ONCOLOGY ISSUES

The Journal of the Association of Community Cancer Centers
January | February 2014

Catalyzing Patient-Centered Care

Patient Navigation
Distress Screening
Cancer Survivorship

NEW

GRANIX™

(TBO-FILGRASTIM) Injection

NOW AVAILABLE

Announcing J-code J 1446
Effective January 1, 2014

Take a bite out of G-CSF acquisition costs*

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

GRANIX™ is a new option in short-acting G-CSF therapy

- **FDA approved through the rigorous BLA† process**
- **Teva's filgrastim, the same compound as GRANIX, was first introduced in Europe in 2008, and is available in 39 countries outside the US‡[1]**
- **An option for hospitals and payers to consider when determining health system budgets**

†Biologics License Application.

‡As of November 2013.

Indication

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

Important Safety Information

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

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

For more information, visit GRANIXhcp.com.

Reference: 1. Data on file. Teva Pharmaceuticals: Filgrastim MA Approvals Worldwide. May 2013.

TEVA Oncology

GRANIX™
(TBO-FILGRASTIM)
Injection

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

1 INDICATIONS AND USAGE

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

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Splenic Rupture

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

5.2 Acute Respiratory Distress Syndrome (ARDS)

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

5.3 Allergic Reactions

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

5.4 Use in Patients with Sickle Cell Disease

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

5.5 Potential for Tumor Growth Stimulatory Effects on Malignant Cells

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

6 ADVERSE REACTIONS

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

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

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

6.1 Clinical Trials Experience

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

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

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

Leukocytosis

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

6.2 Immunogenicity

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

7 DRUG INTERACTIONS

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

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

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

There are no adequate and well-controlled studies of GRANIX in pregnant women. In an embryofetal developmental study, treatment of pregnant rabbits with tbo-filgrastim resulted in adverse embryofetal findings, including increased spontaneous abortion and fetal malformations at a maternally toxic dose. GRANIX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

In the embryofetal developmental study, pregnant rabbits were administered subcutaneous doses of tbo-filgrastim during the period of organogenesis at 1, 10 and 100 mcg/kg/day. Increased abortions were evident in rabbits treated with tbo-filgrastim at 100 mcg/kg/day. This dose was maternally toxic as demonstrated by reduced body weight. Other embryofetal findings at this dose level consisted of post-implantation loss, decrease in mean live litter size and fetal weight, and fetal malformations such as malformed hindlimbs and cleft palate. The dose of 100 mcg/kg/day corresponds to a systemic exposure ($AUC_{0\text{-}24}$) of approximately 50-90 times the exposures observed in patients treated with the clinical tbo-filgrastim dose of 5 mcg/kg/day.

8.3 Nursing Mothers

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

8.4 Pediatric Use

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

8.5 Geriatric Use

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

8.6 Renal Impairment

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

8.7 Hepatic Impairment

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

10 OVERDOSAGE

No case of overdose has been reported.

TEVA Oncology

Manufactured by:
Sicor Biotech UAB
Vilnius, Lithuania
U.S. License No. 1803

Distributed by:
Teva Pharmaceuticals USA, Inc.
North Wales, PA 19454

Product of Israel

FIL-40045 July 2013

This brief summary is based on TBO-003 GRANIX full Prescribing Information.

Oncology MANAGEMENT CONSULTING GROUP

National Hospital Oncology Benchmark Study

for Hospital-based Infusion and Radiation

OMC GROUP…
Outstanding experts, Outstanding results!

The inaugural National Hospital Oncology Benchmark Study (NHOBS) was developed by Teri U. Guidi, President and CEO and her team at the Oncology Management Consulting Group, to respond to the frequent inquiries for staffing and productivity benchmarks. Until now, these benchmarks were simply not available for hospital-based infusion and radiation centers.

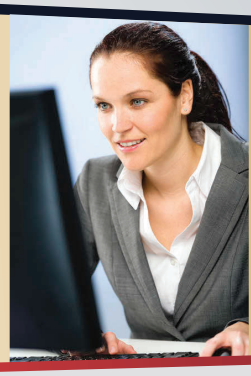
For this initial study we received data from 33 top cancer centers in 17 states and we thank all participating centers for their contribution. Data included volumes and dates of billed services at the individual patient level along with the diagnosis associated with each encounter. Data contributors also answered a brief survey with information about hours of operation, staffing, equipment (e.g. chairs, linacs), and number of physicians.

OMC GROUP
2014 ONCOLOGY WEBINAR SERIES

As part of our 2014 Oncology Webinar Series, OMC Group will be hosting our first webinar of the year - Thursday, January 23 at 12 PM EST

"Results of the Inaugural National Hospital Oncology Benchmark Study (NHOBS)"

To ensure your participation, simply send a request to be added to the mailing list to solutions@oncologymgmt.com.



From this data, OMC Group will show a wide variety of resultant benchmarks for small, medium and large centers. The value of these benchmarks is obvious. With the results of this survey, cancer centers will be able to compare staffing levels and service volumes with their peers to identify opportunities for improved efficiency and increased productivity. Additionally, cancer centers will be able to plan for recruitment and facility growth stemming from market changes, strategic initiatives, and adding new physicians. In fact, the value is so important that OMC Group will expand on this inaugural survey next year, with the goal of receiving data from at least 100 hospital-based centers, and we intend to add data to better understand productivity and utilization of support services such as navigators and financial counselors.

We hope you can join us for this exciting webinar on January 23. As always, our webinars are complimentary to all oncology administrators (hospital and practice) and oncologists. Not an oncology administrator or oncologist? Please contact us at mallen@oncologymgmt.com for fee info.

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contents

Oncology Issues
January | February 2014
Vol. 29 | No. 1

DEPARTMENTS

ACCC
Association of Community Cancer Centers

ONCOLOGY ISSUES

The Journal of the
Association of Community Cancer Centers

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

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

FROM THE EDITOR

Treating the "Whole" Patient

BY CHRISTIAN DOWNS, JD, MHA

Back in 2007 the Institute of Medicine (IOM) released a groundbreaking report, *Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs*. This study opened our eyes to the need to focus on more than just the clinical needs of our patients. Specifically, the report tasked the cancer community to develop and implement strategies to address the wide range of psychosocial issues that can come with a cancer diagnosis.

Today cancer programs have come to understand that caring for the "whole patient" may include providing services for family members and caregivers, as well as help with issues related to the cost of cancer care, survivorship, and end-of-life care.

In this edition of *Oncology Issues*, we focus on several areas that can impact the "whole patient." And, as always, we try to offer practical resources you can put to work in your cancer programs today.

First you'll hear from 2013 ACCC Innovator Award winner GW Cancer Institute. In her article, lead author Mandi Pratt-Chapman shares how the GW Cancer Institute prepared to meet new CoC standards on patient navigation, distress screening, and survivorship that will go into effect next year. With so much experience in this area, GW has launched the GW Cancer Institute Center for the Advancement of Cancer Survivorship, Navigation, and Policy, which has trained nearly 500 healthcare professionals on patient-centered program development.

Next, Dr. Argenbright and the team at UT Southwestern-Moncrief Cancer Institute discuss how they led an effort to collaborate with local cancer care providers to address the psychosocial and behavioral needs of underserved cancer survivors.

The end result was the Fort Worth Program for Community Survivorship, a community wide, coordinated, evidence-based, post-treatment survivorship program that is available to all survivors—regardless of their ability to pay.

Next, circling back to the 2007 IOM report, Dr. Buxton and colleagues offer practical strategies for developing and implementing a comprehensive distress screening program. Their article provides an historical overview of the rationale behind distress screening of cancer patients, and then goes that extra step by identifying training opportunities to prepare for the new CoC standard on distress screening, which goes into effect in 2015.

Finally, read how one ACCC member program improved their adult infusion center patient experience by first understanding their operational inefficiencies. With this understanding, Broward Health Medical Center was able to carry out a unique redesign of their outpatient infusion service line that improved the patient and staff experience, efficiencies, and throughput.

More of these "whole patient" concepts will be discussed at ACCC's upcoming Annual National Meeting, March 31–April 2, 2014, in Arlington Va. Delivering quality care by treating the "whole patient" in turn requires caring for your "whole program," including the business, economic, and policy concerns that will help to shape healthcare delivery today and tomorrow. Take advantage of special rates available now and register to attend this meeting where you can hear from the experts, share experiences from your cancer program, and network with your peers. OI

PRESIDENT'S MESSAGE

Always Be Prepared

BY VIRGINIA T. VAITONES, MSW, OSW-C

Winter has settled in here on the coast of Maine. The tourists are gone, and the highlight of the week is taking the trash and recyclables to the local transfer station to catch up on local gossip. Living and working in a small community, my neighbors and I have become very self-sufficient, plowing our own driveways and relying on generators when the power goes off for days at a time. Our motto: always be prepared.

That motto holds true for the field of oncology as well. Cancer programs and cancer providers across the country must be continually vigilant and armed with the most up-to-date information, as we never know what type of oncological problem will walk through our doors next. Cancer is a complex disease, with so many different variations that the National Cancer Institute (NCI) lists them A to Z alphabetically. So while we are all very familiar with the top four cancers—prostate, breast, lung, and colorectal—there are hundreds of other cancers, including those defined as "rare," that may be seldom seen in the community setting.

So how can you prepare for those times when a patient with a less common cancer presents at your community cancer program? ACCC can help.

One of ACCC's greatest strengths is the networking opportunities it offers its membership—peer-to-peer communication that reaches across disciplines and care settings. ACCC member programs run the gamut from small, rural programs to large academic centers, from solo physician practices to large, multispecialty physician-owned practices. So when your program sees a patient with a rare cancer, I urge you to reach out to your fellow ACCC-member programs. In fact, ACCC is making it easier to do just that.

As part of its mission to educate its members, ACCC has identified several "Community Resource Centers" with expertise in less prevalent cancers, including chronic myeloid leukemia (CML), acute promyelocytic leukemia (APL), and multiple myeloma. In 2014 ACCC will identify Community Resource Centers for gastric cancer, pancreatic cancer, myelofibrosis, and more. These Community Resource Centers have experience with less common cancers and have stepped up to serve as virtual "experts-in-residence" for other community cancer programs.

We all understand that—when possible—patients want to receive their cancer care in the communities where they live. By leveraging tools, such as ACCC's Community Resource Centers, we can often make these wishes a reality. And even when patients with rare cancers must travel to receive treatment at academic or tertiary programs, they are often transitioned back to the community for follow-up. Therefore, it is vital that we, as community providers, remain connected to other cancer programs and updated about the most current treatment methods.

To learn more about this innovative program, turn to page 58. In "Ask ACCC's Community Resource Centers" (the first in a series), Elihu Estey, MD, professor of hematology at the University of Washington, discusses existing protocols for APL and shares an interesting case study that describes what happened when a patient with APL returned to her community oncologist for follow-up.

As you all know by now, my presidential theme is "it takes a team" to deliver quality cancer care. ACCC's Community Resource Centers take my theme to the next level by helping to "team" larger tertiary cancer programs with smaller community cancer centers to ensure quality care for patients with less common and even rare cancers. These Community Resources Centers are a win for all ACCC members—and, most importantly, the patients we treat! OI

Coming in Your 2014 *ONCOLOGY ISSUES*

- Skin Cancer Screening Clinic: A Creative Business Model
- Biosimilars: Emerging Issues for Cancer Programs?
- Clinical Pathway Trends—Payers, Providers, and Healthcare Evolution
- A Model Rural Chemotherapy Program
- Integrating Palliative Care into a Medical Oncology Practice
- Improving Oncology Genetic Counseling
- Creating a Virtual Genetic Counseling Environment
- How to Implement an Outpatient Pharmacy in Oncology Practices
- New Patient Coordinator: Streamlining a Cancer Center's Phone Lines
- Completion of a Community Health Needs Assessment
- SIR-Spheres Microspheres as a Treatment Option for Patients with Metastatic Colorectal Cancer

more online @ www.accc-cancer.org

AWARD

2014 ACCC Innovator Awards

Now in their fourth year, these awards 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, or cost-effectiveness. Apply today at *www.accc-cancer.org/innovator*.

VIDEO

Payment Systems: Current Challenges & Future Models

ACCC's town hall discussion focuses on the transformative shift underway in healthcare payment systems as reimbursement moves from volume-based, fee-for-service models to new value- and quality-based payment methodologies. *www.accc-cancer.org/education/TownHall*.

WEBINAR

Molecular Testing in Melanoma

Amit Jain, MD, MPH, Tallahassee Memorial Healthcare Hematology and Cancer Specialists, and Assistant Professor, FSU College of Medicine, presents on the efficacy and use of molecular markers in the treatment of melanoma. *www.accc-cancer.org/education/melanoma-webinars*.

LISTEN

Session Recordings of 2013 ACCC Innovator Winners

Access award-winning content from ACCC's National Oncology Conference—free of charge! Recordings and presentations cover a wide range of topics, including outpatient palliative care, genetic counseling, survivorship, and much more. *www.accc-cancer.org/innovator.*

INFO

Cancer Care in the Age of HIE Exchange

Hear from thought leaders how community oncology is being affected by the evolution of electronic HIE in ACCC's second white paper from its 2013 Institute for the Future of Oncology. *www.accc-cancer.org/institute*.

Oncology Issues is published bimonthly at the Association of Community Cancer Centers, 11600 Nebel St., Suite 201, Rockville, MD 20852. Editorial correspondence, changes of address, manuscripts, and letters to the editor should be addressed to: Managing Editor, Oncology Issues, 11600 Nebel St., Suite 201, Rockville, MD 20852-2557. Author's instructions available at www.accc-cancer.org.

Articles, editorials, letters to the editor, and other contributed materials represent the opinions of the authors and do not represent the opinions of the Association of Community Cancer Centers or the institution with which the author is affiliated unless the contrary is specified.

Basic rate: $55 per year for healthcare providers, plus $4.99 for shipping. ACCC membership dues pay for general, delegate, and chapter member subscriptions. Back issues available for $12.50 per copy, prepaid. Bulk rates available upon request.

Send correspondence, display advertising, insertion orders, printing materials to Mal Milburn, Oncology Issues, 11600 Nebel St., Suite 201, Rockville, MD 20852. Questions for general information may be directed to 301-984-5704.

Please send address changes to Association of Community Cancer Centers, 11600 Nebel St., Suite 201, Rockville, MD 20852.

fast

Even in the Cold of Winter, Mind These Melanoma Myths

MYTH: Dark skin doesn't burn, so those with it won't get skin cancer.

FACT: All skin types and ethnic groups can develop skin cancer.

MYTH: Putting on sunscreen when you get to the beach will protect against skin cancer.

FACT: Sunscreen takes about 15 to 30 minutes to be absorbed by skin.

MYTH: Unexposed skin can't get melanoma and doesn't need to be checked.

FACT: Whether skin is exposed or not, it is still at risk of melanoma.

MYTH: Only people who tan regularly get skin cancer.

FACT: Anyone can get melanoma. If a mole changes shape or color, or a patch of skin becomes hard or discolored, consult a doctor.

Source. Caliber I.D. *www.caliberid.com.*

5 Best (and Worst) States to Practice Medicine

1. Mississippi
2. Nevada
3. Alabama
4. Texas
5. Tennessee

1. New York
2. Hawaii
3. Maryland
4. Connecticut
5. Massachusetts

Source. Physicians Practice. Best States to Practice: 2013. *www.physicianspractice.com.*

facts

At Risk!

Between **35-60%** of all patients with head and neck cancers are malnourished at the time of diagnosis—the result of intake obstruction caused by the tumor and/or the lack of appetite and loss of muscle mass and fat stores associated with their cancer.

Source. Alshadwi A, Nadershah M, Carlson ER, Young LS, et al. Nutritional considerations for head and neck cancer patients: a review of the literature. *J Oral Maxillofac Surg.* 2013;71(11):1853-1860.

Survey Reveals Knowledge Gap about Blood Cancers

87% of respondents were surprised to learn that about every four minutes one person in the U.S. is diagnosed with a blood cancer.

86% of respondents were surprised to learn that approximately every 10 minutes someone in the U.S. dies from a blood cancer.

82% of respondents were surprised to learn that more than 1 million U.S. adults are currently living with a blood cancer.

Only **46%** of respondents believe that blood cancers are one of three leading causes of cancer death in the U.S. In fact, blood cancers are the third leading cause of cancer death.

Source. The Leukemia & Lymphoma Society. *www.lls.org.*

Emergency Physicians Save More than Lives

Emergency physicians are key decision makers for nearly half of all hospital admissions, highlighting a critical role they can play in reducing healthcare costs, according to a new report from the RAND Corporation.

Source. The RAND Corporation. *www.rand.org.*

ACCC Association of Community Cancer Centers 40 YEARS STRONG

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1981–82..... Herbert D. Kerman, MD
1980–81 ..... Robert W. Frelick, MD
1979–80..... Charles D. Cobau, MD
1978–79 ..... John R. Nelson, MD
1976–78 ..... J. Gale Katterhagen, MD
1974–76 ..... James Donovan, MD

accc

40 Years ago...

In **1974** a small group of physicians seeking to dispel the myth that community physicians were uninterested in and incapable of participation in state-of-the-art cancer care came together to form the Association of Community Cancer Centers (ACCC).

Penrose-St. Francis Health Services, Colorado

30 Years ago...

In **1981** ACCC's Ad Hoc Clinical Research Committee initiated efforts to effectively facilitate clinical trials dialogue with the National Cancer Institute (NCI). In **1982** NCI responded with the Community Clinical Oncology Program (CCOP).

fast facts

20 Years ago...

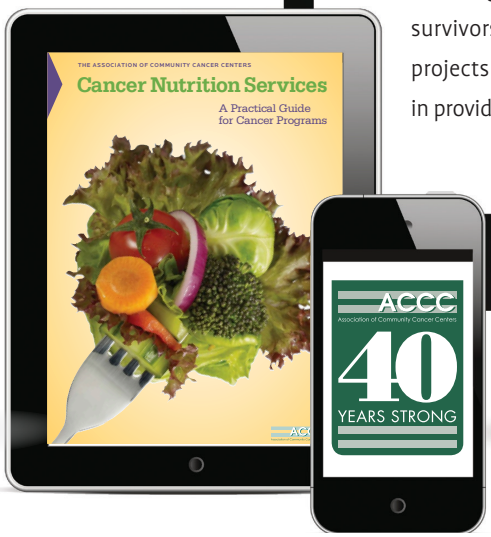
Cancer care began to shift from the inpatient setting to the outpatient hospital setting and physician practices. Keeping the multidisciplinary aspect of oncology care intact in all treatment settings became a major ACCC priority.

10 Years ago...

In December **2003**, the Medicare Modernization Act was enacted. ACCC worked closely with the Centers for Medicare & Medicaid Services and Congress on a number of issues of concern to members, including drug reimbursement, physician supervision requirements, and quality measures, among others.

And Today...

ACCC continues to expand its education programs and resources, including groundbreaking work on patient navigation, cancer survivorship, and cancer nutrition services. ACCC's education projects continue its commitment to support its membership in providing high-quality care for patients close to home.



Recognizing Our Victories and Challenges

BY MATTHEW FARBER, MA

November saw the release of the final 2014 Physician Fee Schedule (PFS) and Hospital Outpatient Prospective Payment System (OPPS) rules. On pages 12-24 Cindy Parman, CPC, CPC-H, RCC, provides an excellent summary of the coding and billing changes associated with these final rules. ACCC members can also access a recording of the Dec. 12, 2013, ACCC conference call summarizing these final rules. However, I wanted to be sure that everyone is aware of some of the "victories" that likely would not have happened had ACCC and other stakeholders not submitted formal comments to the proposed PFS and OPPS rules to the Centers for Medicare & Medicaid Services (CMS) over the summer.

For 2014, CMS was proposing significant changes—in both sites of service—that could have drastically altered how cancer care is delivered in the community setting.

For example, in the hospital outpatient department (HOPD), CMS proposed to bundle together numerous services, including chemotherapy administration. The agency also proposed to collapse the five levels of E&M codes to one level.

On the physician office side, for more than 200 codes, CMS proposed to cap payments at the same level as other sites of service, including some radiation oncology codes, which could have had a detrimental effect on those services being offered in certain settings.

ACCC submitted comments and testified before an advisory panel to CMS in August 2013, to voice our concerns with many of these proposed changes. We believed that these changes would have serious negative effects on cancer programs and cancer service lines, and we wanted to ensure that the agency was aware of the impact these changes might have.

The important takeaway: If ACCC and other stakeholders had not submitted comments, CMS likely would have assumed its proposed changes were fine, and therefore implemented the changes in 2014 as proposed. Remember, the comment period is our opportunity to inform CMS of what these changes would mean to our patients and to those of us "on the ground, in the community." Last year's comments were especially critical, given the complexity of many of the proposed changes for 2014.

So where were we victorious? On the hospital outpatient side, CMS did not finalize the proposal to bundle payments for chemotherapy administration. Codes for additional hours of infusion, sequential infusions, and/or other services used during treatment will continue to be paid separately.

CMS did not finalize its proposal to cap payment rates in the physician office setting at the same payment rates as other sites of service. ACCC believes these cuts appeared to be arbitrary and would have negatively impacted cancer programs across the country.

ACCC believes that the exclusion of these proposals from the final rules will mean more stable reimbursement for 2014.

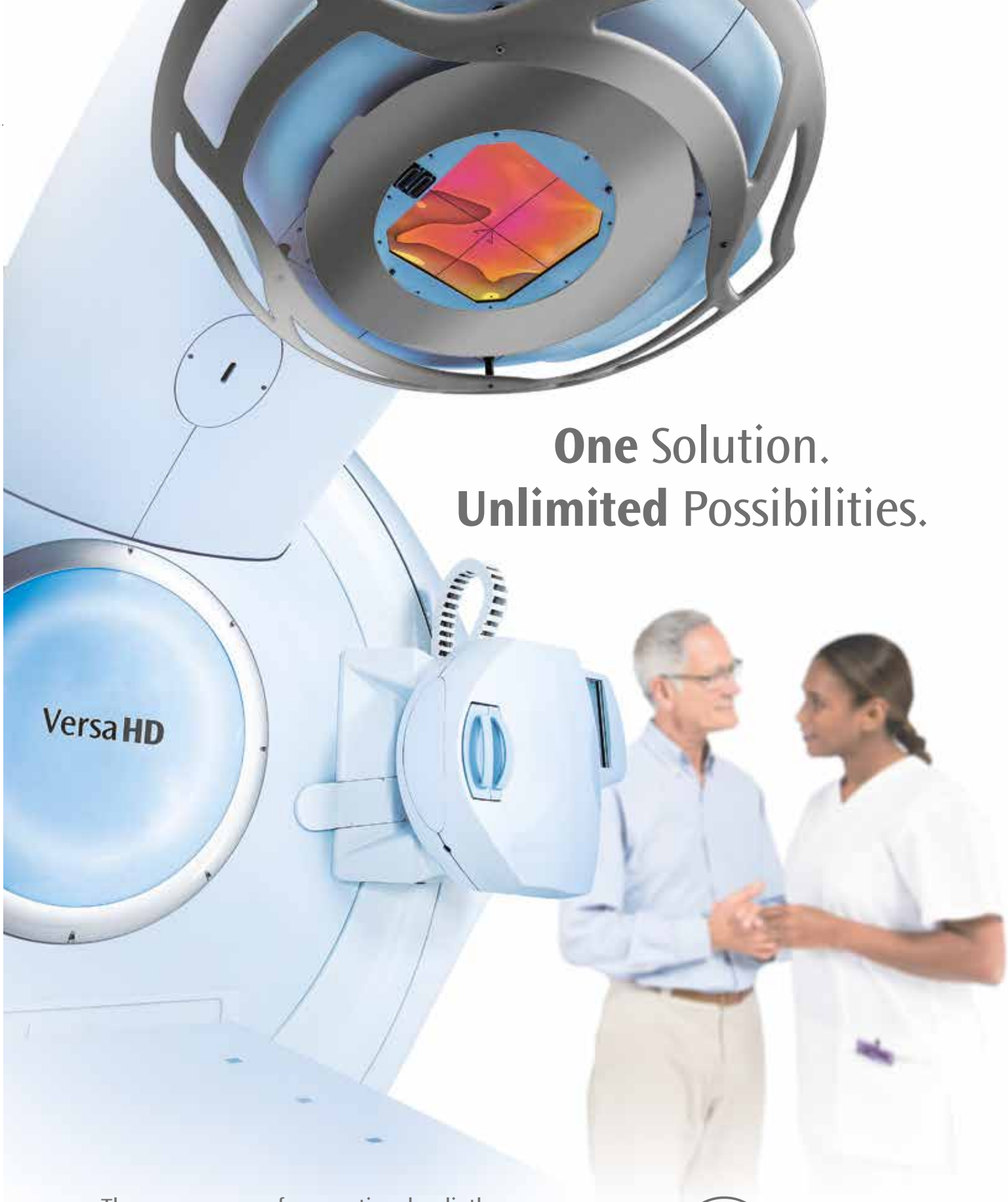
Unfortunately, the news was not all good.

Medical oncology is still slated to receive a roughly 2 percent decline in reimbursement in the physician office setting, due to changes in the Medicare Economic Index.

In addition, CMS did collapse the E&M codes for clinic visits in the HOPD from five codes into one code with reimbursement at about a level three E&M code. ACCC has concerns that this change will have a significant impact on cancer service lines. According to an informal survey of ACCC member hospitals conducted in 2013, oncologists who see new patients with a cancer diagnosis code typically bill the office visit using a level four or five E&M code.

ACCC will continue to participate in the rulemaking process by providing comments to CMS on behalf of its membership. Submitting comments to the agency—whether on proposed rules, local coverage decisions, or national coverage decisions—is an important step to ensure continued access to quality cancer care. We encourage ACCC members to make their voices heard as well. If you are interested in commenting to CMS on future proposals and do not know where to start, we can help. Email Matt Farber at *mfarber@accc-cancer.org* or Sydney Abbott at *sabbott@accc-cancer.org*. OI

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



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Oncology Reimbursement Update 2014

BY CINDY PARMAN, CPC, CPC-H, RCC

Prior to releasing its final rules on Nov. 27, 2013, the Centers for Medicare & Medicaid Services (CMS) published updated beneficiary cost-sharing and premium payments for those enrolled in original Medicare during calendar year (CY) 2014 in Transmittal R82GI, dated Nov. 15, 2013. The inpatient hospital deductible will increase to $1,216 for the first 60 days, and daily coinsurance for days 61 to 90 will increase to $304. The coinsurance amount for days 21 through 100 in a skilled nursing facility will increase to $152 per day. For Medicare Part B services, the annual deductible remains the same at $147.00.[1]

New & Revised Codes

Each year there are new codes, revised codes, and updates to coding guidelines. Effective Jan. 1, 2014, there has been a rewrite of the code definitions for radiation oncology simulation services. The codes are now defined as follows:

- **77280:** Therapeutic radiology simulation-aided field setting; simple simulation of a single treatment area.
- **77285:** Therapeutic radiology simulation-aided field setting; intermediate simulation of two separate treatment areas.
- **77290:** Therapeutic radiology simulation-aided field setting; complex. Three or more treatment areas, or any number of treatment areas if any of the following are involved: particle, rotation, or arc therapy, complex blocking, custom shielding blocks, brachytherapy simulation, hyperthermia probe verification, or any use of contrast materials.

There is a new add-on code for motion management during the radiation simulation process:

- **+77293:** Respiratory motion management simulation. (List separately in addition to the code for the primary procedure).

This code describes the physician work and resources involved in acquiring a respiratory correlated 4D simulation study for conformal planning. This code will only be reported on the same service date as codes **77295** (3D radiation planning) or **77301** (IMRT treatment planning). An "add-on" code represents a service performed in addition to the primary procedure and applies only to procedures or services performed by the same physician. Add-on codes are always performed in addition to the primary procedure and are never reported as a stand-alone code.

The code for 3D simulation was redefined and relocated to a different section of the *CPT Manual*:

- **77295:** Three-dimensional radiotherapy plan, including dose-volume histograms.

Telephone and/or Internet Consultations

There is also a new set of codes to report inter-professional telephone and/or Internet consultations. An inter-professional telephone and/or Internet consultation is an assessment and management service during which a patient's treating physician or other qualified healthcare professional requests an opinion and/or treatment advice of a physician with specialty expertise to assist in the diagnosis and/or management of the patient's condition without the need for a face-to-face patient encounter with the consultant. The consulting physician reports one of the following codes:

- **99446:** Inter-professional telephone and/or Internet assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating and/or requesting physician or other qualified healthcare professional; 5-10 minutes of medical consultative discussion and review.
- **99447:** 11-20 minutes of medical consultative discussion and review.
- **99448:** 21-30 minutes of medical consultative discussion and review.
- **99449:** 31 minutes or more of medical consultative discussion and review.

According to the code definitions included in the 2014 *CPT Manual:*

These services are typically provided in complex and/or urgent situations where a timely face-to-face service with the consultant may not be feasible.

The patient may be either a new patient to the consultant or an established patient with a new problem or exacerbation of an existing problem. The consultant must not have seen the patient in a face-to-face encounter during the prior 14 days. In addition, these codes are not reported if the telephone/Internet consultation leads to an immediate transfer of care or other face-to-face service within the next 14 days or next available appointment. Last, this service should not

be reported more than once within a 7-day interval.

Review of pertinent medical records, laboratory studies, imaging studies, medication profile, or pathology specimens may be required and transmitted electronically by fax or by mail immediately before the telephone/Internet consultation or following the service. The review of this data is included in the telephone/Internet consultation service and not reported separately.

The majority of the service time reported (greater than 50%) must be devoted to the medical consultative verbal/Internet discussion. If more than one telephone/Internet contact is required to complete the consultation request, the entirety of the service and the cumulative discussion should be reported with a single code.

The written or verbal request for advice should be documented in the patient's medical record, including the reason for the request and a written report from the consulting physician to the treating physician. In addition, the requesting physician must notify the patient, since there will be deductible and/or coinsurance due for the service billed by the consultant.

When the sole purpose of the telephone/Internet communication is to arrange a transfer of care or other face-to-face service, these codes are not reported. In addition, telephone/Internet consultations of less than 5 minutes should not be reported.

Clarification in Push Codes

The 2014 *CPT Manual* clarified the correct use of push codes when medication is administered more than once during a hospital stay. According to the updated guidelines:

However, if instead of a continuous infusion, a medication was given by intravenous push at 10 PM and 2 AM, as the service was not continuous, the two administrations would be reported as an initial service (96374) and sequential (96376) as: (1) no other infusion services were performed; and (2) the push of the same drug was performed more than 30 minutes beyond the initial administration.

Last, the American Medical Association (AMA) added cautionary verbiage in the introduction to Appendix C, Clinical Examples. This appendix includes samples of services performed that meet the definition of various patient visit codes. The new verbiage includes:

Therefore, these examples are not appropriately used for any review of correct coding or estimating physician or other qualified health care professional work. These clinical examples do not encompass the entire scope of medical practice.

A particular patient encounter, depending on the specific circumstances, must be judged by the services provided by the physician or other qualified health care professional for that particular patient.

In addition to new and revised procedure coding instructions, there have been some significant updates to HCPCS Level II codes. Table 1 (below) shows the new codes established for drugs effective Jan. 1, 2014. Other HCPCS codes were deleted and replaced with new HCPCS Level II codes (see Table 2, page 14).

Oral Anti-Emetics

A new code was established for oral chlorpromazine hydrochloride, oral 5 mg, and the codes for the 10 mg and 25 mg doses were deleted.

- **New Code Q0161:** Chlorpromazine hydrochloride, 5 mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- **Deleted Code Q0171:** Chlorpromazine

Table 1. New Oral Anti-Emetic HCPCS Level II Codes

CODE	DEFINITION
C9132	Prothrombin complex concentrate (human), KCentra, per i.u. of factor IX activity
C9133	Factor IX (antihemophilic factor, recombinant), Rixubis, per i.u.
C9441	Injection, ferric carboxymaltose, 1 mg
C9497	Loxapine, inhalation powder, 10 mg
J0401	Injection, aripiprazole, extended release, 1 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J9371	Injection, vincristine sulfate liposome, 1 mg

Table 2. New HCPCS Level II Codes That Replaced Deleted Codes

2014 NEW CODE		2013 DELETED CODE	
J1556	Injection, immune globulin (bivigam), 500 mg	**C9130**	Injection, immune globulin (bivigam), 500 mg
J9354	Injection, ado-trastuzumab emtansine, 1 mg	**C9131**	Injection, ado-trastuzumab emtansine, 1 mg
J9306	Injection, pertuzumab, 1 mg	**C9292**	Injection, pertuzumab, 10 mg
J3060	Injection, taliglucerase alfa, 10 units	**C9294**	Injection, taliglucerase alfa, 10 units
J9047	Injection, carfilzomib, 1 mg	**C9295**	Injection, carfilzomib, 1 mg
J9400	Injection, ziv-aflibercept, 1 mg	**C9296**	Injection, ziv-aflibercept, 1 mg
J9262	Injection, omacetaxine mepesuccinate, 0.01 mg	**C9297**	Injection, omacetaxine mepesuccinate, 0.01 mg
Q2050	Injection, doxorubicin hydrochloride, liposomal, not otherwise specified, 10 mg	**J9002**	Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg
Q3027	Injection, interferon beta-1a, 1 mcg for intramuscular use	**Q3025**	Injection, interferon beta-1a, 11 mcg for intramuscular use
Q3028	Injection, interferon beta-1a, 1 mcg for subcutaneous use	**Q3026**	Injection, interferon beta-1a, 11 mcg for subcutaneous use
J0717	Injection, certolizumab pegol, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	**J0718**	Injection, certolizumab pegol, 1 mg

hydrochloride, 10 mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

- **Deleted Code Q0172:** Chlorpromazine hydrochloride, 25 mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

The following oral anti-emetic HCPCS codes were deleted effective Jan. 1, 2014, without the creation of corresponding new codes:

- **Q0165:** Prochlorperazine maleate, 10 mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- **Q0168:** Dronabinol, 5 mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- **Q0170:** Promethazine hydrochloride, 25 mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- **Q0176:** Perphenazine, 8 mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
- **Q0178:** Hydroxyzine pamoate, 50 mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

With the FDA approval in 2013 of Astragraf XL, a sustained-release form of the immunosuppressive drug tacrolimus, the description of the tacrolimus code (**J7507**) was revised and new code **J7508** was created for CY 2014 to distinguish between immediate and sustained release forms of the drug. The new codes are now:

- **J7507:** Tacrolimus, immediate release, oral, 1 mg.
- **J7508:** Tacrolimus, extended release, oral, 0.1 mg.

The three existing codes for the osteoporosis drug zoledronic acid (**J3487**, Zometa; **J3488**, Reclast; and **Q2051**, not otherwise specified), which distinguished between different formulations or brand names, have been deleted and replaced with a single code: **J3489**.

Two existing codes for filgrastim G-CSF (Neupogen) were deleted (**J1440** and **J1441**), and two new codes were established for filgrastim G-CSF and TBO-filgrastim (Granix). The two new codes are:

- **J1442:** Injection, filgrastim (G-CSF), 1 microgram. (When updating code information, note the dosage change.)
- **J1446:** Injection, TBO-filgrastim, 5 micrograms.

In addition to code changes, Table 1 (page 13) shows the new HCPCS Level II oral anti-emetic drug codes that became effective Jan. 1, 2014.

Electrical Stimulation for Cancer Treatment

Two new supply codes were created for devices used in electrical stimulation for cancer treatment:

- **A4555:** Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only.
- **E0766:** Electrical stimulation device used for cancer treatment includes all accessories, any type.

IVIG Demonstration Project

A code was created for supplies used in the Medicare IVIG demonstration project: **Q2052**, services, supplies and accessories used in the home under the Medicare intravenous immune globulin (IVIG) demonstration. OI

References

1. CMS. Update to Medicare Deductible, Coinsurance and Premium Rates for 2014. Available online at: *www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2013-Transmittals-Items/R82GI.html*. Last accessed Dec. 2, 2013.
2. CMS. Transmittal 310: Requirements for Including an 8-Digit Clinical Trial Number on Claims. Available online at: *www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R310OTN.pdf*. Last accessed Dec. 2, 2013.
3. CMS. Transmittal R2805CP: Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims. Available online at: *www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2013-Transmittals-Items/R2805CP.html*. Last accessed Dec. 2, 2013.

Mandatory Clinical Trial Number

While not published as part of a final rule, CMS released information in October 2013 that states the clinical trial number must be included on claims for trial patients beginning Jan. 1, 2014.

Effective April 1, 2008, CMS allowed the *voluntary* submission of the 8-digit clinical trial number on both the hospital and physician claim forms. The number that CMS requested is the number assigned by the National Library of Medicine (NLM) Clinical Trials Data Bank when a sponsor or investigator registers a new study. CMS was using this number to identify all items and services provided to beneficiaries during their participation in a clinical trial.[2] This identifier also permitted CMS to meet the recommendations from the White House Executive Memorandum to increase Medicare participation in clinical trials by tracking Medicare payments for trial services, using the information gathered to make informed coverage decisions and ensuring that research focuses on issues that are important to the Medicare population.

Effective Jan. 1, 2014, CMS no longer considered the inclusion of the clinical trial number to be voluntary; instead, healthcare providers are required to report the 8-digit trial number on all claims during the time period the beneficiary participates in the trial. Transmittal 2805, dated Oct. 30, 2013, includes claim submission details and states:[3]

Medicare Part B clinical trial/registry/study claims with dates of service on and after January 1, 2014, not containing an 8-digit clinical trial number will be returned as unprocessable to the provider for inclusion of the trial number.

This Transmittal includes the following instruction:

The clinical trial number that the Centers for Medicare & Medicaid Services (CMS) is making mandatory is the same number that has been reported voluntarily since the implementation of CR5790, TR310, dated January 18, 2008, the number assigned by the National Library of Medicine (NLM) ClinicalTrials.gov website when a new study appears in the NLM Clinical Trials data base.

All hospitals, freestanding cancer centers, and physicians should keep in mind that once the clinical trial number has been captured by the CMS Common Working File (CWF), any subsequent claim for that patient without the mandatory NLM study number could be rejected. As a result, it is essential that internal tracking of clinical trial patients, manually or electronically, be maintained to ensure that all services, including but not limited to, oncology services, imaging, laboratory, professional charges, surgery, and other related diagnostic and/or therapeutic procedures include the appropriate clinical trial number to prevent claim rejection. In addition, all physicians and facilities providing any part of the trial patient's care must coordinate to appropriately report investigational and routine services performed as part of the trial protocol.

Hospital Regulatory Update 2014

The Outpatient Prospective Payment System (OPPS) is not intended to be a fee schedule, in which separate payment is made for each coded line item. However, the OPPS is currently a prospective payment system that packages some items and services, but not others. CMS' overarching goal is to make payments for all services covered under OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule. For CY 2014, CMS will again base payments on geometric mean costs. Under this methodology, claims are selected for services paid under the OPPS and matched to the most recent cost report filed by the individual hospitals represented in the claims data.

CMS estimates that total payments, including the beneficiary cost-share, to the approximately 4,100 facilities paid under OPPS will be approximately $50.4 billion in CY 2014, an increase of just over $4 billion compared to CY 2013 payments. Outpatient hospital payment rates will increase by 1.7 percent and CMS will continue the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting (OQR) requirements. The CY 2013 conversion factor of $71.313 increases to $72.672 with the 1.7 percent increase, but for hospitals that fail to meet the OQR requirements, the conversion factor will drop to $71.219 in 2014.

CMS will also continue the policy of providing additional payments to cancer hospitals so that the hospitals' payment-to-cost ratio, with the adjustment, is equal to the weighted average for the other OPPS hospitals. And last, CMS will continue to make an outlier payment that equals 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the final fixed dollar threshold of $2,900 are met.

Packaging Update

Effective in CY 2014, CMS will unconditionally or conditionally package the following five categories of items and services:

- Drugs, biologicals, and radiopharmaceuticals used in a diagnostic test or procedure
- Drugs and biologicals when used as supplies in a surgical procedure
- Certain clinical diagnostic laboratory tests
- Procedures described by add-on codes
- Device removal procedures.

However, CMS added that given the frequency of drug administration services in the hospital outpatient department and their use in such a wide variety of different drug treatment protocols for various diseases in all types of hospitals, further study of the payment methodology for these services is warranted at this time. Therefore, CMS did not finalize the proposal to package drug administration add-on codes for CY 2014.

In order to improve the accuracy and transparency of payment for certain device-dependent services, CMS is finalizing the policy to establish 29 comprehensive APCs to prospectively pay for the most costly hospital outpatient device-dependent services, but will delay the implementation of this policy until CY 2015. A comprehensive APC, by definition, will provide a single payment that includes the primary service and all adjunct services performed to support the delivery of the primary service. For services that trigger a comprehensive APC payment, the comprehensive APC will treat all individually reported codes on the claim as representing components of the comprehensive service, resulting in a single prospective payment for the comprehensive service. Hospitals will continue to report procedure codes for all services performed, but will receive a single payment for the total service. According to the 2014 final OPPS rule:

Typically beneficiaries understand the primary procedure to be the OPPS service they receive, and do not generally consider that the other HCPCS codes are separate services. For example, beneficiaries believe that a single service includes procedures such as "getting my gall bladder removed" or "getting a pacemaker." We believe that defining certain services within OPPS in terms of a single comprehensive service delivered to the beneficiary improves transparency for the beneficiary, for physicians, and for hospitals by creating a common reference point with similar meaning for all three groups and using the comprehensive service concept that already identifies these same services when they are performed in an inpatient environment.

In addition to services currently packaged, CMS intends to include ancillary services (status indicator X), certain clinical diagnostic laboratory tests, and drugs that function as supplies when used in a surgical procedure. CMS agrees that hospitals should have time to prepare for a comprehensive payment structure, and the delay in implementation until CY 2015 will allow more

time to operationalize the changes necessary to process comprehensive payments. CMS will also take advantage of this delay to request additional public comments on this packaging methodology.

Hospital Clinic Visit

Since April 7, 2000, CMS has instructed hospitals to report facility resources for clinic and emergency department hospital outpatient visits using the CPT evaluation and management (E/M) codes and to develop internal hospital guidelines for reporting the appropriate visit level. Because there was no national set of hospital visit guidelines, CMS has traditionally stated that internal guidelines should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes. Citing difficulty with the development of national guidelines, accommodating a variety of patient populations and service mix, no single approach to facility visit coding has been evident. According to the 2014 Final Rule:

While we agree that the proposed clinic APC encompasses a range of visits for beneficiaries with different medical issues, we believe that the spectrum of hospital resources provided during an outpatient hospital clinic visit is appropriately captured and reflected in the single level payment for clinic visits. We also believe that a single visit code is consistent with a prospective payment system, where payment is based on an average estimated relative cost for the service, although the cost of individual cases may be more or less costly than the average.

We continue to believe discontinuing the use of the five levels of HCPCS visit codes for clinic visits will reduce hospitals' administrative burden by eliminating the need for them to develop and apply for their own internal guidelines to differentiate among five levels of resource use for every clinic visit they provide... We note that the level of CPT® code is not the only method for assessing patient acuity. Diagnosis coding and the type and frequency of other services billed on a visit claim also communicate patient acuity.

As a result, CMS has finalized its proposal to replace the current five levels of visit codes for hospital technical clinic visits with a single new Level II HCPCS code representing a single level of payment for clinic visits:

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

This visit code will be reported for new patients and established patients and is assigned to new APC 0634 with a payment rate based on the total mean costs of Level 1 through Level 5 clinic visit codes.

Supervision

CMS has established that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare in hospitals, as well as in provider-based departments of hospitals. In the 2010 OPPS rule, CMS finalized a technical correction to the title and text of the applicable regulations (42 CFR 410.27) to clarify that this supervision standard applies in Critical Access Hospitals (CAHs), as well as other hospitals. In response to concerns expressed by CAHs and small rural community hospitals that they would have difficulty meeting this standard, CMS instructed all Medicare contractors not to evaluate or enforce the supervision requirements for therapeutic services provided to outpatients in CAHs while the agency revisited the supervision policy during future rulemaking cycles.

In subsequent calendar years, the OPPS Panel met to consider and advise CMS regarding stakeholder requests for changes in the required level of supervision of individual hospital outpatient therapeutic services. Based on the panel's recommendations, CMS has modified supervision requirements to shift some services to a general supervision requirement. Most comments received on the 2014 proposed rule requested that CMS continue to extend the enforcement of direct supervision or even develop policies exempting CAHs and small rural hospitals from the requirement for direct supervision, citing insufficient staff and difficulty in recruiting physicians and nonphysician practitioners. These commenters believe that if enforced, the CAHs will have to limit their hours of operation for chemotherapy, other intravenous infusions, and radiation oncology.

Effective Jan. 1, 2013, CMS accepted recommendations of the OPPS Panel on Supervision Levels for Select Services. The agency states that it intends to adopt recommendations from the OPPS Panel to update the supervision level of the following oncology services to general supervision:[1]

- **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.

In the 2014 OPPS final rule, CMS states that it continues to believe that direct supervision is the appropriate level of supervision for most hospital outpatient therapeutic services. As a result, effective Jan. 1, 2014, the instruction for Medicare contractors to not enforce supervision requirements in CAHs or small rural hospitals will expire. This means that all hospitals, including CAHs and small rural hospitals, may only provide chemotherapy, therapeutic drug administration, and radiation therapy when all direct supervision requirements are met, including the immediate availability of a qualified physician or nonphysician practitioner who is able to provide assistance and direction, clinically appropriate to redirect the service or provide additional orders.

Scope of Practice

Under current policy, CMS generally defers to hospitals to ensure that state scope of prac-

tice and other state rules relating to healthcare delivery are followed, such that these services are performed only by qualified personnel in accordance with all applicable laws and regulations. After consideration of public comments received, CMS is amending the conditions of payment for therapeutic "incident-to" hospital (including CAH) outpatient services to explicitly require that individuals furnishing these services be in compliance with state law. It is important to note that this final policy does not impose any new requirements on hospitals that bill Medicare because practitioners and other personnel furnishing services already are required to comply with the laws of the state in which the services are furnished. This regulatory change simply adopts the existing requirements as a condition of payment under Medicare. The 2014 OPPS rule adds:

Codifying this requirement provides the Federal government with a clear basis to deny Medicare payment when services are not furnished in accordance with applicable State law, as well as to ensure that Medicare pays for services furnished to beneficiaries only when the services meet the requirements imposed by the States to regulate health care delivery for the health and safety of their citizens.

Off-Campus Provider-Based Departments

In the CY 2014 proposed rule, CMS solicited comments regarding a potential new claims modifier or other data element that would designate services furnished in an off-campus provider-based department. According to CMS, research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resulting increase in the delivery of physician services in a hospital setting. When a Medicare beneficiary receives outpatient services in a hospital, the total payment amount for outpatient services made by Medicare is generally higher than the total payment amount made by Medicare when a physician furnishes those same services in a freestanding clinic or in a physician's office. CMS received a number of comments and recommendations regarding methods for collecting detailed information and stated that it will continue to consider approaches to collecting data on services furnished in off-campus provider-based departments.

Quality Measures & EHRs

CMS also adopted four new quality measures for the Hospital Outpatient Quality Reporting (OQR) Program CY 2016 payment determinations. Three of these measures will require the collection of aggregate data (numerators, denominators, and exclusions) and submission via an online web-based tool located on the CMS website. The other hospital acquired infection quality measure will be submitted through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network. Last, two quality measures will be removed and administrative procedures will be codified.

CMS is also revising regulations to provide a special method for making hospital-based determinations for 2014 only in the cases of those eligible professionals (EPs) who reassign their benefits to Method II CAHs. Previously, CMS has been unable to make electronic health record payments to these EPs for their CAH II claims, or to take those claims into consideration in making hospital-based determinations because of system limitation.

Radiation Oncology Services

CMS previously proposed to conditionally package all codes assigned the ancillary service status indicator "X" for CY 2014. Conditional packaging meant that if a service with an X status was reported on the same service date as a significant procedure, the X status code would not be separately reimbursed. However, after a review of public comments received, CMS has decided not to conditionally package all of these codes, which included simulations and a number of other radiation oncology services. However, the agency indicated that these ancillary services would be reviewed in future years to determine which may be appropriate for packaging.

CMS also indicated a concern with hospital pricing for several different services, including the high-dose rate (HDR) brachytherapy source billed for each brachytherapy treatment. According to the 2014 OPPS rule:

As we have stated in previous OPPS/ASC proposed and final rules, we agree that HDR brachytherapy sources such as HDR Iridium-192 have a fixed active life and must be replaced every 90 days. As a result, hospitals' per-treatment cost for the source would be dependent on the number of treatments furnished per source. The source cost must be amortized over the life of the source. Therefore, when establishing their charges for HDR Iridium-192, we expect hospitals to project the number of treatments that would be provided over the life of the source and establish their charges for the source accordingly. After consideration of public comments we received, we are finalizing our proposal to continue to set the payment rates for brachytherapy sources using our established prospective payment methodology, which is based on geometric mean costs.

This means that hospitals should ensure that charges for procedure code **C1717** (brachytherapy source, high-dose rate Iridium 192, per source) accurately reflect cost of the reusable source for each patient treatment.

Beginning in CY 2008, CMS began providing a single payment allowance under a Composite APC for low-dose rate (LDR) prostate brachytherapy. At least two procedure codes are used to report the composite treatment service because there are separate codes that describe placement of the needles (code **55875**, transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and the application of the brachytherapy (code **77778**, interstitial radiation source application, complex). These codes are generally present together on claims for the same date of service and the same operative session. For CY 2014, CMS will continue to pay for LDR prostate brachytherapy using Composite APC 8001, with a geometric mean cost of approximately $3,858.

Beginning in CY 2014, CMS will conditionally or unconditionally package certain procedures described by an add-on code. According to CMS, procedures described by add-on codes represent an extension or continuation of a primary procedure, which means that they are typically supportive, dependent, or adjunctive to a primary service. The primary code defines the purpose and typical scope of the patient encounter and the add-on code describes incremental work. As a result, the following new code will be packaged when billed by the hospital:

- **+77293:** Respiratory motion management simulation. (List separately in addition to code for primary procedure.)

This means that the hospital will report the add-on code with the correct primary procedure (code **77295**, 3D radiation planning, or code **77301**, IMRT computer planning), but there will be no separate payment for this service.

Effective Jan. 1, 2012, two new procedure codes were added for intraoperative radiation treatment delivery. Code **77424** describes a single treatment by X-ray (photons) and code **77425** describes a single treatment by electrons. For CY 2014, these codes will remain in **APC 0065**, but the APC will be renamed "IORT, MRgFUS, and MEG" with an estimated payment rate of $1,715. In the 2014 proposed rule, CMS noted that both of these codes include the placement and removal of an applicator into the breast, as well as the delivery of radiation therapy. Numerous comments were received, including statements that HCPCS code **C9726** (placement and removal of applicator into breast for radiation therapy) represented the cost of the applicator and hospital costs related to the surgeon's placement of the applicator. Based on the comments received, CMS will not delete this HCPCS code; however, the code will be redefined as "Placement and removal (if performed) of applicator into breast for intraoperative radiation therapy, add-on to primary breast procedure." In addition, this will be an add-on code for which payment is packaged into the reimbursement for the primary procedure. As a result, hospitals will continue to report this code, but there will be no separate reimbursement for this procedure.

Since CY 2007, there have been both HCPCS Level II codes and CPT procedure codes for stereotactic radiosurgery (SRS) and SBRT treatment. According to the OPPS final rule:

However, SRS techniques and equipment have evolved and expanded over time. In light of these developments and our understanding of current SRS technology and clinical practice, we have reexamined the HCPCS G-codes and CPT codes for SRS with the intent of identifying the codes that would best capture the significant differences between the various procedures while eliminating unnecessary complexity, redundancy, and outdated distinctions that no longer represent meaningful distinctions for purposes of OPPS payment. Based on our review of the current SRS technology, we understand that most current linac-based SRS technology incorporates some type of robotic feature. Therefore we believe that it is no longer necessary to continue to distinguish robotic versus non-robotic linac-based SRS through the HCPCS G-codes.

CMS added that they intend to refrain from creating supplemental HCPCS G-codes or C-codes that describe attributes of a particular device under the assumption of more precise coding. Of importance, the agency does not want to risk unintentionally creating a competitive advantage for a particular technology through the establishment of codes that may not be based on the most complete understanding of the clinical science of treatment delivery.

As a result, CMS replaced the HCPCS Level II G-codes (**G0173**, **G0251**, **G0339**, and **G0340**) with CPT procedure codes effective Jan. 1, 2014. The status indicators for the HCPCS codes have been updated to B (alternative code may be available) since the Medicare Physician Fee Schedule (PFS) may continue to use these codes in a "carrier priced" capacity. In response to comments received, CMS provided the following coding guidance for the replacement CPT codes **77371**, **77372**, and **77373**:

CPT code **77371** *is to be used only for single session cranial SRS cases performed with a Cobalt-60 device, and CPT code* **77372** *is to be used only for single session cranial SRS cases performed with a linac-based device. The term "cranial" means that the pathological lesion(s) that are the target of the radiation is located in the patient's cranium or head. The term "single session" means that the entire intracranial lesion or lesions that comprise the patient's diagnosis are treated in their entirety during a single treatment session on a single day.*

CPT code **77372** *is never to be used for the first fraction or any other fraction of fractionated treatment. CPT code* **77372** *is to be used only for single session cranial linac-based SRS treatment. Fractionated SRS treatment is an SRS delivery service requiring more than a single session of SRS treatment for a cranial lesion, up to a total of no more than five fractions, and one to five fractions (but no more than five) for non-cranial lesions.*

CPT code **77373** *is to be used for any fraction (including the first fraction) in any series of fractionated treatments, regardless of the anatomical location of the lesion or lesions being radiated. Fractionated cranial SRS treatment is any cranial SRS delivery service that exceeds one treatment session and fractionated non-cranial SRS treatment is any non-cranial SRS delivery service, regardless of the number of fractions, but never more than five. Therefore, CPT code* **77373** *is the exclusive code (and the use of no other SRS treatment delivery code is permitted) for any and all fractionated SRS treatment services delivered anywhere in the body, including but not limited to, the cranium or head.*

In addition, CMS has assigned code **77371** (radiation treatment delivery, SRS, complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt-60 based) and **77372** (radiation treatment delivery, SRS, complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based) to **APC 0067**, which has been renamed "Level II Stereotactic Radiosurgery."

Procedure code **77373** is assigned to **APC 0066**, which is now titled "Level I Stereotactic Radiosurgery." In response to questions regarding single fraction treatment, CMS stated that it believes the high degree of clinical similarity for the Cobalt-60 and linac-based treatments support grouping these services together.

Medical Oncology & Hematology Services

Based on the OPPS final rule for CY 2014, payment for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status will be set at the statutory default of average sales price (ASP) plus 6 percent. According to CMS, the ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals for CY 2014. In addition, CMS finalized the proposed policy to continue to establish payment rates for blood and blood products using a blood-specific cost-to-charge methodology.

Section 1833 of the Social Security Act permits CMS to make pass-through payments for a period of at least two, but not more than three, years after the product's first payment as a hospital outpatient service under Medicare Part B. The long-standing practice has been to provide pass-through payment for a period of two to three years, with expiration of pass-through status proposed and finalized through the annual rulemaking process. CMS included a list of the drugs for which pass-through status expired on Dec. 31, 2013, in the final rule (see Table 3, page 20).

In addition to drugs and biologicals with expired pass-through status, other medications and substances were approved for pass-through during CY 2014. Payment for drugs and biologicals with pass-through status under the OPPS is currently made at

the physician's office payment rate of ASP+6 percent. If ASP data are not available for a radiopharmaceutical, CMS will provide pass-through payment at wholesale acquisition cost (WAC)+6 percent. And, if WAC information is also not available, CMS will provide payment for the pass-through radiopharmaceutical at 95 percent of its more recent average wholesale price (AWP). Table 4 (page 21) shows the drugs and biologicals that will continue or have been granted pass-through status as of January 2014.

Under the comprehensive service APCs that will be effective for CY 2015, drugs supplied to the patient to fill the reservoir of a pump at the time of pump implantation will be considered adjunctive to the procedure. As reviewed on page 16, costs of costly adjunctive services will be included proportionally into the cost estimation for the primary service. CMS confirmed that drugs used to fill pumps at the time of a comprehensive pump insertion procedure will be considered to be ancillary and supportive to the primary procedure and packaged as part of the comprehensive APC payment regardless of whether the drug was previously packaged within the OPPS payment, was previously separately paid under the OPPS, or was previously paid according to a Durable Medical Equipment fee schedule.

Ambulatory Surgical Center Update

For CY 2014, CMS is increasing payment rates under the Ambulatory Surgical Center (ASC) payment system by 1.2 percent. The final ASC conversion factor for ASCs that meet all quality reporting requirements is $43.471 and for ASCs that do not meet the quality reporting requirements, the conversion factor is $42.612. Based on this update, CMS estimates that total payments to ASCs in CY 2014, including beneficiary cost-share, will be approximately $3.992 billion. This represents an increase of about $143 million compared to CY 2013 payments.

CMS received no comments on the proposal to update the ASC list of ancillary services to reflect the proposed payment status for the same services under the OPPS in CY 2014. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2013 may be proposed for packaged status under CY 2014 OPPS and, therefore, also under the ASC payment system for CY 2014. In the absence of public comments, CMS is finalizing, without modification, the proposal to update the ASC list of covered ancillary services to reflect the payment status for the same services under the OPPS.

For the Ambulatory Surgical Center Quality Reporting (ASCQR) Program, CMS is adopting three new quality measures for the CY 2016 payment determination. Aggregate data (numerators, denominators, and exclusions) will be collected on all ASC patients for these four chart-abstracted measures via an online web tool located on a CMS website. Effective for CY 2016, ASCs will also be required to establish a QualityNet account and security administrator, facility participation, a minimum threshold, and minimum volume for claims-based measures, and data collection

Table 3. Drugs & Biologicals with a Pass-Through Status that Expired Dec. 31, 2013

CY 2014 HCPCS CODE	CY 2014 LONG DESCRIPTOR	CY 2014 STATUS INDICATOR	CY 2014 APC
A9584	Iodine I-123 ioflupane, diagnostic, per study dose, up to 5 millicuries	**N**	**N/A**
C9285	Lidocaine 70 mg/tetracaine 70 mg, per patch	**N**	**9285**
J0131	Injection, acetaminophen, 10 mg	**N**	**9283**
J0485	Injection, belatacept, 1 mg	**K**	**9286**
J0490	Injection, belimumab, 10 mg	**K**	**1353**
J0638	Injection, canakinumab, 1 mg	**K**	**1311**
J0712	Injection, ceftaroline fosamil, 10 mg	**N**	**9282**
J1572	Injection, immune globulin, (flebogamma/flebogamma dif),intravenous, non-lyophilized (e.g., liquid), 500 mg	**K**	**0947**
J2507	Injection, pegloticase, 1 mg	**K**	**9281**
J7180	Injection, factor xiii (antihemophilic factor, human), 1 i.u.	**K**	**1416**
J9042	Injection, brentuximab vedotin, 1 mg	**K**	**9287**
J9179	Injection, eribulin mesylate, 0.1 mg	**K**	**1426**
J9228	Injection, ipilimumab, 10 mg	**K**	**9284**
Q4124	Oasis Ultra Tri-Layer matrix, per square centimeter	**N**	**9365**

and submission for new measures and for certain previously finalized measures. OI

References

1. CMS. CMS' Final Decisions on the August 2012 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/2012-Aug-Final-Supervision-Decisions.pdf.* Last accessed Dec. 3, 2013.

Table 4. Drugs & Biologicals with Pass-Through Status in CY 2014

CY 2013 HCPCS CODE	CY 2014 HCPCS CODE	CY 2014 LONG DESCRIPTOR	CY 2014 STATUS INDICATOR	CY 2014 APC
C1204	A9520	Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries	G	1463
C9130	J1556	Injection, immune globulin (Bivigam), 500 mg	G	9130
C9131	J9354	Injection, ado-trastuzumab emtansine, 1 mg	G	9131
C9132	C9132	Prothrombin complex concentrate (human), KCentra, per i.u. of Factor IX activity	G	9132
C9290	C9290	Injection, bupivicaine liposome, 1 mg	G	9290
C9292	J9306	Injection, pertuzumab, 1 mg	G	9292
C9293	C9293	Injection, glucarpidase, 10 units	G	9293
C9294	J3060	Injection, taliglucerase alfa, 10 units	G	9294
C9295	J9047	Injection, carfilzomib, 1 mg	G	9295
C9296	J9400	Injection, ziv-aflibercept, 1 mg	G	9296
C9297	J9262	Injection, omacetaxine mepesuccinate, 0.01 mg	G	9297
C9298	J7316	Injection, ocriplasmin, 0.125 mg	G	9298
N/A	C9133	Factor ix (antihemophilic factor, recombinant) Rixubus, per i.u.	G	1467
N/A	C9441	Injection, ferric carboxymaltose, 1 mg	G	9441
N/A	C9497	Loxapine, inhalation powder, 10 mg	G	9497
N/A	J7508	Tacrolimus, Extended Release, Oral, 0.1 mg	G	1465
N/A	J9371	Injection, Vincristine Sulfate Liposome, 1 mg	G	1466
J0178	J0178	Injection, aflibercept, 1 mg vial	G	1420
J0716	J0716	Injection, centruroides (scorpion) immune f(ab)2, up to 120 mg	G	1431
J7315	J7315	Mitomycin, ophthalmic, 0.2 mg	G	1448
J9019	J9019	Injection, asparaginase (erwinaze), 1000 i.u.	G	9289
Q4122	Q4122	Dermacell, per square centimeter	G	1419
Q4127	Q4127	Talymed, per square centimeter	G	1449
Q4131	Q4131	Epifix, per square centimeter	G	9366
Q4132	Q4132	Grafix core, per square centimeter	G	9368
Q4133	Q4133	Grafix prime, per square centimeter	G	9369

Physician & Freestanding Center Regulatory Update

Since 1992 Medicare has paid for the services of physicians, nonphysician practitioners, and certain other suppliers under the Medicare Physician Fee Schedule (PFS). For reimbursement purposes, relative values are assigned to each of more than 7,000 services to reflect the amount of work, the direct and indirect (overhead) practice expenses, and the malpractice expenses typically involved in furnishing that specific service. After applying a geographic practice cost indicator, the resulting relative value units (RVUs) are summed for each service and multiplied by a fixed-dollar conversion factor to establish the payment amount for each visit or procedure.

The Sustainable Growth Rate (SGR) is a formula adopted by the Balanced Budget Act of 1997 to determine the conversion factor that may result in steep across-the-board reductions in fee schedule reimbursement. The President's budget calls for averting these cuts and finding a permanent solution to this annual problem, and the legislation preventing the SGR-related cut was signed into law Dec. 26, 2013. As a result, the 2014 PFS conversion factor is $35.8228, a slight increase over 2013. Table 5 (page 23) shows the Estimated Impact Table that projects payment increases or decreases by specialty.

Non-Facility Payment Cap Update

CMS is not finalizing its proposal to adjust relative values under the PFS to effectively cap the physician practice expense payment for procedures furnished in a non-facility setting at the total payment rate for the service when furnished in an ambulatory surgical center or hospital outpatient setting. Instead, CMS will take additional time to consider issues raised by the public commenters and plans to address this issue in future rulemaking. The 2014 PFS final rule states:

As we stated in the proposed rule, when services are furnished in the facility setting, such as an HOPD [hospital outpatient department] or ASC [ambulatory surgical center], the total Medicare payment (made to the facility and the professional combined) typically exceeds the Medicare payment made for the same service when furnished in the physician office or other nonfacility setting. We continue to believe that this payment difference generally reflects the greater costs that facilities incur compared to those incurred by practitioners furnishing services in offices and other nonfacility settings. We also continue to believe that if the total Medicare payment when a service is furnished in the physician office exceeds the total Medicare payment when a service is furnished in an HOPD or ASC, this is generally not the result of appropriate payment differentials between the services furnished in different settings.

Off-Campus Provider-Based Departments

In recent years, research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital and the resultant increase in the delivery of physicians' services in a hospital setting. As more physician practices become hospital-based, news articles have highlighted beneficiary liability, such as higher co-pays, that is incurred when services are furnished in a hospital-based practice. In addition, when a service is furnished in a freestanding clinic or physician office, only one payment is made under the PFS; however, when a service is furnished in a hospital-based clinic, Medicare pays the hospital a facility fee and a separate payment for the physician professional portion of the service. CMS received a number of comments recommending various methodologies to collect information to analyze the frequency, type, and payment of these services, and will take this information into consideration as it continues to consider approaches to collecting data on services furnished in off-campus provider-based departments.

Potentially Misvalued Codes

Consistent with amendments made by the Affordable Care Act (ACA), CMS has been engaged in a vigorous effort over the past several years to identify and review potentially misvalued codes and make adjustments where appropriate. CMS proposed to address nearly 200 procedure codes that appear to have misvalued resource inputs, including radiation oncology code **77301** (intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications). These are codes for which the total PFS payment when furnished in an office or other nonfacility setting would exceed the total Medicare payment when the service is furnished in a facility. In addition, for CY

Table 5. Estimated Impact Table

Specialty	Allowed Charges (mil)	Impact of Work & MP RVU Changes	Impact of PE RVU Changes	Impact of Adjusting the RVUs to Match the Revised MEI Weights	Combined Impact
Hematology/Oncology	$1,896	0%	0%	-2%	**-2%**
Radiation Oncology	$1,788	0%	3%	-2%	**+1%**
Radiation Therapy Centers	$ 63	0%	5%	-6%	**-1%**

Specialty: The Medicare specialty code as reflected in the physician/supplier enrollment files.

Allowed Charges: The aggregate estimated PFS allowed charges for the specialty based on CY 2012 utilization and CY 2013 rates.
Impact of Work & Malpractice RVU Changes: This column shows the estimated CY 2014 impact on total allowed charges of the changes in the work and malpractice RVUs, including the impact of changes due to new, revised, and misvalued codes.
Impact of Practice Expense RVU Changes: This column shows the estimated CY 2014 impact on total allowed charges of the changes in PE RVUs, including the impact due to new, revised, and misvalued codes and miscellaneous minor provisions.
Impact of Adjusting the RVUs to Match the Revised MEI Weights: This column shows the estimated CY 2014 combined impact on total allowed charges of the changes in the RVUs and conversion factor adjustment resulting from adjusting the RVUs to match the revised Medical Economic Index (MEI) weights.

Combined Impact: This column shows the estimated CY 2014 combined impact on total allowed charges of all the changes in the previous columns.

2014 CMS, in consultation with Contractor Medical Directors, is finalizing 18 codes to be reviewed as potentially misvalued services, including the following ultrasound codes that are performed with fiducial marker placement and other radiation services:

- **76942:** Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation.
- **76950:** Ultrasonic guidance for placement of radiation therapy fields.
- **76965:** Ultrasonic guidance for interstitial radioelement application.

Chronic Care Management Services

As part of the ongoing effort to appropriately value primary care services, CMS will make a separate payment for chronic care management services beginning in calendar year 2015. In last year's PFS final rule, CMS established separate payment for transitional care management services for a beneficiary making the transition from a facility to the community setting. In the 2014 PFS final rule, CMS establishes policies to facilitate separate payment for non-face-to-face chronic care management services for Medicare beneficiaries who have multiple (two or more) significant chronic conditions. Chronic care management includes the development, revision, and implementation of a plan of care; communication with the patient, caregivers and other treating health professionals; and medication management. While any specialty can report these codes when the work effort is performed and documented, it is unlikely that oncologists will perform these services.

Telehealth Update

CMS is also modifying regulations describing the geographic criteria for eligible telehealth originating sites to include health professional shortage areas located in rural census tracts of urban areas as determined by the Office of Rural Health Policy. In addition, there will be a policy to determine geographic eligibility for an originating site on an annual basis, consistent with other telehealth policies. Last, CMS will update the list of eligible Medicare telehealth services to include transitional care management services.

Scope of Practice

Section 1861 of the Social Security Act establishes the benefit category for services and supplies furnished as incident-to the professional services of a physician. The statute specifies that "incident-to" services and supplies are "of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in physicians' bills." In addition to the requirements of the statute, CMS regulations establish specific requirements that must be met in order for physicians or qualified practitioners to bill Medicare for incident-to services. According to the 2014 PFS final rule:

As the services commonly furnished in physicians' offices and other nonfacility settings have expanded to include more complicated services, the types of services that can

be furnished "incident to" physicians' services have also expanded. States have increasingly adopted standards regarding the delivery of health care services in all settings, including physicians' offices, in order to protect the health and safety of their citizens. These state standards often include qualifications for the individuals who are permitted to furnish specific services or requirements about the circumstances under which services may actually be furnished.

Over the past years, several situations have come to our attention where Medicare was billed for "incident to" services that were provided by auxiliary personnel who did not meet the state standards for those services in the state in which the services were furnished. The physician or practitioner billing for the services would have been permitted under state law to personally furnish the services, but the services were provided by auxiliary personnel who were not in compliance with state law in providing the particular service (or aspect of the service).

The changes being adopted in this final rule with comment period are consistent with the traditional approach of relying primarily on the states to regulate the health and safety of their residents in the delivery of healthcare services. Throughout the Medicare program the qualifications required for the delivery of healthcare services are generally determined with reference to state law.

As a result, CMS is requiring as a condition of Medicare payment that "incident-to" services be furnished in compliance with applicable state law. This policy eliminates redundant regulations for each type of practitioner, reduces regulatory burden, makes it easier for compliance, and strengthens program integrity by allowing Medicare to deny or recoup payments when services furnished as not in compliance with state law.

Radiosurgery Code Updates

Since CY 2001, CMS has used HCPCS G-codes in addition to the CPT codes for SRS to distinguish robotic and non-robotic methods of treatment delivery. Based on a review of current SRS technology, CMS believes that most services currently furnished with linac-based SRS technology incorporate some type of robotic features. Therefore, CMS believes that it is no longer necessary to continue to distinguish robotic versus non-robotic linac-based SRS through the HCPCS G-codes. For purposes of the OPPS, CMS will replace current codes **G0173**, **G0251**, **G0339**, and **G0340** with the existing CPT codes **77371**, **77372**, and **77373**. However, two of the four current G-codes are paid in the non-facility setting through the Medicare PFS. These codes are **G0339** (image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment) and **G0340** (image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment), both of which describe robotic SRS treatment delivery, and are contractor priced.

CMS did not propose to replace the robotic G-codes with CPT codes for purposes of non-facility billing and codes **G0339** and **G0340** remain active in the PFS. Comments were received regarding the continued retention of these codes and CMS states that it will consider this information during future rulemaking. OI

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

Resources

The two resources listed below were used to compile these coding and regulatory updates:

1. OPPS Final Rule 2014. www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1601-FC-.html. Last accessed Jan. 13, 1014.

2. MPFS Final Rule 2014. www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1600-FC.html. Last accessed Jan. 13, 1014.

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spotlight

UT Southwestern
Harold C. Simmons Comprehensive Cancer Center, Dallas, Texas

The UT Southwestern Harold C. Simmons Comprehensive Cancer Center was established in 1988 from a generous donation from philanthropist Harold C. Simmons and his wife, Annette. Today, the NCI-designated cancer center (designation earned in 2010) offers 13 comprehensive clinical care programs. It is the only NCI-designated cancer center in North Texas.

James K.V. Willson, MD, Director, Harold C. Simmons Comprehensive Cancer Center, says the center's mission is to reduce the impact of cancer today and to work to eliminate the threat of cancer in our community and beyond. "We honor this mission by offering the latest in both basic and clinical research that is advancing treatment options right now and in years to come."

Part of a large medical school with a robust training program, the cancer center's more than 230 members are affiliated with approximately 40 departments or centers across UT Southwestern. These affiliations translate into a wealth of opportunity to blend basic science knowledge with translational and clinical pursuits for the common goal of disease intervention.

The Simmons Cancer Center is headquartered within the Seay Biomedical Building on the UT Southwestern campus in Dallas, which also houses outpatient clinics for bone marrow transplant/hematologic malignancies, breast care, gynecological oncology, and medical and surgical oncology. Simmons Cancer Center has recently opened new clinic locations in Richardson, Texas, and Ft. Worth, Texas.

Connected to the Seay Building is the Moncrief Radiation Oncology Building. All 18 radiation oncologists have offices in this building and utilize state-of-the art treatment modalities, such as IMRT, and technologies, such as CyberKnife and Gamma Knife. Initial consultation, treatments, and follow-up radiation oncology visits occur in this location, as well as two others—the Harold C. Simmons Cancer Center-Radiation Oncology building on the west campus and the Annette Simmons Stereotactic Center in Zale-Lipshy University Hospital.

Simmons Cancer Center's clinical program is organized along disease-oriented teams. Radiation, medical, and surgical oncologists, as well as imaging professionals, researchers, and pathologists, come together to focus on the care of patients with a particular cancer diagnosis. According to Dr. Willson, the "glue" holding these teams together is the patient coordinators, sometimes called navigators.

Given the size and scope of services offered at Simmons, patient coordinators are an essential component of the care team. "They're not simply individuals who get patients from one point to another. They're usually nurses with a strong oncology background and so they become a tremendous resource in helping patients to make treatment decisions, as well as understand the complexity of the cancer experience," said Dr. Willson.

In order to help patients and families manage the stress that can come with care transitions, patients are assigned a Transitional Care Coordinator when they are admitted to the hospital and this person becomes a part of the patient's cancer care team. Oncology Transitional Care Coordinators are medical social workers that coordinate all outpatient appointments after a patient is discharged, act as a point of contact for questions, and address any issues relating to discharge instructions.

"This position is very important since we're a large medical center and we have inpatient care units and we provide ambulatory care. The Transitional Care Coordinator helps build effective communications between those different venues, as well as community services," said Dr. Willson.

Oncology social workers are also available to assist patients in accessing community resources, applying to financial assistance programs, finding support groups, and to address other supportive care issues.

An important component of supportive care is survivorship. For 2015, the Commission on Cancer Standard 3.3 calls for provision of a survivorship care plan. In a unique collaborative effort, Simmons Cancer Center's affiliate Moncrief Cancer Institute, located in Ft. Worth, offers a multi-county, community-based survivorship program for patients learning to live again after treatment. The 60,000-square-foot facility also houses a wellness center, meditation garden, and hosts educational seminars in its auditorium.

"We have strong relationships with our affiliates and safety net hospitals in both Dallas and Tarrant county, which allows us to extend services to a larger group of individuals who otherwise might not have access to those services," said Dr. Willson.

Learn more about this innovative program in the article by Keith Argenbright, MD, and colleagues on page 40.

At the Dallas location, Simmons Cancer Center is launching its EMBRACE Survivorship program in 2014. It has two tracks—one geared toward patients in treatment and the other focused on those who are post treatment.

Complementary Scientific Programs

At Simmons Cancer Center, five complementary scientific programs affiliated with 40 departments or centers across UT Southwestern act as "vehicles of discovery":

- Cancer Cell Networks
- Chemistry and Cancer
- Development and Cancer
- Experimental Therapeutics of Cancer
- Population Science and Cancer Control.

These programs work to translate research findings across disciplines to improve patient care. Simmons further supports this transdisciplinary model by providing researchers with shared resources as well as interactive forums.

CancerGene Connect

Researchers and clinicians at the cancer center are pioneering new ways to assess individual cancer risk. Simmons Cancer Center developed CancerGene Connect, a patient-driven online genetic risk assessment program. Using CancerGene Connect, patients complete a family and medical history online prior to their appointment. This saves time and paperwork and often results in a more accurate history. The program mathematically calculates patient risk for specific hereditary syndromes and specific cancers, and allows genetic counselors to create a complete pedigree prior to the patient's visit.

The program fulfills all the clinical documentation requirements for the new Commission on Cancer Standard 2.3 for Risk Assessment and Genetic Testing and Counseling and NAPBC Standard 2.16. The CancerGene Connect program has allowed the genetic counseling program to cut evaluation and documentation time in half and to expand services without increasing staff or compromising patient care. Simmons Cancer Center received a 2013 ACCC Innovator Award for this program. For more information, please visit *www.accc-cancer.org/innovator* to watch a highlight video.

Building Toward the Future

UT Southwestern is currently constructing the $800 million, 460-bed, 12-story William P. Clements Jr. University Hospital, scheduled to open in late 2014 to complement the 149-bed Zale Lipshy University Hospital. An entire floor will be dedicated to hematology-oncology care, including a 32-bed unit for stem cell transplantation. Designed to be patient-centered, planning input for the new hospital was given by patients, doctors, nurses, and other support staff.

Select Support Services

- Cancer psychology
- Integrative therapies
- Oncology nutrition
- Social work
- Spiritual support
- Transitional care

Newly-registered cancer patients, UTSW University Hospitals and Parkland Health and Hospital System in 2011: 5,053.

tools

Approved Drugs

• The Food and Drug Administration (FDA) has granted regular approval for Pfizer's (*www.pfizer.com*) **Xalkori® (crizotinib) capsules** for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. The approval was based on demonstration of superior progression-free survival and overall response rate for crizotinib-treated patients compared to chemotherapy in patients with ALK-positive NSCLC with disease progression after platinum-based doublet chemotherapy.

• Pharmacyclics, Inc. (*www.pharmacyclics.com*) announced that the FDA approved **Imbruvica™ (ibrutinib)** as a single agent for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication is based on overall response rate. An improvement in survival or disease-related symptoms has not been established. Imbruvica inhibits the function of Bruton's tyrosine kinase (BTK). BTK is a key signaling molecule of the B-cell receptor signaling complex that plays an important role in the survival of malignant B cells. Imbruvica blocks signals that stimulate malignant B cells to grow and divide uncontrollably.

• The FDA approved Genentech's (*www.gene.com*) **Gazyva™ (obinutuzumab)** for use in combination with chlorambucil for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL). Obinutuzumab is approved with a Boxed Warning regarding Hepatitis B virus reactivation and progressive multifocal leukoencephalopathy. Patients should be advised of these risks and assessed for Hepatitis B virus and reactivation risk. Infusion reactions are included in the Warning and Precautions section of the label.

• Bayer Healthcare (*www.bayer.com*) announced that the FDA expanded the approved uses of **Nexavar® (sorafenib)** to treat late-stage (metastatic) differentiated thyroid cancer. Nexavar works by inhibiting multiple proteins in cancer cells, limiting cancer cell growth and division. The drug's new use is intended for patients with locally recurrent or metastatic, progressive differentiated thyroid cancer that no longer responds to radioactive iodine treatment.

Drugs in the News

• **Busulipo™** (Pharmalink AB, *www.pharmalink.se*) has received orphan drug designation from the FDA. Busulipo, a conditioning agent for use in cancer patients prior to hematopoietic stem cell transplantation (HSCT), was developed by Pharmalink as a liposome/lipid complex formulation that improves the safety and stability of the chemotherapy agent busulfan. An early Busulipo formulation has successfully undergone clinical trials with more than 90 patients treated.

• Eli Lilly and Company (*www.lilly.com*) announced that the FDA has assigned priority review to the regulatory submission for **ramucirumab (IMC-1121B)** as a single-agent treatment for advanced gastric cancer following disease progression after initial chemotherapy. The application was based on data from REGARD, a global, randomized, double-blind Phase III study of ramucirumab plus best supportive care compared to placebo plus best supportive care as a treatment in patients with advanced gastric cancer (including adenocarcinomas of the gastro-esophageal junction) following progression after initial chemotherapy.

New Safety Measures for Iclusig®

The FDA is requiring several new safety measures for **Iclusig (ponatinib)** to address the risk of life-threatening blood clots and severe narrowing of blood vessels. Once these new safety measures are in place, the drug manufacturer of Iclusig (Ariad Pharmaceuticals, *www.ariad.com*) is expected to resume marketing to appropriate patients. Healthcare professionals should review these additional safety measures and carefully consider them when evaluating the risks and benefits of Iclusig for each patient.

Approved Devices

• Ventana Medical Systems, Inc. (*www.ventana.com*) announced that it has received 510(k) clearance from the FDA for the **Companion Algorithm ER (SP1) Image Analysis Algorithm** used with the VENTANA iScan Coreo scanner running Virtuoso software. There are two intended uses obtained with the 510(k) clearance: first, clinical use of the software algorithm to semi-quantify the ER biomarker, and second,

digital read, or clearance to manually read and score the ER biomarker using a computer monitor, in lieu of a microscope.

• **Monaco® 5** (Elekta, *www.elekta.com*) has received 510(k) clearance from the FDA. With this latest version of Elekta's Monaco treatment planning system, Monaco now supports the full spectrum of radiotherapy techniques, including VMAT, IMRT and 3D conformal radiation therapy. The system is especially well equipped for sophisticated stereotactic therapies, such as SRS and SRT, with added planning support for specialized beam shaping solutions, including circular cones.

• Novocure (*www.novocure.com*) announced that the FDA has approved its **NovoTAL (Transducer Array Layout) System** through a premarket approval (PMA) supplement. The NovoTAL System allows certified physicians to use the individual MRI data of recurrent glioblastoma multiforme (GBM) patients to optimize the field distribution and intensity of Tumor Treating Fields (TTFields) therapy. The system consists of a dedicated workstation and specialized, PMA supplement-approved software that enables physicians to determine optimal transducer array layouts based on morphological measurements of the head, tumor size and location, and the distribution of TTFields within the brain. OI

New HCPCS Codes for NovoTTF-100A System

The Centers for Medicare & Medicaid Services (CMS) has established new therapy-specific Healthcare Common Procedure Coding System (HCPCS) codes (E0766 and A4555) to describe treatment with the **NovoTTF-100A System** (Novocure, *www.novocure.com*). The new codes were effective Jan. 1, 2014. CMS also designated the product as a frequently serviced item, and as a result all necessary accessories are included in the E0766 code. The designation of a single HCPCS code, as opposed to separate codes for the device and monthly supplies, will enable a straightforward payment structure for payers, replacing the need to use separate codes for the device and standard monthly supplies. CMS issued a separate HCPCS code (A4555) to describe replacement supplies, if provided separately from the bundled accessories.

USPSTF Releases Final Recommendations on Lung Cancer Screening and Genetic Testing for BRCA-related Cancer

On Dec. 30, 2013, the U.S. Preventive Services Task Force (USPSTF) released its final recommendation on screening those at high risk of lung cancer, grading annual low-dose CT screening for individuals at high risk for lung cancer with a B grade. The USPSTF recommends annual screening for lung cancer with low-dose computed tomography in adults aged 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery. Read the full recommendation online at: *www.uspreventiveservicestaskforce.org/uspstf13/lungcan/lungcanfinalrs.htm*.

On Dec. 24, 2013, the USPSTF issued its final recommendation on risk assessment, genetic counseling, and genetic testing for BRCA-related cancer in women. The USPSTF recommends that women with family members who have had breast, ovarian, tubal, or peritoneal cancer talk with a healthcare professional to learn if their history might put them at risk for carrying a BRCA mutation. Women who screen positive should receive genetic counseling and, if indicated after counseling, BRCA testing. Additionally, for the vast majority of American women (90 percent), who do not have a family history associated with an increased risk for the inherited mutations, the USPSTF continues to recommend against genetic counseling and testing. Read the full recommendation online at: *www.uspreventiveservicestaskforce.org/uspstf/uspsbrgen.htm*.

Catalyzing Patient-Centered Care

Start Where You Are and Share What You Know

BY MANDI PRATT-CHAPMAN, MA;
HEATHER KAPP, MPH, LICSW; ANNE WILLIS, MA;
AND JENNIFER BIRES, MSW, LICSW, OSW-C

Over the last decade, patient-centered care has begun to gather momentum spurred on by a series of commissioned reports, insurance reform, and new accreditation standards. The Institute of Medicine (IOM) has issued several reports on quality and cancer care, including the most recent report, *Delivering High Quality Cancer Care: Charting a New Course for a System in Crisis*.[1] This 2013 report espouses a conceptual framework that includes patient engagement at the center of a quality cancer care system. Other IOM reports have focused on the needs of post-treatment cancer survivors[2] and the importance of caring for the whole patient and not simply treating the disease.[3]

With the passage of the Affordable Care Act (ACA) in March 2010, patients benefit from expanded access to care, increased affordability of insurance, new patient protections, elevated quality measures, and new funding for patient-centered research. The ACA established both the Center for Medicare and Medicaid Innovation, which tests new payment models that elevate quality of service over volume of procedures, and the Patient-Centered Outcomes Research Institute (PCORI), which includes patients as key stakeholders in research and focuses on outcomes that are most important to patients.

Finally, the American College of Surgeons' Commission on Cancer (CoC) established new patient-centered standards to be phased in by 2015[4] for its more than 1,500 accredited programs that treat more than 70 percent of newly diagnosed cancer patients in the U.S.[5] These standards include establishing a patient navigation process (3.1), implementing psychosocial distress screening (3.2), and providing survivorship care plans to patients completing treatment for cancer (3.3).

In 2013, in collaboration with its clinical partners, the George Washington (GW) Medical Faculty Associates and the GW Hospital, the GW Cancer Institute:

- Expanded and enhanced its patient navigation program
- Established a distress screening process
- Continued to refine its survivorship services
- Expanded technical support to other institutions to catalyze patient-centered care practices regionally and nationally.

Navigation Across the Continuum

CoC Standard 3.1: Patient Navigation Process requires that accredited institutions develop and implement a process to address disparities and barriers to care experienced by cancer patients and that is responsive to a community needs assessment. Patient navigation refers to individualized assistance offered to patients, families, and caregivers to remove barriers to accessing and completing cancer screening, diagnosis, treatment, and supportive care.

With the passage of the Affordable Care Act (ACA) in March 2010, patients benefit from expanded access to care, increased affordability of insurance, new patient protections, elevated quality measures, and new funding for patient-centered research.

The GW Cancer Institute used local research findings for its community needs assessment. Drawing from research that showed that diagnostic time was reduced by an average of 17 days for women in the District of Columbia at-risk for breast cancer who received navigation versus women who did not receive navigation,[6] the GW Cancer Institute spearheaded a Citywide Patient Navigation Network (CPNN) to provide a safety net for those at risk for cancer or undergoing treatment in the DC area. Under the auspices of CPNN, primary care clinics, community-based organizations, and cancer centers in the region collaborated to remove 26,259 barriers to healthcare experienced by 7,309 individuals at various points along the cancer continuum from August 2010 through July 2013. Approximately 84 percent of individuals served by CPNN were

Figure 1. Sample Evaluation Tool

CPNN PATIENT INTAKE FORM	CPNN Site Location:		Date of Patient Encounter:
	Navigator Name:	Patient ID:	Date Submitted:
Circle One:	First Navigation Encounter		Continuing Navigation

FILL OUT FOR EVERY PATIENT ENCOUNTER – PATIENT DEMOGRAPHICS (circle to indicate choices)

GENDER & RESIDENCY	Male	Female	Transgender	Maryland	Virginia	Other: _____		Washington, DC	
RACE & ETHNICITY	Black	African	Hispanic	White	American Indian	Pacific Islander	Asian	Ward 1	Ward 2
POINT OF ENTRY INTO CPNN	Outreach	Screening	Abnormal Finding	Cancer Diagnosis	Treatment	Survivor-ship	Receiving Palliative	Ward 3	Ward 4
RISK ASSESSMENT AREA	Breast	Prostate	Colorectal	Cervical	Lung	Other: _____		Ward 5	Ward 6
AGE RANGE	18–29	30–39	40–49	50–64	65+	Tobacco User Yes No		Ward 7	Ward 8
SEXUAL ORIENTATION	Lesbian	Gay	Bisexual	Queer/ Questioning	Heterosexual	Referred to DC Quitline Yes No		Type: Cigarette/ Pipe/Snuff	
INSURANCE HELD & LAST PCP VISIT	Uninsured	Uninsured, Navigated to Insurance	Fee for Service	Medicaid	Medicare	Employer/Private/ Commercial Specify: _____		Seen Past 12 Months Yes No	

TIME INTERVALS: Indicate the following time intervals as you know them. Do not indicate intervals prior to your first navigation encounter or after your last encounter with the patient.						
	Screening to Diagnosis	Less than 30 days	30–60 days	More than 60 days	Unknown/Prior to First Navigation Encounter	
	Diagnosis to Treatment	Less than 30 days	30–60 days	More than 60 days	Unknown/Prior to First Navigation Encounter	
	Completed Treatment?	Yes	No	Received survivorship information?	Yes	No

TYPE & NUMBER OF BARRIER(S) PATIENT IS FACING	NUMBER OF REFERRALS		WHO HELPED ADDRESS/RESOLVE THE BARRIER?	
BARRIER TYPE (include total patients this period)	Number of Referrals made for service	Number of Navigators who helped in overcoming the barrier	Which Navigator/CPNN site(s) helped you overcome the barrier? *List all that apply*	Which non-CPNN Agency did you refer for service (i.e. Medicaid, METRO, etc.)? In which state is the agency located?
1. Transportation				
2. Housing				
3. Social/Practical (i.e. Support Group, Food)				
4. Language Barrier/Interpreter needed				
5. Literacy				
6. Dependent (child or adult) care issues				
7. Location of healthcare facility				
8. Financial: insurance, high co-pays, rent				
9. Employment Issues				
10. Communication concerns with medical personnel				
11. Fear or negative perceptions				
12. Patient disability				
13. System problems with scheduling care				
14. Anxiety because of discrimination/stigma				
15. Other, specify: _____				

The GW Cancer Institute collaborates with its clinical affiliates to provide patient navigation services across the cancer continuum to ensure timely access to care for patients.

racial or ethnic minorities, of whom more than 50 percent were African American or African and nearly 32 percent were Latino individuals. Top barriers included:

- Financial barriers (16 percent)
- Social and practical support concerns, such as the need for a support group or help buying food (16 percent)
- System problems with scheduling care (14 percent)
- Language barriers (12 percent).

Additional obstacles to care include transportation, geographic location of healthcare facilities, fear and communication barriers, and employment concerns. Figure 1, left, is an example of an intake form that can be used to assess navigation barriers.

The GW Cancer Institute collaborates with its clinical affiliates to provide patient navigation services across the cancer continuum to ensure timely access to care for patients. The team includes a navigation supervisor, three non-clinically licensed patient navigators, two nurse navigators, one social worker, a research assistant, and rotating practicum students in public health.

Patient navigators without a clinical license focus on eliminating structural and logistical barriers to care. The most common non-clinical navigator interventions include language support, helping eligible patients access insurance or co-pay programs, scheduling necessary follow-up appointments, social and practical support, and transportation assistance.

Two navigators in radiology assist all patients who have an abnormal finding in the breast imaging and intervention center. One navigator specializes in support for Spanish-speaking patients and resolution of logistical barriers to fast-track patients to diagnosis. The navigators in radiology work with navigators in breast surgery and radiation oncology to ensure access to timely biopsy, surgery, and radiation treatments.

A nurse navigator provides clinical education for those at high-risk for breast cancer and diagnosed patients.

A licensed clinical social worker based in hematology and oncology provides support for patients undergoing chemotherapy. The social worker also mentors the navigators, counsels patients in high distress, and coordinates referrals to a specialized survivorship psychiatric services program.

The GW Cancer Institute leverages its educational infrastructure to further support the navigation program. Public health students are provided with concrete projects to assist the navigation team in making quality improvements. In addition, a half-time research assistant coordinates technical support for CPNN and assists with data analysis and evaluation improvements.

In 2013 the navigation team prioritized three areas for improvement. First, the team conducted a new needs assessment to better understand the population it was serving. Second, the team mapped the patient experience across the breast cancer continuum to identify quality improvements. Third, the team researched options for improved efficiency of data capture and identified key metrics for a pilot database.

The needs assessment compared the demographics of navigated patients to the demographics of all patients who are treated at GW based on cancer registry data. The assessment outlined top needs of patients navigated and highlighted areas where important data was missing due to data infrastructure limitations. Findings from the assessment showed that the GW navigators are reaching the neediest population of patients. Of those navigated, 73.8 percent were minorities, favorably comparing to the 48.5 percent minorities noted in the registry data. Navigators also reach a large number of uninsured and Medicaid patients. Nearly 40 percent of patients receiving navigation were uninsured or on Medicaid. The needs assessment also found that while the breast cancer navigation program at GW is strong, work remains to be done to identify those non-breast cancer patients at high-risk of falling through the cracks.

One key limitation of the data is the difference between the comparators: many individuals at-risk for cancer who receive navigation to obtain diagnostic resolution are not captured in the cancer registry data because they are ultimately resolved as benign cases. The registry system also only captures individuals who have received some portion of their care at the GW Hospital, excluding patients who have only received outpatient services. However, the needs assessment was important to highlight areas to improve data capture and expand services for patients in need who are cared for in other clinical departments.

The navigation team also mapped the patient experience across the breast care continuum. A number of quality improvement initiatives resulted. These include:

- Educating community clinics on accurate Current Procedural Terminology (CPT) codes for screening referrals
- Drafting a navigator script to introduce the patient navigator prior to the clinical appointment to proactively assess any barriers to care
- Calling patients lost during follow-up who were recommended for additional imaging

Front (L to R): Heather Kapp, Diana Garcia, Eva Ruiz, Monica Dreyer, and Mandi Pratt-Chapman. Back (L to R): Elizabeth Hatcher, Jennifer Bires, Leshia Hansen, Anne Willis, Megan Matheny, Margaret Chapman, and Elisabeth Reed.

- For biopsied patients, making the next appointment on the same day of biopsy
- Ensuring required authorizations are attained prior to breast surgery
- Tracking patients and following up with those lost during follow-up after simulation planning in radiation oncology
- Sending appointment reminder cards and directly referring eligible patients to survivorship services.

Additionally, the navigation team is exploring the feasibility of a navigation steering committee to increase referrals from clinical areas other than breast.

Finally, the navigation team worked collaboratively to identify key metrics important in showing the value of patient navigation at GW.

Since August 2010, the navigators have tracked demographics, barriers to care, and resolution of barriers on an Excel form and reported aggregate numbers of patients assisted on a quarterly basis to provide information to funders on program impact. A major limitation of this method of data capture is double or triple counting patients if the patient moves across several clinical departments and is assisted by more than one navigator in the process. In 2013 the navigation team added a navigation note to the electronic medical record (EMR). The standardized note provides clear, concise information on navigator-initiated interventions that eliminated barriers to care for that patient. The note improves communication, assists with care coordination, and provides official documentation to clinicians to raise awareness regarding patients' unique concerns. It may also increase referrals due to greater awareness of patient needs. However, the EMR does not compile reports and thus cannot be used to evaluate the program.

Currently, GW is working with its legal and security advisors to implement a navigation database to improve accuracy and efficiency of data capture, increase information sharing, and maintain patient privacy in the year ahead. The database will also expand health equity data captured, enhance barrier tracking, and include a patient satisfaction survey to contribute to ongoing needs assessment, evaluation, and quality improvements.

Distress Screening

According to the National Cancer Institute (NCI), cancer patients' suicide risk can be two to ten times that of the general population. Some studies indicate that suicidal thoughts are common even if patients do not commit suicide, and actual suicide may go underreported in this population. Patients with head and neck, pharyngeal, and lung cancer are at higher risk for depression, which may be linked to heavy alcohol and/or tobacco use. HIV-positive patients with Kaposi Sarcoma are also at higher risk for depression. Other risk factors include advanced disease, poor prognosis, or uncontrolled pain.[7]

Even if cancer patients are not suicidal, many patients can experience significant short- or long-term distress due to their cancer and/or concurrent factors. Distress refers to emotional,

mental, social, or spiritual suffering, and might include anxiety, depression, or feelings of sadness, isolation, or vulnerability.[8] Distress can impact a patient's ability to complete the diagnosis or treatment process, and may decrease overall quality of life.

CoC Standard 3.2, Psychosocial Distress Screening, requires that accredited cancer programs establish a process for integrating and monitoring distress screening and the provision of psychosocial care either on-site or by referral. The CoC is flexible on when and how this screening is done, but recommends that it occur at a "pivotal" visit (broadly defined as diagnosis, pre- or post-surgical visits, pre-chemotherapy, routine radiation oncology visit, post-chemotherapy, or transition off-treatment) and states a preference for using validated screening tools.

To comply with this standard, the GW Cancer Institute brought together nurses, social workers, and patient navigators to create a distress screening procedure and drafted the distress screening policy discussed below. We selected the National Comprehensive Cancer Network (NCCN) Distress Thermometer (DT) as a simple, one-page, validated tool to measure distress in our cancer patient population. The NCCN DT includes a scale from zero (no distress) to ten (extreme distress), as well as a problem checklist that includes practical barriers, family problems, emotional problems, spiritual concerns, and physical problems. The DT is presented to patients on their initial visit in infusion, radiation oncology, and/or medical oncology and prior to breast surgery with a letter explaining the tool. The completed tool is reviewed by a nurse, social worker, or patient navigator.

Some oncologists have begun to document distress as the seventh vital sign, and a working group is advocating for this documentation as a standard practice for our hematologists and oncologists.

Based on the results of the screening, referrals are made to staff and resources. Patients in low distress (self-rating of 0-3), are given a new patient information packet, including a list of support groups and educational classes. Patients are also given contact information for the social worker or the psychosocial care team in the event distress arises later in treatment.

For patients in moderate distress (self-rating of 4-6), the staff person reviewing the tool contacts the patient within 72 hours for further evaluation to confirm presence of physical, psychological, social, spiritual, and/or financial concerns. Resources and referrals are given to meet the patient's needs, which could include a therapist referral.

For patients in high distress (self-rating of 7-10), staff conducts an assessment within 24 hours to confirm the presence of physical, psychological, social, spiritual, and/or financial needs. Resources and treatment are provided to meet the patient's self-identified needs, which can include referrals for two to three therapists to provide options to the patient if therapeutic support is indicated.

For all patients—regardless of the level of distress—practical concerns are referred to the navigation team. The patient is referred to social work, financial counseling, spiritual care, palliative care, or other mental health specialists, depending on their self-reported area of need. The treating oncologist is alerted via the EMR chart note of moderate or high distress. If the cause of distress is primarily physical, the patient is triaged back to their physician. If a patient is deemed suicidal, staff contact psychiatry immediately and if psychiatry cannot consult with the patient right away, security or 911 are called. The patient cannot leave the cancer center without being seen by an advanced practice mental health professional and is not left alone. All patients, again regardless of distress level, are encouraged to contact staff if distress escalates to uncomfortable levels or if additional support or services are needed.

The completed DT is scanned into the patient's EMR and the staff person screening the patient is responsible for sending referrals to the navigation team or to other providers as indicated. Referral or provision of care is also documented in the EMR by the individual screening the patient to facilitate integrated, high-quality care. Follow-up care is documented by the staff member providing the care.

These processes were spelled out in the distress policy presented to the cancer committee, which approved the policy in 2013. Screening was implemented first in the division of hematology and oncology, and then in the breast care center. Currently, we are working to improve screening in radiation oncology and to initiate screening in other clinical areas. Some oncologists have begun to document distress as the seventh vital sign, and a working group is advocating for this documentation as a standard practice for our hematologists and oncologists.

GW continues to evaluate and refine its distress screening process. Based on research stating that the DT is not as accurate in assessing depression as anxiety, the team is considering the inclusion of two additional questions to more accurately screen for depression:[9]

- In the last two weeks, have you experienced little interest or pleasure in doing things?
- In the last two weeks, have you felt down, depressed, or hopeless?

For both questions, patients can answer: not at all (worth zero

(*continued on page 38*)

Figure 2. MFA-GWCI Survivorship Care Plan

Summary of Cancer Treatment and Follow-Up Plan

Name DOB

TREATMENT SUMMARY

Oncologist: _____

Surgeon: _____

Radiation Oncologist: _____

Internist: _____

Diagnosis/Staging/Age: _____

Pertinent Family History/Genetics: _____

_____

SURGERY

Procedure:	Date:

CHEMOTHERAPY/BIOTHERAPY

Regimen:		Dates:	
Drug Name	Dose	Dose Reduction	Cycles

RADIATION THERAPY

Length (fractions)	Field	Total Dose	Dates

HORMONE THERAPY

FOLLOW-UP PLAN

Potential Late Effects	Screening Recommendations*
1. Cancer Recurrence	

*Screening recommendations adapted from the National Comprehensive Cancer Network, NCCN Guidelines Version _____ for Invasive _____ Cancer.

MFA-GWCI Survivorship Care Plan

Summary of Cancer Treatment and Follow-Up Plan *(continued)*

HEALTH MAINTENANCE

- ✓ Physical examinations by internist, annual
- ✓ Colonoscopy, per gastroenterologist
- ✓ Routine self breast exams, monthly
- ✓ Cancer survivorship support through post-treatment breast cancer support group
- ✓ Other

HEALTHY LIFESTYLE RECOMMENDATIONS

- ✓ **DIET** – Eat a heart healthy diet low in salt, fat, red meat, and sugar and high in fresh fruits, vegetables, and whole grains. Follow individual recommendations provided by dietitian.
- ✓ **ALCOHOL** – Limit your alcohol intake to 2 drinks a week.
- ✓ **EXERCISE** – Get 30 minutes of moderate exercise most days of the week or enroll in the GW TACfit program for individual physical activity assessment and plan.

SYMPTOMS TO WATCH FOR

It is important for you and your providers to understand the potential late effects and risks of your cancer treatment.

If progressive and/or persistent report these signs and symptoms to your practitioner:
(*Symptoms listed depending on the cancer type*)

- _____
- _____
- _____

POTENTIAL LATE EFFECTS AND RISKS OF ALL CANCER TREATMENTS

The late side effects of cancer treatment one may develop months to years after treatment depends on which treatment(s) were received.

Surgery: (*specific side effects listed depending on the location and extent of surgery*)

- _____
- _____
- _____

Radiation: (*specific side effects listed depending on the location and dose of radiation*)

- _____
- _____
- _____

Hormone Therapy: (*side effects of the particular hormonal therapy are listed*)

- _____
- _____
- _____

This Survivorship Care Plan was prepared by _____, provided to the patient and sent out to the providers listed on _____.

(*continued from page 35*)
points), several days (1 point), more than half the days (2 points), or nearly every day (3 points). Patients who score a total of at least 3 points on both questions are considered to be at-risk for having depression.

In 2010 the GW Cancer Institute, in collaboration with the Children's National Medical Center, the GW Medical Faculty Associates, and the GW Hospital, established its first survivorship clinic, focusing on adult survivors of pediatric cancer.

Survivorship Care

CoC Standard 3.3, Survivorship Care Planning, requires the cancer committee to develop and implement a process to provide survivorship care plans, including a treatment summary and follow-up plan, to patients completing cancer treatment.

In 2010 the GW Cancer Institute, in collaboration with the Children's National Medical Center, the GW Medical Faculty Associates, and the GW Hospital, established its first survivorship clinic, focusing on adult survivors of pediatric cancer.

In 2012 a second multidisciplinary clinic was established to provide comprehensive care for adult-onset cancer survivors. The clinic is housed in the division of internal medicine and coordinated by an oncology nurse practitioner (NP). Survivors may be referred to the clinic at any point following active cancer treatment. The survivorship nurse navigator conducts patient intake via phone, and the NP prepares the survivorship care plan (see Figure 2, pages 36-37). The survivor benefits from consultation with the NP, an internal medicine physician, and a registered dietitian. During this clinical visit, the NP provides education regarding the survivorship care plan, the internist addresses management of potential medical concerns, and the dietitian reviews the patient's diet and health behaviors. The survivor also meets with the nurse-credentialed survivorship navigator during the visit. The navigator assesses the patient for resource needs, and is available for the patient to contact after the visit.

Survivors may also be referred to specialists as needed, including free, time-limited psychiatric services offered on-site or by referral and an individual exercise assessment and plan by GW's Department of Exercise Science.

The GW Cancer Institute, with its clinical partners, is still determining the best method to expand provision of survivorship care plans to a greater number of patients to comply with the CoC standard. As part of the navigation team's patient experience mapping process, referral to survivorship services was identified as a gap. New processes for referring patients to the survivorship clinic are now being implemented. Future steps also include engaging clinical champions to pilot new approaches to providing survivorship care plans.

Finding Your Patient Focus

The GW Cancer Institute provides technical support to other programs, leveraging lessons learned and best practices across the country. In 2009 the GW Cancer Institute Center for the Advancement of Cancer Survivorship, Navigation, and Policy was launched. Through the center, we have trained nearly 500 healthcare professionals in live trainings focused on patient-centered program development. In April 2013 we launched a free webinar series that provides monthly educational opportunities for healthcare professionals. Content for the webinar series has focused on assessing need for patient-centered programs, case studies, survivorship resources, survivorship care planning practices, and the importance of cancer rehabilitation. In 2014 the GW Cancer Institute will create an online version of its highly reputed *Executive Training in Navigation and Survivorship* to assist institutions aiming to establish patient-centered care practices.

As part of the National Cancer Survivorship Resource Center, a collaboration between the American Cancer Society and the GW Cancer Institute funded by the Centers for Disease Control cooperative agreement #1U55DP003054, the GW Cancer Institute has developed a free Cancer Survivorship e-Learning series for primary care providers available online at: www.cancersurvivorshipcentereducation.org. Modules include:

- The Current State of Survivorship Care and the Role of Primary Care Providers
- Late Effects of Cancer and its Treatments: Managing Comorbidities and Coordinating with Specialty Providers
- Late Effects of Cancer and its Treatment: Meeting the Psychosocial Health Care Needs of Survivors
- The Importance of Prevention in Cancer Survivorship: Empowering Survivors to Live Well
- A Team Approach: Survivorship Care Coordination.

A free *Guide for Delivering Quality Survivorship Care* is available on the same website to support healthcare professionals and program leaders through assessment, planning, implementation, and evaluation of their survivorship program.

The GW Cancer Institute also conducts research to elevate patient-centered care practices. In 2013 PCORI provided funding to the GW Cancer Institute and the GW School of

Public Health and Health Services to evaluate cancer survivorship programs across the country. Key collaborators on the project include the CoC, LIVESTRONG, the Cancer Support Community, and the American Cancer Society. The research team will create a patient-prioritized measure for quality survivorship care and evaluate programs based on outcomes of importance to patients.

The GW Cancer Institute is also collaborating with the Association for Community Cancer Centers, the National Association of Social Work, the Association of Oncology Social Work, the Oncology Nursing Society, and the Association of Oncology Nurse Navigators to delineate roles and responsibilities of patient navigators, sometimes referred to as lay navigators, as compared to community health workers and nurse or social worker navigators. The project will result in identified competency domains for non-clinically-licensed patient navigators and a free online training program. Results from both research projects will inform patient-centered care practices across the country.

The shift from volume to value is here to stay. With a trend toward more engaged and active patients, there is widespread recognition of the need for patient-centered care. Oncology teams have an opportunity to be part of the solution for a more effective care system by responding to the call for improved quality and greater patient engagement in care. The GW Cancer Institute remains committed to catalyzing patient-centered care by engaging patients, improving quality, and sharing what we know with other programs to benefit all patients. OI

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References

1. Levi L, Balogh E, Nass S, Ganz P. *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*. Washington, DC: The National Academies Press; 2013.
2. Hewitt M., Greenfield S., Stovall E. From *Cancer Patient to Cancer Survivor: Lost in Transition*. Washington, DC: The National Academies Press; 2006.
3. Adler N, Page E. *Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs*. Washington, DC: National Academies, Press; 2008.
4. American College of Surgeons. Cancer Program Standards 2012: Ensuring Patient-Centered Care, Version 1.1. Chicago, IL, 2012. Available online at: www.facs.org/cancer/coc/programstandards2012.pdf. Last accessed Nov. 26, 2013.
5. American College of Surgeons. About Accreditation. Available online at: www.facs.org/cancer/coc/whatis.html. Last accessed Nov 26, 2013.
6. Hoffman HJ, LaVerda NL, Young HA, Levine PH, et al. Patient navigation significantly reduces delays in breast cancer in the District of Columbia. *Cancer Epidemiol Biomarkers Prev*. 2012;21(10):1655-1663.
7. NCI. Depression PDQ. Available online at: www.cancer.gov/cancertopics/pdq/supportivecare/depression/HealthProfessional/page1/AllPages. Last accessed Nov. 26, 2013.
8. NCI. Adjustment to Cancer: Anxiety and Distress PDQ. Available online at: http://www.cancer.gov/cancertopics/pdq/supportivecare/adjustment/Patient/page1. Last accessed Nov. 26, 2013.
9. Health Day. Two Key Questions May Reveal Depression in Cancer Patients. Available online at: http://health.usnews.com/health-news/news/articles/2013/09/23/two-key-questions-may-reveal-depression-in-cancer-patients?utm_source=October+caSNP+E-News&utm_campaign=July+caSNP&utm_medium=email&utm_source=CPNN+Newsletter+11&utm_campaign=CPNN+Oct+21&utm_medium=email. Last accessed Nov. 26, 2013.

Acknowledgements

The GW Cancer Institute's patient-centered programs are partially supported by the Susan G. Komen Foundation, the Avon Foundation for Women, and the American Cancer Society. Support for education and research interventions to improve patient-centered care practices is provided by the Patient-Centered Outcomes Research Institute and the Centers for Disease Control and Prevention cooperative agreements #1U55DP003054 and #U38DP004972-01. The contents of this article are solely the responsibility of the authors and do not necessarily reflect the official views of these funders.


Fort Worth Program
for Community
Survivorship

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Using Community Resources to Build a Survivorship Program

In 2012 the Commission on Cancer (CoC) added new standards that enhance patient-centered functions and define performance criteria in quality measurement and outcomes. These standards included the provision of treatment and survivorship plans, palliative care services, genetics services, navigation programs, and psychosocial distress screening. Today, many community cancer centers are challenged to meet these standards in tight economic times and with little to no reimbursement for these services.

In 2010 UT Southwestern-Moncrief Cancer Institute began an innovative effort to unite and collaborate with local cancer care providers to address the psychosocial and behavioral needs of the cancer survivors—particularly underserved populations. Funded by the Cancer Prevention and Research Institute of Texas (CPRIT), the end result was the Fort Worth Program for Community Survivorship (ProComS), a community-wide, coordinated, evidence-based post-treatment survivorship program that is available to all cancer survivors—regardless of their ability to pay.

The Importance of Survivorship Programs

Advances in early detection, diagnosis, and treatment have increased the number of cancer survivors living in the United States to more than 13.7 million,[1,2] and this population is expected to reach 22 million by 2030.[3,4] The survivorship phase of care represents a distinct opportunity to improve the health and quality of life for cancer survivors by:

- Addressing lingering medical and psychosocial effects of illness
- Focusing on recurrent or new cancers
- Promoting health behavior changes.

However, evidence-based cancer survivorship programs are typically only found in large cancer centers and are often limited in scope because these programs are costly and poorly reimbursed.

Several studies highlight the need for a community survivorship program that provides education specific to health behavior change and other practical support needs of cancer survivors. For example, all cancer survivors struggling with health behavior changes should have the opportunity to participate in tobacco cessation, nutrition counseling, exercise programs, and other supportive care services. In addition, with longer survival, many forms of cancer are now regarded as chronic diseases that require long-term follow-up and further impact overall community health.

Program Goals

Fort Worth is the state's fifth largest city with a sophisticated healthcare system and mechanisms in place to provide cancer care for all socioeconomic levels and degrees of insurance coverage. However, prior to ProComS, survivorship services were fragmented, duplicative, and only offered at a few hospitals or clinics. This lack of an organized, integrated approach to cancer survivors, particularly those with few means or resources, supported the need for an evidence-based, coordinated, and systematic cancer survivorship program.

In developing and implementing a community-based survivorship initiative, the goals were to:

1. Create a dynamic city-wide partnership that facilitated referral of eligible cancer survivors and coordinated evidence-based survivorship services.
2. Establish a physical location for a survivorship clinic to serve as the focal point for ProComS, with special emphasis on recruiting and retaining the local medically underserved population.

In February 2011 UT Southwestern-Moncrief Cancer Institute was awarded two years of funding ($803,816) from the Cancer Prevention Institute of Texas to lead the development of ProComS. As the lead partner, the cancer institute provided the multidisciplinary professional team, support staff, and the physical space for the survivorship clinic. The oncology community and local organizations provided support with referrals, services for evidence-based specialty interventions, and clinical follow-up.

Survivorship Model

Various models of adult survivorship care have emerged and been implemented since the Institute of Medicine's (IOM) initial report; however, UT Southwestern-Moncrief Cancer Institute's "community-based" survivorship model is one not often seen nationally.[7-9] The program identifies partners representing all aspects of cancer care from detection through diagnosis, treatment, and follow-up care, ensuring the most complete range of survivorship resources and services or a "community of solution" (see Figure 1, above right). For more background information on this approach, see sidebar on page 43.

While the partners may serve different populations within the community, they maintain the common goal of providing evidence-based care. In keeping with the "community of solution" model, core services are provided on-site while some patient-specific services, such as speech and language therapy and lymphedema services, are delivered by a community partner. The model allows the cancer survivor to benefit from the services of the entire community rather than one provider.

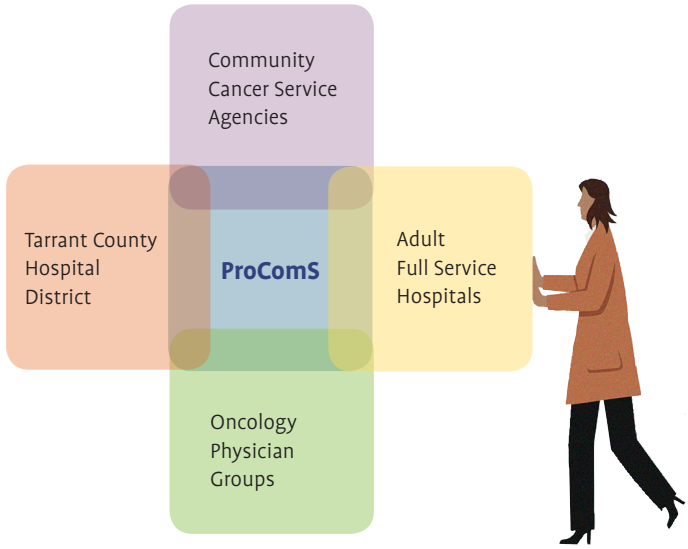
ProComS is open to all adult cancer survivors, enrolling participants regardless of healthcare provider, gender, diagnosis, stage, functional status, insurance level, or ability to pay. Cancer survivors have the option to participate in a longitudinal population science study; more than 50 percent of patients who were offered the study have consented.

Evidence-Based Program Development

Dedicated to addressing the ongoing needs of cancer survivors, ProComS incorporates the four essential components of care patterned after the IOM recommendations:

1. ***Prevention*** of new or recurrent cancers and side effects

Figure 1. ProComS Community Partners



2. ***Surveillance*** for metastases, recurrence, or second cancers, along with assessment of medical, psychosocial, and behavioral late effects
3. ***Intervention*** for consequences of cancer and its treatments
4. ***Coordination of care*** between specialists and the patient's primary care physician to ensure all healthcare providers are well informed and concerns are addressed.[10]

ProComS' quality standards of care are structured using guidelines from such cancer organizations as the:

- National Comprehensive Cancer Network (NCCN)[11]
- American Society of Clinical Oncology[12]
- National Heart Lung and Blood Institute [13]
- American Institute for Cancer Research[14]
- Oncology Nursing Society[15]
- Centers for Disease Control and Prevention[16]
- National Lymphedema Network[17]
- American Pain Society.

Establishing an evidence-based cancer survivorship program, such as ProComS, requires the coordination of multiple community entities and resources. Community partners that commit to the goals of the program and agree to actively promote post-treatment survivorship services in their practices are the foundation of the program. Representatives from local physician-owned oncology practices, hospitals, charitable organizations, and the

safety-net cancer center all serve as part of a community coalition advisory group to problem solve the issue of fragmented survivorship care in the community. Specifically, the community advisory board can:

- Develop methods to reach survivors
- Allow access to their referring staff
- Encourage survivor enrollment
- Provide survivorship care expertise.

Parallel to the "community of solution" concept, the advisory board maintains their commitment to serving the community and participating in the decision-making to provide evidence-based survivorship services.[5]

Clinical Services Program

ProComS' survivorship clinic, located at UT Southwestern-Moncrief Cancer Institute, is dedicated to the ongoing needs of all cancer survivors with special emphasis on uninsured, underinsured, and medically underserved survivors. The clinic includes outpatient clinic space with reception areas, consultation and examination rooms, and a phlebotomy station. A separate fitness area offers cancer survivors cardiovascular exercise, progressive weight training, balance work, resistance training, and group exercise activities.

With its community partners, UT Southwestern-Moncrief Cancer Institute developed a workflow to guide the progress of each cancer survivor (see Figure 2, page 44). This process requires assistance from community partners to identify survivors within their systems, while ProComS staff raise program awareness and recruit, enroll, and engage survivors from various community events.

The multidisciplinary survivorship team is led by an oncology-certified RN, with support from a clinical staff assistant and outreach personnel. Other team members include: oncology certified social workers and dietitians, clinical psychologists, certified genetic counselors, exercise specialists, and a financial advocate (see Figure 3, page 45).

The RN is the first point of contact with the cancer survivor; together they identify the survivor's needs and goals and design a care plan tailored to the individual. Each cancer survivor is offered a Survivorship Care Plan and a Treatment Summary using the Journey Forward™ format.

Next, a social worker assesses the psychosocial needs of survivors, caregivers, and families. If necessary, the social worker connects survivors and families to the team's psychologist.

Cancer survivors or family members may choose to consult with either a male or female psychologist for up to eight counseling sessions—free of charge. Psychologists also provide tobacco cessation counseling and education and, in conjunction with the social worker, facilitate bilingual support groups addressing issues related to diagnosis, treatment, side effects, and family coping.

If needed, the RN refers patients to the dietitian who provides

THE FOLSOM REPORT

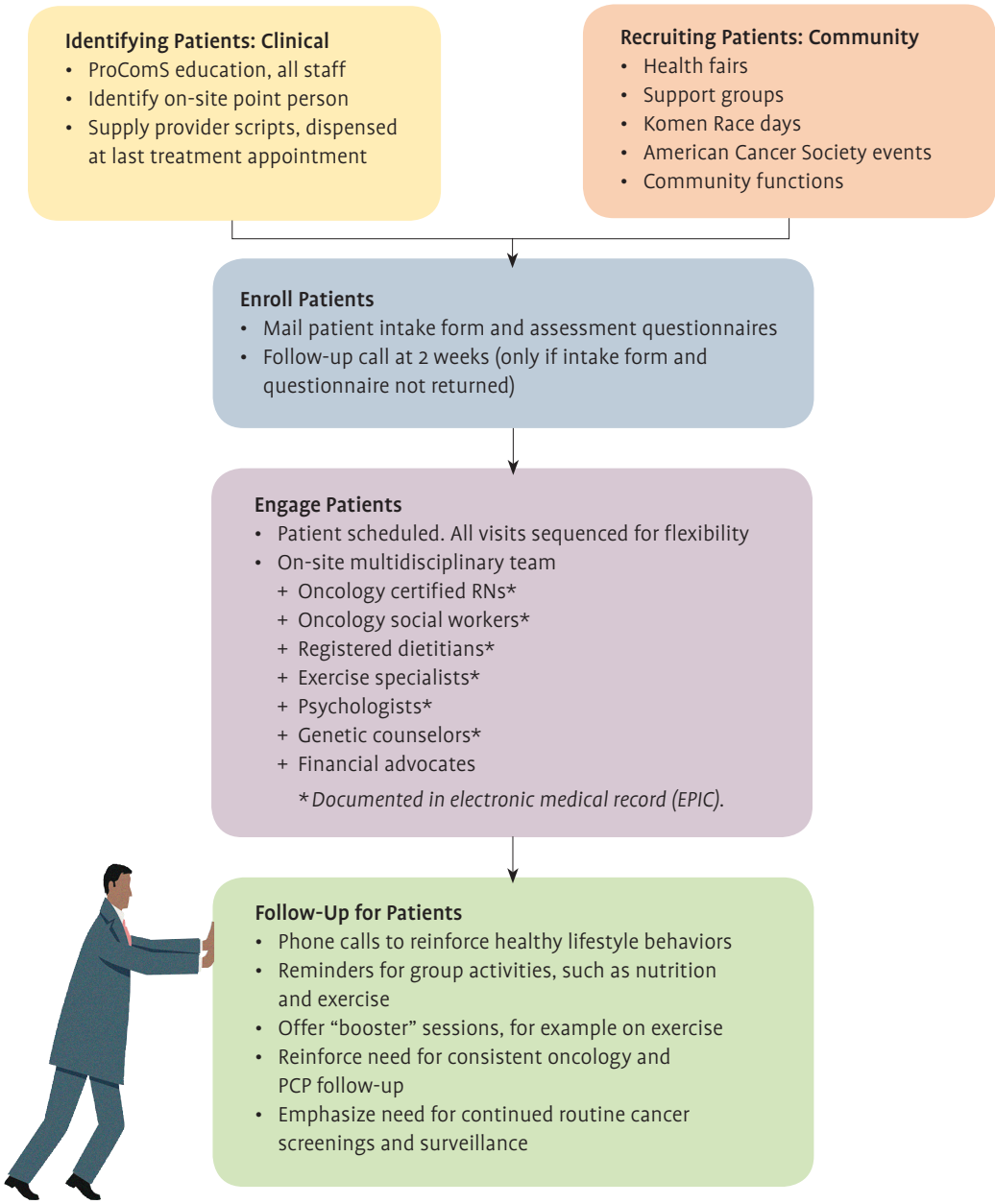
In the 1960s, the National Commission of Community Health Services, chaired by Eastman Kodak Director Marion B. Folsom and comprised of 32 prominent commissioners from the fields of medicine, business, health advocacy, and government, spent three years researching health service needs in 21 selected communities across the United States and formulating a rational action plan. The result was the 1967 Folsom Report, "Health is a Community Affair," which described comprehensive healthcare delivered by integrating services within the community, primary care, and public health, and placed emphasis on collaborations to implement "communities of solution."[5,6]

The Folsom Report provides a roadmap for a sustainable, community-wide endeavor, including:[6]

- The integration of provider communication into survivorship areas
- The reframing of survivorship services into a community health orientation
- Accountability for measurable outcomes
- Connection to overall public health.

The report identifies the integration of community partnerships as the key in developing "communities of solution" when addressing population health issues.[5,6] The Folsom Report provided the framework on which ProComS was built, effectively bridging the community's fragmented survivorship services.

Figure 2. ProComS Workflow



one-on-one consultations for impaired nutrition and weight loss, as well as group nutrition education and cooking instruction in a state-of-the-art demonstration kitchen.

All cancer survivors that choose to participate in the exercise program are referred to both the dietitian and the exercise specialist by the RN. The exercise specialist guides the patient through 12 one-on-one supervised fitness sessions to address the cancer survivor's unique exercise and activity needs. Focus is on increasing physical activity, strengthening, and reconditioning. Group exercise opportunities are also available to survivors for additional cardio and resistance training.

For those cancer survivors who are identified as at-risk due to a family history of cancer, the RN refers them to a certified genetic counselor to receive genetic counseling and testing.

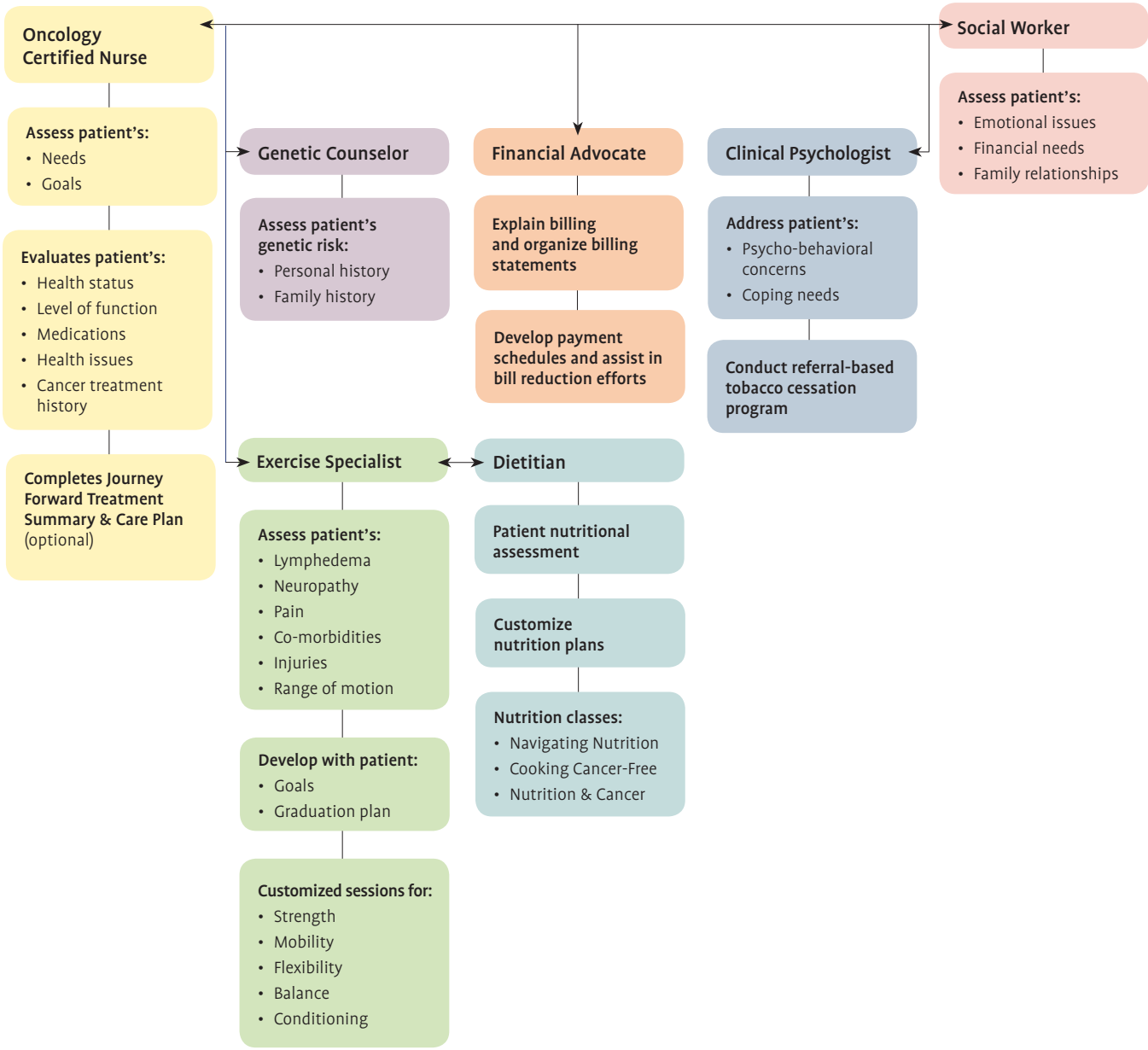
Finally, cancer survivors struggling with financial issues have access to a financial advocate. Any member of the multidisciplinary cancer care team can refer patients to this service.

This model centralizes the services of the multidisciplinary team; however, cancer survivors may be referred to a community partner for specialty services based on need.

Evidence-Based Practice Service Referrals

While UT Southwestern-Moncrief Cancer Institute's survivorship clinic offers an array of services on-site, the program maintains a broad referral stream, using community partners to offer the most comprehensive care possible to cancer survivors. Survivors requiring the specialized medical or rehabilitative services listed below are referred to a community partner program:

Figure 3. ProComS Multidisciplinary Team



- Speech therapy for survivors who have had treatment to the head and neck area
- Professional instruction and support for survivors who have had ostomies
- Interventions for lymphedema
- Palliative care
- Pain management
- Hospice care.

In collaboration with the local YMCA/LIVE**STRONG**,™ ProComS encourages cancer survivors "graduating" from the exercise component to maintain their healthy lifestyle behaviors. Cancer survivors are transitioned from the survivorship clinic to YMCA/LIVE**STRONG** so that they can continue exercising in a safe, structured environment where the staff is educated and trained to meet their unique needs.

Program Results & Outcomes

Over the two years of grant funding, ProComS' location, services, and model of care were developed and implemented. Cancer survivors have benefitted from multidisciplinary services as collaborations between community physicians, hospitals, and local community agencies solidified.

The program has had a huge impact, logging over 4,000 cancer survivor encounters with survivorship clinic staff, and a 43 percent growth in program enrollment since initiation in 2011 (see Table 1, page 46). Demographic data and team encounters on all cancer survivors enrolled in the program are captured in a customized

database allowing for aggregate analysis of program components.

Consistent with other survivorship programs, participants have been primarily Stage II and III breast cancer survivors, who were treated with surgery, chemotherapy, and radiation.

The exercise team provides about 68 percent of all patient encounters, with 98 percent of survivors who received exercise training completing the 12-session survivorship exercise program. At the conclusion of these sessions, 80 percent transitioned to other exercise programs—either a personal gym membership, YMCA/LIVE**STRONG** programs, or a home-based gym. Fifty-five percent chose to attend YMCA/LIVE**STRONG** programs. After conclusion of the formal exercise program, 80 percent of survivors attended a follow-up visit to reinforce exercise techniques.

Adherence to scheduled appointments across all survivorship disciplines is 80 percent and 180 survivors have requested and received a Survivorship Care Plan and Treatment Summary. Overall patient satisfaction with the multidisciplinary survivorship services continues at 93 percent.

Table 1. Multidisciplinary Team Encounters

SERVICE	ENCOUNTERS
RN OCN Navigator	453
Social Worker	270
Exercise	3,980
Dietitian	420
Psychotherapy	477
Genetic Counselor	22
Financial Advocacy	10
Total Encounters	5,632

Discussion & Lessons Learned

With the community engaged and the survivorship clinic operational, persistent outreach to providers and cancer clinics is essential to program success. Clinical collaborations are strengthened by regularly scheduled Community Advisory Board meetings throughout the year. These formal meetings with the board allow communication to remain open.

UT Southwestern-Moncrief Cancer Institute is not a cancer treatment facility, but rather a community cancer foundation that relies on referrals from oncology providers, community and local agencies, self-referrals, and word-of-mouth from program participants. Therefore, maintaining these strategic partnerships is a critical component to programmatic success. Extending outreach directly to primary care practices, treatment centers, service agencies, and survivor-related events, and through local media and public service announcements is essential. For example, 40 Parish nurses, representing 20 African American community churches, attended a structured educational program and were given survivorship brochures to distribute to their congregants.

The primary challenge is consistent referrals and enrollments from underserved patients receiving treatment at Forth Worth's safety-net cancer center. To address this issue, a full time bilingual program manager with a social service background focuses on engaging the community oncologists and safety-net providers.

In the ProComS patient population, barriers to care mirror those described in the literature.[18,19] Transportation needs are met by providing gasoline cards and public transportation vouchers to cancer survivors.

Bilingual staff is available to resolve language barriers. When ProComS focused on meeting the specific social and cultural needs of Hispanic women, it was able to increase their attendance at support groups and exercise sessions—both in terms of total number and consistency. In fact, one group of Hispanic women formed a "spontaneous" support group that chose to exercise at the fitness center at the same time, completing their exercise routines while talking, encouraging one another, and socializing in their primary language.

Cancer survivors returning to work are often unable to attend daytime appointments; these barriers are addressed through "as needed" scheduling of evening appointments.

Complementary and alternative medicine techniques are increasingly popular in the management of post-cancer treatment symptoms. ProComS participants are offered Yoga and Tai Chi on-site at the UT Southwestern-Moncrief Cancer Institute survivorship clinic.

ProComS demonstrates how a local community is able to partner with leadership across different organizational systems to provide multidisciplinary cancer survivorship services. Successful survivorship programs require sensitivity to the local values and culture, particularly with regard to established patterns of healthcare communication. Survivorship staff at UT Southwestern-Moncrief Cancer Institute continue to immerse themselves in this diverse community, and recognize the key to success is the willingness of each provider to operate as a collaborating partner on multiple levels.

Using a community engagement framework, program leaders at all partner organizations are able to provide a "top down, bottom up" approach to community engagement and stakeholder involvement.[20] A critical success factor in the establishment and management of ProComS has been the unceasing effort of the "central organization," in this case UT Southwestern-Moncrief Cancer Institute, to maintain consistent outreach. Cancer patients emerge from treatment with a case of tunnel vision. Many have

been so focused on the next treatment step that they are overwhelmed when there is no clear "next step" in survivorship. While a comprehensive survivorship program can offer those much needed next steps, these patients require guidance and ongoing communication with providers.

Although this approach works for a majority of the survivor population in the ProComS community, the medically underserved cancer survivors remain under-represented in terms of enrollment. Additional recruitment efforts are aimed at engaging the medically disadvantaged who are treated in the safety-net system. Embedding staff directly at the safety-net oncology clinic, direct dialogue with the Cancer Committee, providing additional follow-up telephone calls and transportation vouchers, contacting Parish nurses, and mailing re-invitations, have all been well received.

Further research is still needed to understand how to best educate and engage uninsured, underinsured, and medically underserved patients in essential survivorship services. The services provided to ProComS survivors were funded through a CPRIT grant at no cost to the survivor. The completion of a cost and benefit analysis will be a next step towards a better understanding of survivorship funding and program sustainability. OI

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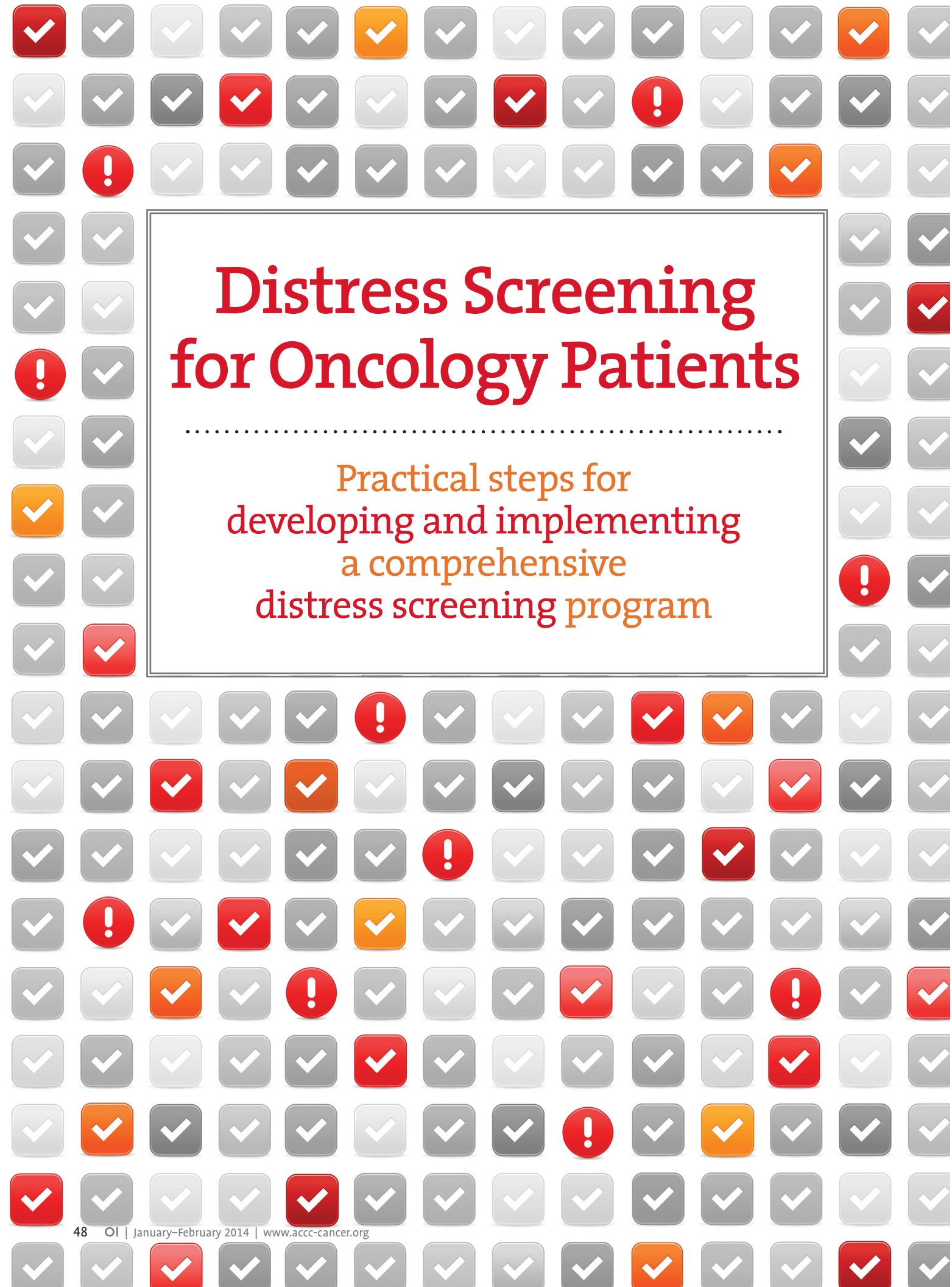
References

1. de Moor JS, Mariotto AB, Parry C, et al. Cancer survivors in the United States: prevalence across the survivorship trajectory and implications for care. *Cancer Epidemiology Biomarkers & Prevention*. 2013;22(4): 561-70.
2. CDC. Cancer Survivors: United States, 2007. *Morbidity and Mortality Weekly Report*. 2011;60(9): 269-72.
3. American Cancer Society. ACS Cancer Facts and Figures 2013. Atlanta, GA, 2013. Available online at: www.cancer.org. Last accessed Nov. 21, 2013.
4. CDC. Cancer survivorship: United States, 1971-2001. *Morbidity and Mortality Weekly Report*. 2004;53(24): 526-9.
5. Pratt-Chapman M, Willis A. Community cancer center administration and support for navigation services. *Seminars in Oncol Nurs*. 2013;29(2): 141-48.
6. Griswold KS, Lesko SE, Westfall JM. Communities of solution: partnerships for population health. *J Amer Board of Family Med*. 2013;26(3): 232-38.
7. Oeffinger KC, McCabe MS. Models for delivering survivorship care. *J Clin Oncol*. 2006;24(32): 5117-24.
8. McCabe MS, Jacobs L. Survivorship care: models and programs. *Sem Oncol Nurs*. 2008;24(3): 202-07.
9. Howell D, Hack TF, Oliver TK, et al. Models of care for post-treatment follow-up of adult cancer survivors: a systematic review and quality appraisal of the evidence. *J Cancer Surviv*. 2012;6(4): 359-371.
10. Hewitt M, Greenfield S, Stovall E. *From Cancer Patient to Cancer Survivor: Lost in Transition*. Washington, DC: Institute of Medicine, National Academies Press, 2006.
11. NCCN. NCCN Clinical Practice Guidelines in Oncology. Available online at: www.nccn.org/professionals/physician_gls/f_guidelines.asp. Last accessed Nov. 21, 2013.
12. American Society of Clinical Oncology: Practice and Guidelines. Available online at: www.asco.org/quality-guidelines/guidelines. Last accessed Nov. 21, 2013.
13. National Heart, Lung, and Blood Institute. Systematic Evidence Reviews and Clinical Practice Guidelines
Available online at: www.nhlbi.nih.gov/guidelines/index.htm. Last accessed Nov. 21, 2013.
14. World Cancer Research Fund and the American Institute for Cancer Research. Food, Nutrition, Physical Activity and the Prevention of Cancer. A Global Perspective. Available online at: www.dietandcancer-report.org. Last accessed Nov. 21, 2013.
15. ONS. Putting Evidence into Practice, Lymphedema. Available online at: www.ons.org/Research/PEP/Lymphedema. Last accessed Nov. 21, 2013.
16. CDC. Cancer Survivorship. Available online at: www.cdc.gov/cancer/survivorship/pdf/brochure.pdf. Last accessed Nov. 21, 2013.
17. National Lymphedema Network. NLN Position Papers. Available online at: www.lymphnet.org/lymphedemaFAQs/positionPapers.htm. Last accessed Nov. 21, 2013.
18. ONS. Cancer Rehabilitation and Survivorship Transdisciplinary Approaches to Personalized Care. Available for purchase at: www.ons.org/Publications/Books/Excerpts/INPU0608toc.
19. Sanders J, Solberg B, Gauger M. Breaking barriers to care: a community of solution for chronic disease management. *J Am Board Fam Med*. 2013;26(3): 311-315.
20. Larson SL, Fleishman JA. Rural-urban differences in usual source of care and ambulatory service care. *Med Care*. 2003;41(7, Supplement): III-65-III-74.

Acknowledgement

Funded by the Cancer Prevention and Research Institute of Texas, Prevention Grant PP110097; Keith Argenbright, MD, MMM, Principal Investigator.



Distress Screening for Oncology Patients

Practical steps for developing and implementing a comprehensive distress screening program

BY DAVID BUXTON, MD; MARK LAZENBY, PHD; ANNE DAUGHERTY, MSW, LCSW; VICKI KENNEDY, LCSW; LYNNE WAGNER, PHD; JESSE R. FANN, MD, MPH; AND WILLIAM F. PIRL, MD, MPH

Meeting the American College of Surgeons (ACoS) Commission on Cancer (CoC) standard related to psychosocial distress screening will require cancer programs to create a comprehensive system that addresses six requirements:

1. Inclusion of a psychosocial representative on the cancer committee and a committee meeting that includes plans for screening
2. Determination of the timing of screening
3. A method of screening, such as electronic or paper and pencil
4. Selection of a screening tool
5. Identification of an assessment and referral plan
6. Documentation of the process.

Each of these components will need careful consideration based on a program's size, resources, location, and patient population. This article will briefly review the rationale behind distress screening, highlight considerations in implementing a distress screening system, and describe training opportunities to prepare for the standard, which goes into effect in 2015.

Psychosocial Distress

The National Comprehensive Cancer Network (NCCN) defines distress as an "unpleasant emotional experience of a psychological (cognitive, behavioral, emotional), social, and/or spiritual nature that may interfere with the ability to cope effectively with cancer, its physical symptoms and its treatment."[1] Although distress is common, a multitude of studies have demonstrated that 50 to 94 percent of patients with cancer who have significant distress are not identified as such during routine oncology visits.[2-3] Undetected distress typically goes unaddressed; indeed, 55 percent of patients with cancer who report distress also report that they do not receive psychosocial treatment.[4]

Complex patient-provider communication dynamics contribute to these missed opportunities to manage distress during cancer care. Screening for distress represents an opportunity to better identify patients with psychological, emotional, social, and/or spiritual concerns. Distress screening is defined as a brief method for prospectively identifying and triaging cancer patients at-risk for illness-related psychosocial complications that undermine the ability to fully benefit from medical care, the efficiency of the clinical encounter, satisfaction, and safety. All patients need to be screened as many report they are unlikely to discuss emotional issues unless asked and oncologists report uncertainty in identifying distress.[5-6]

Screening for and management of distress leads to better patient outcomes. The awareness of screening for distress alone increases the likelihood of oncologists discussing distress during patient interactions.[7] Cancer patients who speak to oncologists about the emotional impact of cancer have higher rates of psychosocial care and feel more satisfied with their cancer treatment.[8] Randomized clinical trials have also shown that screening programs may help to improve levels of distress, anxiety, and depression, but a referral component is necessary.[9] A study conducted in primary care clinics showed that systematic detection and treatment of distress could even lower rates of cancer deaths in older individuals in primary care clinics.[10]

Implementing Distress Screening

Cancer programs will need to plan and organize how best to integrate psychosocial distress screening into their programs by the 2015 deadline. The selection of a screening tool is only one part of this preparation; cancer programs must also identify or create a system of care that ensures adequate treatment for distressed patients.

A comprehensive distress screening program is one that:[11-12]

- Uses a valid instrument to screen patients for distress
- Assesses patients with distress for the sources of their distress
- Refers patients and families to appropriate psychosocial services
- Follows up on referrals and targeted outcomes
- Uses quality improvement to assess the program's effectiveness.

The process of implementing a comprehensive distress screening program is best delineated into a series of four steps.

1. ***Establish a point person for the screening program.*** Begin by identifying a psychosocial representative to oversee the distress screening program and report to the leadership committee. The psychosocial representative should be an "oncology social worker, clinical psychologist, or other licensed mental health professional trained in the psychosocial aspects of cancer care."[1] Once the distress screening is in place, identify an individual, team, or department to help implement, monitor, and evaluate the program. (Training opportunities are on pages 51-52.)

2. ***Create a psychosocial care network.*** Cancer programs will need to identify procedures and personnel for follow-up evaluations and referrals for distress management. This step is critical before launching screening so that patients who are distressed can get further evaluation and, when indicated, referrals in a timely manner. When feasible, an integrated system that can provide population-based, patient-centered psychosocial care is preferred.[13] Cancer programs that do not have a psychosocial oncology practitioner or service can develop written referral agreements with community organizations and other specialty providers to help meet the needs of patients. For example, primary care providers often can complete a follow-up assessment with an option to treat or refer to a mental health provider or appropriate community organization. Patients' insurance companies also have lists of paneled mental health providers who can form part of the referral network. If a patient is an imminent safety risk, emergency rooms can provide acute assessment. Prior to referring patients to psychosocial healthcare providers, cancer programs should offer providers information on patients' needs, thereby ensuring coordinated care. Patients may need to sign a "Release of Information," although HIPAA does permit communication among providers to ensure continuity of care.

3. ***Design a standardized protocol.*** Once a referral source has been identified, cancer programs can put in place a standardized protocol for patients in distress. The protocol should take into account scoring and review of results of the screening instruments, determining the need for a follow-up clinical assessment, and developing a referral plan. Having a protocol ensures that steps are completed in a timely manner so that distress can be promptly addressed in an organized fashion. The protocol should identify personnel and specify their roles in the distress screening process. For example, a non-clinical staff member could oversee initial administration, collection, and triage of screening results to a healthcare team. An identified clinician (oncologist, nurse, nurse navigator, social worker, psychologist, or other psychosocial representative) would be responsible for reviewing screening data and ensuring patients receive appropriate follow-up assessment and referral if they meet certain pre-determined criteria. Further evaluation and treatment could be completed by the established referral base discussed in step two of implementation.

Table 1. Distress Screening Instruments

INSTRUMENT	MEASURES	THRESHOLD
Distress Thermometer	General distress	4[14]
Psychosocial Screen for Cancer (PSCAN)	General distress	8[15]
PHQ-4	Anxiety and depression	≥6=yellow flag; ≥9 red flag[16]
ESAS	Symptoms	4[17]

4. ***Tailor the screening program to the patient population.*** The last step in the process is determining how to screen for distress in a cancer center's patient population. This step will include:

- Selecting a screening tool
- Deciding how and when to administer the tool
- Determining who will conduct the second-level assessment, make referrals, and follow-up on referrals
- Documenting the results
- Assessing the distress screening program's effectiveness.

An essential first step is for the cancer committee to reach consensus on the definition of distress it seeks to measure. The NCCN definition mentioned earlier currently represents the standard of care as it covers emotional, social, and spiritual concerns. A variety of tools are available for distress screening, but currently there is no gold standard or consensus on which tool is best. It is important that cancer programs use distress screening instruments that assess more than one symptom and that have been validated in oncology populations (see Table 1, above). There are also commercial electronic distress screening systems that use validated instruments. Published ranges of thresholds should be considered when using "cut-off scores" (Table 1), rather than changing the threshold in an attempt to limit the numbers of patients who screen in as possibly distressed. Altering thresholds could result in medical, legal, and ethical implications, especially with a negative patient outcome.

Cancer programs should next determine how the selected

Table 2. Curriculum Outline of the *Screening for Psychosocial Distress Program*

YEAR	WORKSHOP CONTENT	ONLINE VIDEOCONFERENCE TOPICS
1st – Introductory	• Components of a Comprehensive Distress Screening Program	• Setting up Screening: Who? With What? How?
	• Communication Skills	• Referral Networks: Who? How?
	• Screening Standards	• Achieving Your Screening Goals
	• Screening Instruments	• Achieving Your Network Goals
	• Building a Referral Network	
2nd – Advanced	• Documentation & Quality Improvement	• Understanding Cost & Reimbursement Strategies
	• Using IT Resources for Distress Screening	• Using the RE-AIM Model to Strengthen Implementation & Maintenance of Your Program
	• Demonstration & Pilot Projects to Strengthen Your Distress Screening Program	
	• Marketing Your Distress Screening Program	

instrument will be administered. Instruments can be completed on paper, electronically with a tablet, or even face-to-face in an interview. Some clinicians may prefer to include distress screening as part of the vital signs or in a review of systems, while others may prefer patients to complete electronic questionnaires that can be scored automatically before seeing the provider. Although distress screening could occur with every patient encounter, ACoS recommends that distress screening occurs "a minimum of one time per patient at a pivotal medical visit to be determined by the program." Pivotal times include initial diagnosis, beginning and ending treatments, and recurrence or progression. Cancer programs might find it administratively difficult to track these pivotal times, so selecting a time anchored to a moment on the cancer-care continuum that happens to every patient, such as initial diagnosis, will ensure that distress screening is conducted at least once. Results of the distress screening should be viewed as important medical information for patient care, and thus, documented in the medical chart. Ideally, the documentation of results should include the name of the clinician who reviewed them and any plans for follow-up.

Implementation Challenges

Implementing new procedures to help manage patient care can bring inherent challenges to a cancer program. Cancer care is often provided across a complex interconnected system between physician-owned oncology practices and hospital-based services, such as inpatient care and radiation oncology. Additionally, systems often have new or more than one electronic medical record (EMR), which may or may not be linked together. Finally, many cancer programs do not currently have personnel trained in psychosocial oncology on staff or the funding to provide these services on a routine basis. These issues make it challenging to follow a patient across the continuum of care—let alone decide pivotal points for distress screening.

Decisions about the timing and frequency of distress screening may vary based on the treatment setting, type of cancer, and resources available in the institution. For example, in radiation oncology, some programs are opting to screen patients for distress at simulation and again at the end of treatment. In the breast cancer clinic, screening might occur at a second visit or first infusion. There are limited data available to suggest optimal timing and frequency of screening and more studies are needed.

Finally, commitment of financial resources either to invest in a computerized program that is integrated into the EMR and/or in psychosocial oncology personnel can be challenging as cancer programs manage tight budgets with decreasing revenues. There are cost-effective solutions in both distress screening and referral resources that can be implemented to successfully meet the standard and more importantly to ensure that untreated patient distress does not interrupt treatment or lead to costly emergency room or hospital readmissions. For example, the *Screening for Psychosocial Distress Program* (www.apos-society.org/screening) trains cancer

care professionals on how to develop, implement, and maintain a comprehensive distress screening program. Funded by a grant (R25CA177553-01) from the National Cancer Institute, this program is a joint project of Yale School of Nursing and the American Psychosocial Oncology Society (APOS). With an international faculty of leading psychosocial cancer care professionals and researchers, the program will train two cancer care professionals from a cancer program, enrolling 18 cancer centers each year. Successful implementation and ongoing maintenance of a comprehensive distress screening program is enhanced by having two people from each cancer center attend the program. The program's funding allows for a stipend for each person toward covering the cost of attending the program.

The *Screening for Psychosocial Distress Program* will consist of two one-day workshops annually, as well as four online videoconferences in the first year and two in the second. Table 2, page 51, outlines the program's curriculum. The first cohort of trainees will begin the course in February 2014.

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Decisions about the timing and frequency of distress screening may vary based on the treatment setting, type of cancer, and resources available in the institution.

References

1. NCCN. *Distress Management Clinical Practice Guidelines in Oncology*. Version 3.2012. Available online at: *www.nccn.org/professionals/physician_gls/pdf/distress.pdf*. Last accessed Nov. 26, 2013.
2. Fallowfield L, Ratcliffe D, Jenkins V, et al. Psychiatric morbidity and its recognition by doctors in patients with cancer. *Br J Cancer*. 2001;84(8):1011-1015.
3. Sollner W, DeVries A, Steixner E, et al. How successful are oncologists in identifying patient distress, perceived social support, and need for psychosocial counseling? *Br J Cancer*. 2001;84(2):179-185.
4. Pascoe S, Edelman S, Kidman A. Prevalence of psychological distress and use of support services by cancer patients at Sydney hospitals. *Aust N Z J Psychiatry*. 2000;34(5):785-791.
5. Detmar SB, Aaronson NK, Wever LD, et al. How are you feeling? Who wants to know? Patients' and oncologists' preferences for discussing health-related quality-of-life issues. *J Clin Oncol*. 2000;18(18):3295-3301.
6. Pirl WF, Muriel A, Hwang V, Greer JA, et al. Screening for psychosocial distress: a national survey of oncologists. *J Support Onc*. 2007;5(10):499-504.
7. Taenzer P, Bultz BD, Carlson LE, Speca M, et al. Impact of computerized quality of life and screening on physician behavior and patient satisfaction in lung cancer outpatients. *Psychooncol*. 2000;9(3): 203-213.
8. Forsythe LP, Kent EE, Weaver KE, Buchann N, et al. Receipt of psychosocial care among cancer survivors in the United States. J *Clin Oncol*. 2013;31(16):1961-1969.
9. Mitchell AJ. Screening for cancer-related distress: when is implementation successful and when is it unsuccessful? *Acta Oncol*. 2013; 52(2):216-224.
10. Gallow JJ, Bogner HR, Morales, et al. The effect of a primary care practice-based depression interventions on mortality in older adults: a randomized trial. *Ann Intern Med*. 2007;146(10): 689-698.
11. Pirl W, Braun I, Deshields T, et al. American Psychosocial Oncology Society, Association of Oncology Social Work and Oncology Nursing Social Joint Recommendations for the Implementation of Distress Screening Programs in Cancer Centers. Available online at: www.apos-society.org. Last accessed Nov. 26, 2013.
12. Lazenby M, Dixon J, Ercolano E, Bai M, et al. Comparing the Distress Thermometer (DT) with the Patient Health Questionnaire (PHQ)-2 for Screening for Possible Cases of Depression among Patients Newly Diagnosed with Advanced Cancer. Palliative & Supportive Care. (In Press).
13. Fann JR, Ell K, Sharpe M. Integrating psychosocial care into cancer services. *J Clin Oncol*. 2012;30(11):1178-1186.
14. Thomas BC, Nandamohan V, Nair MK, Robinson JW, Pandey M. Screening for distress (the 6th vital sign) in a global recession: sustainable approach to maintain patient-centered care. *Future Oncol*. 2009; 5(5): 727-738.
15. Jacobsen PB, Donovan KA, Trask PC, Fleishman SB, et al. Screening for psychologic distress in ambulatory cancer patients. *Cancer*. 2005;103(7):1494-1502.
16. Linden W, Vodermaier AA, McKenzie R, Barroetavena MC, et al. The psychological screen for cancer: further validation and normative data. *Health Qual Life Outcomes*. 2009;7:16.
17. Löwe B, Wahl I, Rose M, Spitzer C, et al. A 4-item measure of depression and anxiety: Validation and standardization of the Patient Health Questionnaire-4 (PHQ-4) in the general population. *J Affective Disorders*. 2010;122(1-2):86–95.

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The Philips Ambient Experience

Broward Health Medical Center partners to create a model infusion center

BY HEATHER MILLER, MSN, RN-BC, CPON

The adult infusion center at Broward Health Medical Center (BHMC), Fort Lauderdale, Fla., is currently comprised of 12 infusion chairs, two beds, and a cancer clinic. Historically, the infusion center has struggled with patient flow, less than optimal chemotherapy turnaround times, operational inefficiencies, and poor design and aesthetics, which ultimately translated to a poor patient experience.

The infusion center sees about 1,300 patients each month. A projected increase in infusion services projected for the near future coupled with a service market saturated with oncology providers underscored the need to transform the infusion service line into a world-class infusion center. Accordingly BHMC sought to identify a partner organization that could assist in revamping all aspects of the patient experience in its infusion center.

In January 2012 BHMC brought together a multidisciplinary team to oversee the selection of this partner and to manage the infusion center project. The team was comprised of the following stakeholders:

- Team leader Heather Miller, MSN, RN-BC, CPON, regional director, cancer service line
- Calvin Glidewell, CEO, BHMC
- Natassia Orr, COO, BHMC
- Hamilton Clark, CFO, BHMC
- Dennis Stefanacci, President/CEO, Broward Health Foundation
- Adele Holman, RN, OCN, coordinator, BHMC Adult Infusion Center
- Delia Guaqueta, MD
- Judith Bowden, RPh
- Karen Scheinberg, a representative from BHMC's Building and Design Department
- Diana Dominguez, manager of Facilities Services, BHMC
- Donna Haley, RN
- Architects from Perkins & Will
- Three patient advocates who were past patients at BHMC.

The team envisioned a redesign with a twofold purpose. First, the redesign would solve the issues related to the logistical aspects of treatment. Second, the redesign would differentiate BHMC by setting it apart from its competitors. The team believed that the end result would be a new concept in the delivery of quality cancer care.

The Philips Ambient Experience

BHMC's team engaged Philips in September 2012 based on the company's unique vision of the total patient experience solution. Philips Ambient Experience designs services that aim to simplify healthcare by focusing on the people in the care cycle—patients *and* providers. By partnering with Philips, the team hoped to reduce patient anxiety and fear related to the hospital experience at each interaction while simultaneously maximizing efficiencies and throughput.

Guided by the principle of "value for people through valuing people," Philips' in-house global team studies the world at a societal, cultural, and individual level to identify macro paradigm shifts, socio-cultural trends, and people's daily needs and desires. In an atmosphere that is psychologically supportive, a patient's experience is based on healing in its truest sense. The company's service is branded as the Philips Ambient Experience, bringing together healthcare solutions from design, process improvement, patient satisfaction enhancement, and operational efficiencies that:

- Integrate architecture and technology innovations, such as lighting, sound, projection, and RFID (radiofrequency identification), to create healthcare spaces that are unique and inviting
- Assist hospitals in creating immersive, multi-sensorial environments that enhance the overall hospital experience and change the culture
- Transform cold, impersonal environments into places that comfort and reassure.

The infusion center at Broward Health Medical Center was the first in the United States to utilize the Philips Ambient Experience.

A key element of the Philips Ambient Experience is the ability for patients to personalize their surroundings with lighting and other aesthetic features, giving patients an increased sense of control over their environment. Personalization benefits the patient by providing greater involvement in treatment, reduced anxiety, increased comfort, higher patient satisfaction, and reduced procedural or treatment time.

Improvements in the physical environment, coupled with process and culture changes, can have a positive influence on patients and their choice of where to receive cancer treatment—one of the key success metrics for BHMC's renovation project.

Getting Started

A five-day workshop was held in December 2012 with two consultants and one researcher from Philips who worked directly with internal and external customers of Broward Health. Philips analyzed turnaround times and efficiency of nursing and pharmacy, which

influenced staffing recommendations. Philips also evaluated relevant cultural and process issues that materially contribute to the patient experience. Research was collected through targeted patient and family interviews, staff interviews, charts and photographs of current flow, and shadowing of staff to determine current processes. The Philips team then developed solutions that it shared with the architectural firm, Perkins & Will, to help guide the redesign. Recommendations for lighting, art work, paint, storage, structure, and flow were mutually determined. Philips then developed processes to effectively communicate all improvements to BHMC's patient population.

Taking into consideration the needs of patients and staff, the collective goal was to design a solution that improved the quality of the patient's experience through technology.

Analyzing the Patient Experience

Mapping out the current experience helped reveal ways that efficiencies could be enhanced. Philips collaboratively created a "to be" patient experience map, illustrating the desired service experience at Broward Health Medical Center that would serve to drive and guide the redesign of the infusion center. During this process, the team discovered that the average patient made nine stops between the lobby, lab, treatment area, and check-out:

1. Entrance to the medical center
2. Check-in upon arrival to guest relations desk at the entrance to the hospital
3. Sit down in waiting area
4. Complete registration in the infusion center
5. Sit back down in waiting area
6. Draw blood work in the lab, located in the rear of the infusion center
7. Receive treatment in the infusion bays
8. Check-out at the registration area located at the entrance to the infusion center
9. Leave.

Broward Health's current and future scenarios were simulated more than 100 times using modeling software to determine potential outcomes. Flow of patients, staff, and lab results was reviewed across the infusion center. Registration, lab, chemo delivery, and treatment were also analyzed.

Based on observations, scheduling data, and simulation modeling, the team estimated average patient turnaround time at 2 hours and 29 minutes. Two months of scheduling data was received and analyzed, indicating an average of 34 patients treated per day, with 50 percent of all patients receiving chemotherapy. Other data revealed:

- The highest number of patients seen in a day was 50, and the lowest was 22
- No-shows represented 16 percent of all scheduled appointments
- Patients were scheduled based on their length of visit in order to maximize volume, but this scheduling often did not align with the ancillary services supporting the infusion center (i.e., blood draw, pharmacy)
- Patient wait times increased and throughput was reduced by the suboptimal processes between blood draw and the delivery of the chemotherapy treatment
- Patients were immediately allocated to chairs—even though in some cases the drug was not available to treat them
- Patients were assessed once seated in a chair, which sometimes resulted in non-value resource allocation when patients could not be treated that day.

Scheduling, pharmacy, and resource allocation were determined to be factors impacting efficiency. The flow of patients, staff, lab results, and medications was observed across the infusion center. The team also analyzed current and future state scenarios to determine how new chairs and a redesign would impact the infusion center. Next, the team looked at current operational baselines and historical data to define a course of action. The following near-term improvement opportunities related to work and patient flow were then defined.

Operational Recommendations

Philips recommended the following steps to improve the patient, physician, and staff experience, while increasing revenues and reducing costs:

- Level load patient schedule to reduce no-shows and bottlenecks, which routinely consumed chair time, and to help ensure the proper patients were scheduled at the appropriate times.
- Perform root cause analysis on no-shows.
- Review pre-appointment process.
- Shift nursing resources to blood draw.
- Create patient record drop off and time.
- Assess constraint-based scheduling software. The computer software will not allow overbooking to ensure operational efficiency; all available time slots will be appropriately programmed for the treatment related times.
- Assess patients earlier in the appointment process.
- Use a signaling system to direct patients; visual cues to alert patients to next areas for treatment.
- Implement a patient status board.
- Draw blood work the day before the treatment appointment.
- Work with pharmacy to deliver just-in-time medication.
- Signal between pharmacy and infusion via use of an electronic message board derived from the EMR to help indicate where the patient is within the care process, which will reduce phone calls and confusion among providers.
- Dedicate a pharmacy to serve the infusion center.
- Use robotic technology to transport chemotherapy drugs, freeing up staff time.
- Assign nurses and patients to specific areas in the infusion center.
- Use EMR (electronic medical record) and CPOE (computerized physician order entry).
- Premix highest volume medications.

Revving-up Registration

Registration takes approximately seven minutes, but is highly variable due to patients who do not have pre-authorizations or who are not pre-registered. There is currently limited visual or electronic connectivity between registration, lab, pharmacy, and the infusion center, resulting in long turnaround times. A temporary area in the hallway is used to stage patients prior to blood work, and there is no line of sight between the main waiting area and the blood draw room. Additionally, there is no easy way to know if chairs are available in the main infusion area, or where patients should sit once they arrive.

The team suggested that patients would be processed in a more timely manner if patients registered, were quickly moved to lab and triage, and then escorted to their infusion suite for the day.

Minimizing Medication Delivery Delay

Medication delivery wait times at the infusion center are high. Philips identified several reasons for these delays:

- The infusion center is not provided information about when to expect medication delivery
- The infusion center pharmacist and nursing staff spend considerable time tracking down chemo medication due to limited line of sight
- Multiple medication checks are conducted between nurses and pharmacy staff prior to the treatment of patients
- All chemotherapy is custom-created on an individual basis once lab work is reviewed
- Resources are misallocated, for example, pharmacists being used to do low-value tasks, such as delivering medication to the patient's room.

Based on these data, it was clear that BHMC should restructure its process for getting medication from the pharmacy to the patient waiting in the infusion center.

The redesigned process includes improved line of sight and communication so that pharmacists and infusion nursing staff can easily determine where and when a patient's medications will be ready. A new dedicated pharmacy is being added to the infusion center, and robotic technology will be used to transport the chemotherapy from the pharmacy to the patient. In addition, clinicians will not have to travel to a variety of storage locations to gain access to supplies; instead, supplies will be built into each infusion station.

Improving Turnaround Time

As turnaround time was found to be an issue throughout the patient visit, Philips performed current state analysis and bottleneck identification to develop prioritized improvement recommendations. The team used a structured approach to capture the baseline environment and identify improvement opportunities by:

- Interviewing key stakeholders
- Collecting and reviewing scheduling and pharmacy cycle time data
- Gathering operational observations
- Modeling current and future state simulation scenarios.

The redesigned process includes improved line of sight and communication so that pharmacists and infusion nursing staff can easily determine where and when a patient's medications will be ready.

The team found that decoupled processes, batching (a process of making multiple patients chemotherapy medications at one time rather than per patient), and limited visual controls resulted in excess patient wait-times and underutilized beds and chairs. Observations and simulation results identified the preparation and delivery of medication from the pharmacy as the bottleneck. Once the bottleneck is resolved using the strategies discussed previously, the team suggested additional changes to improve turnaround time and throughput, including:

- Changing the pharmacy location and capacity
- Optimizing scheduling processes
- Aligning registration and blood draw resource capacity
- Changing the hours of operation at the infusion center (opening earlier and adding weekend hours)
- Increasing RN support of the blood draw processes.

A Better Experience for Patients & Staff

BHMC's redesigned infusion center, scheduled to open in March 2014, will provide a clear pathway for patients that enhances throughput. The infusion center will feature:

- 20 infusion chairs
- 2 beds
- An express clinic that will perform services, such as injections for stimulating agents, medi-port flushes, IV pump disconnects, and procedures or infusions that are less than 15 minutes
- A triage room
- A social services room
- A phlebotomy room.

The cancer clinics currently housed in the infusion center will move into the Physician Cancer Specialty Center, which will also provide a similar environment for physician visits, such as palliative care, surgical oncology, medical oncology, and GYN oncology. Maximum capacity of the new infusion center is projected to increase from 47 patients per day to 62 patients per day. The ultimate goal is to facilitate an environment in which clinicians will have more time to spend with patients and families. Key stakeholders were part of each decision to ensure that the space was both aesthetically pleasing and efficient. Ultimately, BHMC expects its innovative redesign to bring about an enriched patient and staff experience, a higher quality of care, and increased operational efficiency. OI

Heather Miller, MSN, RN-BC, CPON, is regional director, cancer service line, Broward Health Medical Center, Fort Lauderdale, Fla.

Ask ACCC's Community Resource Centers

Acute promyelocytic leukemia (APL) is a rare hematologic malignancy with less than 1,000 newly diagnosed cases annually. When existing protocols are followed, the success rate of treatment for this disease is very high—up to 97 percent. But what happens when a patient's treatment regimen goes awry or the schedule goes off-course? And what happens when patients are treated outside tertiary treatment centers where treatment regimens were developed? Are the same high cure results achieved? *Oncology Issues* asked Elihu Estey, MD, professor of hematology at the University of Washington, for answers.

"APPROPRIATE MANAGEMENT of APL can literally be the difference between life and death," said Dr. Estey, who provides care for APL patients at Seattle Cancer Care Alliance. "Prior to treatment there is a high risk of life-threatening complications, such as bleeding in the brain and lung. Platelet counts must be kept above 20,000, generally between 20,000 and 30,000, and coagulation factors must also be kept above certain threshold levels."

Current treatment for APL is well established: all-*trans* retinoic acid (ATRA; tretinoin) in combination with arsenic trioxide (ATO), often without traditional chemotherapy. Largely developed by Dr. Estey and colleagues at MD Anderson Cancer Center in Houston, the ATRA and arsenic combination treatment regimen is responsible for excellent therapeutic results—as high as 97 percent in multicenter clinical trials.[1] A study presented at the 2012 Annual Meeting of the American Society of Hematology compared standard treatment for newly diagnosed non-high-risk APL—simultaneous ATRA and chemotherapy (idarubicin)—to the combination ATRA and ATO, but without chemotherapy.[2] While complete responses were observed in 97 percent of each arm, the two-year event-free survival was higher in the arm without additional chemotherapy (97 percent) versus the controls (87 percent).[2] Based on that data, the National Comprehensive Cancer Network (NCCN) changed its treatment guidelines for APL (www.nccn.org/ordertemplates/default.asp?did=9).

Despite these studies and the changes made to the NCCN treatment guidelines for APL, an issue that has come to the forefront recently is the discrepancy between the greater than 90 percent cure rates reported from tertiary centers and the 65 percent cure rates found in population-based studies, which include many patients treated in community centers.[3] Reasons behind this discrepancy are not clear. One possible factor could be that patients being treated in the community are "sicker" than those being treated in a tertiary center. In other words, patients are presenting with more advanced disease and complicating co-morbidities. Another factor is likely to be that tertiary centers have more experience managing complex and rare diseases such as APL.

Indeed efforts to disseminate knowledge about management of APL to the broader community are in progress.[3] A key component in ACCC's education project, *Improving Quality of Care in APL*, is the identification of Community Resources Centers,

such as the Seattle Cancer Care Alliance, which are available to answer questions and provide guidance to community-based cancer programs with less experience treating patients with APL. The underlying goal behind ACCC's education program: to help ensure that APL patients who choose to be treated in their community receive the same quality of care they would receive in an academic setting. OI

References

1. Sanz MA, Grimwade D, Tallman MS, Lowenberg B, et al. Management of acute promyelocytic leukemia: recommendations from an expert panel on behalf of the European LeukemiaNet. *Blood*. 2009;113(9):1875-91.
2. Lo-Coco F, Avvisati G, Orlando SM, et al. Retinoic acid and arsenic trioxide for acute promyelocytic leukemia. *N Engl J Med*. 2013;369:111-121.
3. Park JH, Qiao B, Panageas KS, Schymura MJ, et al. Early death rate in APL remains high despite all-trans retinoic acid. *Blood*. 2011;118(5):1248-1254 .
4. Estey E, Guillermo GM, Manero AF, Faderl S, et al. Use of all-*trans* retinoic acid plus arsenic trioxide as an alternative to chemotherapy in untreated acute promyelocytic leukemia. *Blood*. 2006;107(9):3469-3473.

ACCC's Community Resource Centers for APL

Seattle Cancer Care Alliance
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Winship Cancer Institute of Emory University
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Learn more at: www.accc-cancer.org/education/APL.

CASE STUDY

In February 2013, Dr. Estey saw a 33-year-old woman diagnosed with low-risk APL with no bleeding complications at the Seattle Cancer Care Clinic. The patient was initiated on ATRA at 45 mg/m2 divided into two doses, and arsenic (ATO) at 0.15 mg/kg daily.[4] The patient received prednisone as prophylaxis for ATRA differentiation syndrome, but had no tumor lysis, worsening DIC, or ATRA differentiation syndrome. In March 2013, this patient followed up with her medical oncologist in Tacoma. After achieving complete response, she was continued inadvertently on ATRA and ATO continuously, with ATO given five days a week, weekly, and ATRA daily, interruptedly.

"This patient had 60 days of treatment with both medications. There is no data on how to proceed in this case," Estey said. "Patients are usually treated for three to four weeks and then left to let their counts recover. The process then starts again until about 6 months of ATRA and ATO have been given."

Though his patient's counts were fine after the extended treatment period, Estey warns that patients on arsenic require checking of serum potassium and magnesium levels in the blood as low levels in combination with ATO may cause heart arrhythmias. In this example, the patient's white count was less than 10,000.

"Patients with low-risk disease like this patient can be successfully treated with ATRA and arsenic, therefore avoiding chemotherapy," Estey said. For the patient in this case study, he recommended resuming the post-remission protocol of ATO daily for five days, four weeks on and four weeks off, and ATRA daily, for two weeks on and two weeks off, to complete the total number of 80 doses. ATRA and ATO were discontinued at the same time.

Given that relapses are extremely rare in patients who begin ATO + ATRA with white counts < 10,000, experts now agree there is no need to monitor for recurrence. That said, patients often feel more comfortable if routine blood counts are checked every six months.

To talk to Dr. Estey about this case study or any questions you may have related to treating patients with APL, providers can email him directly at: *eestey@seattlecca.org*.

CME/CE Opportunities

The Association of Community Cancer Centers and Medscape Oncology are pleased to provide an online educational initiative that offers a community provider perspective about important cancer treatment and care issues, as well as emerging data and treatment strategies presented at scientific meetings. The programs feature national experts and are available on demand, so you can participate in these leading-edge programs when it's most convenient for you. Visit our website to see all of the programs that are available.

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ACCC 31st National Oncology Conference
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Sheraton San Diego Hotel & Marina
San Diego, Calif.

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www.accc-cancer.org/meetings.

Survey on Lung Cancer Screening

Lung cancer screening has become quite the "hot topic" with ACCC membership—from active discussion on ACCC's listserv to a members-only conference call to a well-received session at the ACCC 30th National Oncology Conference this past October, ACCC members want to know how other cancer programs are developing and implementing lung cancer screening in their communities. To better identify the type of information needed, ACCC surveyed attendees at its 30th National Oncology Conference. Here's what we found.

Only 34 percent of survey respondents reported that they currently have a lung cancer screening program, but 57 percent are in the process of implementing such a program—90 percent of respondents with a lung cancer screening program said that the U.S. Preventive Services Task Force (USPSTF) draft report played a role in the decision to establish the program.

All survey respondents with lung cancer screening programs in place charge for the service, ranging from $100-$300.

While almost three-quarters of survey respondents (73 percent) said they provide primary care providers (PCPs) with information about their lung cancer screening program, only half reported receiving active referrals from PCPs in their community. In addition to a low-dose CT scan, survey respondents also provide these services as part of their lung cancer screening program:

- Tobacco cessation program and/or referrals to a program (100 percent)
- Patient education (93 percent)
- Referrals to patient navigators, financial counselors, and social workers (80 percent).

Survey respondents reported the following barriers and challenges to their lung cancer screening program:

- Low patient volume (75 percent)
- Lack of referral from PCPs (58 percent)
- Issues related to patient follow-up (25 percent).

Survey respondents also cited the cost of screening as a barrier to implementation.

When asked about barriers to getting patients in for screening, respondents identified cost as the biggest challenge (69 percent). Lack of awareness about the lung cancer screening program among patients (62 percent) and PCPs (46 percent) were also identified as barriers.

To listen to ACCC's archived conference call, ACCC members should log onto MyNetwork and click on the ACCCExchange button to access the Resource Library. The call includes pathway information, forecasting templates, implementation barriers, and strategies to overcome those barriers to help programs develop or assess their lung cancer screening programs. The presenter, Andrea McKee, MD, Chairman Department of Radiation Oncology, Sophia Gordon Cancer Center, Lahey Hospital & Medical Center will also write about this topic in the March/April 2014 *Oncology Issues*.

ACCC Welcomes its Newest Members

AnMed Health Cancer Center
Anderson, S.C.
Delegate Rep: Timothy Laugh
Website: *www.anmedhealth.org*

Parker Adventist Hospital
The Cancer Center at
Parker Adventist Hospital
Parker, Colo.
Delegate Rep: Connie Wood
Website: *www.parkerhospital.org/cancer-center*

St. David's Healthcare
(System Membership)
Austin, Tex.
Delegate Rep: Paul Ortiz
Website: *www.stdavids.com*

St. David's Medical Center
St. David's CancerCare
Austin, Tex.
Delegate Rep: Esther Chung
Associate Administrator
Website: *www.stdavids.com/locations-facilities/st-davids-medical-center.aspx*

St. David's North Austin Medical Center
St. David's CancerCare
Austin, Tex.
Delegate Rep: Nancy Etzold
Website: *www.stdavids.com/locations-facilities/north-Austin-medical-center.aspx*

St. David's Round Rock Medical Center
St. David's CancerCare
Round Rock, Tex.
Delegate Rep: Tad A. Hatton
Website: *www.stdavids.com/locations-facilities/round-rock-medical-center.aspx*

St. David's South Austin Medical Center
St. David's CancerCare
Austin, Tex.
Delegate Rep: Nikki Sikes
Website: *www.stdavids.com/locations-facilities/south-austin-medical-center.aspx*

Saint Joseph, Cancer Care Program
Eureka, Calif.
Delegate Rep: Alyson Cornelius
Website: *www.stjosepheureka.org*

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views

A Smile Can Make a Difference!

Oncology Issues recently spoke with the resource coordinator for the San Juan Cancer Center at Montrose Memorial Hospital in Montrose, Colo., Francie Smiles. As part of a rural cancer center, Ms. Smiles strives to go above and beyond for cancer patients in this unique role. She runs the Caring Friends Fund for the cancer center and has a vital role in community fundraising.

Q. *What is your typical day like?*

F.S. My job description is simple: "Find out what patients need and get it for them." From day to day my job isn't the same. When I first come in, I go directly to the cancer center and get a list of all of our patients who are in the hospital. I visit patients and sit with families and ask about their needs. Sometimes patients are pretty unhappy, but mostly they're just grateful to have someone reach out to them.

Unfortunately I do attend far too many funerals. But being able to represent the cancer center where these patients and their families have spent their last days, you realize what a difference you can make. I've had the privilege and the honor of being with more than one family in the intensive care where a patient's journey is going to end. I don't think many other cancer centers have a staff member that does exactly what I do.

Q. *How did you come to take this position?*

F.S. About 16 years ago I was diagnosed with breast cancer. I wish I could say that I was the person who participated in awareness events and helped raise money for worthy causes prior to my cancer diagnosis, but I wasn't. But after my diagnosis, I became very proactive with a breast cancer support group called Bosom Buddies of Southwestern Colorado. My mother was also diagnosed with cancer. Sadly, her battle ended far too early. My mother received all of her treatment in Grand Junction—a 120 mile round trip on a two-lane road.

Q. *As a survivor, does that help you relate to these patients?*

F.S. It was life-changing for me, so I can absolutely relate to these patients and families. Sometimes when someone is told they have cancer, it's a relief to see a non-medical staff member who isn't going to go into the complex details of the treatment process. I can be the person who simply says: "I know your cancer diagnosis is a bummer. I know that spending hours sitting in this infusion chair is a bummer." I can just spend time with patients and families talking and offering hands-on support.

Q. *Is there an application process for the Caring Friends Fund?*

F.S. We don't have a formal application process. The nurses and staff listen to our patients and come to me when they find out that a patient or family has specific needs that are not being met. But we do have a $500 limit per patient, per occurrence.

Q.*What form of aid is given to patients?*

F.S. We pass out a lot of debit cards and we also help with co-pays. Sometimes our fund is able to pay for other items like medication, motel rooms, or food. We make sure patients are eating, that they can get to their appointments, and that they can get home. For example, we don't have a PET scanner in Montrose, so patients have to go to Grand Junction and the trip is 60 miles one way. I've actually picked up patients and taken them to their treatment appointment. It's the last recourse, but sometimes it's the only option available.

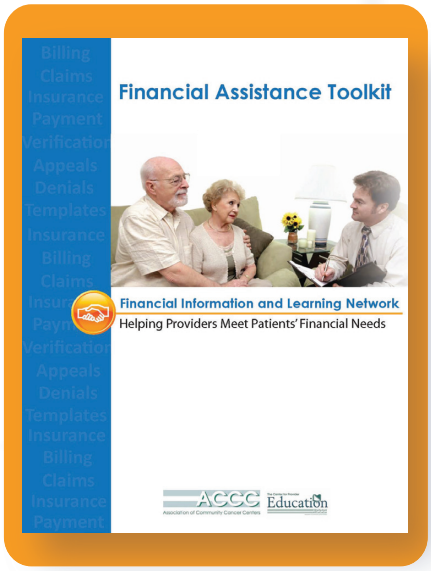
Q. *How do you raise money for the Caring Friends Fund?*

F.S. All proceeds come from our generous community. We hold one event called the "Grin and Barrett Bike Ride," which was started in 2005 by a man who was treated at our cancer center for colon cancer. It has grown to be a very large bike ride here in Montrose County, and we've been able to help close to 100 patients a year with non-medical needs. Another fundraiser is called "Building the Caring Friends Fund One Brick at a Time." We sell small colored bricks, representing 12 types of cancer for $50 each. We started the drive three months ago and have already raised $1,500.

Q. *What advice would you give to other resource coordinators?*

F.S. Practice the art of listening. It's amazing what you will hear when you actually listen. People will open up and share. Aside from listening, just care. People who have cancer are scared. But with you by their side, they're not alone on their journey. OI

Are Your Patients Struggling to Pay for Their Cancer Treatment?



There's no need to reinvent the wheel. The *Financial Assistance Toolkit* is ACCC's newest resource to help you develop a robust patient financial assistance program, and it's filled with the information, tools, and templates you need to help your patients with their financial issues.

TOOLS

The toolkit includes:

- Worksheets to help assess benefits
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- Print Version with Binder: $149 (plus shipping)
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The Financial Information and Learning Network education program has additional resources to strengthen and expand your financial assistance services.

- Video Series
- 10-Part Practical Course
- Financial Assistance Forum

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

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