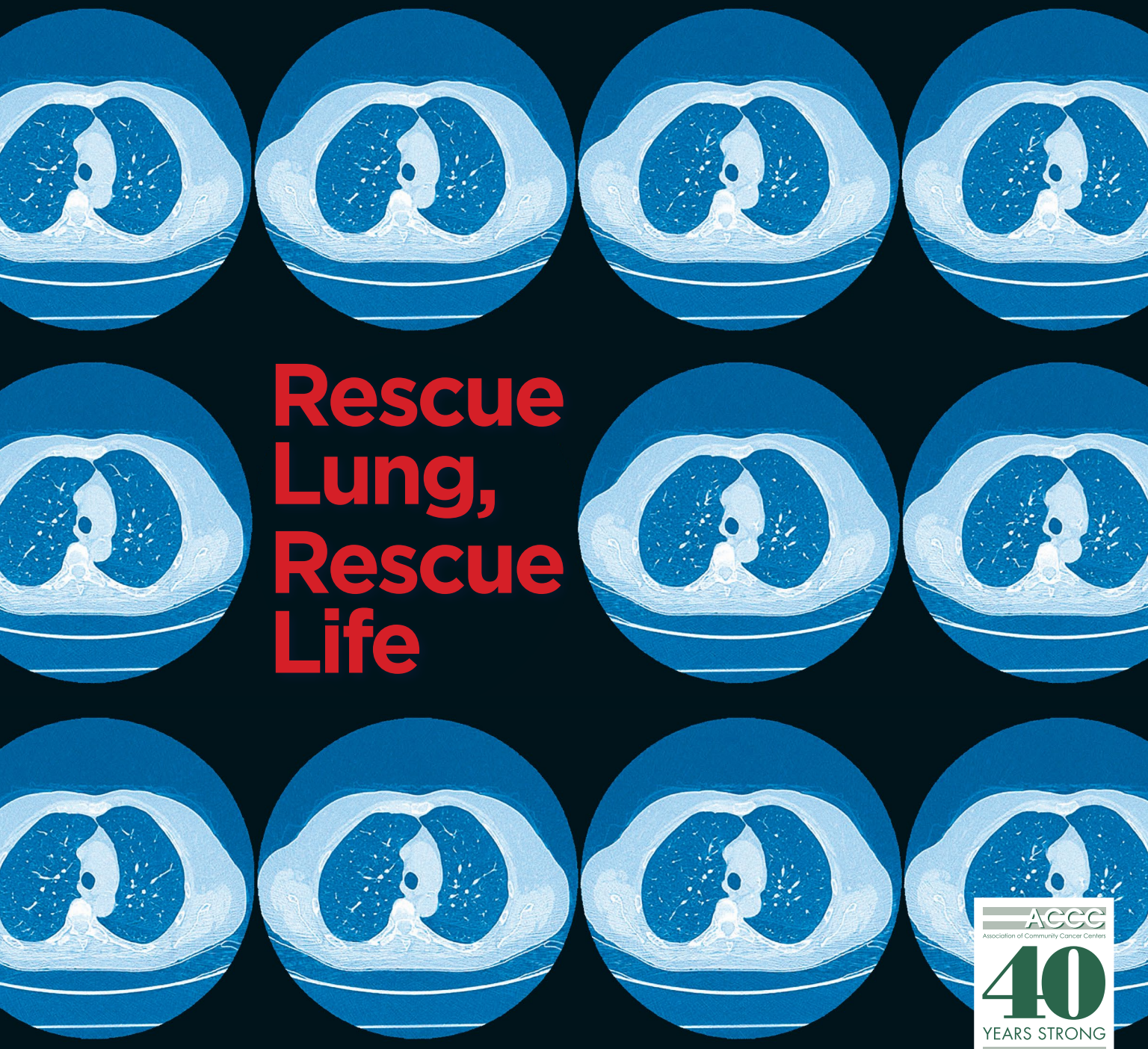
Coding for Lung Cancer Screening | **12**

A Model Rural Chemotherapy Program | **30**

Developing a Disaster Response Plan | **36**

ONCOLOGY ISSUES

The Journal of the Association of Community Cancer Centers
March | April 2014



Rescue Lung, Rescue Life

GRANIX™
(TBO-FILGRASTIM)
Injection

Take a bite out of G-CSF acquisition costs*

GRANIX™ is another option in short-acting G-CSF therapy

GRANIX™ is an option for hospitals and payers to consider when determining health system budgets

- **FDA approved through the rigorous BLA† process**
- **Teva's short-acting G-CSF was first introduced in Europe in 2008 and is available in 42 countries‡[1]**
- **GRANIX J Code: J 1446-Injection, tbo-filgrastim, 5 micrograms, effective January 1, 2014**

†Biologics License Application.
‡As of February 2014.

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

Indication

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

Important Safety Information

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

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

For more information, visit GRANIXhcp.com.

Reference: 1. Data on file. Teva Pharmaceuticals: Filgrastim MA Approvals Worldwide. February 2014.

TEVA Oncology

GRANIX™
(TBO-FILGRASTIM)
Injection

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

1 INDICATIONS AND USAGE

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

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Splenic Rupture

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

5.2 Acute Respiratory Distress Syndrome (ARDS)

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

5.3 Allergic Reactions

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

5.4 Use in Patients with Sickle Cell Disease

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

5.5 Potential for Tumor Growth Stimulatory Effects on Malignant Cells

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

6 ADVERSE REACTIONS

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

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

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

6.1 Clinical Trials Experience

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

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

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

Leukocytosis

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

6.2 Immunogenicity

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

7 DRUG INTERACTIONS

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

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

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

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

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

8.3 Nursing Mothers

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

8.4 Pediatric Use

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

8.5 Geriatric Use

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

8.6 Renal Impairment

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

8.7 Hepatic Impairment

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

10 OVERDOSAGE

No case of overdose has been reported.

TEVA Oncology

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

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

Product of Israel
GRX-40189 January 2014

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

Oncology MANAGEMENT CONSULTING GROUP

Dedicated to helping you and your oncology program achieve and sustain peak performance...OMC Group's experts deliver!

OMC GROUP...
Outstanding experts, Outstanding results!

For more than 12 years, **Oncology Management Consulting Group** has provided the finest professional consultative services to medical oncology and radiation oncology clients across the US. Our clients include oncology practices, community hospitals, children's hospitals, academic medical centers, health networks, free-standing clinics, and other healthcare-related companies. Our highly knowledgeable consultants are nationally recognized specialists that will assist you to achieve your business goals and to maximize your organizational performance. With solutions tailored to your very precise needs, OMC Group offers the leadership, vision, and collaboration that oncology providers need to adapt to - and to succeed in - the rapidly changing healthcare industry.

We invite you to call us at 215-766-1280 or email us at solutions@oncologymgmt.com.

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- New Center Development
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- Strategic Planning
- Operational Assessments
- Revenue Cycle Reviews
- Implementation and Interim Leadership
- Performance and Financial Benchmarking

KINDLE FIRE HDX
from Oncology Management Consulting Group

Check out our new website and enter to WIN...

We have updated our website and in a wonderfully shameless ploy to entice you to take a look, OMC Group is giving away a Kindle Fire HDX tablet to a lucky visitor! Full access to the web, email, and over 100,000 apps, games and movies combine with perfect-color HDX display to make this a great gift for you or a loved one!

Go to **www.oncologymgmt.com** and click on the **PROMOTION** link and register to win! It's easy...name, title, organization and email address (to notify the winner) is all we need. **GOOD LUCK!** (Drawing held on April 15, 2014.)

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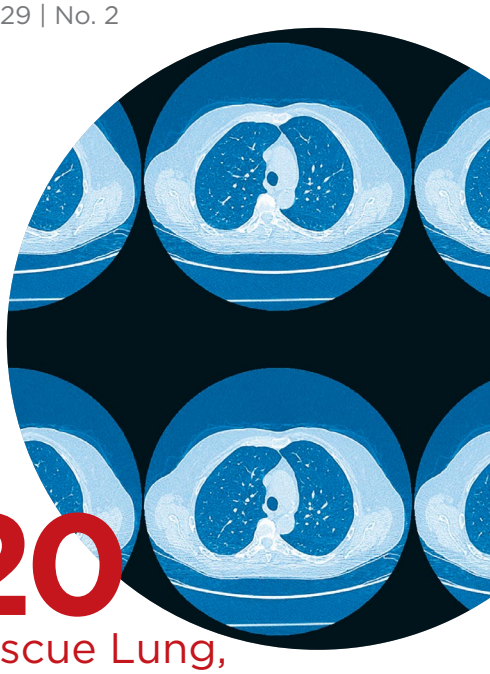
contents

Oncology Issues
March | April 2014
Vol. 29 | No. 2



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

Jack of All Trades

BY CHRISTIAN DOWNS, JD, MHA

I'm sure you've heard someone described as a "Jack of all trades." Many of you in busy multidisciplinary cancer programs live the phrase every day. But do you know its history?

The phrase first appeared in the English language around 1618 in a book by Geffray Mynshul titled, *Essays and Characters of a Prison*. Historians believe the phrase is likely based on the author's experience while he was imprisoned for debt at Gray's Inn in London.

"Jack" was a common term for a male in the 1600s. In fact, to be considered a "Jack of all trades'" in the 17th century was a high form of praise. It meant someone had the skill to successfully handle a variety of different issues and situations.

I look at this edition of *Oncology Issues* as a prime example of the ways in which cancer programs may be called upon to serve as a "Jack of all trades"—highly skilled in handling the complexities involved in the delivery of quality cancer care. For example, many cancer programs must be "experts" in providing care to patients in rural areas. In this issue, Avera Cancer Institute, Aberdeen, S.D., shares strategies developed as part of its rural chemotherapy program, including guidelines and standards of practice that are implemented across all sites. These tools and resources address safety, education, practice, compliance, and supervision when administering chemotherapy. Cancer programs faced with similar challenges caring for rural patients can learn a lot from this 2013 ACCC Innovator Award winner.

Cancer programs must also be "experts" at providing quality care even in the most challenging circumstances, such as the situation in New Orleans post-Hurricane Katrina. After experiencing firsthand how this disaster affected cancer patients in its state, Baton Rouge General Pennington Cancer Center developed a disaster response plan to ensure the quick restart of an evacuated patient's radiation oncology treatment. The plan uses a flash drive to ensure that all patients under active treatment have all the necessary pathology documentation, the initial consult, treatment plans, set up and beam portal images, and a dose-site summary to take with them during any evacuation. Simple, yet effective and very replicable, Baton Rouge General Pennington Cancer Center was awarded a 2013 ACCC Innovator Award for its disaster response plan.

Finally, cancer programs must be "experts" in cancer screening. After the 2010 National Lung Screening Trial showed that low-dose CT screening can, in fact, save the lives of patients who meet certain criteria, Lahey Hospital and Medical Center, Burlington, Mass., developed a lung screening program that eliminated self-pay rates and increased patient and physician awareness about the benefits of low-dose CT lung screening. Lahey's processes and lessons learned are a must read for cancer programs looking to develop a similar program.

These are just three examples in an issue full of information to support an ACCC member program serving as a "Jack of all trades" to meet the needs of the patients it serves. And for those thinking about what many people commonly believe to be the rest of the phrase—Jack of all trades, and master of none—Mynshul did not write the second part. Those derogatory words were added later in an attempt to describe someone who has broad knowledge but little depth. And that certainly does *not* describe the caring and qualified cancer providers at ACCC member programs who exhibit expertise every day across a myriad of disciplines and along the entire cancer care continuum. OI

PRESIDENT'S MESSAGE

40 Years of Teamwork

BY VIRGINIA T. VAITONES, MSW, OSW-C

As I write my last column as ACCC President, I am reminded of all the great opportunities that have come my way this year and all the wonderful colleagues that I have interacted with at various conferences and meetings. It has been an amazing year, thank you!

My presidential theme has focused on the multidisciplinary cancer care team, and teamwork comes in many different forms. A team that is special to me is my "ACCC Team," which is celebrating its 40th birthday in 2014. The ACCC team is made up of two groups. The first is the ACCC staff who work diligently to ensure that we—the members—have the educational tools and resources to keep our programs up to date with the fast changing world of cancer care, as well as a strong and united voice on Capitol Hill and during communications with regulatory agencies, such as the Centers for Medicare & Medicaid Services (CMS).

The other team is the ACCC membership, which totals nearly 20,000 individuals from hospital-based programs, physician-owned practices, oncology state societies, and individual members. The networking of the ACCC membership is like no other organization I have ever been associated with during my long career. ACCC members are active and invested in the Association. For example, ACCCExchange (the Association's listserv) had more than 600 posts in the last quarter of 2013. In January 2014, the digital edition of ACCC's *2014 Patient Assistance and Reimbursement Guide* received more than 18,500 hits.

As we get ready to celebrate ACCC's 40th anniversary, I spent some time looking back at past editions of *Oncology Issues* from 2002—the year I first became involved with the Association. One of the articles that sparked my interest was "Oral Oncology Products: Barriers to Successful Adoption" by Mary Lou Bowers, George Silberman, and Lee E. Mortenson. Among the issues identified by the authors were concerns about patient compliance with oral agents and concerns about reimbursement of oral agents so that programs could afford to prescribe them and patients could afford to take them. Talk about an organization with an eye to the future!

Today ACCC members continue to struggle with these issues, but we have made great progress. As part of its 40th Annual National Meeting, April 1–2, 2014, Arlington, Va., ACCC members will visit their legislators during Capitol Hill Day on March 31. This year, I plan on educating my legislators about S. 1879 and H.R. 1801. These bills have been written to ensure oral parity so that our patients will be able to afford their oral chemotherapy medications, which, in turn, will help with compliance. Two other issues ACCC has asked its membership to advocate for are the repeal of the sustainable growth rate (SGR) S.2000/H.R. 4015 and support for H.R. 1416, legislation that would eliminate costly cancer drugs from the two percent Medicare sequester.

Educating our legislators—whether it is at the state or national level—is imperative to keep cancer care viable for our programs and patients. So please join me for Capitol Hill Day and at ACCC's Annual National Meeting as we celebrate 40 years of multidisciplinary collaboration and teamwork. OI

Coming in Your 2014 *ONCOLOGY ISSUES*

- How Patient Navigation Can Enhance Clinical Trial Education and Promote Accrual
- Results from a National Hospital Oncology Benchmark Study
- Integrating Palliative Care into a Medical Oncology Practice
- Improving Oncology Genetic Counseling
- Developing a Community-Based Program for Cancer Survivors & Caregivers
- A Model for Improving the Care of Very Immunocompromised Patients
- A Community & Corporate Collaboration for Mobile Health Outreach
- Developing & Implementing an Electronic Dosimetry Whiteboard
- Skin Cancer Screening Clinic: A Creative Business Model
- Biosimilars: Emerging Issues for Cancer Programs?
- Clinical Pathway Trends—Payers, Providers and Healthcare Evolution
- Creating a Virtual Genetic Counseling Environment
- How to Implement an Outpatient Pharmacy in Oncology Practices
- New Patient Coordinator: Streamlining a Cancer Center's Phone Lines

fast

WEBSITE

A New Look for ACCC's Website

Bigger, brighter, better! All the current need-to-know information at your fingertips, with links to ACCC and oncology news, provider resources, advocacy efforts, meeting information, and more. Plus, members-only content is now more accessible through ACCC's MyNetwork. www.accc-cancer.org.

INFO

ACCC's New Advocacy Brochure

Read about the issues impacting your program today—a fix for the sustainable growth rate (SGR), oral parity legislation, the sequester, and elimination of the prompt pay discount—then contact your representatives to effect change. www.accc-cancer.org/getinvolved.

MEETING

Oncology Reimbursement Meetings

These free meetings will be held in Minneapolis, Columbus (Ohio), and Salt Lake City. Attend the meeting that's most convenient to you for a 360° look at oncology reimbursement issues, tools to strengthen your program, and information to help you weather market changes. www.accc-cancer.org/reimbursementmeeting.

AWARD

2014 ACCC Innovator Awards

Now in their fourth year, these awards recognize and honor pioneering strategies for the effective delivery of cancer care in the community setting. Innovations should advance the goals of improving access, quality, or cost-effectiveness. Apply today at www.accc-cancer.org/innovator.

Do ACOs Make the Grade?

Accountable Care Organizations (ACOs) are expected to improve the quality of patient care and reduce overall costs. To achieve those goals, ACOs must first leverage optimal medication use. One study found that ACOs reported high readiness in some areas, but have room for improvement in others.

Making the Grade

- Transmit prescriptions electronically (**70%**)
- Integrate medical and pharmacy data into a single database (**54%**)
- Offer formularies that encourage generic use when appropriate (**50%**)

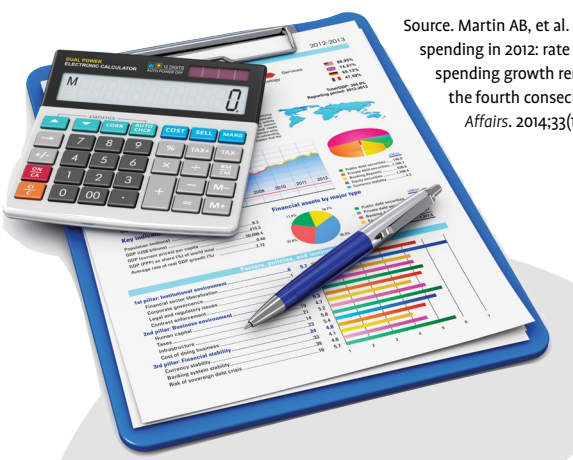
Improvement Needed

- Quantify the cost offsets of medication use and demonstrate the value of appropriate medication use (**7%**)
- Notify a physician when a prescription has been filled (**9%**)
- Have protocols in place to avoid medication duplication and polypharmacy (**17%**)
- Have quality metrics in place for a broad diversity of conditions (**22%**)

Source. Dubois RW, et al. Are ACOs ready to be accountable for medication use? *J Managed Care Pharm*. 2014;20(1):17-21.

4th Consecutive Year of Slow Growth in Healthcare Spending

Healthcare spending in the U.S. rose by just **3.7 percent** in 2012, continuing to reflect the impact of the recent economic recession. Healthcare spending in 2012 reached **$2.8 trillion**, or **$8,915** per person.



Source. Martin AB, et al. National health spending in 2012: rate of health spending growth remained low for the fourth consecutive year. *Health Affairs*. 2014;33(1):67-77.

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

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

facts

Study Finds Out-of-Pocket Costs Play Major Role in Treatment Adherence for Cancer Patients

- Patients with higher co-payments were 70 percent more likely to stop taking their cancer treatment.
- Patients with higher co-payments were 42 percent more likely to skip doses.

Source. Dusetzina SB, et al. Cost sharing and adherence to tyrosine kinase inhibitors for patients with CML. *J Clin Oncol*. 2013 Dec 23.

Effects of Prostate Cancer Go Beyond the Physical

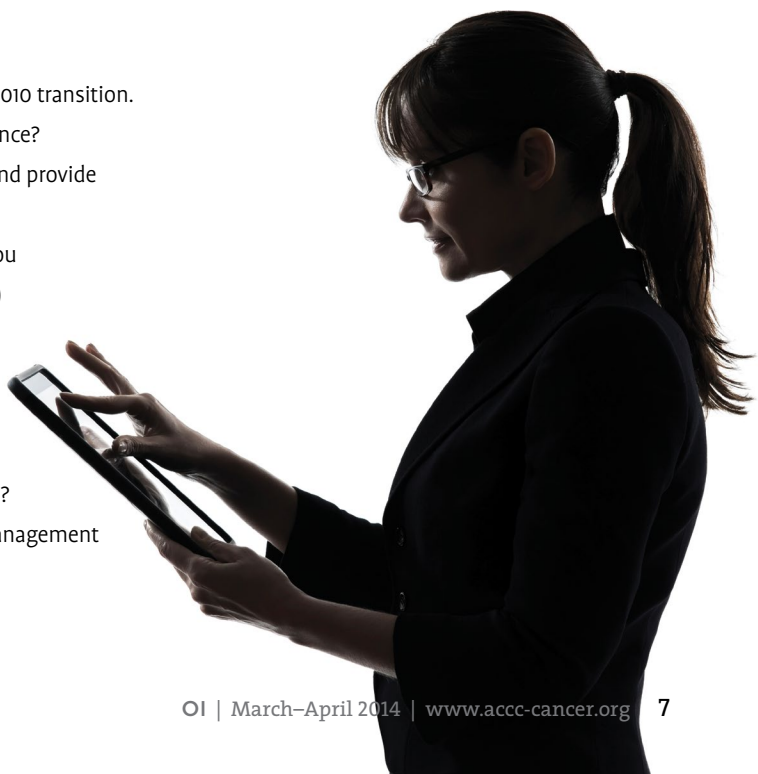
- The majority of men with prostate cancer (**70%**) in the early stage of the disease report having an excellent or very good quality of life compared to only **39%** of those with advanced prostate cancer.
- **36%** of men living with prostate cancer surveyed say the disease has impacted their ability to participate in daily activities, such as using the bathroom, being physically active, and traveling.
- The most reported physical concern (**64%**) for all men surveyed is being unable to maintain an erection.
- Among men with early stage prostate cancer, sexual dysfunction, urinary incontinence, and fatigue are the most common physical challenges experienced.
- Men with advanced (stages 3 and 4) prostate cancer reported psychological concerns (**69%**) and social concerns (**50%**), including feelings of loss of masculinity, loss of dignity, loss of identity, and missing out on important life events.

Source. A survey conducted by Leger Marketing on behalf of Janssen Inc., and in partnership with the Canadian Cancer Survivor Network.

6 ICD-10 Questions for Your Medical Claims Clearinghouse

1. Our practice experienced a disruption of cash flow during the HIPAA 5010 transition. What will you do differently with ICD-10 to prevent a repeat performance?
2. Can you run a report of claims rejections and denials by ICD-9 code, and provide guidance on how to prevent these errors?
3. Can you run a similar report by payer? (Bring this information when you meet with your key payers and discuss their ICD-10 conversion plans.)
4. Can you run a report that identifies the "generic" codes each provider uses regularly? (Generic ICD-9 codes are most likely to be denied by payers going forward. These codes should be your first priority during ICD-9 to ICD-10 mapping.)
5. Could you share advice on mapping my superbill from ICD-9 to ICD-10?
6. Could you share the progress of your discussions with my practice management vendor and my payers? When can we start sending test claims?

Source. Physicians Practice. www.physicianspractice.com.



Association of Community Cancer Centers

Core Purpose, Core Values, and Strategic Objectives

Core Purpose

To be the leading education and advocacy organization for the multidisciplinary cancer team.

Core Values

ACCC will fulfill its core purpose by pursuing and adhering to these core values:

- Integrity
- Collaboration
- Stewardship
- Knowledge
- Service
- Innovation
- Excellence
- Compassion

Strategic Objectives

Long-Range Goal

ACCC will be recognized as the leading organization that advocates for quality comprehensive cancer care for all.

Three-to-Five Year Goals

- **Goal A:** Members will recognize the value of ACCC and utilize its resources for knowledge exchange, education, and networking.
- **Goal B:** ACCC will expand its influence and advocacy for quality cancer care.
- **Goal C:** ACCC will manage its resources to meet its financial objectives.
- **Goal D:** ACCC will establish meaningful collaborations and partnerships.
- **Goal E:** ACCC will examine its leadership and membership structure.

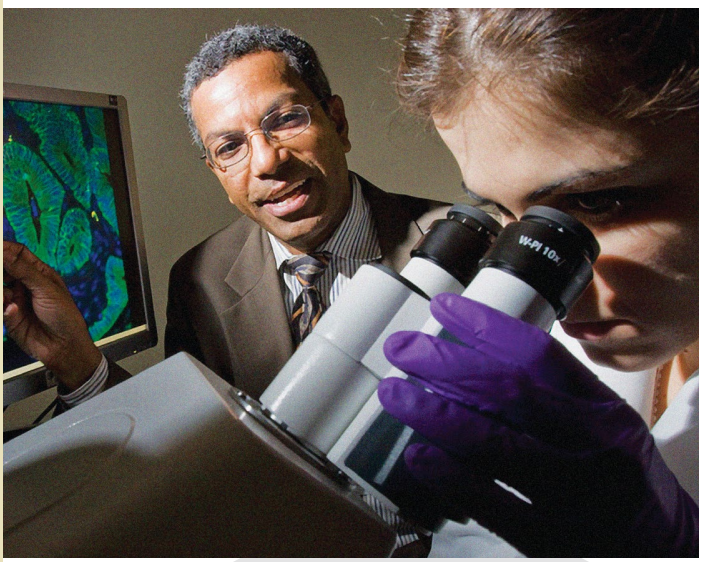
Learn more at www.accc-cancer.org.

The Voice of the Community Physician is Heard

In 1979 J. Gale Katterhagen, MD, past president of ACCC (1976-1978), became the first community physician appointed to the National Cancer Advisory Board. "Community representation on the NCAB was a significant step in vying with the academic centers for NCI research funding," Katterhagen said at the time.

ACCC Instrumental in Bringing Research to Community Programs

ACCC Presidents William M. Dugan, Jr., MD, (1983–1984) and Edward L. Moorhead III, MD, (1985–1986) both testified before Congress about the need and value of clinical trials in the community. ACCC's efforts were rewarded with the CCOP (community clinical oncology program) and CGOP (cooperative group outreach) programs.



Christiana Care Health System, Helen F. Graham Cancer Center

fast facts

ACCC Gives Advocacy Award to Former President

In 1986 ACCC presented former President Richard M. Nixon with an Award for Service to Cancer Patients at its 12th Annual National Meeting. In his remarks, President Nixon said, "The 300 community cancer centers you represent...are the front line troops in the war against cancer. All Americans are in your debt." Today, ACCC represents about 900 hospitals and 900 physician group practices nationwide.

Access to Off-Label Therapies

In 1990, in an effort to get payers to revise coverage policies for off-label indications, ACCC developed uniform health insurance language that defined off-label use and provided legitimate sources for off-label recommendations; 39 states adopted ACCC's model legislation, along with Medicare and Medicaid. Since 1989 ACCC has assisted more than 40 states in developing legislation and regulations requiring coverage for off-label drug indications.

Grassroots Advocacy Campaign

ACCC launched this campaign in 2012, partnering with key stakeholders at the local, state, and federal level to preserve access to quality care, advance Medicare, and ensure appropriate reimbursement. One key effort: oral parity legislation that requires payers to cover oral and infused drugs at the same rate. Today, 27 states and the District of Columbia have passed oral parity legislation. ACCC continues to work with the other states and Congress on similar legislation.

Having an Impact is Easier Than You Think

BY MATTHEW FARBER, MA

Many of you reading this issue are currently in Arlington, Va., at the ACCC 40th Annual National Meeting, listening to and learning about issues impacting the business and economics of cancer care. Hopefully many of you will also have participated in ACCC's Annual Capitol Hill Day, where ACCC members visit with their elected officials to discuss issues affecting reimbursement of and access to quality cancer care. This year, ACCC members focused on four key issues:

1. The sustainable growth rate (SGR)
2. Cuts to reimbursement due to the sequester
3. Oral parity legislation
4. The prompt pay discount.

These issues all impact community cancer care in different ways. For example, the cuts in Medicare reimbursement due to the sequester have affected a majority of oncology care providers, and the impacts are being felt by *all* patients. In 2013 ACCC surveyed its membership about the impact of the sequester; 84 percent of cancer programs have been impacted, and those impacts include layoffs, staff-hour reductions, and a cutback in supportive programs, including nutrition services and survivorship programs.

While most of you in the field know this information firsthand, there is a good chance that members of Congress do not—that is why making your voice heard is so important. Congress often make laws without understanding all of the implications of their actions; they depend on us (their constituents) to educate them. Whether the issue is declining reimbursement, access to innovative therapies, or changing payment methodologies, Congress needs to hear from the oncology community in order to understand the effects on your programs and patients.

Another example of how ACCC members can engage with both Congress and payers is in the area of screening and other diagnostic testing. Over the past few years, Medicare has ratcheted down reimbursement for numerous diagnostic modalities, including both the technical and professional components for MRI and CT tests. ACCC commented against many of these cuts and, at times, our comments have had an impact. Still, the cuts continue to come, so we need to ensure that the decision makers understand what happens when reimbursement for these important tests is reduced.

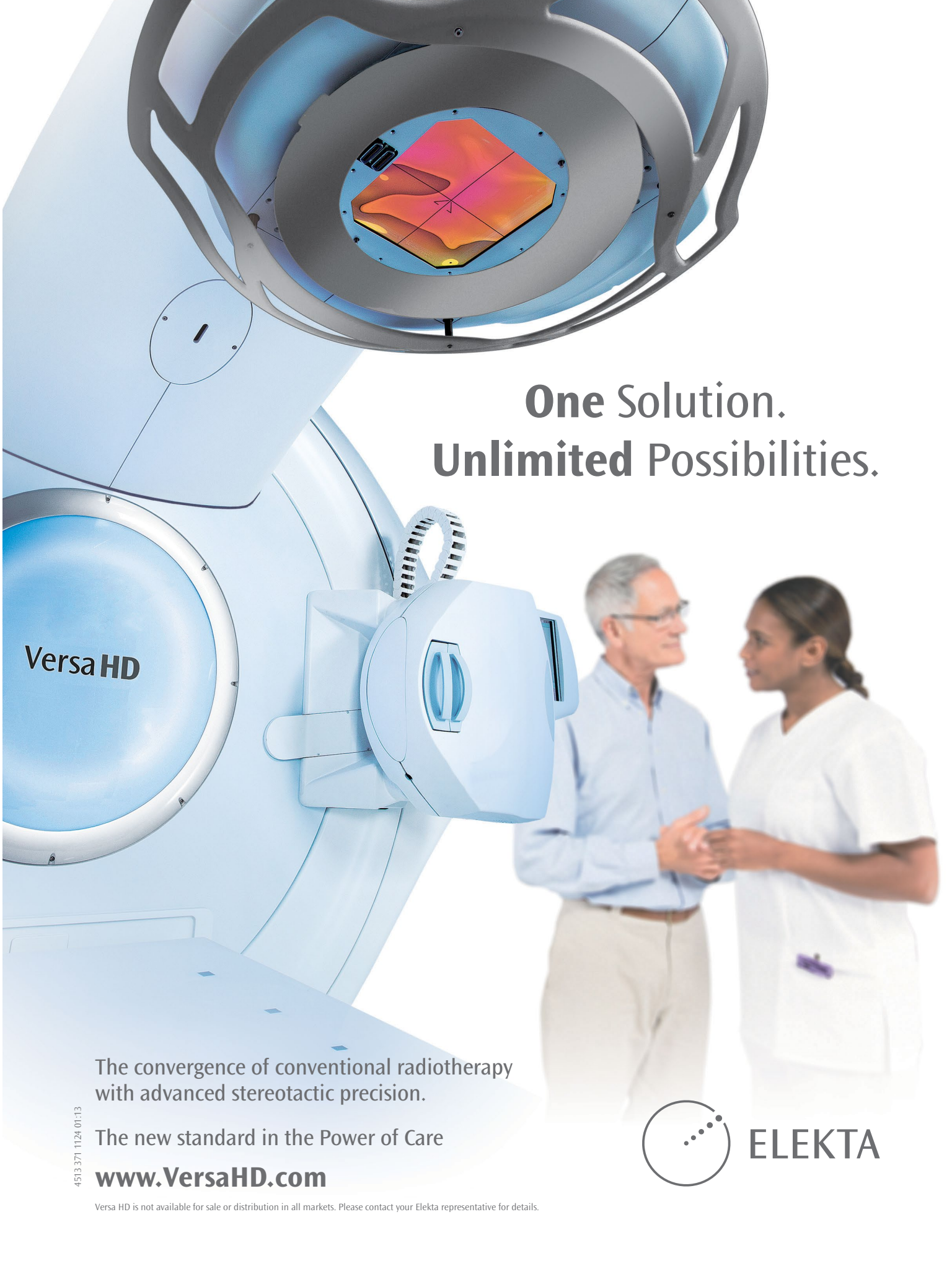
In this *Oncology Issues*, the cover article discusses the life-saving promise that low-dose CT screening may hold for many individuals with lung cancer. Now that payers are required to cover this preventive screening, there are hopes that the technology will be better utilized by the oncology community. That said, access may again become a question if reimbursement rates continue to decline. The best way to avoid these cuts is to speak with regulatory agencies, like the Centers for Medicare & Medicaid Services (CMS), and your elected officials in Congress.

Reimbursement for CT screening is incredibly complicated, and often misunderstood by policy makers. The oncology community is in the unique position of being able to educate decision makers about these complex issues.

Many ACCC members may be somewhat intimidated by offering this type of education, but it is easier than you think. As participants in ACCC's Capitol Hill Day know, meeting with your elected officials is a great way to ensure that your voice—and the needs of your program and patients—are heard. And even if your busy schedule or distance precludes you from traveling to Washington, D.C., you can still write, email, call, blog, tweet, and Facebook your elected officials. Today, there are more opportunities than ever before to reach out to your congressional representatives. In fact, many officials are able to respond more quickly using social media tools such as Twitter and Facebook.

Remember, ACCC is here to help. If you want to get involved with the Association's advocacy efforts and don't know where to start, email me at mfarber@accc-cancer.org. If you can't make it to D.C., we can help set up visits in your home districts. OI

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



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Coding for Lung Cancer Screening

BY CINDY PARMAN, CPC, CPC-H, RCC

There's an old saying that an ounce of prevention is worth a pound of cure, and when treating a malignancy, finding it early may help improve the patient outcome. At present, many insurers reimburse for screening Papanicolaou (PAP) smears to detect cervical cancer, screening prostate specific antigen (PSA) tests to detect prostate malignancy, and screening colonoscopies to detect colon cancer. In addition to these standardized screening services, some cancer programs have initiated or are considering a lung cancer screening program.

Making the Grade

On December 30, 2013, the U.S. Preventive Services Task Force (USPSTF) finalized its grade "B" draft recommendation that current or past heavy smokers between 55 and 80 receive annual CT scans to detect lung cancer. Preventive services given an "A" or "B" rating by the USPSTF must be reimbursed by insurers at no cost to patients under the Affordable Care Act (ACA).[1] However, this recommendation remains controversial; the panel's draft report in July 2013 noted that 96 percent of CT lung cancer tests that initially tested positive were actually *false* positive results. This means that the vast majority of positive results would require confirmation through other tests, exposing the patients to more radiation or more invasive and costly procedures that carry a higher risk of complications.

The USPSTF also advised some caution in the use of CT scans for screening. According to Task Force chair Virginia Moyer, "The benefits of screening may be significantly less in people with serious medical problems and there is no benefit in screening someone for whom treatment is not an option. In these people, screening may lead to unintended harm, such as unnecessary tests and invasive procedures." co-vice chair Michael LeFevre added, "When clinicians are determining who would most benefit from screening, they need to look at a person's age, overall health, how much the person has smoked, and whether the person is still smoking or how many years it has been since the person quit."

Information from *JAMA Internal Medicine* indicates that nearly one in five patients with a history of cigarette smoking who are diagnosed with lung cancer as a result of CT screening do not have clinically significant disease and are overdiagnosed.[2] According to Edward Patz, Jr., MD, lead author of the study and a professor of pathology and radiology at Duke Medical Center, "What we're saying is that in the absence of screening, some of these individuals would never have known they had lung cancer, and never would have been treated for lung cancer, and never would have been labeled for lung cancer, and would have died from other causes rather than from this disease."

Patz says that the research findings in no way suggest that patients at high risk should not undergo lung cancer screening. "But what we do say is that, for full disclosure, you need to let people know that there is this downside of screening." That's because for many of the people who are treated who didn't have clinically significant disease, "some will have inherent complications from their treatment," resulting in morbidity and mortality from treatments and surgery, rather than the disease itself. In addition to the potential for physical harm, there may be concerns related to psychological harm, financial harm, absence from work or job loss, and missed opportunities to be with family and friends.

Lung Cancer Screening

For the purposes of this article, lung cancer screening refers to strategies used to identify early lung cancers before they cause symptoms and at a point where they are more likely to be considered curable. Screening is defined as the use of medical tests to detect disease in asymptomatic individuals. Prevention of disease with screening involves detection of disease at an early stage, such that intervention at that point improves survival.

Blue Cross Blue Shield of Kansas (BCBSKS) has a policy for "Screening for Lung Cancer Using CT Scanning,"[3] which includes the following background information:

Given the poor prognosis of lung cancer, there has been longstanding research interest in developing screening techniques for those at high risk. Previous studies of serial sputum samples or chest x-rays failed to demonstrate that screening improved health outcomes. More recently, there has been interest in low-dose computed tomography (CT) scanning as a screening technique, using either spiral (also referred to as helical) or electron beam (also referred to as ultrafast) CT scanning. Compared to conventional CT scans, these scans allow for the continuous acquisition of images, thus shortening the scan time and

radiation exposure. A complete CT scan can be obtained within 10-20 seconds, or during 1 breath hold in the majority of patients. The radiation exposure for this examination is greater than for that of a chest x-ray but less than for a conventional CT scan.

There are also growing applications of computer-aided detection or diagnosis (CAD) technologies that may have an impact on the use of CT scanning or chest radiographs for lung cancer screening. Computer-aided detection points out possible findings to the radiologist who then decides if the finding is abnormal. Computer-aided detection uses a computer algorithm to analyze features of a lesion to determine the level of suspicion and is intended to enhance the reader's diagnostic performance.

Efficacy of screening is primarily assessed by how significantly a screening test decreases mortality. In general, national organizations with recommendations on lung cancer screening all include a recommendation that the low-dose CT screening of eligible patients occurs in settings that use a multidisciplinary approach and involve participation of a sub-specialty qualified medical team (see "Rescue Lung, Rescue Life, pages 20–29).

Of the 21 leading academic centers identified by *US News and World Report*, 19 responded to a survey regarding screening programs and 15 institutions said they already had CT-based lung cancer screening programs up and running.[4] Eleven of those 15 programs offer optional smoking cessation courses, and three more make the smoking cessation course mandatory for individuals undergoing lung cancer screening. In addition, there may be a number of local and community hospitals that are providing lung cancer screening that were not included in this analysis.

American Lung Association

On April 23, 2012, the American Lung Association (ALA) published a report titled "Providing Guidance on Lung Cancer Screening to Patients and Physicians" that includes, in part:[5]

1. Low-dose CT screening should be recommended for those people who meet the National Lung Screening Trial (NLST) criteria:
   - Current or former smokers, age 55 to 74 years
   - A smoking history of at least 30 pack-years
   - No history of lung cancer.
2. Individuals should not receive a chest X-ray for lung cancer screening.
3. Low-dose CT screening should NOT be recommended for everyone.
4. ALA should develop public health materials describing the lung cancer screening process in order to assist patients in talking with their doctors. This educational portfolio should include information that explains and clarifies for the public:
   - The difference between a screening process and a diagnostic test

Table 1. Procedure Codes, Modifiers & Definitions

CODE/MODIFIER	DEFINITION
71250	Computed tomography thorax; without contrast material.
71260	Computed tomography thorax; with contrast material(s).
71270	Computed tomography thorax; without contrast material, followed by contrast material(s) and further sections.
+0174T	Computer-aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation. (List separately in addition to code for primary procedure.)
0175T	Computer-aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation.
S8092	Electron beam computed tomography (also known as ultrafast CT, cine CT).
Modifier 52	Reduced services: under certain circumstances a service or procedure is partially reduced or eliminated at the discretion of the physician or other qualified healthcare professional. Under these circumstances the service provided can be identified by its usual procedure number and the addition of modifier 52, signifying that the service is reduced. This provides a means of reporting reduced services without disturbing the identification of the basic service.

Table 2. ICD-9-CM Diagnosis Codes

CODE	DEFINITION
V76.0	Special screening for malignant neoplasms, respiratory organs
V15.82	Personal history of tobacco use
305.1	Tobacco use disorder (tobacco dependence)

- The benefits, risks, and costs (emotional, physical, and economic)
- That not all lung cancers will be detected through use of low-dose CT scanning.

5. A call to action should be issued to hospitals and screening centers to:
   - Establish ethical policies for advertising and promoting lung cancer screening services
   - Develop educational materials to assist patients in having careful and thoughtful discussions between patients and their physicians regarding lung cancer screening
   - Provide lung cancer screening services with access to multidisciplinary teams that can deliver the needed follow-up for evaluation of nodules.

Insurance Reimbursement

Some insurers already reimburse for the lung cancer screening CT scan. BCBSKS provides the following payment guidelines for screening CT scans. Of note, the patient selection criteria are based on the National Lung Screening Trial:

A. Low-dose computer tomography (CT) scanning, no more frequently than annually, may be considered medically necessary as a screening technique for lung cancer in individuals who meet ALL of the following criteria:
   - Between 55 and 74 years of age, *and*
   - History of cigarette smoking of at least 30 pack-years, *and*
   - If former smoker, quit within the previous 15 years.

   Number of pack-years = (number of cigarettes smoked per day × number of years smoked) ÷ 20 (1 pack has 20 cigarettes). A pack year is defined as 20 cigarettes smoked every day for one year.

B. Low-dose CT scanning is considered experimental and/or investigational as a screening technique for lung cancer in all other situations.

C. This policy does not apply to individuals with signs and/or symptoms of lung disease. In symptomatic individuals, a diagnostic work-up appropriate to the clinical presentation should be undertaken, rather than screening.

Aetna has similar criteria for reimbursement in its Clinical Policy Bulletin on Lung Cancer Screening (Policy 0380):[6]

1. Aetna considers annual low-dose computed tomography (LDCT) scanning, also known as spiral CT or helical CT scanning, medically necessary for current or former smokers ages 55 to 79 years with a 30 pack-year or more smoking history and, if a former smoker, has quit within the past 15 years. Aetna considers LDCT experimental and investigational as a screening test for all other indications.
2. Aetna considers computer-aided detection for chest radiographs experimental and investigational for screening or diagnosis of lung cancer and for all other indications. There is presently inadequate evidence in the medical literature that population-based mass lung cancer screening with computer-aided detection for chest radiographs will contribute substantially to the detection of smaller cancers, or decreases mortality.

Code Assignment

It's important to keep in mind that the requirement to pay for lung cancer screening under the ACA is limited to reimbursement for the low-dose CT scan. There may be minimal or no reimbursement for any patient visits before or after the scanning service. For example, a visit to discuss the risks, benefits, and/or potential complications of a screening CT scan would not meet the definition of the existing Preventive Medicine codes or Counseling and/or Risk Factor Reduction codes. These codes are reported for "comprehensive" preventive medicine services, instead of discussion of a single body system or single screening focus. If there is no patient visit code that exactly describes the service, the physician or qualified nonphysician healthcare practitioner can report an unlisted code:

- **99499.** Unlisted evaluation and management service.

Remember that when an unlisted patient visit code is reported, there may be a need to submit supporting documentation to obtain reimbursement.

With respect to coding the screening CT service, the following authoritative coding guidance is included in *CPT® Assistant*, July 2007, page 13:

Question: What is the appropriate code to report for screening computed tomography (CT) of the thorax?

Answer: Reporting of CT is based on the anatomic site studied. If a complete study is performed of the thorax, one of the following CPT codes should be reported, based on the use or nonuse of contrast: ***71250****,* ***71260****, or* ***71270****.*

*Please note that if a limited study is performed, it is appropriate to report either the limited code **76380**, computed tomography, limited or localized follow-up study, or the anatomic site code with **modifier 52**, reduced services.*

Additionally, the ICD-9-CM codes reported will inform the payer when a diagnostic or screening study has been performed.

Table 1, page 13, shows a list of potential procedure codes for the screening CT to detect lung cancer. Table 2, left, and Table 3, below, offer a list of diagnosis codes that identify the asymptomatic screening patient.

Nearly 90 million Americans are smokers, and about 7 million of these individuals are in the target group. Estimates are that if these 7 million people each received a CT scan annually for lung cancer screening, the result would be increased healthcare costs of $2.1 to $3.5 billion.[7] Cancer programs that are considering the addition of a lung cancer screening program should analyze current demographics, review existing payer policies, and ensure that the cost of providing the program will be offset with a sufficient number of patients and adequate reimbursement.

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Table 3. ICD-10-CM Diagnosis Codes

CODE	DEFINITION
Z12.2	Encounter for screening for malignant neoplasm of respiratory organs
Z87.891	Personal history of nicotine dependence
F17.210	Nicotine dependence, cigarettes, uncomplicated
F17.211	Nicotine dependence, cigarettes, in remission
F17.213	Nicotine dependence, cigarettes, with withdrawal
F17.218	Nicotine dependence, cigarettes, with other nicotine-induced disorders
F17.219	Nicotine dependence, cigarettes, with unspecified nicotine-induced disorders
F17.290	Nicotine dependence, other tobacco product, uncomplicated
F17.291	Nicotine dependence, other tobacco product, in remission
F17.293	Nicotine dependence, other tobacco product, with withdrawal
F17.298	Nicotine dependence, other tobacco product, with other nicotine-induced disorders
F17.299	Nicotine dependence, other tobacco product, with unspecified nicotine-induced disorders

*ICD-10-CM includes diagnosis codes to describe nicotine dependence, chewing tobacco, and a series of codes for inhalant dependence in addition to the codes listed above. (ICD-10 is scheduled to go into effect Oct. 1, 2014.)

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Approved Drugs

• Janssen Biotech, Inc. (www.janssenbiotech.com) announced that the Food and Drug Administration (FDA) expanded the approved use of **Imbruvica (ibrutinib)** for chronic lymphocytic leukemia (CLL) patients who have received at least one previous therapy. Imbruvica works by blocking the enzyme that allows cancer cells to grow and divide. In November 2013, the FDA granted Imbruvica accelerated approval to treat patients with mantle cell lymphoma, a rare and aggressive type of blood cancer, if those patients received at least one prior therapy.

• The FDA has approved GlaxoSmithKline's (www.gsk.com) **Mekinist® (trametinib)** for use in combination with Tafinlar® (dabrafenib) for the treatment of patients with unresectable melanoma or metastatic melanoma with BRAF V600E or V600K mutations. These mutations must be detected by an FDA-approved test. Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma. The FDA approved the combination of Mekinist and Tafinlar under the agency's accelerated approval program.

Drugs in the News

• Spectrum Pharmaceuticals (www.sppirx.com) announced that its new drug application (NDA) for **Beleodaq**, a novel pan-histone deacetylase (HDAC) inhibitor, has been accepted for filing by the FDA and granted priority review. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date of August 9, 2014. Spectrum is seeking approval of Beleodaq for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (R/R PTCL).

• The FDA has granted orphan drug designation to **BL-8040** (BioLineRx, www.biolinerx.com) as a treatment for stem-cell mobilization. The orphan drug designation was granted for use of BL-8040, in combination with granulocyte colony-stimulating factor (G-CSF), to mobilize human stem cells from the bone marrow to the peripheral blood for collection for autologous or allogeneic (donor-based) transplantation. It is in addition to the orphan drug designation previously granted to BL-8040 as a treatment for acute myeloid leukemia (AML).

Approved Devices

• Miltenyi Biotec (www.miltenyibiotic.com) announced that the FDA has approved the company's **CliniMACS CD34 Reagent System** as a humanitarian use device for the prevention of graft-versus-host disease (GVHD) in patients with AML in first complete remission undergoing allogeneic stem cell transplantation (SCT) from a matched related donor. The FDA approval was based on data from a Phase II, single-arm, multi-center study (BMT CTN 0303) conducted by the Blood and Marrow Transplant Clinical Trials Network.

• **ProBeam™ proton therapy system** (Varian Medical Systems, www.varian.com) has received FDA 510 (k) clearance. The system's scanning beam technology enables intensity-modulated proton therapy (IMPT) by modulating dose levels on a spot-by-spot basis throughout the treatment area. Irradiations from multiple angles are combined in an optimal manner to improve control of dose distributions. Scanning beam technology also eliminates the time-consuming need to manually insert separate shaping accessories for each beam angle in order to match the beam to the shape of the tumor.

• IMRIS Inc. (www.imris.com) announced it has received FDA clearance for the newest generation **VISIUS® Surgical Theatre**, which integrates Siemens' latest high-field MRI scanners. The new core imaging technology based on Siemens Aera 1.5T (tesla) and Skyra 3.0T technology helps IMRIS deliver better image quality with higher signal-to-noise ratio, faster 3D image acquisition, and improved ease-of-use and workflow during neurosurgical procedures using intraoperative MRI.

Genetic Tests and Assays in the News

• **Ventana HER2/neu (4B5) Rabbit Monoclonal Primary Antibody Assay** (Ventana Medical Systems, Inc., http://ventana.com) can be used as a companion diagnostic for detecting HER2 protein expression for patients who, in countries where they are approved, may be appropriate candidates for Perjeta® (pertuzumab) and Kadcycla™ (ado-trastuzumab emtansine). OI

spotlight

Torrance Memorial Medical Center

Hunt Cancer Institute, Torrance, California

RN team building during Oncology Nursing Collaborative.

The Torrance Memorial Medical Center (TMMC) Hunt Cancer Institute, accredited by the American College of Surgeons (ACoS) as a Comprehensive Community Cancer Center since 1980, is one of only three centers in California to achieve the Commission on Cancer's Outstanding Achievement Award (2012).

TMMC serves the South Bay area of California, a coastal region of the southwest peninsula of Los Angeles County which boasts spectacular views of the Pacific Ocean. Charlene Cottrell, RN, Director, emphasized that TMMC strives to offer excellence in both diagnostic services and treatment close to home, so patients do not need to go outside the community or seek out tertiary centers for the majority of their oncology care.

A Robust Oncology Service Line

All oncology care services are housed on the Torrance Memorial Hospital campus, a free-standing not-for-profit facility.

Outpatient infusion and medical offices are in separate buildings near the main campus. TMMC's radiation oncology department is located in the basement level of the Outpatient Center. This department offers state-of-the-art technology, such as RapidArc®, and recently installed a brand new TrueBeam™ linear accelerator. By spring 2014, TMMC will offer stereotactic body radiation therapy (SBRT) for brain and lung. For thoracic oncology patients, TMMC recently added navigational bronchoscopy and endobronchial ultrasound (EBUS) to treatment options; TMMC uses a da Vinci Surgical System® for prostate and gynecologic procedures.

Infusion services are delivered in two locations. The Specialty Center Infusion unit is the dedicated home for outpatient chemotherapy and is supplemented by the 4E outpatient unit located within the hospital. Inpatient chemotherapy and biotherapy infusions are given in the 2 North Lemkin Pavilion, which is located in the main hospital.

Breast care services are housed on the hospital campus in the Polak Breast Diagnostic Center, which is recognized by the American College of Radiology (ACR) as a Breast Imaging Center of Excellence. It is also ACR-accredited in stereotactic breast biopsy and ultrasound and ultrasound breast biopsy and offers 3D mammography. High patient volumes necessitate a weekly tumor board for this disease site. The breast center has three satellite locations in Carson, Manhattan Beach, and Rolling Hills Estates.

Coordinated Care

Since not all oncology services are delivered in one place, coordination of care is a top priority for staff.

Patient navigation services help ensure coordination of multidisciplinary care from diagnosis through survivorship. TMMC's navigation services began with breast cancer patients—the center's largest disease site—in 2006. The Breast Diagnostic Center has two dedicated nurse navigators. Newly-diagnosed breast cancer patients are given the opportunity, via the nurse navigators, to meet with a medical oncologist prior to any scheduled treatment or surgery. Cottrell said this helps patients to better understand their diagnosis, feel more informed in making treatment decisions, and reduce some of their initial panic.

Navigation services are also available for lung cancer patients, radiation oncology, head and neck patients, and newly-diagnosed colon cancer patients.

Community-Wide Survivorship Care

TMMC continues its coordinated care into survivorship. The South Bay Survivorship Consortium is a robust, community-wide survivorship effort. Initiated in 2009, the program came out of a partnership with UCLA, TMMC, a medical oncology private physician practice, and a large managed-care group. As these providers treated the same patient population in the South Bay area, the Consortium looked at how it could bring survivorship services to the community and educate patients and private practice physicians on issues related to survivorship and survivor follow-up care.

The Consortium also develops educational programs for the community based

Select Support Services

- Cancer Resource Center
- Oncology rehabilitation
- Social work
- Navigation
- Support groups

Number of analytic cases seen in 2012: 1,645

on survivors' requests. Past programs have covered:

- Nutrition and cancer myths
- Sexuality and self esteem
- Cancer and the law
- Genetics and cancer
- Complementary therapies
- Management of post-treatment fatigue.

Cottrell notes that it takes a lot of coordination and dedication to offer community-wide survivorship services.

Oncology Nursing Collaborative

When TMMC received patient feedback that fragmented care occurred across settings along the care continuum, oncology nursing leaders took up the challenge. In 2007 a collaborative was organized to focus on improving inter-departmental communication with a goal to foster a positive patient experience by identifying patient barriers to care. Nurses representing inpatient oncology, outpatient infusion, palliative care, radiation oncology, the breast center, and the Cancer Resource Center meet monthly to discuss how to improve the cancer patient experience. These meetings have led to shared problem-solving, process improvement projects geared toward patient education and safety, and interdisciplinary projects to address issues with navigation, rehabilitation, and other supportive services. Patients benefit from the identification of barriers to care, which has led to greater efficiency of care delivered, and overall improved patient education and satisfaction.

Pain Management Quality Improvement Study

TMMC also seeks to improve processes that affect the patient experience. In 2012 inpatient oncology nursing staff initiated a performance improvement project in response to pain, patient experience, and patient satisfaction Hospital Care Quality Information (HCAHPS) scores. Results identified a knowledge gap in pain assessment and pain management strategies and a need for a Pain Resource Nurse (PRN). Outcomes of this project (as of September 2013) include 20 identified PRNs, the launch of a pain education series, and a receipt of a grant to cover the costs of educational materials.

TMMC recently completed another quality improvement project for the Oncology Rehabilitation program. This project assessed patient satisfaction and outcomes. Results from the project were used to improve care coordination and develop strategies to improve patient quality of life.

TMMC also plans to implement distress assessment tools site-wide in order to refer patients to the Cancer Resource Center and oncology social work if needed.

CT Lung Screening Program

In 2011 TMMC began offering a CT Lung Screening Program for early detection of lung malignancy. The program brings together a multidisciplinary group of medical oncologists, radiation oncologists, dedicated surgeons, nurse navigators, and radiologists. The partnership between various departments and radiology ensures that any positive CT scan will be sent to a nurse navigator, who then follows up with both primary care physicians and patients to make sure that no one falls through the cracks. As of July 2013, about 30 patients had undergone screening.

Expansion of Services

Expected to open in 2015 on the Torrance Memorial Hospital campus, the new Lundquist Tower will house all inpatient services. A brand new inpatient oncology unit on the 7th floor will overlook the Palos Verde area of Los Angeles. According to Cottrell, nursing staff, physicians, and donors were heavily involved in the design of the entire floor, especially the patient suites.

The 390,000-square-foot expansion will also feature 256 private patient rooms, 12 operating rooms, and 18 surgery and interventional treatment rooms. With Leadership in Energy and Environmental Design (LEED) accredited staff on the design team, the construction will incorporate environmentally-friendly elements, such as sustainable building materials, natural lighting, and water efficient landscaping. OI

BY ANDREA MCKEE, MD; BRADY MCKEE, MD; CHRISTOPH WALD, MD, PHD; CARLA LAMB, MD FACP, FCCP; PAUL J. HESKETH, MD; AND SEBASTIAN FLACKE, MD, PHD

Rescue Lung, Rescue Life

Translating the NLST results into clinical practice

Lung cancer is the number one cancer killer of men and women in the United States, responsible for approximately 450 deaths every day.[1] In November of 2010, the National Lung Screening Trial (NLST) was halted after a minimum 20 percent disease-specific mortality benefit was observed in participants undergoing three rounds of annual low-dose thoracic CT (CT lung screening) compared to those undergoing chest X-ray evaluation.[2] Four years have passed since closure of the NLST, and while more than a dozen national organizations, including the American Cancer Society and the National Comprehensive Cancer Network (NCCN), recommend CT lung screening (Table 1, page 22), the vast majority of high-risk patients have not enrolled in a screening program.[3-11]

The lack of screening enrollment is somewhat surprising given the magnitude of the mortality benefit and published evidence of significant pre-existing interest among primary care physicians in screening patients at high-risk for lung cancer.[12] Possible causes for this slow adoption include unfamiliarity with new published data in support of CT lung screening and absence of widespread insurance coverage. As a result, even qualified individuals may have to pay out-of-pocket for an exam, which can cost hundreds of dollars.[13] The unavailability of third-party reimbursement may incorrectly suggest to patients and physicians that CT lung screening is either not recommended or of unproven benefit, further weakening enrollment.

In July 2013 the United States Preventive Services Task Force (USPSTF) issued a draft grade "B" recommendation that patients at high-risk for lung cancer undergo annual CT lung screening.[14] The USPSTF defined "high-risk" factors as:

- People ages 55-79
- Those with ≥ 30 pack-year smoking history
- Current or former smokers who have quit within the past 15 years.

The USPSTF grade "B" recommendation was made final on Dec. 30, 2013.[15] with the "high-risk" factors defined as:

- People ages 55-80
- Those with ≥ 30 pack-year smoking history
- Current or former smokers who have quit within the past 15 years.

The Affordable Care Act mandates "first dollar coverage" of preventive services receiving a final USPSTF grade "A" or "B" recommendation.[16]

This article discusses our strategy to translate the NLST results into clinical practice in the face of these challenges and presents necessary building blocks for successful, safe, and responsible CT lung screening program development.

Organizational Change: Preparation

Professor John Kotter of Harvard Business School outlined eight steps necessary to bring about organizational change in his seminal work *Leading Change*.[17] Our team closely followed this roadmap to help overcome the numerous, significant challenges as we established a CT lung screening program at Lahey Hospital & Medical Center (LHMC) (see Figure 1, page 22).

During phase 1 of the process, we began by:

- Creating a sense of urgency around the issue
- Forming a powerful coalition of program champions and supporters
- Creating a vision for our CT lung screening program.

Lung cancer has a disappointing 16 percent five-year survival.[18] In the absence of screening, lung cancer is diagnosed at an advanced stage in two out of three cases—typically after a patient has become symptomatic.[19] The NLST showed that diagnosing these patients in the pre-symptomatic phase of the disease saves lives. In the NLST population, 1 percent of participants were found to have cancer on the initial CT lung screening exam. Other trials have reported even higher prevalence rates.[20] As a result, we know that at least 1 in 100 of our patients with a risk profile similar to the NLST already has lung cancer and could benefit from early detection. Extrapolating this experience to the entire U.S. population, we estimate that there are between 9 and 10 million individuals who meet the USPSTF high-risk profile of which approximately 100,000 are currently living with undiagnosed, potentially treatable lung cancer.[14] Making CT lung screening accessible to this population has the potential to save 50 of the 450 lives lost each day to lung cancer.[21] There is an urgent need to act immediately to rescue these individuals harboring this lethal disease.

Shortly after publication of the NLST, our team at LHMC concluded that eliminating self-pay rates and raising patient and physician awareness about the proven ability of CT lung screening to save lives could unlock the latent need and demand for screening and allow us to begin realizing the mortality reduction promised by the NLST. We did not have any previous experience in CT lung screening (LHMC did not participate in the NLST, I-ELCAP, or other CT lung screening research trials), nor were we able to find any existing models of high-volume clinical CT lung screening to use for guidance. Much work lay ahead for us to begin offering responsible and ethical CT lung screening as a community benefit equally available to all high-risk individuals, regardless of socio-economic status.

In the fall of 2011 physicians, administrators, and staff from the departments of internal medicine, pulmonary and critical care, laboratory medicine, radiation and medical oncology, thoracic surgery, and radiology founded the Rescue Lung, Rescue Life movement at Lahey Hospital & Medical Center with the following mission:

Table 1. Societies Recommending CT Lung Screening

• National Comprehensive Cancer Network
• American Lung Association
• American Thoracic Society
• American College of Chest Physicians
• American Society of Clinical Oncology
• American Association for Thoracic Surgery
• American Cancer Society
• American Association of Bronchology and Interventional Pulmonology
• Society of Thoracic Radiology
• Society of Thoracic Surgeons
• International Association for the Study of Lung Cancer
• Oncology Nursing Society
• European Society of Thoracic Surgeons
• American College of Radiology
• Cancer Care Ontario

Figure 1. Rescue Lung, Rescue Life Implementation of Kotter Model for Organizational Change

1. Create a Sense of Urgency 2. Form a Powerful Coalition 3. Create a Vision	< PREPARE >	1. Rescue Lung, Rescue Life 2. Steering Committee 3. Hospital Mission
4. Communicate the Vision 5. Remove Obstacles	< IMPLEMENT >	4. Approval 5. CME Campaign, Demystify, LungRADS, Radiology Infrastructure
6. Create Short-Term Wins 7. Build on the Change 8. Embed the Change into the Culture	< MANAGE >	6. Quality and Safety Metrics 7. Research 8. Steering Committee Governance

- Save lives through early detection of lung cancer with responsible CT lung screening
- Encourage the government to establish reimbursement for responsible CT lung screening
- Encourage other centers of excellence in the treatment of lung cancer to offer responsible *free* CT lung screening until CMS establishes reimbursement
- Break down barriers and prejudice faced by those at risk for lung cancer
- Raise public awareness of the power of responsible CT lung screening to save lives
- Provide a platform to explore relevant research questions.

To offer CT lung screening as a community benefit, we needed strong support from the numerous clinical and administrative departments touched by the screening process. Common to all clinical CT lung screening programs is the fact that 100 percent of patients interact with the radiology department. A much smaller proportion of screened patients will be seen by interventional radiology for diagnostic and therapeutic procedures.

To achieve cost-effective, decentralized screening, our program requires the primary care team and/or referral base to partner with radiology to identify, inform, and follow all eligible patients. Patients with suspicious findings—in our experience about 4 to 5 percent of individuals screened—are referred to pulmonary medicine. This department assumes the role of "quarterback" in these cases, directing care escalation with support from our multidisciplinary thoracic oncology group, which includes the departments of pulmonary medicine, pathology, radiology, medical and radiation oncology, and thoracic surgery.[22]

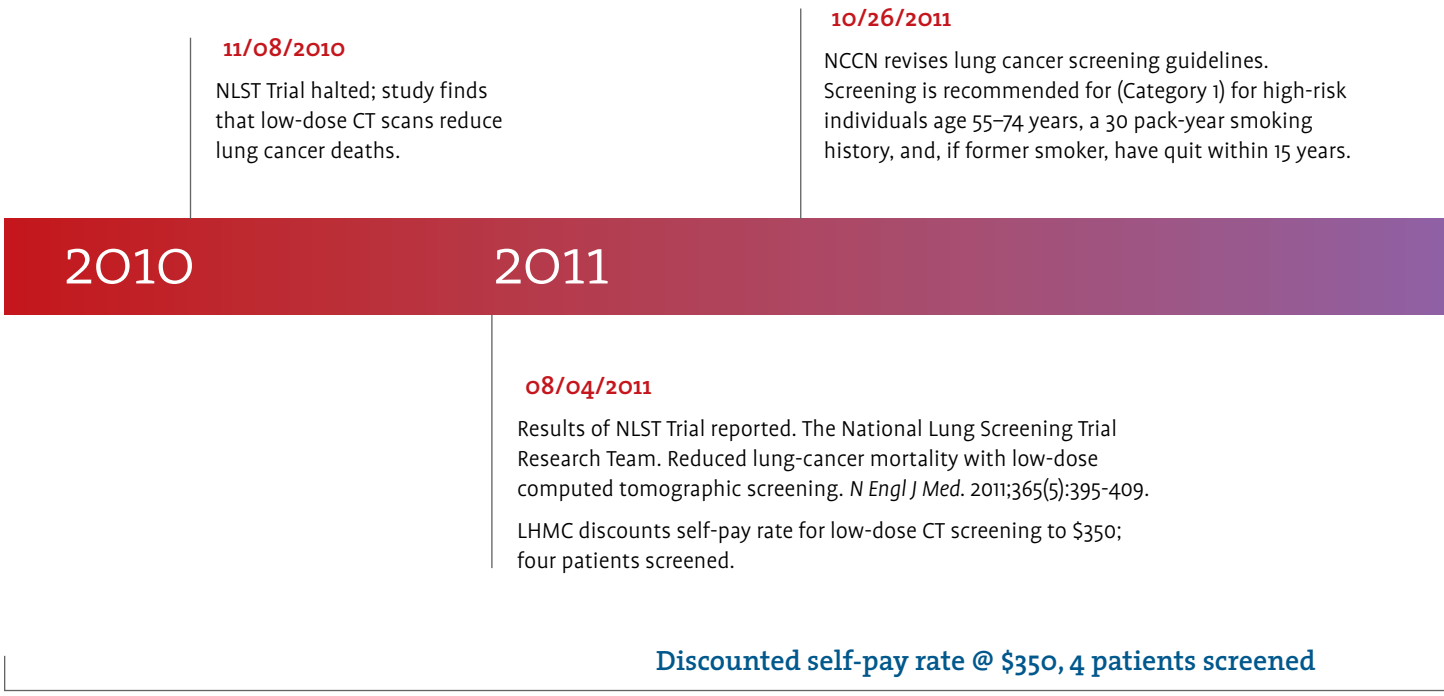
To achieve cost-effective, decentralized screening, our program requires the primary care team and/or referral base to partner with radiology to identify, inform, and follow all eligible patients.

For community-based physician-owned practices, equivalent

Figure 2. Rescue Lung, Rescue Life Steering Committee Members

CLINICAL	ADMINISTRATION
Radiology • Section Head Thoracic Imaging • Vice Chair Clinical Services • Vice Chair Research • Section Head Interventional Radiology • Chief Resident	**Senior** • VP Hospital-Based Clinical Services • VP Cancer Services • Associate Chief Nursing Officer
Primary Care • Chair General Internal Medicine • Resident Representative	**Radiology** • Administrative Director • Rescue Lung, Rescue Life Program Coordinator • Department Manager, CT • Department Manager, Nuclear Medicine
Pulmonary Medicine • Chair & Chief Medical Officer • Director of Interventional Pulmonology • Residency Director	**Cancer Services** • Department Manager, Radiation Oncology • Specialty Program Coordinator, Radiation Oncology • Rescue Lung, Rescue Life Program Coordinator
Oncology • Chair Radiation Oncology • Cancer Center Medical Director	**Marketing**
Thoracic Surgery	**Business Development**
Laboratory Medicine	**Philanthropy**

Figure 3. Rescue Lung, Rescue Life Program Development Timeline



alliances between leading subspecialty practices in a geographic area may be formed to serve the same purpose and represent an opportunity for physicians in the community to distinguish themselves as leaders across specialties and build their respective practices. In addition to these clinical specialties our team needed support from finance, compliance, legal, and philanthropy to assess the impact of offering screening as a community benefit prior to the initial rollout of the program.

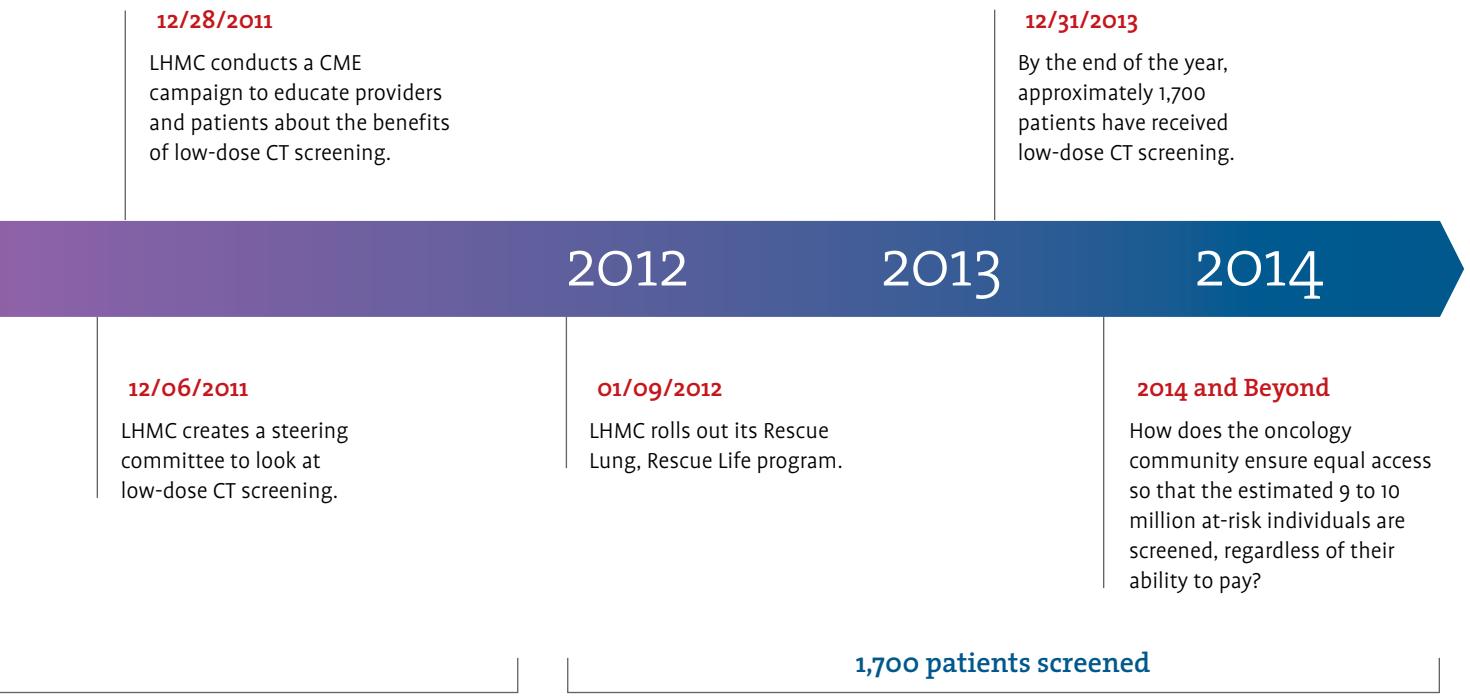
Senior members of the various involved specialties joined together to form the Rescue Lung, Rescue Life steering committee. This powerful coalition guides program development, provides a common forum to establish consensus, and perhaps most importantly acts in concert to overcome obstacles to program implementation (Figure 2, page 23). We specifically invited members for their proven ability to advocate for patients, design program systems, and support implementation on behalf of their specialty.

A radiology working group was created to manage day-to-day operations within the Radiology Department and to report program metrics and opportunities for program improvement back to the steering committee. Participants included thoracic radiologists, radiology administration, information technology, scheduling, and ad hoc representation by members of our mammography team. All infrastructure and systems developed to manage program implementation were designed in concert by the radiology working group and the steering committee.

Presented with this unique opportunity to fulfill the LHMC mission to save lives, grow, innovate, establish sustainability, and promote teamwork, our senior leadership approved the Rescue Lung, Rescue Life program to be run as a community benefit. We set a go live date of January 9, 2012, which gave us six weeks (through the holiday season) to begin to fulfill the Rescue Lung, Rescue Life mission of offering CT lung screening at no cost to patients who met the NCCN Lung Cancer Screening Guidelines® high-risk definition and several LHMC criteria:[3]

- Group 1 (NCCN Category 1 recommendation)
  - 55-74 years of age, 30 pack-year smoking history, quit < 15 years
  - Same as NLST study population
- Group 2 (NCCN Category 2B recommendation)
  - Aged >50 years and older, > 20 pack-year smoking history
  - Require at least one additional lung cancer risk factor, such as:
    - Personal history of smoking-related cancer
    - History of lung cancer in a first degree relative
    - Chronic lung disease, including IPF (idiopathic pulmonary fibrosis) and emphysema
    - Exposure to several known carcinogens
- Additional LHMC qualification criteria
  - Asymptomatic at time of screening
  - Free of lung cancer diagnosis within the past five years
  - No known metastatic disease
  - Order for exam from patient's physician prior to the exam.

Figure 3, above, shows a timeline of Rescue Lung, Rescue Life program development.



Organizational Change: Implementation

In phase 2, our team's goals were to: 1) communicate the vision to all stakeholders, patients, primary care physicians, and the community, 2) remove barriers to implementation, and 3) create short-term wins. Offering CT lung screening as a community benefit mitigated the most formidable barriers to program success, however, significant additional obstacles lay ahead (see Figure 4, page 26).

The Henry Ford Motor Company's assembly line innovations streamlined automobile production and ushered in an era of efficient and cost-effective manufacturing.[23] In a similar manner, scalable, cost-effective screening requires distribution of work responsibilities among the many involved disciplines to ensure success. For example, primary care physicians (PCPs) are preventive care experts who discuss the risks and benefits of a variety of screening choices with their patients on a daily basis. Armed with knowledge from NLST on the benefits and risks of CT lung screening, PCPs are ideally positioned to guide patients in making a decision to enroll in a CT lung screening program. For high-risk patients this discussion may be integrated into their annual well-patient visit without creating an additional patient encounter. CT lung program staff can work with the primary care base to ensure all referred patients meet high-risk criteria and to provide patients and ordering physicians access to additional lung screening resources as needed. The Program Coordinator and the Program Navigator work directly with physicians and patients to provide the needed resources. We believe that a requirement of centralized specialty and multidisciplinary consultation *prior* to enrollment usurps the role of the primary care physician and creates additional barriers to patient access by increasing costs and limiting scalability. Therefore, we advise against that model. Decentralizing patient enrollment through primary care well-patient visits with support from CT lung screening program staff eliminates such barriers and puts the screening discussion into the hands of those physicians most experienced and best positioned to advise patients on screening decisions.

Overcoming many remaining identified barriers required special focus in two important domains, a continuing medical education campaign by LHMC cancer services and infrastructure development in radiology. These components have previously been published in the *Journal of the American College of Radiology* and are reviewed below.[22]

Primary Care Initiative. We anticipated high patient volumes because our program was the only program in the state offering lung cancer screening at no charge to the patient. Using our current mammography volume as a benchmark and the ratio of the number of U.S. women who qualify for mammography to the number of high-risk individuals who qualify for CT lung screening (6:1), we projected LHMC should perform 100 screening exams per week at a steady state.[14, 24]

We currently enroll 20 to 30 new patients and perform around 50 total screening exams each week. The vast majority of patients enter our screening program through a direct referral by their PCP. Patients may self-refer for eligibility assessment, but we must receive an order for screening from their physician prior to screening.

To prepare and enable PCPs to have effective screening enrollment discussions with their patients, we needed to dispel

Figure 4. Obstacles to Program Implementation

- Patient Access
- Uninsured Patients
- Patient Anxiety
- Long Debate
- Busy Practices
- Informed Decision Making
- False Positives
- Competing Demands for Funds
- Cost to Society
- Radiation Risk
- Fear of Encouraging Smoking
- PCP Acceptance
- Managing Findings

misconceptions resulting from the decades-long controversial debate over CT lung screening. During the six weeks leading up to our program launch date, steering committee members conducted numerous face-to-face CME events with local PCP groups to present facts from the NLST, detail the risks and benefits specific to CT lung screening, and explain opportunities to integrate smoking cessation counseling. We reassured our PCP base that the program would be modeled after mammography, most importantly using a structured reporting system with clinical recommendations linked to specific findings, and centralized tracking of patient appointments managed through the radiology department. This model was critical in building support. We discussed the medico-legal risk associated with failure to inform high-risk patients of the proven life-saving potential of CT lung screening in light of the growing number of national medical society endorsements.[25] Finally we emphasized that undergoing screening at LHMC in no way obligates any patient to return to LHMC for follow-up of any findings on the CT lung screening exam or for any other services provided by LHMC as a result of undergoing the initial screening exam.

Radiology Systems. Prior to program inception, LHMC's Rescue Lung, Rescue Life team created a reporting and data system "LungRADS," modeled after BI-RADS® but specifically adapted for the needs of CT lung screening.[22] LungRADS consists of several elements, including an overall exam assessment score, a nodule lexicon, and a structured reporting system (Figure 5, right). As in mammography, a CT lung screening structured reporting and data system links screening findings with standard guideline recommendations and provides a common language to communicate results among members of the care team. In conjunction with our in-house designed CT lung screening database, LungRADS creates a mechanism to track patients, audit results, and facilitate research and training. LungRADS also helps avoid care escalation in those patients unlikely to have lung cancer by triaging high-risk patients into appropriate risk categories based on their screening exam.

Program Statistics. The radiology working group publishes program statistics regularly for steering committee review.

Weekly reports include:

- New inquiries and orders: NCCN Group 1, NCCN Group 2, and Group 3 (not qualified)
- Patients scheduled
- Patients screened: initial and repeat (annual) and interval.

Bi-monthly reports include:

- Positive screens (LungRADS 3 and 4)
- Suspicious screens (LungRADS 4)
- PET/CT
- Biopsies
- Surgeries
- Pathology
- Significant incidental findings
- Complications.

We benchmark results against the corresponding NLST metrics for quality assurance. Opportunities for process improvement are discussed and important program decisions are made collectively through the steering committee. These measures create short-term wins necessary for program sustainability. Since initiating the clinical CT lung screening program, LHMC has screened over 1,700 unique patients (~20 percent from NCCN Group 2) and initial results are similar to those reported in the NLST.[2, 22]

Organizational Change: Management

In phase 3, our team looked to build on the change and embed the change into the culture.

LHMC now has multiple research projects underway to identify methods to further improve on the process of CT lung screening, as well as maintaining engagement of the various involved departments. The evidence-based structured reporting algorithms developed to administer the lung screening program have been well received. In fact, clinical departments have requested that radiology develop a similar structured approach for other disease sites and applications. Our primary care teams have taken the initiative to

build identifiers within the organization's incoming electronic health record (EHR) to automate and facilitate the identification of high-risk patients, thus facilitating their process during the patient office visit.

To accelerate opening access to responsible CT lung screening throughout the U.S., members of our steering committee have presented the Rescue Lung, Rescue Life program at regional, national, and international scientific meetings. We have also made our screening materials and management systems available online at no cost. To date, over 400 centers from around the world have downloaded the more than 40 available documents. We hope that free sharing of our materials reduces the operational barriers to CT screening program development by other cancer programs.

Lessons Learned

For cancer programs looking to implement a similar CT lung screening program, our team shares these lessons.

Change is hard. The more people that are required to make it happen, the harder the change is to bring about. Following proven frameworks for organizational change can help successfully implement organization-wide initiatives, such as the Rescue Lung, Rescue Life CT lung screening program at LHMC.

CT lung screening program development is a team sport. Individual physicians or disciplines cannot do it alone. A successful CT screening program divides the work among appropriate members of the care team and respects the expertise each team member and discipline brings to the program.

Screening in high volume presents its own set of challenges, which will not become widely recognized until reimbursement barriers are removed. A reporting and data system (e.g., LungRADS) is an absolute requirement to effectively manage a high-volume program.

Dr. McKee confers with LHMC's Chief Therapist.

An integrated IT infrastructure in the imaging department, which allows tracking of findings and facilitation of appropriate patient follow-up, is necessary to perform safe, responsible CT lung screening.

Standardized diagnostic work-up protocols for both operable and medically inoperable patients must be established at screening sites given the relatively high percentage of medically inoperable patients we have observed within the high-risk groups (about 25 percent in our program).

Decentralized access to the screening program is necessary for cost-effective, efficient, high-volume screening.

In the absence of a national education campaign, a local CME campaign is required to engage the organization or geographic PCP base. Our experience has been that once educated about the risks and benefits of screening, high-risk patients do enroll in screening programs.

A well-organized, multidisciplinary CT lung screening program offers an extraordinary opportunity to develop research initiatives directed to optimize the screening process and address the many unanswered questions pertaining to early lung cancer diagnosis.

Figure 5. LungRADS Overall Exam Assessment: Part 1

CT LUNG SCREENING REPORTING AND DATA SYSTEM (LungRADS)

Lung Cancer Specific Category (BI-RADS® Based)		NCCN-Guidelines® Based Follow-up Recommendation
Category	**Assessment**	
1	Negative	Routine annual LDCT screen (age < 75)
2	Benign	Routine annual LDCT screen (age < 75)
3	Probably Benign	Interval short-term diagnostic LDCT (1, 2, 3, 6, 12 months)
4	Suspicious	Pulmonary consultation and multidisciplinary clinic review
5	Known Malignancy	PCP and oncology referral

Going Forward

Responsible CT lung screening programs can serve as a model for value-based healthcare delivery as envisioned by the Institute of Medicine (IOM) and Centers for Medicare & Medicaid Services (CMS). The IOM report "Delivering High Quality Cancer Care: Charting a New Course for a System in Crisis" describes a healthcare delivery system in crisis with contributing factors that include an aging population, increasing complexity of cancer care, a shrinking work force, and rising costs.[26] The IOM conceptual framework asks healthcare teams and stakeholders to develop care delivery models that engage patients in decision making. Similar to Rescue Lung, Rescue Life, these models:

- Use a coordinated and adequately trained workforce to the highest level of their abilities
- Provide evidenced-based cancer care
- Use informatics for process improvement
- Translate research into clinical practice
- Provide accessible, affordable cancer care to patients.

CMS has developed measure domains intended to focus stakeholders on developing systems to reduce potential for patient harm; provide superior patient and caregiver experiences and outcomes; systematically coordinate complex care; provide better access to evidence-based strategies proven to reduce mortality and improve outcomes; and develop strategies to improve efficiency and reduce costs.[27] Figure 6, below, illustrates the linkage between the CMS measure domains and design elements of our Rescue Lung, Rescue Life CT lung screening program.

Now that the USPSTF recommendation is final—removing the reimbursement barrier—cancer programs interested in CT lung screening will be challenged by their administrators and the physician and patient base to quickly implement delivery systems needed for responsible, safe screening. We hope that LHMC's Rescue Lung, Rescue Life program can serve as a demonstration of a scalable CT lung screening program design that achieves results similar to those reported in the NLST and paves the way for access to lung cancer screening for the millions of individuals at high-risk not currently enrolled.

By preventing one in five lung cancer deaths in the high-risk population, CT lung screening has the power to rescue tens of thousands of U.S. lives per year. To realize this potential, the medical community must work together to expedite insurance coverage, develop a national education campaign, and build the local program infrastructure needed to make responsible CT lung screening equally accessible to all those at high-risk to develop this deadly disease. OI

Figure 6. CMS Measure Domains

DOMAINS	VALUE BASED DELIVERY SYSTEM
Safety	Reduce potential for patient harm • Unnecessary testing in LungRADS category 3 group • Wrong screening test • Fabrication of symptoms
Patient and Family Experience and Outcomes	Reduce cost to patient Lower burden of Stage IV disease
Care Coordination	Standardize communication among providers
Clinical Care	Prevention Improved outcomes
Population of Community Health	Reduce healthcare disparities Improved access with PCP involvement Integrated smoking cessation
Efficiency and Cost Reduction	Avoid high-cost, low-quality specialty clinics • Centralized specialty clinics that are resource intensive • High marketing costs • Limit litigation risk

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A Model Rural Chemotherapy Program

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IT WAS IN ABERDEEN, SOUTH DAKOTA, population 26,000, where third-grade teacher Pam White received a diagnosis of stage 4 breast cancer. Aberdeen is in the heart of the Northern Great Plains. Major cities are separated by several hours of driving, and the harsh winter climate can often make travel impossible. It was also in Aberdeen where Pam chose to receive her cancer treatment.

"My school is literally across the street from the clinic. I could see my kids playing on the playground," Pam said. "The clinic is just one mile from my home. Knowing that I'm getting excellent care without having to travel through the snow is such a gift."

Thanks to the Rural Chemotherapy Project initiated by the Avera Cancer Institute, Pam could be assured that she was receiving the same high level of care in Aberdeen that she would receive more than three hours away in the larger city of Sioux Falls.

As a complex diagnosis, cancer requires multidisciplinary, multimodality care; a detailed treatment plan; and exact adherence to that plan for best outcomes. The proper administration of chemotherapy according to widely accepted care standards is vital.

The Problem

In 2011 Avera Cancer Institute, Sioux Falls, S.D., noticed an increase in questions from outside facilities asking for assistance when preparing and administering chemotherapy. This uptick in requests gave the cancer care team cause to reexamine its care protocols. Specifically, staff from outlying areas, as well as patients, were expressing concerns about inconsistencies between protocols and processes at the Avera Cancer Institute and those at rural care locations. It soon became clear to the cancer care team that standards were not clearly defined, nor implemented, at all locations where Avera Cancer Institute medical oncologists referred patients for chemotherapy.

The Solution

In response, Avera Cancer Institute's physician-led Cancer Leadership Committee met and subsequently approved the formation of a Rural Chemotherapy Committee to identify solutions to the problem. The Rural Chemotherapy Committee consists of leaders from various aspects of cancer care delivery, including compliance, environmental safety, infusion center, pharmacy, and administration. Through relationships and professional connections, this committee looked to ensure patient safety by implementing unified chemotherapy administration standards among facilities both in and outside of the Avera network. The committee's goal was two fold:

- To establish guidelines and standards of practice at all rural sites outside of the Avera Cancer Institute in an effort to validate patient safety when receiving chemotherapy
- To create a checklist and maintain accountability of all chemotherapy administration sites annually.

Teams from multiple service lines and disciplines came together to develop the checklist and a plan that addressed safety, education, practice, compliance, and supervision when administering chemotherapy (see Figure 1, page 32). The checklist addresses facility requirements, for example:

- Is there a properly ventilated and certified chemotherapy hood or biologic safety cabinet?
- Is there proper personal protective equipment (PPE) for those working with chemotherapy drugs?
- Is a chemotherapy spill kit readily available?

(continued on page 33)

Figure 1. Chemotherapy Preparation and Administration Checklist

(Check each box that is met)

☐ A properly ventilated and certified chemo hood or biologic safety cabinet must be utilized for chemotherapy preparation.

☐ Non-pharmacy personnel must complete the Chemochek™ Training and Certification Program prior to preparing chemotherapy.

☐ Appropriate personal protective equipment for mixing, administering, and clean-up must be available in sufficient quantities prior to implementation of program. Appropriate polices must be in place.

☐ A chemotherapy spill kit must be readily available where chemotherapy is mixed and where chemotherapy is administered.

☐ Where the potential for chemotherapy exposure is greatest, eye-wash station must be available within 10 seconds along an un-obstructed pathway.

☐ A hazardous waste handling policy must be in place prior to mixing or administering any chemotherapy agents.

☐ Nurses must obtain chemotherapy and biotherapy certification through the Oncology Nursing Society's (ONS) core curriculum and maintain certification with renewal every two years.

☐ First doses of the following chemotherapy infusions are preferred to be given in Sioux Falls due to the high rate of reactions to the drugs.

- Rituxan
- Herceptin
- Taxol
- Erbitux
- Avastin
- Bleomycin

☐ All of the following medications need to have appropriate first responder staff available on site to respond to reactions.

- Rituxan
- Cisplatin
- Taxotere
- Taxol
- Bleomycin
- Vectibix
- Carboplatin
- Oxaliplatin

☐ Sites must have a co-signing physician in the facility. This is a billing and payment requirement by the payers, as well as a requirement by CMS (Centers for Medicare & Medicaid Services) to have a supervising physician available in the local facility.

OR

☐ The bylaws created by medical staff at our facility addresses who can order chemotherapy at our setting and who is responsible for the supervision while the chemotherapy is taking place in our facility.

We have read, understand, and meet all the elements listed above.

Facility Name: .....

Signature of Director of Nursing, Manager, or Other Designee: .....

Contact Email: .....

Contact Phone: .....

(continued from page 31)

- Are there eye-wash stations that can be accessed within 10 seconds?
- Is a hazardous waste handling process in place?

Pharmacy staff offered valuable input into the process, reviewing national standards for safety of the patient and the staff preparing the chemotherapy. At Avera Cancer Institute, staff must demonstrate competency in mixing or preparing chemotherapy, and the Rural Chemotherapy Committee felt very strongly that staff in rural settings should complete a similar competency. So, the checklist also addresses staff training.

Regardless of location, all non-pharmacy personnel are required to complete the Chemochek™ Training and Certification Program prior to preparing chemotherapy. Registered nurses must obtain chemotherapy and biotherapy certification with renewal every two years. The Chemochek Training and Certification Program:

- Offers performance-based testing to help users master the skills needed to prepare chemotherapy drugs
- Informs preparers of the risk associated with handling hazardous drugs and precautions that should be taken to reduce exposure
- Provides a system to evaluate knowledge in safe preparation, administration, handling, and disposal of chemotherapy drugs.

The Rural Chemotherapy Project checklist spells out that patients will receive their first doses of certain medications at the Avera Cancer Institute in Sioux Falls, due to the high rate of reactions. The list stipulates medications that cannot be given unless first-responder staff is available.

The checklist also specifies that sites must have a supervising physician, or bylaws created by medical staff stating who is responsible for supervision of chemotherapy at a given site.

To complement its checklist and plan, the Rural Chemotherapy Committee developed and presented webinars to provide additional education and answer questions.

Roll Out

Next, the Rural Chemotherapy Committee needed to identify the sites that should receive the checklist and webinar information. (The Avera Health network is comprised of more than 300 locations in 100 communities throughout a five-state region.) Chemotherapy was taking place not only at rural hospitals, but also at community clinics in and outside of the Avera network. With the help of front-line staff, the Rural Chemotherapy Committee identified 45 sites that administer chemotherapy from direction and orders issued by Avera Cancer Institute oncologists.

Pictured, from left, are Rhonda Roesler, Executive Director of Compliance and Medical Support Services at Avera McKennan; Kris Gaster, Assistant Vice President for Outpatient Cancer Clinics at the Avera Cancer Institute; Emily Laible, Avera McKennan Pharmacy Supervisor; Crystal Enstad, Infusion Center Manager at the Avera Cancer Institute; Kathy Jacobs, Safety Director at Avera McKennan; and Ann Heiman, Director of Cancer Services at Avera McKennan.

As a first step, letters were mailed to the 45 identified sites in October 2011. Then, members of the Rural Chemotherapy Committee presented the checklist and plan to various groups, including Avera regional managers, directors of nursing, and clinic managers.

Three mandatory educational webinars were scheduled in December 2011 and early January 2012; personnel from all 45 participating sites attended.

These sites were required to complete and return the Rural Chemotherapy Project checklist to the Avera Cancer Institute by March 1, 2012. For facilities that could not comply with the requirements and facilities that needed help with an action plan, the Rural Chemotherapy Committee provided a contact person to help address non-compliance issues and/or barriers.

When the Rural Chemotherapy Project checklists were returned, the committee determined that 10 of the 45 sites were not administering chemotherapy at that time. A total of 30 facilities were in full compliance, or had an action plan that was approved by the Rural Chemotherapy Committee.

The Tool & Plan at Work

Deb Baumann, RN, has been a nurse at Avera Marshall Regional Medical Center since she graduated from nursing school 37 years ago. Fifteen years ago, she was instrumental in helping the hospital set up its oncology program, which serves a community of approximately 14,000 people.

Avera Marshall cares for local cancer patients who are referred from numerous locations, including Sioux Falls. Mark Huber, MD, a medical oncologist at Avera Cancer Institute sees patients at this rural location twice a month.

Baumann consulted with experts in Sioux Falls when helping to set up the cancer program at Avera Marshall Regional Medical Center. Today Avera Marshall plans to build its own local cancer center. While Avera Marshall had most of the items on the Rural Chemotherapy Project checklist in place, one item that needed to be addressed was designation of a supervising physician, as Marshall does not as yet have a local oncologist. The solution: appointing 24-hour hospitalists at Avera Marshall to fill the supervisory role. When Avera Marshall opens its cancer center, a nurse practitioner director will assist Dr. Huber with patient care.

Lessons Learned

For cancer programs looking to implement a similar program, the Rural Chemotherapy Committee offers several key takeaway messages. For example, recognize that there is always room to improve, learn, and grow.

Ensure that patient perception is a key focus of the initiative. Imagine if a patient was receiving chemotherapy at a site that did not have the competency to provide certain treatments and had to call the Avera Cancer Institute for direction. That patient might feel insecure and unsafe about the treatment. The Rural Chemotherapy Project provided assurance to patients who were receiving treatment via orders from Avera oncologists that they were receiving care from a facility and staff that were competent, safe, and efficient in chemotherapy administration.

As part of this collaborative effort, physicians, staff, and administrators from rural sites should assist in developing the processes and policies for their own unique facilities, thereby ensuring shared ownership of the project.

Use a central location, such as the Avera Cancer Institute, to develop and implement the policies and tools as it ensures that all participants are on the "same page" and allows rural locations to focus on direct patient care because they do not have to reinvent the wheel.

Avoid blame or finger pointing. Rather, look at this opportunity as collaboration—a way to educate, share, and support a better understanding of expected competencies and regulations with regards to chemotherapy administration. As part of this collaborative effort, physicians, staff, and administrators from rural sites should assist in developing the processes and policies for their own unique facilities, thereby ensuring shared ownership of the project.

The Rural Chemotherapy Committee worked with participating sites in various ways:

- Avera Cancer Institute safety personnel assisted with identifying where the potential for chemo spills was the greatest, and assessing if eye-wash stations were compliant with current regulations.
- Avera Cancer Institute nursing management provided information about when the Oncology Nursing Society offered core curriculum classes and how to get scheduled and renewed every two years.
- Avera pharmacy staff assisted with recommendations on certification and training for anyone mixing chemotherapy. They explained regulations and assisted with supplier information and best pricing.
- Avera Cancer Institute nursing staff assisted with policy recommendations related to nursing.
- The Avera McKennan Safety Department assisted with

The Avera Health network is comprised of 300 locations in 100 communities across a five-state region.

education about and implementation of an OSHA hazardous waste handling policy.
- The Avera Compliance Department assisted with recommendations of language in the bylaws of the rural sites to address the supervision requirements.
- Avera Cancer Institute nursing staff addressed appropriate personal protective equipment and supplied regulations and vendor information.

Where We Are Today?

Post the March 2012 deadline, five facilities continued to work with the Rural Chemotherapy Committee with action plans and policy and procedure reform and became compliant with the Rural Chemotherapy Project checklist by June 2012. Also in June, a new site—McHale Institute—joined Avera, and three additional sites were identified as participants in the Rural Chemotherapy Project. The committee provided education at these four sites, all of which completed the checklist by August 2012.

The Rural Chemotherapy Committee shared project outcomes with cancer leaders and front-line staff, who continue to identify any new sites or areas of concern. The Rural Chemotherapy Committee meets quarterly and continues to hold all participating sites accountable to the initiatives in the checklist.

Certainly, improved patient care was a major outcome of the project. Yet participating organizations benefitted as well. The Rural Chemotherapy Project allowed these sites to continue to deliver quality service in their community and strengthened the relationship between referring rural sites and specialists at the Avera Cancer Institute. Most important, the Rural Chemotherapy Project allows patients to feel safe under the Avera Cancer Institute's standards of administration, giving them the same quality of care and allowing them to be supported by their loved ones in their home community. OI

Rhonda Roesler, RNC, BSN, MS, is executive director of Compliance and Medical Support Services at Avera McKennan; Kris Gaster, RN, MSN, CNP, CNS, is assistant vice president for Outpatient Cancer Clinics at the Avera Cancer Institute; Emily Laible, Pharm D, is Avera McKennan pharmacy supervisor; Crystal Enstad, RN, BSN, OCN, is infusion center manager at the Avera Cancer Institute and a leader of the Rural Chemotherapy Project; Kathy Jacobs, RN, CHSP, CHEP, is safety director at Avera McKennan; and Ann Heiman, MPT, MBA, is director of Cancer Services at Avera McKennan, Sioux Falls, S.D.

OUR PROGRAM AT-A-GLANCE

The Avera Cancer Institute is a community cancer center situated in South Dakota's largest city of Sioux Falls. It is part of an integrated delivery network that includes Avera McKennan Hospital & University Health Center in Sioux Falls, as well as 115 locations in more than 50 communities in four states. Avera carries on the healthcare legacy of its sponsors, the Benedictine and Presentation Sisters. The Presentation Sisters founded McKennan Hospital more than 100 years ago, and the Benedictine Sisters founded other South Dakota hospitals, which are part of the Avera system. Avera's mission is to deliver care in an environment guided by the Christian values of compassion, hospitality, and stewardship. Avera has an organizational goal to ensure continuity of care across systems and services.

Avera Cancer Institute physicians serve patients in a four-state radius. The service area reaches over 71,000 square miles and includes South Dakota and portions of Iowa, Nebraska, and Minnesota. Avera physicians provide these services through the Avera Cancer Institute clinic services, outreach clinics, and telemedicine services. Many patients live in rural communities up to hundreds of miles from the Sioux Falls facility. To save patients thousands of miles of travel, Avera Cancer Institute oncologists order chemotherapy treatments in the patient's home town, when possible.

"An important aspect of Avera McKennan's care philosophy is providing care close to home, so patients do not have to drive long distances to receive a high level of care. We want to ensure Avera patients are receiving the highest quality of care, regardless of if it takes place at the Avera Cancer Institute or in their local community," said Kris Gaster, Assistant Vice President for Outpatient Cancer Clinics at the Avera Cancer Institute.

The Avera Cancer Institute is home to 52 infusion bays and delivers approximately 250 chemotherapy infusions weekly. In its Sioux Falls infusion centers, the Avera Cancer Institute adheres to standards for chemotherapy developed from standards of the Occupational Safety and Health Administration, Oncology Nursing Society, Centers for Medicare and Medicaid Services, and U.S. Pharmacopoeia (USP-797).



Disaster Charts

Information Security Nets for Patients



BY ZACHARY D. SMITH, RT(R)(T), MBA

2013 ACCC INNOVATOR AWARD • ASSOCIATION OF COMMUNITY CANCER CENTERS •

When preparing for potentially dangerous weather, such as a hurricane, flood, or tornado, we often focus on securing our homes and/or fleeing the area. In areas of the United States that regularly suffer storm "seasons," residents are often very adept at boarding up windows, adding sandbag barriers, and obtaining necessary food and supplies. All of these activities are centered on riding out the storm and dealing with the aftermath.

Healthcare facilities follow a surprisingly similar thought process in storm preparation. Plans are made to ensure that the facility will have the necessary power and supplies to care for patients, as well as a speedy return to "normal" operations. However, most hospital disaster plans are concerned with minimizing any potential physical damage to the facility, maintaining adequate staffing, and protecting the troves of EMR (electronic medical record) data. Beyond anticipating a surge of injured patients, little thought or planning is focused on those in the community who may be directly impacted by a large-scale disaster in the hospital's service area. In the case of evacuation or catastrophic damage to the hospital, cancer patients receiving daily radiation therapy are particularly vulnerable to disruptions in their planned treatment regimen.

The Impact of Hurricane Katrina

On Monday, August 29, 2005, Hurricane Katrina struck Louisiana and devastated the city of New Orleans. In the days following the storm's initial impact, water poured in from a damaged levee system and eventually flooded 80 percent of the city. Located just 60 miles to the northwest of New Orleans, Baton Rouge was a routine destination for those seeking to avoid the hurricane's wrath. The initial evacuation prior to the storm and the displacement of nearly 400,000 residents quickly resulted in the population of Baton Rouge swelling from 280,000 to nearly 600,000, becoming the largest city in the state of Louisiana.

As Katrina approached, Baton Rouge General Pennington Cancer Center prepared as we had prepared for previous storms:

- We informed all patients in active treatment that we would be closed on Monday, August 29, and would resume treatment the following day.
- All patient phone numbers were confirmed and distributed to senior staff.
- The facility and computer systems were shut down and secured.

In similar fashion, the same preparation plan was followed by most of the treatment centers in New Orleans.

As planned, our radiation oncology center resumed operations on August 30. However, as soon as the doors opened, cancer patients who were displaced from New Orleans and who had never been seen at our center began to present and say "I am a cancer patient and need to get my treatment." Notifications began to come in from the emergency shelters with similar requests from patients to resume their treatment. These patients had no medical records of any kind. Further, due to a combination of the devastation from storm damage in Baton Rouge and the strain on the city's infrastructure from the doubling in population overnight, phone lines and Internet access were intermittent at best. Even if the phones worked, the treatment centers in New Orleans were either underwater or deserted, so medical records were not accessible.

> Even though many hospitals in New Orleans had redundant onsite and off-site backups, the reality is that the phone, Internet, and power grid are very susceptible to storm damage.

Patients arriving at our center did not realize that, in most cancer programs, radiation oncology services have separate charting and EMRs specific to their departments. As a result, radiation oncology information is not tied into the larger hospital EMR and cannot be remotely accessed. Compounding the

Back (L to R): Brad Barhorst, physicist; Dr. Andrew Lauve, radiation oncologist; Dr. William Russell, radiation oncologist. Front (L to R) Zachary Smith, director; Tracey McDowell, chief therapist; Joe Finnegan, physicist; and Trevor Smith, dosimetrist, comprised the team that identified the treatment information to include on the flash drives provided to evacuated patients (below).

dilemma was the fact that even if the EMR systems in New Orleans were accessible or the phone lines worked, we did not know who to contact and how to reconnect patients with their physicians.

An outside observer may wonder why cancer centers that operate in a disaster-prone area seemed so unprepared for this level of disruption. The answer is a mixture of prior events and culture. In the years leading up to the 2005 hurricane season, several dire storm predictions failed to materialize. In addition, as Katrina began to emerge as a possible threat, many New Orleans residents felt they had been through worse storms in the past and so did not respond to calls for voluntary evacuation. Political indecision and confusion resulted in a call for mandatory evacuations too late to be effective. Of course, no amount of planning could have taken into account the massive flooding that caused the majority of the damage to New Orleans.

Thankfully with hard work and the combined efforts of the cancer centers in Baton Rouge, we were able to care for displaced patients with minimal treatment delays. As we resumed our normal operations, our treatment team questioned: "If the storm had bypassed New Orleans and instead struck Baton Rouge, would our patients have been any better off?" The answer of course was, "No." After the storm repair was complete and we began to shift into a normal scenario, our radiation oncology treatment team began to consider what we could do to ensure that our patients would not experience the high anxiety and uncertainty surrounding a similar situation in the future.

Creating a Disaster Chart

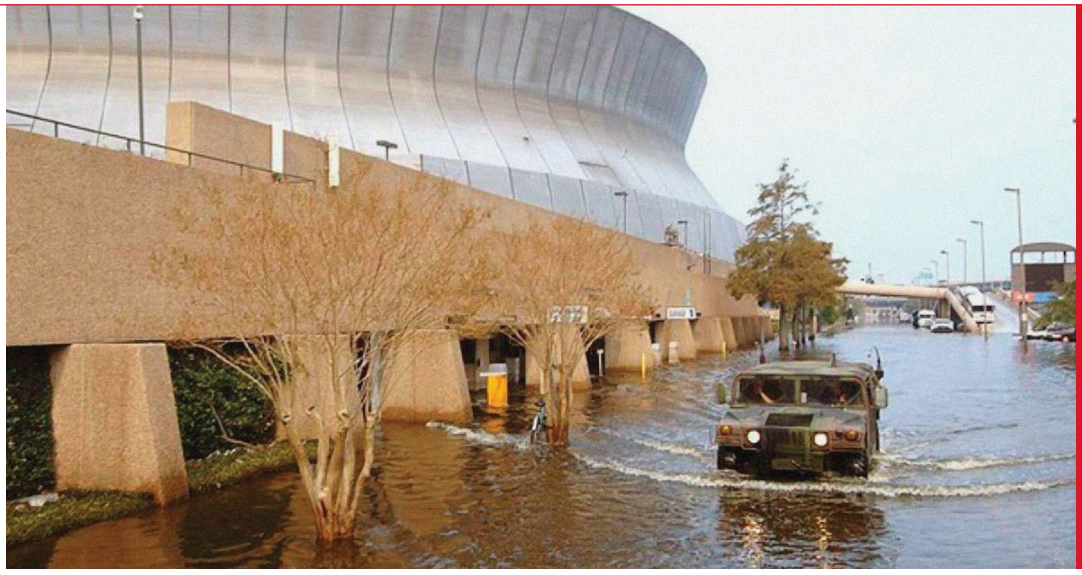
First, our team had to consider what defined a disaster. The definition of a disaster can be somewhat subjective as one person's disaster might just be a "bump in the road" to someone else. We needed to be sure that our plan could meet a patient's need should another disaster on the scale of Katrina occur. For planning purposes, we decided that our disaster charting process should be implemented whenever a potential for evacuation (voluntary or mandatory) existed for our patient population.

Second, in terms of medical information, we had to decide what information would need to be available to facilitate the quick restart of an evacuated patient's treatment. The volume of information in a patient's entire medical record can be substantial. Based on our experience during Katrina, our team came up with a list of documents that we believed any radiation oncology center would need to quickly and correctly reproduce in a patient's treatment plan and resume therapy. Our disaster charting process includes the following list of documents:

1. ***Pathology documentation.*** This information is important as some treatment regimens are tailored to the pathology, as well as the site of the cancer.
2. ***Initial consult.*** This information includes an initial history and physical, medications, and the treating physician's plan for the patient.
3. ***Treatment plans.*** This information defines the approved treatment regimen for daily radiation therapy. This plan includes 3D representations of beam angles, dose per beam, daily dose, and energy.
4. ***Setup and beam portal images.*** This information shows the patient's treatment position and set-up aids, as well as the placement of the treatment isocenter.
5. ***Dose-site summary.*** This information documents the patient's total radiation dose as of his or her last treatment.

Then, as a treatment team, we needed to decide on a format for our disaster charting system. Paper charts (or portions of them) are still used in many departments, while others are operating solely on EMRs. How could we ensure that critical treatment information would be accessible and useable if the need arose?

If you speak with anyone from your hospital information support team about patient data, they may tout the redundant back-ups and other measures in place to ensure no loss of information. Remember however, back-up processes are created to secure data and not to facilitate patient care. In a disaster in which



Even days after the storm, the city of New Orleans was immobilized by high water, power and phone outages. Many who took refuge in the Superdome were stranded.

the phone and Internet services are compromised, off-site backups of data are inaccessible and quite useless. Even though many hospitals in New Orleans had redundant onsite and off-site backups, the reality is that the phone, Internet, and power grid are very susceptible to storm damage.

Our Katrina experience and the lack of priority cancer patients had in the aftermath of this disaster also helped determine our selection of the data format for our new disaster charting system. To be fair, organizations such as FEMA are forced to prioritize where to place resources and assistance and assess situations based on the imminent danger. According to this prioritization model, cancer patients receiving daily treatments or weekly chemotherapy infusions would not be ranked very high (and were not ranked very high during Katrina). During a disaster, the focus for most government resources would be on those who were going to die in the next 24 hours if no interventions were made. Cancer patients that are in no acute distress will not be near the top of the list.

Using Katrina as a "worst case" scenario, our team realized that we would have to create a system that could operate as a stand-alone solution. Having information on hand that we could send out would not work since we could not rely on having the ability to communicate outside the facility. Information would need to be available with the patient at the point of care and in a generally accepted format. Fortunately most radiation oncology centers have a high level of computer technology. Operating with that in mind, we elected to store the information (as a PDF and/or Microsoft Word document) on USB flash drives.

Initially we developed a disaster response plan to address the threats posed by hurricanes. In the plan, the timing of a possible hurricane strike was the driving factor of the decision matrix within the protocol. At 72 hours out from a potential strike, templates for each patient's electronic chart are created. At 48 hours from potential hurricane strike, a complete EMR representation for each active patient is created. At 24 hours out from an imminent hurricane strike, each patient under active treatment receives his or her EMR on a flash drive. Patients are instructed to keep the flash drive with them at all times in the event of a disaster that requires them to evacuate. Each patient is cautioned to protect this health information and treat it just like they would a paper record. This process is HIPPA compliant since patients are given their own medical record, which is intended only for their use.

When the disaster plan is activated, the manpower to create the roughly 60 charts for all of our patients under active treatment is approximately five man hours. To help in this effort, our department developed internal workflows to create the necessary charts as efficiently as possible.

For example, we standardized the patient record format by creating a generic template. Like the individual tabs in paper charts, the disaster chart contains the list for each document as "subfolders." When the plan is activated, a single individual creates the templates for all patients by replicating the global template, essentially creating copies of blank charts with the same subfolder format. Each blank folder is moved into a list by treatment area and then labeled for an individual patient. As a result, each patient record contains the same folders for critical elements, as well a contact sheet that lists the information for our radiation oncologist director, social worker, and patient navigator.

The next step is to "fill" each patient chart with the identified elements. We have found that if a single individual commits to populate one of the subfolders in each patient record, several people can fill pieces of a patient's record in a timely manner.

Overall we believe the process works very well; three staff members working together can complete 60 patient records in just over an hour.

Putting Our Disaster Plan to Work

We have implemented our disaster charting system twice since its creation. The first deployment of the disaster charting system was in 2009 when Hurricane Gustav was on a straight path to Baton Rouge. As per our protocol, flash drives were created and

Thankfully with hard work and the combined efforts of the cancer centers in Baton Rouge, we were able to care for displaced patients with minimal treatment delays.

distributed to patients prior to the storm's arrival. While Gustav turned out to be the worst storm to strike Baton Rouge in over 100 years, the impact to the hospitals and treatment centers was not so severe that a mass evacuation of patients was required.

The second activation of the disaster charting system was in 2012. Massive amounts of rain were causing flooding of the Mississippi River starting as far away as Nashville, and the river was threatening to overflow its banks all the way through its multistate track into Baton Rouge. The Army Corps of Engineers projected a flood stage 10 to 15 feet over the levees that protect the city. One possible scenario outlined a possible breach of the levee that could occur due to the combination of pressure and overflow from the Mississippi River. Such a breach would essentially re-route water through downtown Baton Rouge. As a measure to prevent the levee failure and overflow, the Army Corps of Engineers recommended opening the Morganza spillway to the north of Baton Rouge to relieve the pressure on the levees.

This time, the activation of our disaster charting system varied slightly from our original plan, which covered a time-limited threat. The possibility of a breach meant potential flooding that could occur at any given time during days or even weeks. Since we could not predict exactly when flooding or levee failure would occur, it was harder to determine when patients might need to evacuate.

In response to this less predictive scenario, our treatment team adapted their workflow processes and quickly came up with a solution. The staff knew that an evacuation could be called at any time and the data on each patient's flash drive needed to be current to be useful. So we created a 60-second process to update the dose-site summary document each time a patient presented for treatment. The new summary was copied over the patient's previous version on the flash drive that was presented each day during the emergency activation. This process change ensured that each patient's disaster chart was continually updated throughout the course of treatment. In other words, the EMR version on the flash drive was as current as the patient's last treatment.

At the end of each deployment of the disaster charting system, once the threat had passed, the flash drives were collected from the patients, erased, and stored for the next use.

Patients First

While protecting critical healthcare data is important to hospital systems, it is even more important for patients to have access to their critical medical information. The first time we distributed the disaster charts on flash drives, many patients thanked us for thinking about these "worst case" scenarios and protecting them from what could happen. The patients we care for on a daily basis may have weathered many hurricanes or other natural disasters over their lifetimes, but now they are faced with specific challenges related to being a cancer patient. Our disaster chart not only equips patients with information they need in the event of an evacuation; but it also gives them peace of mind that our center is caring for them under the most adverse circumstances, ensuring the best possible care—no matter what.

Dr. William Russell (L) and Zachary Smith met after each use of the disaster charts to discuss patient feedback and process improvements.

As I look to the future, I often think about other applications for our disaster charting system. In areas of the country prone to flooding, tornadoes, and, of course, hurricanes, a similar system could act as a safety net for displaced patients—whether patients' homes or their treatment facilities face potential damage and/or destruction—safeguarding patients from unnecessary treatment delays.

This disaster charting process worked well when implemented at our program in Baton Rouge. Most important, our patients expressed gratitude that we thought to plan for their treatment needs should disaster strike. The disaster charting system is replicable, and it is our sincere hope it can benefit other centers with patients facing similar challenges. OI

Zachary D. Smith, RT(R)(T), MBA, is director, Radiation Oncology/Tumor Registry, Baton Rouge General Pennington Cancer Center, Baton Rouge, La.

careers

DIRECTOR, ONCOLOGY CLINICAL OPERATIONS
Michigan

Reporting to the Department Chief of Oncology, this individual will assist the Department Chief and Senior Director, Business Development, Oncology in planning, organizing, directing, and evaluating patient care services, personnel, materials, and ancillary services necessary to provide quality, cost effective, interdisciplinary, and collaborative oncology services for Spectrum Health. The Director will provide leadership and operational oversight over the department to include strategic planning, program development, fiscal management, resource allocation, standards of care, policy and procedure development and interpretation, human resource development, performance improvement, and maintenance of collaborative relationships with the physician leaders.

- BSN or BS in Health Services or Business Administration; Master's degree preferred
- 5 years of nursing management experience with 3 years of direct oncology nursing experience
- Proven leadership skills, ability to motivate, set standards, and ensure accountability.

Apply online at *Brad.Sharkey@spectrumhealth.org.*

MANAGER, PATIENT EDUCATION
Nashville, Tenn.

Experienced oncology nurse to evaluate, plan, organize, develop, and implement patient and family education activities for Tennessee Oncology. Essential functions include:

- Evaluate patient education materials for educational merit and appropriateness for patients and families based upon readability, language level, format, illustrations, diversity (including translation), and general presentation
- Assess, plan, develop, and evaluates materials using reliable oncology-based education sources
- Work to incorporate technology and multiple learning modalities
- Develop an annual patient education plan
- Provide effective in-service training for onsite clinical staff
- Strengthen relationships with local and national organizations as patient education resources.

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A Master's prepared RN with at least 3 years of outpatient ambulatory oncology experience. Certification in Oncology Nursing required (OCN). Chemotherapy Certification required.

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MULTIDISCIPLINARY COORDINATOR
Maywood, Illinois

The Cardinal Bernardin Cancer Center seeks a Multidisciplinary Coordinator to coordinate the care of patients from intake, diagnosis, treatment, and follow-up. Responsibilities include:

- Manage the coordination of the diagnostic and staging testing for patients seeking a multidisciplinary approach for the Breast, GI, and Lung populations
- Organize multidisciplinary patient conferences
- Function as the primary nurse in the multidisciplinary clinics
- Assist with procedures, coordination of surgery, chemotherapy, and radiation therapy
- Triage patient calls that include symptom management
- Obtain pre-certifications for medications or diagnostics
- Will cross train into other areas of the service line.

Apply online at *loyolamedicine.org/about/join-loyola-team.*

PRACTICE MANAGER, HEMATOLOGY ONCOLOGY
Michigan

McLaren System has recently affiliated with the Karmanos Cancer Center. McLaren, Northern Michigan, in Petoskey, is recruiting a progressive manager to lead our team in providing community cancer care. We have six dedicated providers and an integrated delivery model to provide excellent care to our patients and their families in Northern Lower Michigan and the Eastern Upper Peninsula.

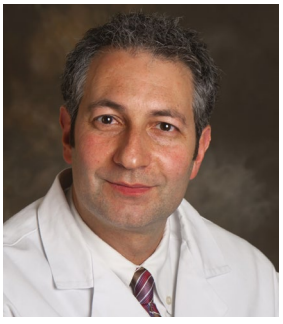
Requirements
We require at least 3 to 5 years of progressive hematology and oncology management experience with a Bachelor's degree. Significant experience in medical office management may be substituted for some, or all, of the educational requirement. A Master's degree is preferred.

To apply, contact Margie Kessler, McLaren Northern Michigan, by email: mkessler@northernhealth.org or phone: 231.487.4054.

Apply online at *mkessler@northernhealth.org.*

Ask ACCC's Community Resource Centers

Chronic myeloid leukemia (CML) is a rare, slow-growing hematologic malignancy affecting mostly older adults and accounting for a little over 10 percent of all new cases of leukemia. (The American Cancer Society estimated 5,920 new cases for 2013.)[1] In CML, leukemia cells can build up in the body over a number of years, often without causing symptoms. Targeted therapy drugs have revolutionized the treatment of CML, allowing many patients to live normal life spans, but successful treatment depends on consistent monitoring and management of the disease and side effects. Winship Cancer Institute of Emory University has established an outpatient coordinated team approach that has proven successful with CML patients. H. Jean Khoury, MD, Director of the Division of Hematology at Winship, and the R. Randal Rollins Chair in the Emory University School of Medicine, explains.



CHRONIC MYELOID LEUKEMIA, also known as chronic myelogenous leukemia, is most often diagnosed in the early, indolent, and asymptomatic phase called the chronic phase (CP-CML). Untreated or with ineffective therapy, CP-CML progresses within three to five years to the advanced phases of the disease called accelerated phase and blast phase.

A change within the chromosomes of the marrow stem cells leads to the formation of the BCR-ABL oncogene that is the driver of this disease. BCR-ABL can be detected by analyzing marrow cells for the presence of the Philadelphia chromosome, or by analyzing the blood using molecular methods: FISH and PCR. Targeting BCR-ABL with tyrosine kinase inhibitors (TKIs) has revolutionized outcomes in patients with CML, and has practically replaced allogeneic hematopoietic stem cell transplantation (HSCT) as first-line therapy.[2,3] Four TKIs are commercially available in the U.S. for the treatment of patients with CML: imatinib, dasatinib, nilotinib, and bosutinib. These oral agents have remarkable activity and are overall well tolerated by patients.

Indeed, the longest available follow-up of patients treated with imatinib shows that responders enjoy a lifespan that is comparable to the general population, and more importantly, no new or chronic toxicities were observed with prolonged exposure to this agent.[4] Recent studies have shown that approximately 50 percent of patients with prolonged and sustained molecular remission have discontinued imatinib, and have so far maintained these remissions, suggesting that cure with TKIs may not be a far fetched reality.[5]

There is also good news for patients for whom first-line TKIs have failed. CP-CML patients with low Sokal risk scores who have tolerated imatinib, achieved a cytogenetic response, and have subsequently failed this first-line agent, can be very effectively rescued by second-line TKIs, and have so far had very encouraging outcomes.

Given the excellent activity of dasatinib, nilotinib, and bosutinib, any of these agents is an excellent second-line therapy. To take maximum advantage of therapy with TKIs, compliance and good understanding of monitoring response to therapy are essential. And given that these pills are taken daily for years, patient monitoring and compliance issues are very important.

Therefore, in 2005, Winship Cancer Institute of Emory University established a coordinated team care approach for patients with CML.[6] The goal of this team approach is to maximize the benefits of TKI therapy through education and by engaging patients, their caretakers, and the referring oncologist in disease management. The team consists of a dedicated hematologist, physician assistant (PA), nurse coordinator, social worker, pharmacist, and research coordinator who comprehensively address patient issues—including psychosocial, financial, insurance coverage, and transportation—from the first visit through the long course of the disease, and provide a good understanding of monitoring results.

In our team model, the patient's understanding of response monitoring results is used to tailor additional education at each subsequent clinic visit. Through frequent communication between the leukemia specialist and the referring physician oncologist, knowledge about the disease and monitoring is relayed beyond the academic medical center to community providers.

This team approach is effective for early detection and management of side effects, which improves patient compliance. Team members deliver a consistent message throughout the course of the disease, using simple graphics and a disease-monitoring flow chart that allows patients to visualize their progress with therapy, which in turn increases the chances of adherence to treatment with TKIs. (Winship's disease-monitoring flow chart is available online at www.accc-cancer.org/oncology_issues/MA2014.asp.)

CASE STUDY

After being diagnosed in November 2003 with chronic phase CML, a 71-year-old woman transformed to lymphoid blast phase (LBP) CML six months after an excellent response and complete cytogenetic remission (CCyR), with imatinib 400 mg/day.

She achieved remission with chemotherapy (HCVAD) that was given for five cycles, but relapsed while on maintenance therapy in November 2005, and was resistant to additional chemotherapy.

Patient was offered to enroll on a clinical trial (protocol CA180015) and started dasatinib 70 mg twice daily in December 2005. Due to gastrointestinal side effects, the dose was reduced to 50 mg twice daily. Patient achieved an excellent response (CCyR) and complete molecular remission (CMR) in April 2006, but due to unexplained and persistent twitching that did not resolve with interruption of dasatinib, patient decided to come off the clinical trial in February 2007.

In March 2007, while in CMR, patient was offered to enroll on another clinical trial (protocol 3160A4-200-WW) and started bosutinib 500 mg/day. Due to gastrointestinal side effects, the dose was reduced to 400 mg/day in July 2007. The patient maintained CMR, but after a diagnosis of pulmonary fibrosis not related to bosutinib, patient decided to come off the clinical trial in December 2011, and no further therapy for CML was started. Patient remained in sustained CMR, now 25 months after bosutinib discontinuation, and perhaps cured from her blast phase CML.

This very unusual case shows that enrollment on clinical trials—and a close monitoring of disease and side effects—can provide patients with opportunities otherwise not readily available for the management of their disease.

To contact Dr. Khoury about treating patients with CML, providers can call him at: 404.778.3932.

In summary, a coordinated team care approach is essential for the management of CML. This approach coaches patients through their cancer journey. Providing patients with education enables them to better understand their disease and put in perspective the results of the monitoring tests. It improves compliance and engages patients as active team members. Additionally, incorporating the referring community oncologist improves alliances between the healthcare team members and extends the tracking of monitoring results to the community practice. In our experience, and based on our very low rates of "clinic no shows," lapses in TKI refills, and "lost to follow-up," we are confident that this coordinated team approach is highly effective for the management of CML patients. OI

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ACCC's Community Resource Centers for CML

Hackensack University Medical Center, John Theurer Cancer Center
Rosemarie Wellman, RN, NP-C
Nurse Practitioner
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The Nebraska Medical Center
Ann Yager, BSRT
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Seattle Cancer Care Alliance
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Winship Cancer Institute of Emory University
Stacie Holloway, RN, BSN, OCN
Nurse Navigator, Hematology and BMT Referral Department
stacie.holloway@emoryhealthcare.org

Learn more at: www.accc-cancer.org/CML.

ACCC's Prostate Education Project Final Report

According to the American Cancer Society, in 2013, there were an estimated 238,590 new cases of prostate cancer, and an estimated 29,720 deaths from the disease.

In 2010 ACCC launched its "Prostate Cancer Programs: Developing Tools and Measuring Effectiveness" education project with a goal of providing cancer programs with data and tools to help improve care and patient satisfaction for those with advanced or metastatic prostate cancer. Phase one components included an initial (2010) survey of ACCC members to better understand how cancer programs measure effectiveness of prostate-specific cancer services, and assess the use of patient education and decision-making tools for patients with metastatic or advanced prostate cancer. The survey found that few practical tools exist to measure effectiveness of the prostate-specific cancer service line. The survey also found variability in the patient education and decision-making tools that cancer programs use with patients who have advanced prostate disease.

Phase Two

In early 2011, ten community cancer programs were chosen to participate in the second phase of this education project, in which ACCC worked to identify both clinical and non-clinical criteria for measuring outcomes that indicate success in treating patients with metastatic or advanced prostate cancer (see box on page 47). These programs completed a questionnaire and participated in follow-up interviews either by phone or email to assess:

- Core services
- Referral sources
- Assessment tools
- Patient and family education
- Use of decision aids
- Use of patient navigators
- Outcomes data collection
- Use of clinical guidelines
- Community outreach
- Patient engagement
- Treatment
- Coordination of care among specialties (i.e., medical oncologist, primary care physician, radiation oncologist, urologist).

For this latest phase, the project's expert Advisory Committee considered a range of outcome measures and agreed to incorporate the following measures into a descriptive study:

- Duration of survival
- Time from diagnosis to androgen deprivation treatment (ADT)
- Time from ADT to chemotherapy
- Time to first medical oncologist visit
- Percent advancing to chemotherapy
- Use of patient navigation services and/or financial counseling for advanced patients
- Cumulative exposure to ADT (in months)
- Cumulative exposure to ADT conditional on receiving chemotherapy
- Referral to and/or use of palliative care, social services, oncology rehabilitation, nutrition counseling, and support groups.

Two selection criteria were used to identify patients eligible for this education project. Selection Criteria 1 (SC1): Biochemically Recurrent Prostate Cancer—those patients who have a rising PSA after local treatment, with or without evidence that the disease has spread to bone or other organs. Selection Criteria 2 (SC2): Metastatic Prostate Cancer—those patients who are diagnosed with metastatic disease at the onset.

Once outcome measures and selection criteria were identified, a data collection protocol, a data dictionary, and a data capture template were created and shared with the project's Advisory Committee and participating sites.

Collection of Outcomes Data

Nine cancer programs submitted outcomes data from their cancer registries for their patients with metastatic or advanced prostate cancer. Data were captured for the entire 2011 calendar year.

Participating cancer programs were asked to use a "toolkit" that included the EPIC-16 CP tool and some additional supplemental educational materials with their advanced prostate cancer patients. (For more on the toolkit, see box on page 47.) Use of the EPIC-16 CP was required, while use of the other materials was suggested. Participating

cancer programs were invited to join in a training webinar to review the EPIC-16 CP, as well as the other materials in the toolkit. Over several months, challenges and successes were gathered through conference calls, email communications, and finally an online survey. Eight of the nine original participating sites took the toolkit evaluation survey; six sites completed the assessment in its entirety. The 27-item survey assessed:

- Use of tools
- Ease of use
- Usefulness in facilitating treatment decision making
- Appropriateness for the population
- Deficiencies or gaps in tools and challenges in their use
- Suggestions or opportunities for adaptation
- Impact on care delivery and referrals to support services.

The project results were described in a final report released to ACCC members in December 2012 (www.accc-cancer.org/prostateinfo).

Initial Findings on Use of EPIC-16 CP

Through ACCC's education program, participating cancer programs implemented the EPIC-16 CP with their advanced prostate cancer patients. Some participating sites also implemented EPIC-16 CP with early-stage disease patients. While urologists most often used the tool, other healthcare professionals involved in care of patients with advanced prostate cancer also successfully implemented the tool. Users overwhelmingly found the EPIC-16 CP to be practical, efficient, and easy to implement in clinical practice with little to no adaptation. The tool provided useful information about prostate cancer patients' quality of life that could be evaluated and meaningfully contribute to treatment decision making for this population. Key findings from the 2012 report include:

- Across the sites the EPIC-16 CP was most often used by urologists (83.3 percent) followed by patient navigators (66.7 percent) and nurses (50 percent).
- 67 percent of the participating sites implemented the EPIC-16 CP at advanced prostate cancer diagnosis; others did so at early stage as well.
- At half the sites a healthcare practitioner administered the EPIC-16 CP, and at half the sites the patient self-administered. All were scored by a healthcare practitioner.
- At two sites patient self-administered tools were returned by postal mail and electronically. Both were then scored by a healthcare professional.
- Most sites found the tool useful in facilitating treatment decision making.

Although challenges with the EPIC-16 CP were few, they included patient discomfort with the questions, a need to explain the questions to patients, and difficulty sharing results across providers.

Some sites indicated that ACCC's educational project in general and the patient decision-making tools heightened awareness of, and referral to, support services. In general, this finding was not attributed to use of the EPIC-16 CP alone. Sites indicated that it was too early to assess the impact on care delivery and referrals, but that they believed use of the tools facilitated patient flow through services. Sites reported that they now had an increased awareness of the tools available and when these tools can be used.

Follow-Up Data Collection

In 2013, five of the cancer programs that participated in the 2012 study continued data collection. These centers were:

1. Augusta Health Cancer Center, Fishersville, Va.
2. Bozeman Deaconess Cancer Center, Bozeman, Mont.
3. Middlesex Hospital Cancer Center, Middletown, Conn.
4. Palo Alto Medical Foundation, Palo Alto, Calif.
5. Southside Regional Medical Center Cancer Center, Petersburg, Va.

The 2013 study included fewer patient records—90 as compared to 175 patient records in the 2012 study. Highlights from the continued data collection include:

Referrals into the program. Both studies show similar results. Urologists were the principal source of referrals for individuals meeting SC1 and SC2, although primary care physicians also referred.

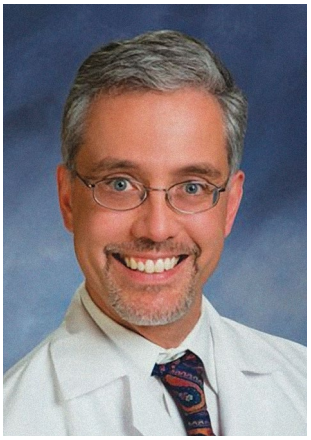
Referrals to palliative care. In the 2013 study the majority of cancer programs referred patients to palliative care, a change from the earlier study in which most programs did not refer to palliative care.

In a follow-up interview, Palo Alto

Dorothy Carvalho, RN, OCN

Frank delaRama, RN, MSN, AOCNS

Moritz Hansen, MD



Edward Myer, MD

Medical Foundation (PAMF) noted that in the past year their program added outpatient palliative care services. "We now offer palliative care, along with oncology nutrition and oncology social work services," said prostate cancer patient navigator Frank delaRama, RN, MSN, AOCNS. "These services are now 'headquartered' in medical oncology. So when we assess these patients with advanced prostate disease, we have more resources for them, including survivorship and caregiver workshops." The palliative care team consists of a physician champion medical director, a nurse practitioner, an RN, and social work and administrative support. Previously, other PAMF staff coordinated hospice and pain management services, but now with dedicated palliative care services, "It's another specialty and support available for patients and their families," he said.

Maine Medical Center, a participant in the original data collection, noted in a 2013 follow-up interview that at their program how palliative care services are offered to patients depends on who is seeing the patient. Many of the advanced prostate cancer patients are seen by the medical oncology group that offers palliative care services. How these services are provided also depends on what the program is palliating. So, for example, if the patient is receiving palliative care for bone metastases, he is sent to radiation oncology for palliative care. If the pain is related to general musculoskeletal pain, the patient would be seen in the Maine Medical Center Pain Clinic. At this program, palliative care services are available throughout inpatient and outpatient services.

Referrals to other supportive care services. The 2013 data reflect low numbers of referrals to social services, oncology rehabilitation, nutrition counseling, and support groups, consistent with the data from the early study. These data may reflect inadequate processes for tracking the use of these services. There were no consistent assessment procedures across the cancer programs.

In follow-up interviews, participating sites were asked whether use of the EPIC-16 CP tool resulted in increased identification of supportive care needs among the population of patients with advanced or metastatic prostate cancer.

Maine Medical Center, which continues to use the EPIC-16 CP tool with all prostate patients, responded with a "qualified yes." "The EPIC-16 tool includes questions related to issues of hot flashes, depression, and lack of energy," said Moritz Hansen, MD. "We certainly see that and review that with all patients with advanced disease. It can certainly help us determine if it's a small problem or a big problem for these patients."

At Middlesex Hospital implementation of the EPIC-16 CP tool did not lead to development of new support services, but did have some impact on the format for support groups with more outside speakers invited to present. In addition, participation in the data collection process and use of the EPIC-16 CP tool with patients helped Middlesex Hospital highlight how it could better use some of the support services available through the program, according to nurse navigator Dorothy Carvalho, RN, OCN. For example, as a result of use of the EPIC-16 CP tool, more patients are being referred to the prostate support group and to the recently established pelvic floor rehabilitation program.

Use of patient navigation services. A greater percentage of patients used patient navigation services in the 2013 study than in the earlier study.

Impact on Care Coordination across Specialties

In follow-up interviews, participating sites were asked if use of the EPIC-16 CP tool had affected care coordination across different specialties involved in the care of prostate cancer patients including medical oncology, radiation oncology, and urology.

"I think any time you have a tool that requires multiple specialists to get together to agree on its use in a like manner it improves assessment of patient needs and the ability to communicate different domains to other providers in the system. I think use of the EPIC-16 [CP] has improved communication [among providers and with patients]," said Dr. Hansen, Maine Medical Center. "I think use of the EPIC-16 clearly improved communication about care, and it ultimately improves care to be able to identify these various domains. If you look at the very end of EPIC-16, there is a whole section on vitality and hormonal symptoms. [These data] were not being routinely collected before. We were mainly interested in urinary and sexual functioning, but this form [EPIC-16 CP] is more inclusive. It's straight forward. It's easy to fill out and collects data in a standardized way," he said.

At Middlesex Hospital, all patients with prostate cancer—not just those with advanced disease—are given the EPIC-16 CP. Use of the tool has helped "open the door to a conversation" between the physician and patient regarding erectile dysfunction, noted Edward Myer, MD. Previously these data were not consistently collected and addressed. Use of the EPIC-16 CP has helped this cancer program "appreciate the problem in a much more quantitative fashion and address the problem better," he said.

Participation in the ACCC project has also affected how Middlesex Hospital is collecting data. "Prior to the EPIC-16 CP score we really hadn't been collecting this type of data. We weren't really measuring erectile dysfunction in any way except in terms of broad subjective picture that the patient was giving us. This allows us to measure the data and record this data in a more quantitative way and it gives us something reproducible that we can compare visit to visit," said Dr. Myer. The program has also

Programs Participating in Initial Data Collection

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

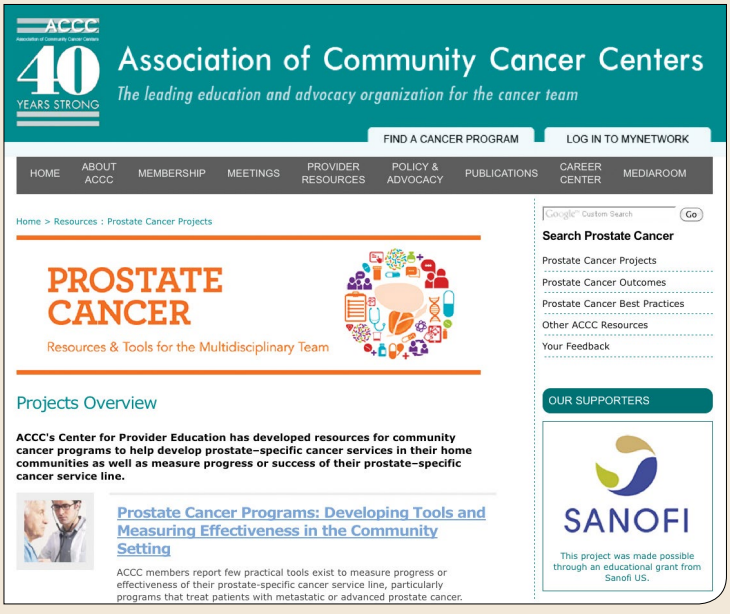
Prostate Cancer Toolkit

The participating sites used this toolkit to help prostate cancer patients participate in decision-making about healthcare options. It included the following resources:

- The EPIC-16 CP Tool
- Us TOO! Advanced Prostate Cancer Resource Kit

Educational materials and resources

- Ottawa Personal Decision Guide
- Ottawa Family Decision Guide Sample
- Ottawa Family Decision Guide
- Ottawa Decision Support Framework
- Ottawa Decision Support Tutorial



implemented an erectile dysfunction treatment plan tracking tool, and has more information available to help patients with this issue.

Carvalho has found that use of the EPIC-16 CP tool has helped in care coordination between urology and radiation oncology. For example, when patients go for their radiation therapy consultation, any symptoms the patient has been complaining of are communicated by urology so that these symptoms can be tracked should they worsen when the patient is undergoing treatment.

At Palo Alto Medical Foundation, all newly diagnosed prostate patients fill out the EPIC-26, an expanded version of the assessment tool. Data are entered electronically into a database for outcomes. Use of the EPIC-26 tool creates consistency in terms of asking questions that cover all aspects of patient quality-of-life related to prostate cancer.

"We have more of a system to ensure we are asking the same questions across all providers," said delaRama. "In terms of how our program is collecting outcomes data, participation in the ACCC project and use of the EPIC-26 provided some good first steps," he said. "We've been trying to collect outcomes data many different ways. At the same time we don't want to overwhelm our patients with questionnaires. When we did this project, we were in the midst of several other prostate improvement projects. I think using the EPIC-26 helped because it is a validated tool. I think the physicians were happy that we were collecting some good data that we could use later on, too, to help other patients and also to try to assess areas for improvement or in which we need to start new programs."

Previously, without a QOL assessment questionnaire, gathering this type of information was more free-flowing, noted delaRama. "Patients would only let providers know what they had on their minds. By using a tool such as the EPIC-26 at every visit, or at certain follow-up appointments, issues are raised or patients are reminded to bring up a problem or concern, and we'll also see it in the data."

"From my perspective as a navigator, I think before this project people thought of me as a navigator helping newly diagnosed patients and that is the bulk of my practice. But this program helped raise awareness that I'm still available to help prostate cancer patients if they need assistance later in life. I think a nurse navigator is a good resource for those patients with advanced diseases," he said. OI

CHEMOTHERAPY SCHEDULING STRATEGIES

Benefits and barriers to expanding patient care hours

ACCC is currently surveying cancer program members that offer extended chemotherapy hours to better understand the implications of evening and weekend infusion times for patients, providers, and program operations. The goal is to clarify the benefits of extended hours—greater patient convenience, the ability to accommodate chemotherapy regimens with unusual dosing schedules, and the potential for reducing patient reliance on emergency room visits—as well as the demands that this change entails for practice managers, nursing staff, and physicians.

Our findings will be summarized in an article slated for publication in the May/June 2014 *Oncology Issues*. Included with this issue will be a one-page "Hot Topics" discussion guide focused on practical strategies for extending patient care hours and chemotherapy treatments with uncommon dosing regimens.

Physician Survey of Impact of Payer Policies on Medically Appropriate Off-Label Use

A report from the the Association of Community Cancer Centers (ACCC), the Biotechnology Industry Organization (BIO), Boston Healthcare Associates, Inc., and Pharmaceutical Research and Manufacturers of America (PhRMA)

In 2013 Boston Healthcare Associates conducted a Web survey among ACCC members from office- and hospital-based oncology practices to assess developments in the use of off-label anticancer therapies. Among survey respondents, off-label use is at least somewhat important to 64 percent; it is extremely important to 27 percent. Off-label use for the treatment of specific types of cancer with no or few on-label treatment options is the primary reason respondents consider off-label use important. About 41% of respondents report that their frequency of off-label use of anticancer therapies has decreased over the past five years; they attribute the change primarily to coverage and reimbursement challenges. In brief, here are the other survey findings.

- For 83% of respondents, peer-reviewed medical literature is somewhat important or extremely important in their use of off-label anticancer therapies.
- 63% consider drug compendia at least somewhat important.
- About 70% report that payers restrict off-label use of anticancer drugs. Notably, the use of post payment audits to restrict off-label use has increased over the last five years.
- 84% report that payers deny coverage for off-label uses supported by peer-reviewed medical literature; 80% report coverage denials for uses supported by compendia.
- 95% report that coverage and reimbursement policies concerning off-label uses of anticancer drugs cause providers to alter their clinical decision making.
- Medicare contractors primarily use claims denials to restrict off-label coverage and reimbursement; private payers most commonly use prior authorization requirements to restrict off-label coverage and reimbursement.
- Compendia publications are the primary means Medicare uses to support off-label coverage and reimbursement; private payers use clinical guidelines as the primary source of information to support off-label coverage and reimbursement.
- For 50% of respondents, off-label coverage and reimbursement policies result in up to five treatment delays per month. Respondents say their primary response to restrictive off-label payer coverage policies is to alter drug regimens.
- 27% have partnerships with payers to follow clinical care pathways for cancer treatment; these respondents see coverage denials of off-label use of an anticancer drug not included in clinical care pathways about four times per month.
- 21% have risk-based contracts with health plans, resulting in standardization of the use of protocols, regimens, and supplies; 88% of these respondents predict that their participation in risk-based contracts will increase over the next three years. OI

Survey Conclusions

- Off-label use of anticancer therapies is a common practice among oncologists.
- Providers consider compendia and peer-reviewed literature to be important sources of information to guide decision making around off-label therapy use.
- Off-label therapy use requires strong clinical evidence to support coverage and reimbursement.
- The changing payment landscape is impacting clinical decision making as providers move towards increased assumption of risk and more defined care pathways.
- Increasingly restrictive requirements for coverage of off-label therapy may result in patient access issues.

Survey Recommendations

- Providers should continue to highlight the clinical importance of off-label therapy throughout a patient's course of treatment.
- In response to increased physician risk and payer scrutiny of off-label use, drug manufacturers should bolster the development of clinical evidence to support decision making around off-label use.
- Payers should have transparent standards for off-label therapies and ensure emerging policies allow for timely access to medically accepted, off-label use.
- As healthcare reform and related policy changes continue to be implemented, stakeholders should actively monitor the impact of these changes on oncology practices and patient access and care.

CME/CE OPPORTUNITIES

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

www.accc-cancer.org/CME

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Provide clinicians with an overview of emerging data presented at the 2013 annual meeting of the American Society of Clinical Oncology and the 18th annual Congress of the European Hematology Association focused on the treatment of patients with myeloid disorders.

James Foran, MD
Mayo Clinic

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Discuss current standards of care regarding molecular testing in advanced non-small cell lung cancer (NSCLC) and its impact on treatment decisions, as well as emerging data on newer testing strategies and molecularly targeted agents and their potential effects on clinical practice.

Alice T. Shaw, MD, PhD
Harvard Medical School

Supported by an independent educational grant from Genentech

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Website: www.keepingyouwell.com

DuPage Medical Group
Lisle, Ill.
Delegate Rep: Debbie Shapert, RN, MSN, OCN
Website: dupagemedicalgroup.com

St. Vincent Frontier
Billings, Mont.
Delegate Rep: Cathy Bealer, RN, MHA
Website: www.svh-mt.org

Baptist Healthcare Systems
Memphis, Tenn.
Delegate Rep: Laura Potts, EdD, FACHE
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Delegate Rep: Ann Miner
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The Front Lines

Radiation therapy's role in multidisciplinary, patient-centric care

BY BRYAN M. SCHMALHOFER, MBA, RT(R)(T)

As a senior radiation therapist at Wellspan Health's York Cancer Center in York, Pa., I have the great privilege to work with an amazing group of therapists who—as part of our multidisciplinary team—provide patient-centric care every day. At my program, radiation therapists take on the role of patient advocate with great vigor and compassion. Our main goal is to support and help patients through this very trying time in their lives. Fighting cancer is a very personal battle—one that most people think they will never have to face. It is both inspiring and humbling to support patients through this battle. When patients' course of therapy involves radiation oncology, radiation therapists are often the "face" of the cancer program. We play a crucial role in providing patient-centric care as we interact daily with patients, and we are in a unique position to ensure that patient needs are met and that their desires are taken into account during treatment.

From a patient's first visit to our offices for CT simulation, a radiation therapist is there to ease the way into the treatment process, answering questions from the patient and family on what to expect during simulation, as well as at daily treatment appointments. Many patients are apprehensive and anxious at the start of radiation therapy treatment. On that first day of simulation, as a radiation therapist, it is a great honor to support patients through this first "giant step" in the cancer treatment process. It has been my experience that patients often form a special attachment to their "simulation" therapist, as this staff member was the first to guide them through a very personal experience.

Seeing patients five days a week allows radiation therapists a unique insight into how patients are feeling on a daily basis. We notice small changes in their behavior, as well as their general well-being, and can work quickly with the multidisciplinary team to get patients the interventions they need to alleviate pain, anxiety, dehydration, and/or psychosocial issues that may delay or interfere with treatment. Further, radiation therapists are able to advocate daily for our patients and voice their issues and concerns in between OTV (on-treatment visit) appointments.

Being on the front line in a patient-centric care environment allows radiation therapists the distinct advantage of getting to know our patients. We can let our multidisciplinary team members know when patients and family members need the services of our social workers, nurses, financial counselors, clergy, and transportation coordinators. Radiation therapists also play a critical role in communicating our patients' dietary needs to the appropriate staff. For example, with the majority of patients receiving CBCT (cone beam computed tomography) daily prior to treatment, radiation therapists are able to tell at a very early stage if patients are losing weight by looking at the CBCT contours and comparing them to the initial planning CT. This early intervention can help our dietitians and other support staff head off any rapid weight loss. Radiation therapists also see daily changes in tumor reduction that can cause a patient's anatomy to shift and not line up correctly. If this occurs, a re-planning CT simulation is often needed to correct for the change in tumor volume.

With so many patients receiving chemotherapy—in addition to radiation therapy—radiation therapists often play an important role in intra-departmental collaboration that is key to coordinated, patient-centric care. For example this winter, when huge amounts of snow blanketed our community, some patients' chemotherapy treatments were canceled, while other patients were simply unable to travel to our center due to the weather conditions. Because of the excellent care coordination between our radiation and medical oncology staff, we were able to ensure that our patients were informed that they would be able to continue their treatment as planned.

For more than 10 years, I've had the great privilege of working side by side with my patients during their battle with cancer. I truly believe that radiation therapists play an integral role in the delivery of patient-centric, multidisciplinary care—the care our patients want and need and the care that payers are now beginning to require. OI

Bryan M. Schmalhofer, MBA, RT(R)(T), is a senior radiation therapist at Wellspan Health's York Cancer Center in York, Pa.

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