ONCOLOGY ISSUES

This publication is a benefit of membership
Association of Community Cancer Centers
May | June 2015

A Web-Based Tool Shines a Light on Quality Palliative Care

ACCC
Association of Community Cancer Centers

GRANIX®
(TBO-FILGRASTIM)
Injection

Take a bite out of G-CSF acquisition costs

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

GRANIX® is an option in short-acting G-CSF therapy

- A 71% reduction in duration of severe neutropenia vs placebo (1.1 days vs 3.8 days, $p<0.0001$)[1]
  - Efficacy was evaluated in a multinational, multicenter, randomized, controlled, Phase III study of chemotherapy-naïve patients with high-risk breast cancer receiving doxorubicin (60 mg/m^2 IV bolus)/docetaxel (75 mg/m^2)[1]
- The safety of GRANIX was established in 3 Phase III trials, with 680 patients receiving chemotherapy for either breast cancer, lung cancer, or non-Hodgkin lymphoma (NHL)[1]
- Now offering a new presentation for self-administration

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.
- **Capillary leak syndrome (CLS):** CLS can occur in patients receiving hG-CSFs and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration. Episodes vary in frequency, severity and may be life-threatening if treatment is delayed. Patients who develop symptoms of CLS should be closely monitored and receive standard symptomatic treatment, which may include a need for intensive care.
- **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. GRANIX® (tbo-filgrastim) Injection Prescribing Information. North Wales, PA: Teva Pharmaceuticals; 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 Capillary Leak Syndrome

Capillary leak syndrome (CLS) can occur in patients receiving human granulocyte colony-stimulating factors and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration. Episodes vary in frequency, severity and may be life-threatening if treatment is delayed. Patients who develop symptoms of capillary leak syndrome should be closely monitored and receive standard symptomatic treatment, which may include a need for intensive care.

5.6 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)*]
- Capillary Leak Syndrome *[see Warnings and Precautions (5.5)]*
- Potential for Tumor Growth Stimulatory Effects on Malignant Cells [*see Warnings and Precautions (5.6)*]

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.

Additional Adverse Reactions

Other adverse reactions known to occur following administration of human granulocyte colony-stimulating factors include myalgia, headache, vomiting, Sweet's syndrome (acute febrile neutrophilic dermatosis), cutaneous vasculitis and thrombocytopenia.

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

Risk Summary

There are no adequate and well-controlled studies of GRANIX in pregnant women. In animal reproduction studies, treatment of pregnant rabbits with tbo-filgrastim resulted in increased spontaneous abortion and fetal malformations at systemic exposures substantially higher than the human exposure. GRANIX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Animal Data

In an 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) 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-40581 January 2015

This brief summary is based on TBO-004 GRANIX full Prescribing Information.

insightful cancer data
at your fingertips

CHAMPS insight$_2$oncology™

Transform your cancer data into actionable information for strategic planning, operational and financial decisions with CHAMPS Oncology's new web-based analytics system.

insight$_2$oncology™ provides you with a new perspective of your current market position and the unique insight to manage and improve your cancer service line.

i$_2$o™ allows you to collaborate with CHAMPS to analyze and interpret your cancer data in order to identify gaps, retain and attract patients, and make informed decisions with confidence.

"CHAMPS i$_2$o™ is changing the way our healthcare system is managing its practices both operationally and strategically," said one i$_2$o™ beta tester.

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contents

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DEPARTMENTS

ACCC
Association of Community Cancer Centers

ONCOLOGY ISSUES
The Journal of the
Association of Community Cancer Centers

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

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

FROM THE EDITOR

Innovation in Patient Care

BY CHRISTIAN DOWNS, JD, MHA

Much of the recent media coverage about cancer has been scientific in nature—immunotherapy, biomarker testing, and new radiotherapeutic techniques, just to name a few. At the same time, on the periphery of this emerging science, some very interesting developments are taking place in the patient care arena.

For example, our cover article focuses on quality palliative care—a critical component of cancer care that has been gaining increased attention in recent years. In their article, Arif H. Kamal, MD, and colleagues share how a regional consortium on palliative care was able to develop and implement QDACT, a web-based quality assessment tool capable of providing real-time, quarterly, and ad-hoc feedback and reporting. After successful implementation of QDACT throughout the state of North Carolina, this 2014 ACCC Innovator Award Winner played a key role in efforts to expand QDACT's reach to a national stage.

This edition of *Oncology Issues* also features another 2014 ACCC Innovator Award Winner, William Beaumont Hospital, Royal Oak, Mich. In the article, "Closing a Gap in Cancer Care," Jan Akervall, MD, and colleagues describe how they implemented an outpatient weekly nutrition clinic for head and neck cancer patients that improved patient quality of life and reduced the cost of care. The evidence is clear: nutrition support is critical in helping improve patient outcomes in cancer care.

Our next feature article discusses a fairly new and emerging component of cancer care. I know you are all familiar with cancer rehabilitation, but have you ever heard the term cancer prehabilitation? In "Improving Patient Outcomes with Cancer Prehabilitation," Julie Silver, MD, shows how ACCC member programs are using cancer prehabilitation to help improve physical and functional outcomes that often translate to a better quality of life for cancer patients. Read more about their successes and Dr. Silver's STAR (Survivorship Training and Rehabilitation) Program® Certification on pages 38-45.

Of course a critical component of the cancer care continuum is cancer prevention, and we can all agree that reaching kids and teenagers with important cancer education is key to cancer prevention in this country. In "Stop Cancer before It Starts," Melanie Gonzales, MSPH, MCHES, and Vicky Jekich, CMP, describe a comprehensive youth-based cancer prevention program that educates school-age children and teenagers on sun-safety, tobacco use, and nutrition and physical activity.

In our final feature article, author Amber Gregg discusses an issue that—while not directly related to cancer care—is critical to keeping the doors open at many cancer programs. In "A Well-Kept Secret," Gregg briefly explains the relationship between the community benefit standard and a non-profit hospital's tax exempt status, including tips on leveraging your cancer registry to document community benefits to key stakeholders—federal, state, and local governments.

So, yes, while the research and science in the field of cancer is exciting, let this edition of *Oncology Issues* be a reminder to us that not all advances come out of the lab. OI

Step into the Future

BY STEVEN L. D'AMATO, BSPharm, BCOP

The future of oncology care looks to be a frightening, challenging, and exciting time. The treatments, diagnostics, technology, and overall management of cancer patients have evolved with lightning speed in the last 10 years. It was not that long ago that 5-fluorouracil, leucovorin, methotrexate, doxorubicin, paclitaxel, and cisplatin were the backbones of cancer chemotherapeutic regimens. Now we have monoclonal antibodies, radio-immunotherapy, and targeted oral agents, and most recently we have seen the birth of immuno-oncology and anti-PD-1 monoclonal antibodies. These advances have occurred in conjunction with improvements in surgical and radiotherapeutic techniques. Diagnostic tools and technology used to predict individual patient responses are outpacing our healthcare system's ability to incorporate them in a standardized fashion.

Not only do we face theses challenges in care delivery, but we have to navigate the tumultuous waters of Meaningful Use, the high cost of new agents and their financial toxicity to our patients, increased administrative burdens from payers and government, the Affordable Care Act, and the development of new payment models.

Finally, there has been a headwind of practice and system consolidation that has changed the dynamics of healthcare.

Not for the faint of heart to be sure, but those of us who live and work in the world of oncology have always faced an ever-changing landscape and adapted to the challenges put before us. Bring oncology providers a problem and we will find a solution!

Innovation is all around us. New care models, such as the COME HOME community oncology medical home model, have demonstrated ways to deliver efficient cancer care and reduce costs. CMS has launched a new Oncology Care Model that may change the way care is monitored and reimbursed. EHRs and practice management systems continue to evolve. Payers have engaged providers to pilot new ways to standardize and reimburse for the care and services we deliver. ASCO is developing CancerLinQ, which will aggregate and analyze a massive network of real-world cancer care data to provide real-time quality feedback to providers, feed personalized insights to physicians, and uncover patterns that can improve care.

The Oncology Medical Home is a concept of multidisciplinary care that is about delivering, ensuring, and measuring quality cancer care, and I have selected it as my presidential theme. Some of the key aspects of the Oncology Medical Home model are:

- Cancer care that is coordinated with the entire focus on patients and their entire medical condition
- Cancer care that uses evidence-based medicine to produce quality outcomes
- Cancer care that is accessible and efficient
- Cancer care that is delivered in a patient-centric, caring environment that optimizes patient satisfaction
- Cancer care that is continuously improved by measuring and benchmarking results against other programs so that best practices in care delivery continue to improve.

This theme builds on the last two ACCC presidential themes—the multidisciplinary team and patient-centered quality and care.

Cancer care in 2015 and beyond requires a multidisciplinary, motivated, and well educated workforce to deliver efficient, cost-effective services that produce quality, value, and safety for our patients. These goals require a platform such as the one that ACCC has developed to help its members stay abreast of recent changes and advocate for those things critical to our mission. Finally, these goals can only be achieved by a dedicated membership that embraces and spreads the words and actions of change. I am privileged to help you and your cancer program step into the future of oncology care. OI

Coming in Your 2015 *ONCOLOGY ISSUES*

- The Journey to Cultural Competence
- Cancer Clinical Trials: Enhancing Infrastructure & Accrual
- An Innovative Patient Companion Program
- Closing the Loop with a Post-Biopsy Breast Clinic
- Implementing Oncology Inpatient Bedside Scheduling
- A Patient Tracking System Helps Transition Patients to a Multidisciplinary Nurse Care Model
- An Oncology Nurse Navigator-Led Psychosocial Program
- The Cancer Care Collaborative—Where Patients are An Active Member of the Cancer Care Team
- Developing & Implementing a Patient Advisory Council
- A Behavioral Oncology Program to Support Medically Complex Patients
- Recent Developments in Genomic Testing for Breast Cancer
- A Support Program for Providers that Prevents Burnout and Improves Care

more online @ www.accc-cancer.org

TOOL

Oncology Care Model: 101

Everything you need to know about this new payment model. Learn who can participate, where to sign up, how services will be reimbursed, and more. www.accc-cancer.org/OCM.

INFO

The End of SGR!

Hear how MACRA (the Medicare Access and CHIP Reauthorization Act) will provide physicians with predictable reimbursement that is necessary for quality cancer care, while transitioning over a 10-year period to a new dual Medicare reimbursement system. The archived call is available to members only at: Mynetwork.accc-cancer.org.

PROFILE

Put a Spotlight on *Your* Cancer Program

Each *Oncology Issues* features a two-page article "spotlighting" the services, achievements, and accomplishments of an ACCC member program or practice. These profiles offer great exposure for your program, including the opportunity to let your referring providers and patients know about your services and staff. Has *your* cancer program been profiled? If not, contact jkornak@accc-cancer.org to schedule an interview today.

TOOL

Oral Therapies—A Patient-Centered Approach

ACCC's web-based tool aims to help providers identify patients needing additional education and support resources before starting oral chemotherapy. Available at www.accc-oralchemo.org.

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

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

fast

Got Sleep?

1/3 to **1/2** of all cancer patients experience sleep disorders. Insomnia, the most common sleep disturbance, is often linked to anxiety and depression—common responses to a cancer diagnosis.

Source. NCI. Sleep Disorders PDQ®. www.cancer.gov/cancertopics/pdq/supportivecare/sleepdisorders/HealthProfessional.

90% of hospitals use GPOs to keep healthcare costs down

Source. Hospital Supply Chain Executives' Perspectives on Group Purchasing: Results from a 2014 National Survey. Report prepared for the AHA and the AHRMM under an AHA/AHRMM Research Grant to the University of Pennsylvania.

More than half of health plans with oncology pathways expect to complete their pathway rollouts by 2016

Source. Health Strategies Group. Health Plan Oncology Pathways Insight and Evolution. www.HealthStrategies.com.

facts

Essential Patient Payment Questions

- Does your financial policy state that payments are due prior to seeing providers? Do appointment-reminder phone calls state that payment is required prior to seeing providers?
- Does the front desk get accurate information on the co-pay, deductible, and past-due balances for all patients? Are there inaccuracies, preventing staff from asking for or collecting the amount due?
- Is there adequate training for front-desk staff in how to ask for payment at the time of visit? Do you have guidelines for staff concerning patients who don't pay prior to seeing providers?
- How do you handle new patients with high-deductible plans? Do you see them after the visit to ensure that the level of services and all services provided are documented and can be collected at check out? Do you provide cost estimates to new patients at intake—on the initial call, as well as at check in?

Source. Dahl O. Managing your practice's revenue cycle in 2015. Physicians Practice. www.physicianspractice.com/medical-billing-collections/managing-your-practices-revenue-cycle-2015?GUID=98EC2E34-74E0-44F8-9021-6474CB220676&rememberme=1&ts=15012015.

Want to Increase Engagement with Your Patient Portal? Try These Tips:

- Reward patients for signing up for the patient portal during a specific time frame.
- Ask your patients to provide feedback through the patient portal for a chance to win a reward.
- Commit to donate a certain amount of money to a charity for each new patient portal sign up or secure message received during a specific time period.
- Consider charging patients a small fee if they choose to receive billing statements or lab results through the mail rather than through the portal.

Source. Newton M. Four strategies to get patients to use your portal. Physicians Practice. www.physicianspractice.com/ehr/four-strategies-get-patients-use-your-portal#st-hash.7FKbV6Lw.dpuf.

ACCC Advocacy at Work

LEAH RALPH

The newest payment model out of the Centers for Medicare and Medicaid Innovation (CMMI) and the first in oncology care, the Oncology Care Model (OCM) is a voluntary, five-year program scheduled to begin in spring 2016. The OCM aims to create incentives to furnish efficient, high-quality care by enhancing services for Medicare Fee-for-Service (FFS) beneficiaries undergoing chemotherapy treatment for cancer—while at the same time lowering the overall cost of care for those beneficiaries. Physician group practices, hospital-based practices, and solo practitioners who provide cancer chemotherapy are eligible to participate and are evaluated based on the cost and quality of care for a six-month episode of chemotherapy administration. The episode is triggered by the administration of a specified list of chemotherapy agents—including IV and oral drugs—and physicians are held accountable for all Part A, Part B, and some of Part D expenditures for that patient during the episode of care.

There are three layers of payment. In addition to a fee-for-service payment, participating physicians will receive a $160 per-beneficiary, per-month care coordination payment to improve quality of care, and will also be eligible to receive a performance-based payment that will be the difference between a risk-adjusted target price and actual expenditures during the episode. The performance payment will be contingent on meeting certain quality measures, and will also vary depending on the amount of risk the practice assumes. The payment arrangement is one-sided risk with the option of converting to two-sided risk in the third year of the model; the more risk a practice assumes, the more opportunity there is to share in savings.

Importantly, the OCM also requires a participating practice to meet six practice transformation requirements:

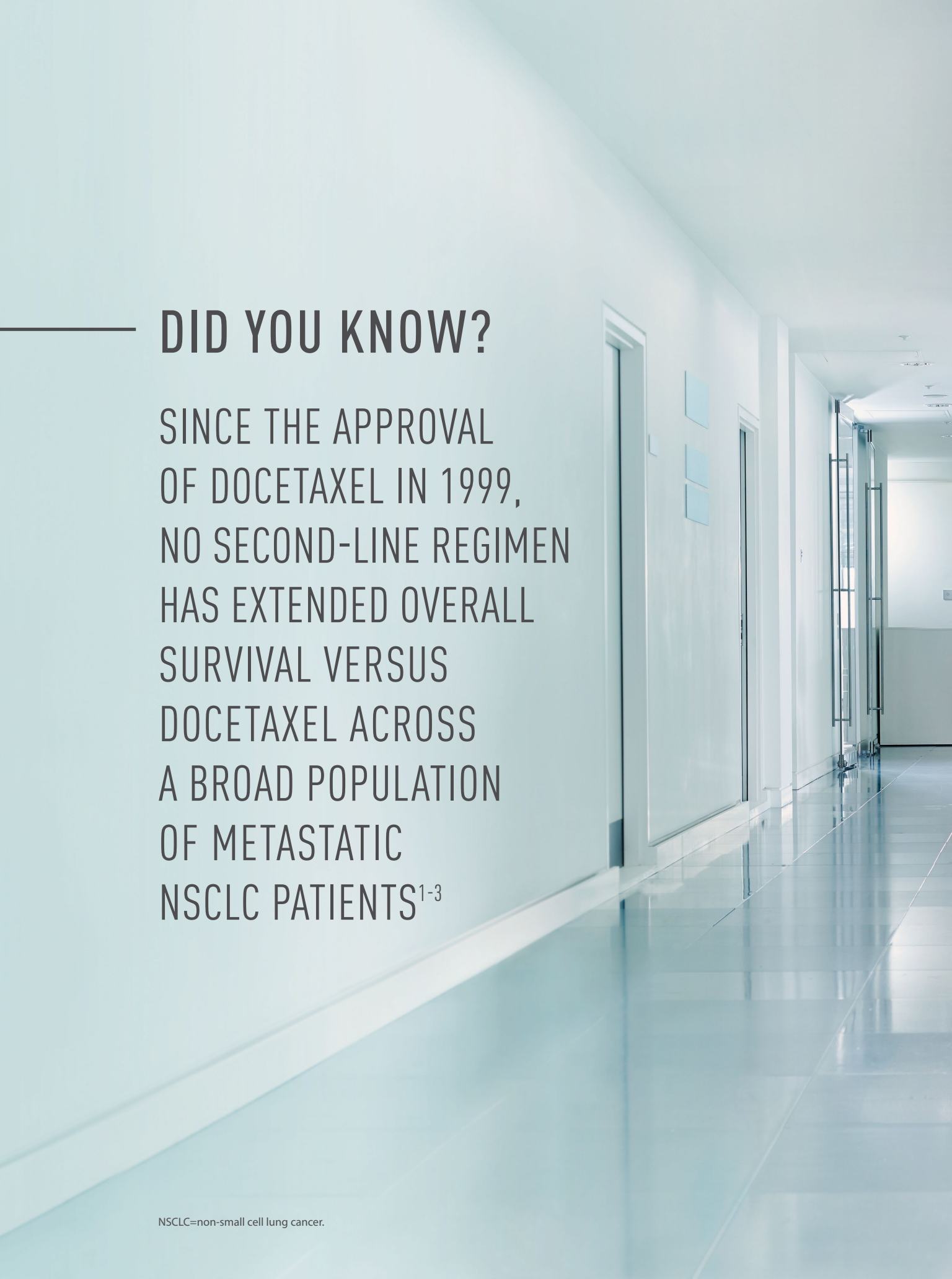
- Provide patient access 24 hours a day/7 days a week to a clinician who has real-time access to the patient's medical records
- Attestation and use of an ONC-certified EMR
- Utilize data to drive Continuous Quality Improvement (CQI)
- Provide core functions of patient navigation
- Document a care plan in accordance with 13 components outlined by the Institute of Medicine (IOM)
- Provide chemotherapy treatment that is consistent with nationally recognized clinical guidelines, such as NCCN or ASCO.

Finally, the OCM is a multi-payer model in which commercial payers and state Medicaid agencies are encouraged to participate. While participating payers may not adhere to the exact payment structure or quality requirements of the OCM, CMS will require they adhere to the principles and goals of the model and hopes that metrics generally align.

Letters of intent (LOI) to participate in the OCM program were due on May 7; applications are due by June 18.

For updates on the OCM program, visit ACCC's recently launched OCM Resource Center at: www.accc-cancer.org/OCM or email: ocm@accc-cancer.org. OI

Leah Ralph is ACCC manager of provider economics & public policy.



DID YOU KNOW?

SINCE THE APPROVAL OF DOCETAXEL IN 1999, NO SECOND-LINE REGIMEN HAS EXTENDED OVERALL SURVIVAL VERSUS DOCETAXEL ACROSS A BROAD POPULATION OF METASTATIC NSCLC PATIENTS[1-3]

NSCLC=non-small cell lung cancer.

NEW FDA APPROVAL

CYRAMZA® (ramucirumab), in combination with docetaxel, is indicated for the treatment of patients with metastatic NSCLC with disease progression on or after platinum-based chemotherapy. Patients with epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving CYRAMZA.

ADVANCING THE SECOND-LINE TREATMENT OF METASTATIC NSCLC[4]

CYRAMZA is the first antiangiogenic agent FDA approved in combination with docetaxel for the second-line treatment of metastatic NSCLC, including nonsquamous and squamous histologies.[4]

CYRAMZA™
ramucirumab injection
10 mg/mL solution

TAKE ACTION

IMPORTANT SAFETY INFORMATION FOR CYRAMZA

WARNING: HEMORRHAGE
CYRAMZA increased the risk of hemorrhage, including severe and sometimes fatal hemorrhagic events. Permanently discontinue CYRAMZA in patients who experience severe bleeding.

Warnings and Precautions

Hemorrhage
- CYRAMZA increased the risk of hemorrhage and gastrointestinal hemorrhage, including severe and sometimes fatal hemorrhagic events. In Study 3, which evaluated CYRAMZA plus docetaxel in metastatic non-small cell lung cancer (NSCLC), the incidence of severe bleeding was 2.4% for CYRAMZA plus docetaxel and 2.3% for placebo plus docetaxel. Patients with NSCLC receiving therapeutic anticoagulation or chronic therapy with NSAIDs or other antiplatelet therapy other than once-daily aspirin or with radiographic evidence of major airway or blood vessel invasion or intratumor cavitation were excluded from Study 3; therefore, the risk of pulmonary hemorrhage in these groups of patients is unknown. Permanently discontinue CYRAMZA in patients who experience severe bleeding.

Arterial Thromboembolic Events
- Serious, sometimes fatal, arterial thromboembolic events (ATEs) including myocardial infarction, cardiac arrest, cerebrovascular accident, and cerebral ischemia occurred in clinical trials including 1.7% of 236 patients who received CYRAMZA as a single agent for gastric cancer in Study 1. Permanently discontinue CYRAMZA in patients who experience a severe ATE.

Hypertension
- An increased incidence of severe hypertension occurred in patients receiving CYRAMZA plus docetaxel (6%) as compared to placebo plus docetaxel (2%). Control hypertension prior to initiating treatment with CYRAMZA. Monitor blood pressure every 2 weeks or more frequently as indicated during treatment. Temporarily suspend CYRAMZA for severe hypertension until medically controlled. Permanently discontinue CYRAMZA if medically significant hypertension cannot be controlled with antihypertensive therapy or in patients with hypertensive crisis or hypertensive encephalopathy.

Infusion-Related Reactions
- Prior to the institution of premedication recommendations across clinical trials of CYRAMZA, infusion-related reactions (IRRs) occurred in 6 out of 37 patients (16%), including 2 severe events. The majority of IRRs across trials occurred during or following a first or second CYRAMZA infusion. Symptoms of IRRs included rigors/tremors, back pain/spasms, chest pain and/or tightness, chills, flushing, dyspnea, wheezing, hypoxia, and paresthesia. In severe cases, symptoms included bronchospasm, supraventricular tachycardia, and hypotension. Monitor patients during the infusion for signs and symptoms of IRRs in a setting with available resuscitation equipment. Immediately and permanently discontinue CYRAMZA for Grade 3 or 4 IRRs.

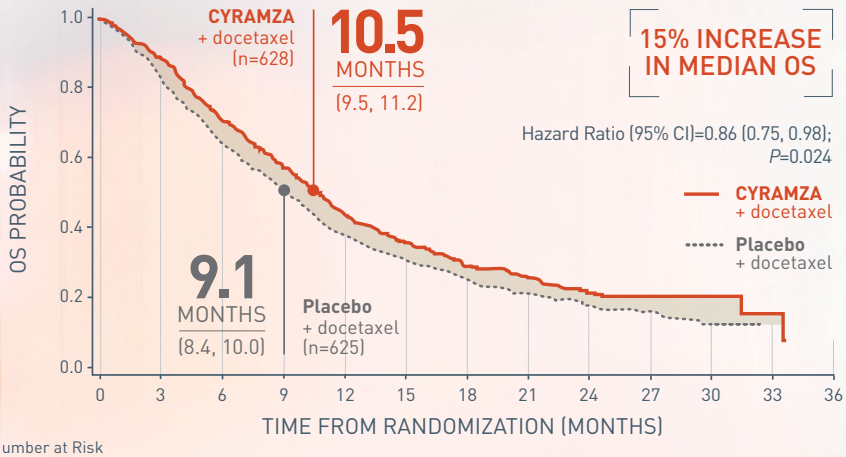
Gastrointestinal Perforations
- CYRAMZA is an antiangiogenic therapy that can increase the risk of gastrointestinal perforation, a potentially fatal event. In Study 3, the incidence of gastrointestinal perforation was 1% for CYRAMZA plus docetaxel versus 0.3% for placebo plus docetaxel. Permanently discontinue CYRAMZA in patients who experience a gastrointestinal perforation.

Impaired Wound Healing
- CYRAMZA has not been studied in patients with serious or nonhealing wounds. CYRAMZA is an antiangiogenic therapy with the potential to adversely affect wound healing. Withhold CYRAMZA prior to surgery. Resume CYRAMZA following the surgical intervention based on clinical judgment of adequate wound healing. If a patient develops wound healing complications during therapy, discontinue CYRAMZA until the wound is fully healed.

Clinical Deterioration in Child-Pugh B or C Cirrhosis
- Clinical deterioration, manifested by new onset or worsening encephalopathy, ascites, or hepatorenal syndrome, was reported in patients with Child-Pugh B or C cirrhosis who received single-agent CYRAMZA. Use CYRAMZA in patients with Child-Pugh B or C cirrhosis only if the potential benefits of treatment are judged to outweigh the risks of clinical deterioration.

CYRAMZA PLUS DOCETAXEL DEMONSTRATED A STATISTICALLY SIGNIFICANT IMPROVEMENT IN OVERALL SURVIVAL VS DOCETAXEL[4]

OVERALL SURVIVAL: MEDIAN - MONTHS (95% CI)



MAJOR OUTCOME MEASURE

15% INCREASE IN MEDIAN OS

Hazard Ratio (95% CI)=0.86 (0.75, 0.98); *P*=0.024

CYRAMZA + docetaxel

Placebo + docetaxel

Number at Risk

CYRAMZA + docetaxel	628	527	415	329	231	156	103	70	45	23	11	2	0
Placebo + docetaxel	625	501	386	306	197	129	86	56	36	23	9	0	0

- The percentage of deaths at the time of analysis was 68% (428 patients) and 73% (456 patients) in the CYRAMZA plus docetaxel and placebo plus docetaxel arms, respectively[4]

Demonstrated improvements across all three efficacy outcomes (OS, PFS, ORR)[4]

- **Median PFS** with CYRAMZA plus docetaxel was 4.5 months (95% CI: 4.2, 5.4) vs 3.0 months (95% CI: 2.8, 3.9) with placebo plus docetaxel (hazard ratio 0.76 [95% CI: 0.68, 0.86]; *P*<0.001)
  - The percentage of events at the time of analysis was 89% (558 patients) and 93% (583 patients) in the CYRAMZA plus docetaxel and placebo plus docetaxel arms, respectively
- **ORR** with CYRAMZA plus docetaxel was 23% (95% CI: 20, 26) vs 14% (95% CI: 11, 17) with placebo plus docetaxel (*P*<0.001)*

CI=confidence interval; OS=overall survival; PFS=progression-free survival; ORR=objective response rate.

*ITT population. Disease progression and tumor response were assessed by investigators in accordance with Response Evaluation Criteria in Solid Tumors (RECIST) 1.1.[5] ORR is defined as complete plus partial response.

REVEL TRIAL DESIGN (N=1253)

The phase III REVEL trial evaluated the efficacy and safety of CYRAMZA plus docetaxel vs placebo plus docetaxel in patients with metastatic NSCLC with disease progression on or after platinum-based chemotherapy. Major efficacy outcome measure was OS. Supportive efficacy outcome measures were PFS and ORR. All patients were required to have Eastern Cooperative Oncology Group performance status 0 or 1. Patients were randomized 1:1 (N=1253) to receive either CYRAMZA 10 mg/kg or placebo, in combination with docetaxel at 75 mg/m^2 every 21 days.[4]

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Reversible Posterior Leukoencephalopathy Syndrome (RPLS)

- RPLS has been reported at a rate of <0.1% in clinical studies with CYRAMZA. Confirm the diagnosis of RPLS with MRI and discontinue CYRAMZA in patients who develop RPLS. Symptoms may resolve or improve within days, although some patients with RPLS can experience ongoing neurologic sequelae or death.

Most Common Adverse Reactions

- The most commonly reported adverse reactions (all grades; Grade 3/4) occurring in ≥5% of patients receiving CYRAMZA plus docetaxel and ≥2% higher than placebo plus docetaxel in Study 3 were neutropenia (55% vs 46%; 49% vs 40%), fatigue/asthenia (55% vs 50%; 14% vs 11%), stomatitis/mucosal inflammation (37% vs 19%; 7% vs 2%), epistaxis (19% vs 7%; <1% vs <1%), febrile neutropenia (16% vs 10%; 16% vs 10%), peripheral edema (16% vs 9%; 0% vs <1%), thrombocytopenia (13% vs 5%; 3% vs <1%), lacrimation increased (13% vs 5%; <1% vs 0%), and hypertension (11% vs 5%; 6% vs 2%).
- The most common serious adverse events with CYRAMZA plus docetaxel in Study 3 were febrile neutropenia (14%), pneumonia (6%), and neutropenia (5%). The use of granulocyte colony-stimulating factors was 42% in CYRAMZA plus docetaxel-treated patients versus 37% in patients who received placebo plus docetaxel.
- Treatment discontinuation due to adverse reactions occurred more frequently in CYRAMZA plus docetaxel-treated patients (9%) than in placebo plus docetaxel-treated patients (5%). The most common adverse events leading to treatment discontinuation of CYRAMZA were infusion-related reaction (0.5%) and epistaxis (0.3%).
- Clinically relevant adverse reactions reported in ≥1% and <5% of CYRAMZA plus docetaxel-treated patients in Study 3 were hyponatremia (4.8% CYRAMZA plus docetaxel versus 2.4% for placebo plus docetaxel) and proteinuria (3.3% CYRAMZA plus docetaxel versus 0.8% placebo plus docetaxel).

Drug Interactions

- No pharmacokinetic interactions were observed between ramucirumab and docetaxel.

Use in Specific Populations

- Pregnancy Category C: Based on its mechanism of action, CYRAMZA may cause fetal harm. Advise females of reproductive potential to avoid getting pregnant, including use of adequate contraception, while receiving CYRAMZA and for at least 3 months after the last dose of CYRAMZA. Animal models link angiogenesis, VEGF and VEGF Receptor 2 to critical aspects of female reproduction, embryofetal development, and postnatal development. There are no adequate or well-controlled studies of ramucirumab in pregnant women. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to a fetus.
- Nursing Mothers: It is recommended to discontinue nursing or discontinue CYRAMZA due to the potential risks to the nursing infant.
- Females of Reproductive Potential: Advise females of reproductive potential that CYRAMZA may impair fertility.

Please see Brief Summary of Prescribing Information for CYRAMZA, including Boxed Warning for hemorrhage, on the next page.

RB-L HCP ISI 17DEC2014

References: 1. Reck M, Kaiser R, Mellemgaard A, et al. Docetaxel plus nintedanib versus docetaxel plus placebo in patients with previously treated non-small-cell lung cancer (LUME-Lung 1): a phase 3, double-blind, randomized controlled trial. *Lancet Oncol*. 2014;15:143-155. **2.** Supplement to: Reck M, Kaiser R, Mellemgaard A, et al. Docetaxel plus nintedanib versus docetaxel plus placebo in patients with previously treated non-small-cell lung cancer (LUME-Lung 1): a phase 3, double-blind, randomized controlled trial. *Lancet Oncol*. 2014;15:143-155. **3.** National Cancer Institute. Cancer drug information. FDA approval for docetaxel. http://www.cancer.gov/cancertopics/druginfo/fda-docetaxel/print. Accessed August 26, 2014. **4.** CYRAMZA (ramucirumab) [package insert]. Indianapolis, IN: Eli Lilly and Company; 2014. **5.** Garon EB, Ciuleanu T-E, Arrieta O, et al. Ramucirumab plus docetaxel versus placebo plus docetaxel for second-line treatment of stage IV non-small-cell lung cancer after disease progression on platinum-based therapy (REVEL): a multicentre, double-blind, randomised phase 3 trial. *Lancet*. 2014;384(9944):665-673.

Lilly

CYRAMZA® (ramucirumab) injection

BRIEF SUMMARY: For complete safety, please consult the full Prescribing Information.

WARNING: HEMORRHAGE

CYRAMZA increased the risk of hemorrhage, including severe and sometimes fatal hemorrhagic events. Permanently discontinue CYRAMZA in patients who experience severe bleeding.

INDICATIONS AND USAGE

Non-Small Cell Lung Cancer:

CYRAMZA, in combination with docetaxel, is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with disease progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving CYRAMZA.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Hemorrhage

CYRAMZA increased the risk of hemorrhage and gastrointestinal hemorrhage, including severe and sometimes fatal hemorrhagic events. In Study 1, the incidence of severe bleeding was 3.4% for CYRAMZA and 2.6% for placebo. In Study 2, the incidence of severe bleeding was 4.3% for CYRAMZA plus paclitaxel and 2.4% for placebo plus paclitaxel. Patients with gastric cancer receiving nonsteroidal anti-inflammatory drugs (NSAIDs) were excluded from enrollment in Studies 1 and 2; therefore, the risk of gastric hemorrhage in CYRAMZA-treated patients with gastric tumors receiving NSAIDs is unknown. In Study 3, the incidence of severe bleeding was 2.4% for CYRAMZA plus docetaxel and 2.3% for placebo plus docetaxel. Patients with NSCLC receiving therapeutic anticoagulation or chronic therapy with NSAIDS or other anti-platelet therapy other than once daily aspirin or with radiographic evidence of major airway or blood vessel invasion or intratumor cavitation were excluded from Study 3; therefore, the risk of pulmonary hemorrhage in these groups of patients is unknown. Permanently discontinue CYRAMZA in patients who experience severe bleeding.

Arterial Thromboembolic Events

Serious, sometimes fatal, arterial thromboembolic events (ATEs) including myocardial infarction, cardiac arrest, cerebrovascular accident, and cerebral ischemia occurred in clinical trials including 1.7% of 236 patients who received CYRAMZA as a single agent for gastric cancer in Study 1. Permanently discontinue CYRAMZA in patients who experience a severe ATE.

Hypertension

An increased incidence of severe hypertension occurred in patients receiving CYRAMZA as a single agent (8%) as compared to placebo (3%) and in patients receiving CYRAMZA plus paclitaxel (15%) as compared to placebo plus paclitaxel (3%) and in patients receiving CYRAMZA plus docetaxel (6%) as compared to placebo plus docetaxel (2%). Control hypertension prior to initiating treatment with CYRAMZA. Monitor blood pressure every two weeks or more frequently as indicated during treatment. Temporarily suspend CYRAMZA for severe hypertension until medically controlled. Permanently discontinue CYRAMZA if medically significant hypertension cannot be controlled with antihypertensive therapy or in patients with hypertensive crisis or hypertensive encephalopathy.

Infusion-Related Reactions

Prior to the institution of premedication recommendations across clinical trials of CYRAMZA, infusion-related reactions (IRRs) occurred in 6 out of 37 patients (16%), including two severe events. The majority of IRRs across trials occurred during or following a first or second CYRAMZA infusion. Symptoms of IRRs included rigors/tremors, back pain/spasms, chest pain and/or tightness, chills, flushing, dyspnea, wheezing, hypoxia, and paresthesia. In severe cases, symptoms included bronchospasm, supraventricular tachycardia, and hypotension. Monitor patients during the infusion for signs and symptoms of IRRs in a setting with available resuscitation equipment. Immediately and permanently discontinue CYRAMZA for Grade 3 or 4 IRRs.

Gastrointestinal Perforations

CYRAMZA is an antiangiogenic therapy that can increase the risk of gastrointestinal perforation, a potentially fatal event. Four of 570 patients (0.7%) who received CYRAMZA as a single agent in clinical trials experienced gastrointestinal perforation. In Study 2, the incidence of gastrointestinal perforations was also increased in patients that received CYRAMZA plus paclitaxel (1.2%) as compared to patients receiving placebo plus paclitaxel (0.3%). In Study 3, the incidence of gastrointestinal perforation was 1% for CYRAMZA plus docetaxel and 0.3% for placebo plus docetaxel. Permanently discontinue CYRAMZA in patients who experience a gastrointestinal perforation.

Impaired Wound Healing

CYRAMZA has not been studied in patients with serious or non-healing wounds. CYRAMZA is an antiangiogenic therapy with the potential to adversely affect wound healing. Withhold CYRAMZA prior to surgery. Resume following the surgical intervention based on clinical judgment of adequate wound healing. If a patient develops wound healing complications during therapy, discontinue CYRAMZA until the wound is fully healed.

Clinical Deterioration in Patients with Child-Pugh B or C Cirrhosis

Clinical deterioration, manifested by new onset or worsening encephalopathy, ascites, or hepatorenal syndrome was reported in patients with Child-Pugh B or C cirrhosis who received single-agent CYRAMZA. Use CYRAMZA in patients with Child-Pugh B or C cirrhosis only if the potential benefits of treatment are judged to outweigh the risks of clinical deterioration.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS)

RPLS has been reported with a rate of <0.1% in clinical studies with CYRAMZA. Confirm the diagnosis of RPLS with MRI and discontinue CYRAMZA in patients who develop RPLS. Symptoms may resolve or improve within days, although some patients with RPLS can experience ongoing neurologic sequelae or death.

ADVERSE REACTIONS

Clinical Trials Experience

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

CYRAMZA Administered in Combination with Docetaxel

Study 3 was a multinational, randomized, double-blind study conducted in patients with NSCLC with disease progression on or after one platinum-based therapy for locally advanced or metastatic disease. Patients received either CYRAMZA 10 mg/kg intravenously plus docetaxel 75 mg/m^2 intravenously every 3 weeks or placebo plus docetaxel 75 mg/m^2 intravenously every 3 weeks. Due to an increased incidence of neutropenia and febrile neutropenia in patients enrolled in East Asian sites, Study 3 was amended and 24 patients (11 CYRAMZA plus docetaxel, 13 placebo plus docetaxel) at East Asian sites received a starting dose of docetaxel at 60 mg/m^2 every 3 weeks. Study 3 excluded patients with an ECOG PS of 2 or greater, bilirubin greater than the upper limit of normal (ULN), uncontrolled hypertension, major surgery within 28 days, radiographic evidence of major airway or blood vessel invasion by cancer, radiographic evidence of intra-tumor cavitation, or gross hemoptysis within the preceding 2 months, and patients receiving therapeutic anticoagulation or chronic anti-platelet therapy other than once daily aspirin. The study also excluded patients whose only prior treatment for advanced NSCLC was a tyrosine kinase (epidermal growth factor receptor [EGFR] or anaplastic lymphoma kinase [ALK]) inhibitor. The data described below reflect exposure to CYRAMZA plus docetaxel in 627 patients in Study 3. Demographics and baseline characteristics were similar between treatment arms. Median age was 62 years; 67% of patients were men; 84% were White and 12% were Asian; 33% had ECOG PS 0; 74% had non-squamous histology and 25% had squamous histology. Patients received a median of 4.5 doses of CYRAMZA; the median duration of exposure was 3.5 months, and 195 (31% of 627) patients received CYRAMZA for at least six months. In Study 3, the most common adverse reactions (all grades) observed in CYRAMZA plus docetaxel-treated patients at a rate of ≥30% and ≥2% higher than placebo plus docetaxel were neutropenia, fatigue/asthenia, and stomatitis/mucosal inflammation. Treatment discontinuation due to adverse reactions occurred more frequently in CYRAMZA plus docetaxel-treated patients (9%) than in placebo plus docetaxel-treated patients (5%). The most common adverse events leading to treatment discontinuation of CYRAMZA were infusion-related reaction (0.5%) and epistaxis (0.3%). For patients with non-squamous histology, the overall incidence of pulmonary hemorrhage was 7% and the incidence of ≥Grade 3 pulmonary hemorrhage was 1% for CYRAMZA plus docetaxel compared to 6% overall incidence and 1% for ≥Grade 3 pulmonary hemorrhage for placebo plus docetaxel. For patients with squamous histology, the overall incidence of pulmonary hemorrhage was 10% and the incidence of ≥Grade 3 pulmonary hemorrhage was 2% for CYRAMZA plus docetaxel compared to 12% overall incidence and 2% for ≥Grade 3 pulmonary hemorrhage for placebo plus docetaxel. The most common serious adverse events with CYRAMZA plus docetaxel were febrile neutropenia (14%), pneumonia (6%), and neutropenia (5%). The use of granulocyte colony-stimulating factors was 42% in CYRAMZA plus docetaxel-treated patients versus 37% in patients who received placebo plus docetaxel. In patients ≥65 years, there were 18 (8%) deaths on treatment or within 30 days of discontinuation for CYRAMZA plus docetaxel and 9 (4%) deaths for placebo plus docetaxel. In patients <65 years, there were 13 (3%) deaths on treatment or within 30 days of discontinuation for CYRAMZA plus docetaxel and 26 (6%) deaths for placebo plus docetaxel. Table 4 provides the frequency and severity of adverse reactions in Study 3.

Table 4: Adverse Reactions Occurring at Incidence Rate ≥5% and a ≥2% Difference Between Arms in Patients Receiving CYRAMZA in Study 3

Adverse Reactions (MedDRA) System Organ Class	CYRAMZA plus docetaxel (N=627)		Placebo plus docetaxel (N=618)	
	All Grades (Frequency %)	Grade 3-4 (Frequency %)	All Grades (Frequency %)	Grade 3-4 (Frequency %)
Blood and Lymphatic System Disorders				
Febrile neutropenia	16	16	10	10
Neutropenia	55	49	46	40
Thrombocytopenia	13	3	5	<1
Gastrointestinal Disorders				
Stomatitis/Mucosal inflammation	37	7	19	2
Eye Disorders				
Lacrimation increased	13	<1	5	0
General Disorders and Administration Site Disorders				
Fatigue/Asthenia	55	14	50	11
Peripheral edema	16	0	9	<1
Respiratory, Thoracic, and Mediastinal Disorders				
Epistaxis	19	<1	7	<1
Vascular Disorders				
Hypertension	11	6	5	2

Clinically relevant adverse drug reactions reported in ≥1% and <5% of the CYRAMZA plus docetaxel-treated patients in Study 3 were hyponatremia (4.8% CYRAMZA plus docetaxel versus 2.4% for placebo plus docetaxel) and proteinuria (3.3% CYRAMZA plus docetaxel versus 0.8% placebo plus docetaxel).

Immunogenicity

As with all therapeutic proteins, there is the potential for immunogenicity. In 19 clinical trials, 70/2131 (3.3%) of CYRAMZA-treated patients with post baseline serum samples tested positive for treatment-emergent anti-ramucirumab antibodies by an enzyme-linked immunosorbent assay (ELISA). Neutralizing antibodies were detected in 12 of the 70 patients who tested positive for treatment-emergent anti-ramucirumab antibodies. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of incidence of antibodies to CYRAMZA with the incidences of antibodies to other products may be misleading.

DRUG INTERACTIONS

No pharmacokinetic (PK) interactions were observed between ramucirumab and docetaxel.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C

Risk Summary

Based on its mechanism of action, CYRAMZA may cause fetal harm. Animal models link angiogenesis, VEGF and VEGF Receptor 2 (VEGFR2) to critical aspects of female reproduction, embryofetal development, and postnatal development. There are no adequate or well-controlled studies of ramucirumab in pregnant women. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to a fetus.

Animal Data

No animal studies have been specifically conducted to evaluate the effect of ramucirumab on reproduction and fetal development. In mice, loss of the VEGFR2 gene resulted in embryofetal death and these fetuses lacked organized blood vessels and blood islands in the yolk sac. In other models, VEGFR2 signaling was associated with development and maintenance of endometrial and placental vascular function, successful blastocyst implantation, maternal and feto-placental vascular differentiation, and development during early pregnancy in rodents and non-human primates. Disruption of VEGF signaling has also been associated with developmental anomalies including poor development of the cranial region, forelimbs, forebrain, heart, and blood vessels.

Nursing Mothers

It is not known whether CYRAMZA is excreted in human milk. No studies have been conducted to assess CYRAMZA's impact on milk production or its presence in breast milk. Human IgG is excreted in human milk, but published data suggests that breast milk antibodies do not enter the neonatal and infant circulation in substantial amounts. Because many drugs are excreted in human milk and because of the potential risk for serious adverse reactions in nursing infants from ramucirumab, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

The safety and effectiveness of CYRAMZA in pediatric patients have not been established. In animal studies, effects on epiphyseal growth plates were identified. In cynomolgus monkeys, anatomical pathology revealed adverse effects on the epiphyseal growth plate (thickening and osteochondropathy) at all doses tested (5-50 mg/kg). Ramucirumab exposure at the lowest weekly dose tested in the cynomolgus monkey was 0.2 times the exposure in humans at the recommended dose of ramucirumab as a single agent.

Geriatric Use

Of the 563 CYRAMZA-treated patients in two randomized gastric cancer clinical studies, 36% were 65 and over, while 7% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. Of the 1253 patients in Study 3, 455 (36%) were 65 and over and 84 (7%) were 75 and over. Of the 627 patients who received CYRAMZA plus docetaxel in Study 3, 237 (38%) were 65 and over, while 45 (7%) were 75 and over. In an exploratory subgroup analysis of Study 3, the hazard ratio for overall survival in patients less than 65 years old was 0.74 (95% CI: 0.62, 0.87) and in patients 65 years or older was 1.10 (95% CI: 0.89, 1.36).

Renal Impairment

No dose adjustment is recommended for patients with renal impairment based on population PK analysis.

Hepatic Impairment

No dose adjustment is recommended for patients with mild hepatic impairment (total bilirubin within upper limit of normal [ULN] and aspartate aminotransferase [AST] >ULN or total bilirubin >1.0-1.5 times ULN and any AST) based on population PK analysis. Clinical deterioration was reported in patients with Child-Pugh B or C cirrhosis who received single-agent CYRAMZA.

Females and Males of Reproductive Potential

Fertility

Advise females of reproductive potential that CYRAMZA may impair fertility.

Contraception

Based on its mechanism of action, CYRAMZA may cause fetal harm. Advise females of reproductive potential to avoid getting pregnant while receiving CYRAMZA and for at least 3 months after the last dose of CYRAMZA.

DOSAGE AND ADMINISTRATION

Do not administer CYRAMZA as an intravenous push or bolus.

Recommended Dose and Schedule

The recommended dose of CYRAMZA is 10 mg/kg administered by intravenous infusion over approximately 60 minutes on day 1 of a 21-day cycle prior to docetaxel infusion. Continue CYRAMZA until disease progression or unacceptable toxicity

Premedication

Prior to each CYRAMZA infusion, premedicate all patients with an intravenous histamine H_1 antagonist (e.g., diphenhydramine hydrochloride). For patients who have experienced a Grade 1 or 2 infusion reaction, also premedicate with dexamethasone (or equivalent) and acetaminophen prior to each CYRAMZA infusion.

Dose Modifications

Infusion-Related Reactions (IRR)

- Reduce the infusion rate of CYRAMZA by 50% for Grade 1 or 2 IRRs.
- Permanently discontinue CYRAMZA for Grade 3 or 4 IRRs.

Hypertension

- Interrupt CYRAMZA for severe hypertension until controlled with medical management.
- Permanently discontinue CYRAMZA for severe hypertension that cannot be controlled with antihypertensive therapy.

Proteinuria

- Interrupt CYRAMZA for urine protein levels ≥2 g/24 hours. Reinitiate treatment at a reduced dose of 8 mg/kg every 2 weeks once the urine protein level returns to <2 g/24 hours. If the protein level ≥2 g/24 hours reoccurs, interrupt CYRAMZA and reduce the dose to 6 mg/kg every 2 weeks once the urine protein level returns to <2 g/24 hours.
- Permanently discontinue CYRAMZA for urine protein level >3 g/24 hours or in the setting of nephrotic syndrome.

Wound Healing Complications

- Interrupt CYRAMZA prior to scheduled surgery until the wound is fully healed.

Arterial Thromboembolic Events, Gastrointestinal Perforation, or Grade 3 or 4 Bleeding

- Permanently discontinue CYRAMZA.

For toxicities related to docetaxel, refer to the current respective prescribing information.

PATIENT COUNSELING INFORMATION

Advise patients:

- That CYRAMZA can cause severe bleeding. Advise patients to contact their health care provider for bleeding or symptoms of bleeding including lightheadedness.
- Of increased risk of an arterial thromboembolic event.
- To undergo routine blood pressure monitoring and to contact their health care provider if blood pressure is elevated or if symptoms from hypertension occur including severe headache, lightheadedness, or neurologic symptoms.
- To notify their health care provider for severe diarrhea, vomiting, or severe abdominal pain.
- That CYRAMZA has the potential to impair wound healing. Instruct patients not to undergo surgery without first discussing this potential risk with their health care provider.
- Of the potential risk for maintaining pregnancy, risk to the fetus, or risk to postnatal development during and following treatment with CYRAMZA and the need to avoid getting pregnant, including use of adequate contraception, for at least 3 months following the last dose of CYRAMZA.
- To discontinue nursing during CYRAMZA treatment.

Additional information can be found at www.CYRAMZAhcp.com.

Lilly

Eli Lilly and Company, Indianapolis, IN 46285, USA

RB-L HCP BS 17Dec2014

CYRAMZA® (ramucirumab) injection RB-L HCP BS 17Dec2014

Compliance Programs—No Longer Voluntary?

BY CINDY PARMAN, CPC, CPC-H, RCC

Healthcare remains one of the most heavily regulated industries in the United States. Physicians, hospitals, and other healthcare organizations are subject to a variety of statutes, regulations, and program requirements. In addition, the Centers for Medicare & Medicaid Services (CMS) has determined that most improper payments in the Medicare program occur because a provider did not comply with Medicare's coverage, coding, or billing rules.

The Affordable Care Act (ACA), as it matures, has increasing requirements for providers and one of these is the establishment of an effective compliance program. While many healthcare entities have already implemented compliance programs, a compliance plan will no longer be voluntary or optional. The mandate is set forth in Section 6401 of the ACA, which established a requirement that all enrolled providers and suppliers must revalidate their enrollment information under new screening provisions, and states that a "provider of medical or other items or services or supplier within a particular industry sector or category" shall establish a compliance program as a condition of enrollment in Medicare, Medicaid, or the Children's Health Insurance Program (CHIP).

The new screening process is required to include a licensure check, and may include a criminal background check, fingerprinting, unscheduled and unannounced site visits, and database checks. The statute requires the Secretary of Health and Human Services (HHS) to establish procedures to provide for a provisional period of not less than 30 days and not more than one year during which new providers and suppliers, as the Secretary determines appropriate, would be subject to enhanced oversight, such as prepayment review and payment caps.[1]

In addition, Section 6401 states that regardless of provider size, implementation of a formal compliance plan is mandatory and that a new practice will not be able to enroll in Medicare or Medicaid without a compliance program in place. Last, the ACA requires that the HHS Secretary work in conjunction with the Office of the Inspector General (OIG) to delineate "core elements" of an acceptable program, and set a deadline for implementation of the program.

At the time this article was completed, HHS had not yet set the final guidelines or a deadline for certifying effectiveness for healthcare providers, including hospitals and physician practices, but a compliance program is still technically mandated by law. The consequences for not having a compliance program in place could be severe, including civil penalties, criminal prosecution, and exclusion from the Medicare, Medicaid, and CHIP programs.[2]

Don't Assume You Have One

Even if you believe the healthcare organization, at a corporate level, has a compliance program in place, do you know how it affects your department, your electronic health record (EHR), or your employees? Does Compliance audit your department, providing ongoing materials and presentations, or do they generally leave you alone to work without ongoing support? Ensuring compliance with the myriad of coding and billing regulations is everyone's job, so make sure you are connected to your Compliance Department, or take the responsibility for compliance into your own hands. A successful compliance plan sends a message to the staff, physicians, payers, and regulators that the cancer program is trying to prevent errors. According to the Jan. 16, 2009, Federal Register:[3]

"Coding is the assignment of a code to a specific clinical condition or procedure; the mechanism used to do this, whether electronic or manual may differ, but codes are still assigned."

This means that every individual who captures a charge in an EHR, checks a code on a fee slip, or uses coding references to report a procedure or diagnosis code on an insurance claim is "coding." As a result, every individual who codes must be trained to ensure compliance with coding and billing guidelines and regulations.

Why Comply?

An effective compliance program is more than just obedience to laws, regulations, and policies. If an ethics and compliance program is to permeate the healthcare organization, it must speak to the concerns of providers who may not link the relevance of charge capture (electronic or via paper charge ticket) to Medicare reimbursement. In addition to complying with the law, there are other good reasons for implementing a compliance program. An effective compliance program can:

- Identify potential lost revenue issues
- Strengthen operational efficiencies
- Reduce denial rates and error correction
- Improve medical record documentation

- Enhance the organization's professional reputation
- Identify existing or new problems before they are too complicated or expensive to correct
- Reduce the risk of lawsuits, fines, and penalties
- Enhance the quality of care.

In addition, the implementation of an effective compliance plan can foster better communication between billing and clinical staff, ensuring increased understanding of coding and billing rules.

An effective compliance plan is an active compliance plan, and an active compliance plan will keep pace with rapidly changing government regulations, payer requirements, office operations, and changes in technology. According to Above Reproach: Developing a Comprehensive Ethics and Compliance Program:[4]

"Fundamentally, an ethics and compliance program has two purposes: to ensure that all individuals in an organization observe pertinent laws and regulations in their work; and to articulate a broader set of aspirational ethical standards that are well-understood within the organization and become a practical guideline for organization members making decisions that raise ethical concerns."

Compliance Guidelines

Although the OIG has provided guidance for various healthcare entities when developing a compliance program, there is no "one-size-fits-all" compliance plan. Therefore, consider using the OIG guidance as a foundation when developing a more customized program to meet physician, facility, or cancer program needs. For example, here are the OIG's "Seven Fundamental Elements of an Effective Compliance Program," which were first published in a 1998 Federal Register:[5]

1. Implement written policies, procedures, and standards of conduct. These standards, policies, and procedures should be easily accessible to everyone in the department or cancer center and should be based on your organization's unique risk areas. Remember that a compliance plan constitutes more than filling out a series of templated forms, placing them in a binder, and letting the resulting product gather dust on a shelf.
2. Designate a compliance officer and Compliance Committee. Every cancer program employee should know who their compliance representative is and how to contact that individual if there is a concern regarding a current practice. Compliance Department staff is empowered to audit billed services, educate other employees, update physicians, and initiate corrective actions should an error be detected.
3. Conduct ongoing training and education. At a minimum this means that all new employees receive general and/or specialized training, based on their job function. In addition, there should be annual refresher classes for all staff. Training should be tracked to include the date, content of each session, delivery method (such as webinar, in-person training), and signatures of all employees who attended the training.
4. Develop effective lines of communication. An open, user-friendly process should be established to report any questionable conduct. The anonymity of those reporting the problems should be maintained, and methods to accomplish this can include a compliance bulletin board, drop box, or posting the compliance hotline number in a prominent location.
5. Conduct internal monitoring and auditing. Monitoring uses the control systems, as designed and implemented by management, to direct and correct day-to-day operations. Auditing, in contrast, predominantly consists of retrospectively testing the established monitoring systems to ensure they are functioning as prescribed. Periodic chart audits should be scheduled to ensure that the medical record documentation supports all diagnosis and procedure codes billed to insurance. The date of service, level of service, performing provider, medical necessity, and other elements to ensure correct billing should be monitored and education performed when deviations are detected.
6. Enforce standards through well-publicized disciplinary guidelines. Any violations of the tenets of the compliance program should be dealt with through disciplinary actions, including reprimands, probation, demotion, suspension, and even termination, depending on the severity of the violation.
7. Respond promptly to detected offenses and undertake corrective action. Once you find a problem, it is essential that there be swift investigation and if

necessary, immediate corrective action. Corrective action may also include the return of any federal program or other payer overpayments and voluntary self-disclosure to appropriate agencies when warranted. It may also be necessary to retain legal counsel to ensure that all legal issues are considered when evaluating and implementing corrective actions.

In addition, the OIG offers "Five Practical Tips for Creating a Culture of Compliance:"[5]

1. Make compliance plans a priority now.
2. Know your fraud and abuse risk areas.
3. Manage your financial relationships.
4. Just because your competitor is doing something doesn't mean that you can or should.
5. When in doubt, ask for help.

The OIG's guidance to individual and small physician practices emphasizes that compliance plans must be active programs:[6]

"Compliance programs are not just written standards and procedures that sit on a shelf in the main office of a practice, but are an everyday part of the practice operations. It is by integrating the compliance program into the practice culture that the practice can best achieve maximum benefit from its compliance program."

In other words, the compliance effort is about individuals on a day-to-day basis knowing what is expected of them and doing it and about never compromising integrity—regardless of the pressures faced. It is by integrating the compliance program into the practice culture that the organization can best achieve maximum benefit from its compliance program.

Reduce Fraud, Waste & Abuse

A key objective of the ACA is to rein in federal healthcare spending, so providers that accept Medicare payments should expect increased efforts to identify overpayments and fraud. The mandate to institute a formal compliance plan shifts part of the burden of preventing fraud, waste, and abuse from the federal government to healthcare providers. This means that CMS will try to minimize the need to "pay and chase" and expect physicians and facilities to more closely monitor their compliance with coding, billing, and anti-kickback regulations. For example, if there is a problem with code assignment, the federal government can in the future point to the compliance program requirement and state that the provider violated their own compliance plan.

It is inevitable—at any time HHS or the OIG can publish the mandated core elements and the timeline for implementation as required by section 6401. But rather than procrastinate, now is the time for all cancer programs to start structuring an effective compliance program. A healthy compliance program is like a living organism that continues to grow and evolve over time, becoming better and stronger at managing risks and continuing to inspire the highest ethical goals for practice employees. The more a cancer program invests in the development and implementation of an effective compliance program, the more likely it is that the program will go beyond mere compliance and become a driver of continuous improvement throughout the entire organization. OI

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spotlight

Bismarck Cancer Center
Bismarck, North Dakota

Bismarck Cancer Center (BCC) is a joint venture between Bismarck's two medical centers—CHI St. Alexius Medical Center and Sanford Bismarck Medical Center. BCC is a freestanding facility providing radiation oncology services to a patient population spanning a 250-mile radius that includes most of North Dakota, and parts of South Dakota and Montana. While the facility is situated in the city of Bismarck, this wide catchment area requires BCC to perform "both a rural approach, as well as a more urban approach" to cancer care, according to Ken Dykes, BCC's executive director.

Outreach and Education

BCC is proactive in its approach to mitigating barriers to care for patients living in more rural areas. "We already have people who drive a considerable distance to receive treatment here, so we try to reach out to them. We provide housing and transportation assistance, and a host of other wrap-around services to try and make access to care as easy and painless as it can possibly be," said Dykes. BCC conducts two outreach clinics each month. Two BCC radiation oncologists, along with nursing staff, travel to these clinics located 100 miles from Bismarck.

The cancer center also employs an outreach coordinator who is responsible for community relations and development. "The idea is that cancer affects everybody, so the better job we do letting people know what's available and where it's available, the better off everyone will be," said Dykes. BCC's outreach efforts focus mainly on education and screening in local communities, as well as making people aware of resources that are available within driving distance of where they live. "Our belief is that if we actually meet, talk to, and establish a relationship with people throughout our service area, then they'll be more likely to pick up the phone and call us if they have specific needs or questions. Or they can call the [outreach] coordinator to ask her to facilitate resources they might like to have brought into the community," said Dykes.

Bismarck Cancer Center Foundation

Since 2007 the Bismarck Cancer Center Foundation has helped to ease some of the additional burdens that accompany a cancer diagnosis. For patients traveling to the Bismarck location to receive treatment, BCC offers both travel assistance and lodging assistance. Through the Bismarck Cancer Center Foundation, patients can receive gas cards and have access to discounted furnished apartments within walking distance of the cancer center and discounted rooms at nearby hotels. In addition to transportation and lodging assistance, foundation funds support a survivorship program, a massage therapist, dietitian/nutrition counseling, physical therapy, occupational therapy with lymphedema, support groups, and survivorship classes.

"Making sure that we provide not only the best technology and treatments, but also care that meets all other patient needs is why BCC can provide wraparound care," said Amy Gross, assistant director of operations.

All BCC staff are empowered to be alert to needs that are expressed or manifest (even if they're not expressed) by patients and families as they come through the cancer center. If staff notes an issue, they can initiate a meeting with the fiscal officer to move forward with setting a patient up with foundation assistance. The foundation raises funds through donations, community events and fundraisers, and local and national grants.

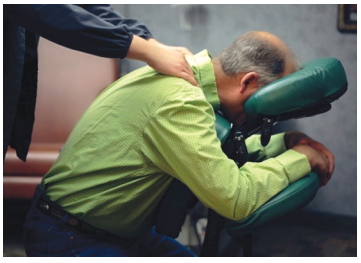
Dykes gives credit to the foundation's advisory board for the success in securing assistance for patients in need. A group of dedicated volunteers, the advisory board is comprised of "leaders in the community" who generously donate their time and energy to help reduce barriers to care for indigent patients.

Additional patient support is provided via BCC's REACH (Resources, Educate, Advocacy, Care, Hope) program. The REACH

Select Support Services

- Support group
- Financial assistance
- Transportation assistance
- Lodging assistance
- Massage therapy
- Spiritual and emotional care
- Nutrition and dietary counseling
- Physical therapy
- Survivorship Care

Number of new analytic cases seen in 2014: 440



coordinator, a licensed independent clinical social worker (LICSW) meets with patients within the first week of treatment and provides the support services that a social worker would, including helping patients apply to financial assistance programs, educating patients on managing stress, and more. Patients have the option of meeting regularly with the REACH coordinator after this initial consult. The REACH program is funded through the BCC Foundation.

A Robust Service Line

BCC offers a full range of radiation oncology treatment modalities and also performs the following special procedures:

- External beam radiation therapy
  - 3D-CRT (conformal radiation therapy)
  - IMRT
  - VMAT (volumetric modulated arc therapy)
  - SRS (stereotactic radiosurgery)
  - SBRT (stereotactic body radiation therapy)
  - 4D-IGRT
- Brachytherapy
  - Low-dose rate brachytherapy (prostate seed implant)
  - High-dose rate brachytherapy (GYN and MammoSite).

BCC radiation oncologists regularly participate in multidisciplinary tumor conferences at area hospitals. In addition, they are actively involved in multidisciplinary breast cancer care conferences at both CHI St. Alexius Medical Center and Sanford Bismarck Medical Center.

Improving Care Coordination

As a cancer survivor, Dykes understands firsthand how draining the logistics of receiving cancer treatment can be. "Even under the best of circumstances, a cancer patient is often overwhelmed with the level of activity necessary to get to all of the people and places providing care. And all of this must take place at a time when the patient isn't feeling very well."

BCC is jointly owned by CHI St. Alexius and Sanford Health and provides radiation oncology services for both hospitals. To ensure smooth care coordination, BCC's patient navigation program establishes the connection between medical oncology and radiation oncology. BCC nurses handle the patient navigation responsibilities, helping patients and their families to find available resources, treatment services, and support options to best fit their unique needs. The BCC navigation program also schedules treatment and follow-up appointments, including imaging and labs; helps patients and their families understand doctors' instructions; and answers questions. In addition, the navigation program connects patients with support services for nutrition, physical therapy, massage therapy, emotional counseling, spiritual counseling, and solving practical problems related to treatment, for example, transportation, financial assistance, lodging, wigs and prosthetics, pain management, and exercise. BCC's nurses work with the doctors and cancer team to make sure patients are aware of services that can help them and ensure no gaps exist between medical and radiation oncology care.

BCC operates a physician hotline which allows doctors to speak directly to a radiation oncologist to get information or seek advice on treatment or side effects. Patients can also easily get their questions or concerns answered; BCC nurses field patient calls that involve the reporting of new symptoms or questions.

BCC employs two nurses specializing in cancer survivorship. They prepare comprehensive survivorship care plans that are provided to patients at the end of their radiation treatment. Survivorship care plans document the treatment patients received, a recommended follow-up schedule, short- and long-term side effects of the disease and treatments, what to look for regarding reoccurrence, chronological list of events in their cancer journey, and a list of various support systems within the community. The survivorship plan helps streamline communication for patients as they transition back to their primary care provider, and provides the patient with a concise treatment summary for use by any future treating personnel. OI

This "Spotlight" is a benefit of ACCC membership. To have your program profiled, email: jkornak@accc-cancer.org.

tools

Approved Drugs

• The Food and Drug Administration (FDA) has approved approved **Cyramza® (ramucirumab)** (Eli Lilly and Company, www.lilly.com) for use in combination with FOLFIRI for the treatment of patients with metastatic colorectal cancer (mCRC) whose disease has progressed on a first line bevacizumab-, oxaliplatin-, and fluoropyrimidine-containing regimen. Cyramza is a recombinant human monoclonal IgG1 antibody that binds to the human vascular endothelial growth factor-receptor 2 (VEGF-R2), preventing the interaction of VEGF-R2 to its ligands.

• Bristol-Myers Squibb Company (www.bms.com) announced that the FDA has approved **Opdivo® (nivolumab)** for the treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy.

• The FDA has approved **Unituxin™ (dinutuximab) Injection** (United Thera- peutics Corporation, www.unither.com) in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to a prior first-line multi-agent, multimodality therapy.

• Sandoz Inc. (www.sandoz.com) announced that the FDA has approved **Zarxio™ (filgrastim-sndz) Injection** as a biosimilar to U.S.- licensed Neupogen for the five indications for which Neupogen is approved. The formulation of Zarxio differs from that of Neupogen in one inactive component.

• The FDA has approved a label update for **Zytiga® plus prednisone** (abiraterone acetate) (Janssen Research and Development, LLC, www.janssenrnd.com) to include treating men with metastatic castration- resistant prostate cancer (mCRPC) prior to chemotherapy. The FDA approval is based on the results from a planned second interim analysis of COU-AA-302, an international, randomized, double-blind, placebo controlled Phase III study that included 1,088 men with mCRPC who had not received prior chemotherapy.

Drugs in the News

• The FDA has granted fast track designation for **CPX-351 (cytarabine-daunorubicin)** (Celator Pharmaceuticals, Inc., www.celatorpharma.com) for the treatment of elderly patients with secondary acute myeloid leukemia (AML).

• Amgen (www.amgen,com) announced that the FDA has accepted a supplemental NDA (sNDA) for **Kyprolis® (carfilzomib) for Injection** for the treatment of patients with relapsed multiple myeloma who have received at least one prior therapy. The sNDA is designed to support the conversion of accelerated approval to full approval and expand the current Kyprolis indication.

• The FDA has granted orphan drug designation to Oncolytics Biotech® Inc. (www.oncolyticsbiotech.com) for its lead product candidate, **Reolysin®**, for the treatment of primary peritoneal cancers. It was also granted orphan drug designation for the treatment of malignant glioma and pancreatic cancer. The company recently submitted an application for orphan drug designation for Reolysin for the treatment of gastric cancer.

• RXi Pharmaceuticals Corporation announced that the FDA has granted orphan drug designation to **Samcyprone™** (a topical formulation of Diphenylcylcopropenone, DPCP) for the treatment of Stage IIb to IV malignant melanoma.

Neulasta® (pegfilgrastim) Delivery Kit Now Available in U.S.

The Neulasta Delivery Kit (Amgen, www.amgen.com) includes a specially designed single-use prefilled syringe co-packaged with the new On-body Injector for Neulasta. The kit will allow the healthcare provider to initiate administration of Neulasta on the same day as cytotoxic chemotherapy—with delivery of the patient's full dose of Neulasta the day following chemotherapy administration, consistent with the Neulasta prescribing information.

• Bexion Pharmaceuticals LLC (www.bexionpharma.com) announced today that the FDA has granted orphan drug designation for **Saposin C**, the active ingredient in its proprietary drug **BXQ-350** for the potential treatment of glioblastoma multiforme.

• The FDA has granted fast track designation to Soligenix, Inc. (www.soligenix.com) for its **SGX301 (synthetic hypericin) Development Program** for the first-line treatment of cutaneous T-cell lymphoma (CTCL). SGX301 is a photodynamic therapy utilizing safe visible light for activation.

• OncoMed Pharmaceuticals, Inc. (www.oncomed.com) announced that the FDA has granted orphan drug designation to **tarextumab (anti-Notch 2/3, OMP-59R5)** for the treatment of both pancreatic cancer and small cell lung cancer.

• Taiho Oncology, Inc. (www.taihooncology.com) announced the NDA for **TAS-102 (nonproprietary names: trifluridine and tipiracil hydrochloride)** has been accepted for review by the FDA. TAS-102 is an oral combination investigational anticancer drug for the treatment of refractory metastatic colorectal cancer (mCRC).

• The FDA has granted priority review for the NDA for **Yondelis® (trabectedin)** (Janssen Research & Development, LLC, www.janssenrnd.com) for patients with advanced soft tissue sarcoma, including liposarcoma and leiomyosarcoma subtypes, who have received prior chemotherapy, including an anthracycline.

Approved Devices

• Koning Corporation (www.koningcorporation.com) announced that the FDA has approved its **Koning Breast CT (KBCT) System** and **KBCT-Guided Biopsy Bracket**. KBCT is a 3D breast CT scanner designed specifically to image the entire breast with a single scan without compression of the breast tissue.

• The FDA has granted 510(k) marketing clearance for Intact Medical Corporation's (www.intactmedical.com) **Intact® System**. Specifically, the minimally-invasive technology has been cleared for its ability to preserve breast lesion architecture in samples of up to 30mm in diameter.

Devices in the News

• Perseon Corporation (www.bsdmedical.com/usa) announced that the company has received clearance from the FDA to market the **MicroThermX® Microwave Ablation System** for the specific indication of ablation procedures requiring partial or complete ablation of non-resectable liver tumors.

Genetic Tests and Assays in the News

• GenomeDx Biosciences (www.GenomeDx.com) announced that Palmetto GBA has issued a positive coverage policy through the MolDX Program for the company's **Decipher® Prostate Cancer Classifier**. Decipher is a genomic test intended for men who have had prostate surgery and are considered by guidelines to be at risk for their cancer returning. These are men who have specific risk factors for cancer recurrence, including positive surgical margins, pathological Stage T3 disease, or rising PSA after initial PSA nadir. The Medicare coverage policy covers men with prostate cancer who have these features and are weighing treatment options after a radical prostatectomy.

• Ventana Medical Systems, Inc. (www.ventana.com), a member of the Roche Group, announced its FDA submission for premarket approval (PMA) of the **Ventana ALK (D5F3) CDx Assay**. The companion diagnostic immunohistochemistry test is designed to identify ALK-positive lung cancer patients that may benefit from treatment with targeted therapy that inhibits the ALK gene. OI

Important Change to Imbruvica Coverage

To ensure that Medicare patients can receive the coverage gap discount for Imbruvica, Pharmacyclics, Inc., has established a contract to participate in the Medicare Coverage Gap Discount Program. Effective Jan. 1, 2015, all dispensing offices and Specialty Pharmacy Providers (SPPs) should no longer use Ortho-McNeil-Janssen Pharmaceuticals' "P" number when billing for Imbruvica and instead use Pharmacyclics, Inc.'s "P" number and labeler code for the drug. A labeler code can only be assigned to one "P" number, thus Medicare claims will not adjudicate properly and patients will not receive the proper discounts under the coverage gap discount program if the incorrect tip "P" number is used. Below are the three things you need to know to effectively make this change:

1. Pharmacyclics, Inc.'s "P" number is P1396.
2. The labeler code for Imbruvica is 57962.
3. For the final billing procedure, submit a Medicare Part D prescription for Imbruvica using: Pharmacyclics, Inc. P1396, labeler code 57962.

Questions? Call 1.877.877.3536 or ask your Pharmacyclics and Janssen field representative.

QDACT

A web-based tool shines a light on quality palliative care

BY ARIF H. KAMAL, MD; JONATHAN M. NICOLLA, MBA; NRUPEN A. BHAVSAR, PhD, MPH; FREDERICK A.P. FRIEDMAN, BA; LAURA M. ROE, BA; MATTHEW J. HARKER, MBA; AMY P. ABERNETHY, MD, PhD; AND JANET H. BULL, MD

A disconnect exists between measuring the quality of healthcare and the subsequent evidence-based improvements needed to treat patients with serious cancer and their caregivers.[1] Though this disparity persists, methods are evolving to measure quality of healthcare, reflecting an increased focus on aligning current practices with accepted best standards of care, and identifying where opportunities for improvement exist. Duke University Medical Center and Four Seasons Compassion for Life have partnered with the Global Palliative Care Quality Alliance to institute an ambitious plan to standardize quality measurement, promote comparison of data on quality, and share best practices across academic and community palliative care organizations. This approach will position the growing and maturing field of palliative care to meet the increasing demands for high-quality care set forth by healthcare reform. This article describes our underlying approach of rapid learning quality improvement (RLQI), the development of our partnerships, and our novel electronic tool to capture data on quality.

RLQI: Improving Care through Data

A major gap in healthcare persists between identified areas for quality improvement (QI), innovations to address these areas, and then processes to implement these discoveries in everyday care. Historically, QI initiatives have relied heavily on antiquated processes that suffer from two key limitations. First, traditional QI approaches address one measure of change and subsequent, downstream changes in only one outcome. For example, conventional methods do not easily perform simultaneous assessments of several, rapidly implemented changes and longitudinal changes in several related clinical, administrative, and financial outcomes. Second, data collection for information on quality usually relies on either paper-based methods or manual abstractions of retrospective clinical data. This approach is quite cumbersome. Further, real-time analysis is virtually impossible. Together, these limitations reinforce current QI methods within a rigid, retrospective construct that does not have the flexibility needed to dynamically improve the care of patients.

> By combining the three benefits of RLQI, clinicians can make actionable decisions that rapidly impact a patient's overall well-being with greater certainty...

RLQI leverages the core concepts of quality improvement by integrating the Institute of Medicine's (IOM) vision and principles for a rapid learning healthcare system to drive quality improvement (see Figure 1, page 24). This approach requires the principles of:

- Rapid collection, summation, and analysis of data
- Rapid integration of new knowledge back into clinical delivery
- Continuous learning from everyday clinical care delivery.

Just as Rapid Learning Health Systems as proposed by the IOM revolutionized thinking about how new research knowledge is developed, RLQI empowers palliative care organizations to use data on quality to advance how clinical care is delivered. By

Essentially, RLQI allows a clinician to determine and then implement positive processes of healthcare delivery much more quickly than standard QI or research-based methods.

Figure 1. Rapid Learning Quality Improvement Clinical Workflow

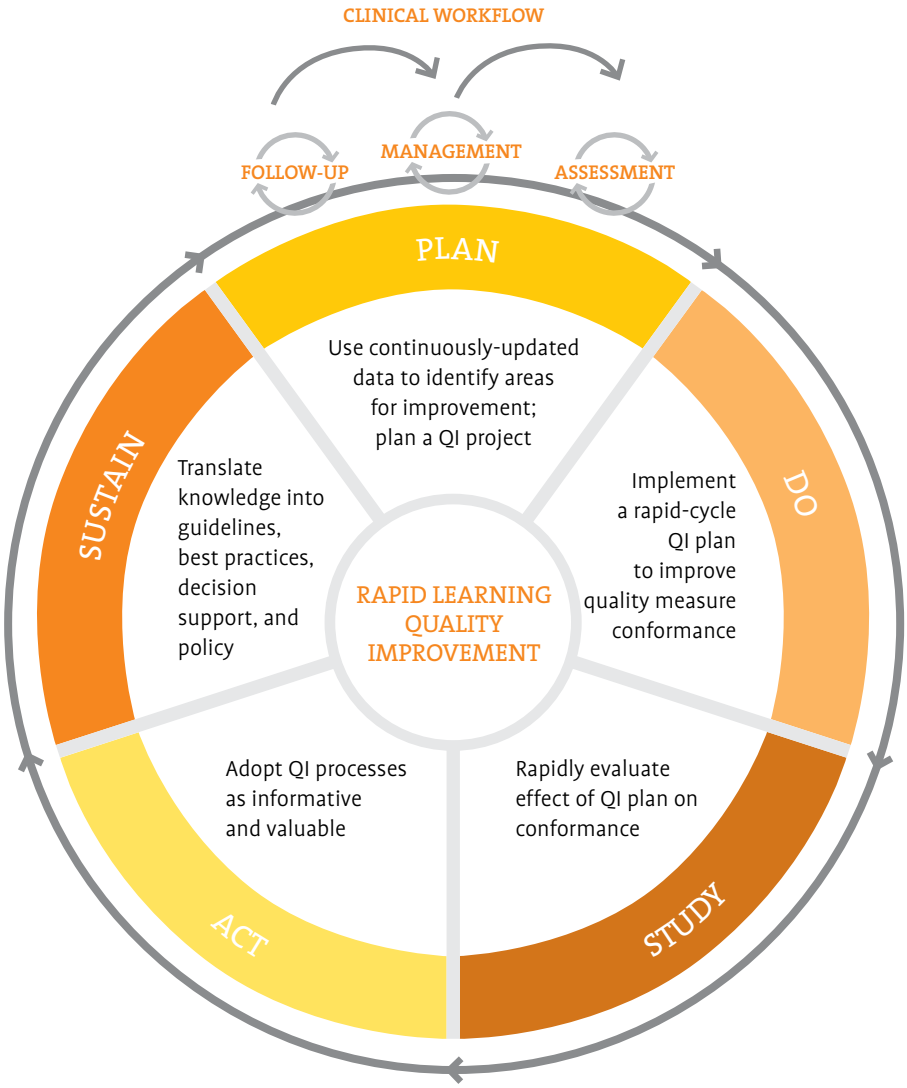


Table 1. Quality Measures Informed by QDACT

QUALITY DOMAIN	PERCENT OF ALL PATIENT-REPORTED QUALITY MEASURES INFORMED BY QDACT	QUALITY MEASURES EXCLUDED FROM QDACT
Structure and processes of care	13/14 = 93%	Structural measures involving team structure and competencies
Physical aspects of care	69/85 = 81%	Measures specific to chemotherapy or radiation treatments in cancer patients, those specific to diarrhea and skin rash, workup for anemia, and invasive interventions for pleural effusion, causes, and treatment of delirium
Psychiatric and psychological aspects of care	12/13 = 92%	Caregiver grief, bereavement, and satisfaction with care
Spiritual and existential aspects of care	2/4 = 50%	Caregiver satisfaction, value of life
Social aspects of care	1/3 = 33%	Family structure, caregiver preference, caregiver satisfaction with patient life stance
Cultural aspects of care	1/1 = 100%	Most not measured by patient response
Care of the imminently dying	1/1 = 100%	Most that involve information sharing with family
Ethical and legal aspects of care	26/31 = 84%	Patient preferences for location of care; informed decision making regarding chemotherapy
All domains and measures	125/152 = 82%	

combining these three benefits of RLQI, clinicians can make actionable decisions that rapidly impact a patient's overall well-being with greater certainty, while determining the effects of a single clinical instrument (such as the web-based assessment tool discussed later in this article) on multiple clinical outcomes.[2] Essentially, RLQI allows a clinician to determine and then implement positive processes of healthcare delivery much more quickly than standard QI or research-based methods. The end result: patients receive the best care possible, as quickly as possible.

Developing a Regional Consortium on Quality in Palliative Care

Recognizing the need to test and adopt this new model of quality improvement, the Carolinas Palliative Care Consortium ("Carolinas Consortium") was created in 2007. This academic and community collaboration was comprised of five sites throughout the state:

1. Duke University Medical Center, Durham, N.C.
2. Four Seasons Compassion for Life, Flat Rock, N.C.
3. Forsyth Palliative Care, Winston-Salem, N.C.
4. Hospice of Wake, Raleigh, N.C.
5. Horizons Palliative Care, Raleigh, N.C.

Each of these locations collected patient-level data on paper, entered this information into a local database, and intermittently transmitted the data to a centralized dataset maintained at Duke for analysis and quality reporting. The information contributed to a growing data resource, which the Consortium called the Palliative Care Database. From June 2008 through October 2011, data from a total of 6,957 unique patients were collected. The Palliative Care Database provided proof of concept that collecting data on quality is feasible in community settings and that these data can inform both clinical practice and institutional priorities in community-based palliative care.[3] Data collection processes, however, were inefficient and the data collected did not always map to emerging quality measures. The Carolinas Consortium recognized that a web-based solution that would align with expectations for quality monitoring in palliative care was needed.[4]

A Web-Based Solution

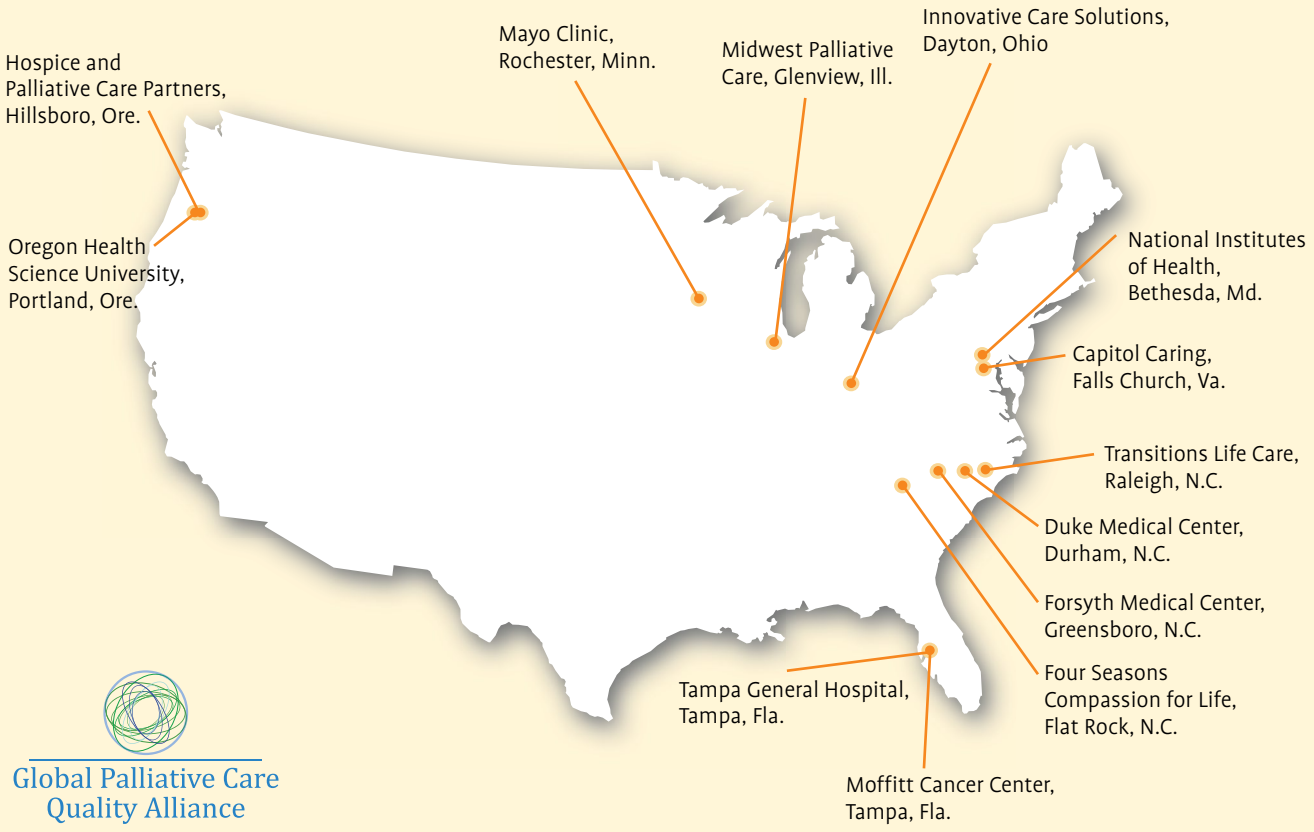
In developing a quality assessment tool that would be applicable to everyday practice, the Consortium followed six steps. These steps were accomplished over the course of a year through biweekly telephone conferences and three in-person meetings between the members of the Carolinas Consortium. These members included community palliative care providers and an interdisciplinary team of clinicians, researchers, graphic designers, software programmers, database analysts, and information security experts to ensure the new system met the rigorous demands of all stakeholders. The development process included conducting a needs assessment of clinicians to ensure that sustainability and validity of data collection practices demonstrate value for the time clinicians spend collecting the data.

Step 1. The Carolinas Consortium reviewed the Palliative Care Database project and then surveyed participating clinicians to identify the strengths and weaknesses of the database and to seek suggestions for improvement. Additionally, during a two-day retreat, the Carolinas Consortium facilitated an in-person group discussion with clinicians and administrative stakeholders from

Table 2. Domains and Components of QDACT

QDACT CLINICAL DOMAIN	QUALITY DOMAIN	NUMBER OF ITEMS	QUESTION SOURCES
Demographics	Cultural aspects of care, structure, and processes of care	20	Consortium-developed, Palliative Care Research Cooperative (http://palliativecareresearch.org); National Cancer Institute Bioinformatics Grid and Cancer Data Standards Registry and Repository (http://cbiit.nci.nih.gov/ncip); Australian Palliative Care Outcomes Collaborative (http://ahsri.uow.edu.au/pcoc/index.html)
Symptom assessment and management	Physical aspects of care; structure and processes of care	50	Edmonton Symptom Assessment Scale (ESAS); Memorial Symptom Assessment Scale (MSAS); two-question depression assessment, Consortium-developed
Advance care planning	Ethical and legal aspects of care	3	Consortium-developed
Psychosocial	Psychiatric and psychological aspects of care; social aspects of care	4	Consortium-developed; The Spitzer QOL Uniscale; the Perceived Family Burden Scale (PFBS); Linear Analog Scales of Assessment (LASA)
Independence & function	Consortium-developed	2	AKPS (Australia-modified Karnofsky Performance Scale); PPS (Palliative Performance Scale)
Spirituality	Spiritual and existential aspects of care	3	Consortium-developed; LASA; Johnson et al. "Are you at peace?" question
Prognosis	Consortium-developed	2	Consortium-developed
Transitions and discharge	Consortium-developed	7	Consortium-developed
Physician Quality Reporting System (PQRS)	None	4	Centers for Medicare & Medicaid Services (CMS) PQRS 2011 Measures

Figure 2. Global Palliative Care Quality Alliance (GPCQA)



each of the five sites to critically inventory lessons learned from the Palliative Care Database and to design and conceptualize improvements to the evolving quality tool.

Step 2. Next, the Carolinas Consortium performed a systematic review of all published quality measures relevant to palliative care, supportive oncology, and end-of-life care to identify measures from which the Consortium could choose to establish priorities for assessment.[5] Part of this process was to ensure that data collected would accurately and completely inform the scope of published quality measures found. Further, we needed to confirm that data on quality conformance would truly reflect the definitions, numerators, and denominators as meticulously outlined by the developers in the definitions of the quality metrics. These definitions include aspects of patient populations, timing, and settings for these measures (see Table 1, page 25).

Step 3. The Carolinas Consortium then developed a list of validated tools from a literature review that would inform these quality measures. When available, the Consortium tried to incorporate tools familiar to palliative care providers. In some instances, the Consortium added metrics and associated data elements based on group consensus. These metrics and data were necessary to ensure that applicability and familiarity of the instrument would extend to palliative care programs outside of the Carolinas Consortium (see Table 2, page 26).

Step 4. The Consortium wanted to ensure that the new system would be interoperable with other large databases to ensure future data comparisons and collaboration. We identified other applicable national and international databases and registries that would

Front row, left to right: Jonathan Nicolla, Fred Friedman, Laura Roe, Abigail Goodman, Arif Kamal, Laura Guth, Cheryl Brewer. Back row, left to right: Sajal Kumar, Quinn Chen, Ursula Rogers, Laura Criscione-Hodgson, Nrupen Bhavsar. (Not pictured: Amy Abernethy, Janet Bull.)

serve as references and completed the critical crosswalks to standardize definitions and terms. This step is a requirement of a sustainable and broadly applicable rapid learning healthcare system based on patient-reported outcomes.

Step 5. Next, the Consortium began to develop a new instrument that demonstrated scalability across expected future changes in the collection and sharing of palliative care data. Understanding how electronic health record (EHR) systems and platforms for collecting data evolve and change, it was important that we avoid making a new instrument that was operable only on specific operating systems, hardware, or Internet platforms, and instead would be compatible with the diverse IT resources used by palliative care programs nationwide.

Step 6. The Consortium's last task was to test the entire process—from data collection through transmission, storage, analysis, and management—while conforming to the highest data security standards for protected health information. This includes a thorough understanding of the threats to data security that stem from both hardware and software used at point-of-care, as well as the potential risks of transmitting data over diverse networks to a shared database.

The end result of all this work: the Quality Data Collection Tool (QDACT), a web-based, provider-entered, point-of-care quality assessment and reporting tool for palliative care. QDACT was a platform-agnostic, scalable, and open-sourced solution designed for data collection during clinical encounters. The Carolinas Consortium tested the tool from August 2010 through August 2011.

Data security and storage for undertakings like QDACT are a fundamental concern. After conforming to Health Insurance Portability and Accountability Act (HIPAA) and Duke University standards for data protection, the Consortium hired an external security-consulting firm to conduct a threats analysis to test for weaknesses of the data transmission process and the security of the QDACT database. Based on feedback from this analysis, appropriate revisions were made to ensure the utmost protection of each patient's protected health information. Further, the Consortium developed a central database, with corresponding business associate agreements between organizations, which outlined standards for data handling, use, and reporting.

Finally, the Consortium developed a structure for real-time, quarterly, and ad-hoc graphics-based feedback and reporting. The real-time component displays immediate feedback on unmet

A continually expanding entity, GPCQA is the first palliative care collaboration to perform a nationwide uniform, rapid-learning quality improvement project.

needs while providers enter data. For example, a color-code system reflects whether responses meet an "alarm threshold," which is an evidence- or consensus-based parameter (e.g., pain score greater than 7 out of 10). Once the threshold is reached, the clinician is alerted during the current visit and at subsequent visits. Other aggregate reports include longitudinal summaries that can be customized to the provider and the organization. Further, Consortium members requested that reports provide both numerical and graphical presentations of descriptive statistics on patient needs, conformance to quality measures, comparative performance between reporting levels, and longitudinal changes.

The Global Palliative Care Quality Alliance

QDACT's successful implementation into multiple clinical settings throughout North Carolina prompted the Carolinas Consortium leadership to expand QDACT's reach beyond the state (and Consortium) to a national stage. Subsequently, the Consortium has grown into the Global Palliative Care Quality Alliance (GPCQA), which is an expanding multi-institutional collaboration for quality assessment and improvement in specialty palliative care. To date, GPCQA is comprised of 11 academic and community organizations (see Figure 2, page 27). A continually expanding entity, GPCQA is the first palliative care collaboration to perform a nationwide uniform, rapid-learning quality improvement project. Currently, GPCQA is conducting its initial nationally implemented RLQI project to test the impact of a spirituality assessment on patient outcomes.

Last Words

The evaluation and reporting of healthcare data on quality is evolving quickly. Annual changes proposed by payers, regulators, accreditors, and membership organizations require clinicians and researchers to be creative and innovative about how assessing high-quality care can become a routine task. The days of manual chart abstractions and other resource-intensive methods to demonstrate and verify the delivery of quality care are, hopefully, moving behind us because of new approaches that are technology-enhanced and data-empowered. Armed with rapid learning methods and a continuous shift in culture towards regular and rapid quality improvement, collaborations between clinicians and patients are being built, with community and academic centers answering the call to not only do better (walk the walk), but to prove we are doing better (talk the talk). We are fortunate at Duke University and Four Seasons, along with our partners, to be on that journey towards universal high-quality palliative care. OI

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Closing a Gap in Cancer Care

In Brief

In 2014 a retrospective analysis of head and neck cancer patients coming through a multidisciplinary clinic at William Beaumont Hospital, Royal Oak, Mich., revealed a 38 percent hospitalization rate—this despite a PEG tube placement rate of 83 percent.[1] The main reasons for the admissions were dehydration and/or malnutrition, leading our clinicians to conclude that patients had not received sufficient education about their PEG tubes and the need for tube feeding. To close this gap in care, William Beaumont Hospital implemented a weekly nutrition clinic for its head and neck cancer patients. In a small, initial cohort of patients, this clinic resulted in shorter hospital stays and a lower hospitalization rate for dehydration and malnutrition. Read how this weekly nutrition clinic had a positive impact on our patients' quality of life, improved our patient education efforts, and reduced the cost of care.

BY JAN AKERVALL, MD, PHD; JAN PARSLOW, RN, MS, CCRP, OCN; ERIN MAXON, MS, RD, CNSC; NATHAN TONLAAR, MD; AND THOMAS LANNI JR., MBA, FACHE

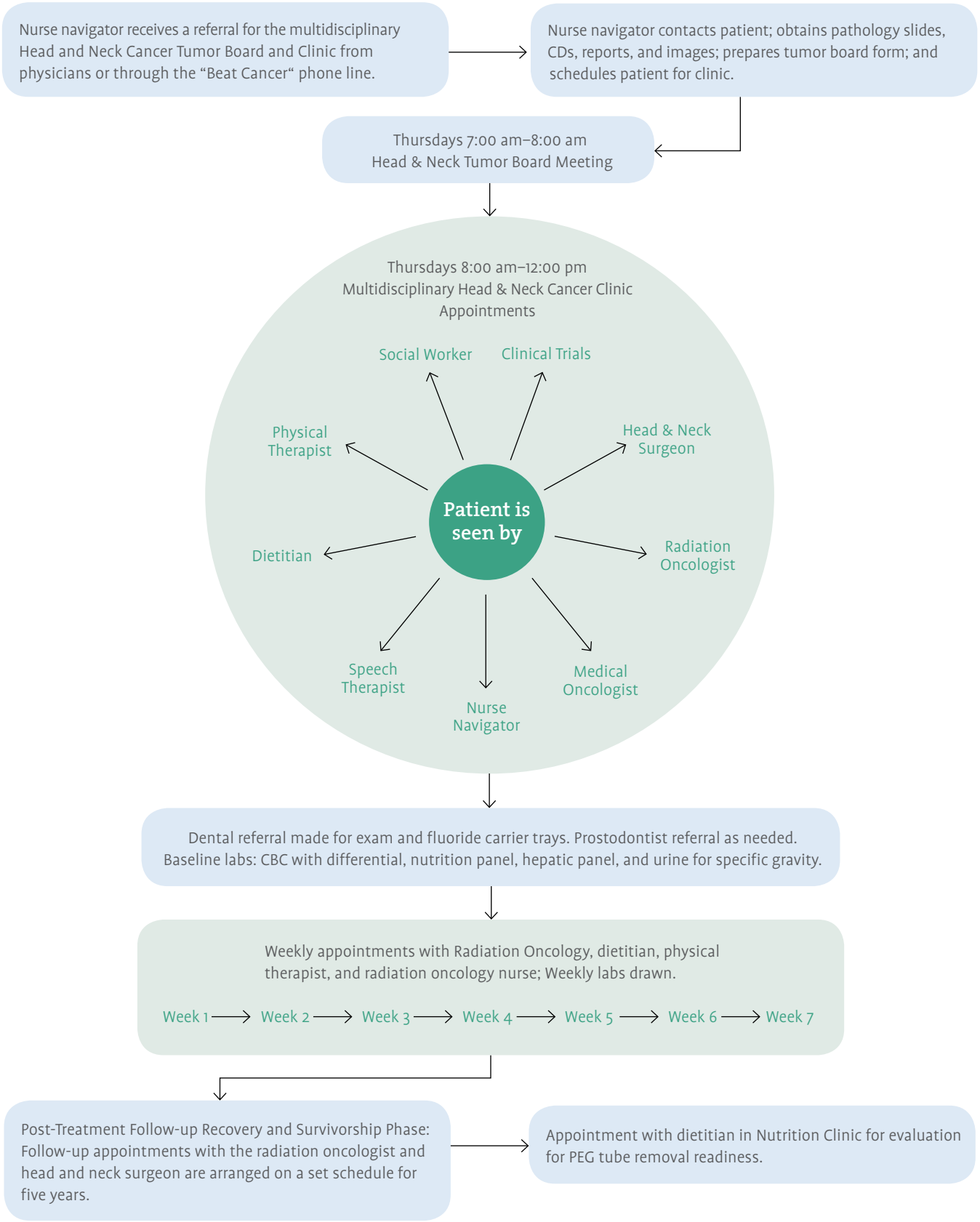
An outpatient weekly nutrition clinic for head and neck cancer patients

Beaumont Health System is a three-hospital system based in southeastern Michigan that provides a wide array of cancer services to the community. In 2013 Beaumont Cancer Institute diagnosed 6,493 new patients with 5,546 being analytical cases. Beginning in 2008 Beaumont Cancer Institute implemented multidisciplinary clinics to improve the coordination of care and outcomes for its patients. Over the past six years, Beaumont Cancer Institute has added these multidisciplinary clinics at all three hospitals.

Our Multidisciplinary Head and Neck Cancer Clinic

In 2011 Beaumont Cancer Institute clinicians noticed that patients diagnosed with head and neck cancer seemed to be experiencing a long delay from diagnosis to their first treatment. After making this measure a goal for its Cancer Committee, Beaumont Cancer Institute established and implemented a multidisciplinary Head and Neck Cancer Clinic to support not only its physicians, but also its patients and their families. This multidisciplinary clinic addressed all of the patients' ancillary needs at a single visit, including speech pathology, physical therapy, dietary needs, etc. Since 2011 the multidisciplinary Head and Neck Cancer Tumor Board and Clinic has met every Thursday morning to discuss and treat complicated, loco-regionally advanced head and neck cancers. First, a team of physicians from treating specialties (head and neck and reconstructive surgery, radiation oncology, and medical oncology) and ancillary specialties (neuro-radiology, pathology, and nuclear medicine), along with staff from ancillary services (speech pathology, rehabilitation, social services, and nutrition) gather to review the cases. Then, the team selects the patients to be seen in the multidisciplinary clinic. Figure 1, page 32, is a flowchart that illustrates how our multidisciplinary Head and Neck Cancer Clinic and Nutrition Clinic works.

Figure 1. Multidisciplinary Head and Neck Cancer Clinic and Nutrition Clinic Flowchart



Our goal is to offer a seamless one-stop-shop for these difficult to treat patients, spanning from diagnosis, through staging, to treatment and management planning, ensuring the delivery of proper, coherent, and consistent information about the diagnosis and management plan. Over the last few years, we have fine-tuned the process for the approximately 200 advanced head and neck cancer patients seen annually. At the Head and Neck Cancer Tumor Board and Clinic, our team discusses every available treatment option with the patient, including organ preservation protocols for concurrent chemoradiation and brachytherapy and minimally invasive surgical techniques, such as transoral laser and robotic surgeries, as well as a wide variety of ancillary services (i.e., voice and swallowing rehabilitation).

Continuous Quality Improvement

As a part of Beaumont Cancer Institute's continuous quality improvement (QI) strategy, we arrange an annual multidisciplinary Head and Neck Symposium with invited national speakers and presentations from all participating specialties and ancillary services, including our translational research group that analyzes biospecimens from our patients for biomarker discovery studies. Most importantly, we have a head and neck cancer workgroup that consists of representatives from participating specialties and ancillary services that meets regularly to discuss innovative, pragmatic solutions to daily issues.

At one such meeting, the workgroup decided to analyze our current practice of PEG tube placements and nutritional patient education. We knew that a vast majority of our patients received a feeding tube, but we wondered if and how the patients really used them. A retrospective study of 193 patients who received primary chemoradiation for head and neck cancer at our institution revealed that 83 percent of our patients received a PEG tube. Despite that fairly high percentage, 38 percent of patients were still admitted during treatment for dehydration and malnutrition—in some cases resulting in death.[2]

These numbers were striking to our clinicians. After conducting a sub-analysis, it became clear that even though we offer PEG tubes and provide education on how to use them, patients were clearly not getting the message. The workgroup concluded that, as clinicians, we must pay more attention to this issue. Specifically, we had to better guide our patients through the treatment steps and help them start using their PEG tubes before they encountered hydration and nutrition issues. This QI initiative led to the conception and implementation of a nutrition clinic for head and neck patients in 2014.

Our Weekly Nutrition Clinic

The rationale for a weekly nutrition clinic for head and neck cancer patients is intuitive; if we see our patients every week during treatment, we can better inform them how and when to use their PEG tubes and closely monitor their nutritional status. The weekly nutrition clinic helps us identify patients who may be at risk for potential nutritional problems and, hopefully, prevent serious adverse events related to dehydration and malnutrition. This type of care is not only patient-centered, it can lead to important cost-savings, as hospital admissions and more expensive treatment of serious nutritional complications (intensive care treatments, etc.) are reduced or even prevented.

Our weekly nutrition clinic focuses on preventing serious side effects and hospitalizations from dehydration and malnutrition by improving how clinicians monitor head and neck patients during radiation treatment.

Our weekly nutrition clinic focuses on preventing serious side effects and hospitalizations from dehydration and malnutrition by improving how clinicians monitor head and neck patients during radiation treatment. The nutrition clinic consists of an initial 60-minute post-PEG-tube placement instruction and weekly visits with the registered dietitian thereafter. The goal is to prevent or reduce enteral access complications by providing hands-on monitoring of the PEG tube, including site care, free-water flushes, and feeding instructions. Clinicians believed that this care would decrease complications and prevent a lapse in PEG tube usage, thus reducing the incidence of weight loss, protein calorie malnutrition, and dehydration. (To achieve the benefits of enteral nutrition, the PEG must consistently function to prevent interruption of use.)

Symptoms of tube feeding intolerance, such as nausea or diarrhea, are better managed with availability of an onsite resource for patients to turn to when complications occur. In addition to evaluating the patient's tolerance to tube feeding and compliance with the recommended tube-feeding regimen, the dietitian monitors the patient's nutrition panel and weight weekly. Table 1, page 34, outlines the evaluations and interventions offered during the weekly nutrition clinic.

Patients have weekly labs drawn for monitoring by the medical oncologist. A nephrologist oversees the lab work, including a complete blood count with differential, a nutrition panel, a hepatic panel, and a urine check for specific gravity. If pump-managed tube feedings are needed, the dietitian or the nurse navigator makes a referral to Home Care.

Table 1. Evaluation and Interventions Offered at the Weekly Nutrition Clinic for Head and Neck Cancer Patients

REGISTERED DIETITIAN NUTRITION EVALUATION	NUTRITION INTERVENTION
Pre-Treatment Visit in Multidisciplinary Clinic	• Nutrition assessment completed, including patient calorie needs • Protein and fluid needs calculated • 24-hour recall and weight history obtained • Patient instructed on a high-calorie, high-protein diet prior to treatment
Post-PEG Placement	• One-hour PEG instruction, including care of PEG site, water flushes, and formula instruction
OTV (On Treatment Visits) Weeks 1-7	• Monitoring of oral intake of calories, protein, and fluids via 24-hour recall • Weekly weights • Weekly nutrition panel to monitor pre-albumin status • PEG tube site monitoring and continued reinforcement of PEG tube usage, including water flushes and formula • Tolerance to tube feeding closely monitored, including checking of gastric residuals and symptoms of nausea, vomiting, diarrhea, and constipation
Post-Treatment	• Follow-up phone call one week post-treatment • If patient experiences difficulty eating, drinking, or tolerating tube feeding, an appointment is made to follow up with registered dietitian in weekly nutrition clinic • Standard follow-up appointment; patient seen on visit with MD at six-week check-up • Weight and oral fluid intake monitored; fluid needs assessed

Our Nutrition Clinic Results

We have so far managed 25 head and neck cancer patients through our weekly nutrition clinic; 18 of these patients received concurrent chemoradiation, which makes them comparable with the retrospective study cohort. Of these, 14 had PEG tubes placed, 12 prophylactically and 2 reactively. While long-term data are not yet available, we have conducted a short-term analysis of hospitalization rates during treatment for this limted cohort of patients. Looking at this data, our weekly nutrition clinic appears to have improved our patient monitoring and management, leading to shortened hospital stays and decreased hospitalization rates due to dehydration and malnutrition (see Table 2, right).

Nine of eighteen patients from the weekly nutrition clinic were admitted to the hospital, but only three admissions (17 percent) were due to primary dehydration and malnutrition. One of those three was known to be non-compliant with his PEG tube usage. Of the remaining 6 patients, 2 were admitted for reactive placement of PEG tubes due to dysphagia, 2 were hospitalized for nausea and vomiting due to cisplatinum chemotherapy, 1 was admitted for hemoptysis, and 1 was admitted for a c-diff (clostridium difficile) infection.

Hospital stays were significantly shorter for the patients in the nutrition clinic cohort (median 4 days) compared with patients from the retrospective study (median 7 days), which reflects less severity with regards to the reasons for admission. The median length of

stay for those hospitalized for dehydration or malnutrition versus other reasons was 3 versus 16.5 days respectively. One patient who was a post-kidney transplant and blind from diabetic retinopathy died from apparent complications from hypoglycemia.

These preliminary findings from our nutrition clinic led to a change in our treatment regimens. All patients on cisplatinum now receive IV steroids, which has reduced the incidence of treatment-related nausea and emesis. Our close monitoring of these patients led to this intervention opportunity, and we were able to implement a rapid change in treatment protocols.

Benefits & Lessons Learned

Information and education on PEG tubes is normally given to patients several weeks before treatment starts, when the patients are eating and drinking without difficulty, and when their focus is on treatment, prognosis, and financial concerns rather than possible downstream nutritional issues. PEG tubes are placed by radiology, GI physicians, or general surgeons under sedation or anesthesia. This means that much of the information about the PEG tube is given to the person who drives the patient home—not directly to the patient. All of these factors combine to create a gap in patient understanding of PEG tube usage during hospitalization—when they are least likely to retain the information post-PEG placement. Unfortunately, a patient's lack of understanding can lead to noncompliance at home.[2] Inadequate education about PEG tube usage can also cause patients to delay use of the PEG tube until it's too late, resulting in unnecessary hospitalizations. Our weekly nutrition clinic has changed the way our clinicians educate our patients and how we prepare them for the dysphagia that they will likely face during treatment.

Inadequate education about PEG tube usage can also cause patients to delay use of the PEG tube until it's too late, resulting in unnecessary hospitalizations. Our weekly nutrition clinic has changed the way our clinicians educate our patients and how we prepare them for the dysphagia that they will likely face during treatment.

Multiple retrospective studies have demonstrated the importance of PEG tube usage in decreasing weight loss and hospitalizations.[3-7] Our data from this small preliminary cohort of patients demonstrates lower rates of hospitalization secondary to dehydration and malnutrition for patients enrolled in our nutrition clinic compared to our retrospectively analyzed cohort. Because

Table 2. Patient Data from the Weekly Nutrition Clinic

EVENT	PROSPECTIVE COHORT (NUTRITION CLINIC)	PUBLISHED RETROSPECTIVE COHORT
Hospitalization due to dehydration and malnutrition	3/18 (17%)	62/161 (38%)
Median hospital stay	4 days (1–28 days)	7 days (4–26 days)
Radiation therapy interruption due to hospitalization	0 patients	4 patients
Chemotherapy interruption	1 patient	1 patient
PEG tube complication	1/18 (6%)	16/161 (10%)
Death	1 patient	2 patients

In addition to improving care and education for our patients, the weekly nutrition clinic has opened up the possibility of implementing a translational research program.

of the close monitoring that takes place at the nutrition clinic, we were able to identify patients having increased difficulty with treatment much earlier in their treatment course. Specifically, this improved management allowed our clinicians to more closely monitor diet, tube feeding, and fluid intake, likely contributing to the lower hospitalization rates seen in this patient cohort.

Implementation of our nutrition clinic resulted in numerous other benefits including:

- Clinicians had the opportunity to improve their treatment practices. As stated previously, in an effort to decrease chemotherapy-associated nausea, our clinicians changed their treatment of head and neck cancer patients to include IV steroids with the administration of cisplatinum chemotherapy.
- Clinicians are now able to detect problems with prescribing and filling tube feedings much earlier in the treatment course. Before implementation of the nutrition clinic, we often saw significant delays in getting the tube-feeding formula to patients' homes, which, in turn, triggered malnutrition and hospitalizations. Leveraging nutrition clinic resources, we are now able to ensure timely prescription and delivery of tube-feeding formula.
- A dietitian now assesses patients for readiness for PEG tube removal.
- Clinicians can more easily identify patients who need to come to the nutrition clinic following completion of treatment for ongoing nutritional support needs.
- Clinicians have improved their early intervention efforts for head and neck cancer patients. This early intervention begins at the patient's first Head and Neck Multidisciplinary Cancer Tumor Board and Clinic visit prior to start of treatment, and continues throughout the course of treatment, closing any potential gaps in care.
- Hands-on teaching in the nutrition clinic decreases the patient's fears and anxiety. This enhanced education empowers both patients and their support persons and caregivers.

In addition to improving care and education for our patients, the weekly nutrition clinic has opened up the possibility of implementing a translational research program. Through Beaumont's Biobank, patients in the nutrition clinic can participate in a prospective study that aims at identifying predicting biomarkers that can identify patients at risk to develop dehydration and malnutrition before it actually happens. Longitudinally collected blood, urine, and saliva samples are analyzed by proteomics and metabolomics in our core molecular laboratory, which is financed through philanthropy. Data analysis from this study is projected for the spring of 2015.

The success of our nutrition clinic has allowed the department of radiation oncology to incorporate a permanent dietitian into the program. This staff member not only addresses the needs of our head and neck cancer patients, but also provides services to other patients who can benefit from continual education about nutritional health during treatment.

Beaumont Cancer Institute will continue to support nutritional consultations for all of its multidisciplinary clinics, as well other educational opportunities, such as cooking classes for our patients and resources for picking healthy options while grocery shopping. In the future, we hope to continue expanding these vital services with the continued support of the hospital, along with philanthropic contributions from our generous patients and community. OI

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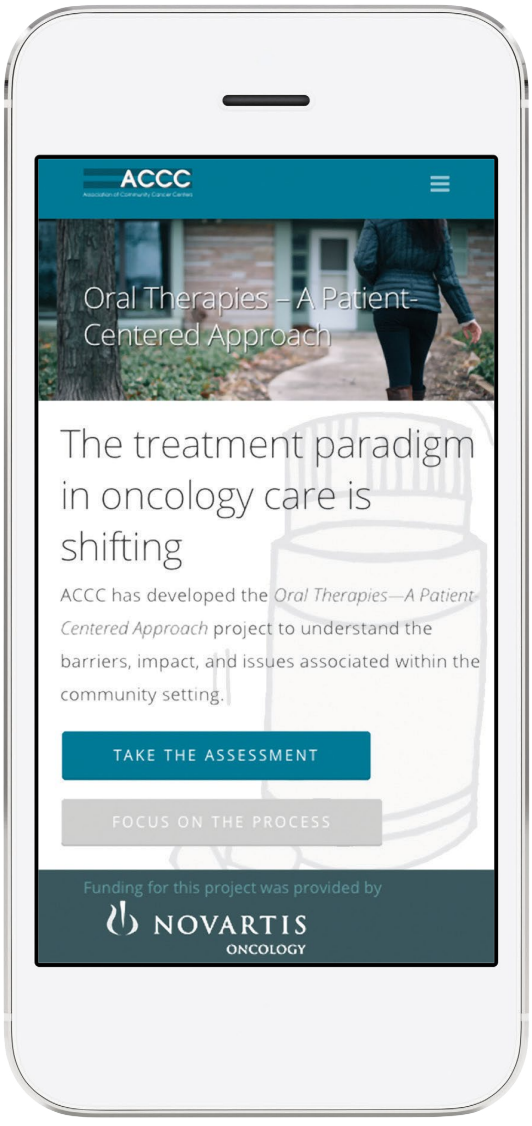

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Improving Patient Outcomes with Cancer

BY JULIE SILVER, MD

Prehabilitation is defined as "a process on the cancer continuum of care that occurs between the time of cancer diagnosis and the beginning of acute treatment and includes physical and psychological assessments that establish a baseline functional level, identify impairments, and provide interventions that promote physical and psychological health to reduce the incidence and/or severity of future impairments."[1] Further, cancer prehabilitation can help improve physical and functional outcomes that often translate to improved quality of life for cancer patients. A growing number of cancer programs offer prehabilitation services, and here's what some of them had to say about the benefits of adding this service line.

Prehabilitation Delivers Medical Care at Diagnosis

"We need to focus on survivorship care beginning at the time of diagnosis," says Lillie Shockney, RN, BS, MAS, director of the cancer survivorship programs at the Sidney Kimmel Cancer Center at Johns Hopkins, Baltimore, Md. "For decades, we've told our cancer patients to expect fatigue, to expect weakness." Shockney notes that the historical focus has been on survival as the only benchmark of success, but patient-centered care is changing the landscape. The new goal is now "survival with good quality of life," Shockney concludes.

While the majority of prehabilitation studies have been conducted on surgical cancer patients with intent to cure, interventions to improve physical and emotional reserve prior to the start of oncology therapy in non-surgical patients, including those with advanced cancer, may be helpful. Shockney explains, "Metastatic breast cancer is one of my specialties and something I am passionate about. Energy conservation is important. Quality of life is important. These patients should be given the same opportunities for reducing side effects and maintaining quality of life."

B.P. was 74 years old when she was diagnosed with lung cancer at Mary Washington Hospital, Fredericksburg, Va. Because she had already suffered a stroke and was living with chronic obstructive pulmonary disease (COPD), her thoracic surgeon, Timothy Sherwood, MD, informed his patient that she had two possible treatment paths: palliative radiation therapy or potentially curative surgery. B.P. chose surgery. Dr. Sherwood routinely checks his patients' stamina during office visits by having them climb stairs, and he put B.P. to the test. After the patient walked up two flights of stairs and experienced severe breathing difficulties, Dr. Sherwood referred her for prehabilitation, believing it would help B.P. get through surgery more safely and with a faster recovery time.

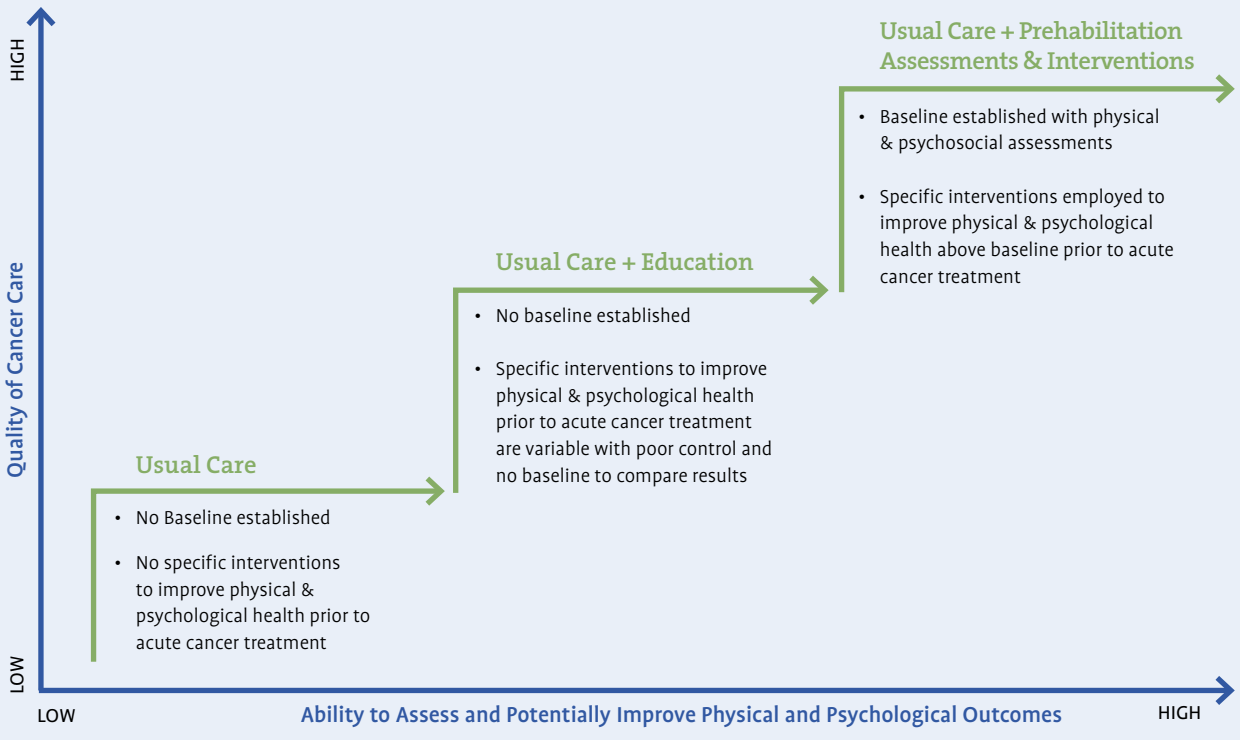
> "We need to focus on survivorship care beginning at the time of diagnosis....The new goal is now survival with good quality of life."

Prehabilitation should be incorporated into an existing high-quality cancer rehabilitation service line and clearly defined as being distinct from "usual care," including pre-operative testing and patient education (see Figure 1, page 40).

High-quality prehabilitation services are designed to improve physical and emotional health outcomes for a specific patient population and should work synergistically with other best practice protocols, such as peri-operative "fast track" or "early recovery" interventions developed by the Enhanced Recovery after Surgery (ERAS) Society for Perioperative Care. (Learn more at: www.erassociety.org/index.php/eras-guidelines.) Understanding what drives morbidity, decreased functional status, disability, and reduced quality of life in a given patient population is a critical part of being able to develop and deliver prehabilitation services that improve on the current level of care. So, prehabilitation is outcomes focused and data driven, but also time-based—typically occurring between diagnosis and the start of acute cancer treatments, such as surgery. Often the interventions, such as therapeutic exercise, are continued after cancer treatment begins.

The field of cancer prehabilitation is evolving rapidly, and new studies, as well as reviews and meta-analyses, have generally reported positive results. For example, one trimodal randomized control trial demonstrated that prehabilitation had a significant impact on function in colorectal cancer patients.[2] The study

Figure 1. Defining Prehabilitation Services as "Distinct" from Usual Patient Care



compared two groups—one that received prehabilitation and post-operative rehabilitation and the other that received only post-operative rehabilitation. While awaiting elective colorectal surgery, patients were divided into two groups—a prehabilitation group that received a trimodal intervention before surgery and a rehabilitation group that received an identical intervention after surgery. All patients were tested using the 6-Minute Walk Test and, prior to surgery, the patients who received prehabilitation for four weeks significantly improved walking distance by an average of +25.2 meters, while patients who did not receive the trimodal intervention declined by an average of -16.4 meters. Eight weeks post-operatively, a much higher proportion of the prehabilitation group was at or above their initial 6-Minute Walk Test baseline (84 percent) compared to the rehabilitation only group (62 percent).[2]

Prehabilitation May Increase Cancer Treatment Options

While research demonstrates that prehabilitation can help improve physical and functional outcomes, it may also potentially increase a newly diagnosed patient's treatment options—making curative treatment available and safe. Although Dr. Sherwood was not convinced initially that B.P. would be a good surgical candidate, he believed that if she underwent prehabilitation she likely would improve enough to safely undergo an operation to remove the cancer. To motivate her, he set the surgery date for a couple of months out and informed her that he would proceed if she improved her physical status. B.P. went to physical therapy (PT) twice a week for about a month and then three times a week for a few more weeks. She also followed the physical therapist's recommendation for a complementary

home exercise program that included walking on the treadmill and other exercises targeted at improving her strength and respiratory muscles. B.P. had her surgery as scheduled and two days later, she was discharged to home.

Dr. Sherwood has been working closely with the Mary Washington Hospital rehabilitation team, implementing prehabilitation lung cancer protocols. He sends all of his "mid-risk" and "high-risk" patients through prehabilitation for approximately four to eight weeks, depending on their physical status at baseline. When asked about treatment delays, he says, "I would rather have my patients get through surgery safely than have a horrific post-operative outcome." Dr. Sherwood says that as a thoracic surgeon, he's been trained to be concerned with performance status. During the time that the patient is having prehabilitation, he says, "I am doing the staging, and I see them for several visits and monitor their progress. I have them climb two flights of stairs every time I see them, and I assess their progress."

Often prehabilitation services can be delivered during the "window of time" between diagnosis and the start of active oncology treatment, to improve outcomes. Delays in surgery or other oncology therapies may be appropriate, especially in patients who are elderly, deconditioned, and/or have co-morbidities. Surgeons and oncologists should carefully consider patients on an individual basis and monitor them during prehabilitation, if delays are anticipated, as Dr. Sherwood described. When considering delays, it is important to do so in the context of all cancer treatment—not just surgery or whichever treatment comes first. For example, if a patient has post-operative complications, then adjuvant chemotherapy may be delayed. Similarly, if the patient has neoadjuvant chemotherapy and becomes very deconditioned, surgery may be delayed. In the end, prehabilitation may be appropriate if the patient's clinician believes that it will help the patient tolerate all of the recommended cancer treatments with the least risk for side-effects and complications and for optimal physical and emotional outcomes.

Delays are often not necessary or appropriate. Matt LeBlanc, RN, BSN, an oncology rehabilitation nurse navigator at Anne Arundel Medical Center, Annapolis, Md., worked with his team to embed a speech therapist in the radiation department. This improved the time it takes for head and neck cancer patients to receive a consultation by more than two months. The average consultation is now given approximately one week prior to beginning radiation therapy (see Figure 2, page 42). LeBlanc says, "We set a goal that all head and neck patients would see the speech therapist either the week before or the week they started radiation. When we showed the oncologists a strategy, goal, and data, it was easy to get them on board."

With Prehabilitation, Patients May be Healthier Post-Cancer than Pre-Cancer

Usually the expectation healthcare professionals and patients have is that the patient's health will be worse after cancer treatment than before. Indeed, the concept of "new normal" has been extensively written about in the oncology literature and almost universally refers to a decline in health and function due to treatments—necessitating an emotional adjustment as well. However, what if directed cancer treatment, including prehabilitation, demonstrated that some patients could actually be healthier after treatment than they were at diagnosis? This is an exciting paradigm shift and one that is important to consider in both research and clinical care.

B.P. is not the only patient of Dr. Sherwood's who felt stronger and healthier after cancer treatment than at diagnosis. Seventy-five-year-old A.H. had recently undergone a lumbar spinal fusion surgery when she was diagnosed with lung cancer in the fall of 2013. She was referred to Dr. Sherwood, and he raised the possibility of sending A.H. to a sub-acute nursing facility for rehabilitation after surgery. The mere mention of a "nursing home," temporary or not, motivated the patient to fully participate in prehabilitation.

A.H. went to PT for six weeks (prehabilitation) and improved her physical and functional status significantly. After she underwent lung resection, A.H. had six additional weeks of PT, followed by transition to a community-based exercise program at the YMCA.

Mary Washington Hospital wrote up this patient case study and presented it at the Academy of Oncology Nurse and Patient Navigators Annual Conference in the fall of 2014, and the outcomes were subsequently published.[3] Two of the validated performance tools that are frequently used in research studies include the 6-Minute Walk Test and Timed Up and Go (TUG). A.H.'s functional outcomes included a 6-Minute Walk Test baseline score of 992 feet, a score of 1,120 feet after prehabilitation (a 13 percent improvement), and a score of 1,130 feet after surgery and the additional 6 weeks of rehabilitation (a 14 percent improvement). A.H.'s baseline TUG score was 13 seconds; after prehabilitation, surgery, and post-operative rehabilitation her score was 8 seconds, which represented a 38 percent improvement. Further, A.H.'s hospital length of stay (LOS) was three days—two days less than the average five days for patients undergoing a similar surgical procedure.

As this patient case study shows, there is a subset of cancer patients that will have a "new normal" above their diagnostic baseline. These outcomes are very exciting, and may occur in other cancer populations as well. For example, the Canadian study of colorectal cancer survivors discussed earlier demonstrated improvements in physical function in some of the participants over their baseline status.[2]

Prehabilitation Can Improve Patient-Centered Care

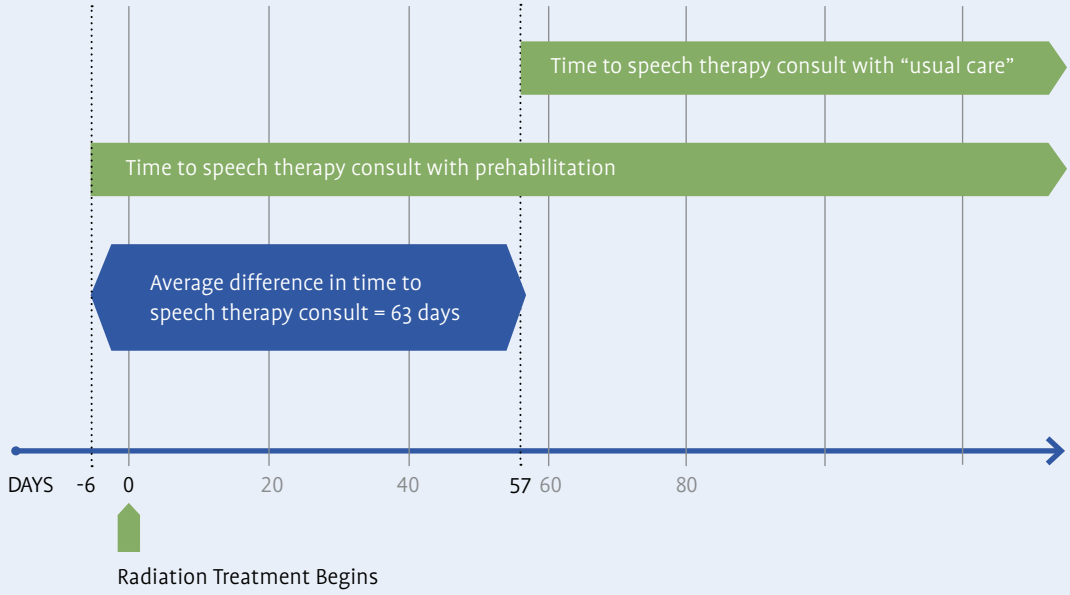
Sally Luehring, MSL, RHIA, is the executive director of cancer services for the Hospital Sisters Health System—Eastern Wisconsin Division—which includes St. Vincent Hospital, Green Bay, Wisc.; St. Mary's Hospital Medical Center, Green Bay, Wisc.; and St. Nicholas Hospital. Luehring says, "Enhancing and supporting our patients' quality of life throughout their cancer journey is one of our service line goals."

James Leenstra, MD, a radiation oncologist at St. Vincent Regional Cancer Center in Green Bay, Wisc., thinks cancer prehabilitation encourages patient-centered care because, "It helps both providers and patients see where they are functionally and more clearly identify where they want to be."

To support its initial prehabilitation pilot, St. Vincent received a $5,000 grant from the American Cancer Society and the Wisconsin Comprehensive Cancer Control Program. The grant supported embedding a "rehabilitation navigator" in the cancer center for a three-month period to assess newly-diagnosed cancer patients. Megan Pfarr, DPT, CLT, is the rehabilitation navigator and spearheaded the pilot study. Newly-diagnosed patients were offered a prehabilitation assessment and could decide whether they wanted to participate. Because of the pilot grant funding, patients were not charged for this initial visit.

During the three-month period, Pfarr assessed 28 newly-diagnosed cancer patients with various diagnoses. The baseline assessment included, but was not limited to, manual muscle testing, joint range of motion, and balance testing. Examples of the validated tools included in this pilot were the 6-Minute Walk Test, FACIT-F, FACT-Cog, and Tinetti Balance and Gait Assessment Tools. Of the 28 participants, 6 (21 percent) were found to have baseline physical impairments and were referred to PT prior to the start of cancer treatment. Following treatment, reassessments revealed that 10 patients (36 percent) had decreased functional status and were referred for rehabilitation. In this pilot, the six patients who were treated with PT prior to their cancer treatment improved their functional status above baseline. This type of prehabilitation is an

Figure 2. Outcomes after Embedding a Speech Therapist in a Radiation Oncology Department*



* Data from Anne Arundel Medical Center, Annapolis, Md.

important component of patient-centered oncology care because it helps people to maintain the highest level of function possible.

Prehabilitation Makes Financial Sense

There are many financial benefits associated with cancer prehabilitation that affect patients and their families, hospitals, and society.[4] Further, prehabilitation supports the goals of the Institute for Healthcare Improvement's "Triple Aim" to:[5]

1. Improve the patient experience of care (including quality and satisfaction)
2. Improve the health of populations
3. Reduce the per capita cost of healthcare.

Some of the potential financial benefits with prehabilitation are obvious and some are not as intuitive. Clearly, a case can be made that prehabilitation—by reducing pain and increasing physical function—will help employed patients remain productive at work.[6]

Daniel Santa Mina, PhD, is a scientist studying the effects of prehabilitation at the Princess Margaret Cancer Centre in Canada. Recently, he and his colleagues published a systematic review and meta-analysis on whole-body prehabilitation and its impact on post-operative outcomes.[7] Dr. Santa Mina summarized his findings in this way: "At the time of publication, we retrieved 21 trials that met our inclusion criteria and found that, compared to no prehabilitation, a majority of the studies demonstrated improved pain, length of stay, and physical function for patients that underwent prehabilitation."

Reducing hospital length of stay is an important goal in the U.S. and other countries. According to Dr. Santa Mina, "Our meta-analysis indicated that post-operative length of stay was reduced by approximately half a day."

At Mary Washington Hospital Center, Kathy Duval, SLP, and Messina Corder, RN, work closely to coordinate the prehabilitation services and track the team's outcomes. Currently, prehabilitation is demonstrating a downward trend in length of stay for surgical lung cancer patients—from approximately five days to three days.

At Johns Hopkins, Lillie Shockney experienced a similar decline saying, "I know from our own experience at Hopkins that by referring patients having DIEP flap reconstruction to prehab to learn the correct technique for core strengthening, we were able to reduce length of stay by one day and patients recovered faster. I personally had this procedure done and was back to work at four weeks post-op. I credit my prehab combined with excellent surgical care for making that possible," she said.

The Evolving Field of Cancer Prehabilitation

Many of the early cancer prehabilitation studies focused only on general exercise to improve overall fitness;[1] however, there are two important new trends in the scientific literature. The first is targeted exercises, in addition to general conditioning. For example, in lung cancer patients, targeted exercises focus on the muscles of respiration to improve breathing and help prevent post-operative complications and hospital readmissions. In the lung cancer surgical population, pneumonia is a frequent cause of post-operative morbidity and mortality. Dr. Sherwood explains, "Patients will have pain due to their incision and if they cough, they will have more pain. This means they may take very shallow breaths and get atelectasis and are at risk for pneumonia. Targeted exercises are really important to help prevent complications."

In prostate cancer survivors, targeted exercises include pelvic floor strengthening to reduce the likelihood of significant urinary incontinence problems after surgery, and in the head and neck cancer population, the focus is on swallowing exercises.

The second trend is to include more than one modality—going beyond just general exercise and conditioning. Franco Carli, MD, MPhil, professor of anesthesia, McGill University, Montréal, Canada, has been studying surgical prehabilitation in patients with colorectal cancer. Dr. Carli was one of the researchers on the Gillis et al. study discussed earlier that used a trimodal prehabilitation approach—combining nutritional supplementation, stress reduction, and exercise.

Dr. Carli explains the reasoning behind this study approach. "In our first randomized control trial using intense exercise, we found that many of the participants were unable to sustain such efforts. Also, we found almost 20 percent of patients experienced high anxiety and depression. Finally, we did not control for nutrition, and we believed this was an important component to control together with the other elements."

According to Dr. Carli, when newly-diagnosed cancer patients increase their physical activity levels and undergo surgery, they are naturally in a catabolic state. Therefore, it makes sense to give them protein supplementation—similar to what is done with athletes. "Under-nutrition, before or after surgery, is associated with higher mortality, morbidity, and costs, and delayed recovery after abdominal surgery. This implies that nutrition ought to be considered in the perioperative period."

Implementing High-Quality Prehabilitation Services

Building a high-quality cancer rehabilitation service line is an essential step in offering prehabilitation services, because baseline assessments will undoubtedly uncover physical impairments that need to be addressed by professionals. One resource available to cancer programs is STAR (Survivorship Training and Rehabilitation) Program® Certification, which provides hospitals, cancer programs, and group practices with the training, protocols, and clinical support needed to deliver evidence-based and best practices cancer rehabilitation services.

During the implementation phase of a STAR Program, teams initially focus on building the rehabilitation service line, and when that is established, they can turn their efforts to prehabilitation.

For example, Kathleen Michie, PT, MT, CLT, the oncology services program manager for Poudre Valley Hospital, Fort Collins, Colo., (affiliated with the NCI-designated University of Colorado Cancer Center) is embedded in the oncology department. She and the outpatient rehabilitation manager, Kerri Applegate, PT, are leading a four-phase process to implement prehabilitation. The first phase was to establish a pilot multidisciplinary survivorship clinic, including a nurse practitioner, physical therapists, an oncology social worker, and a massage therapist. The pilot began in November 2013 and focused on the subset of survivors with various types of cancer who were treated with curative intent and had completed active therapy. After one year, 102 patients were assessed and given survivorship care plans. Eighty of the 102 participants (78.4 percent) had further physical therapy. Forty patients (39.2 percent) had follow-up mental health services. Patient reported outcomes revealed that the most significant improvements were in activities at home (24 percent), employment (23 percent), feelings of isolation (19 percent), and fatigue (17 percent).

Phase 2 is designed to expand this successful pilot to other sites. Phase 3 will pilot the STAR Program Prehab, and Phase 4 will expand the prehabilitation services. Michie says, "When we ask our patients how we could improve their experience they tell us they wish they had started sooner." Applegate agrees, "Now that we have integrated rehab into the ongoing management of cancer survivors, we are eager to implement a model of prehabilitation that focuses on improving the outcomes of patients."

Even with research support, it often takes many years to incorporate new concepts into clinical care. STAR Program Prehab, an evidence-based best practices model for cancer prehabilitation, is designed to quickly translate important new research into its practice model. STAR Program Prehab uses a five-prong multimodal approach: general exercise for conditioning, targeted exercise based on the cancer diagnosis, stress reduction strategies, nutrition, and smoking cessation (see Figure 3, right).

Evaluating what services are already in place and determining whether there are synergies that may be easily incorporated into high quality prehabilitation care is the first step in implementation of STAR Program Prehab. This data informs the entire process, and what many STAR Program teams have learned is that the services that are already in place may not be ideal for oncology patients. For example, many hospitals offer conventional pulmonary rehabilitation; however, this may not be ideal for newly-diagnosed lung cancer patients.

Dr. Sherwood highlights some of the problems associated with using services that are not specifically developed for oncology patients. "Conventional pulmonary rehabilitation was not designed to improve surgical outcomes in lung cancer patients, but rather to treat patients who have serious cardiac and/or pulmonary disease." Further, with conventional rehab his patients would often have to wait weeks to get into the program, whereas the cancer rehabilitation team was able to see his patients within a day or two.

"STAR Program care is generally covered by my insurers," Dr. Sherwood said. "But with other services, my patients would have to qualify by having a reduced cardiac ejection fraction or cardiac valvular disease. Even if I could get patients seen, it wasn't always covered, because they weren't sick enough based on cardiac and pulmonary criteria."

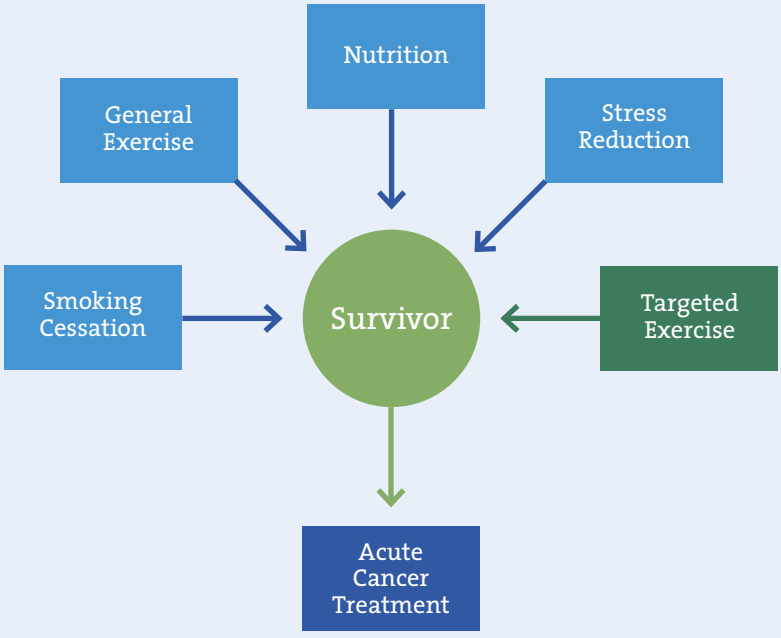
In the March/April 2014 *Oncology Issues*, Lahey Hospital and Medical Center, Burlington, Mass., was featured for its low-dose lung screening service model. Newly STAR Program certified, Lahey is adding multimodal lung cancer prehabilitation services. Radiation oncologist Andrea McKee, MD, is championing this effort and says, "We believe prehab offers an opportunity to enhance patient outcomes by integrating and maximizing evidence-based techniques earlier in the course of our patient's care continuum."

Many healthcare professionals believe that because their institution offers services such as pre-operative education, smoking cessation services, and "chemo classes," they have prehab covered. Although these services may be helpful to newly-diagnosed patients, prehabilitation is aimed at driving specific outcomes that are measurable. Lahey clinicians are learning that lung cancer prehabilitation involves a strategic approach that is different than what they have done in the past. Stacey Pare, a physical therapist and a STAR Program Clinical Consultant, is working with many hospitals throughout the United States on their prehab implementation—including Lahey—and says, "It takes some time for programs to operationalize well-coordinated prehabilitation services, but Lahey will succeed because they have high-level support from their oncologists, administrators, and rehabilitation director."

Prior to implementing the STAR Program Prehab lung cancer protocol, Lahey, like most hospitals and cancer programs, had some services that might be considered prehabilitation. The first step of the STAR Program Prehab protocol is to evaluate services that are already in place, so that efficiencies and economies of scale can be utilized as the program grows. Currently, Lahey is transitioning to a more strategic and quality prehabilitation approach that will track and improve patient outcomes. Dr. McKee explains, "The elements included in our pulmonary prehab program already existed within our center but had been introduced to patients at various points later in their cancer journeys. By introducing these concepts earlier and as a package, at a minimum our patients will benefit sooner than they had before." After reviewing the recent research on lung cancer prehabilitation, including a review that highlighted decreased morbidity and hospital lengths of stay, Dr. McKee is very optimistic about their new prehabilitation lung cancer services: "Ultimately, our hope is to demonstrate synergies and improved outcomes over what we have been able to previously offer our patients."

Ron Ponchak, PT, MBA, was recently hired at Lahey as the director of rehabilitation services. He says, "The barriers are what you might expect—they are related to time and trying to coordinate various individuals and departments—trying to get the human resources collaborating." Ponchak, who came to Lahey from another hospital that had adopted the STAR Program, insists this is a barrier that can be overcome through effective and consistent communication between departments and the STAR Program and by explaining—repeatedly, if need be—why prehabilitation is so important.

Figure 3. STAR Program Prehab Multimodal Model



Dr. McKee is excited to oversee the expansion of lung cancer prehabilitation at Lahey. She believes a well-trained team that understands prehabilitation best practices and has the right tools to implement these services will continue to improve the high quality oncology care that her institution is able to deliver. "We are huge fans of the STAR Program. For years we searched for a way to make our rehabilitation, supportive oncology, and psychosocial services more accessible to patients."

For more information on the STAR Program and/or STAR Program Prehab, go to: www.oncologyrehabpartners.com. OI

Julie Silver, MD, is an associate professor at Harvard Medical School and a founder of Oncology Rehab Partners, which developed the STAR Program, a service-line model for high-quality cancer prehabilitation and rehabilitation care that has been adopted by more than 200 hospitals and cancer centers and is now available at hundreds of sites throughout the United States.

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MILK

BY MELANIE GONZALES, MSPH, MCHES,
AND VICKY JEKICH, CMP

A focus on youth cancer prevention education

Decreasing the impact of cancer is vital. Cancer education interventions can help ease the impact of cancer in a variety of ways. They can increase general knowledge about cancer, including modifiable and non-modifiable risk factors. These include early warning signs, screening and diagnostic options, prevention strategies, treatment options, and clinical trials. Cancer education interventions have the potential to benefit the public by increasing the frequency of constructive health behaviors being practiced (e.g., using sunscreen, not smoking, and obtaining cancer screening). The overall desired outcome of education interventions is that cancer morbidity and mortality rates will decrease, because individuals are taking measures that have been associated with reducing cancer risks.

BOOKER A, ET AL. EVALUATING OUTCOMES OF COMMUNITY-BASED CANCER EDUCATION INTERVENTIONS: A 10-YEAR REVIEW OF STUDIES. *J CANCER EDUCATION*. 2014;29:233-240.

While young people across the U.S. are able to access more information through technology with greater speed, they may be misinformed or lack understanding of how unhealthy behaviors can put their health at risk. Data underscores this concern. In Idaho, over 33 percent of high school students surveyed have tried cigarette smoking[1]; melanoma is the second most common form of cancer for adolescents and young adults 15 to 29 years old[2]; and 1 in 3 kids in Idaho is overweight or obese.[3] St. Luke's Mountain States Tumor Institute (MSTI)—a multi-site cancer program serving southern Idaho, eastern Oregon, and northern Nevada—used a community-based approach to develop cancer prevention education programs to help address these concerns.

Developing a Youth-Based Prevention Education Program

In 2006 St. Luke's MSTI identified a need for cancer prevention services in its community. This type of cancer education not only supported the mission of St. Luke's MSTI "to improve the health of the people in our region," but also made good economic sense. For example, one report cited that an investment of $10 per person per year in proven community-based programs to increase physical

Volunteer presenter provides classroom-based cancer prevention education at a local school.

activity, improve nutrition, and prevent smoking and other tobacco use could save the country more than $16 billion annually within five years. The result: a return of $5.60 for every $1 invested.[4]

Accordingly, the leadership team at St. Luke's MSTI added cancer prevention as part of the cancer program's scope of community services. After discussions with staff, the leadership team decided that these efforts should focus on prevention messages that would most benefit children and teens, primarily targeting school-aged youth. Little did the St. Luke's MSTI leadership team know how much that 2006 decision would still resonate with today's current healthcare paradigm. In "Cancer Prevention and Control: Where are the Kids?" author E.R. Burns states: "…this is the age group that begins to make lifestyle choices such as tobacco and/or tanning booth use. Without proper health science information regarding these practices, youngsters are at risk of making uninformed, and therefore poor, lifestyle decisions. School-aged children should be a major target for cancer prevention education."[5]

The St. Luke's MSTI leadership team decided that its youth-based prevention education program would focus primarily on tobacco, sun-safety education, and nutrition and physical activity. These topics have direct association with cancer, as well as prevention messages that are geared to youth audiences. The goal: to provide students with quality, evidence-based content that would hopefully translate to lower cancer rates in the future.

St. Luke's MSTI began implementation of its youth-based risk reduction program, starting with a focus on nutrition and physical activity. Efforts included educating children about healthy food choices through educational games shared at health fairs and schools, and bringing the message to cancer awareness community events, such as the American Cancer Society's Relay for Life. The program continued to evolve based on the results of these initial programs and the recognized need to expand beyond nutrition and physical activity.

Addressing Youth-Based Health Risks

In 2007 St. Luke's MSTI added tobacco prevention and education as part of the message to this targeted group with the adoption of the American Academy of Family Physicians nationally-recognized Tar Wars educational program curriculum. The customizable and easy-to-follow format provided an ideal tool for presenting tobacco prevention education for 5th grade students in Idaho. A one-hour classroom presentation emphasizes the message "don't ever start," while educating students on the marketing tactics tobacco companies use to get kids to start using their products. This program continues to be popular among teachers and students alike, as it provides needed information at a critical time in students' growth and development. (Learn more at: www.aafp.org/patient-care/public-health/tobacco-nicotine/tar-wars.html.)

> Education is the most powerful weapon you can use to change the world.
>
> NELSON MANDELA (1918-2013)

The following year, St. Luke's MSTI added sun-safety to its youth-based prevention education program, implementing an evidence-informed, classroom presentation targeted for middle school, junior high, and high school students. St. Luke's MSTI leadership team determined that sun-safety for teen-aged students was an important area of focus as this age group is more independent than their elementary school counterparts; teenagers are beginning to make their own purchases, and they are making personal decisions about sunscreen, protective clothing, and tanning bed usage. Educating students at this age helps them discover how the choices they make now may impact their health and lifestyle in the future. To keep the one-hour classroom presentation engaging and to reinforce the lessons learned, the program features a brief video about sun-safety in which a teenage girl learns about melanoma as she is producing a web-based video. The content and setting are very relatable to the teen audience. At the conclusion of the program, students are offered an opportunity to see areas of their face that may have sun damage using a tabletop skin analyzer provided by St. Luke's MSTI (see photo on page 53).

In 2012 St. Luke's MSTI adopted the evidence-based POOL COOL program to extend sun-safety education beyond the classroom. This program uses a train-the-trainer format, where pool swim staff are taught key sun-safety concepts and activities. Pool staff, in-turn, teach children about the risks of overexposure to the sun and encourage them to develop healthy habits for a lifetime. The sun-safety messages are seamlessly integrated into the swimming lessons, with the curriculum combining education, interactive activities at the pool, and pool-wide environmental changes, such as signage and sunscreen dispensers.

The latest addition to MSTI's youth-based prevention education program was introduced in 2013 and uses community partnerships and an interactive approach to the traditional classroom presentation. Developed in conjunction with Boise State University, St. Luke MSTI's Healthy Habits, Healthy U (HHHU) program targets 4th and 8th grade students and aims to increase awareness of the link between obesity and cancer. Students learn how healthy eating and physical activity can reduce their risks of developing cancer. HHHU's two-day lesson plan includes a cancer prevention overview provided by the classroom teacher and includes hands-on activities. Students have the opportunity to see and safely handle preserved organ specimens, allowing them to compare and contrast organs with and without cancer.

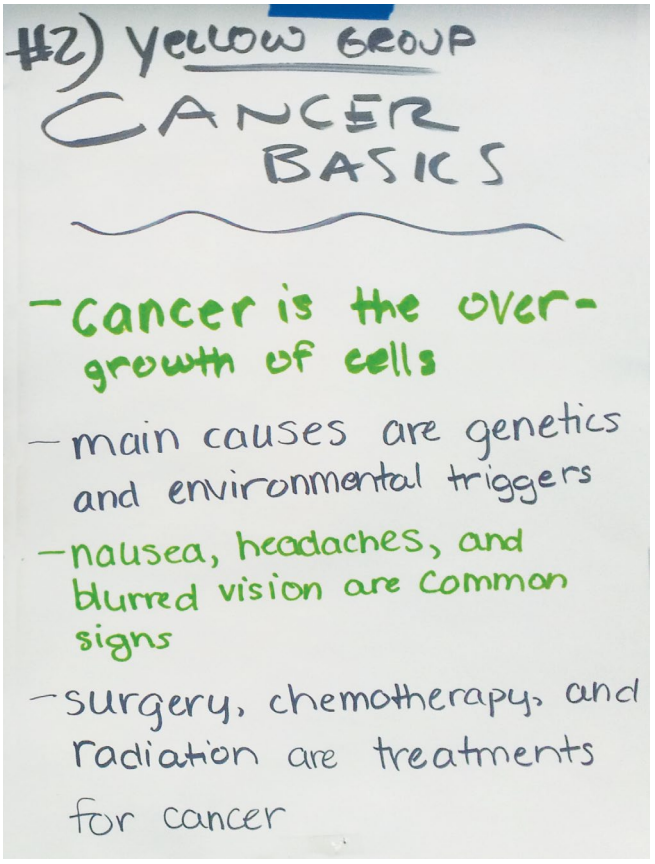
Identifying Evidence-Based Resources

Providing students with quality, evidence-based content has been a challenging aspect of program development. While many options are available, it is not always easy to quantify the effectiveness of these resources. The need to use resources wisely to achieve the best outcome is a top priority for St. Luke's MSTI; fortunately, research around these issues has been standardized and evidence-based resources are becoming more readily available.

One available tool is a website that houses the official collection of all Community Preventive Services Task Force findings and the systematic reviews on which these tools are based. The Community Guide is a credible resource with many uses because it is based on a scientific, systematic review process and answers critical questions such as:[6]

- What interventions have and have not worked?
- In which populations and settings has the intervention worked or not worked?
- What might the intervention cost? What should I expect for my investment?
- Does the intervention lead to any other benefits or harms?
- What interventions need more research before we know if they work or not?

This website provides the evidence basis for choosing interventions that work within specific populations and environments. For organizations that serve diverse communities, such as St. Luke's MSTI, the Community Guide can be very useful in providing direction, justification, and the evidence needed to support local prevention interventions.



8th grade student poster summarizing HHHU cancer education.

Another helpful resource is the National Cancer Institute (NCI) Research-tested Intervention Programs (RTIPs) website: http://rtips.cancer.gov/rtips/index.do. One of the evidence-based online resource tools on the Cancer Control P.L.A.N.E.T. portal (http://cancercontrolplanet.cancer.gov/), RTIPs is a searchable database of cancer control interventions and related program materials. The website is designed to provide program planners and public health practitioners with easy and immediate access to research-tested materials available for use in a community or clinical setting.[7] The POOL COOL program discussed earlier is an RTIPs program that St. Luke's MSTI adapted for use in communities across southern Idaho. These websites also provide useful information for ideas and planning for many other cancer prevention interventions.

Table 1. Community-Clinical Linkages for St. Luke's MSTI Youth Cancer Prevention Education Programs

ST. LUKE'S MSTI CANCER PREVENTION INTERVENTION	COMMUNITY LINKAGE	CANCER PREVENTION PROGRAM
Tobacco-use prevention education	Idaho Chapter of the American Academy of Family Physicians (AAFP), local schools and school districts	Idaho Chapter of the American Academy of Family Physicians (AAFP), local schools and school districts
Sun-safety education	Local schools and school districts	Skin Cancer Prevention (Source: St. Luke's MSTI)
	Local outdoor swimming pools and Parks and Recreation Departments	POOL COOL (Source: RTIPs website)
Obesity and cancer risk education	Boise State University and Boise School District	Healthy Habits, Healthy U (Source: Partnership between St. Luke's MSTI and Boise State University)

Community-Clinical Linkages

St. Luke's MSTI identified the collaboration or partnership with community resources—often referred to as a community-clinical linkage—as an important factor to the success of its youth-based prevention education program. These relationships provide critical resources to aid in the continuation of the program for subsequent years. In developing its youth-based prevention education program, St. Luke's MSTI acknowledged that children and adolescents are establishing patterns of behavior and making lifestyle choices that affect their current and future health. Program success depends on families, schools, and communities working together to create an environment that facilitates the health development of these children and adolescents.[7] Partnering with other community organizations and entities allows community-based prevention education programs to thrive and undergo modification as the environment changes. Table 1, above, identifies the community-clinical linkages involved in St. Luke's MSTI youth-based prevention education programs.

Below we take a deeper dive into each component of St. Luke's MSTI Youth Cancer Prevention Education Program, including program goals and outcomes.

Tar Wars

In its guide, Best Practices for Comprehensive Tobacco Control Programs, the Centers for Disease Control and Prevention (CDC) recommends statewide programs that combine and coordinate community-based interventions that focus on preventing initiation of tobacco use among youth and young adults.[8] One such program (as mentioned earlier) is the AAFP's Tar Wars, a tobacco-free education program for 4th and 5th grade students. The evidence-based program is designed to teach children about the short-term health effects and image-based consequences of tobacco use and about being tobacco-free. It provides tools for children to make positive decisions regarding their health and promotes personal responsibility for their well-being.

St. Luke's MSTI staff works with volunteers to bring Tar Wars to Idaho classrooms. Tar Wars uses a community-based approach to mobilize family physicians, educators, and other healthcare professionals (like St. Luke's MSTI), to accomplish its program goals of:[9]

- Increasing knowledge of short-term health effects and image-based consequences of tobacco use
- Illustrating the cost and financial impact of using tobacco and ways that money could be better spent
- Identifying reasons why people use tobacco
- Explaining how tobacco advertising, tobacco use in movies, and the tobacco industry market their products to children.

A number of studies have evaluated the Tar Wars program and found that it does, in fact, achieve these goals.[10-13] For example, one quantitative evaluation of the longitudinal impact of Tar Wars showed sustained improvements in students' knowledge and attitudes related to tobacco use. Students exhibited greater recognition of the health effects, cost, and image distortion

associated with tobacco use compared to their peer control group. Based on student, teacher, and presenter perspectives, this qualitative evaluation of Tar Wars found a high level of satisfaction with the program and positive, short-term changes in knowledge of tobacco use. Students indicated an understanding of key program elements, and classroom teachers believed the program was worthwhile and presented unique information.[14]

Research from St. Luke's MSTI backs up the positive, short-term changes in knowledge of tobacco use in our local communities. A Tar Wars post-presentation questionnaire of school year 2012-2013 participants (n= 1,121) found that:

- 98.6 percent agreed that smoking causes bad breath.
- 92.1 percent stated that "Smoking a pack of cigarettes daily would cost hundreds of dollars yearly."
- 86.7 percent acknowledged that "Smokeless tobacco products are harmful to the body."
- 81.2 percent agreed that "Advertisers did not tell the truth about tobacco products."

Sun-Safety Education

Skin cancer is the most common form of cancer in the U.S. and, unlike most other cancers, skin cancer rates are climbing. Idaho consistently ranks among the highest states for melanoma incidence and death rates. The call to action from the Comprehensive Cancer Alliance of Idaho is to educate patients of all races and ethnicities on sun-safety and skin cancer prevention.[2] To address this issue, St. Luke's MSTI developed a presentation intended to meet the needs of the school curriculum and area schools. The presentation includes recommendations for primary and middle school interventions to reduce risk of skin cancer based on strong evidence of their effectiveness in increasing sun-protective behaviors and decreasing ultraviolet exposure related to sunburn incidence and formation of new moles.[15]

The goal of St. Luke's MSTI's sun-safety classroom presentation is to:

- Increase knowledge among middle and high school students of the health effects of ultraviolet exposure, including an increased risk of skin cancers

Lifeguards lead a skin cancer prevention learning activity—the Sunscreen Stretch—during a POOL COOL lesson.

In Their Own Words

Yesterday, several weeks after your visit, I had a mother come into my classroom after school to say thanks for teaching her daughter the importance of sunscreen. They had been skiing and her daughter, who had fought wearing it [sunscreen] for years, asked if her mom had remembered to pack it. Authentic learning at its best!

Boise School District
Middle School Health Educator

I do think that it [POOL COOL] has and will make a difference if we all continue making our community aware of small steps to lower their chances [of skin cancer]. We see such a difference in the awareness of children and their parents. Programs such as these are worthwhile and important to continue. Thank you for your support.

Manager, Filer City Pool
Filer, Idaho

Thank you again for a wonderful, well-designed lesson presentation. Your time and commitment to changing how today's kids look at nutrition and physical activities are appreciated and essential. Hopefully your proactive approach is the beginning of an enduring method that assists in changing the tide of society's current attitudes toward fitness, proper eating habits, and the eventual ramifications they have on their personal health and the healthcare system.

4th Grade Teacher
Garfield Elementary
Boise, Idaho

- Provide an engaging and interactive presentation to help students learn and relate to the sun-safety messages.

After completion of the sun-safety presentation, participants will:
- List at least two ways they can reduce their risk for skin cancer
- Understand that ultraviolet exposure occurs year round and that it's important to protect exposed skin all year
- Know that tanning and tanning bed use can lead to higher risk of skin cancer.

A short post-presentation assessment given to a sample of participants after presentations in school years 2012-13 and 2013-14 (n=581) demonstrated we are reaching our educational objectives.
- 92 percent of participants correctly identified at least two ways they can reduce their risk for skin cancer.
- 89 percent answered in the affirmative when asked if "Sun screen should be worn every day, including during the winter and on cloudy days."
- 97 percent correctly indicated that "Indoor tanning or tanning beds are not a safe way to get a tan."

POOL COOL

Skin cancer prevention is both an Idaho state priority and a local priority of St. Luke's MSTI. In keeping with the need for expanding skin protection practices, St. Luke's MSTI wanted to expand the reach of its efforts and impact the youngest children at risk of exposure to harmful rays of the sun.

The Community Guide recommends interventions in outdoor recreational and tourism settings that include skin cancer prevention messages or educational activities for visitors, and may also provide free sunscreen of SPF 15 or greater. This recommendation is based on strong evidence of effectiveness for increasing sunscreen use, avoidance of sun exposure, and decreasing incidence of sunburns.[16]

The POOL COOL program is a multi-component sun-safety education program designed for use at swimming pools. The program goal: to increase awareness, motivation, and sun protection practices among children ages 5-10 who take swimming lessons, parents of the children, pool staff, and other pool users.[17]

After completion of the POOL COOL education presentation, lifeguards and swim instructors will:
- Describe how to reduce risk of skin cancer
- Define positive and negative aspects of the UV rays from the sun
- List causes of skin cancer
- Demonstrate at least one POOL COOL activity or lesson.

The POOL COOL program teaches children about the dangers of overexposure to the sun and encourages them to develop healthy habits for a lifetime. Lessons are taught in conjunction with regular swimming lessons, with the curriculum combining

education, interactive activities at the pool, and pool-wide environmental changes.

St. Luke's MSTI adapted POOL COOL based on the following factors: 1) the program is evidence-based; 2) St. Luke's MSTI and local outdoor pools had the resources and time commitment required to implement the program; and 3) cancer program leadership found the program to be feasible, sustainable, and potentially expandable.[18]

Another advantage of the POOL COOL program was that it allowed St. Luke's MSTI to establish clinical-community linkages with state Parks and Recreation Departments. Specifically, St. Luke's MSTI educated Parks and Recreation employees about the importance of skin cancer prevention measures and helped them to establish policies that will help ensure that shade is part of the planning for future parks, playgrounds, and ball fields.

POOL COOL has proven to be an efficient program to provide skin cancer prevention education to children, teens, and parents. It uses a train-the-trainer format, which allows St. Luke's MSTI to educate a large number of pool staff, usually teens and young adults, about the importance of practicing sun-safety behaviors. Staff is also taught the daily curriculum they will provide to children in their classes. St. Luke's MSTI has found that for each staff member trained, the sun-safety education is passed on to an average of 26 children (range 17 to 41 children) over the summer. An added benefit is that parents also hear the important prevention messages provided by the pool staff. Although the impact on parents has not been measured, many pool staff report positive parental sun-safety changes as a result of the messages.

An important consideration for program development is expense. For POOL COOL, St. Luke's MSTI found the cost to start and maintain the program minimal. In 2013 the cost to establish POOL COOL at a new outdoor facility averaged $280 (with most of the money spent on sunscreen and dispensers, pool signage, etc.). While this amount can vary based on the needs and the size of the specific location, it averages about $1.70 per person (pool staff and swim students). The cost for an established POOL COOL site is even lower, with a yearly total cost of about $106 per pool, or about $0.26 per person.

A volunteer uses the skin analyzer device, which reveals underlying and unseen damage to the skin caused by UV exposure.

> In the long history of humankind (and animal kind, too) those who learned to collaborate and improvise most effectively have prevailed.
>
> CHARLES DARWIN

Healthy Habits, Healthy U

Global research from the World Cancer Research Fund shows that about one third of the most common cancers can be prevented through diet, maintaining a healthy weight, and engaging in regular physical activity.[19] Since 2008 cancer has been the leading cause of death in Idaho.[20] With these alarming statistics in mind, St. Luke's MSTI is working to educate students on the benefits of a healthy lifestyle. As mentioned previously, Healthy Habits, Healthy U (HHHU) is an interactive classroom presentation designed to educate children in 4th and 8th grades on the importance of lifestyle choices now and the impact these choices could have on their future health.

According to research published by The Cochrane Library, "becoming obese is strongly linked to inappropriate nutrition and low levels of physical activity, so unsurprisingly [many intervention programs] aim to improve either or both of these behaviours."[21] The Community Guide finds insufficient evidence to determine the effectiveness of school-based programs to prevent or reduce overweight and obesity among children and adolescents, because of the limited number of qualifying studies reporting non-comparable outcomes.[22-23] With this in mind and recognizing the critical need to take action for the health of the children in its community, St. Luke's MSTI co-developed (with Boise State University) HHHU. The program brings the Boise School District, Boise State University, and St. Luke's MSTI together to help reduce obesity and cancer risk, while supporting parents, teachers, and other staff as they implement health promotion strategies and activities. The goal of the HHHU program: to educate students about the relationship between healthy habits, nutrition, physical activity, and cancer risk reduction.

POOL COOL deck signage at local pool reminds patrons to use sunscreen.

After completion of the HHHU program:

- All participants will be able to differentiate between healthy and cancerous organs
- 4th grade participants will state multiple healthy eating tactics they will complete over a five-day period
- 4th grade participants will state a variety of physical activities they plan to complete over a five-day period
- 8th grade participants will list key health practices that can reduce cancer risk.

HHHU program implementation began with a pilot phase that was completed during the 2013-2014 school year. The program served 180 4th graders and 225 8th graders in their 2014 spring semester. Program evaluation found:

- Students successfully differentiated between the healthy and cancerous organs.
- 4th graders identified healthy eating and physical activity behaviors they planned to complete over a five-day period.
- 8th graders summarized key facts from the presentation, connected concepts to health practices that can reduce cancer, and brainstormed health behavior changes they could make to increase their overall health.
- Teachers reported HHHU lessons integrated well with their current health curriculum, they would partner with HHHU again, and they would recommend the program to other teachers.

While HHHU is still in its formative stages, the program has helped establish a new, creative approach to address critical health needs, and provides critical community linkages. Without the collaboration between St. Luke's MSTI, Boise State University, and the Boise School District, HHHU may not have been developed. These relationships make HHHU a stronger and more effective program.

The Role of Cancer Programs in Youth-Based Prevention Education

As the successes of St. Luke's MSTI illustrate, cancer programs are ideal organizations to support or lead cancer prevention efforts in their communities. Further, cancer programs accredited by the American College of Surgeons Commission on Cancer (CoC) are required to provide at least one cancer prevention program annually. Specifically, CoC 2012 Standards requirements include this provision: "At least one cancer prevention program that is targeted to meet the needs of the community and should be designed to reduce the incidence of a specific cancer type. The prevention program is consistent with evidence-based national guidelines for cancer prevention."[24]

NCI estimates that only about 15 percent of U.S. cancer patients are diagnosed and treated at the nation's major academic-based cancer centers; the vast majority of cancer patients (about 85 percent) are treated at community hospitals in or near the communities in which they live.[25] Many patients choose community hospitals because they are close to family, friends, and jobs, whereas treatment at academic or tertiary cancer programs may require long commutes or extended stays away from home.[25] Youth cancer prevention education provides a way for a cancer program to engage its community in a positive and beneficial environment. The community-clinical linkages provide opportunities for collaboration that will support the next generation to be healthier and better educated about cancer prevention and the role their choices play in the future. St. Luke's MSTI will continue its decades-long commitment to educational programs to the communities we serve, especially the youth population. OI

Melanie Gonzales, MSPH, MCHES, is community cancer education coordinator, and Vicky Jekich, CMP, is supervisor, Community Cancer Education & Outreach, St. Luke's Mountain States Tumor Institute, Boise, Idaho.

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A Well-Kept

Cancer registries are powerful, essential tools in the battle against cancer. Successful cancer programs mine the data contained within their cancer registries to identify areas where they can improve health for patients, at-risk populations, and their communities.

For cancer care providers immersed in the daily battle to eradicate cancer, staying apprised of the latest policy changes that apply to their work can be challenging. One significant policy that is important for cancer care leaders to be aware of—and recognize their role in supporting—relates to hospital community-benefit reporting. The cancer registry's role in providing benefits to the community and improving public health is essential for cancer care providers to convey to hospital leaders, who are under mounting pressure to justify their non-profit tax exemption to government officials.

With the countless laws and regulations that govern healthcare providers, cancer programs may not be aware that the cancer registry can be counted as part of a hospital's community-benefit costs, specifically as a research activity. And while it is nearly impossible to stay on top of every new healthcare policy, this one is certainly worth exploring since it ties not only to hospitals' missions but also to their non-profit tax status.

Federal Community-benefit Requirement

The majority of U.S. community hospitals (57.9 percent) are 501(c)(3) organizations, or what are commonly referred to as non-profit hospitals.[1] Caring for the most vulnerable members of our society has always been central to non-profit hospitals' missions.

In recognition of the important role that non-profit hospitals play in either reducing government burden or providing community-benefit, these hospitals are exempted from certain taxes at the federal, state, and local levels. In exchange for these tax exemptions, non-profit hospitals are expected—and their missions back them up—to provide charitable services to the communities they serve. At the federal level, the criteria for ensuring that non-profit hospitals are fully addressing the needs of the community have changed over time. In addition to federal laws that govern non-profit hospitals, many states and local governments have community-benefit requirements that non-profit hospitals must comply with if they want to be exempted from state and local taxes.[2]

Section 501 of the Internal Revenue Code (IRC) describes the criteria most organizations must meet to qualify for federal tax exemptions. Given the complex nature of tax law, from time to time the Internal Revenue Service (IRS) issues rulings to help clarify its policies. The history of the requirements guiding non-profit hospitals' tax exemption at the federal level—and how the community-benefit standard was established—can be traced by reviewing key IRS rulings over the years (see timeline on pages 58-59).

The past decade witnessed increased activity and scrutiny from members of Congress keen on investigating hospitals' charitable contributions and community-benefit activities. The culmination of this activity led to the redesign of IRS federal tax Form 990 in 2007, which is the federal reporting form that tax-exempt organizations have been required to file since 1950.[3] Form 990 provides state and federal regulators with access to financial and programmatic information about exempt organizations; as such it serves as an oversight tool.

BY AMBER GREGG, MSHCPM

Secret

The cancer registry's link to community-benefit reporting

Schedule H

The redesign of Form 990 led to a core tax form that all tax-exempt organizations must file, supplemented with various schedules that are required, depending on a non-profit organization's type and activities. Of particular significance to the hospital community was the creation of Schedule H, which was designed to gather more detailed information about hospitals' community-benefit activities and to increase transparency. Community-benefits are defined as programs and services designed to improve health in communities and increase access to care. Under this definition, a hospital's cancer registry expenses should be reported as a research expense (see Figure 1, page 58).

The Cancer Registry's Link to Community-benefit

Community-benefit costs include the amount a hospital spends on charity care, as well as the unreimbursed amounts spent on programs targeted at vulnerable populations, community-based programs, donations, research, and education initiatives. Many hospital administrators may not be aware that expenses related to their cancer registries can be counted toward their healthcare institution's community-benefit contribution. Often overlooked, the expenses associated with a hospital's cancer registry can show a substantial amount of added value to what is already being provided to the community.

Tracking and reporting expenses that support community-benefit initiatives is important when demonstrating a hospital's community-benefit contribution. Cancer registry expenses can be added to each hospital's list of community-benefit expenses and are relatively straightforward calculations compared to some of the other items that might be included on a hospital's community-benefit reporting.

Guidance from the Catholic Health Association of the United States suggests that hospitals should report expenses for cancer registries under the "research" community-benefit category. The rationale is that in addition to meeting a need identified in the community, the cancer registry meets the community-benefit objective of advancing knowledge because information is shared broadly.[6]

Cost of the Cancer Registry

Cancer registries provide invaluable data, yet the costs to healthcare institutions are not insignificant. Smaller hospitals with a caseload of 100 to 500 new cases per year could require a cancer registry staff of 1.6 full-time employees (FTEs).[7] For larger facilities with 5,000+ new cases per year, registry staffing could require 15 to 20 FTEs. According to Toni Hare, RHIT, CTR, Commission on Cancer-trained consultant and vice president of CHAMPS Oncology, "When all of the costs associated with maintaining a cancer registry are added up—including software, staffing, and workspace and equipment fees—total annual cancer registry costs can range from $100,000 for a small hospital to upwards of $1 million for a large healthcare system."

Last Words

Cancer registries are integral to helping hospitals across the country achieve their collective mission of serving communities by providing outstanding patient care. Since the first hospital cancer registry was created in 1926 at Yale-New Haven Hospital, the number of cancer registries has grown, as has their ability to

Figure 1. 990 Form Schedule H+

7 Financial Assistance and Certain Other Community Benefits at Cost

Financial Assistance and Means-Tested Government Programs	(a) Number of activities or programs (optional)	(b) Persons served (optional)	(c) Total community benefit expense	(d) Direct offsetting revenue	(e) Net community benefit expense	(f) Percent of total expense
a Financial Assistance at cost (from Worksheet 1)						
b Medicaid (from Worksheet 3, column a)						
c Costs of other means-tested government programs (from Worksheet 3, column b)						
d **Total** Financial Assistance and Means-Tested Government Programs						
Other Benefits						
e Community health improvement services and community benefit operations (from Worksheet 4)						
f Health professions education (from Worksheet 5)						
g Subsidized health services (from Worksheet 6)						
h Research (from Worksheet 7)						
i Cash and in-kind contributions for community benefit (from Worksheet 8)						
j **Total.** Other Benefits						
k **Total.** Add lines 7d and 7j						

For Paperwork Reduction Act Notice, see the Instructions for Form 990. Cat. No. 50192T **Schedule H (Form 990) 2014**

inform and improve cancer care.[8] Today, cancer registries play a central role in helping us understand the effectiveness of different cancer treatments, learn where new cancer cases are coming from, and pinpoint where to target outreach activities.

Beyond implications for public health, the costs associated with cancer registries can help hospitals demonstrate to government officials, patients, and other stakeholders the myriad ways they benefit members of the community. While cancer care experts recognize the importance of cancer registries, communicating the value of cancer registries to other hospital leaders, clinical teams, government officials, and community members is a more challenging yet vital task.

1956

Initially, hospitals were required to provide charity care to qualify for tax exemption at the federal level. A 1956 IRS ruling required hospitals to provide as much charity care as they could afford to qualify for and maintain their tax-exempt status. Thus, the volume of charity care provided by non-profit hospitals was initially the federal standard that guided hospital tax exemption.[3]

1969

A shift occurred in 1969 when the community-benefit standard became the legal standard for hospital tax exemption at the federal level. The 1965 creation of the Medicare and Medicaid programs, and the assumption that hospitals would be providing less uncompensated care given that more people would have access to health insurance, prompted the IRS to issue a new ruling. This new ruling expanded the requirements hospitals must meet to qualify for and maintain tax exemptions at the federal level beyond charity care alone. IRS Ruling 69-545 suggested that hospitals must provide benefits to the community, commonly termed "the community-benefit standard," to qualify for and maintain tax exemption at the federal level.[4]

Over time, healthcare leaders expect that the amount hospitals spend on charity care and uncompensated care will lessen as key provisions of the Affordable Care Act (ACA) are implemented and fewer individuals are uninsured. This healthcare trend is a step in the right direction, but it heightens the importance of hospitals thinking broadly about the vast array of community-benefits they provide. Tracking the expenses associated with cancer registries is crucial for hospitals that want to demonstrate the benefit they provide. OI

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The National Cancer Registrars Association (NCRA) defines a cancer registry as "an information system designed for the collection, management, and analysis of data on persons with the diagnosis of a malignant or neoplastic disease (cancer)." According to NCRA there are three main types of cancer registries:

- Healthcare institution-specific registries (data is maintained for all cancer cases diagnosed and/or treated at an institution, such as a hospital, and then submitted to the central or state registry as required by law)
- Central registries (population-based for a specific geographic region)
- Special purpose registries (e.g., brain tumor registry).[8]

Every Commission on Cancer accredited hospital must have a cancer registry. As of January 1, 2015, all current cancer registrars must have achieved Certified Tumor Registrar (CTR) credentials to collect and submit data to the National Cancer Data Base. (Note: There is a three-year grace period for newly hired cancer registrars to achieve CTR certification.)

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1983

Another important IRS ruling further clarified the community-benefit standard (83-157) by finding that the "operation of a full time emergency room providing emergency medical services to all members of the public regardless of their ability to pay for such services is strong evidence that a hospital is operating to benefit the community."[5]

2007

IRS federal tax Form 990—which tax-exempt organizations have been required to file since 1950—is redesigned.[3]

CANCERSCAPE 2015 Wrap-Up

ACCC's 41st Annual Meeting, CANCERSCAPE, kicked off on March 16 with Capitol Hill Day. ACCC members from across the country fanned out across the Capitol for more than 70 scheduled meetings with legislators and key staff members from both the House and Senate.

On Tuesday, March 17, more than 400 attendees at ACCC's Annual Meeting Cancerscape gathered to hear Ron Kline, MD, Medical Officer with the Center for Medicare and Medicaid Innovation (CMMI), and Kavita Patel, MD, MS, of the Brookings Institution discuss CMMI's new Oncology Care Model.

Wendy Andrews, BS, practice manager, Hematology/Oncology at the University of Arizona Cancer Center; George Dahlman, executive vice president, Federal Affairs & Operations, National Patient Advocate Foundation; and Steven D'Amato, BSPharm, BCOP, executive director, New England Cancer Specialists, explored the impact of the ACA from the patient advocate and provider perspective.

(Left) Stacy Maciuk accepts ACCC's 2015 David King Community Clinical Scientist Award presented posthumously to her father, Eric Lee Raefsky, MD. (Right) Stuart L. Goldberg, MD, Chief Division of Leukemia, John Theurer Cancer Center, accepts ACCC's 2015 David King Community Clinical Scientist Award. (Also pictured Becky L. DeKay, ACCC Immediate Past-President.)

ACCC Welcomes its Newest Members

Arizona Oncology Associates, PC
Phoenix, Ariz.
Delegate Rep: Brian Schade, MBA
Website: www.arizonaoncology.com

Blanchard Valley Health System
Armes Family Cancer Care Center
Findlay, Ohio
Delegate Rep: Jamie Thompson, CTR
Website: www.bvhealthsystem.org

Cancer Center at Ohio Valley Medical Center
Wheeling, W. Va.
Delegate Rep: Breezie Ogilbee, RT(T), BA
Website: www.ovmc-eorh.com

Polyclinic Cancer Program
Seattle, Wash.
Delegate Rep: Kelly Shaw, MPH
Website: www.polyclinic.com

Southeast Georgia Health System
Brunswick, Ga.
Delegate Rep: Cindy A, Rockhill, RN, BSN, NNA, NE-BC
Website: www.sghs.org

ACCC: MEETING YOUR NEEDS

Gear up for a full menu of meetings with need-to-know information for the entire cancer care team. Don't miss out on unparalleled opportunities to advance your learning in critical areas, and earn CE credits. Be sure to share this information with your colleagues who can benefit from these events.

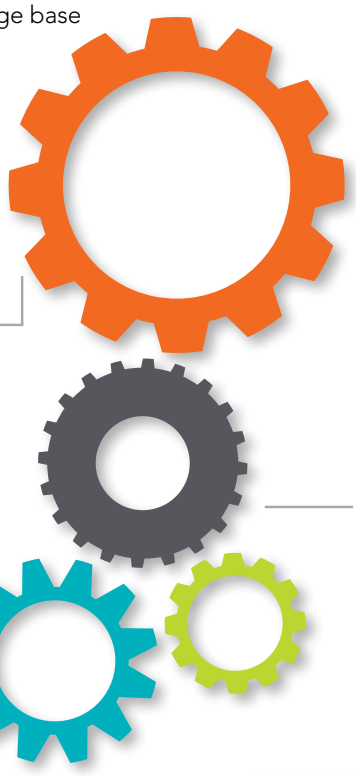
ACCC
Association of Community Cancer Centers

FINANCIAL ADVOCACY NETWORK REGIONAL MEETINGS

Bridging the Gap between Patient Needs and Financial Resources
These FREE one-day meetings help sharpen the skills and knowledge base of financial advocates.

Tuesday, June 2, 2015
Silver Spring, Maryland

Tuesday, June 23, 2015
Burlingame, California



ONCOLOGY PHARMACY EDUCATION NETWORK (OPEN) REGIONAL MEETINGS

These two-day meetings provide take-away tools and information to oncology pharmacists and members of the cancer care team in pharmacy operations.

June 26–27, 2015
Fort Lauderdale, Florida

July 10–11, 2015
Charlotte, North Carolina

ONCOLOGY REIMBURSEMENT MEETINGS

Any member of the cancer care team who deals with oncology business and reimbursement will benefit from these FREE one-day meetings. Gain a full-spectrum perspective with sessions on payment reform; the latest trends in coding and billing; proper management of financial data; and the practical application of radiation oncology CPT codes.

Tuesday, August 25, 2015
Indianapolis, Indiana

Tuesday, November 17, 2015
Boston, Massachusetts

Thursday, December 10, 2015
Birmingham, Alabama

32ND NATIONAL ONCOLOGY CONFERENCE

The ACCC National Oncology Conference delivers innovative ideas, solutions, and strategies to implement in your cancer program. How-to sessions focus on proven approaches to real-world challenges. Plus, the 2015 Innovator Award winners will present their pioneering programs.

Stay Tuned!

October 21–23, 2015
Portland Marriott Downtown Waterfront
Portland, Oregon

For details on all ACCC meetings go to www.accc-cancer.org/meetings

Passionate Financial Support —An Antidote for Financial Toxicity

BY MICHAEL J. REFF, RPH, MBA; HANNAH B. PEABODY, CPHT; AND DEBORAH R. WALTERS, RN, OCN

Financial toxicity has become an urgent issue in the field of oncology due to the ever-growing number of patients having difficulty paying for their complex oncolytic treatments. This financial toxicity can lead to a decrease in adherence to cancer therapy. In a study of 10,508 patients with Medicare and commercial insurance, the abandonment rate of newly-initiated oral oncoloytics was 10 percent. In addition, claims with cost sharing greater than $500 were four times more likely to be abandoned than claims with cost sharing of $100 or less.[1] With the average monthly cost of new oral oncolytics approaching $12,000, cancer programs must create strategies to minimize the impact of high out-of-pocket costs and remove the financial barriers to patients' access to these medications. In January 2013 Hematology-Oncology Associates of Central New York (HOACNY), East Syracuse, N.Y., made the decision to focus on its patients' oral medication needs by establishing a physician dispensing platform. HOACNY's vision was simple: to be the best physician dispensing service for patients in community oncology. To execute and operationalize this vision, practice management afforded the pharmacy team generous lead time to develop and implement all the necessary foundational elements to better ensure success.

Planning & Implementation

Development of The Patient Rx Center (TPRxC) began with the creation of a formulary that revolved around oral oncolytics, supportive medications, and neutraceuticals. Next, the TPRxC team created a mission statement that provided the framework necessary for programmatic success (see box on page 64). One of the main tenets of this mission statement is the provision of financial support to patients.

During the planning phase of TPRxC, our team met with representatives from every pharmaceutical company that manufactures an oral agent to gather:

- Relevant clinical data
- Dosing and administration information
- Information on adverse event management
- Medication-specific, patient-centered tools and resources
- Information about financial support for patients, including co-pay savings cards, patient assistance programs, and foundations and non-profits.

With this information, the TPRxC team was able to create a database that we use internally to better serve our patients. (This database is updated as elements change within the oral oncolytic marketplace.)

Passionate Financial Support

Faced with the ever-growing cost of oral chemotherapy, our TPRxC team is passionate about securing financial support for our patients. In fact, one of the main responsibilities of our dispensing nurse navigator and certified pharmacy technician is to work closely with patients and their families to ensure oral adherence is not interrupted due to the high cost of their therapy. To do so, the TPRxC team proactively pursues every resource available to financially assist our patients before we dispense a medication; we call our efforts Passionate Financial Support.

So how do you go about providing Passionate Financial Support? One option is to research and identify a grant that has open funding for a patient's specific diagnosis. Our TPRxC team works closely with numerous foundations, including the Patient Access Network (PAN) Foundation, the Patient Advocate Foundation Co-pay Relief, Patient Services Inc., the HealthWell Foundation, and the Good Days from CDF. Eligibility depends largely on a patient's household size, income, cancer diagnosis, and medication.

Another option is the free medication programs and co-pay assistance cards that are available from most pharmaceutical manufacturers. A good resource to find information about these pharmaceutical patient assistance programs is ACCC's annual Patient Assistance and Reimbursement Guide (www.accc-cancer.org/PatientAssistanceGuide).

A last option for our patients who are in need of financial assistance is our employee-sponsored and funded Pot of Gold program. This program is an extension of HOACNY's Fun Committee, which raises money through creative programs, such as holiday and sporting event raffles, and by selling HOACNY apparel. When our team has exhausted all other options available to the patient, our Pot of Gold can provide assistance up to a maximum of $200.

(*continued on page 64*)

ADVERTISER'S INDEX

(*continued from page 62*)

Tracking Our Financial Support

Our Passionate Financial Support is tracked through our electronic health record (EHR)—not only by TPRxC, but by the practice as a whole. Departmental teams, such as the Patient Advocate Team, the Social Work Team, and TPRxC Team, monitor this information to ensure that patient funds are not exhausted or expired while patients are still on therapy. If the patient's treatment is discontinued by the provider or funding is no longer needed, the TPRxC team contacts the appropriate foundation to cancel the grant so that funding may be available for others.

Shortly after TPRxC opened its doors, our team created an Excel spreadsheet for tracking financial assistance provided to patients. This tracker captures all of the financial assistance secured through various foundations, non-profits, or pharmaceutical manufacturer programs. Data has revealed that our team has secured more than $2.1 million in Passionate Financial Support for our patients since TPRxC opened its doors in April 2013.

Our team uses these metrics to demonstrate to multiple stakeholders the value (and commitment!) TPRxC delivers. Specifically, TPRxC uses this data to help develop a value proposition for all internal (physicians, administration, co-workers) and external (employers, payers, advocacy groups, pharmacy benefit managers) stakeholders.

With a focus on continuous improvement, TPRxC developed a patient satisfaction survey to help refine our mission and our processes. An important survey component centers on the financial assistance services TPRxC provides to its patients. While patient feedback has been very favorable, as a team we strive to improve our services and how we engage our patients.

Accordingly, in October 2014, HOACNY implemented a Patient Assistance Committee where practice leaders and the TPRxC team convened and developed a plan of action to better understand the practice's internal processes and how it meets the needs of its patients and caregivers. The committee has made great strides, enhancing our existing communication and tracking systems so that we can better address financial toxicity in our patient community.

Our TPRxC team, in concert with every department within the HOACNY family, will continue to work passionately to address the financial concerns of our patients. By eliminating the uncertainty our patients have in understanding where and how to secure funding for their cancer treatment, Passionate Financial Support has indeed proven a trusted antidote for our patients' financial toxicity. OI

Michael J. Reff, RPh, MBA, is manager, TPRxC, Hematology-Oncology Associates of Central New York, East Syracuse, N.Y., and founder of the National Community Oncology Dispensing Association, Inc. (NCODA), a grassroots, not-for-profit organization focused on addressing the growing needs of dispensing cancer clinics to improve operations at the pharmacy level in order to deliver quality and sustainable value to the many stakeholders involved in the care of cancer patients receiving oral therapy. Learn more at www.ncoda.org. Hannah B. Peabody, CPhT, is Pharmacy Technician Certification Board's 2014 Pharmacy Technician of the Year and is pharmacy technician, TPRxC, Hematology-Oncology Associates of Central New York. Deborah R. Walters, RN, OCN, is dispensing nurse navigator, TPRxC, Hematology-Oncology Associates of Central New York. Read more about TPRxC in the May/June 2014 Oncology Issues available to members only at: http://mynetwork.accc-cancer.org/.

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TPRxC Mission

Our team mission is to be a valuable resource to patients and HOACNY staff in a convenient, patient-centered environment. We are committed to maintaining the highest level of care by accurately and efficiently dispensing medications, and providing educational and financial support, while enhancing patient compliance.

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