ONCOLOGY ISSUES

The Journal of the Association of Community Cancer Centers
January | February 2013

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January | February 2013
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ONCOLOGY ISSUES
The Journal of the
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Oncology Issues serves the multidisciplinary specialty of oncology care and cancer program management.

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FROM THE EDITOR

Born to Learn?

BY CHRISTIAN DOWNS, JD, MHA

A predominant trait among healthcare providers is a love of learning. A brief look at the formal educational requirements for physicians, nurses, pharmacists, and licensed social workers attests to this fact. And even those of us in the healthcare field who do not have clinical backgrounds usually have an advanced degree or two.

Yes, the formal education process is a requirement to enter the healthcare field. But this alone does not explain the desire to continually learn. Surely this is something in the providers' DNA.

This trait is particularly true for providers of cancer care. In these pages, I have often written about how the unique demands of oncology make caring for patients with cancer more of a calling than a vocation. Many of my columns have touched on the compassion and exceptional level of commitment cancer care providers have for the patients and families they serve.

The field of oncology is also unique in that it requires constant and consistent learning by its providers. What are the latest clinical studies? How will these affect patients? What information is available on supportive and integrative care for patients? How can we improve the care delivery system?

Cancer care providers are involved in the learning process both as students and as teachers. Many providers teach on a daily basis, helping members of the cancer care team stay current on the latest advances in care.

Some highlights of this edition of *Oncology Issues* focus on learning from both the student and the teacher perspectives. Sheila Stephens and Maria Tria Tirona write about an innovative collaboration to increase the number of medical oncology fellows. Their article describes how hospitals and their cancer programs can partner with schools of medicine to develop and fund oncology fellowship programs. Read how one community cancer center did just that. In its first year, this innovative program received 84 applications for its two fellowship positions.

Community outreach is another way that oncology providers often serve as teachers. Margaret Parniawski shares the story of Bridgeport Hospital's One-Day Cancer College. This free educational event helps to inform the community about cancer treatments, survivorship, and the services offered by the hospital's Norma F. Pfriem Cancer Institute and its five Centers of Excellence.

As the leading education and advocacy organization for the cancer team, ACCC's commitment to learning is evidenced by its national and regional meetings and the variety of programs offered through its Center for Provider Education. This March, ACCC invites you to participate in both learning and teaching. Join us for Capitol Hill Day on March 6. The program includes a morning orientation—learning how to advocate with your elected officials on Capitol Hill. In the afternoon, you will be "teaching" your legislative representatives about the critical issues affecting delivery of quality cancer care. Then, plan to stay for ACCC's 39th Annual National Meeting, March 6-8, with sessions on Medicaid expansion, payment reform, ACOs, regulatory changes under the ACA, and more. This year's new Leadership Track is designed to help foster new leaders within your program. Learn more and register at *www.accc-cancer.org/annualmeeting*.

How can you resist? It's in your DNA. OI

PRESIDENT'S MESSAGE

The Right Treatment at the Right Time

BY GEORGE KOVACH, MD

As implementation of the Affordable Care Act (ACA) rolls out, much still remains to be learned. The healthcare community faces an avalanche of regulations that aim to control healthcare costs while simultaneously increasing access to healthcare. Since "the devil is in the details," it remains to be seen whether these efforts will succeed. Still, now is the time for the oncology community to speak up.

As community providers, we experience the challenges of providing quality cancer care on a daily basis. For my term as ACCC President I've chosen to focus on the advocacy message of "the right treatment at the right time." Central to this theme is my belief that ACCC members are best positioned to educate decision-makers on how coverage and reimbursement issues affect community oncology. In order to advocate successfully for continued access to quality cancer care, we must prioritize the key issues and engage with government leadership, our elected representatives, and policymakers at both the federal and local level. And we must be prepared to continue our advocacy efforts until we achieve our goal.

With a long history of advocacy on behalf of access to care, ACCC is the ideal partner for this effort. A recent example of ACCC's advocacy success is reflected in CMS's 2013 Hospital Outpatient Department final rule, in which reimbursement in the hospital outpatient setting was increased from ASP+4 percent to ASP+6 percent. Over recent years, ACCC consistently voiced the need for appropriate reimbursement, provided specific information on the flawed ASP calculation methodology, and ultimately succeeded in preventing the anticipated reimbursement rate reduction. This consistent, informed, positive advocacy approach can help ACCC members affect the future of ACA regulations and healthcare legislation.

ACCC's new Grassroots Advocacy Campaign provides tools and resources to help our members find their voice. This effort will focus on three core areas that we believe must be addressed in the coming months:

Preserve Patient Access to Care
- Oral Parity
- Medical Malpractice Reform
- Access to New Drugs
- Establish Comprehensive Health Benefits

Advance Medicare
- Eliminate the Independent Payment Advisory Board (IPAB)
- Establish Appropriate Payment Models
- Appropriate Care for Dually Eligible Patients

Create Appropriate Reimbursement
- Eliminate the Sequester
- Permanently Fix the SGR
- Eliminate the Prompt Pay Discount in the ASP Calculation
- Establish Codes for Chemotherapy Planning and Teaching
- Establish Codes for Palliative Care
- Remove Radiation Oncology Reimbursement Cuts.

For more on these issues, visit *www.accc-cancer.org/advocacy/QualityCare.asp*. Click on "Grassroots Advocacy Campaign" and get involved. I encourage you to join our campaign, visit the website, and provide feedback. Your comments can help provide the details needed to explain the impact of new legislation and regulations on the delivery of quality cancer care. Then, plan to join us on March 6 in Washington, D.C., for ACCC's Capitol Hill Day.

Together we can have a voice in ensuring the "right treatment at the right time" for our patients. OI

Coming in Your 2013 *ONCOLOGY ISSUES*

- Utilizing a Dedicated Quality Improvement Program
- Improving QOL for Patients with Brain Cancer
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- Developing a Centralized Process to Review & Track Clinical Studies
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What to Look for When Hiring a Financial Counselor

VIDEO

This video discusses the roles and responsibilities of a financial specialist, how to develop and establish an efficient financial assistance process, and key characteristics to look for to ensure the "right" person is hired for this key position. Watch today at: *www.accc-cancer.org/FILN*.

ACCC's 2013 Capitol Hill Day

BLOGS

Play a major role in lawmakers' decisions regarding cancer care in 2013 and beyond. Visit your Congressional representatives and share your experiences and perspective as a community oncology provider. Register for the March 6 event and read about ACCC's hugely successful 2011 Capitol Hill Day at: *www.accc-cancer.org/meetings/AM2013.asp*.

2013 ACCC Innovator Awards

AWARD

Now in their third year, these awards are sponsored by GE Healthcare and recognize and honor pioneering strategies for the effective delivery of cancer care in the community setting. Innovations should advance the goals of improving access, quality, and/or cost effectiveness of cancer care. Learn more and apply today at: *www.accc-cancer.org/innovator*.

Prostate Cancer Toolkit

TOOL

This toolkit includes patient education materials and decision-making resources, such as the EPIC-16 CP tool, to measure specific outcomes and patient satisfaction. ACCC members can access the toolkit at: *www.accc-cancer.org/education/prostateCancer-Outcomes.asp*.

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fast

Home Alone? Family Caregivers Providing Complex Chronic Care

- There are more than 42 million unpaid family caregivers in the U.S.
- 46% perform medical and nursing tasks for loved ones with multiple chronic physical and cognitive conditions
- 78% of caregivers who provide medical and nursing tasks manage medications, including administering intravenous fluids and injections
- Most family caregivers believe they are helping their family member avoid institutionalization.

Source: AARP Public Policy Institute and the United Hospital Fund. Home Alone: Family Caregivers Providing Complex Chronic Care. Available online at: *www.aarp.org*.

SURVEY ON DRUG SHORTAGES

- 99% of respondents experienced a drug shortage last year
- In more than 60% of patients, the cancer progressed more quickly as a result of the drug shortages
- More than 70% of patients had more severe side effects as a result of the drug shortages
- About 58% of respondents indicated that the shortage in cancer care drugs is increasing.

Source: The Community Oncology Alliance (COA). A Survey of 200 COA Member Practices representing 525 physicians across the U.S. *www.communityoncology.org*.

facts

What Happens When Patients Access Medical Records Online?

Patients who use patient portals or access their medical records online and have secure email communications with their clinicians showed increased rates of office visits, as well as telephone encounters, compared with patients who did not have online access to their records, according to a study released Nov. 20 by *JAMA*. Results contrast with the assumption many health professionals hold that online access to medical services would reduce the use of in-person visits or telephone services, the study said.

Source: Palen TE, et al. Association of online patient access to clinicians and medical records with use of clinical services. *JAMA*. 2012;308(19):2012-2019.

5 Considerations When Acquiring a Physician Practice

1. *The seller's motivation*. Does the practice have the resources to cover expenditures, or does the group need a capital infusion? Are any principal physicians nearing retirement?
2. *Nonfinancial factors*. Might physicians or key staff leave if the deal were to go through, potentially taking patients with them? Is there any history of fraud in the practice?
3. *Primary-care or specialty practice?* Primary-care practices can provide hospitals with additional sources of patients; medical specialty practices tend to have higher reimbursement rates.
4. *Post-merger integration*. The team needs to work on behalf of both the hospital and the practice and be able to negotiate issues effectively and fairly.
5. *Cash-flow considerations*. Prepare for possible cash-flow delays, depending on whether the acquisition is structured as a stock or asset purchase.

Source: Crowe Horwath LLP. *www.crowehorwath.com*.

Federal Health Spending for Poor Has Grown by 37% Since 2008

- **Federal healthcare spending for the low-income population increased by 37% between 2008 and 2011**
- **Healthcare spending totaled $339.4 billion in 2011, compared with $247.7 billion in 2008**
- **Federal dollars spent on healthcare exceeded the amount spent in any other single category, including food assistance, education, housing, energy, and cash assistance**
- **Overall federal spending on federal poverty programs grew by 33%.**

Source: Congressional Research Service. Spending for Federal Benefits and Services for People with Low Income, FY2008–FY2011. Dated Oct. 16, 2012. As reported in the Oct. 19, 2012, *BNA Health Care Daily Report*.

Why *Your* Voice Matters

BY MATTHEW FARBER, MA

ACCC President George Kovach, MD, has chosen "the right treatment at the right time" as the theme message of his term. Central to Dr. Kovach's theme is the idea that ACCC members—community cancer care providers—are the best positioned to determine what that "right treatment" should be for each cancer patient. However, the concept is not that simple. A multitude of coverage and reimbursement factors come into play, and decisions that are made far from the exam room impact the decisions that can be made in it.

As community cancer care providers who experience first-hand the challenges of providing quality cancer care, ACCC members are in the best position to educate legislators and policy-makers at both the federal and local level. To help ensure community oncology providers' ability to choose "the right treatment at the right time," ACCC is launching a new Grassroots Advocacy Campaign.

There is a host of critical issues in oncology right now—from drug shortages, to adequate reimbursement, to access to clinical trials, to name just a few. ACCC's interdisciplinary membership provides perspectives from across the oncology care spectrum on these issues—and is central to advocating for "the right treatment at the right time." What matters to a physician in the office setting may not matter to the pharmacist in a small hospital or to the nurse in a large health system—so finding common ground is an important step in effectively advocating for our concerns. As part of its Grassroots Advocacy Campaign, ACCC has identified and grouped the major concerns that could impact oncology care in 2013, into three main areas:

1. Preserving Patient Access to Care
2. Advancing Medicare
3. Creating Appropriate Reimbursement.

Under each of these categories, ACCC further details specific pressing concerns such as drug shortages, oral parity, sequestration, the need for chemotherapy teaching codes, and others, that may directly affect many different segments of ACCC membership. Visit *www.accc-cancer.org/advocacy/QualityCare.asp* to read more on these issues and find those of most concern to your cancer program.

Get Involved!

The goal of ACCC's Grassroots Advocacy Campaign is to have ACCC members engage with their Congressional representatives, present the three core issues mentioned above, and then drill down to the specific concerns that matter most to them. We believe ACCC members can help Congress become better educated on how these issues affect cancer patients and their care providers on a day-to-day basis. Most legislators do not understand what the cuts from sequestration would mean for oncology physician practices. Likewise, they do not understand the benefit that having accurate chemotherapy teaching codes would bring to providers and patients. Even more important, they may not realize that these codes, in addition to codes for palliative care, might actually decrease costs in the long term. And without your voice, your elected officials may never know these important facts.

Therefore, ACCC needs you. Getting involved in a grassroots initiative can take as little as five minutes—and to help you get started, we've created new resources at *www.accc-cancer.org/advocacy*. ACCC's new Legislative Action Center features information on these issues and templates to help you discuss them. If you want to write a letter on any of the identified concerns, find the appropriate form letter and fill in your name, some basic information about your practice or hospital, and your ZIP Code. ACCC will send the letter for you. If you prefer to call to express your concerns, use our advocacy scripts to guide you during the call.

Of course, advocating in person may be the most powerful way to get involved, so join us for ACCC's Capitol Hill Day on March 6. ACCC will schedule meetings with your elected officials in Washington, D.C. We will provide an introductory session on advocacy basics in the morning, and in the afternoon, we will visit Capitol Hill. For more information on Capitol Hill Day and ACCC's Grassroots Advocacy Campaign, contact me at *mfarber@accc-cancer.org* or fill out the form on our website at *www.accc-cancer.org/advocacy/Feedback.asp*. OI

—Matthew Farber, MA, is ACCC's director of provider economics & public policy.

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SPOTLIGHT ON OMC GROUP'S EXPERTS - E. STRODE WEAVER, FACHE, MBA, MHSA

Strode Weaver is a Senior Advisor with the Oncology Management Consulting Group. His experience spans over 30 years in a wide variety of settings including large tertiary hospitals and NCI-Designated Centers, multi-hospital systems, leading academic research centers, and small rural hospitals. His positions have included serving as the Executive Director of academic and teaching hospital cancer centers, and as Administrator for Professional Services for a community hospital. Among Mr. Weaver's greatest strengths is his demonstrated skill in communications and negotiations. His interests span multiple and diverse areas such as program development, physician practice management, human resources, payer contract negotiations, facilities construction coordination and planning, and he enjoys a strong history of developing and managing a broad span of cost-effective, high quality operations.

Mr. Weaver received his undergraduate degree from Stanford University, earned a Master of Business Administration from UCLA, and a Master of Health Services Administration from Arizona State University. He is a Fellow of the American College of Healthcare Executives, and he has served in numerous leadership roles in professional societies, including as the President of the Association of Community Cancer Centers.

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Essential Requirements

The ideal candidate will have a current Texas RN license, BSN (prefer MSN), and 5+ years clinical nursing experience; BMT experience strongly preferred. Must also have at least 2 years management experience. Requires BLS and ACLS; OCN certification preferred.

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- Providing treatment summaries and outlining future plans of care and pathology report
- Conducting assessment, education, and review of screening guidelines
- Conducting education and management and/or referrals for long-term effects of cancer treatments
- Marketing to and educating other healthcare providers on the need for survivorship clinics and care.

Previous experience in oncology and Advanced Oncology Certified Nurse Practitioner (AOCNP) designation preferred.

Greenville is a beautiful place to live and work. Located on the I-85 corridor between Atlanta and Charlotte, the city is one of the fastest growing areas in the country.

GHS is an equal opportunity employer that proudly values diversity. Candidates of all backgrounds are encouraged to apply.

Please apply online at *www.ghscareers.org*, job #2012-0788. For more information, please contact Kendra Hall, *kbhall@ghs.org*.

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- 5–10 years experience in cancer program administration at a senior level (hospital-based or practice-based; hospital-based preferred)
- Clinical background in one modality preferred (not required)
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ONCOLOGY CLINICAL NURSE SUPERVISOR
Bozeman, Montana

Candidates should have knowledge of cancer diseases and treatments in the outpatient setting; all aspects of State and Federal regulation related to cancer care; personal computers, hardware, and basic software programs including email, word processing, and Varis; and MediTech systems, and HIPAA and confidentiality requirements.

Skills

- Demonstrated competence in the skills and knowledge pertinent to the practice of nursing
- Intravenous therapy
- Managerial and organizational skills
- Staff supervision; evaluation and development promoting conflict resolution among clinical and clerical staff.

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- Prior supervisory experience of RN clinical staff teams.

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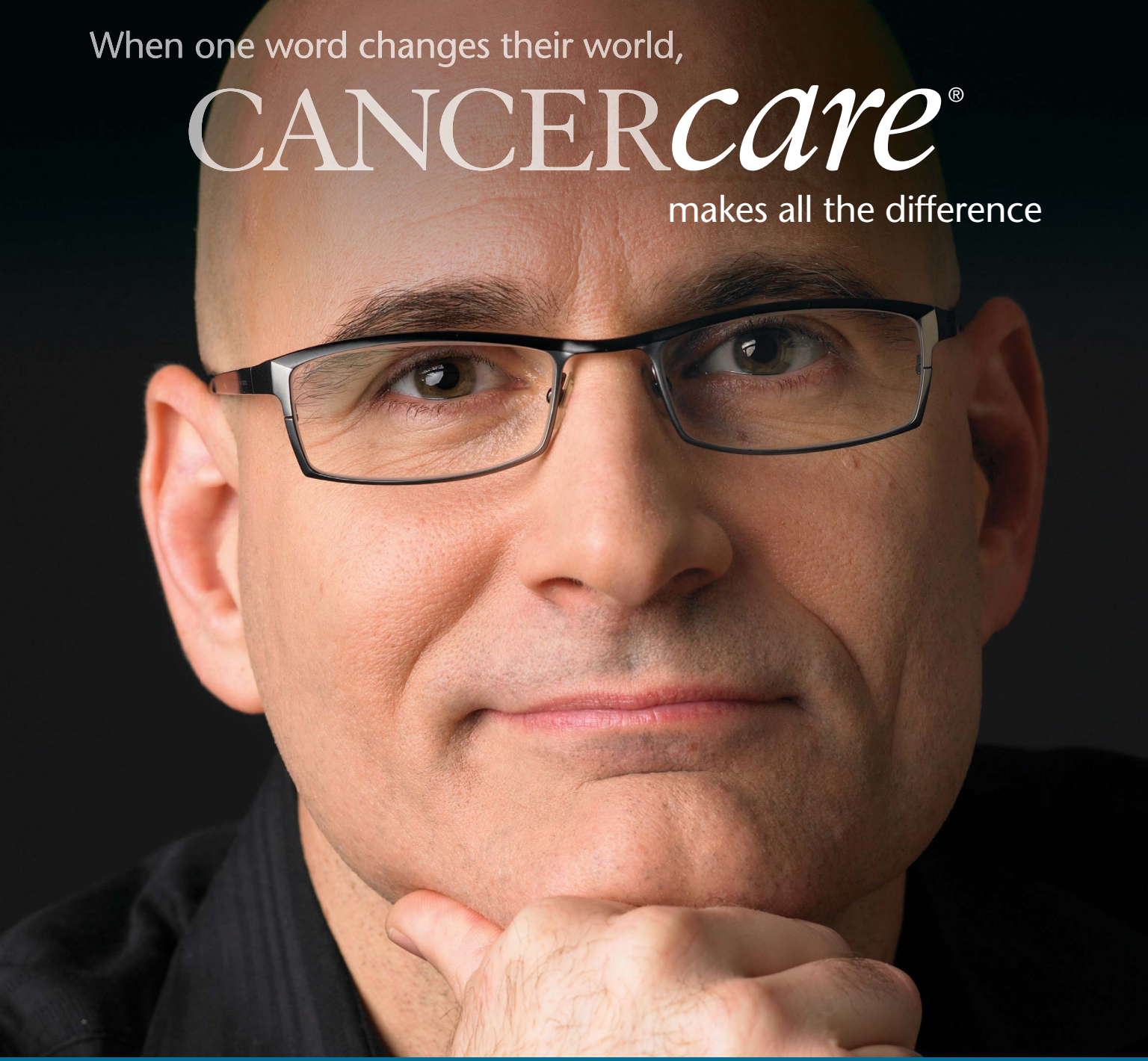

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2013 Oncology Code Update

BY CINDY C. PARMAN, CPC, CPC-H, RCC

Another year come and gone and still more code changes, new regulations, and nearly 3,000 pages of rules and guidelines to digest and incorporate into our hospitals, physician practices, and programs. In brief, here's what every community cancer center needs to know.

NEW AND REVISED CODES

Each year new codes are added, deleted, and revised. There are also updates to coding guidelines. All of these changes mean that community cancer centers must revise charge tickets, fee schedules, and other medical coding and financial documents to ensure that procedures are accurately charged. The following are key changes to CPT® procedure codes affecting oncology providers for calendar year (CY) 2013. Remember that new codes are effective Jan. 1, 2013, and cannot be reported during the final months of CY 2012.

One significant change is the widespread revision throughout the *CPT® Manual* to eliminate the word "physician" or to add the term "other qualified healthcare professional" to existing code descriptions. All of the office and outpatient visit codes and hospital inpatient and observation care codes were revised with the exception of discharge day management (codes **99238-99239**). This verbiage change ensures that non-physician practitioners can charge for services rendered in their own name and NPI number.

The 2013 *CPT Manual* also includes a clarification regarding the determination of new versus established patients for coding purposes:

When advanced practice nurses and physician assistants are working with physicians, they are considered as working in the exact same specialty and exact same subspecialties as the physician.

This means that if a mid-level provider working for an oncology practice evaluates a patient in the hospital and the patient is subsequently seen after discharge by an oncology physician of the same practice in the office, the office visit will be considered an established patient encounter.

There is a new code for target delineation for stereotactic body radiotherapy (SBRT), but this code will not be billed by the radiation oncologist. The code may be reported once per course of treatment by the pulmonary specialist who actively participates in computer planning and treatment management for thoracic SBRT:

- **32701:** Thoracic target(s) delineation for stereotactic body radiation therapy (SRS/SBRT), (photon or particle beam), entire course of treatment.

According to the 2013 *CPT® Manual:*

Target delineation involves specific determination of tumor borders to identify tumor volume and relationship with adjacent structures (e.g., chest wall, intraparenchymal vasculature, and atelectatic lung) and previously placed fiducial markers, when present. Target delineation also includes availability to identify and validate the thoracic target prior to treatment delivery when a fiducial-less tracking system is utilized.

One code revision affects radiation therapy. The code for removal of tongs or halo (**20665,** Removal of tongs or halo applied by another physician) has been revised for 2013 to reflect removal by another "individual" rather than another physician.

In the same manner as previously described, the physician venipuncture codes **36400-36410** have been revised to state they require the skill of "a physician or other qualified healthcare professional."

In addition, stem cell codes **38240, 38241,** and **38242** have been revised, and new code **38243** has been added. There has also been a change in terminology from bone marrow transplant to "hematopoietic progenitor cell (HPC) transplant." Hematopoietic cell transplantation (HCT) refers to the infusion of HPCs obtained from bone marrow, peripheral blood apheresis, and/or umbilical cord blood. These codes now report:

- **38240:** Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
- **38241:** Autologous transplantation
- **38242:** Allogeneic lymphocyte infusions
- **38243:** Hematopoietic progenitor cell (HPC); HPC boost.

Table 1. New Hematology & Oncology Codes for 2013

CODE	DEFINITION
C9294	Injection, taliglucerase alfa, 10 units
C9295	Injection, carfilzomib, 1 mg
C9296	Injection, ziv-aflibercept, 1 mg
J1744	Injection, icatibant, 1 mg
J7315	Mitomycin, ophthalmic, 0.2 mg

Table 2. Hematology & Oncology Drug Codes with Revised Verbiage for 2013

CODE	DEFINITION
J9280	Injection, mitomycin, 5 mg
J1561	Injection, immune globulin, (Gamunex-C/Gammaked), non-lyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard liquid), non-lyophilized (e.g., liquid), 500 mg

Table 3. Deleted Codes Replaced with New HCPCS Codes

2012 CODE (DELETED)		2013 CODE (NEW)	
Q2046	Injection, aflibercept, 1 mg	**J0178**	Injection, aflibercept, 1 mg
Q2047	Injection, peginesatide, 0.1 mg (for ESRD on dialysis)	**J0890**	Injection, peginesatide, 0.1 mg (for ESRD on dialysis)
C9279	Injection, ibuprofen, 100 mg	**J1741**	Injection, ibuprofen, 100 mg
J8561	Everolimus, oral, 0.25 mg	**J7527**	Everolimus, oral, 0.25 mg
Q2045	Injection, human fibrinogen concentrate, 1 mg	**J7178**	Injection, human fibrinogen concentrate, 1 mg
J1680	Injection, human fibrinogen concentrate, 100 mg		
C9289	Injection, asparaginase erwinia chrysanthemi, 1000 IU	**J9019**	Injection, asparaginase (erwinaze), 1000 IU
J9020	Injection, asparaginase, 10,000 units	**J9020**	Injection, asparaginase, not otherwise specified, 10,000 units
C9287	Injection, brentuximab vedotin, 1 mg	**J9042**	Injection, brentuximab vedotin, 1 mg

These procedures include:

- Physician monitoring of multiple physiologic parameters
- Physician verification of cell processing
- Evaluation of the patient during as well as immediately before and after the HPC or lymphocyte infusion
- Physician presence during the infusion with associated direct physician supervision of clinical staff
- Management of uncomplicated adverse events (e.g., nausea, urticaria).

While management of these uncomplicated effects is not separately charged, post-transplant infusion management of significant adverse reactions is reported separately using the evaluation and management, prolonged services, or critical care codes.

Last, incidental hydration and the infusion of medications concurrently with the transplant infusion are not separately reported. The new coding instructions add:

However, hydration or administration of medications (e.g., antibiotics, narcotics) unrelated to the transplant are separately reportable using modifier 59.

There is also a new HCPCS Level II code that will only be reported in Ambulatory Surgical Centers (ASCs):

- **G0458:** Low dose rate (LDR) prostate brachytherapy, composite rate.

Effective Jan. 1, 2013, ASCs will report this single HCPCS code for LDR prostate brachytherapy performed in an ambulatory surgical center, instead of codes **77778** (Complex interstitial source application) and **55875** (Transperineal placement of needles into prostate) for the components of the procedure. This new code provides for a single reimbursement for the facility service; the physician(s) performing the procedure will continue to report the respective procedure code(s) for the portion of the service performed.

According to CMS in the 2013 final rule:[1]

We are finalizing our proposal, without modification, to establish the CY 2013 ASC payment rate for LDR prostate brachytherapy services based on the OPPS relative payment weight applicable to APC 8001 when CPT codes 55875 and 77778 are performed on the same date of service in an ASC. ASCs will use the corresponding HCPCS Level II G-code (G0458) for proper reporting when the procedures described by CPT codes 55875 and 77778 are performed on the same date of service, and therefore receive the appropriate LDR prostate brachytherapy composite payment. When not performed on the same day as the service described by CPT code 55875, the service described by CPT code 77778 will continue to be assigned to APC 0651. When not performed on the same day as the service described by CPT code 77778, the service described by CPT code 55875 will continue to be assigned to APC 0163.

Table 1 (page 11) lists the new codes established for hematology and oncology drugs. Drug codes with revised verbiage for CY 2013 are in Table 2 (above). Table 3 (above) shows codes that were deleted and replaced with new HCPCS codes.

During CY 2012, two new Q codes (**Q2048** and **Q2049**) were created for liposomal doxorubicin, which is used to treat ovarian and other cancers. The new codes were created to distinguish between Doxil® **(Q2048),** which was in short supply, and Lipodox® **(Q2049),** an imported drug that the FDA allowed on a temporary basis during the Doxil shortage. The Doxil code **(Q2048)** will be deleted along with code **J9001,** which was used for Doxil prior to creation of the Q codes. Doxil will now be reported with new HCPCS code **J9002.** Note that the Lipodox code **(Q2049)** has not been deleted. Also, code **J9000,** which represents non-liposomal doxorubicin, has not been revised or deleted.

While it is important to know these changes so that community cancer centers can code correctly for services provided, the existence of a procedure or supply code *does not* guarantee reimbursement. Instead, payment for a service depends on the patient's insurance policy, medical necessity, and other determining factors.

continued on page 16

For appropriate patients receiving highly emetogenic chemotherapy who are at risk of chemotherapy-induced nausea and vomiting (CINV)

PREVENTION BEGINS WHERE TRIPLE THERAPY STARTS

On Cycle 1, Day 1, start with Triple Therapy—EMEND® (fosaprepitant dimeglumine) for Injection, a 5-HT_3 antagonist, and a corticosteroid—for first-line prevention of CINV.

EMEND for Injection, in combination with other antiemetic agents, is indicated in adults for prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy, including high-dose cisplatin.

EMEND for Injection has not been studied for treatment of established nausea and vomiting. Chronic continuous administration of EMEND for Injection is not recommended.

Selected Important Safety Information

- EMEND for Injection is contraindicated in patients who are hypersensitive to EMEND for Injection, aprepitant, polysorbate 80, or any other components of the product. Known hypersensitivity reactions include flushing, erythema, dyspnea, and anaphylactic reactions.
- Aprepitant, when administered orally, is a moderate cytochrome P450 isoenzyme 3A4 (CYP3A4) inhibitor. Because fosaprepitant is rapidly converted to aprepitant, neither drug should be used concurrently with pimozide or cisapride. Inhibition of CYP3A4 by aprepitant could result in elevated plasma concentrations of these drugs, potentially causing serious or life-threatening reactions.
- EMEND for Injection should be used with caution in patients receiving concomitant medications, including chemotherapy agents, that are primarily metabolized through CYP3A4. Inhibition of CYP3A4 by EMEND for Injection could result in elevated plasma concentrations of these concomitant medications. Conversely, when EMEND for Injection is used concomitantly with another CYP3A4 inhibitor, aprepitant plasma concentrations could be elevated. When EMEND for Injection is used concomitantly with medications that induce CYP3A4 activity, aprepitant plasma concentrations could be reduced, and this may result in decreased efficacy of aprepitant.
- Chemotherapy agents that are known to be metabolized by CYP3A4 include docetaxel, paclitaxel, etoposide, irinotecan, ifosfamide, imatinib, vinorelbine, vinblastine, and vincristine. In clinical studies, EMEND® (aprepitant) was administered commonly with etoposide, vinorelbine, or paclitaxel. The doses of these agents were not adjusted to account for potential drug interactions. In separate pharmacokinetic studies, EMEND did not influence the pharmacokinetics of docetaxel or vinorelbine.
- Because a small number of patients in clinical studies received the CYP3A4 substrates vinblastine, vincristine, or ifosfamide, particular caution and careful monitoring are advised in patients receiving these agents or other chemotherapy agents metabolized primarily by CYP3A4 that were not studied.

Selected Important Safety Information *(continued)*

- There have been isolated reports of immediate hypersensitivity reactions including flushing, erythema, dyspnea, and anaphylaxis during infusion of fosaprepitant. These hypersensitivity reactions have generally responded to discontinuation of the infusion and administration of appropriate therapy. It is not recommended to reinitiate the infusion in patients who have experienced these symptoms during first-time use.
- Coadministration of EMEND for Injection with warfarin (a CYP2C9 substrate) may result in a clinically significant decrease in international normalized ratio (INR) of prothrombin time. In patients on chronic warfarin therapy, the INR should be closely monitored in the 2-week period, particularly at 7 to 10 days, following initiation of EMEND for Injection with each chemotherapy cycle.
- The efficacy of hormonal contraceptives may be reduced during coadministration with and for 28 days after the last dose of EMEND for Injection. Alternative or backup methods of contraception should be used during treatment with and for 1 month after the last dose of EMEND for Injection.
- Chronic continuous use of EMEND for Injection for prevention of nausea and vomiting is not recommended because it has not been studied and because the drug interaction profile may change during chronic continuous use.
- In clinical trials of EMEND® (aprepitant) in patients receiving highly emetogenic chemotherapy, the most common adverse events reported at a frequency greater than with standard therapy, and at an incidence of 1% or greater were hiccups (4.6% EMEND vs 2.9% standard therapy), asthenia/fatigue (2.9% vs 1.6%), increased ALT (2.8% vs 1.5%), increased AST (1.1% vs 0.9%), constipation (2.2% vs 2.0%), dyspepsia (1.5% vs 0.7%), diarrhea (1.1% vs 0.9%), headache (2.2% vs 1.8%), and anorexia (2.0% vs 0.5%).
- In a clinical trial evaluating safety of the 1-day regimen of EMEND for Injection 150 mg compared with the 3-day regimen of EMEND, the safety profile was generally similar to that seen in prior highly emetogenic chemotherapy studies with aprepitant. However, infusion-site reactions occurred at a higher incidence in patients who received fosaprepitant (3.0%) than in those who received aprepitant (0.5%). Those infusion-site reactions included infusion-site erythema, infusion-site pruritus, infusion-site pain, infusion-site induration, and infusion-site thrombophlebitis.

Please see the adjacent Brief Summary of the Prescribing Information.

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Merck Oncology

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emendforinjection.com

An antiemetic regimen including

EMEND® (fosaprepitant dimeglumine) for Injection

Prevention From the Start

Brief Summary of the Prescribing Information for

EMEND® (fosaprepitant dimeglumine) For Injection

INDICATIONS AND USAGE

EMEND for Injection is a substance P/neurokinin 1 (NK_1) receptor antagonist indicated in adults for use in combination with other antiemetic agents for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin.

Limitations of Use: EMEND for Injection has not been studied for the treatment of established nausea and vomiting.

Chronic continuous administration is not recommended *[see Warnings and Precautions]*.

CONTRAINDICATIONS

Hypersensitivity: EMEND for Injection is contraindicated in patients who are hypersensitive to EMEND for Injection, aprepitant, polysorbate 80, or any other components of the product. Known hypersensitivity reactions include flushing, erythema, dyspnea, and anaphylactic reactions *[see Adverse Reactions]*.

Concomitant Use With Pimozide or Cisapride: Aprepitant, when administered orally, is a moderate cytochrome P450 isoenzyme 3A4 (CYP3A4) inhibitor following the 3-day antiemetic dosing regimen for CINV. Since fosaprepitant is rapidly converted to aprepitant, do not use fosaprepitant concurrently with pimozide or cisapride. Inhibition of CYP3A4 by aprepitant could result in elevated plasma concentrations of these drugs, potentially causing serious or life-threatening reactions *[see Drug Interactions]*.

WARNINGS AND PRECAUTIONS

CYP3A4 Interactions: Fosaprepitant is rapidly converted to aprepitant, which is a moderate inhibitor of CYP3A4 when administered as a 3-day antiemetic dosing regimen for CINV. Fosaprepitant should be used with caution in patients receiving concomitant medications that are primarily metabolized through CYP3A4. Inhibition of CYP3A4 by aprepitant or fosaprepitant could result in elevated plasma concentrations of these concomitant medications. When fosaprepitant is used concomitantly with another CYP3A4 inhibitor, aprepitant plasma concentrations could be elevated. When aprepitant is used concomitantly with medications that induce CYP3A4 activity, aprepitant plasma concentrations could be reduced, and this may result in decreased efficacy of aprepitant *[see Drug Interactions]*.

Chemotherapy agents that are known to be metabolized by CYP3A4 include docetaxel, paclitaxel, etoposide, irinotecan, ifosfamide, imatinib, vinorelbine, vinblastine, and vincristine. In clinical studies, the oral aprepitant regimen was administered commonly with etoposide, vinorelbine, or paclitaxel. The doses of these agents were not adjusted to account for potential drug interactions.

In separate pharmacokinetic studies, no clinically significant change in docetaxel or vinorelbine pharmacokinetics was observed when the oral aprepitant regimen was coadministered. Due to the small number of patients in clinical studies who received the CYP3A4 substrates vinblastine, vincristine, or ifosfamide, particular caution and careful monitoring are advised in patients receiving these agents or other chemotherapy agents metabolized primarily by CYP3A4 that were not studied *[see Drug Interactions]*.

Hypersensitivity Reactions: Isolated reports of immediate hypersensitivity reactions including flushing, erythema, dyspnea, and anaphylaxis have occurred during infusion of fosaprepitant. These hypersensitivity reactions have generally responded to discontinuation of the infusion and administration of appropriate therapy. Reinitiation of the infusion is not recommended in patients who experience these symptoms during first-time use.

Coadministration With Warfarin (a CYP2C9 substrate): Coadministration of fosaprepitant or aprepitant with warfarin may result in a clinically significant decrease in international normalized ratio (INR) of prothrombin time. In patients on chronic warfarin therapy, the INR should be closely monitored in the 2-week period, particularly at 7 to 10 days, following initiation of fosaprepitant with each chemotherapy cycle *[see Drug Interactions]*.

Coadministration With Hormonal Contraceptives: Upon coadministration with fosaprepitant or aprepitant, the efficacy of hormonal contraceptives may be reduced during and for 28 days following the last dose of either fosaprepitant or aprepitant. Alternative or backup methods of contraception should be used during treatment with and for 1 month following the last dose of fosaprepitant or aprepitant *[see Drug Interactions]*.

Chronic Continuous Use: Chronic continuous use of EMEND for Injection for prevention of nausea and vomiting is not recommended because it has not been studied and because the drug interaction profile may change during chronic continuous use.

ADVERSE REACTIONS

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse-reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Since EMEND for Injection is converted to aprepitant, those adverse reactions associated with aprepitant might also be expected to occur with EMEND for Injection.

The overall safety of fosaprepitant was evaluated in approximately 1,100 individuals and the overall safety of aprepitant was evaluated in approximately 6,500 individuals.

Oral Aprepitant: Highly Emetogenic Chemotherapy (HEC): In 2 well-controlled clinical trials in patients receiving highly emetogenic cancer chemotherapy, 544 patients were treated with aprepitant during Cycle 1 of chemotherapy and 413 of these patients continued into the multiple-cycle extension for up to 6 cycles of chemotherapy. Oral aprepitant was given in combination with ondansetron and dexamethasone.

In Cycle 1, adverse reactions were reported in approximately 17% of patients treated with the aprepitant regimen compared with approximately 13% of patients treated with standard therapy. Treatment was discontinued due to adverse reactions in 0.6% of patients treated with the aprepitant regimen compared with 0.4% of patients treated with standard therapy.

The most common adverse reactions reported in patients treated with the aprepitant regimen (n=544) with an incidence of >1% and greater than with standard therapy (n=550), respectively, are listed below:

Respiratory system: hiccups 4.6 vs 2.9

Body as a whole/Site unspecified: asthenia/fatigue 2.9 vs 1.6

Investigations: increased ALT 2.8 vs 1.5, increased AST 1.1 vs 0.9

Digestive system: constipation 2.2 vs 2.0, dyspepsia 1.5 vs 0.7, diarrhea 1.1 vs 0.9

Nervous system: headache 2.2 vs 1.8

Metabolism and nutrition: anorexia 2.0 vs 0.5

A listing of adverse reactions in the aprepitant regimen (incidence <1%) that occurred at a greater incidence than with standard therapy are presented in the *Less Common Adverse Reactions* subsection below.

In an additional active-controlled clinical study in 1,169 patients receiving aprepitant and HEC, the adverse-experience profile was generally similar to that seen in the other HEC studies with aprepitant.

Less Common Adverse Reactions: Adverse reactions reported in either HEC or moderately emetogenic chemotherapy (MEC) studies in patients treated with the aprepitant regimen with an incidence of <1% and greater than with standard therapy are listed below.

Infection and infestations: candidiasis, staphylococcal infection

Blood and lymphatic system disorders: anemia, febrile neutropenia

Metabolism and nutrition disorders: weight gain, polydipsia

Psychiatric disorders: disorientation, euphoria, anxiety

Nervous system disorders: dizziness, dream abnormality, cognitive disorder, lethargy, somnolence

Eye disorders: conjunctivitis

Ear and labyrinth disorders: tinnitus

Cardiac disorders: bradycardia, cardiovascular disorder, palpitations

Vascular disorders: hot flush, flushing

Respiratory, thoracic, and mediastinal disorders: pharyngitis, sneezing, cough, postnasal drip, throat irritation

Gastrointestinal disorders: nausea, acid reflux, dysgeusia, epigastric discomfort, obstipation, gastroesophageal reflux disease, perforating duodenal ulcer, vomiting, abdominal pain, dry mouth, abdominal distension, hard feces, neutropenic colitis, flatulence, stomatitis

Skin and subcutaneous tissue disorders: rash, acne, photosensitivity, hyperhidrosis, oily skin, pruritus, skin lesion

Musculoskeletal and connective tissue disorders: muscle cramp, myalgia, muscular weakness

Renal and urinary disorders: polyuria, dysuria, pollakiuria

General disorders and administration site conditions: edema, chest discomfort, malaise, thirst, chills, gait disturbance

Investigations: increased alkaline phosphatase, hyperglycemia, microscopic hematuria, hyponatremia, decreased weight, decreased neutrophil count

In another chemotherapy-induced nausea and vomiting (CINV) study, Stevens-Johnson syndrome was reported as a serious adverse reaction in a patient receiving aprepitant with cancer chemotherapy.

The adverse-experience profiles in the multiple-cycle extensions of HEC studies for up to 6 cycles of chemotherapy were similar to that observed in Cycle 1.

Fosaprepitant: In an active-controlled clinical study in patients receiving HEC, safety was evaluated for 1,143 patients receiving the 1-day regimen of EMEND for Injection 150 mg compared with 1,169 patients receiving the 3-day regimen of EMEND. The safety profile was generally similar to that seen in prior HEC studies with aprepitant. However, infusion-site reactions occurred at a higher incidence in patients in the fosaprepitant group (3.0%) compared with those in the aprepitant group (0.5%). The reported infusion-site reactions included infusion-site erythema, infusion-site pruritus, infusion-site pain, infusion-site induration, and infusion-site thrombophlebitis.

The following additional adverse reactions occurred with fosaprepitant 150 mg and were not reported with the oral aprepitant regimen in the corresponding section above:

General disorders and administration site conditions: infusion-site erythema, infusion-site pruritus, infusion-site induration, infusion-site pain

Investigations: increased blood pressure

Skin and subcutaneous tissue disorders: erythema

Vascular disorders: thrombophlebitis (predominantly infusion-site thrombophlebitis)

Other Studies: Angioedema and urticaria were reported as serious adverse reactions in a patient receiving aprepitant in a non-CINV/non-PONV study.

Postmarketing Experience: The following adverse reactions have been identified during postapproval use of fosaprepitant and aprepitant. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the drug.

Skin and subcutaneous tissue disorders: pruritus, rash, urticaria, rarely Stevens-Johnson syndrome/toxic epidermal necrolysis

Immune system disorders: hypersensitivity reactions including anaphylactic reactions

DRUG INTERACTIONS

Drug interactions following administration of fosaprepitant are likely to occur with drugs that interact with oral aprepitant.

Aprepitant is a substrate, a moderate inhibitor, and an inducer of CYP3A4 when administered as a 3-day antiemetic dosing regimen for CINV. Aprepitant is also an inducer of CYP2C9.

Fosaprepitant 150 mg, given as a single dose, is a weak inhibitor of CYP3A4 and does not induce CYP3A4. Fosaprepitant and aprepitant are unlikely to interact with drugs that are substrates for the P-glycoprotein transporter.

The following information was derived from data with oral aprepitant, 2 studies conducted with fosaprepitant and oral midazolam, and 1 study conducted with fosaprepitant and dexamethasone.

Effect of Fosaprepitant/Aprepitant on the Pharmacokinetics of Other Agents: CYP3A4 Substrates: Aprepitant, as a moderate inhibitor of CYP3A4, and fosaprepitant 150 mg, as a weak inhibitor of CYP3A4, can increase plasma concentrations of concomitantly coadministered oral medications that are metabolized through CYP3A4 *[see Contraindications]*.

$5\text{-}HT_3$ antagonists: In clinical drug interaction studies, aprepitant did not have clinically important effects on the pharmacokinetics of ondansetron, granisetron, or hydrodolasetron (the active metabolite of dolasetron).

Corticosteroids: *Dexamethasone:* Fosaprepitant 150 mg administered as a single intravenous dose on Day 1 increased the AUC_{0-24hr} of dexamethasone, administered as a single 8-mg oral dose on Days 1, 2, and 3, by approximately 2-fold on Days 1 and 2. The oral dexamethasone dose on Days 1 and 2 should be reduced by approximately 50% when coadministered with fosaprepitant 150 mg I.V. on Day 1.

An oral aprepitant regimen of 125 mg on Day 1 and 80 mg/day on Days 2 through 5, coadministered with 20-mg oral dexamethasone on Day 1 and 8-mg oral dexamethasone on Days 2 through 5, increased the AUC of dexamethasone by 2.2-fold on Days 1 and 5. The oral dexamethasone doses should be reduced by approximately 50% when coadministered with a regimen of fosaprepitant 115 mg followed by aprepitant.

Methylprednisolone: An oral aprepitant regimen of 125 mg on Day 1 and 80 mg/day on Days 2 and 3 increased the AUC of methylprednisolone by 1.34-fold on Day 1 and by 2.5-fold on Day 3, when methylprednisolone was coadministered intravenously as 125 mg on Day 1 and orally as 40 mg on Days 2 and 3. The intravenous methylprednisolone dose should be reduced by approximately 25% and the oral methylprednisolone dose should be reduced by approximately 50% when coadministered with a regimen of fosaprepitant 115 mg followed by aprepitant.

Chemotherapeutic agents: *Docetaxel:* In a pharmacokinetic study, oral aprepitant (CINV regimen) did not influence the pharmacokinetics of docetaxel *[see Warnings and Precautions]*.

Vinorelbine: In a pharmacokinetic study, oral aprepitant (CINV regimen) did not influence the pharmacokinetics of vinorelbine to a clinically significant degree *[see Warnings and Precautions]*.

Oral contraceptives: When oral aprepitant, ondansetron, and dexamethasone were coadministered with an oral contraceptive containing ethinyl estradiol and norethindrone, the trough concentrations of both ethinyl estradiol and norethindrone were reduced by as much as 64% for 3 weeks posttreatment.

The coadministration of fosaprepitant or aprepitant may reduce the efficacy of hormonal contraceptives (these can include birth control pills, skin patches, implants, and certain IUDs) during and for 28 days after administration of the last dose of fosaprepitant or aprepitant. Alternative or backup methods of contraception should be used during treatment with and for 1 month following the last dose of fosaprepitant or aprepitant.

Midazolam: Interactions between aprepitant or fosaprepitant and coadministered midazolam are listed below (increase is indicated as ↑, decrease as ↓, no change as ↔):

Fosaprepitant 150 mg on Day 1, oral midazolam 2 mg on Days 1 and 4: AUC ↑ 1.8-fold on Day 1 and AUC ↔ on Day 4

Fosaprepitant 100 mg on Day 1, oral midazolam 2 mg: oral midazolam AUC ↑ 1.6-fold

Oral aprepitant 125 mg on Day 1 and 80 mg on Days 2 to 5, oral midazolam 2 mg SD on Days 1 and 5: oral midazolam AUC ↑ 2.3-fold on Day 1 and ↑ 3.3-fold on Day 5

Oral aprepitant 125 mg on Day 1 and 80 mg on Days 2 and 3, intravenous midazolam 2 mg prior to 3-day

regimen of aprepitant and on Days 4, 8, and 15: intravenous midazolam AUC ↑ 25% on Day 4, AUC ↓ 19% on Day 8, and AUC ↓ 4% on Day 15

Oral aprepitant 125 mg, intravenous midazolam 2 mg given 1 hour after aprepitant: intravenous midazolam AUC ↑ 1.5-fold

A difference of less than 2-fold increase of midazolam AUC was not considered clinically important.

The potential effects of increased plasma concentrations of midazolam or other benzodiazepines metabolized via CYP3A4 (alprazolam, triazolam) should be considered when coadministering these agents with fosaprepitant or aprepitant.

CYP2C9 Substrates (Warfarin, Tolbutamide): *Warfarin:* A single 125-mg dose of oral aprepitant was administered on Day 1 and 80 mg/day on Days 2 and 3 to healthy subjects who were stabilized on chronic warfarin therapy. Although there was no effect of oral aprepitant on the plasma AUC of R(+) or S(–) warfarin determined on Day 3, there was a 34% decrease in S(–) warfarin trough concentration accompanied by a 14% decrease in the prothrombin time (reported as INR) 5 days after completion of dosing with oral aprepitant. In patients on chronic warfarin therapy, the prothrombin time (INR) should be closely monitored in the 2-week period, particularly at 7 to 10 days, following initiation of fosaprepitant with each chemotherapy cycle.

Tolbutamide: Oral aprepitant, when given as 125 mg on Day 1 and 80 mg/day on Days 2 and 3, decreased the AUC of tolbutamide by 23% on Day 4, 28% on Day 8, and 15% on Day 15, when a single dose of tolbutamide 500 mg was administered orally prior to the administration of the 3-day regimen of oral aprepitant and on Days 4, 8, and 15.

Effect of Other Agents on the Pharmacokinetics of Aprepitant: Aprepitant is a substrate for CYP3A4; therefore, coadministration of fosaprepitant or aprepitant with drugs that inhibit CYP3A4 activity may result in increased plasma concentrations of aprepitant. Consequently, concomitant administration of fosaprepitant or aprepitant with strong CYP3A4 inhibitors (eg, ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir, nelfinavir) should be approached with caution. Because moderate CYP3A4 inhibitors (eg, diltiazem) result in a 2-fold increase in plasma concentrations of aprepitant, concomitant administration should also be approached with caution.

Aprepitant is a substrate for CYP3A4; therefore, coadministration of fosaprepitant or aprepitant with drugs that strongly induce CYP3A4 activity (eg, rifampin, carbamazepine, phenytoin) may result in reduced plasma concentrations and decreased efficacy.

Ketoconazole: When a single 125-mg dose of oral aprepitant was administered on Day 5 of a 10-day regimen of 400 mg/day of ketoconazole, a strong CYP3A4 inhibitor, the AUC of aprepitant increased approximately 5-fold and the mean terminal half-life of aprepitant increased approximately 3-fold. Concomitant administration of fosaprepitant or aprepitant with strong CYP3A4 inhibitors should be approached cautiously.

Rifampin: When a single 375-mg dose of oral aprepitant was administered on Day 9 of a 14-day regimen of 600 mg/day of rifampin, a strong CYP3A4 inducer, the AUC of aprepitant decreased approximately 11-fold and the mean terminal half-life decreased approximately 3-fold.

Coadministration of fosaprepitant or aprepitant with drugs that induce CYP3A4 activity may result in reduced plasma concentrations and decreased efficacy.

Additional Interactions: *Diltiazem:* In a study in 10 patients with mild to moderate hypertension, intravenous infusion of 100 mg of fosaprepitant with diltiazem 120 mg 3 times daily resulted in a 1.5-fold increase of aprepitant AUC and a 1.4-fold increase in diltiazem AUC. It also resulted in a small but clinically meaningful further maximum decrease in diastolic blood pressure (mean [SD] of 24.3 [±10.2] mmHg with fosaprepitant vs 15.6 [±4.1] mmHg without fosaprepitant) and resulted in a small further maximum decrease in systolic blood pressure (mean [SD] of 29.5 [±7.9] mmHg with fosaprepitant vs 23.8 [±4.8] mmHg without fosaprepitant), which may be clinically meaningful, but did not result in a clinically meaningful further change in heart rate or PR interval beyond those changes induced by diltiazem alone.

In the same study, administration of aprepitant once daily as a tablet formulation comparable to 230 mg of the capsule formulation, with diltiazem 120 mg 3 times daily for 5 days, resulted in a 2-fold increase of aprepitant AUC and a simultaneous 1.7-fold increase of diltiazem AUC. These pharmacokinetic effects did not result in clinically meaningful changes in ECG, heart rate, or blood pressure beyond those changes induced by diltiazem alone.

Paroxetine: Coadministration of once-daily doses of aprepitant as a tablet formulation comparable to 85 mg or 170 mg of the capsule formulation, with paroxetine 20 mg once daily, resulted in a decrease in AUC by approximately 25% and C_{max} by approximately 20% of both aprepitant and paroxetine.

USE IN SPECIFIC POPULATIONS

Pregnancy: *Teratogenic effects: Pregnancy Category B:* In the reproduction studies conducted with fosaprepitant and aprepitant, the highest systemic exposures to aprepitant were obtained following oral administration of aprepitant. Reproduction studies performed in rats at oral doses of aprepitant of up to 1000 mg/kg twice daily (plasma AUC_{0-24hr} of 31.3 mcg•hr/mL, about 1.6 times the human exposure at the recommended dose) and in rabbits at oral doses of up to 25 mg/kg/day (plasma AUC_{0-24hr} of 26.9 mcg•hr/mL, about 1.4 times the human exposure at the recommended dose) revealed no evidence of impaired fertility or harm to the fetus due to aprepitant. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: Aprepitant is excreted in the milk of rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for possible serious adverse reactions in nursing infants from aprepitant and because of the potential for tumorigenicity shown for aprepitant in rodent carcinogenicity studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness of EMEND for Injection in pediatric patients have not been established.

Geriatric Use: In 2 well-controlled CINV clinical studies, of the total number of patients (N=544) treated with oral aprepitant, 31% were 65 and over, while 5% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. Greater sensitivity of some older individuals cannot be ruled out. Dosage adjustment in the elderly is not necessary.

Patients With Severe Hepatic Impairment: There are no clinical or pharmacokinetic data in patients with severe hepatic impairment (Child-Pugh score >9). Therefore, caution should be exercised when fosaprepitant or aprepitant is administered in these patients.

OVERDOSAGE

There is no specific information on the treatment of overdosage with fosaprepitant or aprepitant.

In the event of overdose, fosaprepitant and/or oral aprepitant should be discontinued and general supportive treatment and monitoring should be provided. Because of the antiemetic activity of aprepitant, drug-induced emesis may not be effective. Aprepitant cannot be removed by hemodialysis.

Thirteen patients in the randomized controlled trial of EMEND for Injection received both fosaprepitant 150 mg and at least one dose of oral aprepitant, 125 mg or 80 mg. Three patients reported adverse reactions that were similar to those experienced by the total study population.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenicity studies were conducted in Sprague-Dawley rats and in CD-1 mice for 2 years. In the rat carcinogenicity studies, animals were treated with oral doses ranging from 0.05 to 1000 mg/kg twice daily. The highest dose produced a systemic exposure to aprepitant (plasma AUC_{0-24hr}) of 0.7 to 1.6 times the human exposure (AUC_{0-24hr}=19.6 mcg•hr/mL) at the recommended dose of 125 mg/day. Treatment with aprepitant at doses of 5 to 1000 mg/kg twice daily caused an increase in the incidences of thyroid follicular cell adenomas and carcinomas in male rats. In female rats, it produced hepatocellular adenomas at 5 to 1000 mg/kg twice daily and hepatocellular carcinomas and thyroid follicular cell adenomas at 125 to 1000 mg/kg twice daily. In the mouse carcinogenicity studies, the animals were treated with oral doses ranging from 2.5 to 2000 mg/kg/day. The highest dose produced a systemic exposure of about 2.8 to 3.6 times the human exposure at the recommended dose. Treatment with aprepitant produced skin fibrosarcomas at 125 and 500 mg/kg/day doses in male mice. Carcinogenicity studies were not conducted with fosaprepitant.

Aprepitant and fosaprepitant were not genotoxic in the Ames test, the human lymphoblastoid cell (TK6) mutagenesis test, the rat hepatocyte DNA strand break test, the Chinese hamster ovary (CHO) cell chromosome aberration test and the mouse micronucleus test.

Fosaprepitant, when administered intravenously, is rapidly converted to aprepitant. In the fertility studies conducted with fosaprepitant and aprepitant, the highest systemic exposures to aprepitant were obtained following oral administration of aprepitant. Oral aprepitant did not affect the fertility or general reproductive performance of male or female rats at doses up to the maximum feasible dose of 1000 mg/kg twice daily (providing exposure in male rats lower than the exposure at the recommended human dose and exposure in female rats at about 1.6 times the human exposure).

PATIENT COUNSELING INFORMATION

[See FDA-Approved Patient Labeling]: Physicians should instruct their patients to read the patient package insert before starting therapy with EMEND for Injection and to reread it each time the prescription is renewed.

Patients should follow the physician's instructions for the regimen of EMEND for Injection.

Allergic reactions, which may be sudden and/or serious, and may include hives, rash, itching, redness of the face/skin, and may cause difficulty in breathing or swallowing, have been reported. Physicians should instruct their patients to stop using EMEND and call their doctor right away if they experience an allergic reaction. In addition, severe skin reactions may occur rarely.

Patients who develop an infusion-site reaction such as erythema, edema, pain, or thrombophlebitis should be instructed on how to care for the local reaction and when to seek further evaluation.

EMEND for Injection may interact with some drugs, including chemotherapy; therefore, patients should be advised to report to their doctor the use of any other prescription or nonprescription medication or herbal products.

Patients on chronic warfarin therapy should be instructed to have their clotting status closely monitored in the 2-week period, particularly at 7 to 10 days, following initiation of fosaprepitant with each chemotherapy cycle.

Administration of EMEND for Injection may reduce the efficacy of hormonal contraceptives. Patients should be advised to use alternative or backup methods of contraception during treatment with and for 1 month following the last dose of fosaprepitant or aprepitant.

For detailed information, please read the Prescribing Information.

Rx only

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HOSPITAL REGULATORY UPDATE

On Nov. 2, 2012, the Centers for Medicare & Medicaid services (CMS) released its final rule updating the Medicare Hospital Outpatient Prospective Payment System (HOPPS or OPPS) for CY 2013.[1] This final rule was published in the Nov. 15 *Federal Register,* and affects more than 4,000 hospital outpatient departments and 5,000 Medicare-participating ASCs. The rates and policies set in the CY 2013 final rule increase payment rates for outpatient hospital departments by 1.8 percent and ASC payment rates by 0.6 percent.

In addition, the rule contained a significant change from prior policy: as proposed, the rule bases relative payment weights on geometric mean costs rather than median costs. CMS believes that basing payments on mean costs better reflects average costs of services and aligns the metric used for rate-setting for the OPPS with the IPPS (Inpatient Prospective Payment System).

The final rule also made several changes to the quality reporting program for outpatient hospital departments. While CMS did not add any new measures to those finalized for the CY 2014 payment determination, it did confirm the removal of one measure, deferred data collection for a second measure, and suspended data collection for a third measure. Finally, the rule strengthened the operations of the Quality Improvement Organizations (QIOs), making them more responsive to beneficiary complaints regarding quality of care.

Outpatient Supervision

There was no change to the outpatient supervision requirements for radiation oncology. At present, radiation oncology services require direct supervision, which CMS lists as the default supervision level for outpatient therapeutic services. There was no change to the definition or requirements of direct supervision (immediately available, interruptible, and able to provide direction and assistance) in the final rule.

CMS did not alter hospital outpatient supervision guidelines for infusion center services in this final rule, but a Sept. 24, 2012, document titled *CMS' Preliminary Decisions on the Recommendations of the Hospital Outpatient Payment Panel on Supervision Levels for Select Services*[2] states that CMS intends to adopt recommendations from the Hospital Outpatient Payment Panel to update the supervision level of the following services from direct supervision to general supervision:

- **36000:** Introduction of needle or intracatheter vein
- **36591:** Collection of blood specimen from a completely implantable venous access device
- **36592:** Collection of blood specimen using established central or peripheral catheter, venous, not otherwise specified
- **96360:** Intravenous infusion, hydration; initial, 31 minutes to 1 hour
- **96361:** Intravenous infusion, hydration; each additional hour
- **96521:** Refilling and maintenance of portable pump
- **96523:** Irrigation of implanted venous access device for drug delivery systems.

Last, CMS again issued instructions to contractors to not enforce the direct supervision requirement in Critical Access Hospitals (CAHs) for CY 2013 and will continue to expand this non-enforcement to include small rural hospitals with 100 or fewer beds. CMS states: "Regarding the enforcement instruction, as we discussed in the CY 2013 OPPS/ASC proposed rule, we will extend the enforcement instruction one additional year through CY 2013. This additional year, which we expect to be the final year of the extension, will provide additional opportunities for stakeholders to bring their issues to the [Hospital Outpatient Payment] Panel, and for the Panel to evaluate and provide us with recommendations on those issues."

Brachytherapy

CMS will continue paying for LDR prostate brachytherapy services performed in the hospital outpatient department using the composite APC methodology implemented for previous years. The final CY 2013 median cost for composite APC **8001** is approximately $3348.00. In addition, CMS finalized the proposal to reimburse brachytherapy sources at prospective payment rates based on their source-specific geometric mean costs for CY 2013. A comment received and published in the final rule relating to brachytherapy states:[1]

COMMENT: One commenter requested that CMS add a new C-code and APC for a high-activity cesium-131 brachytherapy source, which is designed to generate isotropic emission of therapeutic radiation and to be used primarily for the treatment of head and neck and eye cancer.

RESPONSE: We appreciate the commenter informing us of a new high-activity cesium-131 source. However, our evaluation process of new sources for addition to our set of codes is beyond the scope of this rulemaking. As we state elsewhere in this final rule with comment period, and in previous rules, such as the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163), we ask parties to submit recommendations to us for new HCPCS codes to describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources. We suggest to the commenter to send its recommendation for this new brachytherapy source, along with the detailed rationale to support the new source, to the address provided at the end of this section. We will continue to add new brachytherapy source codes and descriptors to our systems on a quarterly basis.

Other Radiation Oncology Issues

APCs **0664** and **0667** for proton beam treatment delivery will undergo a 4 percent and 56 percent payment reduction, respectively. APC **0664** includes the codes for simple proton therapy (codes **77520** and **77522**) and APC **0667** includes the codes for intermediate **(77523)** and complex **(77525)** proton treatments. While several commenters indicated that the decrease in the cost of APC **0667** can be attributed to inaccurate coding and incorrect cost reporting from one facility, CMS has updated the payment rates based on data received from all providers. This change means that simple proton therapy treatment will pay approximately $1169.00 per treatment, while intermediate and complex proton treatments will only reimburse about $702.00 per treatment in CY 2013.

As in the previous year, claims cost data for the IMRT device (code **77338**) illustrates an average reported cost of $293.00; as a result, CMS will continue to assign this code to APC **305,** with a final rule geometric mean cost of approximately $297.00.

During CY 2012, CMS packaged the payment for intraoperative radiation therapy (IORT) services into the payment for the principal surgical procedure performed during the same operative session. After review, CMS agrees that codes **77424** and **77425** should be separately reimbursed, but do not qualify for a new technology APC. As a result, these codes will be assigned to APC **0065** (Level I Stereotactic Radiosurgery) with a geometric mean cost of approximately $1006.00.

Packaged Services

CMS continues to package image guidance procedures under the OPPS in 2013 and assigns these codes a status indicator of "N" (items and services packaged into APC rates). This policy affects codes:

- **76950:** Ultrasonic guidance for placement of radiation fields
- **76965:** Ultrasonic guidance for interstitial radioelement application
- **77014:** CT guidance for placement of radiation fields
- **77417:** Therapeutic radiology port films
- **77421:** Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy.

While hospitals will continue to bill for these packaged services separately, there will be no separate payment for radiation therapy image guidance in 2013.

The final rule includes the following comment and response:[1]

COMMENT: One commenter asked that CMS reinstate separate payment for radiation oncology guidance procedures because these services are vital to the safe provision of radiation therapy and unconditionally packaging payment for them may discourage hospitals from providing them.

RESPONSE: As we stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188), we recognize that radiation oncology guidance services, like most packaged services, are important to providing safe and high quality care to patients. However, we continue to believe that hospitals will invest in services that represent genuinely increased value to patient care. We will continue to pay separately for innovative technologies if a device meets the conditions for separate payment as a pass-through device or if a new procedure meets the criteria for payment as a new technology APC.

CMS continues to stress that hospitals should report all HCPCS codes that describe packaged services provided, unless the CPT Editorial Panel or CMS provide other guidance. CMS stated that failure to report codes for packaged services makes it difficult to track utilization patterns and resource costs.

Table 4. Hematology & Oncology Drugs that Lost Pass-Through Status Effective Dec. 31, 2012

CY 2013 HCPCS CODE	CY 2013 LONG DESCRIPTOR	CY 2013 SI*	CY 2013 APC
J0597	Injection, C-1 esterase inhibitor (human), Berinert, 10 units	K	9269
J0897	Injection, denosumab, 1 mg	K	9272
J1290	Injection, ecallantide, 1 mg	K	9263
J1557	Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg	K	9270
J1741	Injection, ibuprofen, 100 mg	N	N/A
J3385	Injection, velaglucerase alfa, 100 units	K	9271
J7183	Injection, von Willebrand factor complex (human), Wilate, per 100 IU VWF: RCO	K	1352
J8562	Fludarabine phosphate, oral, 10 mg	K	1339
J9043	Injection, cabazitaxel, 1 mg	K	1339
J9302	Injection, ofatumumab, 10 mg	K	9260
J9307	Injection, pralatrexate, 1 mg	K	9259
J9315	Injection, romidepsin, 1 mg	K	9265
Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion	K	9373

Table 5. Hematology & Oncology Drugs With Pass-Through Status in 2013

CODE	DEFINITION
C9292	Injection, pertuzumab, 10 mg
C9293	Injection, glucarpidase, 10 units
C9294	Injection, taliglucerase alfa, 100 units
C9295	Injection, carfilzomib, 1 mg
C9296	Injection, ziv-aflibercept, 1 mg
J9042	Injection, brentuximab vedotin, 1 mg
J9019	Injection, asparaginase (erwinaze), 1000 IU
J0131	Injection, acetaminophen, 10 mg
J0178	Injection, aflibercept, 1 mg
J0490	Injection, belimumab, 10 mg
J0638	Injection, canakinumab, 1 mg
J1572	Injection, immune globulin, (Flebogamma/Flebogamma dif), intravenous, non-lyophilized (e.g., liquid), 500 mg
J7180	Injection, factor XIII (antihemophilic factor, human), 1 IU
J9179	Injection, eribulin mesylate, 1 mg
J9228	Injection, ipilimumab, 1 mg

Payments to Cancer Hospitals

Since the inception of the OPPS, Medicare has paid designated cancer hospitals for covered outpatient hospital services. There are 11 cancer hospitals that meet the classification criteria. The Affordable Care Act (ACA) states that if the cancer hospitals' costs are determined to be greater than the costs of other hospitals paid under the OPPS, the Secretary shall provide an appropriate adjustment to reflect these higher costs. Section 3138 of the Act also requires that this adjustment be budget-neutral.

CMS has concluded that cancer hospitals are more costly than other hospitals paid under the OPPS. CMS estimates that on average, the OPPS payments to the 11 cancer hospitals are approximately 67 percent of reasonable costs, whereas, CMS estimates the OPPS payments to other hospitals are approximately 91 percent of reasonable costs.

For CY 2013, CMS will continue to provide additional payments to cancer hospitals so that the hospital's payment-to-cost ratio (PCR) with the payment adjustment is equal to the weighted average PCR for the other OPPS hospitals using the most recent submitted or settled cost-report data.

Infusion Center Issues

For CY 2013 CMS will pay for both pass-through drugs and biologicals and for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals without pass-through status at ASP+6 percent. CMS will also continue to include antiemetic drugs in the drug packaging rules. These drugs will be paid separately only if their average cost per day is greater than $80, which is the 2013 OPPS drug packaging threshold. Currently, the only 5-HT3 antiemetic that meets the criteria for separate payment is palonosetron HCl (code **J2469**).

In the 2013 OPPS Final Rule, CMS provides the following comments on 5-HT3 antiemetics:[1]

We continue to believe that the use of these antiemetics is an integral part of an anticancer treatment regimen and that OPPS claims data demonstrates their increasingly common hospital outpatient utilization. As we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60488), we no longer believe that a specific exemption to our standard drug payment methodology is necessary to ensure access to the most appropriate antiemetic products for Medicare beneficiaries. We continue to believe that our analysis conducted in the CY 2010 OPPS/ASC proposed rule on 5-HT3 antiemetics (74 FR 35320), along with the historical stability in prescribing patterns for these products and the availability of generic alternatives for several of these products, allows us to continue our policy of not specifically exempting these products from the OPPS drug packaging threshold.

CMS also finalized its proposal to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS (ASP+6 percent) and to continue payment of an updated furnishing fee (to be posted on the CMS website at a later date).

CMS announced that a total of 23 medicines and biological substances, including the hematology and oncology drugs in Table 4, page 17, are losing their pass-through status effective Dec. 31, 2012. Once pass-through status expires, the drug will be paid separately only if the estimated cost per day is greater than the OPPS packaging threshold of $80. Status Indicator N means that the charge will be packaged into the reimbursement for the primary service that day. Status indicator K indicates that this drug is a non-pass-through drug subject to payment at the APC allowance.

CMS has granted or will continue pass-through status to 26 drugs and biologicals in CY 2013, including the hematology and oncology drugs in Table 5, left.

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1. CMS. 2013 Medicare OPPS Final Rule. Available online at: *www.gpo.gov/fdsys/pkg/FR-2012-11-15/pdf/2012-26902.pdf*. Last accessed Dec. 4, 2012.
2. CMS. Preliminary Decisions on the Recommendations of the Hospital Outpatient Payment Panel on Supervision Levels for Select Services. Available online at: *www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/Prelim-Supervision-Decisions092412.pdf*. Last accessed Dec. 3, 2012.

PHYSICIAN PRACTICES & FREESTANDING CENTERS

The Medicare Physician Fee Schedule (MPFS) specifies payment rates to physicians and other providers, including freestanding radiation oncology centers, for more than 7,000 healthcare services and procedures, ranging from simple office visits to complex surgery. The 2012 MPFS final rule was posted to the CMS website on Nov. 2, 2012, and was published in the Nov. 16 *Federal Register*.[1] All payments and policies are effective Jan. 1, 2013.

Conversion Factor

The conversion factor is updated on an annual basis according to a formula specified by statute, which is designed to rein in the growth in outlays for physician services. The formula requires CMS to adjust the conversion factor up or down depending on how actual expenditures compare to a target rate called the Sustainable Growth Rate (SGR).

The SGR is a formula that was adopted in 1997 under the Balanced Budget Act. If actual expenditures exceed the expenditures allowed by the formula, the conversion factor update is reduced. Congress has taken a series of legislative actions to avoid reductions to MPFS rates since 2003; however, a long-term solution is critical. There is currently a substantial difference between target and actual spending that must be accounted for through future reductions to MPFS rates.

On Jan. 1, 2013, Congress once again stepped in with a "doc fix" preventing an overall reduction of 26.5 percent to the conversion factor used to calculate payment for services provided by more than 1 million physician and qualified midlevel providers. In addition, payments to primary care specialties will increase and payments to select other specialties will decrease due to several changes in how CMS calculated payments for CY 2013.

The largest payment increase for primary care specialties overall will result from a new payment for managing a beneficiary's care when the beneficiary is discharged from an inpatient hospital, a skilled nursing facility, an outpatient hospital observation, partial hospitalization services, or a community mental health center. Payments to primary care specialties also will increase due to redistributions from changes in payments for services furnished by other specialties. Remember that because of the budget-neutral nature of this system, increases in payments for one service result in decreases in payments for other services.

Radiation Oncology Updates

CMS finalized its proposal to adjust intra-service procedure time assumptions for IMRT delivery (code **77418**) from 60 to 30 minutes and SBRT delivery (code **77373**) from 90 to 60 minutes. However, CMS adjusted other direct practice expense inputs for these services, which results in 2013 interim RVUs of 11.92 for **77418** and 37.30 for **77373** with decreases from 2012 payment rates of 14.7 percent and 20.5 percent, respectively. According to the final rule:[1]

Because the physician work associated with these treatments is reported using codes distinct from the treatment delivery, the primary determinant of PE RVUs for these codes is the number of minutes allocated for the procedure time to both the clinical labor (radiation therapist) and the resource-intensive capital equipment included as direct PE inputs.

It has come to our attention that there are discrepancies between the procedure time assumptions used in establishing nonfacility PE RVUs for these codes and the procedure times made widely available to Medicare beneficiaries and the general public.

Specifically, the direct PE inputs for IMRT treatment delivery (code 77418) reflect a procedure time assumption of 60 minutes. Information available to Medicare beneficiaries and the general public indicates that IMRT sessions typically last between 10 and 30 minutes.

The direct PE inputs for SBRT treatment delivery (code 77373) reflect a procedure time assumption of 90 minutes. In 2012, information available to Medicare beneficiaries and the general public states that SBRT treatment typically lasts no longer than 60 minutes.

Table 6. 2013 Procedure Code Recommendations & RVU Assignments

HCPCS CODE	CY 2012 WORK RVU	AMA RUC/HCPAC Recommended Work RVU	CY 2013 Interim Final Work RVU	Agree/Disagree with AMA RUC/HCPAC Recommended Work RVU	CMS Refinement to AMA/HCPAC Recommended RVU
38240	2.24	4.00	3.00	Disagree	No
38241	2.24	3.00	3.00	Agree	No
38242	1.71	2.11	2.11	Agree	No
38243	New	2.13	2.13	Agree	No

Table 7. Combined 2013 Total Allowed Charge Impact by Specialty*

SPECIALTY	IMPACT END OF PPIS TRANSITION	NEW & REVISED CODES, MPPR, NEW UTILIZATION & OTHER FACTORS	UPDATED EQUIPMENT INTEREST RATE ASSUMPTION	TRANSITIONAL CARE MANAGEMENT	INPUT CHANGES FOR CERTAIN RADIATION THERAPY PROCEDURES	TOTAL (CUMULATIVE IMPACT)
Hematology Oncology	-1%	3%	1%	-1%	0%	2%
Radiation Oncology	-4%	2%	-3%	-1%	-1%	-7%
Radiation Therapy Centers	-5%	4%	-5%	-1%	-1%	-9%

Column Definitions:
1. Impact of End of PPIS Transition: This column shows the estimated CY 2013 impact on total allowed charges of the changes in the RVUs due to the final year of the PPIS transition.
2. Impact of New and Revised Codes, Updated Claims Data, MPPR on the TC of Ophthalmology and Cardiovascular Diagnostic Tests and Other Factors: This column shows the estimated CY 2013 impact on total allowed charges of the changes in the RVUs, due to new and revised codes, proposed multiple procedure payment reduction for the TC of cardiovascular and ophthalmology diagnostic tests furnished on the same day and other final policies that resulted in minimal redistribution of payments under the PFS, the use of CY 2011 claims data to model payment rates, and other factors.
3. Impact of Updated Equipment Interest Rate Assumption: This column shows the estimated CY 2013 impact on total allowed charges of the changes in RVUs resulting from our update to the equipment interest rate assumption as discussed in section III.A.2.f of this Final Rule with comment period.
4. Impact of Discharge Transitional Care Management Services: This column shows the estimated CY 2013 combined impact on total allowed charges of the changes in the RVUs resulting from CMS policy to recognize new CPT codes that pay for post-discharge transitional care management services in the 30 days following an inpatient hospital, outpatient observation or partial hospitalization, skilled nursing facility (SNF), or community mental health center (CMHC) discharge as discussed in section III.H.1 of this Final Rule with comment period.
5. Impact of Input and Price Changes for Certain Radiation Therapy Procedures: This column shows the estimated CY 2013 combined impact on total allowed charges of the changes in the RVUs resulting from CMS policy to adjust inputs on certain radiation therapy procedures.
6. Cumulative Impact: This column shows the estimated CY 2013 combined impact on total allowed charges of all changes from the policies in this Final Rule with comment period in the previous columns.

We believe medical societies and practitioners strive to offer their cancer patients accurate information regarding the IMRT or SBRT treatment experience. Therefore, we believe that the typical procedure time for IMRT delivery is between 10 and 30 minutes and that the typical procedure time for SBRT delivery is under 60 minutes.

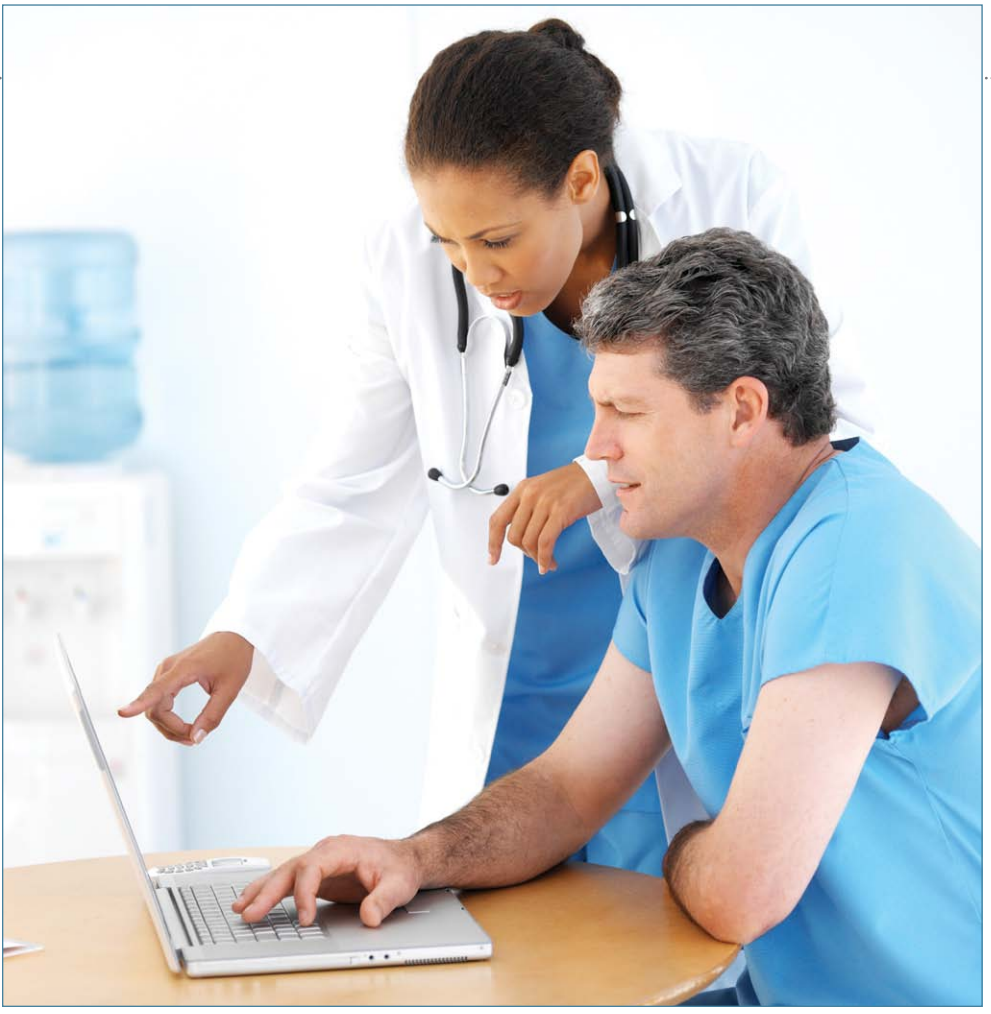
While we generally have not used publicly available resources to establish procedure time assumptions, we believe that the procedure time assumptions used in setting payment rates for the Medicare PFS should be derived from the most accurate information available. In the case of these services, we believe that the need to reconcile the discrepancies between our existing assumptions and more accurate information outweighs the potential value in maintaining relativity offered by only considering data from one source.

CMS also finalized the proposal to review procedure code **77336,** continuing physics consultation, as a potentially misvalued code due to changes in technology, knowledge required, and effort expended. The AMA RUC will review this service and provide recommendations to CMS on its valuation, and the AAPM will submit information on practice expense inputs and other data to support the revaluation of this code. In addition, CMS finalized the proposal to review and make adjustments to procedure codes with stand-alone procedure time assumptions used in developing PE RVUs, including the following radiation oncology codes:

- **77280-77290:** Therapeutic radiology simulation-aided field setting
- **77301:** Intensity modulated radiotherapy plan
- **77338:** MLC devices for IMRT
- **77372:** SRS radiation treatment delivery
- **77373:** SBRT radiation treatment delivery
- **77402-77416:** Radiation treatment delivery
- **77418:** IMRT treatment delivery
- **77600:** Hyperthermia, externally generated
- **77785-77787:** HDR brachytherapy administration.

Another area that will have a negative impact on radiation oncology reimbursement surrounds CMS' decision to finalize its proposal to replace the current interest rate assumption of 11 percent with a "sliding scale approach" based on current Small Business Administration (SBA) maximum interest rates for different categories of loan size. In addition, this final rule reviews the CMS initiative to bundle payments and provide a single allowance for an entire course of treatment. Specifically, this rule states:

Additionally, we have had representatives of specialty groups such as radiation oncologists volunteer to work with us to



create a bundled payment for their services. If we were to engage in a bundling project for radiation therapy, we would want to do more than provide a single episode payment for normal course of radiation therapy that aggregates the sum of the individual treatments. Radiation therapy has many common side effects that can vary based on the type of cancer the patient has and how it is being treated. Common side effects associated with radiation therapy include fatigue, skin problems, eating problems, blood count changes, emotional issues such as depression, etc. If we were to engage in a bundling project that includes radiation therapy, we would be interested in exploring whether it could also include treating and managing the side effects that result from radiation therapy in addition to the radiation therapy itself. Such an episode-based payment would allow Medicare to pay for the full course of the typical radiation therapy as well as the many medical services the patient may be receiving to treat side effects.

Although CMS has not adopted a bundled reimbursement for any oncology services to date, government and non-government payers continue to explore this option.

Medical Oncology Updates

Procedure codes **38240, 38241, 38242,** and **38443** were reviewed by the CPT Editorial Panel for CY 2013; the recommendations and RVU assignments can be found in Table 6, page 19.

CMS states that it will continue to maintain 5 percent widely available market price (WAMP) and average manufacturer price (AMP) thresholds, which have been stable at the current rate since CY 2005. As noted in the proposed rule, available data are limited and there is no information that would prompt CMS to believe different thresholds are necessary.

Transitional Care Coordination Codes

The MPFS final rule replaces a proposed HCPCS Level II code with the transitional care management codes created by the American Medical Association and effective Jan. 1, 2013. These two new codes require a face-to-face visit with the beneficiary within 7 to 14 days of discharge by the physician who will coordinate all of the beneficiary's care for 30 days following hospital or other inpatient stay. The goal of this care is to prevent hospital readmissions by monitoring all patient medical conditions, and the intent is to benefit primary care physicians through an estimated 7 percent overall payment increase.

Summary

Based on reimbursement changes associated with this final rule, radiation therapy centers will see an estimated overall decrease of 9 percent, primarily as a result of the PPIS (Physician Practice Information Survey) transition discussed above and a change in the interest rate assumption used to calculate practice expense. Radiation oncologists (professional services) will experience an approximate 7 percent decrease for the same reasons as those listed for radiation therapy centers.

Table 7, left, shows the combined 2013 total allowed charge impact by specialty listed by CMS. Note: these percentages do *not* include the potential cost factor reduction. OI

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

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spotlight

The Park Nicollet Frauenshuh Cancer Center, St. Louis Park, Minnesota | Simplifying the cancer care process for patients

The story is one that is familiar to many cancer programs: fragmented oncology services, increasing patient volumes, and space so tight that closets are converted into physician offices. Oncology leadership and administration recognize a significant need for change. In the case of Park Nicollet Frauenshuh Cancer Center, the solution was unique. Why not bring everything to the patient? Prior to that solution, cancer care was being provided in two locations: Methodist Hospital and Park Nicollet Clinic in St. Louis Park. Oncology services were set up in what Mark Wilkowske, MD, medical director of Frauenshuh, described as a very typical way. A check-in area, a waiting area, a laboratory, doctors' offices, a treatment area—all the different components of care that patients had to travel to; many times all in one visit. Wilkowske and the cancer team saw the opening of a new center as a chance to implement an innovative "non-moving patient" strategy.

Going "Lean"

The program used the LEAN quality improvement process to remove errors, waste, and inefficient processes to streamline services and better serve patients and their families. As part of the LEAN process, administration held a week-long focus group prior to building the new center. A group of physicians, nurses, administrators, receptionists, architects, patients, and quality improvement specialists mapped out the existing care process to see how patients transitioned during their course of care. The focus group measured how many feet patients had to walk, the time spent waiting, and the amount of energy they expended while going through the care process.

"This idea came to mind: what if we just had patients arrive, and go back to a room and have everything come to them?" said Wilkowske. The plan was for patients to experience the infusion process, blood draw, the nursing evaluation, the doctor visit, the treatment itself, and then the checkout process including future appointment scheduling without ever having to venture to any other part of the cancer center. Even integrative therapy services such as massage, healing touch, acupressure, and music therapy would travel to patients in their treatment rooms.

The cancer care team piloted the program prior to building the new center—mock treatment rooms were set up for nurses, clinicians, front desk staff, and patients to test drive—and received positive feedback from patients and staff alike.

According to Laura Holasek, administrative director of Frauenshuh, the vision for the new cancer center was a calm healing environment to decrease the patients' stress as much as possible while conserving their energy. The cancer center could not look like your traditional healthcare setting.

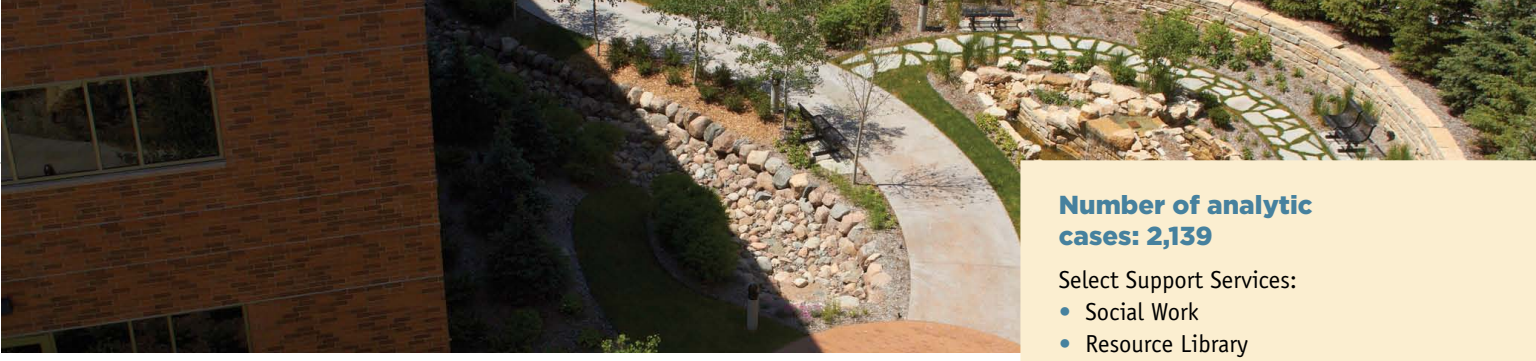
In 2009 the new 47,100-square-foot Frauenshuh Cancer Center opened its doors, inviting both patients and staff to experience a new model of delivering cancer services. In 2011 the cancer program received accreditation with commendation from the ACoS Commission on Cancer (CoC) and also earned Quality Oncology Practice Initiative (QOPI) certification from ASCO. Frauenshuh is the only cancer program in Minnesota to receive QOPI certification.

Quality Care in a Soothing Environment

The new center design incorporates as much natural light as possible along with soothing, earth-tone aesthetics. Patients and visitors enter through large glass doors and are immediately greeted by staff at the welcome desk. Adjacent to this area are volunteer services. Once patients are checked in, volunteers escort them directly to their treatment or exam room. Volunteers make sure patients are comfortable and offer them a pillow or blanket. The cancer center has more than 60 volunteers, many of whom are cancer survivors. Holasek said these volunteers offer not just a friendly face for patients, but also a level of understanding and deep commitment to the center from the volunteer staff.

Treatment rooms feature large windows that not only provide natural light but also offer views to the outside, reducing the feeling of being confined in a clinical setting. Scenic views are available throughout the facility benefiting both patients and staff. A wall of windows in the second floor staff break room overlooks the cancer center's healing garden.

One thing you won't find at Frauenshuh is an area with a straight row of 10 plastic chairs. The facility has several smaller sitting spaces for a cozier feel, as well



Number of analytic cases: 2,139

Select Support Services:

- Social Work
- Resource Library
- Support Groups
- Patient Navigation
- Integrative Therapy
- Palliative Care
- Patient Advisory Board
- Genetics Counseling
- Financial Services Representative.

as a garden room that includes views of the healing garden for friends and family members of patients to enjoy. Patients and visitors can meander through the tranquil healing garden as well.

Just about everything patients could need is located on the ground floor of the center, which facilitates ease of access for patients as well as an open, functional environment for staff to work together. The center design includes a special parking area for radiation patients with a door that leads directly to that department. "Patients receiving treatment can park easily, come right in, do self check-in, and get their treatment and get on with their day with as little interruption in their lives as possible," said Wilkowske.

The radiation oncology department is staffed by 3 FTE radiation oncologists, 2 FTE radiation oncology nurses, 2 FTE dosimetrists, 6.6 FTE radiation therapists, and 3 FTE physicists. State-of-the-art technology offered includes PET/CT, Varian 21EX linear accelerator, 21IX linear accelerator, and Novalis® shaped beam robotic surgery. Right down the hall is the medical oncology department staffed by 12 FTE medical oncologists and 14 FTE oncology nurses. Breast and general (incorporating GYN and brain) tumor boards meet weekly, with GI and Lung meeting about twice per month. The center is also staffed by 23.5 FTE treatment nurses, 3.3 FTE nurse practitioners, and 18.1 FTE frontline staff.

Adjacent to the radiation oncology and medical oncology departments is the pharmacy, psychotherapy services, psychiatry, and a chapel. Next to the center's entranceway is a dedicated meeting room for patient support and education groups.

A Better Way

In the past, one complaint patients voiced was that the chemotherapy chairs were uncomfortable. For the new non-moving patient model to succeed, Holasek knew that chair comfort was essential. "If we were going to provide a non-moving patient model for patients and for clinicians that chair also needed to lie flat like an exam table," she said. After doing research, they found that the chair they needed didn't exist on the market. The cancer team worked with a national design company; heavily involving patients and staff in the chair creation process. The resulting chair looked and felt like a comfortable recliner, allowing patients to put their feet up and control heat panels, but when it came time for the clinician exam, the chair could unfurl into a flat exam table.

Another tool instrumental in the success of the non-moving patient care model is Frauenshuh's electronic patient tracker. "Because the patient isn't moving we're not seeing the patient wait in the waiting room or seeing them in the lab or standing in front of the scheduling desk," said Holasek. The patient tracker identifies for staff where patients are in their care process; whether medication is being prepared for them or if they're waiting to see the clinician. This electronic system has helped the cancer team identify delays in the care process.

48-Hour Promise

While implementing the non-moving patient model was a significant commitment to providing patient-centered care, Frauenshuh has continued to look at ways to improve the patient experience. An issue that patients continued to bring up was wait time until their first appointment. Frauenshuh set a goal to get newly-diagnosed cancer patients in to see a doctor within the first 48 hours of diagnosis. So far, the cancer program has kept this promise, an achievement in which they take pride, but Wilkowske acknowledges that at times it can be a stretch. "It's been a point of controversy and discussion amongst the oncologists at various times along the way but overall we've continued to be very, very committed to the goal," he said. One of the adjustments made by the center was providing more guaranteed appointment slots for the 48-hour promise for newly-diagnosed patients. Overall, Wilkowske said patients are appreciative of this system and amazed at how quickly they can see an oncologist.

Research & Education

In 2011 the Frauenshuh Cancer Center accrued approximately 19 percent of its patients to clinical trials. Having an oncology research department conducting research studies right in the cancer center has been instrumental in this impressive accrual rate. The center's research nurses proactively seek patients to enroll in studies, often pre-reviewing charts and checking patient calendars to see what study opportunities are available so they can inform the oncologist prior to the patient's visit. Frauenshuh is also a part of the Metro CCOP system.

The cancer center's patient advisory board is very involved in outreach and education and is currently helping to create a new care guide for patients. Their focus going forward is helping to support the patient through learning and education in multiple modalities such as video, written material, discussions with staff and clinicians, and support groups.

Though the Frauenshuh Cancer Center boasts a robust and innovative program, it is constantly striving to better serve its patient population. "As our volumes grow, we want to continue to balance this innovative process that we have with the needs of the community," said Holasek. OI

tools

Approved Drugs

- Janssen Biotech, Inc. (*www.janssenbiotech.com*) announced that the U.S. Food and Drug Administration (FDA) has approved an expanded indication for **Zytiga® (abiraterone acetate)** in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer. The approval was based on a trial randomizing patients with metastatic castration-resistant prostate cancer who had not received cytotoxic chemotherapy to either abiraterone acetate plus prednisone or placebo plus prednisone. Treatment with abiraterone acetate improved radiographic progression-free survival.

- The FDA approved **Cometriq (cabozantinib)** (Exelixis, *www.exelixis.com*) to treat meduallary thyroid cancer that has spread to other parts of the body. The approval is based on a clinical study involving 330 patients with medullary thyroid cancer. Treatment with Cometriq increased the length of time a patient lived without cancer progressing (progression-free survival) and, in some patients, reduced the size of tumors (response rate).

- The FDA approved **Iclusig (ponatinib)** (Ariad Pharmaceuticals, *www.ariad.com*) to treat adults with chronic myeloid leukemia (CML) and Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). Iclusig blocks certain proteins that promote the development of cancerous cells. The drug is taken once a day to treat patients with chronic, accelerated, and blast phases of CML and Ph+ ALL whose leukemia is resistant or intolerant to a class of drugs called tyrosine kinase inhibitors (TKIs). Iclusig targets CML cells that have a particular mutation, known as T315I, which makes these cells resistant to currently approved TKIs.

- The FDA granted accelerated approval to **Synribo (omacetaxine mepesuccinate) for Injection** (Teva Pharmaceutical Industries Ltd., *www.tevapharm.com*) for the treatment of adult patients with chronic or accelerated phase CML with resistance and/or intolerance to two or more TKIs. The accelerated approval is based on combined data from two open label single-arm trials enrolling patients with CML in chronic phase or in accelerated phase.

- Genentech Inc. (*www.gene.com*) has received FDA approval of a 90-minute infusion for **Rituxan (rituximab) Injection**, starting at Cycle 2 for patients with non-Hodgkin's lymphoma (NHL) who did not experience a grade 3 or 4 infusion-related adverse reaction during Cycle 1. Patients with clinically significant cardiovascular disease and high circulating lymphocyte counts (>5000/mcL) are not recommended to receive the faster infusion.

Drugs in the News

- The FDA has granted Cell Therapeutics, Inc. *(www.celltherapeutics.com)* orphan drug designation for **Opaxio™ (paclitaxel poliglumex, CT-2103)** for the treatment of glioblastoma multiforme, a malignant brain cancer. The designation was granted based on preliminary activity seen from Phase II results of Opaxio when added to standard therapy (temozolamide [TMZ] plus radiation).

- OXiGENE, Inc. *(www.oxigene.com)* announced that its product candidate **OXi4503** has been granted orphan drug designation by the FDA for the treatment of acute myelogenous leukemia (AML). A Phase I study of OXi4503 for the treatment of patients with AML or myelodysplastic syndrome (MDS) is currently underway.

- The FDA has expanded labeling to include the results of an additional trial evaluating the safety and efficacy of **pemetrexed** (Alimta, Eli Lilly and Company, *www.lilly.com*) for the initial treatment of patients with locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC) followed by pemetrexed maintenance in patients whose disease has not progressed after four cycles of platinum and pemetrexed as first-line chemotherapy.

- Bayer HealthCare *(www.bayer.com)* and Onyx Pharmaceuticals *(www.onyx.com)* announced that the FDA granted priority review to the New Drug Application (NDA) for **Stivarga® (regorafenib) tablets** to treat patients with metstatic and/or unresectable gastrointestinal stromal tumors whose disease has progressed despite prior treatment with two kinase inhibitors. The submission was based on data from the Phase III GRID study.

- Astellas Pharma US, Inc. *(www.astellas.us)* has submitted a supplemental NDA to the FDA seeking approval for **Tarceva® (erlotinib) tablets** for first-line treatment of patients with locally advanced or metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) activating mutations as detected by an approved test. The sNDA submission is based on results of the international EURTAC trial, a prospective, randomized, controlled Phase III trial evaluating the first-line use of Tarceva versus platinum-based chemotherapy in patients with EGFR activating mutation-positive advanced NSCLC.

- XBiotech *(www.xbiotech.com)* announced that the FDA has granted Fast Track Designation for its anti-cachexia drug **Xilonix™**. The therapeutic antibody was shown in a previous clinical study to stop or reverse cachexia in about a third of all advanced cancer patients treated. Under the Fast Track program, XBiotech will now launch a Phase III study to treat advanced colorectal cancer patients suffering from cachexia.

Assays and Genetic Tests in the News

- Hologic, Inc. *(www.hologic.com)* announced that the FDA approved the **APTIMA HPV 16 18/45 Genotype Assay** for use on its TIGRIS instrument system. The test is intended to test specimens from women with APTIMA HPV Assay positive results and is approved for two uses: adjunctively with the APTIMA HPV Assay in women 30 years and older in combination with cervical cytology to assess the presence or absence of specific high-risk genotypes 16, 18, and/or 45; adjunctively with the test in women 21 years or older with atypical squamous cells of undetermined significance cervical oncology results to assess the presence of genotypes 16, 18, and/or 45. The results of this test are not intended to prevent women from proceeding to colposcopy.

- Phenogen Sciences, Inc. *(www.phenogensciences.com)* announced the immediate availability of **BREVAGen™**, a predictive risk test for women for sporadic, hormone-dependent breast cancer. The risk assessment test examines a woman's clinical risk factors, such as her lifetime exposure to estrogen, combined with scientifically-validated genetic markers to determine each patient's personalized five-year and lifetime risk of developing breast cancer, regardless of family history.

- Quest Diagnostics *(www.questdiagnostics.com)* announced the availability of a new laboratory test that identifies molecular changes to cervical cells that increase the likelihood a woman may develop cervical cancer. The **Cervical Cancer *TERC* Test** is designed to help physicians identify women who are at increased risk of developing malignancy, unless treated, after receiving unclear results for cervical cancer from standard screening tests. The new test is designed as an adjunct to conventional Pap and human papillomavirus (HPV) tests. It detects abnormal changes to the TERC gene and chromosome 3 to provide a risk assessment of progression to cervical cancer in women who receive indeterminate Pap and/or HPV test results.

- Cytocell Ltd. *(www.cytocell.com)* announced the availability of a new molecular cytogenetic test designed to identify the presence of gene rearrangements associated with a specific form of non-small cell lung cancer. The **Cytocell ROS1 Breakapart FISH probe** uses Fluorescence *In Situ* Hybridization (FISH) technology to detect rearrangements of the ROS1 gene on chromosome 6 in band 6q22 in tumors.

- Roche *(www.roche.com)* announced the U.S. market availability of the **Elecsys HE4 assay**, an FDA-approved test used in monitoring patients with ovarian cancer. The HE4 test is used as an aid in monitoring the recurrence of progressive disease in patients with epithelial ovarian cancer.

Approved Devices

- The FDA has approved **ExAblate® MRI-guided Focused Ultrasound** (InSightec Ltd., *www.insightec.com*) as a therapy to treat pain from bone metastases in patients who do not respond or cannot undergo radiation treatment for their pain. ExAblate was also approved by the FDA in 2004 as a non-invasive, outpatient therapy for uterine fibroids. This second approval was based on results from an international, multi-center, randomized clinical study in which patients who underwent ExAblate therapy reported clinically significant pain relief and improvement of quality-of-life during follow-up three months after treatment.

Devices in the News

- Life Technologies Corporation *(www.lifetechnologies.com)* announced it has received FDA 510 (k) clearance for its **OpTmizer™ CTS™ T-Cell Expansion Tissue Culture Medium,** a reagent that is now cleared as a Class 2 medical device and offers cost and time-saving advantages for transitioning studies from the research bench to clinical trials. It is currently being used in multiple clinical trials in the United States.

- DFINE, Inc. *(www.dfineinc.com)* announced the launch of the **STAR™ Tumor Ablation System** which, along with targeted Radiofrequency Ablation™ (t-RFA) therapy, allows physicians to provide patients with rapid pain relief from metastatic spinal tumors in a single, minimally invasive treatment. The STAR system was developed specifically for the palliative treatment of metastatic vertebral body tumors. t-RFA therapy is typically an outpatient procedure and can be performed using local anesthesia through a small incision.

New C-Code for Perjeta™ (pertuzumab)

The code: C9292 (injection, pertuzumab, 10 mg) is for infusions administered to Medicare patients in hospital outpatient facilities. The C-code went into effect on Oct. 1, 2012 and can be used until a permanent J-code is assigned in 2013.

Building an Oncology Fellowship Program

A unique hospital and school of medicine collaborative

BY SHEILA STEPHENS, DNP, MBA, AOCN®, AND MARIA TRIA TIRONA, MD, FACP

Maria Tria Tirona, MD, FACP, director of medical oncology at the Edwards Comprehensive Cancer Center and the director of the oncology fellowship program.

By 2020 the United States will experience a shortage of 2,550 to 4,080 oncologists.[1] At the same time, demand for their services is estimated to increase by 48 percent.[1] Even though the number of new oncologists entering the market is projected to outnumber the oncologists retiring from the workforce, there will still be a 34 percent deficiency in visit capacity.[2] The American Society for Clinical Oncology's (ASCO) Workforce Strategic Plan, developed in response to this analysis, has made a number of recommendations, including increasing the number of fellowship openings and expanding sources of funding for fellowship programs.[3] However, few existing oncology fellowship programs have plans to expand, citing lack of financial resources as the major barrier.[2]

Community cancer centers can play an important role in increasing the number of future oncologists by partnering with schools of medicine and graduate medical education committees to develop oncology fellowship programs and assist with the funding of such programs. Cabell Huntington Hospital, a regional hospital in West Virginia, stepped up to the challenge. The hospital's Edwards Comprehensive Cancer Center (an ACCC-member institution) came together with the Joan C. Edwards School of Medicine at Marshall University to create a collaborative medical oncology fellowship program. Interest in this innovative fellowship program was immediate; the program accepted its first two fellows in 2012 out of a pool of 84 applicants.

This article describes the lessons learned in the development of our medical oncology fellowship program and delineates the responsibilities of each partner (see Table 1, page 28).

The Players

Opened in 1954 as a county hospital, Cabell Huntington Hospital in Huntington, West Virginia, has cared for patients for more than 50 years. The bond between the community and the hospital remains strong and serves as the foundation for its commitment to care. Marshall University School of Medicine was established in 1977 as a state-supported, community-based medical school. Cabell Huntington Hospital has maintained a strong affiliation with both the university and the school of medicine, playing an integral role in the education of medical students, residents, fellows, and a variety of other specialized healthcare providers.

A generous donation from a local philanthropist who had needed to travel outside Appalachia for cancer care funded construction of the Edwards Comprehensive Cancer Center. This donation set the stage for collaboration between the hospital, the school of medicine, and the foundation (the Edwards Foundation, Inc.) that was created to realize the vision of the comprehensive cancer center. Medical staff at the cancer center is provided through a faculty lease agreement between Cabell Huntington Hospital and the Joan C. Edwards School of Medicine at Marshall University. Cabell Huntington Hospital also provides the staff, operational expenses, and day-to-day operation of the cancer center. The idea of a collaborative medical oncology fellowship began at the groundbreaking of the Edwards Comprehensive Cancer Center. Support from the foundation came from funds set aside for construction costs and to recruit and retain physicians at the new cancer center.

Program Development

While fellowship programs are overseen at the national level by the Accreditation Council for Graduate Medical Education (ACGME), Marshall University School of Medicine's Graduate Medical Education Committee (GMEC) provides local oversight.[4] Medical oncology faculty at Edwards Comprehensive Cancer Center is responsible for individual oversight of the fellows.[4] When recruiting medical staff for the new cancer center, the hospital gave strong consideration to potential faculty for a fellowship program.

A physician with experience related to oncology fellowship programs was recruited and named as program director for the Medical Oncology Fellowship Program. When the minimum number of key faculty was in place, Cabell Huntington Hospital then recruited a fellowship coordinator. This two-person team (program director and coordinator) began the process that resulted in an application to ACGME, the private professional organization responsible for the accreditation of graduate medical education programs. The application provides the framework for the fellowship program and demonstrates how requirements will be met. This application (also

Table 1. Oncology Fellowship Program Responsibilities

CABELL HUNTINGTON HOSPITAL	FOUNDATION	JOAN C. EDWARDS SCHOOL OF MEDICINE
Faculty lease agreement, including administrative time for program director	Reimbursement for fellows' salaries and benefits	Employer: medical oncology faculty and fellows, other physician faculty, residents, and fellows
Fellowship coordinator and administrative support	Conference expenses, including travel and registration	GMEC oversight and internal review
Office and clinic space for faculty and fellows	Reference texts and software	Faculty development
Clinic staff: RNs, medical assistants, infusion, scheduling, receptionists, billing, financial support, psychosocial support, and housekeeping	Lodging during BMT rotation	Guidance for program director and fellowship coordinator
Grand Rounds, Tumor Board, Multidisciplinary Clinics, and other required educational lectures and meetings		General policies and orientation
Genetic NP, clinical trials, clinical nurse specialist, and palliative care		Email and library access
Computers, phones, office supplies, Internet access, and pagers		
Lab coats and laundry service		
Meeting rooms, equipment, and refreshments		
EMR		
Pharmacy support		
Specific policies, orientation, and fellowship manual		

called the Program Information Form) must reflect a thorough knowledge of the requirements, along with the description of a well-designed program.[5]

ACGME sets the standards on requirements for key faculty along with the faculty-to-fellow ratio. With four key faculty members (board-certified medical oncologists) in place and the acceptance of the Program Information Form, the team began to develop a competency-based curriculum specific to our medical oncology fellowship program. The plan: to accept two fellows for each fellowship training year.

Although Cabell Huntington Hospital is accredited by the American College of Surgeons' Commission on Cancer (CoC) and has an active cancer conference, other components needed to be in place to provide the foundation for a medical oncology fellowship program. The program director forged a bond with the bench scientists at Marshall University and began a monthly Grand Rounds series, bringing nationally renowned speakers and researchers for faculty development. Another component was the development of an annual conference to educate primary care providers on how to recognize and treat common problems in hematology and oncology often seen in the primary care setting.

Competency-Based Fellowship Curriculum

The curriculum for the oncology fellowship program must meet specific requirements based on the six competencies required by all graduate medical education programs as the basis of instruction. It is also important to strike a balance between clinical experience and educational activities, such as mandatory lectures, journal club, research committee, case conferences, etc. While ACGME provides the oversight and the minimum criteria for an approved fellowship program, the American Board of Internal Medicine (ABIM) is the certifying body for internists and internal medicine subspecialties. With a goal for all fellows to earn board certification on successful completion of the program, the ABIM content blueprint served as a backdrop for our curriculum development.[6] It was also necessary to integrate both the ABIM and ACGME requirements with the core curriculum recommended by ASCO.[7] Support and review by the school of medicine's GMEC was a valuable resource for our program development and implementation.

Clinical Setting

An important aspect of our medical oncology fellowship program is the clinical experience. Cabell Huntington Hospital provides an enriched inpatient rotation and the Edwards Comprehensive Cancer Center offers patients and staff a continuity clinic and outpatient rotations. The hospital hosts an all-private 18-bed oncology unit, including four positive-air-flow patient rooms with attached ante rooms. The 70,000-square-foot cancer center houses:

- Physician offices
- Exam rooms

- A 14-chair infusion center
- A satellite lab
- An onsite pharmacy with hood
- A NAPBC-accredited breast center with mammography, ultrasound, and stereotactic biopsy
- Radiation oncology services.

The number of patients has doubled since our cancer center opened. In 2011, there were 1,098 cases diagnosed or treated, assuring an adequate number of cases and diversity of diagnoses and patients for our fellowship program.

The complement of physicians and services at the Edwards Comprehensive Cancer Center includes fellowship-trained oncology surgeons in breast, head and neck, urology, orthopedics, and gynecology, along with radiation oncologists. Other cancer center staff includes nurses, advance practice nurses, physician assistants, medical assistants, billing experts, front desk staff, technicians, and other support staff to assure optimal care and support of the cancer patient. Cabell Huntington Hospital offers specialized pathologists, radiologists, intensivists, infectious disease specialists, hospitalists, and pain and palliative medicine physicians to provide the range of experiences necessary to train future medical oncologists.

Our team developed an affiliation with a regional NCI-designated facility, The Ohio State University Comprehensive Cancer Center, to offer a bone marrow transplant rotation in the second year of the fellowship program. Fellows will be provided paid lodging near the NCI-designated facility during that rotation. In addition, the Joan C. Edwards School of Medicine has a translational research lab on the top floor of the Edwards Comprehensive Cancer Center that can be used during the research component of the fellowship, depending on each fellow's interest.

Funding the Program

The faculty lease agreement is already in place between Cabell Huntington Hospital and the Joan C. Edwards School of Medicine to provide a clinical practice site for oncology physicians at the cancer center. The school of medicine employs our oncologists as faculty and the hospital provides the school of medicine reimbursement for physician services, based on a fixed salary and productivity scale. The program director of the oncology fellowship program carves out time from her clinic schedule to carry out the program's administrative responsibilities and required duties. The program director and other key faculty must also contribute education and oversight time, which can result in decreased productivity for clinical operations. In the end, Cabell Huntington Hospital assumes fiscal responsibility for the operation of the clinical practice and the cancer center, including office and support staff, accreditation requirements, facility maintenance, overhead, equipment, supplies, and billing.

The fellows are also employees of the Joan C. Edwards School of Medicine, with their salaries and benefits reimbursed by the Edwards Foundation. The foundation also reimburses the expenses for registration and travel to conferences outside the facility and required texts and software to assist in the education process. Cabell Huntington Hospital underwrites other expenses for the fellows, including:

- Office space
- Computers
- Phones
- Pagers
- Office support and clinical staff
- Pharmacy support
- Expenses related to the fellowship coordinator position.

One study found that annual non-salary costs of a fellowship program could be as high as $25,000 per fellow,[4] and all of these costs are provided by Cabell Huntington Hospital.

Lessons Learned

While the ACGME does not recommend an associate program director for fellowship programs of this size, our team believes that it should be a requirement. We suggest all oncology fellowship programs name an associate program director and that all key faculty be involved from the beginning in the development of the oncology fellowship program and the Program Information Form. When our original program director abruptly resigned and we were unsuccessful in recruiting another seasoned program director, we faced a steep learning curve to keep forward momentum for the fellowship program. Luckily, a key faculty member stepped forward to assume program director duties. Additionally, Cabell Huntington Hospital was able to provide an assistant with experience in residency programs, writing a competency-based curriculum, and developing rotation schedules and orientation manuals to aid the new program director and fellowship coordinator. Still, the start of our oncology fellowship program was delayed six months and, fortunately, the fellows who had already been accepted were able to work within the changes.

In retrospect, we've found that it would have been helpful to lay out all expenses and responsibilities prior to the beginning of our fellowship program. There have been times when it has been unclear who should receive the charge for a specific item or service.

Despite these challenges, the future shortage of oncologists remains a real concern and we believe it is important

We suggest that all oncology fellowship programs name an associate program director and that all key faculty be involved from the beginning in the development of the oncology fellowship program…

Edwards Comprehensive Cancer Center at Cabell Huntington Hospital opened in 2006 to treat children and adults. In addition to adult and pediatric medical oncologists, hematologists, and radiation oncologists, it has the area's only fellowship-trained surgical oncologists in the fields of breast cancer, head and neck cancer, orthopedics, and urology.

12 13 14 15

to develop similar oncology fellowship programs. Hospitals can play an important role. In partnership with schools of medicine, ACCC-member hospitals can help expand the number of medical oncology fellowship programs and available training slots.

Our new program welcomed its first fellows in July 2012, and we continue to learn together. We have found that the oncologist shortage is not due to the number of residents wanting to specialize. In fact, the first year our program was listed by the National Residency Matching Program, we received 84 applications via the Electronic Residency Application System for our two positions. We are currently reviewing applications and interviewing candidates for the second year of our fellowship program. OI

—Maria Tria Tirona, MD, FACP, is director of medical oncology at the Edwards Comprehensive Cancer Center, Huntington, W.V., and director of the oncology fellowship program. Sheila Stephens, DNP, MBA, AOCN, is a palliative care nurse at the Edwards Comprehensive Cancer Center, Huntington, W.V.

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Community Health Needs Assessments

EVERYTHING COMMUNITY CANCER CENTERS NEED TO KNOW TODAY

BY D. WESLEY SMITH, MD, FACS

This article defines Community Health Needs Assessments (CHNAs), explains what information should go into the assessment, and describes how hospitals should use their CHNA to develop an implementation strategy. Included is a process timeline and suggestions for what hospitals need to be doing *now* to prepare.

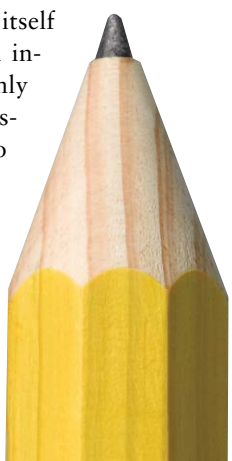
The Community Health Needs Assessment

A Community Health Needs Assessment (CHNA) is a systemic process that involves the entire community in identifying and analyzing the community's health needs and the assets that are available in the community to prioritize, plan, and act on unmet needs. CHNAs are part of the Affordable Care Act (Public Law 111-148), under Section 9007, which largely applies to not-for-profit hospitals [501(c)(3) organizations]. (Note: for-profit hospitals are not required to submit a CHNA. These hospitals may *choose* to do something similar, but they do not have to do it.)

The Affordable Care Act (ACA) requires that a qualifying hospital must perform a CHNA every three years. The first CHNA must be completed and made widely available within the fiscal year which begins after March 23, 2012, the second anniversary of the enactment of the ACA.

Why Are CHNAs Important?

While the IRS has promised "further guidance," the rules and regulations that will guide the CHNA process have yet to be fully defined. However, the legislative language within the ACA has led some to believe that CHNAs may become a part of the new standard by which hospitals will be measured in determining not-for-profit status. Despite the current questions, the idea behind this potential use for the CHNAs is simple. By and large, most not-for-profit hospitals have been able to qualify for 501(c)(3) status by virtue of the care they provide to uninsured individuals, known as "uncompensated care." The current administration's position is that by 2014 (if the states in which the hospitals are located decide to expand their Medicaid programs) most hospitals should see their uninsured burden reduced and eventually eliminated as the ACA is fully implemented and the majority of the U.S. population avails itself of the increased opportunities for health insurance. While this transition will certainly take longer than originally envisioned, hospitals may find it increasingly difficult to use uncompensated care as the sole justification for not-for-profit status. Bottom line: CHNAs may be one of the vehicles that the federal government



will use to decide which hospitals deserve and receive 501(c)(3) status.

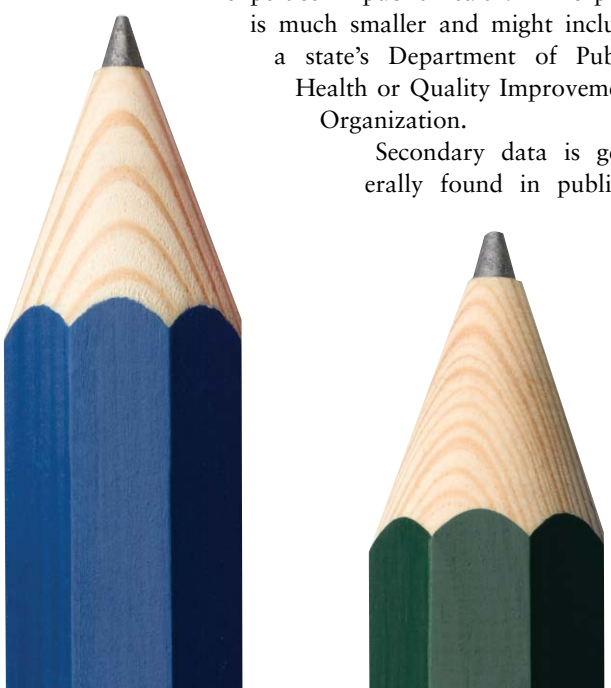
CHNA Requirements

Qualifying hospitals must not only create the CHNA, they must also develop an implementation strategy. They must:

1. Conduct the needs assessment
2. Develop a formal implementation strategy to address the unmet health needs in the community.

The hospital's CHNA must include several components: a description of the community; the assessment process used by the hospital; and finally a prioritized list of the top healthcare issues the hospital sees in its community. The CHNA must also identify the organizations or other groups that the hospital is partnering with. This component is unique in that it may open opportunities for collaboration. For example, two competing hospitals might come together to work on data collection and implementation efforts related to the CHNA.

The Community Description. This section describes the community served by the hospital. For this component, hospitals will need to collect several types of data. Primary data will come from the hospital itself. Using either admissions or discharge data, the hospital will determine the "community" served by the hospital. This community can be defined geographically (e.g., city, county, zip codes), by service line (e.g., OB services, cardiology services) or by some combination of the two. With the community defined, hospitals will then identify and gather information from "key informants" within their community. Key informants might include elected officials or professionals in the local community. Hospitals must also gain input from "those with special knowledge and expertise in public health." This pool is much smaller and might include a state's Department of Public Health or Quality Improvement Organization.



Secondary data is generally found in publicly available resources. Hospitals will likely find it useful to identify comparison communities. Websites, such as *www.communityhealth.HHS.org,* can assist a hospital in finding an array of comparison communities. The secondary data will help hospitals compare their communities to other community, state, and national healthcare norms.

The Assessment Process. When the primary and secondary data are collected and tabulated the analysis is performed. The methodology of the data collection and the process of analysis must be documented within the final CHNA report.

The Community's Top Healthcare Needs. Finally, the CHNA must include a prioritized needs list of the top healthcare issues derived from the analysis of the primary and secondary data. The list should be concise; it may even fit on a 3x5 index card, for example, obesity, smoking, teenage pregnancies, etc.

Also Required: An Implementation Strategy

A hospital's board of directors or governing body (or a group designated by the board or governing body) is responsible for developing the implementation strategy, which must include a plan for what the hospital is going to do regarding the needs identified in the CHNA.

Once the implementation strategy is completed, it must be approved by the hospital board. With the implementation strategic plan in place, hospitals must then begin work to implement the plan. It is important to note that the CHNA *and* the corresponding implementation strategy must both be completed within the fiscal year of record. So, for example, if a qualifying hospital's fiscal year began on April 1, 2012, the facility has until March 31, 2013, to complete the CHNA and to develop an implementation strategy that is approved by the hospital board.

Putting the Implementation Strategy to Work

Let's go back to that 3x5 index card listing the hospital's top community healthcare issues. The hospital must now determine which of these issues to target. The facility does not have to work on all issues at once, but the implementation plan must clearly identify which issues the hospital will address, and provide justification for those issues not addressed. In other words, the hospital's implementation strategy must clearly spell out:

- The top community health issues
- The issues the hospital plans to address in its implementation strategy
- The issues the hospital does *not* plan to currently address in its implementation strategy
- The reasoning behind these choices
- The anticipated impact of the implementation strategy.

Dr. Smith presented this information at ACCC's 29th National Oncology Conference. To hear the entire presentation, as well as sessions on ICD-10 implementation, delivering effective navigation services, and integrating hospitals and practices, go to: *www.accc-cancer.org/meetings/NOC2012-Virtual.asp*.

Hospitals will need about six months to gather and analyze the required data for their Community Health Needs Assessment.

At present "anticipated impact" is a somewhat nebulous term, and we are awaiting further clarification from the federal government. That said, a concept more familiar to the healthcare industry is "community benefit." Hospitals spend a lot of time calculating their community benefit, often expressed in terms of a dollar amount. Many believe that there are indications from the IRS that over time more and more requirements will begin to restrict the definition of "community benefit."

Here is a possible scenario for consideration. In the past, Hospital A conducted an anti-smoking campaign. The hospital produced or purchased literature, sent staff to schools or other community venues, and spent time and resources educating the community about the dangers of smoking. It was a fairly straightforward process for Hospital A to put a dollar amount on that campaign and call it a "community benefit." Many think it's likely that the federal government will require hospitals to gather follow-up data to measure the impact of these programs. For example:

- What is your teenage smoking rate?
- What is your adult smoking rate?
- How do you know that this campaign will be effective in reducing those rates?
- What outcomes will the campaign measure and report on?
- What did Hospital A gain from spending X amount of dollars on this campaign?

If "anticipated impact" develops along these lines, hospitals will have to carefully vet the interventions they choose to support. Further, hospitals will have to re-measure the impact of these interventions over time, and likely demonstrate that they have been able to move the needle on these issues.

An Opportunity for Collaboration

It's important to remember that hospitals don't have to go it alone. CHNAs offer opportunities for collaboration and partnership. Think about your marketplace competitors. Are their health needs assessments going to differ greatly from yours? Probably not. In fact, most CHNAs are likely to identify similar needs across an entire state; stakeholders will face the same issues. The legislative language allows for collaboration on these initiatives, supporting the thought that combined efforts may have a larger impact than many smaller, unaligned efforts.

At present, hospitals must report on the "anticipated impact" of their implementation strategy by clearly communicating:

- What the hospital is going to do to solve the issues; what interventions will be used
- Who the hospital will partner with
- What resources the hospital will commit to address the needs
- What will be the result of the interventions.

The Timeline

As mentioned above, hospitals are required to perform a CHNA every three years beginning with the fiscal year which begins after March 23, 2013. Hospitals will need about six months to gather and analyze the required data for their Community Health Needs Assessment. The hospital board is then required to develop an Implementation Strategy that addresses the unmet needs identified in the CHNA. The strategy should include: the needs to be addressed, the interventions selected to address the needs, the resources to be expended in deploying the interventions, and finally the anticipated results of the hospital's efforts. The CHNA should be made widely available and the hospital board should sign-off on the implementation strategy within the fiscal year of record.

Final Takeaways

CHNAs are a requirement for most not-for-profit hospitals. Be aware that your hospital may be required to do a CHNA. In areas with more than one hospital, more than one facility may have to do a CHNA, creating strong possibilities for collaboration. Most important, CHNAs offer many potential benefits for your patients by helping to develop real-world solutions for issues related to underserved and minority populations, uninsured or underinsured patients, and high-risk patients. OI

—D. Wesley Smith, MD, FACS, is CEO of the Alabama Quality Assurance Foundation, Birmingham, Ala.

CALL FOR ENTRIES

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Deadline for Submissions: March 18, 2013

RECEIVE RECOGNITION FOR THE VALUE YOU BRING TO PATIENTS AND YOUR COMMUNITY

"Winning the Innovator Award is a great way to validate that our organization is thinking 'outside the box' in respect to outreach programs. We appreciate opportunities to showcase our achievements and share our program processes and outcomes."

Jamie Harness
Program Coordinator,
Cancer Services, OhioHealth - Grant Medical Center

"The national recognition helped support continued efforts to promote the program. Even though our program is not a money maker, its recognition through this award has helped keep our supportive care clinics in the spotlight as something requiring continual improvement vs. something to be tossed aside."

Robert Mancini, PharmD, BCOP
Oncology Pharmacist, St. Luke's Mountain States Tumor Institute

Now in their third year, the Association of Community Cancer Centers Innovator Awards, sponsored by GE Healthcare, recognize and honor pioneering strategies for the effective delivery of cancer care in the community setting. Winners gain national visibility as both ACCC and GE Healthcare promote your innovations to oncology care providers and the broader healthcare community.

Innovations should advance the goals of improving access, quality, and/or cost effectiveness of cancer care in one of the following categories:

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- ★ Treatment and Technology
- ★ Outreach

Innovator Award winners will share their innovations through presentations at ACCC's National Oncology Conference (October 2–5, 2013, in Boston, Massachusetts), online, and in print.

All entries will be peer reviewed. Applicants must be affiliated with ACCC as Cancer Program Members.

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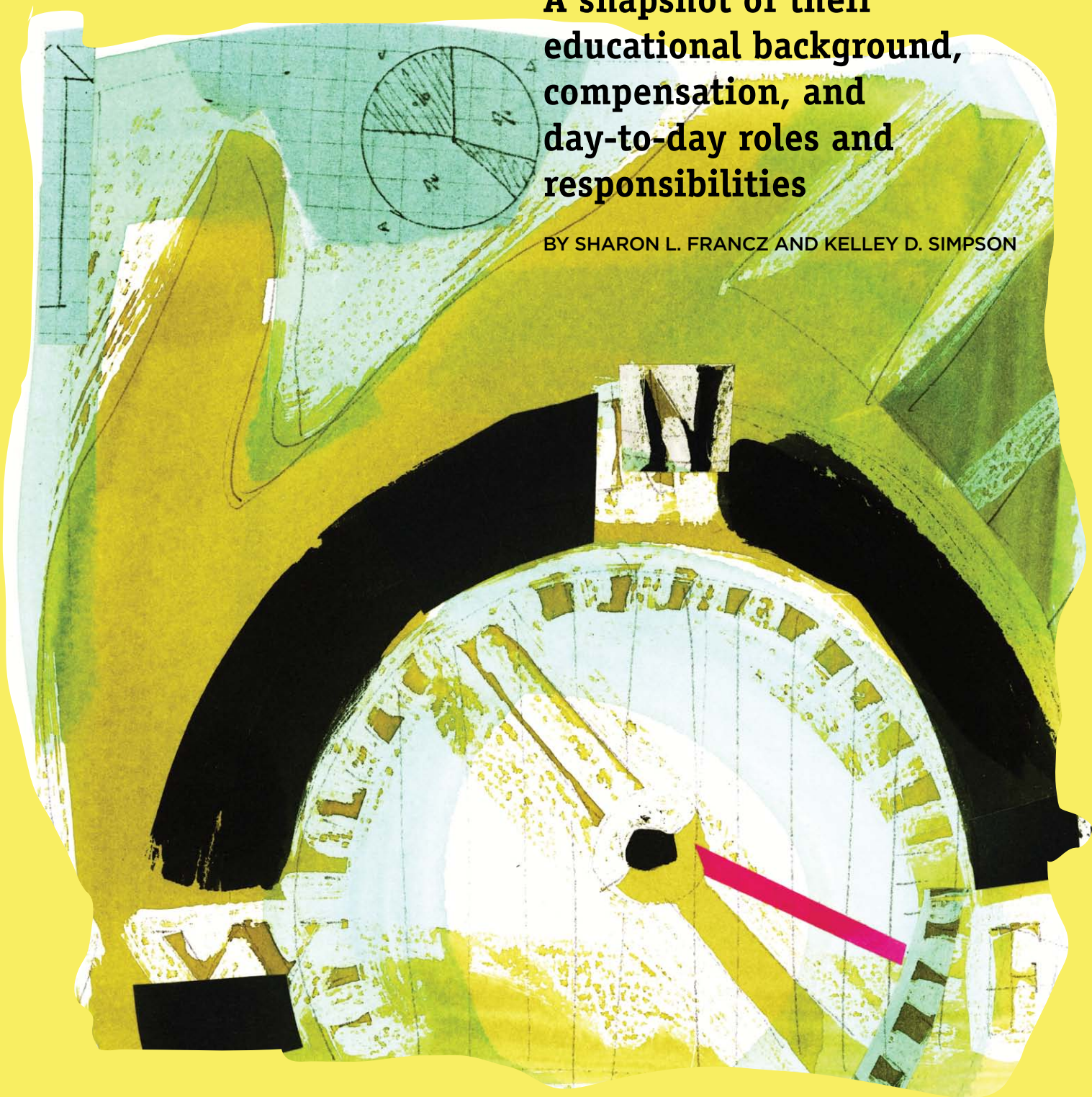
Oncology

A snapshot of their educational background, compensation, and day-to-day roles and responsibilities

BY SHARON L. FRANCZ AND KELLEY D. SIMPSON



Nurse Navigators

The life-changing event of a cancer diagnosis causes fear, anxiety, and confusion for patients and families. In addition to questions and concerns about the disease and its impact on their quality of life, today patients and families also face far more complex treatment and follow-up decisions than they have in the past. Treatment may involve surgery, followed by several rounds of chemotherapy and radiation, which can last hours at a single session. Patient care teams may also include up to a dozen specialists. Hospital and health systems nationwide are increasingly turning to oncology nurse navigators to provide needed support and guidance to help patients and families traverse the complexities of the cancer care delivery system.

A New Standard in Cancer Care

Across the country, patient navigation has rapidly become an essential component of cancer care. Since its early days in the 1990s with Harold Freeman's model (see box on page 42), patient navigation has demonstrated great promise with reducing or eliminating many of the common barriers associated with cancer care. Recent studies have also found that cancer patients assigned to a patient navigator were about 20 to 30 percent more likely than control subjects to comply with diagnostic follow-up care after an abnormality was detected.[1]

This finding and similar evidence-based research has led oncology-related accrediting organizations to integrate patient navigation as a required standard for program accreditation, including the National Accreditation Program for Breast Centers, which instituted a patient navigation standard in 2009. Most recently, the Commission on Cancer (CoC) of the American College of Surgeons added standard 3.1 that emphasizes the need and importance of navigation services. This standard, initiated in 2012, requires the phase-in and documentation of navigation services by 2015. To meet the standard, the CoC requires cancer programs to:

1. Conduct a community health needs assessment at least once every three years to address healthcare disparities and barriers to care for patients (see pages 32–34 for more)
2. Establish a patient navigation process and identify resources to address barriers that are provided either on site or by referral to community-based or national organizations
3. Annually assess barriers to care and the navigation process to evaluate, document, and report findings to the cancer committee
4. Modify or enhance annually the patient navigation process to address additional barriers identified by the community health needs assessment.

Oncology Nurse Navigators

Institutions are increasingly using oncology nurse navigators to assist with the management of cancer patient access, diagnosis, and treatment because of the navigators' deep understanding of our healthcare system and experience communicating with a range of healthcare professionals within our communities.

A focus on coordinating and improving patient care and outcomes is consistent across all navigation programs; however, the dynamics of each institution and patient population shape the specific roles and responsibilities of oncology nurse navigators within each program. Some key factors that could influence the development of a navigation program include:

- Patient dynamics (e.g., the number of patients, race, incidence and case mix, ethnicity, and income distribution)
- The medical staff model of the cancer center (e.g., employed, private practice, and/or mixed)
- Administration and physician support for the navigation program
- Commitment to tumor-specific, supportive care, and/or disparities programs
- Personality, credentials, and "flexibility" of the oncology nurse navigator
- Size, scope, and geographic proximity of all program elements—the total program.

The Role of the Oncology Nurse Navigator

Working on a multidisciplinary cancer care team, oncology nurse navigators serve in many roles—both within and beyond the scope of their clinical responsibilities—to benefit the patient. According to the National Coalition of Oncology Nurse Navigators (NCONN), navigators often serve as clinical facilitators, care providers, educators, counselors, and patient advocates. For example, in a recent NCONN survey, one breast care navigator described her duties at a busy breast center as "ensuring timely follow-up and care coordination for patients with diagnostic mammograms with BIRADS (Breast Imaging Reporting and Data System) 4 classifications, or possible malignancies." In addition to educating patients on the biopsy procedures (ultrasound and stereotactic) and assisting with both scheduling and performing the actual biopsy, this nurse navigator also provides critical follow-up with the patient and referring physician in the six months following the procedure.

Oncology nurse navigators provide an ongoing, consistent point of contact for patients and families as they transition between different care delivery settings along the care continuum, including diagnostic services, inpatient and outpatient settings, specialty consultations, research, hospice, and/or palliative care.

They help expedite the time to diagnosis, ensure fewer delays in treatment, facilitate communications between the various care providers, and answer questions and clarify complicated clinical information for patients and families. As patient advocates, oncology nurse navigators help connect patients and families to other medical or community resources they may need during or following their course of treatment, such as nutrition, transportation, financial assistance, and/or support groups.

The National Coalition of Oncology Nurse Navigators

NCONN defines the oncology nurse navigator as a professional whose clinical nursing expertise guides patients, families, and caregivers to informed decision-making; collaborating with a multidisciplinary team to allow for timely cancer screening, diagnosis, treatment, and increased supportive care across the cancer continuum. When NCONN first formed in 2008, the majority of oncology nurse navigators were employed by hospital systems; however, this trend is slowly changing. More and more medical and radiation oncology practices are adding navigation as a service offering. According to data that individuals must provide on the NCONN membership application, oncology nurse navigators are most often found in the community hospital setting, with about 60 percent employed by a hospital or health system, and the remaining working for oncology clinics or medical oncology practices. The oncology nurse navigator's role in patient education is vast, encompassing:

- Disease-specific navigation
- Treatment options
- Processes
- Clarification on physician-provided information
- Directives
- Information on what patients can expect overall on the cancer journey.

In 2009 NCONN published the first competencies that defined the role of the oncology nurse navigator (see page 41). NCONN developed these competencies through consultation with active practicing professional oncology nurse navigators in a wide variety of healthcare settings throughout the United States. The core competencies cover five areas of proficiency, including:

1. Professional, Legal, and Ethical Nursing Practice
2. Health Promotion and Health Education
3. Management and Leadership
4. Negotiating the Healthcare Delivery System and Advocacy
5. Personal Effectiveness and Professional Development.

Table 1. Common Patient Barriers

FINANCIAL BARRIERS
Unable to afford health insurance
Medicare or Medicaid ineligibility
Losing employment that provides healthcare insurance
Lack of affordable cancer services
LOGISTICAL BARRIERS
Lack of transportation
Living at a far geographic distance from healthcare
Lack of reminder system(s)
Lack of understandable cancer information
SOCIO-CULTURAL BARRIERS
Limited social support
Inadequate health literacy

Source: American Cancer Society. *Report to the Nation: Cancer in the Poor.*

What the Data Tells Us

According to NCONN membership data, oncology nurse navigators are concentrated most heavily in the Midwest,

Figure 1. NCONN Members by U.S. Region

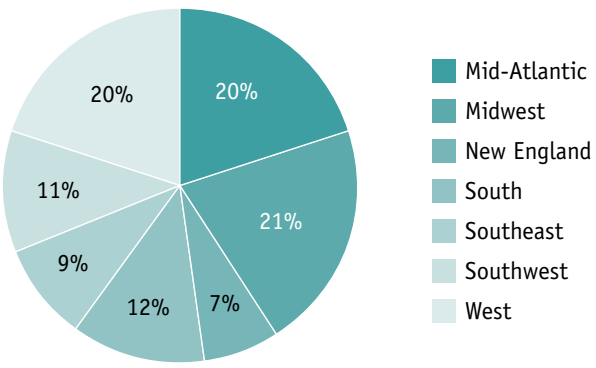
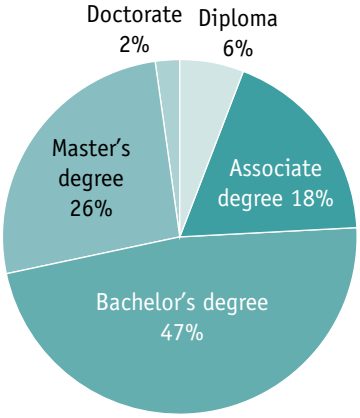


Figure 2. Educational Background of Oncology Nurse Navigators



Mid-Atlantic, and Western regions, representing more than 60 percent of all navigators nationally (see Figure 1, page 38). While there is no specific professional experience, degree, or certification required for nurses to be classified as "oncology navigators," NCONN's current membership data indicates the majority of the organization's 1,000 plus members (73 percent) earned bachelor's and master's degree-level training (Figure 2, page 38). When surveyed about annual compensation a majority of NCONN members (almost 80 percent) report earning a salary in the $60,000 to 90,000+ range, which is consistent with national salary ranges for bachelor's and master's prepared nursing staff (Figure 3, right). Obviously, these salary ranges can vary widely based on geographic region, caseload management expectations, and the navigator organizational model.

To gain a better understanding of the roles and responsibilities of oncology nurse navigators, the authors of this article—in partnership with NCONN—conducted a random survey of about 725 oncology nurse navigators who are subscribed to the NCONN Listserv. The survey tool "A Day in the Life of a Patient Navigator" can be found on page 43. All survey responses were voluntary and represent a snapshot of the educational background, compensation, and day-to-day roles and responsibilities of oncology nurse navigators. Their tasks and responsibilities varied widely, depending on:

- The specific needs of their patients and organizations
- Disease type
- Patient flow through the system
- Emotional, financial, and physical needs of the patient
- Physician interaction, level of support, and requests for services.

In brief, here are a few key findings from the survey.

As shown in Figure 4 (right), more than half of all oncology nurse navigators are practitioners with professional experience ranging between 21 and 31 years. These oncology navigators consistently reported six main duties:

1. Providing patient education
2. Explaining diagnosis and treatment
3. Coordinating care across multidisciplinary teams and providers
4. Assisting with financial issues
5. Providing psychosocial support
6. Initiating and completing treatment summary plans.

When asked to quantify the amount of time spent on each of their core responsibilities, respondents reported that they spend the majority of their time on the following tasks:

- New patient intake, patient education, appointment scheduling, accompanying patients to visits, etc.
- Patient phone and in-person follow-up
- Transportation issues
- Financial issues
- Social work and counseling.

When asked the number of patients navigated on average

Table 2. Metrics Tracked & Measured by Nurse Navigators

Patient satisfaction and feedback
Physician satisfaction and feedback
Timeliness to diagnosis and treatment
Improved patient outcomes
Preventable ER visits
Referrals to clinical trials
Patient outmigration and retention
Revenue generated for navigated vs. non-navigated patients
Adherence to NAPBC Guidelines
Number and type of patient contacts
Number of new patients seen
Number of referrals to other services
Number of barriers to care
Patient education preferences
Community contacts, including speaking engagements and healthcare fairs

Figure 3. Oncology Nurse Navigator Salary Ranges

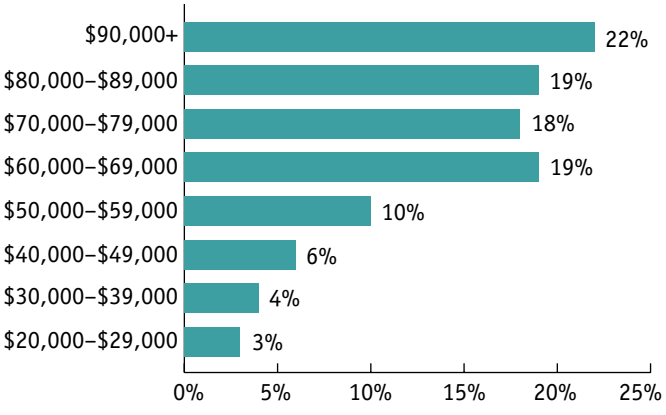
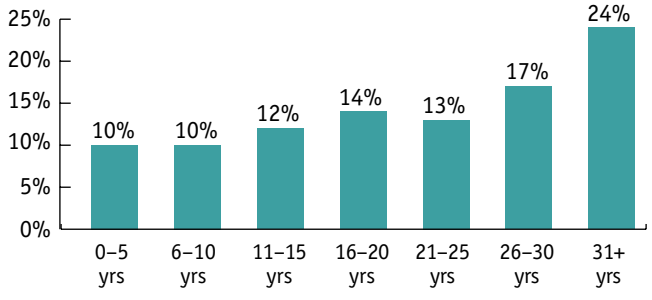


Figure 4. Career Experience of Oncology Nurse Navigators



IN THEIR OWN WORDS

No two oncology nurse navigator programs are alike. Further, programs are highly variable dependent on administration and physician support, as well as the flexibility, personality, and commitment of the individual navigator. Here's what oncology nurse navigators have to say about their profession:

> *"Oncology nurse navigators don't have all the answers, but they know how to find the information to guide patients to informed decision-making."*
>
> —Kathleen Gambin, RN, BSN, OCN
> Northside Hospital
> Atlanta, Ga.

> *"Oncology patient navigation is different multi-tasking, every day with every patient…your day consistently evolves, dependent upon the type of patient and his or her individual needs."*
>
> —Helen Roorda, RN, BSN, OCN
> Florida Hospital Cancer Institute
> Orlando, Fla.

> *"Truly the responsibilities of a navigator are endless. It is a role of great diversity and flexibility—to really say that I have a set schedule would not portray this work very well. My days vary every day, and I really never know what each day holds and what each person or professional may need from me. I remain on the go with a cell phone in hand to be available for the next person in need."*
>
> —Anonymous

per FTE oncology nurse navigator, answers varied by type of disease and by program size and scope. On average, most responded that they navigate 150 to 350 total patients (new and ongoing) annually. (This number seemed to back up similar findings on ACCC's online community, MyNetwork, *www.mynetwork.accc-cancer.org*. In a September 2012 exchange, members indicated they navigated an average number of between 120 to 350 new and ongoing patients annually.)

Challenges to Establishing & Expanding Navigation Services

In "A Day in the Life of an Oncology Nurse Navigator" survey, respondents reported facing similar challenges establishing and expanding navigation services. The majority of survey respondents noted the greatest area of challenge is improving physician buy-in and utilization of navigation services. Many described obtaining and sustaining long-term physician support and enthusiasm for the navigation program as hurdles. One respondent shared that physician support tended to wane the longer the navigation program operated.

Another survey respondent commented that, "[her program's] physician champions had really not stepped up to promote the program." As a result, the oncology nurse navigator had to spend a significant amount of time promoting the navigation program—both internally and externally, which was very discouraging to her as a "one-person operation."

Respondents listed resistance from internal staff as an additional barrier. Some reported that internal or external breast and cancer program staff members may believe navigators replace or overlap existing roles—rather than complement them by filling in gaps in services and facilitating the delivery of care. Another survey respondent said that education and open dialogue between cancer care staff and navigators could help to ensure better cooperation among all members of the team and establish more clearly-defined roles and boundaries.

In summary, the most consistently reported challenges to expanding oncology nurse navigator services included:

- A process for obtaining physician buy-in and ongoing support
- A process to ensure that physicians fully utilize services
- Time management
- An effective method for documenting and tracking patients
- A lack of secretarial and resource support
- A process for documenting time and justifying the navigator role to hospital executives.

Measuring & Reporting Program Return on Investment

While oncology nurse navigators receive anecdotal information from patients on the value of their services, quantifying the impact of navigation can often be challenging, particularly given that navigation is not a reimbursed service. Only half of the respondents to the "A Day in the Life of an Oncology Nurse Navigator" survey have some formalized process for tracking and measuring the impact of their services. For

CORE COMPETENCIES FOR THE ONCOLOGY NURSE NAVIGATOR

By enforcing competencies, healthcare professionals establish expectations for performance excellence, resulting in a systematic approach to professional development, improved job satisfaction, and better learner performance. The role of the oncology nurse navigator is evolving as the healthcare delivery system continues to undergo major changes. Technology and access to the Internet have opened new avenues for patients and family members to educate themselves and gain resource information. While this increased capacity to access resources has improved care and reduced delays in treatment, it has also resulted in an overwhelming amount of information to interpret and manage. Navigators continuously emerge from the field of oncology nursing in response to the growing need for patient navigation within the healthcare system for all types of cancer patients.

One major responsibility of an oncology nurse navigator is the coordination of care across the cancer continuum. By accompanying patients through every aspect of their cancer journey, the oncology nurse navigator is best positioned to advocate for and provide guidance to patients and their families. The oncology nurse navigator ensures access to the information necessary for the patient to make the best possible decisions about treatment. The navigator provides counsel and advice to improve the patient's quality of life—and ultimately improve patient satisfaction. Furthermore, the oncology nurse navigator helps decrease healthcare costs through appropriate utilization of healthcare resources.

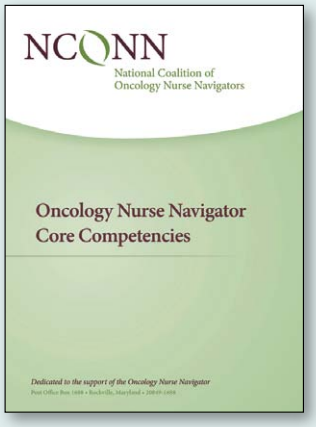
Apart from the role of a licensed nurse, the oncology nurse navigator needs to develop competencies to integrate the roles of healthcare promoter, educator, counselor, care coordinator, case manager, researcher, and patient advocate. Hence, education programs that prepare oncology nurse navigators must ensure that professional nurses are equipped with the essential competencies that enable them to fulfill these roles capably and ethically. Consistent with national trends, NCONN is developing a healthcare oncology nurse navigator model that provides education and support for the professional nurse navigator.

NCONN's core competencies provide a philosophy for oncology nurse navigation and a framework to integrate the oncology nurse navigator's myriad of roles—one of the first items addressed when NCONN formed. The core competencies developed serve the following purposes:

- To frame the philosophy of oncology nurse navigation based on accepted nursing practice
- To define the professional role of oncology nurse navigation and the competencies required to successfully fulfill the role
- To lead the development of curriculum and navigation models that prepare oncology nurse navigators who guide and support cancer patients in a safe and ethical manner
- To inform healthcare employers and the public of what they may expect from an oncology nurse navigator upon entry to practice
- To educate currently practicing oncology nurse navigators to further develop and/or establish a successful navigation program regardless of size, type, or geographical location.

NCONN acknowledges that its core competencies are just a starting point; simply creating the core competencies is not enough. The fluidity of the competencies means NCONN must always be prepared to adapt them, recognizing that as the healthcare delivery systems change, these competencies must update and evolve to meet the current healthcare delivery standards.

To receive a copy of the *Oncology Nurse Navigator Core Competencies,* contact the National Coalition of Oncology Nurse Navigators by visiting: *www.nconn.org*.



most respondents, it is a manual process, typically using Excel worksheets, that begins with the establishment of clearly defined goals and a measure of baseline performance on key metrics or concerns the cancer program aims to address.

When queried about metrics that oncology nurse navigators track and measure, respondents offered a range of answers, including patient and physician satisfaction scores, improved patient outcomes, and patient outmigration and retention (Table 2, page 39). Outcome measurement results will ultimately satisfy program leadership who ask the question: "What is the return on the investment on hiring an oncology nurse navigator?"

Still, few published studies exist on the cost-effectiveness of patient navigation or its benefits to patients. Without outcomes measurement, oncology nurse navigators are not able to show what they know empirically—that positive outcomes are related to navigators and navigation programs. Barriers known to exist and prohibit effective outcome measurements today include:[2]

- Staff resistance

- Lack of appropriate software for data collection
- Decreased time and resources required to collect, analyze, interpret, and report the data
- Lack of knowledge
- Varied storage and reporting mechanisms across the organization.

As patient navigation continues to grow, the need for defined standards and common metrics will be essential to compare results across projects and demonstrate both the efficacy and cost-effectiveness of such programs.

The Future of Oncology Nurse Navigation

Current demonstration programs indicate interest at the federal level for exploring patient navigation, but long-term sustainability of these programs, particularly in an increasingly constrained budget environment, is uncertain. However, some in the healthcare field point to the new CoC requirement for patient navigation services as a step toward ensuring the long-term sustainability of these programs. By 2015 all cancer programs will be required to demonstrate the processes and measureable outcomes of patient navigation. In addition, the Affordable Care Act (ACA), which shares many of the same objectives of patient navigation, may also present new opportunities to apply patient navigation to help improve the quality and efficiency of care delivered. One fact is certain, navigation programs, while not widespread statistically, can have a significant impact on the care and well-being of cancer patients with an insatiable need for information and companionship throughout their individual cancer journey. OI

—Sharon L. Francz, is president and co-founder of the National Coalition of Oncology Nurse Navigators, Rockville, Md. Kelley D. Simpson is senior partner at Oncology Solutions, LLC, Decatur, Ga.

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THE HISTORY OF PATIENT NAVIGATION

In 1989 the American Cancer Society (ACS) released a report entitled, *Report to the Nation: Cancer in the Poor,* which indicated that poor individuals faced significant barriers that prevented them from obtaining needed oncology care (see Table 1, page 38).

In response to these report findings, oncologist Harold P. Freeman, MD, partnered with ACS to create the first patient navigation program in Harlem, N.Y., in 1990. Targeting women with historically poor breast cancer outcomes, the program helped low-income women overcome barriers to breast cancer screening and follow-up care. Dr. Freeman paired women with suspicious clinical findings with a "navigator" who could help guide them through the maze of the healthcare system. Navigators coordinated appointments with work schedules and stressed the importance of consistent treatment and follow-up. Freeman's model was the first instance that lay navigators, or specially-trained, nonmedical professionals, were used in cancer management. The pilot successfully improved follow-up, reduced wait times for breast biopsies for positive mammograms, and increased early diagnosis of breast cancer.

Given the success of this pilot, in 2001 the President's Cancer Panel recommended that funding be provided to promote community-based programs, such as patient navigator programs, to assist individuals with obtaining cancer information, screening, treatment, and supportive services.

Funding provided by private foundations, including ACS, the Avon Foundation for Women, and Susan G. Komen for the Cure, as well as federal, state, and local governments has led to the implementation and study of more patient navigation programs. In addition, the emergence of several oncology-specific professional organizations, such as the National Coalition of Oncology Nurse Navigators (NCONN) and the Academy of Oncology Nurse Navigators (AONN) also helped fuel the widespread adoption of this growing discipline in cancer care.

Today, the focus of navigation has expanded beyond Freeman's original model to include the timely movement of an individual across the entire cancer care continuum. Now navigators work with patients of all cancer diagnoses and treatment plans, and in a variety of care settings including hospitals, health systems, freestanding cancer centers, and oncology practices.

In fact, the recent ACS *Cancer Treatment and Survivorship Facts & Figures 2012–2013* report stated that "in 2011, 90,000 people relied on the [ACS] Patient Navigator Program to help them through their diagnosis and treatment." ACS collaborates with a variety of organizations, including the National Cancer Institute's Center to Reduce Cancer Health Disparities, the Center for Medicare & Medicaid Services (CMS), numerous cancer centers, and others to implement and evaluate the ACS navigation program.

NCCNN
National Coalition of
Oncology Nurse Navigators

A DAY IN THE LIFE OF AN ONCOLOGY NURSE NAVIGATOR

1. What tumor sites (cancer patients) do you navigate?

2. Approximately how many patients do you navigate at any given time during a year? You may list low and high range.

3. How many years have you been in a navigator position?

4. What are your credentials? RN? OCN? MSW? Other?

5. How would you describe a day in the life of a patient navigator?

6. Based on 100% of your time, how much time do you spend on average for certain responsibilities of your position? Please make sure the items you select as responsibilities total 100%. These may include some of the following:
   - New patient intake
   - Patient education
   - Outreach and community education
   - Appointment scheduling
   - Accompany patients to visits
   - Patient phone or in-person follow-ups
   - Physician calls and/or discussions
   - Arrange and/or discuss transportation issues
   - Assist, discuss, and/or arrange financial issues
   - Social work and counseling related discussions
   - In-house meetings, such as tumor board or cancer conferences, please list.

7. What are the greatest challenges of your position?

8. How do you measure results and benefits of your position for administrators?

9. Do you use any specific navigation software? If so, what system? If not, how do you track and record interventions and activities? Homemade system? What type? Excel? Other?

10. Do you assist with preparation and/or facilitation of tumor specific cancer conferences? If so, what are your responsibilities?

11. Please indicate any other critical information you feel would be beneficial to share in this survey.

©Faye Flemming, RN, BSN, OCN

Get Schooled

Bridgeport Hospital's One-Day Cancer College

BY MARGARET PARNIAWSKI, RN, MSN

In 2007 philanthropist Norma F. Pfriem provided a substantial gift to Bridgeport Hospital that resulted in the renaming of the hospital's cancer services as the Norma F. Pfriem Cancer Institute. To help market this new umbrella name and the hospital's cancer specialty services, the cancer care team collaborated with the hospital marketing department to develop a One-Day Cancer College. The specific objectives of the Cancer College are to:

- Understand the community need for education regarding cancer treatment and survivorship
- Promote the services of the Norma F. Pfriem Cancer Institute by focusing on its five established Centers of Excellence (Breast Cancer, Gastrointestinal Cancer, Genitourinary Cancer, Gynecologic Cancer, and Thoracic Cancer)
- Provide culturally appropriate community health promotion programs
- Provide counseling about cancer prevention.

The target audiences for the One-Day Cancer College are:

- The Greater Bridgeport community
- Cancer survivors
- Caretakers
- Physicians, nurses, and other healthcare professionals.

Our One-Day Cancer College is a free educational event for the community. During the course of a few hours in one convenient location, cancer patients, their families, and others can learn first-hand from more than a dozen physicians and other healthcare professionals about the latest information on cancer prevention, diagnosis, and treatment. The One-Day Cancer College also showcases a sampling of the various support groups and survivorship programs offered by the hospital.

Curriculum Development

Key representatives from the cancer care team develop the course curriculum. The five Centers of Excellence at the Norma F. Pfriem Cancer Institute serve as the framework, with input from experts at each Center of Excellence informing topics, presenters, and educational materials. Feedback from patients and families, including written evaluations from past conference attendees, is also used to plan the curriculum. In the end, the One-Day Cancer College provides a balance between promoting our hospital's newest technologies, treatments, and interventions and delivering information requested directly by cancer patients, families, and caregivers.

Led by key representatives from the cancer care team, the hospital's marketing department and a volunteer staff of more than 30 hospital employees work collaboratively to ensure that conference attendees have an enjoyable, relaxed, and informative experience. In total, more than 140 hospital staff members work about 300 hours throughout the year to plan and execute our One-Day Cancer College.

Active involvement of physicians and other cancer care providers is vital to the program's success. One incentive for busy providers: the positive exposure received from marketing and media relations initiatives related to the One-Day Cancer College. For example, we run a full-page ad in our local newspaper about the event. The ad lists all of the

sessions, presenters, and participating physicians. We also purchase airtime on local radio channels. After our last One-Day Cancer College, our dietitians saw 40 new patients from people who attended the conference. Between sessions, we market the cancer center's survivorship and other support programs.

The lobby area features information tables and—when possible—cancer screening exhibits. In addition to hospital representatives, such as our mammography team, our community partners also exhibit here, including the American Cancer Society and Cancer*Care*.

"The face-to-face contact between physicians and the audience is a defining characteristic of the One-Day Cancer College," said Scott Thornton, MD, Co-Medical Director of the Norma F. Pfriem Cancer Institute. "Attendees truly appreciate the opportunity to receive first-hand information from medical experts in an intimate setting, where they are also free to ask specific questions about cancer care. From the physicians' perspective, the interaction with cancer survivors and their families affirms that what they do is meaningful on a very personal level."

Nuts & Bolts

The annual budget for the One-Day Cancer College is $60,000, which includes the venue, guest speaker, print and broadcast advertising, fulfillment, and printing costs. Costs are shared between Bridgeport Hospital's marketing department and the Norma F. Pfriem Cancer Institute.

The planning process begins about 10 months out from the event. The planning team is comprised of staff from the hospital's marketing department and the Norma F. Pfriem Cancer Institute; lead coordinators are the oncology patient navigator and cancer resource specialist Kim Bielecki, RN, and marketing specialist Stephanie Weirsman. The oncology steering committee and co-medical directors of the cancer institute, Dr. Thornton and Dr. Robert Folman, also offer key recommendations and input during the planning process.

The first steps are securing a venue, date, and keynote speaker. The next step is selecting between 18 to 21 physician and allied health experts to speak at the One-Day Cancer College.

Since we launched our One-Day Cancer College in 2008 the event venue has been the Trumbull Marriott Hotel, which is easily accessible from major highway arteries. The grand ballroom at the Marriott comfortably accommodates a seating arrangement for 300 people, and the hotel has several smaller meeting rooms for break-out lectures on specific cancer topics. Additionally, for cancer programs looking to develop a similar conference, the venue should have ample space for information tables and displays, be able to supply food and beverages for the event, and offer audiovisual support during the lectures and keynote speech.

Marketing efforts for our One-Day Cancer College include internal direct mail advertising to more than 100,000 homes in the Greater Bridgeport area, print advertising in the region's major daily newspapers and town-specific weekly papers, and broadcast ads on the area's leading AM and FM radio stations.

Our Program At-a-Glance

Our One-Day Cancer College began in 2008 with two tracks of speakers answering questions and addressing concerns voiced by the audience. Attendees could attend one track or customize their schedule to hear different cancer topics from each track.

In 2009 the Cancer College expanded to three tracks, providing a greater opportunity for community education. Specifically, we added a "Mind, Body, and Spirit" track that focused on subjects such as: Coping with Cancer, Reiki for Stress Management, and What to Eat & What to Avoid During and After Cancer Treatment. This third track allowed for a total of 18 educational opportunities throughout the day.

The following are sample topics for the other two tracks (all based around the five Centers of Excellence). For example, the breast cancer track might include topics such as:

- New Options for Breast Reconstruction
- The Gene Factor
- Recent Developments: Medical Management of Breast Cancer
- Considering Surgery for Breast Cancer
- Should I Consider Oncoplastic Breast Surgery?

The gastrointestinal cancer track might feature sessions on:

- Prevention and Detection of Gastrointestinal Cancers
- Advances in Colorectal Surgery
- Stopping Cancer in its Tracks: Barrett's Esophagus and Radiofrequency Ablation
- How to Protect Your Family from Colon Cancer: Is There a Genetic Link?
- New Surgical Options for Colon Cancer
- Is Colon Cancer Hereditary?

Sample sessions in the genitourinary cancer track might include:

- GPS for the Prostate: Advances in Radiation Therapy for Prostate Cancer
- Understanding Prostate Cancer
- Advances in Kidney Cancer Treatment
- The Facts About Kidney Cancer
- Living with Prostate Cancer
- Benefits of Robot-Assisted Minimally Invasive Surgery.

Gynecologic cancer sessions might cover:

- Robot-Assisted Minimally Invasive Surgery for Gynecologic Cancer
- Am I Ready for This? Cancer and Intimacy
- Latest Advances in Uterine Cancer Treatment
- Treatment Options for Gynecologic Cancer
- Effects of Cancer Treatment on Fertility
- Radiation Treatments for Gynecologic Cancers
- Diagnosis and Treatment for Endometrial Cancer.

The track on thoracic cancer may offer topics on:

- Surgical Advances in Lung Cancer
- Palliative Care for Cancer Patients
- Advances in Lung Cancer Treatment
- Understanding Lung Cancer Tests
- Medical Management of Lung Cancer Symptoms
- Minimally Invasive Surgery for Lung Cancer.

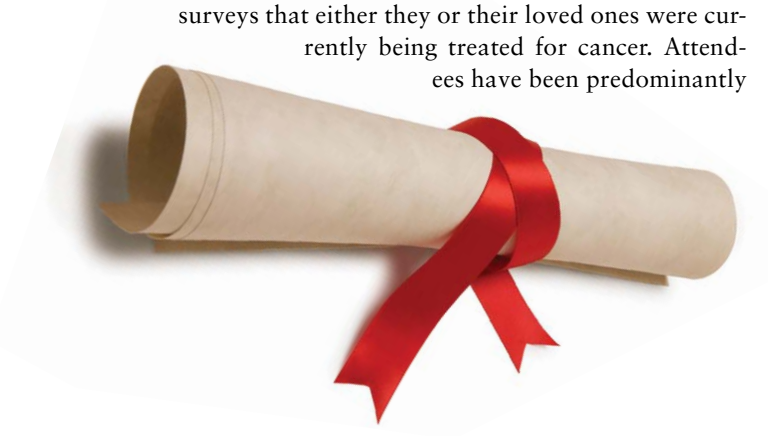
The Keynote Speaker

A highlight of our One-Day Cancer College is the annual keynote address. The keynote speakers are responsible for putting together their own presentations. Since 2008 our One-Day Cancer College has featured these keynote speakers:

- Holly Clegg, writer, recipe-developer, and author of *Eating Well Through Cancer,* who spoke about recipe creation for patients going through cancer treatment.
- Saranne Rothberg, founder and CEO of the ComedyCures Foundation, who shared her personal cancer journey and her simple goal of helping people with cancer use the power of comic perspective and the positive benefits of laughter for the mind, body, and spirit.
- Alan Hobson, mountain climber, best-selling author, and cancer survivor, who inspired the audience with the story of his quest to climb Mount Everest and his courage to overcome a diagnosis of acute leukemia.
- Hoda Kotb, breast cancer survivor and co-host of NBC's TODAY show, who painted a vivid picture of the day-to-day physical and emotional struggles of undergoing cancer treatment.

The Feedback

Average attendance at our One-Day Cancer College exceeds 300, with 70 percent of those attending stating in post-event surveys that either they or their loved ones were currently being treated for cancer. Attendees have been predominantly female (83 percent); nearly all (99 percent) were over the age of 40:



- 40–49 years of age (11 percent)
- 50–59 years of age (30 percent)
- 60–69 years of age (27 percent)
- 70–79 years of age (19 percent)
- 80–89 years of age (11 percent)

On our most recent post-conference evaluation forms, 100 percent of attendees responded in the affirmative to the question: "Did you enjoy the event?" Importantly, 95 percent of those attendees said they learned more about prevention and treatment of cancer having attended the event. When asked whether they were more likely to seek services from the Norma F. Pfriem Cancer Institute after attending our One-Day Cancer College, 72 percent of respondents answered in the affirmative.

The success of our One-Day Cancer College is measured not only by the positive feedback of attendees, but also by the number of referrals to Bridgeport Hospital that the event has generated. Of the 320 people who registered by phone for the most recent Cancer College, 50 (more than 15 percent) sought referrals to hospital experts and services before the event. Asked on evaluation forms if they were more likely to seek services from the Norma F. Pfriem Cancer Institute and/or its affiliated physicians after attending our One-Day Cancer College, 72 percent of attendees responded "yes."

Lessons Learned

When developing a One-Day Cancer College, or any type of similar conference, an organized production schedule is the key, along with a firm commitment from your team members. For community cancer centers looking to implement a similar event, our team offers the following tips.

First, collaboration and details make all the difference in planning an event. Having a designated representative from the cancer care team and marketing department is very beneficial.

Second, maintain open communication and hold frequent meetings—monthly at first and then weekly if necessary in the final weeks leading up to the event

Third, you will need an excellent marketing team to most effectively highlight the event to internal stakeholders and publicize the event to external stakeholders and the public.

Listen to your audience, and include information about topics that interest them. Learn what works and what you can improve upon from past events.

Finally, as stated previously, physicians are key to this type of event, so be very nice to your doctors, who come together on their own time to share their medical expertise. OI

—Margaret "Peg" Parniawski, MSN, RN, is director of nursing, Norma F. Pfriem Cancer Institute, Bridgeport Hospital/Yale New Haven Health System, Bridgeport, Conn.

Who's Participating?

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Administrators

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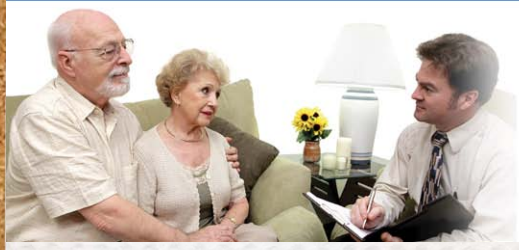

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- ARCHIVED — Course 7: **Archived** Financial Specialists as Part of the Multidisciplinary Cancer Care Team
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For more information
www.accc-cancer.org/filn

ACCC Association of Community Cancer Centers
Education

This project is sponsored by Bristol-Myers Squibb, Genentech, Lilly Oncology, Novartis Oncology, and Teva Oncology

ACCC's Prostate Cancer Projects

DEVELOPING TOOLS AND MEASURING EFFECTIVENESS

BY KIM LEMAITRE, MS

In 2010 the Association of Community Cancer Centers (ACCC), through its Center for Provider Education, launched the "Prostate Cancer Programs: Developing Tools and Measuring Effectiveness" education project to provide tools, materials, and data that cancer programs can apply in their specific programs to improve outcomes and satisfaction among their patients with metastatic or advanced prostate cancer. The two-phase project was developed with the following objectives:

- **To develop criteria** for measuring outcomes that indicate success in treating patients with metastatic or advanced prostate cancer.
- **To develop practical tools** to assist programs in both measuring specific outcomes and improving care for patients with metastatic or advanced prostate cancer.
- **To apply these criteria** and tools at cancer programs actively involved in treating patients with metastatic or advanced prostate cancer.
- **To determine and measure** which criteria and tools affect outcomes and increase success in treating patients with metastatic or advanced prostate cancer.
- **To share effective tools and report the study results** in a formal educational venue available to all providers.

Phase I of the project assessed core services, use of patient education materials and patient decision aids, outcomes data collection, and a number of other key variables in care of patients with metastatic or advanced prostate cancer.

Phase II of the project identified both clinical and non-clinical criteria for measuring outcomes and explored tools to assist programs in measuring specific outcomes and improving care. Nine cancer programs submitted outcomes data from their cancer registries for their patients with metastatic or advanced prostate cancer. These participating cancer programs then used specific "tools" designed to help their prostate cancer patients participate in decision-making about healthcare options. The core question was whether collection of outcomes data and use of patient decision aids can improve patient care processes.

The following nine cancer programs participated in this educational project:

1. Augusta Health Cancer Center, Fishersville, Va.
2. Bozeman Deaconess Cancer Center, Bozeman, Mont.
3. Ironwood Cancer and Research Centers, Mesa, Ariz.
4. Maine Medical Center Cancer Institute, Scarborough, Maine
5. Middlesex Hospital Cancer Center, Middletown, Conn.
6. Palo Alto Medical Foundation, Palo Alto, Calif.
7. Saint Joseph's Hospital of Atlanta, Atlanta, Ga.
8. Southside Regional Medical Center Cancer Center, Petersburg, Va.
9. West Georgia Health, Enoch Callaway Cancer Clinic, LaGrange, Ga.

These sites used a Prostate Cancer Toolkit (see below) to help their prostate cancer patients participate in decision-making about healthcare options.

For this study, ACCC examined a number of patient education materials and decision-making tools to assess their usefulness during treatment of metastatic or advanced prostate cancer. Patient decision tools provide information on the treatment options and help patients clarify and communicate the personal value they associate with different features of the options.

The project's Advisory Board reviewed an annotated bibliography developed for this educational program, and identified a broad range of specific patient tools, which were then categorized into measurement tools, patient decision aids, or clinical decision support tools. These tools assessed a wide variety of factors, including quality of care, quality of life, patient satisfaction, decision-making, treatment choice, supportive care, economics and cost, anxiety, decisional conflict, and decisional regret, for example. The Advisory Board chose to focus on tools that best facilitate decision-making and to pilot-test those tools at the participating sites. Select tools were used to create a Prostate Cancer Toolkit that includes patient education materials and decision-making tools, such as the EPIC-16 CP tool, to measure specific outcomes and patient satisfaction. The Toolkit, available at *www.accc-cancer.*

org/prostateinfo, includes the following resources:

- Expanded Prostate Index Composite-16 for Clinical Practice (EPIC-16 CP) *(www.accc-cancer.org/education/pdf/PCP-EPIC.pdf)*
- *Us TOO! Advanced Prostate Cancer Resource Kit,* educational materials and resources *(www.ustoo.org/Advanced_Disease.asp)*
- *Ottawa Personal Decision Guide (www.accc-cancer.org/education/pdf/PCP-OPDGuide.pdf),* a general patient treatment decision-making tool to help patients evaluate, clarify, and communicate their preferences based on their values
- *Ottawa Family Decision Guide (www.accc-cancer.org/education/pdf/PCP-OFDGuide-Sample.pdf),* a two-page guide to assist families facing tough health and social decisions
- *Ottawa Decision Support Tutorial (https://decisionaid.ohri.ca/ODST/),* a self-paced, free online tutorial to help cancer program staff increase their skills in providing patient treatment decision-making support.

Key Findings

Study findings were presented at ACCC's 29th National Oncology Conference in fall 2012. The study's full final report is available on the ACCC members-only website at *www.accc-cancer.org*. Key study findings include:

1. Cancer programs in this study used a number of different education materials for patients with advanced prostate disease. Education efforts were generally not coordinated among members of the multidisciplinary team.
2. Cancer programs differed in the degree to which patients had input into their own treatment decisions. In some programs the urologist made treatment decisions largely without patient input, while in other programs the patient had access to multiple specialists who worked with the patient to determine the best treatment option based on patient feedback.
3. Most cancer programs were not using patient decision-making tools, which provide information on the options and help patients clarify and communicate the personal value they associate with different features of the options.
4. Through ACCC's educational project, participating cancer programs implemented the EPIC-16 CP, a patient decision-making tool designed to evaluate patient function and quality of life after prostate cancer treatment. While urologists most often used the tool, a wide variety of other healthcare professionals involved in advanced prostate cancer patient care also successfully implemented the tool. Users overwhelmingly found the tool to be practical, efficient, and easy to implement in clinical practice with little to no adaptation. The tool provided useful information about prostate cancer patients' quality of life that could be evaluated and meaningfully contribute to treatment decision-making for this population. Some sites found additional tools useful, such as prostate cancer educational materials and decision guides, in conjunction with the EPIC-16 CP to facilitate patient understanding and treatment decision-making processes.
5. All cancer programs in the study followed clinical guidelines for diagnosis and treatment of prostate cancer. Most programs based treatment decisions on National Comprehensive Cancer Network (NCCN) guidelines. Still, staff education about clinical guidelines was inconsistent across cancer programs.
6. Use of patient navigation services and the role of the patient navigator varied across all cancer programs. Few cancer programs had a patient navigator designated specifically to prostate cancer patients. Instead, programs used GU, general, and/or urology navigators. Navigators addressed psychosocial needs, referred patients to community resources, provided education, coordinated services and schedules, and assisted with patient decision-making. Social workers and nutrition professionals assisted the navigator.
7. Use of patient navigation services and financial counseling, as well as referrals to social services, rehabilitation, nutrition counseling, and support groups were surprisingly low for all patients in the study and may reflect inadequate processes for tracking the use of these services.
8. Many cancer programs were not collecting sufficient outcomes data to assess the quality of the care they provide to patients with metastatic or advanced prostate cancer.
9. Coordination of care among members of the multidisciplinary team appeared to be best if all members used the same electronic medical record (EMR). Most cancer programs, however, did not coordinate care for their patients with advanced prostate disease.

During the course of the project, study leaders encouraged participating sites to examine their EMR systems and processes for data capture and look for ways to improve intake of information from referral sources. Project resources including, study highlights, the annotated bibliography, and the "Prostate Cancer Toolkit" are available at: *www.accc-cancer.org/prostateinfo*.

Next Steps

ACCC plans to collect data at additional cancer programs, conduct training at participating sites on strategies to enhance data collection for supportive services, and continue its efforts to educate the oncology community about decision-making tools for patients with advanced prostate disease. ACCC will continue to broaden understanding of whether collection of outcomes data and use of patient decision-making aids can improve patient care processes. OI

—Kim LeMaitre, MS, is director of education services at the Association of Community Cancer Centers, Rockville, Md.

action

ACCC Welcomes its Newest Members

Wake Forest Baptist Medical Center, NCI Comprehensive Cancer Center
Winston-Salem, N.C.
Delegate Rep: Kerry Snyder-Husted
Website: *www.wakehealth.edu*

Cape Fear Cancer Specialists
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Delegate Rep: Nora Landry
Website: *www.nhrmc.org*

Saint Francis Hospital
Natalie Warren Bryant Cancer Center
Tulsa, Okla.
Delegate Rep: Nancy Thomas
Website: *www.saintfrancis.com/services/cancer.aspx*

Sanford Bemidji Medical Center
Sanford Benidji Cancer Center
Bemidji, Minn.
Delegate Rep: Shari Hahn
Website: *www.sanfordhealth.org*

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- Provides monthly statistical reports on trials.

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- BSN required
- Background in Statistics preferred
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Contact Megan Wills, Recruiter, at: 517.364.5813 or: *megan.wills@sparrow.org*.

Play On

BY MIRIAM HILLMER, MME, MT-BC, NICU MT

Patients receiving treatment for cancer expect to encounter doctors, nurses, treatment therapists, and dietitians during their cancer journey. Few would expect to see a music therapist as part of their treatment experience. At Tallahassee Memorial Healthcare in Tallahassee, Florida, the Music Therapy department has been providing ground-breaking music therapy services to oncology patients and family members for the past 13 years. As one of Florida's largest not-for-profit hospitals, Tallahassee Memorial Healthcare serves ten counties in North Florida and six counties in South Georgia.

Tallahassee Memorial Cancer Center is Florida's longest continually accredited comprehensive cancer program in the community hospital category through the Commission on Cancer (CoC). Patients receiving treatment at the cancer center can experience music therapy services in waiting areas, during procedures, and while receiving chemotherapy. Music therapy is provided by a board-certified music therapist implementing techniques individually tailored to reduce anxiety, pain perception, nausea, and emotional distress. This vital service is supported by a partnership with a local university, grants, and donations.

What's Music Therapy?

Music therapy interventions are tailored to address the physical, cognitive, and emotional needs of oncology patients. Individuals facing a cancer diagnosis and treatment deal with a variety of symptoms and emotions. Anxiety is common and ranges from slight with minimal effect on the patient to severe with significant effect on the patient. Anxiety in cancer patients can affect pain perception, sleep patterns, emotional stability, and cause nausea and vomiting. Music has been shown to be effective at addressing both the physical and psychological factors associated with cancer treatment.[1] Techniques like live patient-preferred music have produced positive results such as increased relaxation and improvements in mood and quality of life, as well as decreased feelings of depression, fear, and fatigue.[2–5]

How Do Patients Receive Music Therapy?

Tallahassee Memorial Cancer Center offers music therapy in several areas of the facility. For patients receiving chemotherapy infusion, visits to the cancer center can be an all-day affair. These long treatment hours are both mentally and physically draining on patients. Music therapy services in the infusion area range from music and relaxation techniques to song-writing—depending on the needs, desire, and ability of the individual patient. Goals for therapy focus on decreasing pain perception, nausea, and anxiety, and improving patient mood and coping skills. Patients interact with the therapist while receiving their infusion and are encouraged to participate as they desire, including:

- Passive listening
- Sing-along opportunities
- The chance to play an instrument
- Verbal processing of a song or situation.

Something as familiar and relatable as music provides an often-needed distraction and support for the patient.

In 2010 oncology staff and the Music Therapy department initiated a creative solution to a problem they were noticing among patients preparing for and receiving radiation therapy. The issue centered on patient anxiety, claustrophobia, and other fears relating to treatment. Several patients exhibited signs of distress when arriving for CT Simulation prior to receiving their radiation treatment. In some instances, the anxiety was so great that patients stopped treatment altogether.

Our solution: to arrange for a music therapist to be present to play live music during a patient's CT Simulation session to distract and relax the patient. One research study indicated that patients receiving music therapy during their CT Simulation reported significantly less anxiety heading into their first treatment than those receiving standard care with no music.[6]

The cost of music intervention is low and implementation is simple. The therapist plays music in the control room, which is piped into the CT room as the patient's immobilizing device is made and the CT scan completed. The therapist can watch the patient and adjust to any signs of distress, as well as change music tempo to assist with regulating breathing. For patients suffering from claustrophobia, the live music intervention often

helps calm and distract them enough for the therapist to complete the mask-making process and subsequent radiation treatments.

Tallahassee Memorial Cancer Center frequently provides live music in waiting areas. While waiting for lab results, or the start of a first treatment, anxiety levels are usually high for both patients and family members. Research studies conducted in both surgical and emergency waiting areas found that live music had a significant positive effect on an individual's anxiety and relaxation levels.[7,8] Therefore, we deemed it appropriate to incorporate this type of intervention in hospital and cancer center waiting areas.

What Our Patients Say

A few years ago we surveyed a focus group of people who had received music therapy services; 90 percent indicated their enjoyment of the music therapy, 80 percent expressed benefiting from the music therapy, and the remainder of the survey was neutral. Such a simple intervention yielded no negative reactions and only serves to brighten visitors' day.

After receiving music therapy during an infusion treatment, one patient wrote the hospital administration about being in the middle of a long treatment and feeling down both mentally and physically. For this patient, the music therapist showed up at just the right moment to uplift and support her.

We are proud of this innovative, low cost, and non-invasive approach to addressing patient and family needs through the use of live music therapy.

Our Team

Our Music Therapy department consists of two full-time music therapists, one part-time music therapist, and two full-time interns. These individuals do not limit their services solely to Tallahassee Memorial Cancer Center, but see patients throughout the hospital system.

The department is funded partly by a partnership with a local university, Florida State University, which provides funds for one full-time position and one part-time position. The hospital funds the remaining staff and operational costs through grants and donations.

Music therapy is provided at set times in specific areas each week. During this time, staff refers patients for specific reasons: pain reduction, nausea, anxiety, or emotional needs. Patients can also request to receive music therapy services—although priority is given to individuals referred by staff. Appointments can be made outside of the designated time each week as needed.

With music therapy interventions promoting relaxation, pain reduction, and anxiety reduction, the cost relative to the benefits is low. More and more healthcare facilities are recognizing the benefits of providing complementary therapeutic approaches to treatment, such as music therapy, and implementing programs similar to ours. When treating a patient, keep in mind their physical and emotional needs can affect a patient's overall health and ability to recover. Music therapy assists in managing both physical symptoms and emotional factors relating to cancer treatment. When compared to the cost and side effects of pharmacological solutions to managing these symptoms, music therapy is a viable and sometimes preferable option. What is better than walking into a treatment area and hearing the soothing sounds of a live rendition of your favorite song? Music can soothe, distract, and uplift.

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