
Retain special majority or reserve powers regarding specified actions, such as sale of assets, changes to the compensation system, acquisition of other oncology groups, and purchase of a new EHR.
Documentation of valuation opinion(s), as required, for either physician compensation terms and/or practice acquisition terms.
Determine compensation and benefits for staff, including any employment agreements and severance packages.
Clarify operational issues and responsibilities, such as:
Will infusion services be provider-based (i.e., hospital-based)?
How will patient access be affected to meet hospital revenue cycle requirements?
How will staffing levels and budgets be determined?
What billing and EHR systems will be used, and who will support them?
How will physician recruitment and selection be managed?
Who will negotiate payer contracting for the physicians?
Who will manage the personnel decisions for front office, clinical, and administrative staff?
Document the timing and conditions under which either party could terminate the relationship and specify the provisions for unwinding the relationship if necessary.

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Definitive Agreements

After preparing a detailed LOI, the lawyers are asked to develop the necessary legal documents for signature based on the terms defined by the parties. The task may seem straightforward, but a number of documents need to be prepared, reviewed, revised, and signed before the transaction is complete. These include, but are not limited to:

- Acquisition Agreement (covering governance and operations)
- Asset Purchase Agreement
- Real Estate Lease Agreement
- Physician Employment Agreement
- Fair market value documentation
- Contract assignments
- Bylaws and Articles of Incorporation for any new physician entity
- Severance notification for group staff
- Escrow Agreements
- Promissory Note and Security Agreement.

Substantive issues often arise when these documents are prepared that require continuing negotiation and may necessitate a return to the negotiating table. In addition, due diligence reviews must be completed to determine that the financial and operational information used to fashion the agreement is accurate.

While the definitive agreements are being developed, each organization must undertake the process of securing internal approvals from its leadership. This process involves communicating the details of the proposed acquisition and its likely impacts to both the hospital board and each of the physician shareholders of the practice who will ultimately vote on the transaction. Whenever possible, both hospital and oncology group leaders should jointly make the presentations to both the hospital board and physician shareholders, as well as answer any questions that may arise.

Making It Work

The steps in completing the transaction may seem imposing, but once it is completed, the real work of transitioning to a cancer service line begins. While there are many "moving parts" to pay attention to, our experience shows that three factors are essential to success:

1. ***Expertise in oncology practice management and operations.*** You cannot place a hospital manager, even one with considerable ambulatory experience, in charge of an oncology physician network and expect good results. Respect the fact that specific expertise is required and find an experienced oncology executive to direct your efforts.
2. ***Physician leadership.*** The strategy is a partnership with physicians, so management and governance must reflect this commitment. Physicians with potential should be nurtured as managers and administrators and placed in decision-making roles in the cancer service line, the hospital, and at the system level.
3. ***Physician commitment to system-wide goals.*** When forming a cancer service line, too often behavior or performance expectations are minimized in order to be seen as "physician-friendly." The reality is that providers in an integrated oncology network must be committed to the success of the service line and compliant with cancer center policies.

Given the major cultural differences between hospitals and physicians, achieving alignment is one of the most difficult challenges that either party will undertake. Many integration initiatives encounter conflict between the strategic goals and the entrenched culture of the organizations. It requires commitment and focus to work through these conflicts and form the new culture needed to sustain a cancer service line.

Is Integration Really Necessary?

When considering the steps involved in creating a cancer service line, the logical question is whether there are alternatives that are less time-consuming and expensive. While hospital and physician practice mergers are just one of a number of options for affiliation, in our view these remain the most viable structure in terms of effectiveness and stability for oncology services.

From an economic perspective, we believe there are two keys to success for an oncology program: 1) access to capital and 2) the assembling of a sophisticated management team that includes physician leadership. Both of these success factors are significantly affected by scale (i.e., hospitals and physicians that participate in a large, integrated, and disciplined cancer service line will be more competitive than the small, independent oncology groups). In terms of patient care, it will be very difficult for less integrated models (contractual or partnership arrangements) to be effective in the long term in achieving needed levels of coordination of care and documenting quality. While other affiliation models can be effective, especially as transitional structures, our experience points to the fact that comprehensive, economically integrated cancer service lines are the most efficient and appropriate for cancer care. OI

—Matthew R. Sturm, MBA, and Jessica L. Turgon, MBA, are senior managers at ECG Management Consultants, Inc. For more information, visit: www.ecgmc.com.

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CLINICAL PHARMACISTS

Care and Collaboration in the Community Cancer Center

BY ANNIE LAMBERT, PHARMD

Annie Lambert, PharmD, oncology pharmacy supervisor for MultiCare Regional Cancer Center, Tacoma, Wash.

In Brief

MultiCare Regional Cancer Center (MRCC) is comprised of four outpatient infusion clinics across Pierce and King Counties in Western Washington, with a total of 84 infusion chairs and 10 employed medical oncologists. Our flagship location is in Tacoma, Wash., with three satellite clinics in Auburn, Gig Harbor, and Puyallup. At MRCC, clinical pharmacists have been an integral member of the cancer care team for over 10 years, starting with our Tacoma General clinic, providing supportive care management through collaborative practice agreements approved by the Washington State Board of Pharmacy. Pharmacists also work closely with our physicians, providing order review and ongoing management of treatment protocols in the electronic health record (EHR). MRCC pharmacists are a crucial component of a system of double-checks that ensure safe care, optimal charge capture, and compliance with both external and internal guidelines. As our program has grown to include additional satellite locations, we have replicated our service model to deliver quality cancer care close to the homes of our patients. This article will focus on how clinical pharmacy services have evolved at MRCC, strategies for implementation of a similar model, and the impact onsite pharmacists can have on patient safety, patient satisfaction, and overall healthcare costs.

The role of pharmacists on the cancer care team has been discussed in *Oncology Issues* and other oncology journals in recent years.[1-3] Most of these articles tend to focus on the operational role of pharmacists in managing drug inventory, tracking drug waste, and overseeing chemotherapy admixture services. Another role of the pharmacist is a safety check for appropriate prescribing based on FDA indication and renal or hepatic function. It is a common misperception that pharmacists are limited to this dispensing capacity. Others, like ACCC, recognize the unique skill set the pharmacist brings to the table and the importance of clinical pharmacy services.[4]

Our Clinical Pharmacy Services

Clearly, pharmacists can and should be an integral part of the cancer care team. However, if a pharmacist is not already part of your team, you will need to take steps to introduce the pharmacist's services and gain the understanding and trust of physicians and clinic staff for this new team member. At MRCC Tacoma General, clinic nursing staff and physicians needed a few months to fully understand how a pharmacist could be helpful in the clinic setting. While staff was familiar with the role of pharmacists on the inpatient care team, they were less clear about the benefits a pharmacist would bring to the clinic setting. For example, our cancer program administrator was accustomed to having nursing staff mix and administer chemotherapy. When the pharmacist and pharmacy technician took over admixture services from the nursing staff, our administrator quickly came to understand that pharmacists can also multi-task and provide services that nurses cannot.

Even if pharmacists begin with a dispensing focus, their ability to review orders for appropriateness includes:

- Clinical assessment
- Knowledge of current issues in oncology and drug indications
- An understanding of the whole plan of care for the patient.

As new treatments or regimens become available, the pharmacist is an excellent resource for providing updated information and education to physicians and infusion nurses. These skills offer pharmacists a natural process to begin developing

MRCC clinical pharmacist, Paul Wallace, PharmD, BCOP, consults chair side in the infusion center.

valuable working relationships with physicians and other clinicians and to demonstrate the knowledge and expertise these staff members possess.

Collaborative Practice Agreements

The next evolution of clinical pharmacy services at MRCC included the development of several collaborative practice agreements that were approved by the Washington State Board of Pharmacy. Also known as collaborative drug therapy management,[5] these are agreements between our physicians and pharmacists to manage certain aspects of care based on national guidelines and practice standards. Depending on the protocol, pharmacists are allowed to initiate or modify drug therapy, order related laboratory tests, and assess a patient's response to therapy.

The first protocol was for antiemetic management and this continues to be a mainstay of our program today. Physicians were eager to involve pharmacists in this aspect of patient care as it not only eased their workload, but also improved the quality of care. As part of the care team, the pharmacist could assess the patient's symptoms in real time every time the patient came in for treatment and make changes to the patient's antiemetic medications immediately. Check with your state Board of Pharmacy to see what prescribing authority pharmacists are allowed and the requirements for establishing collaborative practice agreements. Refer to National Comprehensive Cancer Network (NCCN) Guidelines and other national guidelines to develop protocols and algorithms for various supportive care needs.

MRCC's model of oncology pharmacy services described above has been so successful, that we have committed to providing the same level of care at all of our locations. Each clinic has a licensed parenteral pharmacy fully compliant with USP 797 standards. In other words, distributive and clinical services are in place at each of our satellite locations. MRCC employs a total of 7.0 FTE pharmacists and 5.0 FTE technicians, under various staffing models related to the volume of infusion chairs and patient visits. Pharmacy services are available Monday through Friday during business hours. MRCC also has a network of retail pharmacy services and anticoagulation clinics, which we partner with on a regular basis.

On any given day, you will be more likely to find a pharmacist at the chair-side rather than in the pharmacy itself. MRCC pharmacists spend much of their time talking with patients about how they tolerated their last cycle of chemotherapy, reviewing their medications, and making adjustments to help gain better control of their nausea, diarrhea, or constipation.

As our locations and pharmacy team grew, we were also able to expand our clinical services. Currently, MRCC providers

and pharmacists operate under several collaborative practice agreements including:

- Management of erythropoetic stimulating agents (ESAs)
- Renal dose adjustment
- Electrolyte replacement
- Cancer pain management
- Anticoagulation
- Management of hypersensitivity reactions
- GI symptom management
- Appropriate use of colony stimulating factors.

Revised Model for Growth

When our Tacoma General clinic expanded in 2010 to serve 35 infusion chairs and 5 oncologists, we increased the clinic's pharmacy team to include 3 pharmacists. Previously, at our satellite clinics, one pharmacist provided all the services, both dispensing and cognitive. With the Tacoma clinic seeing an average daily census of 80 to 100 patients for treatment and office visits, we needed to revise our approach to care.

Now at Tacoma General, the work is divided into three pharmacist positions: infusion, IV room, and physician office visits. The infusion pharmacist focuses on the patients coming in for chemotherapy, reviewing their treatment plans, recent labs, and events since their last visit. The infusion pharmacist also meets with patients during their infusion to adjust antiemetics and manage any other symptoms, based on our protocols. The IV room pharmacist is primarily responsible for dispensing duties, verifying orders, and checking final admixture products. Since these functions involve such high-risk medications and are time sensitive, it is critical to reduce interruptions to this position. Both the infusion and IV pharmacists participate in the multidisciplinary morning report, reviewing patient care plans for the day. These two pharmacists cover the majority of issues that come up in the clinic day-to-day.

Patients coming in for physician office visits have needs as well. The "MD pharmacist" has an office close to the physician offices so that the pharmacist has easy access to providers as questions arise. Providers and the pharmacist review proposed changes to the plan of care for patients coming in that day. The pharmacist then prepares patient education materials to assist with the treatment consent process.

We have found that pharmacists provide a unique perspective on chemotherapy patient education. Pharmacists are often the first person the patient sees after receiving the plan of care from the physician. These professionals use their clinical expertise to help translate the care plan to the patient level, describing what to expect and how our team will help prevent and manage symptoms and side effects. Pharmacists also take into account the patient's current medications, disease states, lab results, and insurance needs. By completing this assessment early in the process, the pharmacists can identify possible issues with the treatment plan, potentially reducing wait time on the day of treatment.

The "MD pharmacist" is able to:

- Field questions from providers and patients about specific medications or drug interactions.
- Coordinate with specialty pharmacies for oral chemotherapy preparations and assist in managing refills. This role is especially important for medications that include a REMS (Risk Evaluation and Mitigation Strategy) program, such as Revlimid. With the volume of oral chemotherapy regimens, the need for this coordination and medication review is increasing.
- Collaborate with social workers and drug recovery specialists when patients need financial assistance.
- Act as a liaison with the inpatient pharmacy team, helping to coordinate planned admissions for chemotherapy.

Research & Clinical Trials

Cancer research and clinical trials are an important part of the MRCC program. While pioneer pharmacist Richard Shine, PharmD, still has his roots in oncology pharmacy, he now serves as the director of the MultiCare Research Institute. The Institute coordinates clinical trials via the Northwest Community Clinical Oncology Program (NWCCOP), industry-sponsored trials, and studies available through our network affiliation with Seattle Cancer Care Alliance (SCCA). In the absence of an Investigational Drug Service, our individual clinic pharmacists are involved in research in many ways, from the Institutional Review Board to management of study product inventory. These duties are in addition to routine dispensing and clinical services.

Patient Safety & Patient Satisfaction

Pharmacists provide an additional level of safety checks in the chemotherapy process. At MRCC we added process steps in the early years of our clinic-based pharmacy program. The oncology pharmacist began by printing Medication Administration Records (MARs) from the pharmacy computer system, providing a more organized method of documenting chemotherapy doses and administration than the handwritten information on the flow chart.

In 2007 MultiCare upgraded to a fully integrated Epic© EHR, including the Beacon oncology module. Pharmacists played a key role in EHR implementation, first by helping to develop MultiCare standards for antiemetic and emergency medications, then by reviewing chemotherapy protocols prior to release, and finally by converting paper treatment plans to Beacon protocols. This process involved research on current

best practices and national guidelines, as well as immense attention to detail to ensure accuracy of information on a general and patient-specific level. During the process, our providers were also involved, and commented many times that they could not imagine going through this process without our pharmacists.

Now after four years on our EHR, the pharmacist safety checks remain as important as ever. With the EHR system, information is easier to access and to communicate to physicians. Pharmacists can easily track trends in key lab results, doses, and weight changes. These data help pharmacists alert physicians to the need for a potential dose adjustment, always ensuring we have the right drug and the right dose based on information available through the EHR.

Not only do physicians and clinical staff value a pharmacist on the cancer care team, so do patients. Sometimes patients need some time to understand the difference between a clinical pharmacist and other pharmacists they've had contact with. Patients are excited to have a "drug expert" as part of their care team. Being in the clinic every day, right alongside the physicians and nurses, gives pharmacists the opportunity to interact directly with patients. Patients appreciate the support with their medication regimens and in managing their symptoms. And the pharmacists, in turn, appreciate the instant feedback from patients about the success of their interventions. Patients often comment on how accessible the pharmacist is and how grateful they are for the time pharmacists spend with them. Happy patients and families help increase patient satisfaction scores for our clinics.

Cost Effectiveness

With an average salary of $115,500, pharmacists are not an inexpensive resource.[6] So how can implementing a clinical pharmacy model in the community cancer program setting be cost effective? The value of pharmacists in managing the bottom line has been described by others—both in terms of inventory management and contract negotiation.[7] MRCC pharmacists have also played a significant role in managing drug shortages, not only to track and acquire products, but also in proposing alternate therapies when the usual medications are not available.

The financial impact of pharmacy services expands when the clinical component is included, although this data is often challenging to quantify. Some examples of the intuitive financial contributions pharmacists provide center around appropriate selection of therapy and in serving as physician extenders. Clinical pharmacists review physician orders for appropriateness related to FDA indications and assist in providing evidence-based support for off-label or experimental

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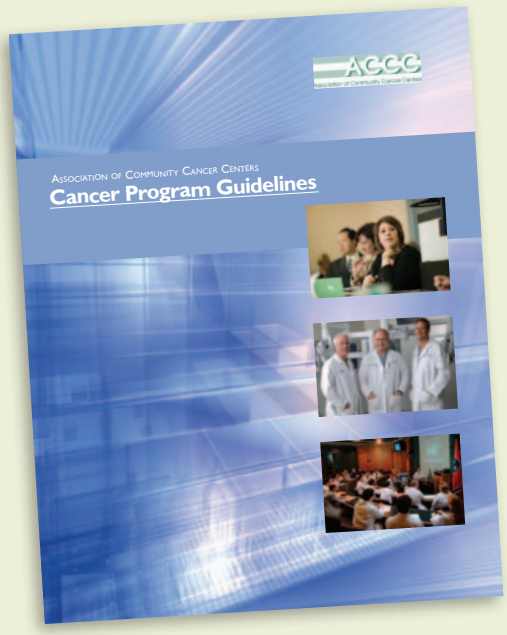

ACCC'S *CANCER PROGRAM GUIDELINES*

Chapter 4, Section 5, Guideline III: Clinical Pharmacy Services will be established to ensure the appropriateness and safety of therapy.

Rationale: A multidisciplinary approach should be used in assessing the patient, obtaining medication history, and developing a therapy plan based on the patient's current condition, physiological changes, and reaction to previous therapy. Current medication plans will be reconciled with other providers to ensure coordination and optimizing of the patient's total care.

Chapter 4, Section 5, Guideline IV: Appropriate drug-related education will be provided to patients and staff.

Rationale: It is important to incorporate new scientific discoveries and standards into practice as soon as possible, by educating patients and members of the multidisciplinary team. Training new staff and retraining established staff on a regular basis are important. Specific areas of focus include pharmacology, pharmacokinetics, pharmacodynamics, drug compatibility, drug administration, drug therapy interactions in patients taking multiple therapeutic agents, adverse effects of medication, medication outcomes, and taking comprehensive medication histories.

Read ACCC's full Pharmacy Services Guidelines at: *www.accc-cancer.org*.

IN THEIR OWN WORDS

The clinic administrator was reluctant to hire a pharmacist because he thought pharmacists were limited in their skills and abilities. In a short period of time, I branched out from distributive services and started providing education to patients. I then went on to provide cognitive services to the physicians and nurses, helping patients with their medication regimens, and more. It didn't take long for the nursing and physician staff to realize the value of pharmacy services in the clinic.—Richard Shine, PharmD, pioneer pharmacist at Tacoma General Oncology Clinic, MRCC

I think the pharmacists here at MRCC are one of the core strengths of the oncology program. They are very approachable and willing to work with physicians and staff to coordinate and facilitate patient care, including following up on symptom management in clinic and even by telephone as an interval follow-up for patients.—Umesh Chitaley, MD, medical oncology chief, Tacoma General, MRCC

I am new to MultiCare, having just joined the MultiCare Regional Cancer Center in November 2011. Previously, I was in private practice in hematology and medical oncology for the last 30 years. In all that time I've never had the opportunity to work with a clinical pharmacist as an integral part of the cancer care team. After the physician, they [pharmacists] are the key point of contact for patients regarding establishing informed consent for treatment. They [the pharmacists] provide education and support for the oncology nurses, in addition to supporting patients and their families. Clearly, the sophistication of our cancer program overall is tremendously enhanced by the presence of our dedicated clinical pharmacy team. I am delighted to now be a part of this team. This [practice model] is like traveling first class for the first time—if you've not done it, you don't know what you're missing. If you have done it, there's no going back.—Jack Keech, DO, Gig Harbour Clinic, MRCC

The pharmacy team is an excellent resource. Without any hesitation, I can say that the pharmacist is part of a group that is hard-working, enthusiastic, eager to explore and research unusual interactions, and able to collaborate with SCCA in getting regimens implemented here.—Umesh Chitaley, MD, medical oncology chief, Tacoma General, MRCC

indications, increasing the likelihood of reimbursement and minimizing the burden on the pre-authorization team. Medication use evaluations on classes of drugs, such as antiemetics or anti-resorptive agents, can identify not only compliance with treatment guidelines, but also opportunities for more favorable reimbursement within the class.

Clinical pharmacists can also play a key role in compliance with local or national coverage criteria, such as that governing eyrthropoesis stimulating agents (ESAs), resulting in cost avoidance by preventing lost revenue. MRCC pharmacy team is now the "gatekeeper" for all ESA medications. We revised our collaborative practice agreement to include prescriptive authority for key lab tests that require assessment prior to and during ESA therapy. The physician prescribes the initial dose, but all further dose titrations are prescribed by a pharmacist. Pharmacists also review physician notes for documentation of medical necessity as required by the coverage criteria, and participate in an internal audit team of all ESA claims. This process allowed us to maintain compliance and achieve significant improvement in our Medicare reimbursement rate for ESA therapy.

Pharmacists as Extenders

The most significant and long-term impact of clinical pharmacy services in the MRCC care model is as a physician extender. With physicians challenged to see more patients in less time, someone must still be available to manage symptoms and answer patient questions. While many on the care team are capable, clinical pharmacists fill an important part of that gap at MRCC. The physician can trust that a qualified clinician is monitoring for, assessing, and managing many of the side effects of treatment on a day-to-day basis. Pharmacist interventions can also reduce unnecessary visits to the emergency department when a physician is not otherwise available, thus reducing costs to the patient and the healthcare system overall.

The next step in creating a more financially sustainable oncology pharmacist model is to be able to bill for these clinical services. Some commercial payers recognize pharmacists as providers, but the majority—including Medicare—do not. Others have described some successful billing mechanisms, but the barriers outweigh the wins.[8,9] MultiCare has achieved reimbursement for medication therapy management services in other areas, such as anticoagulation and chronic disease management. In 2012 we will explore this possibility for oncology pharmacy services as well.

While inclusion of pharmacists in the oncology team is becoming more common, we feel we have developed a unique model for pharmacy services at MRCC that thrives on our clinical expertise, collaboration, and contributions to patient care. Our pharmacists' accessibility and credibility make them a valued partner of MRCC physicians, practice administrators, and patients alike. OI

MRCC pharmacy staff, Kelly Hackney, PharmD, and Ivan Cordova, CPhT, prepare and check chemotherapy.

—Annie Lambert, PharmD, has worked as oncology pharmacy supervisor for MultiCare Regional Cancer Center since 2007. MultiCare Health System, MultiCare Regional Cancer Center was a 2011 ACCC Innovator Award recipient.

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STAR Program Certification at Jupiter Medical Center

BY STACEY JUSTINE, MS

MORE ONLINE!

Read an interview with Julie Silver, MD, co-founder of Oncology Rehab Partners and developer of STAR (Survivor Training and Rehabilitation) Program Certification online at: *www.accc-cancer.org/oi/MJ2012.*

In March 2012 Oncology Rehab Partners—a healthcare company providing facilities and clinicians with tools and programs to deliver oncology rehabilitation care—contacted our program, Jupiter Medical Center (JMC), to discuss the benefits of becoming a STAR-certified provider. Sue Goulding, oncology administrative coordinator at Jupiter Medical Center's Ella Milbank Foshay Cancer Center, recognized the excellent opportunity to provide our cancer survivors with certified rehabilitation. Accordingly, Oncology Rehab Partners and our Director of Oncology Services began discussions to evaluate the program. It was apparent that this program far exceeded our offerings at the time. Our leadership was impressed with the program's promise to train JMC team members to help deliver outstanding cancer rehabilitation services. Over the years, JMC's Outpatient Rehabilitation Department had tried to implement a cancer rehab program. However, these attempts met with minimal success for several reasons. The main challenges were a lack of tools and systematic processes to deliver the appropriate rehabilitation to the cancer survivors. We enlisted the support of several key physician champions, including Marcelle Bertrand, MD, medical oncologist and then chair, Cancer Committee; John A.P. Rimmer, MD, medical director, Kristin Hoke Breast Health Program at JMC; and David Herold, MD, medical director, Radiation Oncology at JMC—all of whom remain supportive of the STAR Program to this day.

Three-Phase Implementation

Implementing the STAR Program at JMC was a three-phase process. The first phase involved training members of the Oncology and Rehabilitation Departments throughout the hospital. We trained 45 members of our staff, representing nine different clinical and support specialties. These included nurses; mental health professionals; physical, occupational and speech therapists; massage therapists; exercise physiologists; and dietitians. Over the four-month certification process, the STAR team spent approximately 20 hours each to complete the self-directed computer-based training modules. In addition to the online training, the members of the STAR team met regularly for in-services designed to bring the team members together.

The second phase involved implementing protocols to help direct care, as well as identify problems patients were experiencing that might be amenable to rehabilitation interventions. Examples of tools implemented include:

- *Timed Up and Go*
- A 6-Minute Walk Test
- A brief pain inventory.

We also established a "front door," which is the most direct route for patients to access the cancer rehabilitation services. By having patients and physicians use one phone number, or one point of contact, it established an easy-to-access entry point for the STAR Program. To facilitate the referral process and trouble shoot, the directors of the Oncology and Rehabilitation Departments met regularly. Bringing these two departments together was critical to the program's success.

The post-launch and third phase involved tracking outcomes and continuing education for our staff on an ongoing basis. Less than one year post-launch, we have seen more than a 50 percent increase in oncology patient referrals to the Rehabilitation Department and we anticipate rapid growth over the next 12 months. Jupiter Medical Center was the first cancer program in Florida to earn the STAR Program Certification from Oncology Rehab Partners.

Why STAR Program Certification?

The STAR Program is the gold standard in cancer rehabilitation for hospitals and cancer centers that offer multidisciplinary survivorship care. Julie Silver, MD, assistant professor at Harvard Medical School, cancer survivor, and author of several books on oncology rehabilitation, developed the STAR Program certification with her team of clinicians. Certification through the STAR Program appealed to JMC as a credible comprehensive training program that complemented our ongoing commitment to provide world-class healthcare to the patients in our community. The program allowed use of evidence-based medicine to effectively care for cancer survivors, and addressed the unique health and quality-of-life

OPPOSITE PHOTOGRAPH COURTESY OF JUPITER MEDICAL CENTER; PHOTOGRAPH TO RIGHT COURTESY OF ONCOLOGY REHAB PARTNERS

issues by cancer survivors who are undergoing treatment or living with its aftermath.

In addition, JMC's STAR Program fulfilled the Commission on Cancer's accreditation requirements to ensure patient-centered care by establishing a program that offered access to rehabilitation services to help patients affected by cancer cope with the activities of daily living and enable them to resume normal activities. Currently, our STAR Program connects cancer survivors to a multidisciplinary team of clinicians, including physical therapists, occupational therapists, speech therapists, social workers, dietitians, and nurses who are trained to help them manage and heal the physical and psychological effects that can arise during and after cancer treatment. Information about the STAR Program is given to all cancer patients. Appropriate referrals would include:

- Patients who are unable to return to their previous activity level—including work, home, recreation, and their social activities
- Patients with pain that is not due to tumor and/or malignancy
- Patients who are having difficulty lifting an arm overhead
- Patients experiencing fatigue that interferes with function
- Patients with untreated or worsening lymphedema, to name a few.

The total investment for the STAR Program Certification—generously funded by the JMC Foundation—was approximately $22,000, and included two expert-directed webinars, access to the online STAR self-directed modules, and four in-service presentations. In addition, the STAR Program included 50 Survivor Guidebooks, two press releases, website content about the JMC STAR Program, a Joint Solution Sheet with Oncology Rehab Partners, an article to send to local media to help market the new program, and a referral letter for STAR services.

Our team continues to meet when STAR Program updates are presented through Oncology Rehab Partners. Kelly Raymond, senior physical therapist at JMC's Health and Rehab, is the STAR Program coordinator in charge of quarterly STAR Program meetings. These sessions are designed to keep the team together to ensure the program thrives and that all cancer survivors have access to the healthcare services they need.

Treating the Whole Patient

STAR Program certification continues to advance our survivorship care, to provide an increase in patient referrals, and to systematically train dedicated clinicians to become oncology rehab experts. JMC found it could use existing interdisciplinary resources while creating a reimbursable oncology rehab program. The program allowed JMC to track outcomes, expand our survivorship research, and assist in applying for continuing education units (CEUs) for our clinicians.

At JMC, we pride ourselves on treating the whole patient—not just the patient's illness. Our comprehensive cancer program takes a holistic approach to caring for our patients. The opportunity to further enhance our program by implementing the STAR Program through Oncology Rehab Partners made perfect sense, as JMC is committed to finding ways to bring the best possible cancer care services to our community. Oncology rehabilitation should be the standard of care in all hospitals that treat cancer patients. By developing a cancer rehabilitation and survivorship program, we have made survivorship a distinct and important part of the care continuum. Our goal is to provide cancer patients, and all our patients, with the most comprehensive medical care available, and the best possible outcomes for recovery. OI

—Stacey Justine, MS, is director, Outpatient Rehabilitation, Jupiter Medical Center, in Jupiter, Fla.

I am so glad that Jupiter Medical Center had the STAR Program. I was actually considering moving until I found out that Jupiter Medical Center could provide the care that I needed. I think that every cancer survivor should have the opportunity to get the care that they need. I was looking at all the major cancer centers in the United States and was relieved to know that I didn't need to look any further than Jupiter Medical Center.—Sandra Wade, a STAR Program patient currently receiving physical therapy treatment at Jupiter Medical Center's Health and Rehab and advocate of the STAR Program

OTHER ACCC MEMBERS WITH STAR PROGRAM CERTIFICATION

- Alexian Brothers Medical Center, Elk Grove Village, Illinois (launch date, April 2012)
- Bassett Healthcare Network, Cooperstown, New York
- Bridgeport Hospital, Bridgeport, Connecticut (launch date, spring 2012)
- Centra Regional Cancer Center, Lynchburg, Virginia. (This ACCC-member program saw an 82 percent increase in referrals over the first year of the program, with an additional 60 percent in year two.)
- Johns Hopkins, Baltimore, Maryland
- Kent Hospital, Warwick, Rhode Island
- McLaren Bay Regional Medical Center, Bay City, Michigan (launch date, May 2012)
- Saint Alphonsus Regional Medical Center, Boise, Idaho
- St. Francis (Bon Secours), Greenville, South Carolina. (This ACCC-member program saw a 53 percent increase in referrals to the program over the first 4 months.)
- St. Luke's Hospital, Chesterfield, Missouri
- South County Hospital, Wakefield, Rhode Island (launch date TBD)

Source: Oncology Rehab Partners

PHOTOGRAPH COURTESY OF JUPITER MEDICAL CENTER

Jupiter Medical Center STAR Program-certified clinicians and providers are a multidisciplinary group that includes inpatient and outpatient therapists, cancer center staff, psychosocial therapist, wellness coordinators, and nutritionist (not pictured).

careers

DIRECTOR
Twin Falls, Idaho

In partnership with the Medical Site Manager, the Director of Mountain States Tumor Institute (MSTI) provides leadership, direction, and administration for the operations of the MSTI Magic Valley Cancer Center, as well as clinics in Burley and Hailey, Idaho. The Director has direct oversight for all operations of the Center, including medical oncology, radiation oncology, lab, pharmacy, infusion therapy, and supportive services. The Director has matrix leadership responsibilities for MSTI system leaders in the areas of research, registration, medical records, social work, pharmacy, integrative medicine, physician services, and registry. The Director shall report to the Administrator, St. Luke's MSTI. There shall also be a matrix reporting relationship to appropriate leadership staff of St. Luke's Magic Valley Regional Medical Center. The Director acts as a catalyst and leader between hospital departments, physicians, and staff to ensure continuity and quality of service and care, and seamless integration across the system.

Minimum Qualifications

- Bachelor's degree in business, healthcare, or related field, with a master's degree strongly preferred.
- Five years demonstrated management experience in healthcare operations (clinical operations preferred) including but not limited to areas such as Marketing, Finance, Management, Strategic Planning, Human Resource Management, and Process and Quality Improvement.
- Applicable experience and knowledge with working within a matrix organization.

St. Luke's Magic Valley's new state-of-the-art medical center opened its doors in 2011 to meet the healthcare needs of our rapidly growing region. The new St. Luke's Magic Valley is built for the 21st Century, incorporating features designed to promote maximum patient comfort and quality patient care. Our new medical center is a 186-bed, 700,000 square-foot healthcare facility, featuring all private rooms. It serves an eight-county region in South Central Idaho and Northern Nevada.

To apply, visit our website at: *www.stlukesonline.org/employment*. Job Posting #14798.

MANAGER, RADIATION ONCOLOGY
Wilmington, Delaware

As one of the largest, privately owned, not-for-profit academic affiliated healthcare systems in the United States, Christiana Care Health System is the region's premier healthcare provider. With over 1,100 beds between its two hospitals (Christiana Hospital and Wilmington Hospital) and the only Level I trauma service on the East Coast corridor between Philadelphia and Baltimore, it has been honored repeatedly as "One of America's Best Hospitals" by *U.S. News & World Report*. This independent academic medical center combines the best of both community and academic hospital systems. Christiana Care Health System is always seeking like-minded professionals to join us in our commitment to providing the best patient care in the region.

Assisting the Medical Director, the Manager, Radiation Oncology will manage the daily operations of the Radiation Oncology Department, driving and achieving the department's goals by coordinating fiscal, human resources, administrative, and programmatic activities. The selected candidate will possess a bachelor's degree in healthcare, business administration, or a related field, and at least five years progressive responsible healthcare management experience.

The Radiation Oncology Department has 4 clinical locations, 6 linear accelerators, Cyberknife, HDR, and ACR accreditation.

Besides proximity to Wilmington, Philadelphia, and Baltimore, our location offers residents a low cost of living, tax-free shopping, a four season climate close to shore points, and a thriving, highly connected medical community. As a valued member of our team, you'll enjoy an exceptionally supportive environment, excellent resources, state-of-the-art technology, unsurpassed teamwork, and the opportunity to grow with a progressive organization focused on excellence.

Christiana Care offers outstanding family benefits for full- and part-time employees, competitive salaries, and multiple opportunities for career growth. EOE.

Learn more and apply for this position at: *careers.christianacare.org*.

MANAGER, ONCOLOGY INFUSION CENTER
Atlanta, Georgia

Are you ready to lead an award-winning team at one of Georgia's premier healthcare systems? If so, we have an exciting and challenging opportunity that may be just for you. Northside Hospital Atlanta is searching for a Manager for our outpatient Oncology Infusion Center. This is your chance to become a member of the management team in a nationally recognized Cancer Institute.

The Northside Hospital Cancer Institute is a leader in cancer diagnosis, treatment, and research. Northside diagnoses and treats more prostate, breast, and gynecologic cancers than anyone else in Georgia and ranks #1 in the nation for best survival outcomes for bone marrow transplant. Northside was chosen by the National Cancer Institute to be a part of its Community Cancer Centers Program (NCCCP). Northside's Cancer Institute offers the best of both worlds: clinical excellence on par with an academic-based program and the personalized and attentive care typically associated with a community hospital.

Essential Responsibilities

As Manager, you'll oversee all of the daily clinical and administrative operations of the outpatient Oncology Infusion Center. This includes managing staff, ensuring the quality and safety of patient care, managing departmental budgets and expenses, and developing and administering a quality improvement plan. You'll also monitor compliance with applicable regulatory and accreditation agencies.

Essential Qualifications

Qualifications for this challenging and rewarding opportunity include:

- BSN.
- 5 years of nursing experience with at least 2 years in oncology nursing.
- 2+ years in a supervisory capacity.
- Strong oral and written communication skills.

Apply online at: http://northside.attnhr.com/jobs/111/26308/.

CLINICAL NURSE MANAGER
Colorado Springs, Colorado

The Clinical Manager is accountable for excellence in leadership and management in the delivery of patient care and clinical practice on a selected unit(s) by focusing on the Memorial Health System (MHS) Mission and Vision to create an outstanding health system where patients heal and people thrive.

Essential Responsibilities

- Manages human, fiscal, and other resources as needed; directs and supervises all functions and activities; implements and interprets performance improvement monitors and outcomes, policies, procedures, standards, and regulations for personnel, patients, medical staff, and the public.
- Functions as an expert in their field, not only as a professional resource to the hospital and community, but also in clinical practice within their area.

In this role, the manager identifies and removes potential barriers to business unit success; manages effective processes and leads people; pursues ways to meet customer needs and expectations; selects supervisors and staff: coaches, mentors, counsels, hires, fires; is the retention officer for direct reports and staff; reviews and signs off on evaluations; resolves problems and issues; assures employees have equipment necessary to perform duties; prepares and managers budget; engages and collaborates with physicians; and participates in Professional Development Planning Process.

Demonstrates Trusted Colleague behaviors which include: being a team player; being responsive and respectful to those we serve; having an understanding nature by listening; learning without judgment; and being safe and easy to approach.

Minimum Education

Bachelor of Science in Nursing (BSN). Must be licensed to practice as a Registered Nurse in the state of Colorado or willing to obtain a Colorado license. Current BLS certification.

Minimum Experience

At least 3 years clinical nurse manager experience in an acute care setting.

Strength (Medium Work)

Exerting 20 to 50 lbs of force occasionally, 10 to 25 lbs of force frequently, or greater than negligible up to 10 lbs of force constantly to move objects.

To apply, contact Edina Hanes, Nurse Recruiter by phone: 719.365.8132 or email: edina.hanes@memorialhealthsystem.com.

Highlights from the ACCC 2012 Annual National Meeting

Albert B. Einstein, Jr., MD, (center) was honored with ACCC's David King Community Clinical Scientist Award for his outstanding service, leadership, and commitment to the oncology community. Recently retired, Dr. Einstein was the executive director of the Swedish Cancer Institute in Seattle, Wash., and a medical oncologist. Dr. Einstein is nationally recognized for his work in cancer program development and chemotherapy for genitourinary cancers. A former ACCC President, he has been the principal investigator in numerous research studies and has been widely published on such topics as clinical research in the community setting, oncology economics, and cancer program development. Also shown are then-ACCC President Thomas L. Whittaker, MD, (right) and ACCC Executive Director Christian Downs, JD, MHA.

Knowledge is Power was this year's Annual National Meeting theme. Attendees gathered in Baltimore to learn how to guide their cancer program toward fiscal stability and opportunity. Keynote speaker Mara Liasson, correspondent for National Public Radio and Fox News, provided a behind-the-scenes look at the political landscape in this election year and commented on the future of healthcare reform. *"The fact is that healthcare reform was passed…We have made progress… Maybe something has been set in motion that is really unstoppable,"* she said. Liasson believes the Supreme Court will decide this year about the constitutionality of the Affordable Care Act, but she doesn't know if the Court will decide before the election, or if they will uphold the law, throw it out altogether, or just strike the individual mandate. If the individual mandate is thrown out, the insurers will be hurt, said Liasson, but other parts of the Affordable Care Act will stand.

Healthcare Reform

March 23 marks the second anniversary of the Patient Protection and Affordable Care Act, and yet there's still significant confusion about what the law encompasses, said Deborah E. Trautman, PhD, RN, executive director, Johns Hopkins Medicine Center for Health Policy and Healthcare Transformation. Trautman gave an update on the status of healthcare reform during a Tuesday morning session, and urged attendees to become informed and help influence policy decisions. *"I believe there's opportunity for* [medical professionals] *to do more,"* Trautman said. The not-so-funny joke is that, *"If you're not at the table, you're likely to be on the menu."* Trautman said we are a very divided nation about reform and some of this is due to lack of information. She pointed out that a poll shows 22 percent of Americans think the Affordable Care Act has been repealed, and another 26 percent are not sure of its legal status.

New National Healthcare and Payment Models

The Centers for Medicare & Medicaid Services (CMS) is moving full-speed ahead with funds already appropriated to change the way healthcare is delivered and paid for in the United States. *"CMS is a constructive force and a trustworthy partner for the continual improvement of health and healthcare for all Americans,"* said Richard Gilfillan, MD, acting director of the CMS Innovation Center. The CMS Innovation Center's mission is to identify, test, evaluate, and scale innovative payment and service delivery models to reduce program expenditures under Medicare, Medicaid, and CHIP, while preserving the quality of care furnished. With resources of $10 billion for 2011 through 2019, the Health and Human Services Secretary has the authority to expand successful models to the national level. How does CMS define success? Better health, better healthcare, and lower costs through the way we deliver healthcare, said Gilfillan.

Trends & Hot Topics

Hot topics in cancer care were up for discussion as an array of sessions addressed the changing landscape of cancer treatment and payments. One of the most provocative topics examined in a panel discussion was cancer drugs—both their expense and their lack of availability. It's easy to blame the government and regulations, the panel agreed, but also suggested that we need the FDA to step in, be more proactive, engage the industry, enforce communications, and make it a priority to monitor manufacturers. Drug companies need to be profitable, said panelist Michael Kolodziej, MD. If a vial of methotrexate costs less than a bottle of water, how can we expect the drug company to manufacture it, he asked, and noted that Europeans don't have this problem because generics are not so low priced as in the U.S. OI

careers

ONCOLOGY REIMBURSEMENT SPECIALIST
Harrisburg, Pennsylvania

Key Responsibilities
- Review of all patients requiring chemotherapy and infusions, including confirmation of insurance benefits, reimbursement, and determination of patient responsibility.
- Review open accounts to evaluate claim status and intervene appropriately to assure proper payment.
- Determine availability of oncology-specific assistance programs.

Essential Requirements
- High school graduate with good mathematical skills, accuracy, and attention to detail.
- Two to three years experience in insurance verification, claim adjudication, medical office billing or outpatient billing.

Preferred Qualifications
- Experience in oncology.
- Knowledge of medical terminology.
- Knowledge of ICD-9 and CPT coding.

To explore all opportunities at PinnacleHealth System, go to: *pinnaclehealth.org/careers*.

CLINICAL COORDINATOR, ONCOLOGY
Harrisburg, Pennsylvania

Key Responsibilities
- Responsible for the outpatient oncology population.
- Exhibits specific knowledge relating to needs of cancer patients.
- Serves as a resource to other members of the healthcare team and the oncology program.
- Supports the essential process of improving and sustaining performance.

Essential Requirements
- Current Pennsylvania RN license with a minimum of two years of experience in oncology.
- Documentation of certification of an approved chemotherapy course.
- Ability to demonstrate strong leadership skills and clinical competency.

Preferred Qualifications
- BSN with IV therapy skills.

To explore all opportunities at Pinnacle Health System, go to: *pinnaclehealth.org/careers*.

CLINICAL NURSE MANAGER, ONCOLOGY
Colorado Springs, Colorado

Key Responsibilities
- Implements and interprets performance improvement monitors and outcomes, policies, procedures, standards, and regulations
- Identifies and removes potential barriers to business unit success; resolves problems and issues.
- Pursues ways to meet customer needs and expectations.
- Selects supervisors and staff; coaches, mentors, counsels, hires, and fires; and reviews and signs off on evaluations.
- Prepares and manages budget.
- Engages and collaborates with physicians and participates in professional development planning process.

Minimum Education
Bachelor of Science in Nursing. Must be licensed to practice as an RN the state of Colorado or willing to obtain a Colorado license. Current BLS certification.

Minimum Experience
At least 3 years clinical nurse manager experience.

Edina Hanes, nurse recruiter at 719.365.8132 or email: *edina.hanes@memorialhealthsystem.com*.

VICE PRESIDENT, NATIONAL ONCOLOGY SERVICE
Englewood, Colorado

Key Responsibilities
- Provides physician leadership, including the development of priorities for oncology practices and performance metrics.
- Oversees oncology practice structures and acquisitions, oncology physician recruitment efforts, and physician compensation standards and processes.
- Oversees the development and implementation of oncology quality initiatives, monitors oncology quality outcomes, and identifies best practices.
- Serves as the PI for grants and federal contracts.
- Champions clinical research initiatives.

Essential Requirements
- Medical degree required; Board certified in an oncology or oncology-related specialty; masters in healthcare administration or related field is preferred.
- 10 years of progressively responsible physician leadership experience in clinical oncology and/or a healthcare system.
- Demonstrated ability to lead multi-specialty groups of physicians.

Catholic Health Initiatives at: *www.catholichealthinit.org*.

action

Meet ACCC's New President

In March 2012 George Kovach, MD, became President of the Association of Community Cancer Centers. Dr. Kovach is the medical director of the Genesis Cancer Center, Davenport, Iowa. He was a founding member of the Iowa Oncology Society and served as president (1995-1997 and 1999–2002) and vice president (1997–1999). Dr. Kovach has served as treasurer for ACCC and co-chair of ACCC's sub-committee on reimbursement.

OI. *Tell us about your career in oncology, your present position, and how you first became involved with ACCC?*

Kovach. I began my practice in Flint, Michigan, in 1977 as a solo practitioner working with the Hurley Medical Center cancer program. Hurley Medical Center—an early member of ACCC—was my introduction to the Association. During the first years, I focused primarily on building the practice. Initially a mixed practice, it evolved to focus only on hematology and oncology.

Hospital competition created an opportunity at St. Josephs Hospital (now Genesys). So, in 1980 I moved my practice there and began to develop its cancer program, introducing clinical trials through affiliations with NSABP and SWOG.

In 1985 an opportunity to develop a community cancer program in Davenport, Iowa, became available. While I had accomplished my goals in Flint, competition was impeding progress and program growth. I would use lessons learned from that experience elsewhere in my career. ACCC membership was integral to the development of the Davenport cancer program, helping to make the program what it is today.

OI. *What role do you see ACCC playing in meeting the challenges facing the oncology community today?*

Kovach. ACCC has a unique position in the oncology community in that the Association represents all the clinical disciplines and the administrative branches, thus giving the organization the complete picture of cancer care. ACCC is in the position to influence the understanding of comprehensive cancer care to the public, third-party payers, and policy makers. We can raise awareness that a focus on cost of treatment alone without regard to the quality of that treatment would be disastrous. Quality is a commonly used term in healthcare legislation; however, its definition is often ambiguous and requires clarity. ACCC can provide that clarity.

OI. *What do you see as the most significant challenges facing oncology today?*

Kovach. I believe the critical challenge is oncology's loss of voice in the determination and delivery of appropriate care to third-party private and public payers—driven primarily by cost, the increasing price and availability of drugs, and care rationing.

Through my 30-plus years of practice, a voice at the table has allowed us to continue to deliver the necessary care our patients deserve. Losing effective input serves none—especially not our patients. Participation in organizations like ACCC allows the medical community to influence healthcare delivery and must be encouraged and expanded.

OI. *What would you like to accomplish during your term?*

Kovach. As healthcare reform takes center stage this year, ACCC must continue to define quality cancer care and be a strong national advocate with a seat at the discussion table, and represent the needs and goals of the multidisciplinary cancer care team. My goal is to permanently insert ACCC in policy development to define and validate value (quality and cost) in cancer care, and to ensure patients receive the right treatment at the right time. This will require:

- **A**dvocacy & Activism
- **C**ollection & Collation of clinical pathways and guidelines, as well as best practices
- **C**ollaboration & Coordination with the oncology community
- **C**ommunication with policy makers and the public.

ACCC's education programs contain the elements needed for defining quality and the minimum standard of care, and should be used in developing healthcare coverage. My primary goals as ACCC President 2012-2013 are to:

- Define "Quality" and "Value" with real-world clinical examples.
- Identify the key stakeholders defining quality and value in order to bring ACCC's positions to them.
- Identify and engage policy makers whose interests are consistent with our objectives and work with them in developing a coherent and effective healthcare reform platform.
- Coordinate ACCC recommendations with NCCN, ASCO, ONS, ACCC membership, and other stakeholders.
- Canvas ACCC membership for their input in improving value by cutting waste and duplication. OI

ADVERTISER'S INDEX

action

SAVE THE DATES!

Free to ACCC Members! ACCC Regional Oncology Economic & Management Meetings

Mid-Atlantic Regional | June 19, 2012
Bethesda North Marriott Hotel & Conference Center | Rockville, Maryland

Western Regional | June 27, 2012
(co-hosted by the Association of Northern California Oncologists)
Doubletree by Hilton Berkeley Marino
Berkeley, California

Learn more and register at: *www.accc-cancer.org/meetings/meetings-regionalMeetings.asp*

ACCC Blackboard

Community Clinical Perspectives

A Joint ACCC and Medscape Project, this online education initiative offers a community provider perspective about emerging data and treatment strategies presented at scientific meetings, such as those of ASCO and ASH.

Peer-Based Strategies in Preventing Chemotherapy-Induced Nausea and Vomiting CME/CE

The goal of this activity is to provide education on the prevention and management of chemotherapy-induced nausea and vomiting in patients with cancer. Upon completion of this activity, participants will be able to:

1. Assess patients' level of risk for chemotherapy-induced nausea and vomiting on the basis of the emetogenicity of the chemotherapy regimen and other risk factors
2. Compare and contrast the roles of the 5-hydroxytryptamine type 3 (5-HT3) antagonists, neurokinin 1 (NK-1) antagonists, and dexamethasone in the prevention of nausea and vomiting
3. Review the indications for the inclusion of an NK-1 antagonist in an antiemesis regimen according to evidence-based guidelines.

Faculty: Mark G. Kris, MD, and Stephen A. Mayer, MD, PhD.
This activity is intended for oncologists, oncology nurses, and pharmacists.

- Physicians—maximum of 0.50 *AMA PRA Category 1 Credit(s)*™
- Nurses—0.50 *ANCC Contact Hour(s)* (0.5 contact hours are in the area of pharmacology)
- Pharmacists—0.50 *Knowledge-based ACPE* (0.050 CEUs).

Supported by an independent educational grant from Eisai.

Learn more and register at: *www.accc-cancer.org/education/education-CCP.asp*.

SAVE THIS DATE, TOO!

ACCC 29th National Oncology Conference
October 3–6, 2012
Grand Hyatt San Antonio
San Antonio, Texas

Learn more and register at: *www.accc-cancer.org/meetings/NOC2012.asp*

New Resources!

NCCCP Monograph

In 2011 *Oncology Issues* highlighted the experiences of the National Cancer Institute (NCI) Community Cancer Centers Program (NCCCP) sites in the meeting the program's goals during the initial three-year pilot phase. Now the article series is compiled in one online monograph, available on ACCC's website at: *www.accc-cancer.org/NCCCP*. Learn how NCCCP sites have improved multidisciplinary cancer care, expanded research, integrated information technology, and more.

ACCC's 2012 Patient Assistance and Reimbursement Guide

This publication is now available only to ACCC Members. To access the online edition, ACCC members will need to log in to the Members-only section of ACCC's website. Click on Member Resources and find the *2012 Patient Assistance and Reimbursement Guide*. This year, we are also making a PDF of the publication available to ACCC Cancer Program Members. Save it. Click on hot links directly to patient assistance programs. Use it every day. To get your PDF today, email Tonieh Hansford at: *thansford@accc-cancer.org*.

Give Us Your Feedback

Like the journal redesign? Finding the information and tools you need? Let us know by taking our annual readers' survey at: https://*www.surveymonkey.com/s/LJKPS5H*

A New "Normal" in the Wake of Disaster

BY DELLA CASTILLO

The evening of Sunday, May 22, 2011, began quietly, but ended in a disaster that forever changed my home, Joplin, Missouri. An EF-5 tornado touched down at 5:41 pm and spent 32 minutes grinding its way from one side of town to the other. It devastated more than 30 percent of the city, including a large portion of the medical community and one of the two hospitals. A total of 161 people died as a result of the storm, which has been designated as the seventh deadliest single tornado in U.S. history.

My employer, Freeman Health System, immediately initiated a disaster plan we had practiced, but hoped to never use. Hundreds of patients streamed into Freeman Hospital West that night. They arrived in ambulances, helicopters, cars, and pickup trucks. Some even traveled on foot. In the hours immediately following the tornado, we treated more than 500 patients at Freeman Hospital West and 39 at Freeman Neosho Hospital, our critical access facility 20 miles south of Joplin. Sadly, some of our own Freeman staff members were among those patients seeking medical care.

The storm's impact on cancer patients within our community became evident the first week after the storm. Freeman Cancer Institute started receiving calls and walk-ins from other cancer treatment offices in the community. After the initial shock of the disaster, reality set in for these patients and concern for their future treatments became the priority. Freeman Cancer Institute, with a staff of five board-certified medical oncologists and hematologists, reached out to the other five medical oncologists in Joplin for information that could help their patients.

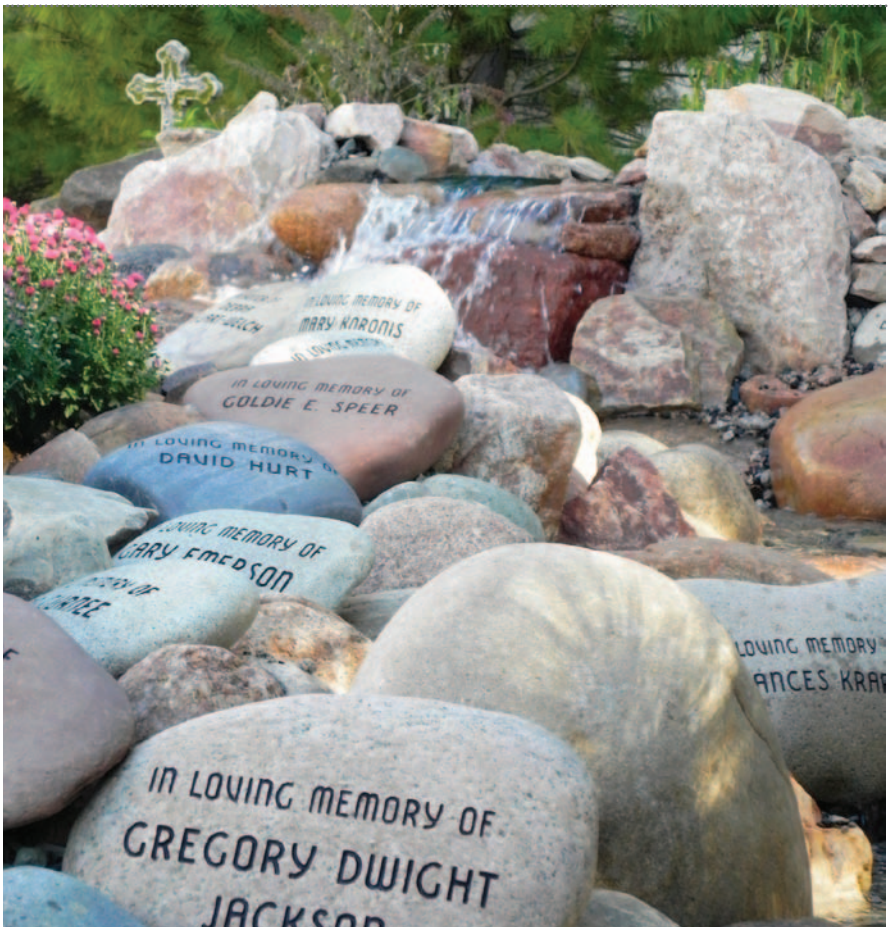
Soon thereafter, Freeman Cancer Institute agreed to take the patients of two medical oncologists whose office was destroyed by the tornado. When we learned this practice would not reopen, we immediately offered our services. Our leadership team met to determine how Freeman Cancer Institute would absorb another practice and get patients back into treatment quickly.

Questions we immediately identified included:

- How do we act quickly enough to take care of these patients?
- How many patients will we receive?
- Will we get records or have all records been destroyed?
- How will we notify patients?
- How will we determine priority for patient scheduling?
- How many additional patient appointments can our doctors' schedules accommodate?
- Do we need to expand our clinic hours?
- Do we have enough staff?
- Do we have enough infusion chairs?

Our team immediately started putting together a plan of action, establishing a very good line of communication with

Freeman Cancer Institute, Joplin, Missouri. ACCC Member Program since 2002.



The Reflection Garden at Freeman Cancer Institute.

the closing practice. An initial assessment revealed Freeman Cancer Institute would take on approximately 150 patient transfers from this practice. We implemented the following plan:

- The closing practice would contact patients regarding its decision to close.
- They would get permission to send records to our clinic. In some cases this step would not be easy because several patients had lost homes in the tornado.
- They would copy the paper medical records they were able to salvage. (They did not have electronic medical records.)
- They would prioritize and start with records of patients in active chemotherapy treatment.
- They would bring records to our clinic daily.
- We would triage patients according to their medical records to prioritize how soon to schedule appointments. (All cancer patients are important, but we had to prioritize for scheduling purposes.)
- Our physicians increased appointment availability on their daily schedules.
- We divided patient appointments among our five doctors and also allowed for new patient referrals.
- We called priority patients with their appointment date and time.
- We mailed a welcome letter to all non-priority patients with their appointment date and time.
- We hired an additional chemo nurse and a receptionist.
- We added two chairs to our infusion suite.

With this plan, we started our new normal and continued to provide quality patient care. Within the first six weeks after the tornado, we cared for 80 patients from the closed practice. All remaining patient appointments were scheduled before December 2011, adding more than 170 patients to our program.

This effort truly took a team to carry out, and every staff member at Freeman Cancer Institute played an important role in this plan. I'm very proud and thankful to have the best staff that gives compassionate, quality care to the patients of our community.

The one year anniversary of the tornado disaster is quickly approaching. A "Day of Unity" is planned by the city of Joplin, honoring survivors and in memory of the 161 people who lost their lives due to the tornado.

Just as spring is a time of renewal and rebirth, we are in full rebuilding mode. Residents and businesses alike are resilient and with the help of countless volunteers, Joplin is coming back stronger than ever. Freeman Cancer Institute continues to grow, and we are adding two new physicians to our staff in July. OI

—Della Castillo, director of Freeman Cancer Institute, has worked in healthcare since high school, working her way up from secretary to management. She has been with Freeman Cancer Institute for more than nine years, her true calling after losing her daughter to cancer. In May 2011, she spent her birthday riding out the Joplin tornado in her bathroom—her house was completely destroyed by the storm.

MORE ONLINE!

ACCC Member Program St. John's Regional Medical Center (now Mercy Hospital Joplin) was destroyed by the EF-5 tornado. One year out, read about their rebuilding efforts at: *www.accc-cancer.org/MJ2012*.

PHOTOGRAPHS COURTESY OF FREEMAN CANCER INSTITUTE AND MERCY HOSPITAL JOPLIN

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Greg, myeloma survivor

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