ONCOLOGY ISSUES

The Journal of the Association of Community Cancer Centers
November | December 2012

AYA Survivorship

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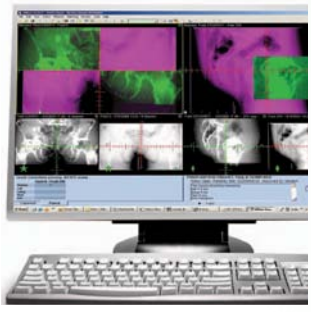

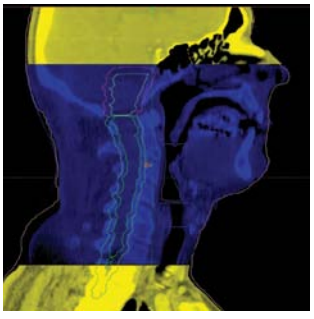

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DEPARTMENTS

ACCC
Association of Community Cancer Centers

ONCOLOGY ISSUES
The Journal of the
Association of Community Cancer Centers

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

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

FROM THE EDITOR

Combining "Book" and "Street" Smarts

BY CHRISTIAN DOWNS, JD, MHA

We have all run across a colleague, employee, or speaker whom we would call "book smart." And while this statement is a compliment on one level, it can also imply that the person may not have what we would call "street smarts" or a practical understanding of the way the world works. Since at various times I have been accused of having neither, I feel completely comfortable commenting on both.

Clearly in cancer care delivery "book smarts" are important. Given the nature of healthcare, intelligent and learned people are attracted to the field.

I am amazed at the range of skills and knowledge our providers have—not only in clinical expertise, but also in marketing, communication, finance, accounting, management, and psychology. But I am also interested in seeking out those individuals and programs that demonstrate "street smarts." They tackle the situation or the issue at hand, they get things done, and they meet real-world challenges.

In this edition of *Oncology Issues,* we highlight a few members who used their "book smarts" and "street smarts" to better serve their patients. For example, adolescents and young adults often have unmet survivorship needs. In our cover story, learn how the Seton Cancer Survivor Center bridges this gap through clinical care, navigation services, and provider and patient education.

Another prime example: the experience of UT Southwestern Harold C. Simmons Comprehensive Cancer Center. New American College of Surgeons Commission on Cancer standards now *require* a process to integrate and monitor psychosocial distress screening of cancer patients. This program is way ahead of the curve, developing and using its own screening instrument.

I find that the people and programs that successfully combine "book" and "street" smarts also display "out-of-the-box thinking." And such was the case at Roper St. Francis Hospital. Faced with a shortage of registrars, the manager of the cancer registry department hired out-of-state employees. The solution worked well, and then came change. Legal issues required that these abstractors move from being employees to becoming contractors. Read the rest of the article to help identify the staffing model that may best fit your program.

Finally, Feist-Weiller Cancer Center's Arts in Medicine (AIM) program combines "book" and "street" smarts with a generous dose of empathy. This low-cost, volunteer-driven program improves the patient experience through art. Read on to hear about the positive effects this innovative program has had on patients, staff, and volunteers.

ACCC is an organization that—through meetings, publications, education programs, *MyNetwork,* and other resources—helps you tap into the experiences of programs and providers who combine "book" and "street" smarts. If you attended the ACCC 29th National Oncology Conference in San Antonio in October, you heard from 11 programs that won 2012 ACCC Innovator Awards. (ACCC's Annual Innovator Awards are sponsored by GE Healthcare—the company that created the healthymagination challenge to identify and accelerate ideas to advance breast cancer early detection and diagnostics, and ultimately help save lives affected by breast cancer.) All of our 2012 Innovator Award Winners demonstrated this combination of "smarts." If you didn't make it to the conference, ACCC's Virtual Conference lets you access all the "smarts" at your convenience. Visit *www.accc-cancer.org/oncologyconference.* OI

PRESIDENT'S MESSAGE

Where Do We Go From Here?

BY GEORGE KOVACH, MD

As I write this column we are still several weeks away from Election Day, and by the time you read this, the election results will be old news. Still, I can safely make one prediction. Whether or not we have a change in administration in January, healthcare changes are coming and we, the practicing oncology community, need to be engaged. For too long healthcare policy has been crafted with a top-down rather than a bottom-up approach, which may help to explain many of the ACA's shortcomings. Rather than creating bold initiatives, the ACA continues along familiar paths, for example, accountable care organizations (ACOs), which are essentially the same as the managed care programs we saw in the 1980s. How did that work out?

Health insurance through employment continues to limit employee choice, and insurance competition remains regionalized, thus hindering competitive pricing. What if all insurance carriers participated in a national risk pool of more than 300 million covered lives rather than regionalized state exchanges?

The Centers for Medicare & Medicaid Services (CMS) continues to cover the older, higher-risk population and to underpay, thus shifting costs to the private sector. This scenario has not changed since "mandatory" insurance shifts costs to the younger populations by charging higher premiums than needed for this lower-risk population.

Reimbursement issues continue with the specter of the SGR "fix," bundled payments, and sequestration looming. Increased regulation and mandates, such as EMR requirements, increase the cost of compliance without adequate reimbursement. In a recent *Wall Street Journal* article, "A Major Glitch for Digitized Health-Care Records," the authors discuss EMR implementation and question the return on value due to the high cost and lack of a common data exchange, which is a significant barrier to realizing the major advantages of electronic records. An EMR should not only meet "meaningful use," but should also be meaningful and useful to the provider, which is not always the case.

Comparative effectiveness (CE) as a means of cost control may be used as the basis for selection of treatment on cost rather than value. This situation needs to be watched closely so innovation is not hampered.

Malpractice reform has yet to be addressed adequately due to the perception that the cost is "minimal" as compared to overall healthcare expenditures. At the same time, the cost of practicing "defensive" medicine remains underestimated (see my column in the July/August 2012 issue).

So what's the good news? I can make one additional prediction. As the healthcare debate continues, we have the opportunity to be at the forefront of the discussion by:

- Offering meaningful information on how current policies are adversely affecting our ability to provide appropriate care for our patients
- Supporting those policies that have merit
- Proposing alternative solutions to those that do not.

As part of the 39th Annual National Meeting, ACCC will host a Capitol Hill Day. But don't wait until March, become more involved now! ACCC has a long record of effective grassroots advocacy to carry our message to our elected officials at the state and national levels. Then plan to come to Washington in March and make the voice of community oncology heard on Capitol Hill.

Become engaged, our patients depend on it! OI

Coming in Your 2013 *ONCOLOGY ISSUES*

- A Day in the Life of an Oncology Nurse Navigator
- Utilizing a Dedicated Quality Improvement Program
- Improving QOL for Patients with Brain Cancer
- A One-Day Cancer College
- What You Need to Know Before Acquiring an Oncology Group
- Developing a Centralized Process to Review & Track Clinical Studies
- Increasing the Number of Medical Oncology Fellows Through a Community Hospital and School of Medicine Collaborative
- Developing a Multidisciplinary Thoracic Oncology Clinic in the Community Setting
- A Model Rapid Access Chest & Lung Assessment Program
- Physician-Hospital Alignment: Bringing Together the PSA and MSA
- Community Health Needs Assessment: A Requirement of the ACA
- Engaging Patients & Staff in Process Improvement

more online @ www.accc-cancer.org

Financial Assistance Videos

VIDEO

Facing challenges with non-compliant patients? Seeing an increase in undocumented patients? ACCC's video series offers strategies and tips from experienced financial assistance specialists. Watch today at: *www.accc-cancer.org/FILN*.

New Oncology Drug Reference Guide

TOOL

ACCC's *Oncology Drug Reference Guide* helps you navigate the complex area of drug information, HCPCS codes, generic and brand names, billing units, and manufacturer contact information on the drugs commonly used to treat cancer. Learn more at: *www.accc-cancer.org/drugguide*.

Virtual National Oncology Conference

VIDEO

Missed ACCC's conference in San Antonio? Watch the sessions from the comfort of your own computer. Read conference highlights and learn more: *www.accc-cancer.org/oncologyconference*.

New Cancer Program Guidelines

TOOL

Just released! ACCC's *Patient Advocacy and Financial Assistance Guidelines*—the first guidelines aimed at helping cancer programs develop and deliver comprehensive financial assistance services to patients. Download the PDF of ACCC's revised *Cancer Program Guidelines* at: *www.accc-cancer.org/guidelines*.

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*.

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fast

Employers Expect 7% Increase in Health Benefit Costs in 2013

In response, U.S. employers plan to implement multiple cost-control measures:

- ✔ 60% plan to raise the percentage of the premiums that employees pay in 2013, although the majority of those employers indicated that the increase would be less than 5%.
- ✔ 40% plan to increase in-network deductibles.
- ✔ About one-third will raise out-of-network deductibles and out-of-pocket maximums.
- ✔ Other strategies to reduce costs include onsite health centers, health savings accounts, and online cost-transparency tools.

Source. National Business Group on Health. Large Employers 2013 Health Plan Design Survey. *www.businessgrouphealth.org.*

5 Steps to Help Prepare for ICD-10 Today

1. ***Use existing resources to comply with ICD-10.*** Have you completed HITECH requirements? Run hypothetical scenarios to see what your processes would look like under ICD-10.
2. ***Anticipate the potential impact of ICD-10 on productivity and revenues.*** Perform risk assessments and then develop plans to mitigate potential negative impacts on productivity and revenue collection.
3. ***Assess current risk levels in key business areas.*** Identify your key business areas. Then assess current risk levels and remediate weaknesses in each.
4. ***Identify training needs for all levels of the organization.*** Consider running parallel systems using both ICD-9 and ICD-10 before the conversion date.
5. ***Establish a cross-functional governance model with executive support.*** Identify leaders with experience in healthcare services, technology implementation, and regulatory compliance.

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

facts

Millions in Savings for Healthcare Consumers

The 80/20 rule in the Affordable Care Act (ACA) requires insurance companies to reveal how much of premium dollars they actually spend on healthcare and how much on profits and administrative costs. Those that do not spend at least 80% of premium dollars on actual healthcare benefits and quality improvement measures must refund consumers the difference. Based on initial findings, the rule is helping to slow premium growth and has resulted in real savings to U.S. consumers:

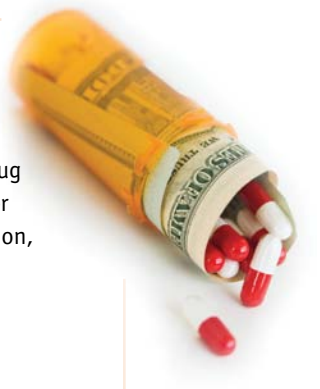
- Americans have saved an estimated $1 billion on their health insurance premiums thanks to rate review (another ACA requirement).
- 13 million Americans have benefitted from $1.1 billion in rebates made possible by the 80/20 rule.

Source. 2012 Annual Rate Review Report: Rate Review Saves Estimated $1 Billion for Consumers: Executive Summary. Available online at: *www.healthcare.gov.*

MEDICARE MONTHLY DRUG PREMIUMS PROJECTED TO BE $30 IN 2013

Average basic premiums for the Medicare drug benefit in 2013 will remain at about $30 per month—about the same as 2012. Competition, generic usage, and branded drugs going off patent all contributed to the stable rates.

Source. *BNA Health Care Daily Report.* August 7, 2012, No. 151.



6 Core Structural Components Needed to Implement an Effective ACO

1 | A commitment to providing care that puts people at the center of all clinical decision-making 2 | A health home that provides primary and preventive care 3 | Population health and data management capabilities 4 | A provider network that delivers top outcomes at a reduced cost 5 | An established ACO governance structure 6 | Payer partnership arrangements.

Source. The Commonwealth Fund. Accountable Care Strategies: Lessons from the Premier Health Care Alliance's Accountable Care Collaborative. *www.commonwealthfund.org.*

issues

News from Capitol Hill, Regulatory Agencies & Oncology Stakeholders

ACCC Comments on Proposed OPPS Rule, Physician Fee Schedule

The Association of Community Cancer Centers (ACCC) submitted comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed Hospital Outpatient Prospective Payment System (OPPS) rule and the proposed Physician Fee Schedule (PFS) rule for 2013.

In its comments to the proposed OPPS rule, ACCC noted that CMS has made significant adjustments to its rate-setting methodology, which ACCC believes will provide for more appropriate and stable reimbursement levels for drugs and pharmacy-related services. In 2013 the agency proposes to reimburse separately payable drugs at ASP+6 percent.

In its comments to the proposed PFS, ACCC urged Congress to develop a long-term fix to the Sustainable Growth Rate (SGR) formula and avert a 27.4 percent reduction to the conversion factor in 2013. Among other recommendations, ACCC also advised that CMS should *not* implement the proposed changes to the time inputs for CPT codes 77418 (intensity modulated treatment delivery) and 77373 (stereotactic body radiation therapy).

AMA, ASCO, ASTRO & Others Outline Payment Reforms to Congress

The American Medical Association (AMA), the American Society of Clinical Oncology (ASCO), the American Society for Radiation Oncology (ASTRO), and more than 100 state and specialty medical societies have outlined to Congress a set of principles needed to transition from Medicare's current physician payment system to a new one. In an Oct. 15 letter to the Senate Finance Committee, the groups said the first step toward crafting a new Medicare payment system would be to repeal the sustainable growth rate (SGR) formula. In conjunction with SGR repeal, the groups suggest a transition plan that includes the following core elements:

- Reflect the diversity of physician practices and provide opportunities for physicians to choose payment models that work for their patients, practice, specialty, and region
- Encourage incremental changes with positive incentives and rewards during a defined timetable, instead of using penalties to order abrupt changes in care delivery
- Provide a way to measure progress and show policymakers that physicians are taking accountability for quality and costs.

In addition, the transition plan needs to be structured in a way that will:

- Reward physicians for savings achieved across the healthcare spectrum
- Enhance prospects for physicians adopting new models to achieve positive updates
- Tie incentives to physicians' own actions, not the actions of others or factors beyond their influence
- Enhance prospects to harmonize measures and alter incentives in current law
- Encourage systems of care, regional collaborative efforts, and primary care and specialist cooperation while preserving patient choice
- Allow specialty and state society initiatives to be credited as delivery improvements (deeming authority) and recognize the central role of the profession in determining and measuring quality
- Provide exemptions and alternative pathways for physicians in practice situations in which making or recovering the investments that may be needed to reform care delivery would constitute a hardship.

Read the letter at: *www.ama-assn.org/resources/doc/washington/sgr-transition-principles-sign-on-letter.pdf*.

It's Official! ICD-10 Implementation Delayed Until 2014

Department of Health and Human Services (HHS) Secretary Kathleen Sebelius announced a one-year delay in the compliance deadline for the nationwide conversion to ICD-10 code sets. The delay, first proposed in April, moves the compliance deadline to Oct. 1, 2014. HHS said the extra time would allow healthcare organizations—small organizations in particular—adequate time to get ready for the changeover.

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

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

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"By delaying the compliance date of ICD-10 from October 1, 2013, to October 1, 2014, we are allowing more time for covered entities to prepare for the transition to ICD-10 and to conduct thorough testing," HHS said in the rule. "By allowing more time to prepare, covered entities may be able to avoid costly obstacles that would otherwise emerge while in production."

Despite this delay, Cindy Parman, CPC, CPC-H, PCS, FCS, RCC, contributing author of the "Compliance" column (page 12) and presenter at the ACCC 29th National Oncology Conference, states that the time to prepare for ICD-10 implementation is now. Not only will ICD-10 help with strategic planning, data mining, benchmarking, and quality assessment, ICD-10 will bring other benefits, including:

- It incorporates new diagnoses
- It reflects advances in medicine and technology
- It will provide more detail about individual patients
- It will provide more socioeconomic details; e.g., you will be able to code for patients with financial hardship.

For more information, visit *http://acccbuzz.wordpress.com*.

Insurance Exchange Update—Eight States Receive $766.5 Million in Grants

On Aug. 23, the Department of Health and Human Services (HHS) announced that eight states received $766.5 million in federal grants to build online health insurance exchange markets that are required to be operational by 2014 under the Affordable Care Act (ACA). To date, 34 states and the District of Columbia have received exchange "establishment" grants, according to *BNA Health Care Daily Report*.

Establishment grants recognize that states are making progress toward establishing exchanges but at different speeds. States can choose when to apply for grant funding based on their needs and planned expenditures. Those moving forward using a step-by-step approach can apply for funding each project year (level one establishment grants). States moving ahead at a faster pace can apply for multi-year funding (level two establishment grants). States can initially apply for either level one or level two establishment grants, based on their progress.

In the Aug. 23 grant announcement, four states (California, Hawaii, Iowa, and New York) received level one grants and four states (Connecticut, Maryland, Nevada, and Vermont) received level two grants. States can apply for multiple level one grants, and will have multiple opportunities to apply for funding in the years ahead.

An interactive map showing establishment grant awards by state is available at: *www.healthcare.gov/news/factsheets/2011/05/exchanges05232011a.html*.

OIG 2013 Work Plan to Focus on Hospital Billing, Medicare Contractors

For 2013, the HHS Office of Inspector General (OIG) will focus investigative and audit efforts on hospital billing and payment issues and oversight issues related to Medicare contractors, according to the agency's *Work Plan for Fiscal Year 2013*. The work plan, which was released Oct. 2, highlights several new areas of concern related to hospitals, including payments for mechanical ventilation, payments for canceled surgical procedures, and compliance with Medicare's transfer policy, according to *BNA Health Care Daily Report*.

The OIG will also review the effectiveness of Medicare contractors, including Medicare Administrative Contractors (MACs), Recovery Audit Contractors (RACs), and Zone Program Integrity Contractors (ZPICs). The work plan is available at: *https://oig.hhs.gov/reports-and-publications/archives/workplan/2013/Work-Plan-2013.pdf*.

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

PREVENTION BEGINS WHERE TRIPLE THERAPY STARTS

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

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

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

Selected Important Safety Information

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

Selected Important Safety Information *(continued)*

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

Please see the adjacent Brief Summary of the Prescribing Information.

An antiemetic regimen including

EMEND® (fosaprepitant dimeglumine) for Injection

Prevention From the Start

MERCK

Merck Oncology

emendforinjection.com

Brief Summary of the Prescribing Information for

EMEND® (fosaprepitant dimeglumine) For Injection

INDICATIONS AND USAGE

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

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

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

CONTRAINDICATIONS

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

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

WARNINGS AND PRECAUTIONS

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

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

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

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

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

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

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

ADVERSE REACTIONS

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

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

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

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

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

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

Respiratory system: hiccups 4.6 vs 2.9

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

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

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

Nervous system: headache 2.2 vs 1.8

Metabolism and nutrition: anorexia 2.0 vs 0.5

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

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

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

Infection and infestations: candidiasis, staphylococcal infection

Blood and lymphatic system disorders: anemia, febrile neutropenia

Metabolism and nutrition disorders: weight gain, polydipsia

Psychiatric disorders: disorientation, euphoria, anxiety

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

Eye disorders: conjunctivitis

Ear and labyrinth disorders: tinnitus

Cardiac disorders: bradycardia, cardiovascular disorder, palpitations

Vascular disorders: hot flush, flushing

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

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

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

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

Renal and urinary disorders: polyuria, dysuria, pollakiuria

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

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

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

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

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

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

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

Investigations: increased blood pressure

Skin and subcutaneous tissue disorders: erythema

Vascular disorders: thrombophlebitis (predominantly infusion-site thrombophlebitis)

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

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

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

Immune system disorders: hypersensitivity reactions including anaphylactic reactions

DRUG INTERACTIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

USE IN SPECIFIC POPULATIONS

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

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

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

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

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

OVERDOSAGE

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

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

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

NONCLINICAL TOXICOLOGY

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

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

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

PATIENT COUNSELING INFORMATION

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

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

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

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

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

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

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

For detailed information, please read the Prescribing Information.

Rx only

MERCK

Supervising Oncology Services

BY CINDY PARMAN, CPC, CPC-H, RCC

The supervision of office-based and provider-based services has been a hot topic, not just in the specialty of oncology but across the healthcare spectrum. In addition to Medicare requirements that differentiate based on practice setting, differences exist between medical and radiation oncology. State laws that impact supervision and scope of practice for practitioners can also vary widely. While no single article can address the multitude of state-level regulations and scope of practice limitations, the following is a summary of the current Medicare guidelines.

Radiation Oncology: Office

Radiation oncology services performed in an office, freestanding center, or other non-provider-based facility require supervision by a qualified physician. CMS includes the *Medicare Benefit Policy Manual* on its website and Chapter 15, Section 90 states:[1]

X-ray, radium, and radioactive isotope therapy furnished in a non-provider facility require direct personal supervision of a physician. The physician need not be in the same room, but must be in the area and immediately available to provide assistance and direction throughout the time the procedure is being performed.

There are several requirements included in this manual section that may need further definition. First, a "non-provider facility" is a freestanding treatment center, physician's office, or other site of service that is not classified as a hospital or facility. According to the Social Security Act, the definition of "provider" includes:[2]

The term "provider of services" means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program…

Next, you need to know the accurate definition of "direct supervision." Although this CMS document refers to "direct personal supervision," the common term is "direct supervision." According to the Code of Federal Regulations, Title 42, Section 410.32:[3]

Direct supervision in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

In addition, the supervising physician must be "immediately available," which means that the supervisor must not be performing another procedure or service that renders them unavailable. In addition, CMS states that it would be inappropriate for a supervising physician to be responsible for patients and services that are outside the scope of their knowledge, skills, licensure, or privileges. The supervising physician must be prepared to step in and perform the service, not just respond to an emergency.

According to the CMS 1500 claim filing guidelines (*Medicare Claims Processing Manual,* Chapter 26), the physician reported on the claim form for each service is the physician who either personally performed or supervised the service. Specifically, the agency states:[4]

Item 24J: Enter the rendering provider's NPI number in the lower unshaded portion. In the case of a service provided incident to the service of a physician or non-physician practitioner, when the person who ordered the service is not supervising, enter the NPI of the supervisor in the lower unshaded portion.

So how do we know which physician to list on the CMS 1500 claim form? If the service is not personally performed by a physician practice member, then the name and NPI number of the physician who supervised the service must be reported on the claim form. For example, if Dr. A supervises radiation treatment delivery in the office setting on Monday and Tuesday, Dr. A's provider information would be listed on all CMS 1500 claim lines for those delivery services.

Medical Oncology: Office

The same definitions of non-provider-based location and direct supervision apply when drug administration is performed in an office or freestanding setting. According to the *Medicare Claims Processing Manual:*[5]

Physician work related to hydration, injection, and infusion services involves the affirmation of the treatment plan and the supervision (pursuant to incident to requirements) of nonphysician clinical staff.

If the RN, LPN or other auxiliary personnel furnishes the injection in the office and the physician is not present in the office to meet the supervision requirement, which is

one of the requirements for coverage of an incident to service, then the injection is not covered.

In addition, guidelines published by the American Medical Association (AMA) in the *CPT® Manual* indicate that direct supervision is required for all infusion and injection services:[6]

Physician work related to hydration, injection, and infusion services predominantly involves affirmation of treatment plan and direct supervision of staff.

CMS provides the following information in the *Medicare Claims Processing Manual,* Chapter 12:[7]

Effective on January 1, 1998 and after, restrictions were removed on the type of areas and settings in which the professional services of NPs, CNSs, and PAs are paid under Medicare.

Although there is a restriction relating to supervision for radiation therapy, there is no requirement that a physician must supervise drug administration. However, if a midlevel provider supervises drug administration, their name and NPI must be listed on the CMS 1500 claim form. Remember that services billed in the name of the midlevel provider will be paid at 85 percent of the Medicare Physician Fee Schedule.

Oncology Services: Outpatient Hospital

For calendar year 2012, CMS continues to recognize a limited set of services with a significant monitoring component that can extend for a sizable period of time. These services, known as "extended duration services," are not surgical and typically have a low risk of complication after assessment at the beginning of the services. For these specific services, there is a requirement for direct supervision at the initiation of the service, followed by general supervision for the remainder of the service. CMS states that the point of transition from direct supervision to general supervision should be "documented prominently in progress notes or in the medical record."

Extended duration services that may be transitioned to general supervision include hydration (procedure codes **96360, 96361**) and therapeutic drug administration (procedure codes **96365-96376, C8957**).

CMS provides the following information in the 2011 Outpatient Prospective Payment System (OPPS) Final Rule:[8]

We do not believe it would be appropriate without further assessment to define chemotherapy, blood transfusion, and the recovery period for surgical services as nonsurgical, extended duration therapeutic services.

The agency further revised the definition of "direct supervision" to simply require immediate availability, meaning physically present, interruptible, and able to furnish assistance and direction throughout the performance of the procedure but without reference to any particular physical boundary. This Final Rule states:[8]

We wish to emphasize that once we remove reference to "in the hospital" or "in the provider based department," we continue to expect the supervisory practitioner to be physically present for the services he or she is supervising. As in the past, we are not defining immediate availability in terms of time or distance.

With respect to supervision by midlevel providers, the *Medicare Benefit Policy Manual* states:[9]

Considering that hospitals furnish a wide array of very complex outpatient services and procedures, including surgical procedures, CMS would expect that hospitals already have the credentialing procedures, bylaws, and other policies in place to ensure that hospital outpatient services furnished to Medicare beneficiaries are being provided only by qualified practitioners in accordance with all applicable laws and regulations. For services not furnished directly by a physician or nonphysician practitioner, CMS would expect that these hospital bylaws and policies would ensure that the therapeutic services are being supervised in a manner commensurate with their complexity, including personal supervision where appropriate.

And through calendar year 2012 (based on information in the 2012 OPPS final rule), the therapeutic supervision requirements will not be enforced in Critical Access Hospitals (CAHs) or small rural hospitals with 100 or fewer beds. While these facilities will not be penalized for violations of supervision guidelines, this is a temporary exception from the regulatory requirements.

Other Payers

CMS has published the radiation supervision requirements at a national level, but what about other payers? Most, if not all, managed care contracts and participation agreements include a "non-discrimination clause" that states patients of these insurers will not be treated in a different manner from members or beneficiaries of other plans. For example:

5.1 Nondiscrimination. *Medical Services Entity agrees that it, and each of its Qualified Physicians, shall not differentiate or discriminate in its provision of Covered Services to Enrollees because of race, color, ethnic origin, national origin, religion, sex, marital status, sexual orientation, income, disability, or age. Further, Medical Services Entity agrees that its Qualified Physicians shall render Covered Services to Enrollees in the same manner, in accordance with the same standards, and within the same time availability as such services are offered to patients not associated with MCO or any Plan, consistent with medical ethics and applicable legal requirements for providing continuity of care.*

Based on this sample contract language, all patients must receive the same level of care, including the same direct supervision of services performed.

Table 1. Supervision Requirements

SPECIALTY	SETTING	SUPERVISION REQUIRED
Medical Oncology	Office or Freestanding	· Direct Supervision · Qualified Physician or Nonphysician Practitioner
Medical Oncology: Chemotherapy	Outpatient Hospital	· Direct Supervision · Qualified Physician or Nonphysician Practitioner
Medical Oncology: Hydration & Therapeutic Drugs	Outpatient Hospital	· Direct Supervision Transitioned to General Supervision · Qualified Physician or Nonphysician Practitioner
Radiation Oncology	Office or Freestanding	· Direct Supervision · Qualified Physician
Radiation Oncology	Outpatient Hospital	· Direct Supervision · Qualified Physician or Nonphysician Practitioner

Final Thoughts

Although the cancer center may be comfortable knowing that all supervision requirements have been met or exceeded, it is essential that documentation exists that verifies physician and/or midlevel provider supervision. In an audit, a schedule or calendar listing planned supervision may not be sufficient to confirm which individuals actually provided infusion or radiation supervision on a daily or hourly basis. As a result, you may need to create a schedule that can be signed and dated by the supervising practitioner, a card swipe in/out system, or other method to document the presence of a supervisor at all times.

Cancer centers should ensure that their compliance department and/or healthcare counsel review state and federal supervision requirements to ensure compliance. According to the Advisory Board:[10]

CMS does not explicitly state that radiation therapy must be supervised by a radiation oncologist or trained NP. However, a strict interpretation of the regulation would indicate that a radiation oncologist or specially trained NP or PA would have to supervise all radiation therapy services. That said, many hospital-based cancer programs currently provide radiation therapy services without specialist supervision. The leaders of these programs should consult with their institution's legal counsel to formulate a policy that they feel is clinically defensible.

There are many different interpretations, legal and otherwise, regarding what the supervision rules actually represent and what interpretation should be applied to the CMS regulations. OI

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tools

Approved Drugs

- Celgene Corp. *(www.celgene.com)* announced that the Food and Drug Administration (FDA) has approved **Abraxane® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension, albumin-bound)** for use in combination with carboplatin for the initial treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who are not candidates for curative surgery or radiation therapy. In 2005 Abraxane was approved for the treatment of metastatic breast cancer after failure of combination chemotherapy.

- A pediatric dosage form of **Afinitor Disperz® (everolimus)** (Novartis, *www.novartis.com*) was approved by the FDA to treat subependymal giant cell astrocytoma (SEGA). Everolimus is recommended to treat patients aged 1 year and older with tuberous sclerosis complex who are diagnosed with inoperable SEGA. Studies are under way to further evaluate the long-term safety and effectiveness of everolimus in both pediatric and adult patients with SEGA.

- The FDA approved **Bosulif® (bosutinib tablets)** (Pfizer, Inc., *www.pfizer.com*) for the treatment of chronic, accelerated, or blast phase Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in adult patients with resistance or intolerance to prior therapy. The recommended dose and schedule for bosutinib is 500 mg orally once daily with food.

- Bayer HealthCare *(www.bayer.com)* and Onyx Pharmaceuticals, Inc. announced that the FDA approved **Stivarga® (regorafenib)** tablets for the treatment of patients with metastatic colorectal cancer (mCRC) who have been previously treated with currently available therapies (including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy). Stivarga is an oral multi-kinase inhibitor that inhibits various kinases without the mechanisms involved in tumor growth and progression-angiogenesis, oncogenesis, and the tumor microenvironment.

- The FDA approved **Xtandi Capsules® (enzalutamide)** (Medivation, Inc., and Astellas Pharma US, Inc.) for the treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel. The recommended dose and schedule for enzalutamide is 160 mg orally once daily. OI

CMS Grants Temporary Add-On Payment for Voraxaze

BTG International Inc. *(www.btgplc.com)* announced that the Centers for Medicare & Medicaid Services (CMS) has granted a temporary New Technology Add-on Payment **(NTAP) for Voraxaze® (glucarpidase)**, effective Oct. 1, 2012. CMS will pay up to 50 percent of the cost of Voraxaze to hospitals in addition to the standard diagnosis-related group (DRG) reimbursement payment. NTAPs are only available for new technologies that provide a substantial clinical benefit and meet appropriate cost criterion.

CMS will provide a maximum add-on payment for Voraxaze of $45,000 per case. Along with the add-on payment, CMS has granted Voraxaze a new ICD-9 procedure code 00.95 (injection or infusion of glucarpidase).

Voraxaze received U.S. regulatory approval in January 2012 for the treatment of toxic plasma methotrexate concentrations (>1 micromole per liter) in patients with delayed methotrexate clearance due to impaired renal function.

spotlight

Dale & Frances Hughes Cancer Center, Pocono Medical Center

East Stroudsburg, Pennsylvania

New Facility Designed to be Patient and Environmentally Friendly

In June 2012 the doors of the new 59,000-square-foot, $31 million Dale & Frances Hughes Cancer Center opened, realizing the goal of bringing all outpatient cancer services under one roof. The culmination of years of work and planning, the new three-story facility is a dramatic expansion from the previous 8,000-square-foot cancer center that had been located across the street from the hospital.

The decision to build the new facility stemmed from the region's rapid population growth along with a need to consolidate cancer services. Pocono Medical Center is located in Monroe County in northeastern Pennsylvania, the second fastest growing county in the state. Along with the population boom has come a higher incidence of cancer.

"The American College of Surgeons Commission on Cancer-accredited cancer program was robust," said Stacy Goetz, executive director of Oncology Services at Pocono Medical Center. In 2011, in the midst of building the new facility, the Hughes Center received the 2011 Outstanding Achievement Award from the Commission on Cancer. "It was a very strong program with great physicians, it's just that we were fragmented," said Goetz. The cancer program is accredited by the American College of Radiation Oncology, National Quality Measures for Breast Centers for its breast program, and is currently applying for American College of Radiology accreditation.

Planning for the new cancer center began more than four years ago, and the community has been involved every step of the way. Focus groups of current and former patients expressed a strong wish to have access to all oncology services in one location. They also wanted the new cancer center to be attached or close to the hospital. Previously, inpatients receiving radiation therapy had to travel by ambulance from the hospital to the cancer center to receive treatment. Today, an enclosed bridge connects the main hospital building to the new Hughes Cancer Center, easing transportation of patients to treatment. Designers included a two-sided elevator so that patients can move between facilities with privacy.

Patient-Centered Design

The architectural firm EwingCole designed the cancer center as a healing, comforting environment of care with an emphasis on nature. "We wanted this to be a patient-centered building," said Goetz. "We didn't want it to feel intimidating. We wanted it to feel warm and comfortable and not to create any more anxiety than patients already have." Inspired by the scenic and nearby mountains and woodlands, natural elements are incorporated into the building's aesthetics. The facility is also environmentally friendly—designed to LEED Silver standards.

The L-shaped, three-story building features a centrally located healing garden, and a rooftop garden sits atop the linear accelerator vault. A soothing water feature graces the lobby and a complementary outdoor water feature, which is visible through the lobby's windows, creates the illusion that one flows seamlessly into the other, bringing the outside in. Inset within the walls are echoes of the local landscape including pieces of birch, while boulders serve as accent pieces within the spacious lobby area. Visitors entering the building are greeted by a three-story glass curtain wall that serves as the entranceway. Immediately to the right is the registration desk, framed by views of the healing garden. Volunteers are stationed at the desk to escort patients who need assistance finding their way in the new cancer center.

Located on the first floor are PET/CT and radiation oncology services. State-of-the-art technology includes a new Varian TrueBeam linear accelerator and a GE CT simulator. The cancer program was an early adaptor of IMRT, IGRT, and prostate seed implant, and also offers MammoSite, Contoura, Savi, and SenoRx for breast cancer. An amenity unique to the radiation therapy treatment rooms is ceiling monitors that display moving images such as swimming fish, birds in flight, and changing sky views—all helping to create a less claustrophobic atmosphere for patients. This wing also houses a dedicated HDR brachytherapy area. A staff of one radiation oncologist, six radiation therapists, two physicists, and two dosimetrists comprise this unit of the center.

Also located on the first floor are the

PHOTOGRAPHS COURTESY OF EWINGCOLE

nurse navigators' offices and a conference room for meetings with patients and families. Currently, navigation services are available for breast, prostate/GI, and thoracic patients; plans are underway to expand to include additional cancer sites.

As an added convenience for patients and families, the first floor will include a retail boutique that will offer a variety of products that patients may need, such as wigs, special creams, prostheses, and more.

Directly across from the boutique space is a dietary teaching kitchen, designed so that the cancer center's dietitian can conduct group cooking demonstrations, as well as one-on-one nutrition teaching. Adjacent to the kitchen is volunteer office space. The cancer center partners closely with local Lymphoma & Leukemia Society and American Cancer Society chapters. This space provides room for these programs to store materials and facilitates their hosting of programs in the new cancer center.

From the lobby area a graceful open staircase leads to the second floor, which is also accessible by elevator. An open atrium on the second floor looks out over the lobby below. This area features a retail café offering coffee, snacks, and sandwiches, as well as several computers programmed with an e-library of cancer-related resources. Centrally located on this floor is a meditation room, which provides a quiet oasis for patients and family members to rest and reflect.

A Focus on Multidisciplinary, Disease-Site Specific Care

Clinical areas on the second floor include dedicated space for the cancer center's multidisciplinary disease-site-specific clinics. Surgical offices are located in this same area with a dedicated breast surgeon and surgical oncologist on staff. Eight exam rooms are set aside for this clinic, which will also be available for use by the surgeons if no clinic is occurring. The cancer center holds twice weekly site-specific tumor boards for breast and thoracic cancers, as well as a general tumor board.

Adjacent to this area are medical oncology services with dedicated exam rooms and consultation space. The cancer program employs three medical oncologists and five oncology nurses. Within this area is a dedicated lab and oncology pharmacy staffed by two FTE pharmacists.

In designing the infusion suite, consideration was given to providing patients as many options as possible for controlling their environment. They can choose between private, semi-private, or public infusion treatment space. The infusion suite has four private rooms, 12 semi-private rooms with sliding glass doors that patients can open or close, and a centrally located "buddy room" for patients who want to socialize during treatment. Here, four recliners are arranged in a living-room-like setting that even includes a wall fireplace. Patients can regulate the radiant heat panels in the ceiling from their chairs to adjust the temperature to their liking. Each treatment bay includes a computer and television. The nurses' stations are located to allow visual contact with patients at all times, another patient request. Nurses check on patients in private rooms via monitors.

Continued Expansion

Plans are underway to move all of the cancer support group meetings to the new cancer center, as well as expand integrative service offerings to include a creative expressions group, yoga, massage therapy, and pet therapy.

Pocono Medical Center partners with nearby East Stroudsburg University and local agencies as part of its community outreach efforts to provide educational programs, awareness campaigns, and annual events, such as free breast cancer screenings during the month of October.

The Hughes Cancer Center also partners with Thomas Jefferson University and the Jefferson Cancer Network to expand patient access to clinical trials. The cancer center accrues approximately four percent of patients to clinical trials each year.

With the opening of the new Hughes Cancer Center, the goal of bringing comprehensive cancer services under one roof has been realized. Under the motto "Where hope lives, excellence thrives," the Hughes Cancer Center offers close-to-home care in an environment of care designed to put patients and their families at ease. OI

Select Support Services

- Social Work Services
- Support Groups:
  - –Breast Cancer
  - –Prostate Cancer
  - –Lymphoma/Leukemia/ Blood-related cancer
  - –Bereavement
  - –Stress Reduction
- Hospice Care
- Pastoral Care

- Number of new analytic cases seen in 2011: 550

Closing the Gap

Developing an AYA Cancer Survivorship Center

BY CHRISTOPHER HAMILTON, MPH

The adolescent and young adult (AYA) cancer survivor population, ages 15 to 39 as defined by the National Cancer Institute,[1] faces many barriers and challenges in its journey from diagnosis to survivorship. For example, AYA cancer survivors experience poorer outcomes[1] and have a lack of access to insurance. This scenario is particularly true in the state of Texas, which has an overall uninsured rate of 25 percent.[2] Other barriers facing AYA cancer survivors include:

- Life challenges and changes during the adolescent and young adult developmental period, such as starting careers or families and making independent medical decisions.
- Incomplete knowledge about cancer treatment and its consequences because of their age at diagnosis.
- A lack of survivorship care plans and treatment summaries. It was not until 2005 that these tools were first recommended by the Institute of Medicine.[3] The American College of Surgeons Commission on Cancer did not require survivorship care plans and treatment summaries until its 2012 accreditation standards.[4]

- Late effect(s) from cancer treatment and the possibility of developing chronic conditions later in life.
- A lack of awareness of the preventive guidelines for secondary cancers.
- A lack of recognition about the importance of educating their current medical team about their history with cancer.

A New Care Paradigm: The Seton Cancer Survivor Center

The Seton Healthcare Family, a not-for-profit healthcare system, provides services for adults in 11 counties of central Texas, and for pediatric patients in 46 counties. The Seton network is comprised of 11 hospitals and numerous ambulatory clinics throughout the service area.

Childhood cancer survivors are seen in the LIVE**STRONG** Childhood Cancer Survivorship Center at Dell Children's Medical Center, part of the Seton Healthcare Family. But as pediatric patients aged into their late 20s and 30s, no formal program existed to transition them into an adult-survivor care setting. Recognizing that adolescents and young adults in central Texas had unmet needs—specifically, access to post-treatment survivorship services, Seton built upon the success of its pediatric program to address this gap and created the Seton Cancer Survivor Center for adolescents and young adults in 2011, with funding from LIVE**STRONG**.

Today, the Seton Cancer Survivor Center cares for post-treatment cancer survivors, ages 18 to 39, residing in our 11-county service area of central Texas—regardless of diagnosis or where the patient received treatment. We chose this age range specifically so that patients under 18 years of age would continue to receive care in a pediatric center.

Staffed by two FTE staff, in addition to a medical director, and with an annual budget of approximately $150,000, the Seton Cancer Survivor Center offers a range of services to address the four components of survivorship: coordination, intervention, surveillance, and prevention. We created a system of support, centering on the AYA patient and a medical home that includes:

- Clinical navigation
- Clinical care
- Provider and patient education.

Clinical Navigation

Clinical navigation is the entry point and foundation for AYA survivors. At the Seton Cancer Survivor Center, an RN clinical nurse navigator focuses on the medical issues related to cancer survivorship. With a signed release of information request, the nurse navigator first obtains medical records from the clinic or hospital where the patient was treated and then develops a written treatment summary and survivorship care plan. Next, the nurse navigator schedules a visit with the patient to review the treatment summary and survivorship care plan and assess for any other needs, including medical care and psychosocial and practical needs. The nurse navigator looks closely for issues that may create barriers for patients in fulfilling their care plans.

At the Seton Cancer Survivor Center, we have developed a shared navigation model with the assistance of LIVE**STRONG**. Our RN nurse navigator provides clinical navigation, and the LIVE**STRONG** Navigation Center in Austin, Tex., helps to address patients' psychosocial and practical needs, such as help with insurance, counseling, and cooking classes, as well as many other services.

Our nurse navigator helps each patient establish care in a medical home for his or her primary care needs, as well as for survivorship screening and surveillance. To provide patient-centered care and choice in medical providers, patients have the option of obtaining survivorship care through the Seton Cancer Survivor Center. If this is not possible—due to lack of insurance coverage—the nurse navigator will provide the survivorship care plan and treatment summary to the patient's primary care physician. The nurse navigator is available to the young adult survivor to coordinate care among specialists, the primary care provider (PCP), and the Seton Cancer Survivor Center.

Clinical Care

AYA survivors scheduled for survivorship care at the Seton Cancer Survivor Center are seen by an internal medicine physician who is well versed in late effects of chemotherapy and

radiation, as well as current surveillance practices. The survivorship clinical program takes place in the physician's private practice, with support from the nurse navigator along with consultation, when needed, from a medical oncologist that treats adult cancer patients or from a pediatric hematologist/oncologist. Care is focused on screenings and surveillance, along with overall health and well-being. Many survivors view this visit as an annual "survivorship check-up"—a time to revisit and update their survivorship plan and to make arrangements for screening and follow-up on other recommendations for a healthy survivorship. For patients who choose to have their survivorship care through their PCP, a copy of their treatment summary and survivorship care plan, along with a matrix of recommended screenings, is sent to the PCP.

Complementing the Seton Cancer Survivor Center care is our connection to the other resources in our system, including the Seton Heart Institute and the Seton Brain and Spine Institute, among others. For example, we are able to connect AYA survivors with Seton cardiologists that have received additional education on chemo- and radiation-related cardiomyopathies, and we are working toward a specific cardio-oncology program.

Education & Training for Providers, Survivors, & Caregivers

Through a grant from the Cancer Prevention and Research Institute of Texas (CPRIT), Seton Cancer Survivor Center developed an educational program, *After Cancer Care Ends Survivorship Starts for Adolescents and Young Adults (ACCESS-AYA)*, to support primary care providers, community nurses, and other healthcare providers who see AYA cancer survivors in their practices. This educational program consists of:

- Online CME and CNE credit options
- Provider seminars
- Brief detailing sessions known as Prompt Evidence Assessment and Review of the Literature Service (PEARLS).

The goal is to reach providers online, in person through traditional seminars, or in person at their practice sites by delivering PEARLS in 15-minute sessions. Because the nurse navigator tracks each patient's PCP, we can generate a list of providers to target our offered educational programming.

In addition to provider education, the ACCESS-AYA program has specific goals to provide education to AYA cancer survivors and their family members and caregivers. We have created a series of "video diaries" through which AYA survivors share their cancer and survivorship experiences. These video diaries are available on the Seton Cancer Survivor Center's website (*www.seton.net/survivorship*). The ACCESS-AYA project provided input and support for the development of an iPhone app, *AYA Healthy Survivorship*, which was developed by Texas A&M School of Rural Public Health CTxCARES program, a CDC-funded cancer control and prevention program. The app allows survivors to assess their health habits, get daily tips, and begin to create a survivorship care plan.

Referrals

Patients are referred to the Seton Cancer Survivor Center from four sources:

1. Transition from the LIVE**STRONG** Survivorship Center at Dell Children's Medical Center
2. Transition from treatment at Shivers Cancer Center at University Medical Center Brackenridge
3. Referrals from community providers
4. Self-referrals.

LIVESTRONG Survivorship Center at Dell Children's Medical Center. Our nurse navigator visits the pediatric center to meet the young adult patient and family to seamlessly transition their care to the Seton Cancer Survivor Center. This introductory meeting allows the nurse navigator to establish rapport and trust with the patient and family, as well as educate them about the services provided by the Seton Cancer Survivor Center. The patient's treatment summary and survivorship care plan—already developed by the pediatric clinic—transfer over to the Seton Cancer Survivor Center.

Shivers Cancer Center at University Medical Center Brackenridge. Shivers Cancer Center, an ambulatory clinic of the University Medical Center Brackenridge and the only indigent cancer care clinic in central Texas, is an additional referral source to the Seton Cancer Survivor Center. As patients complete their active treatment, a health promoter prepares a treatment summary and survivorship care plan, using ASCO care plan templates and the online LIVESTRONG Care Plan, and writes a cover letter to the patient's PCP with specific recommendations for follow-up. The treatment nurse navigator and treating oncologist then review all the materials and sign the care plan and cover letter, respectively; a survivorship transition session is then scheduled with the patient. At this

session, AYA patients meet with their treatment nurse navigator, the health promoter, and the Seton Cancer Survivor Center survivorship nurse navigator. This session is designed to:

- Educate patients and their families about the next phase of their cancer journey and survivorship
- Review the survivorship care plan
- Allow the patient and family to meet the Seton Cancer Survivor Center navigator who will help them from this point on.

Patients Outside of the Seton Healthcare Family. Our third method of enrolling AYA survivors is to reach out to PCPs, specialists, community oncologists, and the community at large to find survivors who have not received a treatment summary and survivorship care plan, and/or are not engaged in any kind of long-term follow-up from their cancer treatment. To do so, we routinely meet with various physician practices, hospital staff, nurses, clinic administrators, and others to educate about the program and share with them how they may refer patients to the Seton Cancer Survivor Center.

Self-Referrals. Currently, a small number of survivors arrive at the Seton Cancer Survivor Center through self-referral or referral from friends or family members who have heard of the program through word-of-mouth, media coverage, or the Seton website. We anticipate the number of self-referrals will grow as we work with more cancer survivors and develop additional programs and public outreach.

In less than one year, we have enrolled 88 patients in navigation services. Close to 80 percent of patients are established with a primary care provider and medical home and our nurse navigator continues to assist others with establishing care.

Among the metrics we monitor are:

- Percent of patients established with a primary care provider and medical home within 12 months of enrolling in navigation (currently 88 percent)
- The percent of patients provided a treatment summary and survivorship care plan within three months of enrolling in navigation (currently at 90 percent)
- The percent of patients that implement a wellness activity within 12 months of enrolling in navigation services (33 percent at 6 months of data collection).

Barriers

One of the biggest challenges we face is recruiting patients who completed treatment years before survivorship centers developed. This population may not have received information on the importance of survivorship—long-term follow-up, screening, and surveillance. Patients may have a mindset that once treatment is completed, they are done with cancer. We strive to overcome this through our community outreach and educational programming to survivors through our ACCESS-AYA program.

Some AYA survivors face a gap in insurance coverage. Those without insurance are concerned about accruing large medical debts, especially since they may have outstanding bills from their treatment. Thanks to the LIVESTRONG grant funding, our nurse navigation services, including the provision of treatment summaries and survivorship care plans, are completely free of charge to survivors. While navigation seeks to reduce or eliminate barriers to care for patients, we want to reduce or eliminate barriers to patients enrolling in the Seton Cancer Survivor Center by informing patients at the start that our navigation services are free of charge.

Keys to Success

Several critical success factors came together to create the Seton Cancer Survivor Center, including:

- A physician interested in providing long-term follow-up care to AYA cancer survivors
- A health system executive leader committed to the continuum of cancer care services
- A provider community that sees the benefits of cancer survivorship services
- An existing infrastructure that allowed adaptation to include survivorship
- The initial grant from LIVESTRONG that allowed the program to get up and running
- The CPRIT grant, which supports provider and patient education.

Our future plans include carrying out a research agenda that includes some short- and long-term research projects in collaboration with The University of Texas at Austin, and with The University of Texas Southwestern Medical Center and Simmons Cancer Center, among others.

We will continue to build on the success of our adolescent and young adult program to offer survivorship services and navigation to patients ages 40 and above, closing the cancer survivorship continuum of care gap in central Texas. OI

—Christopher Hamilton, MPH, is manager, the Seton Cancer Survivor Center, Austin, Tex.

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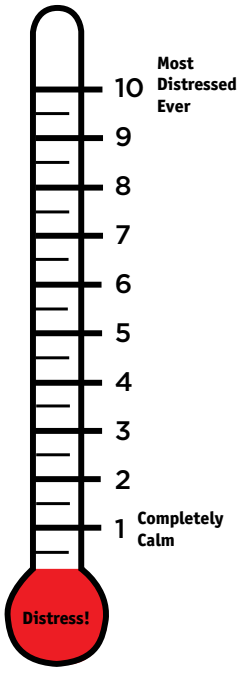
BY JEFF KENDALL, PSYD;
HEIDI HAMANN, PHD; AND
STEPHANIE CLAYTON, MHSM, CMPE

Oncology Distress Screening



Distress prevalence, new standards, and implementation

The diagnosis and treatment of cancer can generate significant levels of distress for cancer patients and their families. Although often considered a normal reaction, symptoms of distress should not be considered benign. Psychosocial distress can lead to disruptions in medical care and negatively influence all aspects of daily life. Recognizing the importance of addressing the emotional and social concerns of oncology patients, the National Comprehensive Cancer Network (NCCN) issued a consensus statement recommending distress screening and management as a standard of care within oncology health services delivery.[1] The label "distress" is used because it:

- Is less stigmatizing to patients and families than psychiatric diagnoses or psychological jargon
- Facilitates an understanding that distress is a normal process which ranges from mild to debilitating
- Facilitates an understanding that distress severity can change across the cancer continuum.

Figure 1. Simmons Cancer Center Distress Screening Procedure

RECEPTION DESK

✔ Staff gives all outpatients the Distress Screening Tool.

✔ Patients complete Distress Screening Tool in the waiting area and return it to the reception desk.

SUPPORT SERVICES

✔ Oncology Support Services team collects the Distress Screening Tool from the reception desk.

More specifically, the NCCN defines distress in cancer as:[1]

> *A multifactorial, unpleasant experience of an emotional, psychological, social, or spiritual nature that interferes with the ability to cope with cancer, its physical symptoms, and its treatment. Distress extends along a continuum ranging from normal feelings of vulnerability, sadness, and fear to disabling conditions such as clinical depression, anxiety, panic, isolation, and existential or spiritual crisis.*

The American Psychosocial Oncology Society (APOS) subsequently endorsed this consensus statement and distress definition.[2] APOS augmented the NCCN guidelines by recommending that screening tools be easy to administer, score, and interpret, and be brief and non-stigmatizing for the patient population. In 2008 the Institute of Medicine's (IOM) report, *Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs*, underscored the NCCN and APOS recommendations to establish a screening mechanism to identify psychosocial needs in cancer patients.[3] In addition, the IOM report advanced the guidelines for the detection and management of distress by recommending the incorporation of psychosocial services within oncology as a national standard of care to be implemented across all types of cancer treatment settings.

In spite of these recommendations, distress often goes undetected and untreated.[3] The lack of detection and resulting under-treatment of distress has been shown to contribute to a number of negative outcomes:[3]

- Increased suffering
- Decreased quality of life for both patients and family members
- Reduced adherence to medical treatment
- Longer hospitalizations
- The possibility of decreased survival odds.

Several factors contribute to the low rates of distress screening within cancer programs, including lack of training among oncologists and nurses to detect distress, limitations in time allotted for patient visits, and lack of psychosocial professionals within cancer programs.[3]

Accreditation Standards

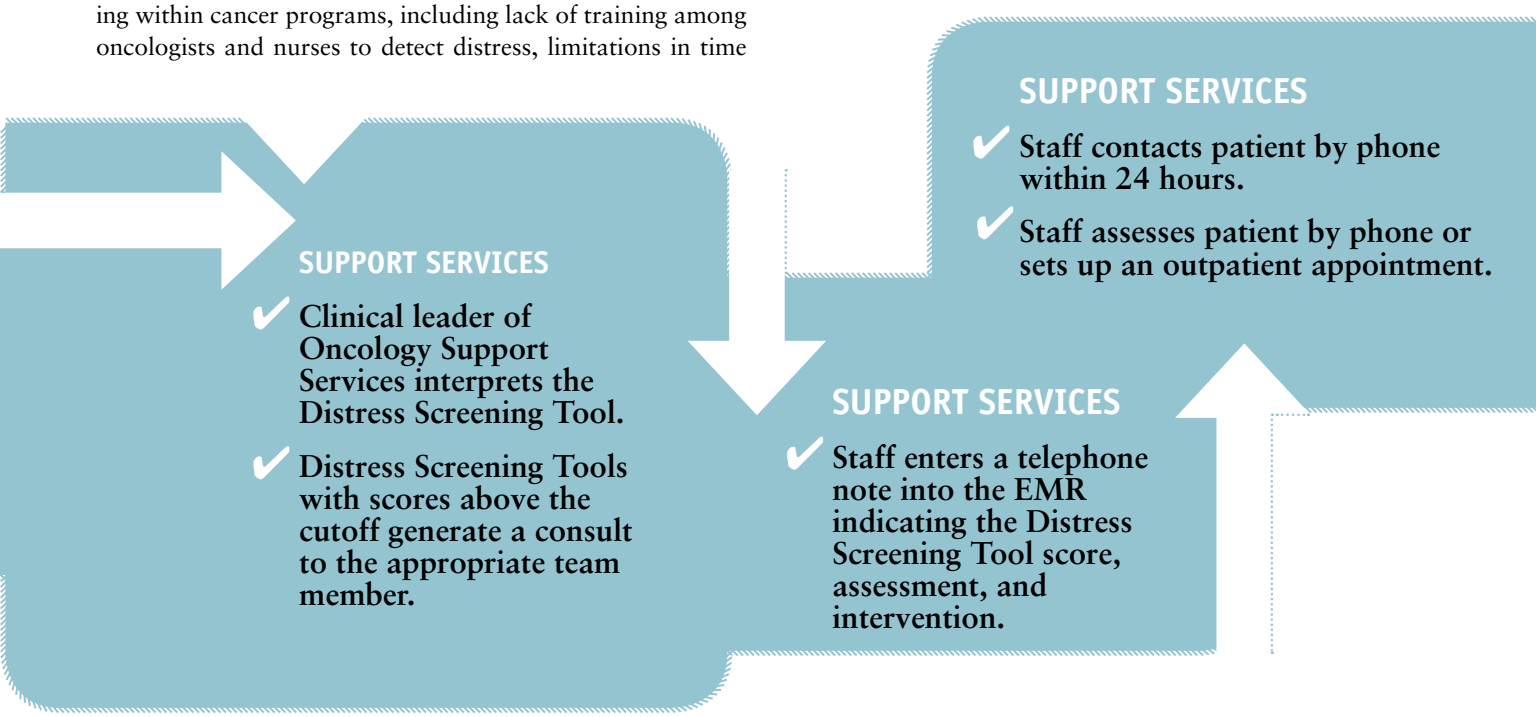
The screening and management of psychosocial distress is garnering significant national attention since the American College of Surgeons (ACoS) Commission on Cancer (CoC) published the *Cancer Program Standards 2012: Ensuring Patient-Centered Care*.[4] These new standards are designed to help accredited programs focus on patient-centered care with the goal of improving the quality of cancer care throughout the United States. The CoC requires that these new standards be in place by 2015.

One of the new standards is Standard 3.2: Psychosocial Distress Screening, which states:[4]

> *The cancer committee develops and implements a process to integrate and monitor on-site psychosocial distress screening and referral for the provision of psychosocial care.*

In order to comply with this standard, cancer programs are required to screen their patients at least once during the cancer patient's course of treatment; this screening should occur during a pivotal medical visit. Cancer programs determine for themselves the mechanism used to screen for distress. Common methodologies range from self-report patient questionnaires to clinician administered questionnaires to clinical interview. The CoC prefers that patients are screened using standardized, validated instruments with established clinical cutoffs; however cancer programs are not penalized for developing their own instruments and constructing their own cutoff scores. Specific examples of screening tools are discussed in the sidebar on page 26.

The American Society of Clinical Oncology's (ASCO) Quality Oncology Practice Initiative (QOPI®) also supports



the importance of screening for emotional distress in cancer patients.[5] QOPI is a voluntary quality assessment and improvement program for outpatient hematology and oncology practices within the United States, and is designed by oncologists with a goal of improving patient-centered cancer care. Practices can obtain QOPI certification by achieving a defined performance level on QOPI measures. QOPI includes distress screening and intervention within its Core Module measures:

- Core Module #24: Patient emotional well-being assessed by the second office visit.
- Core Module #25: Action taken to address emotional problems by the second office visit.

Distress Prevalence: How Big is the Problem?

Considerable empirical evidence demonstrates the psychological and social morbidity of a cancer diagnosis. Research shows that 25 to 50 percent of all cancer patients experience significant levels of distress. More specifically, within this 25 to 50 percent exists two sub-groups: those who meet the criteria for psychiatric illnesses, such as major depression or adjustment disorders (up to 25 percent of all patients), and patients who report distress levels that do not meet criteria for a psychiatric diagnosis but experience distress that significantly interferes with quality of life and functional status (15 to 20 percent of all patients).[6-8] Using the term "distress" allows cancer programs to identify patients who fall into either of these two groups and provide interventions that decrease the impact of the distress etiology in order to reduce suffering and improve quality of life variables.

The literature reports that intensity of distress levels may increase with recurrence,[6–8] advanced disease,[8,9] and increased pain and disability, which would suggest that cancer patients' distress levels may fluctuate as they progress through cancer treatment.[6-8] These data come from a limited number of studies and National Cancer Institute-designated comprehensive cancer center patient samples. Therefore, these data may not fully represent patient populations found in community cancer center settings.

One study presented distress screening data for 1,281 cancer patients from a community cancer center.[10] In this study, Kendall and colleagues reported that 32 percent of the cancer patients treated within a community cancer center reported distress intensity above the cutoff value for the distress measure used.[10] These data mirror the distress ranges reported in previous studies, which indicated 25 to 50 percent of cancer patients have distress levels that interfere with adaptation and functioning. To put this study's findings into perspective, in this sample of 1,281 patients, 410 patients would require additional assessment and possible intervention from a psychosocial professional.[10] To meet the requirements of the CoC, QOPI, and the IOM report, this cancer program would need to have adequate psychosocial staffing to not only administer and score the screening instrument, but also provide the appropriate follow-up assessment and necessary clinical interventions resulting from the assessments.

Screening Implementation: One Program's Experience

Although screening and detection for distress may appear simple, cancer programs throughout the United States are struggling to achieve this standard. When 1,000 randomly selected members of ASCO were surveyed in 2006, only 32 percent of respondents reported awareness of the NCCN Distress Screening Guidelines and a mere 14 percent reported they performed distress screening using a standardized tool. In addition, one third of this sample reported they did not have any mechanism for distress screening. These data are further supported by a NCCN study of screening behaviors that indicated only 8 of 15 NCCN member institutions routinely screen for distress in at least some of their patients.

At the UT Southwestern Harold C. Simmons Comprehensive Cancer Center in Dallas, Texas, a distress screening instrument (at right) was developed for internal use. The distress screening instrument has two sections. The first section consists of eight visual analogue scales (0= no symptoms and 10= severe symptoms) in which patients rate their distress severity for the following concerns:

1. Appetite
2. Weight loss
3. Depression
4. Anxiety
5. Concerns about children
6. Insurance
7. Spouse and family concerns
8. Other concern(s).

The second section provides patients with an opportunity to request contact from a member of the supportive care team regardless of the symptom severity rating in the first section. For instance, a patient can indicate that appetite is good with no weight loss (scores 0–4) but still request to be contacted by a dietitian.

The decision to screen patients using this type of visual analogue scale came after an examination of our site-specific needs and a review of the strengths and weaknesses of available screening instruments (see page 26). We appreciated the ease of administration and empirical support for visual analogue scales, but needed to develop an instrument that provided clearer lines of referral than those of existing measurement tools. For example, on the Distress Thermometer, when a patient endorses high distress and then identifies multiple checklist domains (i.e., diet, emotional, financial), there is no way of knowing how each of those problems contributed to the overall distress score. Therefore, such an instrument does not indicate whether the high-distress rating needs to be addressed by a dietitian, social worker, and/or financial counselor. Similarly, instruments such as the HADS and the ESAS were judged to be too narrow in focus (i.e., primarily focused on anxiety and depression, with insufficient attention to dietary and social work concerns) to suit the breadth of our supportive care resources.

Medical and surgical oncology patients are asked to complete a paper version of the distress screening instrument prior to their outpatient clinic appointment (see Figure 1, pages 22–23). Once the patient completes the form, they are asked to return it to staff at the check-in desk. The distress screening forms are kept

(continued on page 27)

UT SOUTHWESTERN
Harold C. Simmons Cancer Center

SIMMONS CANCER CENTER DISTRESS SCREENING INSTRUMENT

We care about you and want to help with your emotional, social, and financial needs. Please tell us how you are doing today by completing this screening tool.

☐ Check this box if there are no changes since the last time you completed this screener.

STEP 1: Please circle the number for each symptom that best describes how you feel now (0=no complaints; 10=severe complaints).

Good Appetite	0	1	2	3	4	5	6	7	8	9	10	No Appetite
No Weight Loss	0	1	2	3	4	5	6	7	8	9	10	Significant Weight Loss
No Depression	0	1	2	3	4	5	6	7	8	9	10	Severe Depression
No Anxiety	0	1	2	3	4	5	6	7	8	9	10	Severe Anxiety
No Concerns about Your Children	0	1	2	3	4	5	6	7	8	9	10	Significant Concerns about Your Children
No Insurance Issues	0	1	2	3	4	5	6	7	8	9	10	Severe Insurance Issues
No Spouse or Family Concerns	0	1	2	3	4	5	6	7	8	9	10	Severe Spouse or Family Concerns
Other Problem	0	1	2	3	4	5	6	7	8	9	10	Tell Us:_____

STEP 2: If you want to be contacted by one of our professionals, please check the box next to the professional and he or she will contact you by phone.

☐ UTSW Billing
☐ Cancer Psychologist
☐ Cancer Social Worker
☐ UTSW Chaplain
☐ Cancer Dietitian

☐ Check this box if you do not want to be contacted by the support services staff

Your Cancer Physician is:_____

SCREENING INSTRUMENTS

The paucity of distress screening within cancer programs might lead to an assumption there is a lack of screening instruments that meet the criteria of being brief; easy to administer, score, and interpret; and established by multiple organizations. Fortunately many different types of screening instruments are available to cancer programs. A select few are listed below.

Distress Thermometer

One of the best known distress screening instruments is the Distress Thermometer (DT).[11] Endorsed by the NCCN Distress Practice Guidelines panel, the DT consists of simply asking patients to rate their distress using a vertically aligned (thermometer) visual analogue scale with scores ranging from 0 ("no distress") to 10 ("extreme distress"). The NCCN Clinical Practice Guidelines for Distress Management added a 34-item problem checklist to the DT to assist in identifying the source of the patient's distress. The problem checklist is grouped into five categories: practical, physical, family, emotional, and spiritual. Under this screening process, patients are asked to answer the single-item DT and identify any of the problem items in the problem checklist they may have experienced in the past week. Initially, the NCCN Clinical Practice Guidelines for Distress Management recommended a cutoff score of 5 on the DT as indicative of significant distress that warrants a referral to appropriate supportive services.

The DT is a robust and accepted instrument for assessing distress and has been validated through comparison with more comprehensive and lengthy instruments. The Distress Thermometer has been shown to have sensitivity ratings ranging from 0.65 to 0.77 and specificity ratings from 0.68 to 0.78 when compared to the Hospital Anxiety and Depression Scale (HADS). In addition, the DT—with the addition of the problem checklist—satisfies the APOS guidelines for ease in administration, scoring, and interpretation.

Hospital Anxiety and Depression Scale

HADS is a brief screening instrument designed to assess the psychological states of physically ill patients.[12] The strength of this instrument is that it assesses anxiety and depression without emphasizing the somatic symptoms, such as changes in appetite or sleep. This is relevant because when somatic symptoms of anxiety and depression are included in screening instruments for oncology patients, an increase in false-positives occurs. The HADS is accepted as an effective screening tool for anxiety and depression and has been widely used in both research protocols and clinical practice. It consists of 14 items, 7 for depression and 7 for anxiety, and each item is answered on a 4-point (0–3) Likert-type scale. Higher scores indicate greater anxiety and/or depression. The recommended cutoff score of 11 is used for probable cases or 8 for possible cases. Using a cutoff of 8 gives a specificity of 0.78 and a sensitivity of 0.9 for anxiety, and a specificity of 0.79 and a sensitivity of 0.83 for depression in cancer patients. The HADS also produces a total score, which can be used as a measure of distress. The HADS satisfies criteria for ease of administration; however, scoring is more complicated and time consuming than the DT.

Edmonton Symptom Assessment Scale

The Edmonton Symptom Assessment Scale (ESAS) is a brief screening instrument developed for use in palliative care patients and validated with oncology patients.[13] It consists of nine visual analogue scales with which patients rate the severity of the following symptoms:

- Pain
- Activity
- Nausea
- Depression
- Anxiety
- Drowsiness
- Lack of appetite
- Well-being
- Shortness of breath.

There is an optional tenth symptom, which can be added by the patient. Therefore, each symptom is listed with its own visual analogue scale so the patient can indicate the amount of distress caused by that specific symptom. The sum of patient responses to these nine symptoms is the ESAS total distress score. The ESAS satisfies criteria for internal consistency, criterion, and concurrent validity. The ESAS also satisfies the APOS guidelines for ease in administration, scoring, and interpretation.

(continued from page 24)
at the check-in desk until a member of the supportive services team collects them. Once collected, the forms are reviewed by the clinical leader of oncology supportive services who is a licensed psychologist. Distress screeners with distress scores above the cutoff for any of the eight concerns are then directed to the cancer program professional whose expertise is related to that question (see Figure 2, below). For example, if a patient reports a 9 out of 10 symptom severity rating on the appetite question, then that patient information would be relayed to the dietitian. The appropriate professional is notified of this self-reported score and contacts the patient by phone within 24 hours. The psychosocial provider uses the phone contact to assess the patient's responses to the distress screening instrument and then determines the appropriate intervention. The phone assessment is recorded in the cancer center electronic medical record, as well as the intervention employed by the psychosocial provider. Currently, oncology patients are screened at each visit to our outpatient clinics.

Overall, we have found our measure to be patient-friendly in both its administration and responsiveness to patient needs and concerns.

Lessons Learned

Our distress screening instrument satisfies the requirements of being brief; easy to administer, score, and interpret; and does not stigmatize our patients. The instrument is flexible in that it is very simple to add a question based on patient or provider feedback. One limitation of this instrument is the lack of empirical data for a specific cutoff value and specific validity and reliability data. A second limitation is the need to build an electronic administration and referral system that can function with the electronic health record. We look to address those issues in the future.

Adequate and successful distress screening requires input and cooperation from many layers of the cancer program staff. All staff involved should understand the importance of distress screening and the process involved. It is valuable to have distress screening champions identified at multiple stages of the process.

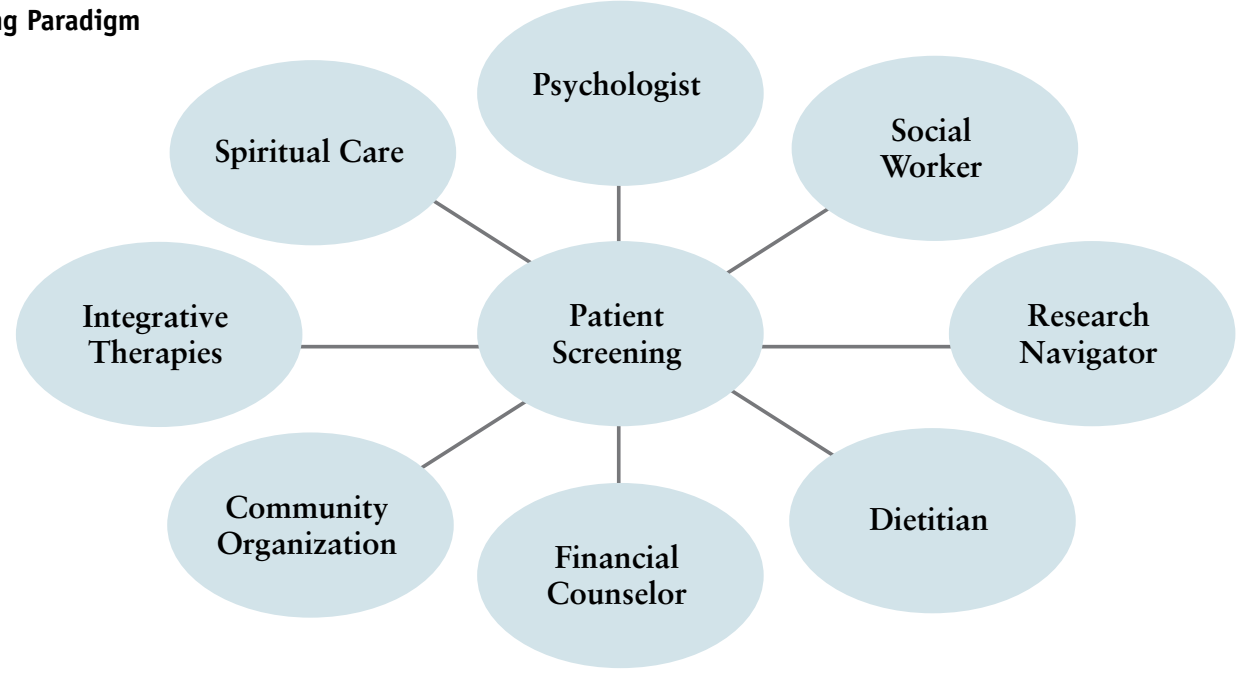
The most difficult barrier to distress screening is that it requires staff resources to accomplish. Cancer programs must have adequate staff to:

- Determine which screening instrument to use
- Develop the screening policies and procedures
- Evaluate and interpret the screening instrument
- Develop the interventions for positively screened patients.

Anecdotally we have found that the distress screening process is helping us uncover patient problems at an earlier point, thus facilitating problem solving while these problems are still manageable. Cancer programs that do not have psychologists, dietitians, social workers, or chaplains should look to professionals in the community, community organizations, and local universities to develop a referral network that can help address the psychological and social concerns of their patients.

Electronic tools for distress screening are available and are more efficient than paper screening instruments. It is important to develop the electronic screening instruments so that these can interface with an electronic health record. For example, an efficient system for distress screening could allow patients to complete a distress screening instrument electronically, populate the data within the EHR,

Figure 2. Simmons Cancer Center Distress Screening Paradigm



OUR PROGRAM AT-A-GLANCE

In 1988 Harold C. Simmons and his wife Annette, through a generous endowment, made provision for the Harold C. Simmons Cancer Center and Clinics, part of the University Of Texas Southwestern (UT Southwestern) Medical Center. UT Southwestern consolidated in January 2005, and now consists of two hospitals, University Hospital Zale Lipshy and University Hospital St. Paul, and outpatient ambulatory clinics that provide comprehensive patient care to Dallas and surrounding areas. The Simmons Cancer Center sees nearly 3,000 analytic patients per year and has comprehensive cancer treatment programs in the following 10 areas:

1. Brain and spinal cord
2. Breast
3. Gastrointestinal
4. Gynecological
5. Head and neck
6. Lung
7. Hematological (including BMT)
8. Melanoma
9. Sarcoma
10. Urologic.

In addition to medical care, we offer a full complement of support services, including nutrition, clinical social work, psychology, and integrative therapies to enhance each medical treatment program. In 2010 Simmons Cancer Center was granted NCI cancer center designation; the entire program is currently working to achieve comprehensive cancer center designation.

and generate automatic referrals to the appropriate supportive services staff.

Distress screening can be accomplished within community cancer centers. Screening and appropriate intervention for psychosocial concerns are just the beginning of a truly integrative model of cancer care. In addition, prospective and systematic screening may address psychosocial problems before they become time consuming and disruptive to the medical treatment plan. Once needs are identified, it is important to have internal and/or external resources available to meet the identified needs. OI

—Jeff Kendall, PsyD, is clinical leader of Oncology Supportive Services; Heidi Hamann, PhD, is research leader of Cancer Survivorship Research; and Stephanie Clayton, MHSM, CMPE, is the associate vice president for Cancer Programs for the Harold C. Simmons Comprehensive Cancer Center at UT Southwestern Medical Center in Dallas, Tex.

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Cancer Data Management Department, Roper St. Francis Cancer Center

To Employ or to Contract?

What model is the best fit for your cancer registry?

BY ELLEN R. KOLENDER

Finding qualified personnel for the Cancer Registry Department has become more and more difficult in recent years as experienced abstractors retire and cancer diagnoses increase. Faced with hiring challenges, many managers have turned to telecommuters to fill positions in their cancer registry departments. However, creating telecommuting positions requires approval from the legal department and human resources. Even after you have a system in place, circumstances can change rapidly. For example, when a hospital hires new legal staff, all worker telecommuting agreements are reviewed, and the question may again arise—what's the better option: employing or contracting cancer registry staff?

Telecommuter Registry Staff: The Roper St. Francis Healthcare Experience

In 2009, unable to find certified abstracting personnel locally, I extended my search beyond our city and state. Today's technology allows for easy telecommuting options, and with the extended search I was able to hire qualified abstractors from across the U.S. In fact, these telecommuting employees were my Cancer Data Management Department's answer to open positions. By using out-of-state employees to fill abstracting positions, our hiring turnaround time was reduced from one year to one month. The ability to hire quickly also helped us reduce gaps in production.

Within three years of hiring certified registry staff from outside our city and state, our department increased production from abstracting eight months after the date of first contact to three months. Hiring abstractors as telecommuting employees had advantages for our Cancer Management Department as well as for the employee. I was able to control work hours and work distribution. Employees were guaranteed a bi-weekly paycheck and employee benefits, such as health insurance, life insurance, worker's compensation, and leave with pay.

Our Cancer Data Management Department employs an experienced cancer tumor registrar (CTR) to work onsite training employees, checking quality, and keeping all registry staff (including telecommuting staff) on the same page. Changes in procedures and updates to software are easily communicated by conference calls and email. A second onsite employee:

- Coordinates conferences
- Enters pathology reports
- Ensures quality data completion to meet Commission on Cancer quality metrics
- Obtains needed information from physician offices to complete abstracts.

Our department budgets for an annual retreat in our city, which all employees attend. The retreat allows cancer registry staff the opportunity to get to know one another face to face. Since every staff member is employed by the hospital, all travel related to training, the retreat, and continuing education was covered by our Cancer Data Management Department's budget.

This staffing model seemed to work well for everyone. Then in 2011, Human Resources instructed me to terminate my out-of-state employees and instead negotiate independent contracts with them. Not only did this decision disrupt our current staffing and employment process, it was not well understood by the Cancer Data Management Department or cancer registry staff.

Why the Change?

Our hospital had recently hired a new attorney who reviewed all telecommuting employee agreements. He ultimately concluded that the hospital had been paying employee tax to

our state and not the state for which each employee was a resident. Legally this methodology was wrong. The state in which the employee lives may consider the hospital as doing business in that state, which may subject our hospital to business filings, taxes, insurances, and more in that state. At a minimum, this subjects our hospital to income tax withholdings in the telecommuter's state (and not our state) for the wages we pay staff.

For a better understanding of the definition of an employee vs. an independent contractor, I refer readers to an article from the *South Carolina Lawyer,* "Independent Contractor or Employee? Getting It Wrong Can Be Costly."[1] This article is one interpretation, defining the difference between the contractor and the employee and how an employer can determine in what category their workers fall. There are "tests used to determine whether workers are employees or independent contractors, IRS enforcement policies regarding worker misclassification, and the current state of the law in South Carolina pertaining to worker classification issues."[1] Three main tests are used by federal courts and agencies:

1. The common law test
2. The economics reality test
3. The hybrid test.

Defining Employee vs. Contractor

State courts and administrative agencies use the three federal tests in various ways. States may also develop their own, and possibly more stringent, tests.[1] The variability of tests can mean that a worker may be classified as "an independent contractor under one law or in one state and as an employee under another law or in another state."[1]

The IRS developed the common law test, which consists of numerous factors. The main focus of this test is the amount of control the employer has over the employee. Some factors used include:

- Is training provided?
- What is the degree of integration between the employer's business and the contractor's services?
- Are services rendered personally?
- Does the contractor hire, supervise, and pay assistants?
- Is the relationship continuing?
- Are there set hours of work?
- Is the contractor required to work full-time?
- Does the contractor work on the employer's premises?
- Is there an order or sequence of work?
- Are oral or written reports required?
- What are the payment methods?
- Who furnishes the tools and materials?
- Does the contractor make a significant investment?
- Does the employer pay business and/or travel expenses?
- Does the contractor realize a profit or loss?
- Can the contractor work for more than one firm at a time?
- Does the contractor make services available to the general public?
- Does the employer have the right to discharge the contractor?
- Does the contractor have the right to terminate the relationship?

The economics reality test considers workers to be employees if they are economically dependent on the employer for continual employment. This test also reviews the relationship between the employer and worker. The independent contractor typically provides services and is paid by many different employers.

The hybrid test considers economic factors of the work relationship although it emphasizes the employer's right to control the work process to distinguish employees from contractors.

The IRS has revised its test into a three-category exam, factoring in: 1) behavioral control, 2) financial control, and 3) relationship between worker and business.[2]

The Lawyers' Decision: The Roper St. Francis Experience

Based on the above criteria, the hospital determined that our telecommuters were actually independent contractors and needed to be paid as such. At that time, the Cancer Data Management Department had six out-of-state telecommuters, the two onsite employees, and three contractors. The biggest change for the contractors was how they would be paid. A new contract was created specifying multiple details—many of which are covered in the common law test. When determining if a worker is an employee vs. an independent contractor, I recommend reading the IRS guidelines, which cover many state labor laws.[3]

Our legal department needed to understand how the "employed" telecommuters paid their state income taxes while employed by our hospital. To determine this, we first had to ask our telecommuters a number of tax questions:

- For each year that you have been an out-of-state telecommuter, did you file an income tax return in your home state for the applicable year? If so, what form number?
- For each year that you have been an out-of-state telecommuter, were the wages paid to you by Roper St. Francis Healthcare (RSFH) reported on the home state income tax return?
- For each year that you have been an out-of-state telecommuter, did you pay income taxes on RSFH wages to your home state?
- For each year that you have been an out-of-state telecommuter, did you file for a refund with the South Carolina Department of Revenue for the income taxes withheld by RSFH and paid to the South Carolina Department of Revenue? If so, how much was the requested refund? Did you receive the refund?
- For each year that you have been an out-of-state telecommuter, have you filed any other tax returns with the South Carolina Department of Revenue for the applicable year? If so, what form numbers?
- Please provide the name and contact information of a

tax professional in your community that you would like to work with. If you need our assistance in locating one, please let us know.

Our hospital offered to pay a tax professional of the telecommuter's choice a reasonable amount (up to a maximum of $300 for each year that he or she had been an out-of-state employee) to help answer these questions and to assist with any amendments these employees may need to make to their tax returns.

The Transition: The Roper St. Francis Experience

Roper St. Francis Healthcare sent a letter to each out-of-state telecommuting employee stating that the hospital could not maintain a remote workforce in other states because it may subject the hospital to other states' business filings and laws. Therefore, the hospital had made a business decision to no longer employ out-of-state telecommuters and their current employment would end on December 18, 2011.

As hard as it was to read the above statement and know I had no control in this situation, the news was even more difficult to tell my employees. The Human Resource Director and I called each employee to discuss their future employment status. Needless to say, the out-of-state employees were devastated. Being presented with such news just before the holidays and the year's end was a shock. Telecommuting staff had 30 days to digest this information. We repeatedly communicated to each worker their value to the hospital and Cancer Data Management Department. We could only hope the telecommuting staff would strongly consider continuing to work with Roper St. Francis Healthcare in another capacity.

Successes & Challenges

A positive consequence of this difficult decision was that the hospital was able to offer our telecommuters an alternative: the opportunity to join our contract labor workforce. According to our Human Resources Department, "The proposal would change [the telecommuting employee's] role from an employee to a business professional with which we contract for services." The change would also give our former telecommuting employees the flexibility to decide how much they want to work, when to work, and the potential to make more money than they were currently making.

On the downside, the change in employment status meant that I would no longer control the hours or methods of their work—as I do for our hospital employees. The independent contractor is contracted to get the work done and paid per performance—not by the hour. Contractors would be paid one amount for abstracting a case and another amount for follow-up and other tasks. Determining the amount to pay for each task was quite challenging.

Determining Pay per Performance

My intent was to pay the contractors at minimum what they had been paid as employees—more if they produced more work. I require all employees to complete and submit weekly productivity reports. I used these reports to determine the average productivity for abstracting, follow-up, and other tasks. Knowing the average number of abstracts completed per week helped me determine the rate of pay for each abstract equating it to their previous hourly rate. I determined a lower rate for follow-up and other tasks by breaking out each task performed. Follow-up work was defined as "any task for any work which had the potential to update a case." Other abstracting tasks included case finding, adding treatment data, deleting cases, case reviews only, etc.

The contractor would not receive payment for time spent in educational activities, phone calls, or preparing weekly productivity reports and invoices. In addition, telephone and cable services would now be paid for by the contractor.

In the end, five of the six former telecommuters signed the new contract. We began applying the new payment method on January 1, 2012, and have agreed to closely monitor the rate of pay. In six months we will review the success or challenges arising from this new staffing method with the workers. As of today, September 24, 2012, we employ four onsite workers; two off-site (in our state) workers; and four CTR independent contractors. The telecommuter who did not sign the contract in 2011 was replaced by an onsite CTR. We were also fortunate to add a position to coordinate cancer conferences. This position was filled with an individual having a medical background, though no experience in cancer registry.

The contractors have worked out well. They are making more money than they did as employees; however, considering lost benefits, the salary ends up being close to what they were making as employees. The contractors are all very happy with the arrangement as they have control of how much money they make. My department is able to control costs by increasing or decreasing the maximum abstracts to complete. I have found it necessary to keep a careful watch on our contract spending versus budget allowance, taking into account compliance with the CoC requirement of abstracting cases within six months of first contact (first date the patient had treatment or diagnoses at the hospital).

Already some contractors have expressed concern about running out of work. Although I do not anticipate a lack of work, if this happens I will know we made the right decision, and that I have too many abstractors. OI

—Ellen R. Kolender, RHIA, CTR, is manager, Cancer Data Management at Roper St. Francis Cancer Care, Charleston, S.C.

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Contact or send a resume to: Renee Muellenbach, MSN, RN, Senior Director Duke Oncology Network, *Renee.muellenbach@duke.edu*, 3100 Tower Blvd. St. 600, Durham, NC 27707, 919.419.4635.

CREATE | DISPLAY

AN INNOVATIVE ARTS IN MEDICINE PROGRAM

BY BECKY DEKAY, MBA

As we all know, a cancer diagnosis and its subsequent treatment takes a heavy toll on the individual with cancer and his or her family. This is especially true of patients receiving infused chemotherapy. Accordingly, those of us who work at a community cancer center seek to provide comfort and support to patients and their families. Creation of a "healing environment" can provide comfort through the use of nature, for example, with a meditation garden or an indoor water feature; through music, perhaps with a soothing pianist outside the waiting area; or through integrative therapies such as a seated massage. Many community cancer centers use art to improve the patient experience. For patients receiving cancer treatment at Feist-Weiller Cancer Center, our Arts in Medicine (AIM) Program is one tool we use to "brighten" the lives of our patients.

Developed in 2002, our AIM Program is led by spouses of faculty members and community volunteers. This unique art program offers patients who wish to work with a palette of color and a paintbrush the opportunity to paint or create a piece of wearable art while they receive IV chemotherapy or other treatment(s). Now part of our Integrative Oncology Program, our Arts in Medicine Program has produced more than 200 works of art by adults and 100 works of art by children in the St. Jude Children's Research Hospital Domestic Affiliate Program at Feist-Weiller Cancer Center.

Art for All

Cancer patients receiving treatment in both the inpatient unit and outpatient clinic setting have the opportunity to recreate works of art by the Grand Masters, such as Van Gogh, Matisse, O'Keefe, and others—including contemporary artists. And because individuals being treated for cancer do not need a critique of their artistic talent, our AIM Program makes it easy for anyone to create a work of art—regardless of skill level.

The process is simple. An AIM volunteer will approach the patient while he or she is receiving treatment. The volunteer will show the patient a copy of the piece of artwork the coordinating artist, Darlene Whitaker, has chosen to work on that day and ask if he or she would like to participate in this activity. Previously, the coordinating artist has sketched the work of art across multiple grids (canvases). One challenge: finding paintings in the public domain that, when sketched into grids, will have "activity" in each panel. It's important to select paintings that incorporate vibrant colors that help lift the spirits of patients. Once painted, all of the grids will be assembled into a single art display.

If the patient wants to create an original artwork instead, the coordinating artist can also sketch this onto a single grid. These individual paintings may be taken home by the patient.

The AIM Program volunteers deliver individual grid(s), paints, brushes, and other necessary supplies to patients and, occasionally, caregivers. Participants paint while they receive chemotherapy or while they are hospitalized for cancer treatments. Volunteers are careful to tell patients

HEAL

that they cannot ruin a grid. In fact, the use of different colors or less than perfect lines simply adds to the charm of the finished piece. And because patients paint "by numbers" on the grids, whatever they paint blends beautifully into the larger finished piece. Most cancer patients can finish a grid in a two- to three-hour session.

With all the grids painted, the coordinating artist assembles the entire work on foam core. The completed work of art is matted and framed—along with a plaque listing the names of the participants.

Completed paintings are displayed in the hallways, clinics, and lobbies of the Feist-Weiller Cancer Center, the Hematology and Oncology Unit, and the Oncology and Bone Marrow Transplantation Units at LSU Health Shreveport, where they are viewed by patients, friends and families, staff, and the general public. Participants are particularly proud to have their names on the plaques attached to each work of art. In addition, our staff reports that the artwork display fosters a sense of camaraderie and belonging, allowing patients to know that they are not alone in this journey. Some works of art have been purchased by patients and family members; occasionally a hospice patient will request a particular painting that provided them comfort while receiving curative treatment.

Finally, each participant in the AIM Program receives by mail an 8x10-inch color copy of their "painting." This packet also includes a description of the piece of art and a brief history of the artist.

Because some patients find it hard to put their brushes down, our AIM Program also offers individual grids that patients can paint by themselves. Patients choose their colors and take the paints and grid home to complete, frame, or display on their refrigerator (we affix a magnet to the back of the grids). Among the take-home grid options are a variety of fleur-de-lis patterns and Mardi Gras masks.

Most recently, our AIM Program volunteers have begun to collect large buttons from patients and staff members. By adding sparkling beads, colorful gemstones, and a loop or pin, the button is transformed into a piece of wearable art. We've found these buttons to be especially popular with cancer patients during the holiday season as they make good gifts for friends and family.

> Our Arts in Medicine Program would not work without our volunteers, who typically work for a three-hour session once a month.

Anecdotally, our staff has heard from patients and families that the opportunity to paint or create a work of art can reduce stress and provide a new dimension of comfort while they receive treatment.

Funding the AIM Program

Our AIM Program would not work without our volunteers, who typically work for a three-hour session once a month. Scheduling of the AIM Program activities varies each month to coordinate with volunteer schedules. Our AIM Program volunteers are often the only non-medical persons the cancer patients see during their treatments. This group of long-time volunteers allows us to keep program expenses to a minimum.

In addition to our dedicated volunteers, we employ a part-time AIM coordinator (the coordinating artist) who works 15 hours per week on the Arts in Medicine Program. Today, this coordinator also works with a growing number of middle school and high school students who sketch simple projects off-site for our cancer patients.

Supply budget for the AIM Program is less than $10,000 a year. This includes paints, brushes, illustration boards, foam core, framing with matting and Plexiglas, and miscellaneous expenses.

Feist-Weiller Cancer Center has a 10-year history of acquiring grants and community support to pay for its Arts in Medicine Program, including grants from the Shreveport Regional Arts Council with funding from the City of Shreveport and the Louisiana Division of the Arts. The Junior League of Shreveport and Bossier City is sponsoring the Alphabet Alley in LSU Children's Hospital (see "Growing the Program," on page 36). The Jo Jane Ladymon Children's Art Program was

established to ensure the continuation of the AIM Program in the St. Jude Clinic through memorials made in the benefactor's name.

Grant funds are used to pay the contract part-time artist, to purchase some supplies, and to cover the cost of framing the artwork and engraving the plaques.

Another revenue source is the artwork itself. Paintings are available for sale after they have been displayed at Feist-Weiller Cancer Center for a minimum of six months. We typically sell two or three paintings each year.

Our Arts in Medicine Program has helped us reduce the stress of our cancer patients by offering a brief respite from treatment-related concerns and challenges. An unexpected bonus of the AIM Program has been the beautiful artwork our volunteers, staff, and patients have created. Perhaps the best part of the program, however, is the joy on a patient's face when he or she proudly points to his or her painting. Create, display, heal. These words have become the very foundation of our Arts in Medicine Program.

Growing the Program

When the AIM Program was first taken into the children's treatment area, the first pieces of art created were cartoon characters that all children love—Cookie Monster, Big Bird, Cinderella, Scooby Doo, along with a wide range of fun, childish art. More recently in the St. Jude Clinic, an artist will sketch a portrait of the child. The child then chooses his or her own colors to paint the portrait.

Our "Wall of Fame" in the pediatric clinic now features these amazing portraits of smiling faces and hair of all different colors—white, black, green, purple, and so on. Enjoying their turn as a "celebrity," the children are always excited to have their pictures hung and admired by other patients, family members, and staff.

The next project for our pediatric cancer patients will be for them to paint a series of the alphabet and a corresponding medical word. For example, H is for Hospital, or X is for X-ray. The 16x20-inch canvases will be displayed at LSU Children's Hospital in the pediatric rehabilitation department. Staff will use the pieces of art to inform and educate the children: *Let's walk to the letter "I" which stands for the IV that holds your medicine.* OI

—Becky DeKay, MBA, is director, Oncology Services at LSU Health Shreveport, Feist-Weiller Cancer Center, Shreveport, La.

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THE VOLUNTEER PERSPECTIVE

One long-time volunteer tells a story of a patient who came in for treatment with a frown on his face and who scowled when first asked if he was interested in participating in the AIM Program. Undeterred, the volunteer showed him the painting another patient was working on. Her eight years of volunteer experience with the AIM Program helped her to recognize that the patient was a bit overwhelmed by the detail on the individual grids. So instead she gave the patient a simple fleur-de-lis and a few paint colors from which to choose. The patient first selected black. After leaving him alone for several minutes, the volunteer asked the patient if he wanted to use any other colors. He chose purple. About 30 minutes later, the patient waved his arm for the basket of paint colors. This time he chose bright lime and magenta. With words of praise from the nurses, other patients, and the AIM Program volunteer, the patient left with a bright and cheerful work of art.

In the volunteer's own words: *"I didn't change his life, disease, prognosis, or pain, but that patient came in with a frown and left with a smile. And that made my day. I give so little, and I get so much. That's why I'm an Arts in Medicine volunteer."*

ART'S IMPACT ON CANCER PATIENTS

Cancer patients are often hospitalized for long stays or spend long days as outpatients in the chemotherapy clinic. All too frequently these patients are sapped of energy, in pain, and depressed by their illnesses. Our cancer program staff has noted that these symptoms are often lessened or even alleviated by participation in the AIM Program. During the 10 years our AIM Program has been in operation, we have found that patients who immerse themselves in a creative activity seem more hopeful and happy and report feeling better and having less pain.

The literature also supports the benefits of art therapy for cancer patients. For example, one study published in the *Journal of Pain and Symptom Management* found that art therapy can reduce a broad spectrum of symptoms related to pain and anxiety in cancer patients.[1] According to Judith Paice, PhD, RN, director of the Cancer Pain Program at Northwestern Memorial Hospital and one of the study authors—"Art therapy provides a distraction that allows patients to focus on something positive instead of their health for a time, and it also gives patients something they can control."[1] The most surprising study finding: patients participating in art therapy reported a reduction in fatigue (tiredness). In fact, cancer patients reported significant reductions in eight of nine symptoms measured by the Edmonton Symptom Assessment Scale (ESAS) after spending an hour working on art projects of their choice.

Wood and colleagues conducted a systematic review on the use of art to manage symptoms of adult cancer patients.[2] Their findings demonstrated that: "Art therapy is a psychotherapeutic approach being used by adults with cancer to manage a spectrum of treatment-related symptoms and facilitate the process of psychological readjustment to the loss, change, and uncertainty characteristic of cancer survivorship."[2]

The Patient's Perspective

Prior to our AIM Program, many cancer patients had either never held a paint brush or had very little experience with art. These patients, in particular, enjoy the AIM Program's guided introduction into the world of painting and creativity. In the words of a patient who participated in the Arts in Medicine Program, the benefits are numerous:

With much trepidation I entered the front door of Feist-Weiller Cancer Center for my first visit. I'd been stunned by my diagnosis and remained virtually numb to everything around me. I wondered if I could actually make it through the maze of paperwork and people to get to the doctor without my daughter's help. Making my way to the receptionist desk, I stopped dead in my tracks to take in the beauty of the paintings before me. I lingered for a brief moment of delight, and then went about the serious business at hand.

As I waited on the second floor, I noticed more paintings displayed up and down the hall. I thought to myself: "Is this an art gallery or a medical clinic?" I glanced at each one as I walked down the hall to the dreaded doctor's visit.

I told my daughter about the fabulous paintings hanging throughout the cancer center, so when she came with me on my second visit, we took time to study and enjoy each one. To my complete surprise, I could see that they were not painted by professional artists, but instead were done by patients in the Arts in Medicine Program.

I now participate in the program in a small way. I find that as I paint I am removed from the world of worry, sadness, pain, cancer, chemotherapy, needles, and more, and transported to a world of bright colors and pleasure. This program has inspired me to paint again. My favorite subject is sunflowers—the happiest flower. The process is bringing me much joy as I go through the most difficult of times.

The Role of Histology and Molecular Markers in NSCLC

An innovative PI CME Initiative has implications for practice

BY LATHA SHIVAKUMAR, PHD, CCMEP; CHARMAINE CUMMINGS RN, PHD, CCMEP; JAY KATZ, CCMEP; THOMAS SULLIVAN; SHERETA R. WILEY, MPH; TERRY ANN GLAUSER, MD, MPH; WENDY CERENZIA, MS; AND CHAD WILLIAMSON, MS, MBA

Historically, the only important decision-making point in lung cancer management used to be determining whether a tumor was small cell lung cancer (SCLC) or non-small lung cancer (NSCLC). However, it is now becoming increasingly evident that histologic and molecular characteristics are very important for making treatment decisions for patients with NSCLC. Clinical trials of targeted agents have yielded outcomes differences based on histologic subgroups, providing clinicians a rationale for histology-based treatment approaches. For example, several studies have indicated survival differences among patients with NSCLC in response to specific agents (e.g., pemetrexed, bevacizumab) based on histologic type of the tumor.[1-3]

Similarly molecularly targeted agents have demonstrated clinical activity in specific subsets of patients expressing the molecular targets. Epidermal growth factor receptor (EGFR) mutations are almost exclusively found in NSCLC adenocarcinomas, and the association of these mutations with clinical response to gefitinib and erlotinib has provided clinicians an opportunity to tailor treatment to the EGFR mutation profile of the tumor. A number of retrospective reviews and prospective trials have established that EGFR-inhibitor therapy leads to radiographic responses in approximately 75 to 80 percent of patients with EGFR mutation-positive NSCLC.[4]

An oncogenic fusion between echinoderm microtubule-associated protein-like 4 (EML4) and anaplastic lymphoma kinase (ALK) was recently identified in a small subset of NSCLC patients.[5] Like EGFR mutations, EML4-ALK gene fusions occur almost exclusively in adenocarcinoma and in female nonsmokers or light smokers.[6] Crizotinib, a recently approved drug targeting the EML4-ALK fusion protein, resulted in a dramatic regression or disappearance of tumor in 57 percent of patients harboring the EML4-ALK fusion gene and a 2-year survival of 54 percent.[7,8]

As histologic and molecular characteristics become increasingly important in treatment decision-making for patients with NSCLC, community oncologists need education on the role of histology and molecular biomarkers in personalizing therapy for patients with NSCLC.

PI CME Methodology

In this article, we describe a performance improvement (PI) continuing medical education (CME) initiative designed to improve adherence to evidence-based recommendation guidelines related to histologic and molecular testing for NSCLC. The strategic partners in this collaborative initiative (the Potomac Center for Medical Education, Rockpointe Division of Oncology, ACCC, and CE Outcomes, LLC) identified "improvement of physician performance with respect to the use of histologic and molecular data for guiding treatment decisions in patients with NSCLC" as the goal of the PI CME initiative. The initiative uses a two-part strategy:

Part one is a PI activity focused on a specific group of treating clinicians and their practices. Performance measures used to assess performance changes will be linked to all components of the PI CME activity through an online system. This will ensure robust data capture and ease of use for participants. Tools and resources will be provided to participants to implement the changes identified from the activity into clinical practice.

Part two will use strategies and methods devised by participants in the PI CME activity to design educational interventions, tools, and resources for the wider audience.

The results of this PI initiative will be described in a subsequent publication that will be published following data analysis.

Identifying QI Measures

There are few validated performance measures for NSCLC. Many established measures from such organizations as the Agency for Healthcare Research and Quality (AHRQ) and Quality Oncology Practice Initiative (QOPI) focus on time to treatment and surgical specifics, rather than treatment choice. ACCC assembled an expert panel to identify the quality improvement measures that can be assessed in this PI CME initiative. After careful consideration of the most recent clinical data available on this topic, national clinical practice guidelines

(NCCN and ASCO), and opinions of thought leaders in this field, the expert panel identified the following three quality improvement measures:

1. Percentage of patients diagnosed with NSCLC whose predominant histologic type was confirmed prior to initiation of treatment
2. Percentage of patients diagnosed with NSCLC who underwent EGFR and EML4-ALK testing prior to initiation of treatment
3. Percentage of patients diagnosed with NSCLC where adequate tissue was available from the initial biopsy for molecular testing.

This PI CME initiative will attempt to measure physician changes with respect to these three quality improvement measures. The aggregate data will be reviewed to assess the impact of the activity, uncover barriers, and to document successful strategies that participants employed to overcome the barriers. The information will be used to develop additional educational activities to educate a wider audience of oncologists.

Participant Eligibility & Recruitment

All practicing physicians involved in the treatment of patients with NSCLC are eligible to participate in this PI CME initiative. Potential participation benefits include:

- Obtaining 20 AMA PRA Category 1 credits for completing the PI CME Initiative
- Demonstrating experience in performance and quality improvement activities that will support Commission on Cancer (CoC) accreditation
- Having the ability to impact treatment standards in NSCLC within the practice and nationwide.

The goal is to recruit 100 participants to complete the PI CME initiative and 100 participants to serve as a baseline group to assess the barriers and perceptions of practicing oncologists involved in the treatment of patients with NSCLC. The data gathered from the baseline group will be used to refine the quality improvement measures, the assessment tools' content, the educational interventions, and as a comparison to the participant group for self-assessment.

The PI CME guides physicians through a three-stage process that enables them to easily collect and enter data from their own practices using self-assessments and chart reviews.

Stage A: Self-Assessment of Current Practice

Stage A consists of a self-assessment survey, patient chart data, personal goals, and an improvement plan. Using the self-assessment, participants will evaluate their knowledge, attitudes, and competence in the treatment of patients with NSCLC. In the chart abstraction section, participants enter information from 10 patient charts regarding patient age, gender, smoking status, and pathology tests ordered. The information will then be compared against the PI CME's proposed measures and guidelines. Participants will receive a personalized report of the self-assessment and chart abstraction portions of Stage A. The correct answer, along with supporting evidence and faculty commentary, will be displayed alongside each question and answer pair. The participant Action Plan will include:

- The educational interventions selected for each participant based on answers in the self-assessment and chart abstraction portion of Stage A
- A list of optional activities
- Tools and resources to aid in implementing the information contained in the interventions.

Participants may also add a personal goal, which will be included in the Action Plan. This plan will be displayed to participants each time they log into the system. Reports and certificates are automatically generated in the system and participants may reprint these documents at any time. At the completion of Stage A, participants will be awarded 5 AMA PRA Category 1 credits.™

Stage B: Educational Interventions

Participants will complete the educational activities recommended to them based on their performance in the Stage A self-assessment portion. The three educational interventions in this PI CME initiative are:

1. ***A webcourse.*** Two medical oncologists and a pathologist discuss a patient case regarding the diagnosis of the histologic and molecular subtype of NSCLC, factors for consideration in treatment, and treatment decision points supported by clinical evidence.
2. ***An online monograph.*** The monograph will consist of five short summaries of key clinical data presented and/or published related to the diagnosis, treatment, and management of patients with NSCLC, with an emphasis on histology and molecular testing.

Figure 1. Three-Stage PI CME Process

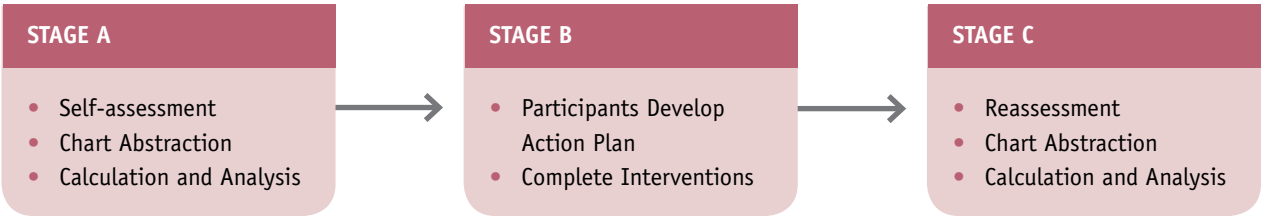
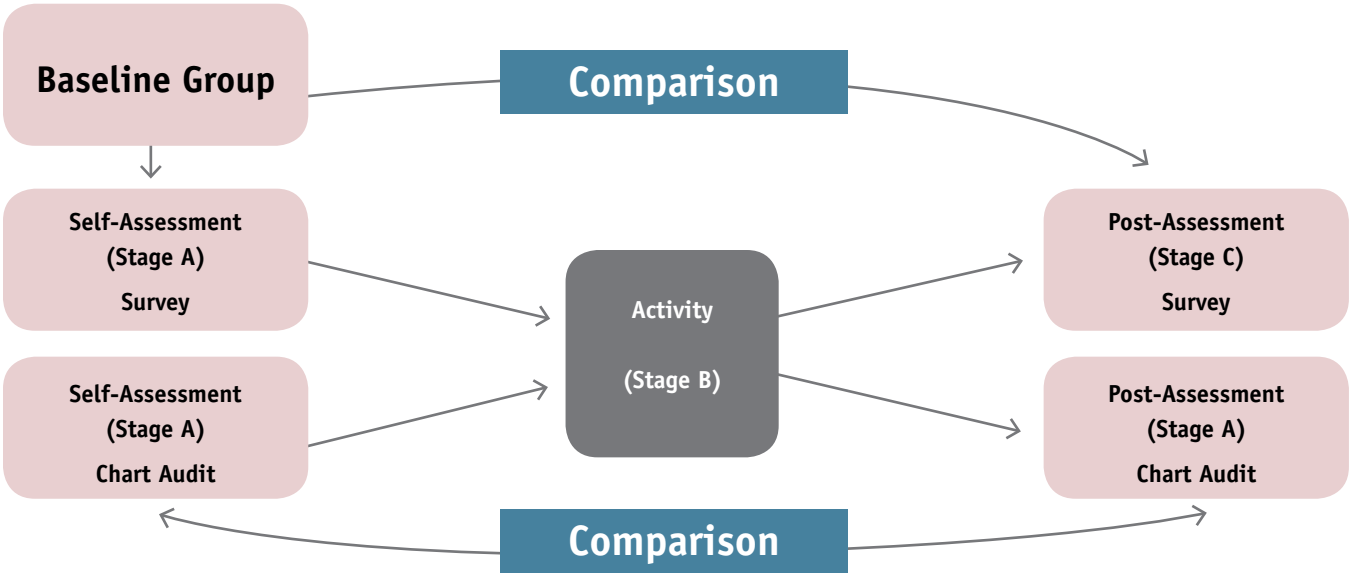


Figure 2. Study Design of the PI-CME Initiative



3. ***Online clinical challenge vignettes.*** Three vignettes will highlight unique aspects of the patient interaction that stimulated an interesting learning issue. All will focus on the application of histologic and molecular testing in the diagnosis and treatment of patients with NSCLC.

The PI CME activity will also include an expert commentary, providing participants with insight into the potential implications for practice change. Interactive questions will be interspersed throughout to track participant progress. Each educational intervention will include questions to assess practice patterns and changes in knowledge and competency of the participants. At the completion of Stage B, participants will be awarded 5 AMA PRA Category 1 credits™.

Stage C: Reassessment & Reflection on Practice

In Stage C, participants complete another self-assessment and enter data for 10 additional patient chart reviews (similar to Stage A), allowing participants to reflect and review their practice and compare against prior performance. Participants will receive a personalized report of the self-assessment and chart abstraction portions of Stage C. As in Stage A, the correct answer, along with supporting evidence and faculty commentary, will be displayed alongside each question and answer pair.

On completion of Stage C, participants will be awarded an additional 5 AMA PRA Category 1 credits™, for a total of 20 AMA PRA Category 1 credits.™

Data Analysis

Chi-squared ($\chi 2$) analyses will be performed on categorical data. T-tests will evaluate normally distributed continuous data. Comparisons of non-normally distributed continuous data are analyzed using the non-parametric Wilcoxon-Mann-Whitney test. The level of statistical significance is set at $p < 0.05$. All data will be presented in an aggregate form that does not reveal individual responses. Additionally, CE Outcomes, LLC, will calculate a Quality of Education Index (QoE)® score. This score is used to assess the summary impact of an educational activity on participant behavioral intentions, knowledge, and attitudes in a single reportable measure. OI

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action

ACCC and GE Healthcare Honor 2012 Innovator Award Winners in San Antonio

More than 400 oncology professionals gathered in San Antonio, Texas, for the ACCC 29th National Oncology Conference, Oct. 3–6.

▲ Winners of ACCC'S 2012 Innovator Awards, sponsored by GE Healthcare, were honored during the conference opening ceremonies. Award winners shared their creative strategies and solutions throughout ACCC's National Oncology Conference.

▲ Janet Dennis, BS, PT, CLT, accepts a 2012 Innovator Award on behalf of Dorcy Cancer Center at St. Mary-Corwin Medical Center. She is pictured with (L to R) ACCC President George Kovach, MD; Joe Camaratta, General Manager, Category Solutions and Marketing in GE Healthcare, Americas; and ACCC Executive Director Christian Downs, JD, MHA. Last year, GE launched its healthymagination initiative aimed at accelerating cancer innovation and improving care for cancer patients worldwide by 2020. "We are pleased to have a part in recognizing these fellow innovators through this award," said Camaratta.

▲ Keynote speaker Kevin Freiberg, EdD, urged attendees to challenge assumptions and act as agents for change by creating a culture in which people are comfortable questioning the "unquestionable." "Unquestionables are what every person believes it's impossible to do in oncology," he said. "…I think every cancer center in this room has to be prepared to accelerate innovation."

◀ Donna Berry, PhD, RN, AOCN, FAAN, received the 2012 ACCC Outstanding Achievement in Clinical Research Award. "I think about my career as asking two questions: 'Why?' and 'Why not?' It epitomizes what I've done," she told attendees during a luncheon in her honor. Dr. Berry is director of the Phyllis F. Cancer Center for Nursing & Patient Care Services at the Dana-Farber Cancer Institute and an associate professor of medicine at Harvard Medical School. Characterizing her work as a lifetime of inquiry, Dr. Berry said she has asked these questions with one consistent goal: to maximize health outcomes for individuals with cancers. The same goal shared by "every one of you in this room."

action

The Center for Provider Education ACCC

ACCC EDUCATION UPDATES

SAVE THE DATE!

ACCC 39th Annual National Meeting
March 6–8, 2013
Washington Marriott Wardman Park
Washington, D.C.

ACCC 30th National Oncology Conference
October 2–5, 2013
The Westin Boston Waterfront
Boston, Mass.

Improving Quality Care in Small-Population Cancers

Multiple Myeloma

The Latest Tools, Resources, and Updates

ACCC is working on a number of comprehensive tools and resources as part of this project. Check out the new blog from Edward Faber, MD, one of the expert speakers at the ACCC 29th National Oncology Conference in San Antonio. In his blog, Dr. Faber discusses the challenges in treating patients with multiple myeloma. Also new is the clinical data aggregator, a news feed containing the latest information for providers about multiple myeloma. And in coming months, look for a compendium of effective practices and the launch of the Multiple Myeloma Community Resource Centers. Visit *accc-cancer.org/multiplemyeloma* for more.

Financial Information and Learning Network

Helping Providers Meet Patients' Financial Needs

Get Connected!

Did you know that there's a place where you can ask questions about patient financial assistance issues and get answers in real time? If your cancer center provides financial assistance to patients, join the ACCC Financial Assistance Forum today to connect with your colleagues. Visit *mynetwork.accc-cancer.org* to subscribe. Other provider tools include: online courses and videos on topics such as dealing with financially noncompliant patients and improving the patient experience. Finally, consider attending one of our CE-accredited regional workshops. This half-day session is designed for any staff that provides financial assistance services. See Regional Oncology Meetings (right) for dates and locations.

ACCC Welcomes its Newest Members

Advocate Health Care (System Member)
Oak Brook, Ill.
Delegate Rep: Ashish Tripathy
Website: *www.advocatehealth.com*

Aurora Sheyboygan Memorial Medical Center
Aurora Cancer Care
Sheboygan, Wisc.
Delegate Rep: Kathy Becker
Website: *www.aurorahealthcare.org*

Aurora BayCare Medical Center
Aurora Cancer Care
Green Bay, Wisc.
Delegate Rep: Dhimant Patel, MD
Website: *www.aurorahealthcare.org*

CaroMont Health
Gastonia, N.C.
Delegate Rep: Rick Varterasian
Website: *www.caromonthealth.org*

Hudson Valley Hospital Center
Cheryl R. Lindenbaum Comprehensive Cancer Center
Cortlandt Manor, N.Y.
Delegate Rep: Anne Campbell-Maxwell
Website: *www.hvhc.org*

Indiana University Health West Hospital
Avon, Ind.
Delegate Rep: Denise Clark
Website: *http://iuhealth.org/west*

IU Health Ball Memorial Hospital
IU Health Ball Memorial Cancer Center
Muncie, Ind.
Delegate Rep: Terry Pence
Website: *www.iuhealth.org*

Siouxland Regional Cancer Center
June E. Nylen Cancer Center
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Website: *www.nylencancercenter.com*

UT Southwestern Medical Center
Harold C. Simmons Comprehensive Cancer Center
Dallas, Tex.
Delegate Rep: Stephanie Clayton
Website: *http://simmonscancercenter.org*

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Jersey City, New Jersey
Hyatt Regency Jersey
November 28

Louisville, Kentucky
Hyatt Regency Louisville
December 5

Denver, Colorado
Doubletree by Hilton Denver
December 13

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

ADVERTISER'S INDEX

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GiveForward Empowers Cancer Patients & Families

BY ARIANA VARGAS

In the United States the average out-of-pocket expenses for cancer during the first year of treatment total $8,500.[1] A recent Duke study revealed that more than 50 percent of Americans could not come up with $2,000 in a pinch if needed.[2] Obviously, a huge disparity exists between patients' payment expectations and what they can actually afford. This gap forces many families to prioritize cancer treatment and ensure that co-pays and high deductibles are paid first—often putting other living expenses on high-interest credit cards. The end result is often bankruptcy for these cancer patients and families. In fact, 62 percent of all bankruptcies in this country are directly caused by medical debt.[3] Cancer patients, specifically, are four times more likely than the average American to declare bankruptcy within five years of remission.[4]

GiveForward *(www.GiveForward.com)* is an online resource dedicated to resolving this problem. By providing free online fundraising pages, GiveForward helps cancer patients and their families empower themselves financially. Since launching in 2008, GiveForward has helped more than 20,000 families raise more than $23 million to help pay the out-of-pocket expenses that direct aid does not cover. GiveForward has been called: "The future of medical fundraising in the internet age." CNN reported that GiveForward is "reinventing healthcare."

What is most important to us at GiveForward, however, is that we have become an online community-building arena. Our integration with social media tools, such as Facebook and Twitter, allows patients and their families to exponentially increase the number of people in a patient's support network. Visitors to a GiveForward fundraising page can sign up to receive updates and stay current on a friend or family member's progress. Unlike traditional patient blogging sites, GiveForward also enables visitors to give directly to the patient.

Because funds donated to a patient's page are used at the patient's discretion, GiveForward differs greatly from most forms of direct aid offered today. One patient may need money to supplement lost income while she recovers from a double mastectomy, while another person may need money to cover daycare for his children while he cares for a parent with lymphoma. GiveForward is revolutionary because we provide the means for friends and family to help a loved one facing a medical crisis without eligibility requirements or a formal application process. If someone has a need that friends and family deem worthy, GiveForward provides the platform to request assistance.

Today GiveForward is the #1 online fundraising platform for medical expenses in the country. We are the only platform that provides personal fundraising coaches to every single user on the site. Upon publishing a page, users are sent the photograph, email address, and direct phone number of a GiveForward fundraising coach who can assist them with issues ranging from technical questions (i.e., how to upload a photo) to more complex strategies (i.e., how to maintain momentum for an online fundraiser).

Our advocates appear in more than 650 hospitals nationwide. Social workers, case managers, admissions officers, financial counselors, and discharge planners are just some of the many hospital workers who share our information with patients. However, most referrals come by word-of-mouth. Our GiveForward users frequently express that the emotional support received through donation comments of love and encouragement meant more than the money itself. This positive endorsement is often enough to movivate a friend or family member to start another page.

GiveForward is focused on staying at the forefront of technology. We are constantly changing our site by adding enhancements and innovative features. The ability to manage your fundraiser via a mobile device and make online payments with credit cards, debit cards, and PayPal mean that it's never been easier to give to a loved one in need. We are committed to listening to patient and caregiver needs and leveraging feedback to continually evolve our service. As a result, GiveForward is the easiest and most effective way to provide emotional and financial support to a loved one facing cancer. OI

—Ariana Vargas is director of Business Development, GiveForward, Chicago, Ill.

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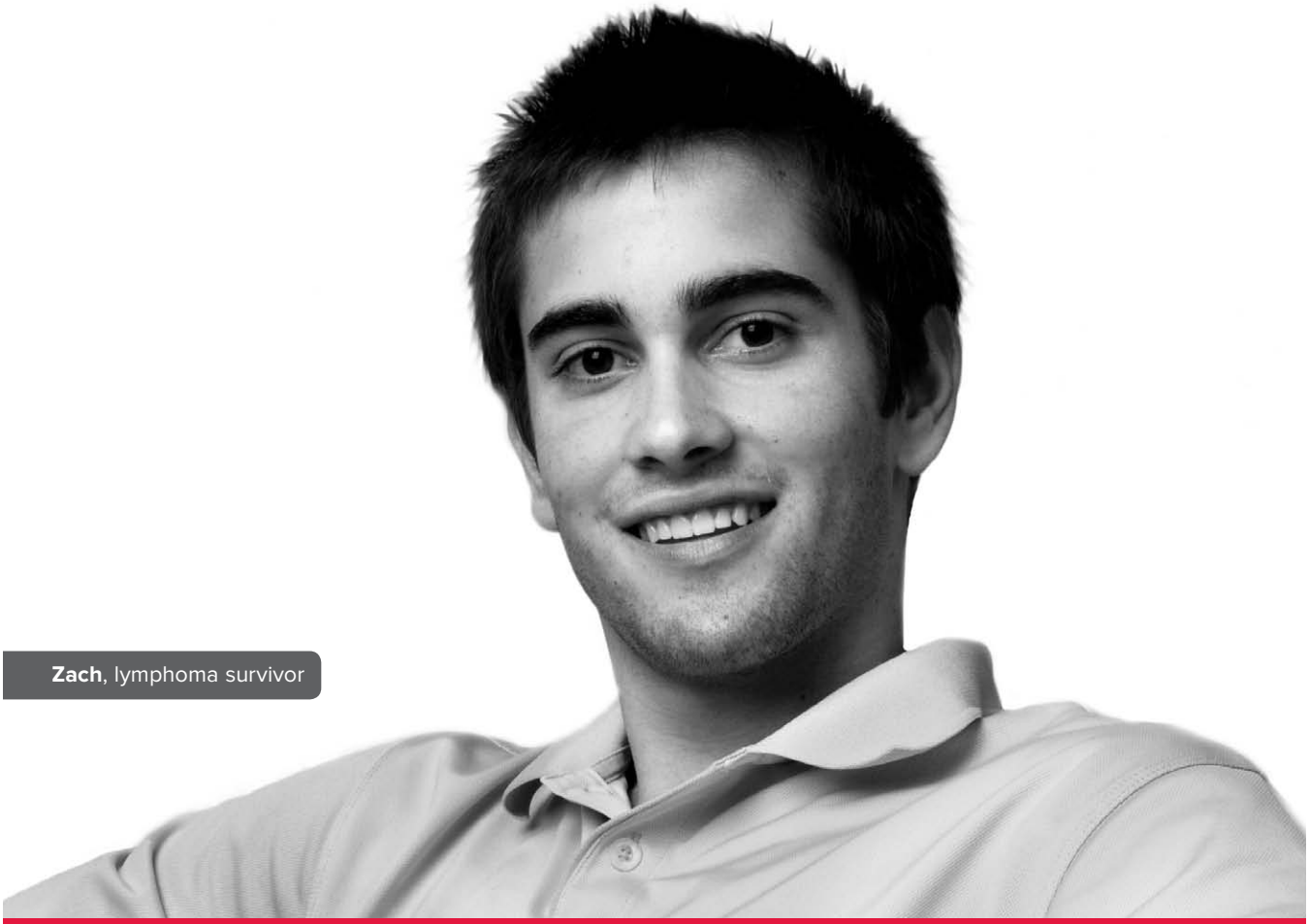

Zach, lymphoma survivor

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