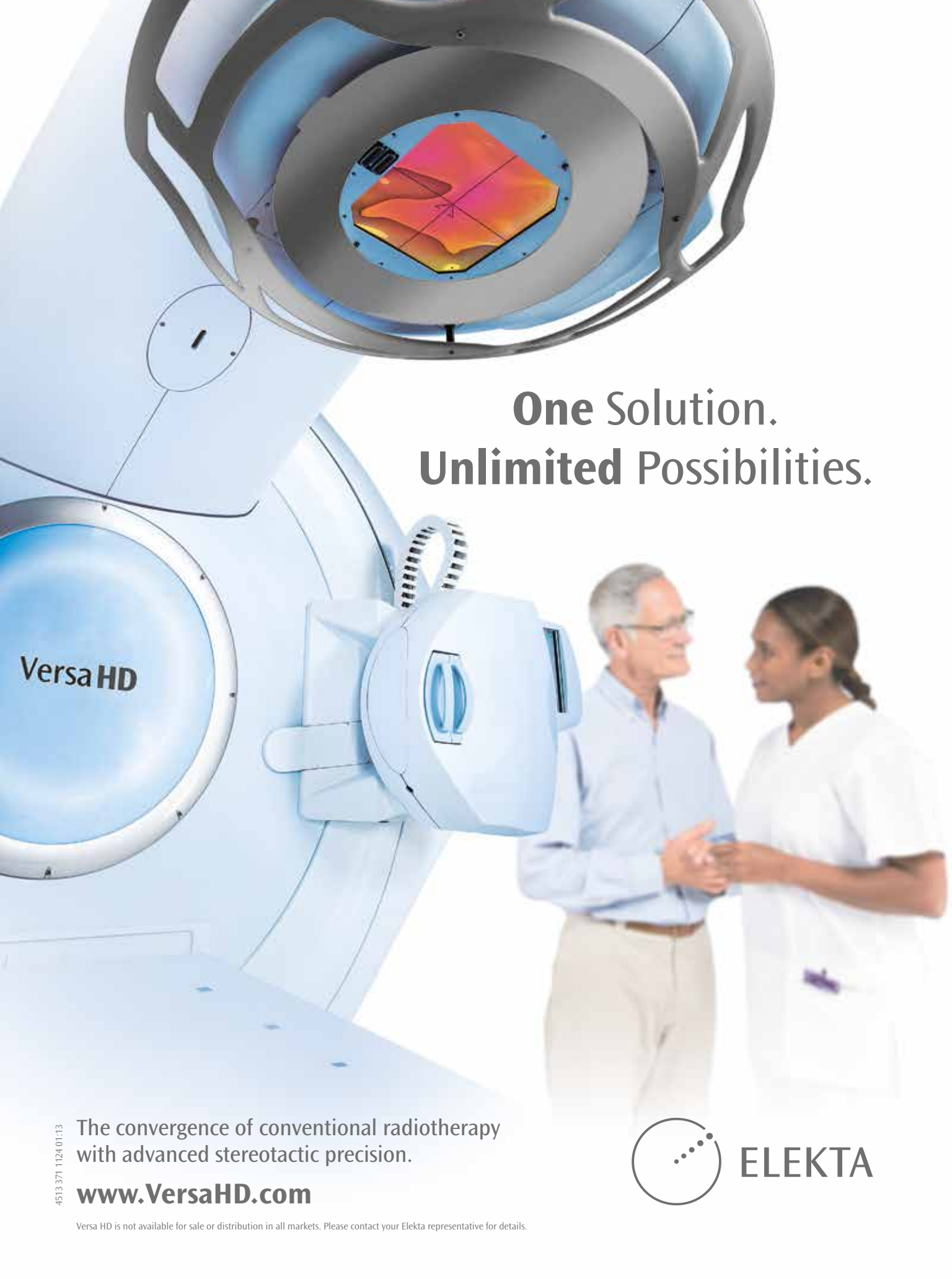
ONCOLOGY ISSUES

The Journal of the Association of Community Cancer Centers
November | December 2013

Is Your Outpatient Infusion Center Financially Sound?



One Solution.
Unlimited Possibilities.

The convergence of conventional radiotherapy with advanced stereotactic precision.

www.VersaHD.com

ELEKTA

4513 371 1124 01:13

Versa HD is not available for sale or distribution in all markets. Please contact your Elekta representative for details.

contents

Oncology Issues
November | December 2013
Vol. 28 | No. 6

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

The Individuality of Cancer Care

BY CHRISTIAN DOWNS, JD, MHA

Cancer as a disease has frustrated clinicians, policymakers, and patients since the time of Hippocrates. One of the main reasons for this frustration, and what separates cancer from other diseases, is the individual nature of each patient's cancer.

Clinicians try to understand why a particular therapy works in one patient and not in another. Policymakers try to understand why cancer treatment is so expensive. Patients, often, just try to understand the "new normal" of life after a cancer diagnosis.

Clearly the oncology community is on the precipice of understanding cancer as an individual disease. Just look at the breakthroughs happening in genomics, immunotherapy, and genetic testing.

So how do you—the backbone of the cancer delivery system in this country—prepare yourself for these changes?

You can start with this edition of *Oncology Issues*, which offers practical, hands-on strategies that you can replicate in your program now.

For example, take the article on "The NCCCP Cancer Genetic Counseling Assessment Tool" by Patricia D. Hegedus, RN, OCN, MBA, and colleagues. Funded in part by tax dollars, the National Cancer Institute Community Cancer Centers Program (NCCCP) is a public-private partnership of the National Cancer Institute (NCI) and a network of community hospital-based cancer centers from around the United States—many of whom are ACCC member programs. The genetic counseling tool on pages 38-39 is a prime example of how the NCCCP has shared its knowledge with the larger oncology community. Any oncology program can use this self-assessment tool to identify strengths and weaknesses in their cancer genetics service line and develop quality improvement plans.

Next, James Pellicane, MD, discusses genomic testing for breast cancer in the community setting. With genomic testing many patients can choose to forgo chemotherapy—without worrying about an increased risk of recurrence. Yet, adoption of this new technology has been slow. This article explores the reasons for lagging adoption; details the advantages genomic testing can have for patients and providers; and describes practical implementation steps for programs looking to move forward with adoption.

Finally, take another look at our cover story on improving profitability and service in an outpatient infusion center. Castle and colleagues offer practical strategies to improve a program's bottom line by focusing on revenue and expenses, as well as common-sense process improvements.

Yes, new and cutting-edge evidence continues to support the concept that cancer is an individualized disease. But to the physician who breaks the news of a cancer diagnosis to a patient, the nurse who holds that person's hand, and the social worker who reaches out to the patient and his or her family, that is old news. OI

PRESIDENT'S MESSAGE

A Time to Celebrate

BY VIRGINIA T. VAITONES, MSW, OSW-C

Greetings! As I write this column, I've just returned from the hugely successful ACCC 30th National Oncology Conference, held for the first time in Boston. The sessions and education programs were innovative and thought-provoking. Here's one comment I overheard from a meeting attendee coming out of a session on rural chemotherapy, which was presented by 2103 Innovator Award Winner Avera McKennan Hospital and University Health Center, Avera Cancer Institute.

"I just implemented new competences for my nurses, and I was questioning myself. After hearing this speaker, I knew I'd done the right thing!"

I hope that each attendee came away from ACCC's meeting with at least one such take-away message.

Once again I would like to thank everyone who attended the 30th National Oncology Conference. And for those of you not able to attend, I urge you to join us at ACCC's Annual Meeting, March 31-April 2, 2014, in Arlington, Va., as we celebrate the Association's 40th Anniversary. In fact, our first "celebration" arrived with this edition of *Oncology Issues:* ACCC's 2014 Wall Calendar—believe it or not, a first for the Association!

Along with marking ACCC's 40 years of service, the calendar also helps to spread my presidential theme—saluting the contributions of all members of the multidisciplinary cancer care team. I hope you will share this calendar with your colleagues and patients and display it proudly in your programs and offices so that we can celebrate together all year long. A special thanks to the ACCC member programs that shared images of their staff. As always, it takes a village at ACCC, and we would not be half as successful without the support and participation of our members.

But before we can hang this beautiful and useful calendar—pre-populated with dates and information of interest to the oncology community—we must first make it through the very hectic holiday season ahead.

Hopefully, we can look forward to many happy family gatherings and celebrations—for ourselves, our colleagues, and our patients. However, the difficult reality is that, for some of our patients and their families, this may be the last holiday they are all able to spend together. This knowledge, along with the added stressors of the holiday season, can be very challenging for these patients and families. While, as cancer care providers we do everything we can to help alleviate this stress, much of this responsibility rests on the shoulders of our psychosocial support services. So I would like to take this opportunity to personally thank all of the oncology social workers, child-life specialists, chaplains, psychologists, and other mental health professionals who remain vigilant and on the frontline, providing vital services to our patients and their caregivers during these sometimes tumultuous times.

As an oncology social worker, I understand that the holidays can also be somewhat stressful for our staff as well. My advice? First, adjust your expectations and give yourself permission to say "No" to activities or tasks that may overwhelm you physically and emotionally. Remember our patients rely on us for care, but we must first take care of ourselves.

Second, consider establishing some new traditions to reduce stressors, such as using technology to bring you closer to family and friends when traveling is too stressful.

Finally, enjoy the support of your multidisciplinary team colleagues. Leveraging the unique skills and strengths of each team member allow us to more fully appreciate time spent together in the workplace and at home during this holiday season and into the New Year. OI

Coming in Your 2014 *ONCOLOGY ISSUES*

- Skin Cancer Screening Clinic: A Creative Business Model
- Biosimilars: Emerging Issues for Cancer Programs?
- Clinical Pathway Trends—Payers, Providers, and Healthcare Evolution
- A Holistic Approach to Infusion Center Renovation
- A Model Rural Chemotherapy Program
- Integrating Palliative Care into a Medical Oncology Practice
- Implementing a Community-Based Program for Cancer Survivors & Caregivers
- Improving Oncology Genetic Counseling
- Creating a Virtual Genetic Counseling Environment
- How to Implement an Outpatient Pharmacy in Oncology Practices
- New Patient Coordinator: Streamlining a Cancer Center's Phone Lines
- Completion of a Community Health Needs Assessment

more online @ www.accc-cancer.org

WEBINAR

Nutrition for the Gastrectomy Patient

Webinar discussion topics for patients who have had a partial or full gastrectomy, including dealing with appetite changes, minimizing weight loss, maintaining nutritional status, and more. www.accc-cancer.org/gastric.

NOMINATE

Call for Nominations for ACCC Board of Trustees

ACCC is now accepting nominations for its 2014 Board of Trustees' election. Nominations must include the nominee's name and program affiliation and be emailed to Careen Campbell at ccampbell@accc-cancer.org. All nominations must be received by November 30, 2013.

VIDEO

Get to Know ACCC's Community Resource Centers

These cancer programs have volunteered to provide resources and answer questions on patients with cancers your program may not see every day, including CML, APL, and multiple myeloma. www.accc-cancer.org/CRC.

INFO

Opportunities and New Realities in Cancer Care

Read ACCC's first whitepaper from its 2013 Institute for the Future of Oncology. The second white paper, "Cancer Care in the Age of Electronic Health Information Exchange," is also available at www.accc-cancer.org/institute.

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

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

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

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

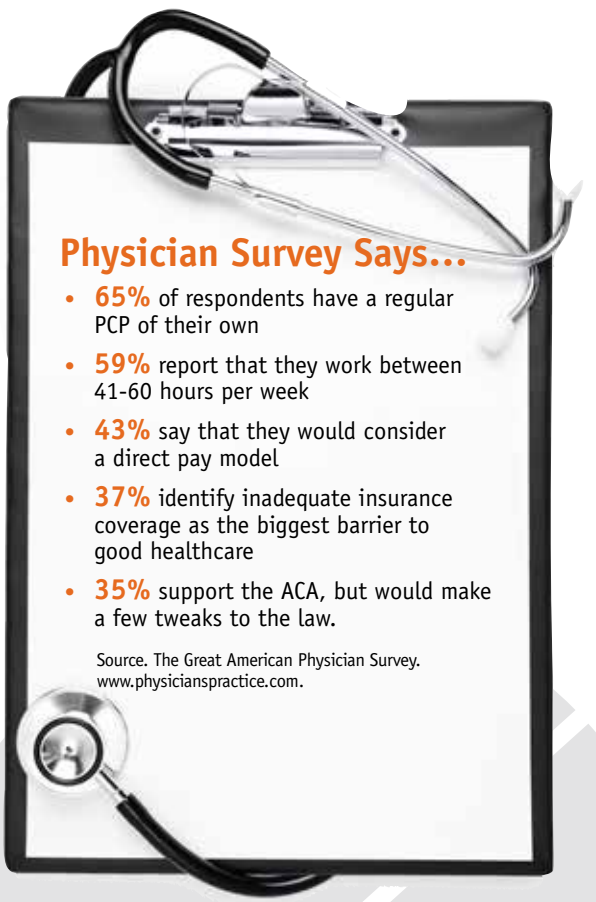
Please send address changes to Association of Community Cancer Centers, 11600 Nebel St., Suite 201, Rockville, MD 20852.

fast

6 Practical Steps to Better Healthcare

1. Effective, evidence-based workforce planning for patients and physicians
2. Allocation of residency training positions that aligns with population needs and job availability
3. Improvements to the work environment in rural areas to attract and retain new physicians in local communities
4. Career counseling throughout medical training
5. Promotion of a culture of social accountability in medical training
6. Succession planning.

Source. The Canadian Association of Internes and Residents. www.cair.ca.



Physician Survey Says...

- **65%** of respondents have a regular PCP of their own
- **59%** report that they work between 41-60 hours per week
- **43%** say that they would consider a direct pay model
- **37%** identify inadequate insurance coverage as the biggest barrier to good healthcare
- **35%** support the ACA, but would make a few tweaks to the law.

Source. The Great American Physician Survey. www.physicianspractice.com.

facts

Practice Ownership Drops, but More than Half of Docs Still Self-Employed

- The percentage of physicians who owned their practice in 2012 is down **8%** from 2008; physicians in solo practice are down by **6%**.
- Although data indicates a shift toward hospital employment, **53.2%** of physicians are self-employed.
- **60%** are in practices wholly owned by physicians; only **23%** work in practices that are at least partly owned by a hospital.
- **6%** of physicians are directly employed by a hospital.
- A larger percentage of men **60%** own their own practices, compared with women **39%**.
- Ownership is less common among younger physicians—**43.3%** for physicians under age 40 and **60%** for physicians age 55 and up.

Source. A Survey by the American Medical Association. www.ama-assn.org.

The Cost of Healthcare

Healthcare spending is expected to rise just **3.8%** in 2013—the fifth consecutive year it will have stayed below **4%**. Why the modest rise? Experts say it's due to the recent recession and slow recovery, increases in patient cost-sharing requirements, and slow growth in public programs. Expected growth for 2014 is **6.1%**, with an average projected growth of **6.2%** per year thereafter.

Source. National Health Expenditure Projections, 2012–22: Slow Growth Until Coverage Expands And Economy Improves. *Health Affairs*.

5 Easy Questions All Breast Cancer Patients Should Ask

1. **WHO** will be the team of doctors assigned to my care? Typically it's not just a surgeon or oncologist outlining the recommended course of treatment but a team that includes various specialists.
2. **WHAT** type of treatment is recommended? There are pros and cons to all medical procedures. Every treatment is customized to the patient.
3. **WHERE** does the treatment take place?
4. **WHEN** would the treatment take place, how often, and for how long? Lifestyles and daily demands should be taken into consideration.
5. **WHY** is this the treatment that is being recommended? Understand the relevance of the treatment to the diagnosis and if it is the most effective treatment for the type of cancer.

Source. The BC5 Project. www.bc5project.com.

Not to Be Forgotten—Off-Label Use in Oncology

BY MATTHEW FARBER, MA

With everything that is happening in healthcare policy, it is easy to overlook some of the everyday issues that ACCC members face with regard to providing quality cancer care. Today's busy healthcare practitioners are continually buffeted by concerns such as government shutdowns, the sequester, the SGR fix, and challenges related to ACOs, Health Insurance Exchanges, and Health Information Exchanges. However, one issue has remained a constant for the past five years—off-label therapy. Off-label therapies play a critical role in a physician's ability to provide quality care. Despite the fact that the oncology community as a whole understands the importance of off-label therapy, these services still face significant payment and reimbursement challenges.

In August-September 2013, ACCC and PhRMA released results of a joint survey on the impact of payer coverage and reimbursement policies on off-label use of anticancer therapies. This survey was a follow-up to a survey conducted five years ago, which measured the same issues. One hundred and sixty-five ACCC members responded to the 2013 survey and, as expected, a vast majority (91 percent) responded that they find off-label therapy important to their ability to provide quality care to their patients.

We did find some interesting differences between the two surveys. For example, using a 5-point scale with 5 being extremely important, this year's respondents rated the importance of off-label therapy an average of 3.6, compared to 4.1 in the 2008 survey. In what may be a related change, this year's respondents also assigned less importance to drug compendia—one of the main sources practitioners use to help justify off-label therapies with payers. In 2013 respondents rated the importance of drug compendia as 3.7, down from 4.2 in 2008.

Despite these survey results, the drug compendia are still an important tool for payers and providers alike. Additionally, the 2013 survey clearly showed that providers continue to wrestle with issues related to off-label therapy; 80 percent of respondents report that payers have denied coverage for medicines that are listed in compendia. Other challenges include:

- ***Prior authorizations.*** A little more than 90 percent of respondents report that private payers are using prior authorizations to restrict coverage and reimbursement for off-label uses of anticancer drugs.
- ***Post-payment audits.*** Respondents in this year's survey report increased use of post-payment audits by Medicare (40 percent in 2013, up from 27 percent in 2008) and private payers (47 percent in 2013, up from 25 percent in 2008.)

One of the new survey questions asked in 2013 had to do with the use of guidelines and pathways. Pathway utilization has grown significantly in the last five years, and these treatment parameters may have had an effect on off-label drug use, including how people are using drug compendia. For example, if the off-label indication is on the approved pathway, then the practitioner may no longer be responsible for providing compendia or journal evidence with the claim. In the 2013 survey, 27 percent of respondents report having some type of partnership with payers regarding clinical pathways.

The bottom line remains: a compendia listing does not guarantee coverage or payment, and coverage policies of public and private payers continue to have a major impact on treatment decisions. In fact, 95 percent of survey respondents report that coverage and reimbursement policies cause clinicians to alter their clinical decision-making. Further, the increasing utilization of pathways and guidelines may continue to alter the oncology landscape, and ACCC will continue to monitor these changes to determine how off-label therapy impacts its membership.

Oncology MANAGEMENT CONSULTING GROUP

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

OMC GROUP…
Outstanding experts, Outstanding results!

- Financial and Market Analyses
- New Center Development
- Hospital/Physician Integration
- Strategic Planning
- Operational Assessments
- Revenue Cycle Reviews
- Implementation and Interim Leadership
- Performance and Financial Benchmarking

OMC GROUP
2013 ONCOLOGY WEBINAR SERIES

Our most recent webinar **"QUALITY IN ONCOLOGY: How and Why Everyone Should Get QOPI Certification"** is now available to view in full at **https://vimeo.com/76542144.**

Our next webinar will be **"Results of OMC GROUP's 2013 Benchmarking Study"** Date to be announced.

To ensure participation in our complimentary webinars, please send an email to **solutions@oncologymgmt.com.**

OMC GROUP
2013 BENCHMARKING STUDY

Sincere thanks to those of you that have submitted data for OMC Group's Benchmarking Study and to all of you that have expressed interest in the results. As of Nov. 15, we have received all essential data from the study participants and we are well into data analysis. We anticipate that the analysis and reports will likely be complete by late November or early December. Although we are unable to schedule the webinar to disseminate the results of the study at this time, we expect to schedule it during the week of December 16-20. As always, there is no cost to oncology administrators or oncologists for our webinars and the invitation to register will be sent out shortly. We look forward to a very informative and exceptionally beneficial presentation for all.

To summarize, this benchmarking study is examining performance and productivity benchmarks in both infusion centers and radiation centers. If you would like to ensure receipt of the invitation to register for this webinar, please send an email to **solutions@oncologymgmt.com.**

Sunshine or Stormy Weather?

BY CINDY PARMAN, CPC, CPC-H, RCC

The Sunshine Act appears as Section 6002 of the Patient Protection and Affordable Care Act (PPACA or ACA) and requires manufacturers to report to the Centers for Medicare & Medicaid Services (CMS) virtually all payments and gifts made to physicians and teaching hospitals. The Final Rule for the ACA's Open Payments program (the government's updated name for the Sunshine Act) was issued in February 2013 and will soon result in publicly distributed financial information.

According to CMS in a public presentation on Aug. 8, 2013, the objectives of the Open Payments program include making financial relationships transparent on a national scale and providing consumers with the information needed to ask questions and make informed decisions about their healthcare professionals. The CMS role in this program is to ensure that reports and disclosures are complete, accurate, and clear, while remaining neutral when presenting the data on a public website.

According to the CMS Open Payments webpage:[1]

Collaboration among physicians, teaching hospitals, and industry manufacturers can contribute to the design and delivery of life-saving drugs and devices. However, while some collaboration is beneficial, payments from manufacturers to physicians and teaching hospitals can also introduce conflicts of interests.

While financial ties alone do not signify an inappropriate relationship, Open Payments is necessary to:

- *Encourage transparency of reporting financial ties;*
- *Reveal the nature and extent of relationships;*
- *Prevent inappropriate influence on research, education, and clinical decision-making;*
- *Avoid conflicts of interest that can compromise clinical integrity and patient care; and*
- *Minimize risk of increased health care costs.*

More than 90 percent of physicians report having some type of business relationship; about 80 percent report receiving food or beverages in the workplace from industry sources.[2] According to an April 26, 2010 article published by Kaiser Health News:[3]

Research suggests that those details matter to some patients. Kevin P. Weinfurt, an associate professor of psychology and neuroscience at Duke University, has studied how patients participating in clinical trials react to physician disclosures. He found that patients were particularly troubled when doctors owned stock in the companies that were managing the clinical trials. "They felt somehow that this physician could do something in the trial that could make the company a lot of money, which would then make him a lot of money," Weinfurt says.

According to Dr. Shantanu Agrawal, director of the CMS data-sharing and partnership group, "Pharmaceutical companies spent $15.7 billion in 2011 on face-to-face sales and promotional activities."[2]

As part of a separate agreement with the government, Amgen Inc., a biotechnology manufacturing company, recently released records of physician payments made during the first quarter of 2013.[4] Although the majority of payments to physicians were for less than $100 in food costs, at least ten individual physicians received more than $20,000 in payments and other transfers of value during this three-month period.

What Providers are Affected?

For the purposes of Open Payments, a "physician" is any of the following types of professionals that are legally authorized to practice—regardless of whether they are Medicare, Medicaid, or Children's Health Insurance Program (CHIP) providers. (Medical residents are currently excluded from the definition of physicians for the purpose of this program.)

- Doctor of Medicine
- Doctor of Osteopathy
- Doctor of Dentistry
- Doctor of Dental Surgery
- Doctor of Podiatry
- Doctor of Optometry
- Doctor of Chiropractic Medicine.

Open Payments will not initially apply to midlevel providers, such as nurse practitioners and physician assistants.

For the purposes of Open Payments, "teaching hospitals" are hospitals that received payment for Medicare direct graduate medical education (GME), inpatient prospective payment system (IPPS) indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year for which such

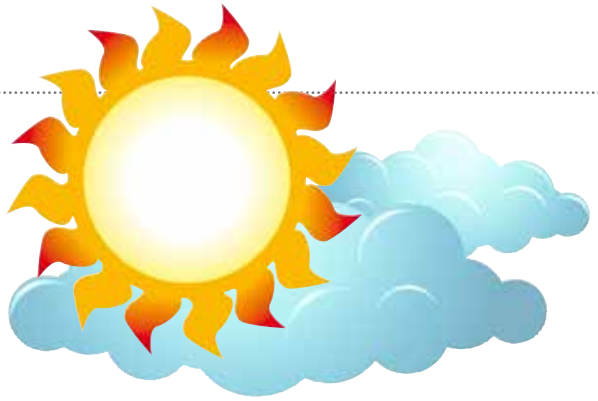


Table 1. 2013 Open Payments Program Cycle

Industry Will: Collect information on payments and other transfers of value, as well as ownership or investment interests held by physicians and their family members.	**Industry Will:** Register and submit 2013 information to CMS.	**Industry Will:** Correct disputed information.	**CMS Public Website:** 2013 information posted.
August – December 2013	**1st Quarter 2013**	**2nd Quarter 2013**	**September 2014**
Physicians Should: Keep track of payments and transfers of value made and be mindful of ownership and investment interests held by both the physician and their immediate family.	**Physicians Should:** Register with CMS in order to receive notifications and information submitted by the industry.	**Physicians Should:** Review information for accuracy.	

information is available. CMS has posted a list of these teaching hospitals on the Open Payments program webpage and this list will be updated annually.

Who is an Applicable Manufacturer or GPO?

Open Payments defines applicable manufacturers as those that:

- Operate in the United States (meaning that they have a physical location within the U.S. or otherwise conduct activities in the U.S., either directly or through a legally-authorized agent); AND either
- Produce, prepare, propagate, or compound at least one covered drug, device, biological, or medical supply; OR
- Operate under common ownership with an applicable manufacturer and provide assistance or support to the applicable manufacturer in the manufacturing, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply.

Applicable manufacturers of at least one covered product must report to CMS all payments and other transfers of value made to physicians and teaching hospitals. CMS defines a "covered product" as any drug, device, biological, or medical supply that is eligible for payment by Medicare, Medicaid, or CHIP, either individually or as a part of a bundled payment (such as the IPPS) and that requires a prescription to be dispensed (for drugs and biologicals) or requires pre-market approval by or pre-market notification to the U.S. Food and Drug Administration (for devices, including medical supplies that are devices).

Open Payments defines applicable GPOs as those that:

(*continued on page 13*)

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.

Indication

» GRANIX™ (tbo-filgrastim) Injection 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.

NEW

GRANIX™

(TBO-FILGRASTIM)
Injection

NOW AVAILABLE

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

- GRANIX demonstrated a 71% reduction in duration of severe neutropenia (DSN) vs placebo[1]
  - GRANIX significantly reduced DSN when compared to placebo (1.1 days vs 3.8 days; $p<0.001$)[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]
- Safety was evaluated in 3 Phase III clinical trials[1]

Important Safety Information (continued)

- **Use in patients with sickle cell disease:** Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disease receiving hG-CSFs. Consider the potential risks and benefits prior to the administration of GRANIX in patients with sickle cell disease. Discontinue GRANIX in patients undergoing a sickle cell crisis.
- **Potential for tumor growth stimulatory effects on malignant cells:** The granulocyte colony-stimulating factor (G-CSF) receptor, through which GRANIX acts, has been found on tumor cell lines. The possibility that GRANIX acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which GRANIX is not approved, cannot be excluded.
- **Most common treatment-emergent adverse reaction:** The most common treatment-emergent adverse reaction that occurred in patients treated with GRANIX at the recommended dose with an incidence of at least 1% or greater and two times more frequent than in the placebo group was bone pain.

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

For more information, visit GRANIXhcp.com.

Reference: 1. GRANIX™ (tbo-filgrastim) Injection Prescribing Information. North Wales, PA: Teva Pharmaceuticals; 2013.

TEVA Oncology

GRANIX™
(TBO-FILGRASTIM)
Injection

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

SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Splenic Rupture

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

5.2 Acute Respiratory Distress Syndrome (ARDS)

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

5.3 Allergic Reactions

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

5.4 Use in Patients with Sickle Cell Disease

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

5.5 Potential for Tumor Growth Stimulatory Effects on Malignant Cells

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

6 ADVERSE REACTIONS

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

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

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

6.1 Clinical Trials Experience

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

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

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

Leukocytosis

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

6.2 Immunogenicity

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

7 DRUG INTERACTIONS

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

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

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

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

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

8.3 Nursing Mothers

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

8.4 Pediatric Use

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

8.5 Geriatric Use

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

8.6 Renal Impairment

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

8.7 Hepatic Impairment

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

10 OVERDOSAGE

No case of overdose has been reported.

TEVA Oncology

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

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

Product of Israel

FIL-40046 July 2013

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

(*continued from page 9*)

- Operate in the United States (meaning that they have a physical location within the U.S. or otherwise conduct activities in the U.S., either directly or through a legally-authorized agent); AND
- Purchase, arrange for purchase, or negotiate the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the purchasing entity itself.

Applicable GPOs must report information on ownership and investment interest held by physicians and their immediate family members, as well as any payments or other transfers of value made to physician owners or investors.

What Payments Are Included?

"Nature of payment" categories must be used to describe why a payment or other transfer of value was made. The categories are:

- Consulting fees
- Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program
- Honoraria
- Gifts
- Entertainment
- Food and beverage
- Travel and lodging
- Education
- Research
- Charitable contributions
- Royalty or license
- Current or prospective ownership or investment interest
- Direct compensation for serving as faculty or as a speaker for a medical education program (unaccredited or non-accredited)
- Grants
- Space rental or facility fees (teaching hospital only).

CMS has also clarified that in addition to direct payments to physicians and teaching hospitals, the manufacturers and GPOs must also report indirect payments and payments that are transferred to a third party. For example, if the manufacturer contracts with an agency to distribute funds to physicians who endorse a certain product, these payments would be reported under the Open Payments program.

In another scenario, if the physician scheduled to receive a payment for serving as a speaker directs the company to forward his compensation to a charity, this action must still be reported as a payment to the physician.

There are, however, limited exceptions for compensation for speaking at a continuing education program when all published criteria are met. But even if the compensation is exempt from the reporting requirements, it is possible that the manufacturer will have to report the costs of meals, travel, lodging, and educational materials for these continuing education events.

Excluded from the reporting requirements are items that directly benefit patients or are intended to be used by patients, including the value of a manufacturer's services to educate patients regarding a covered drug, device, biological, or medical supply. For example, if the transfer of value consists of a wall chart or anatomical model, these costs are not reportable. That said, CMS has clearly stated that the provision of a textbook by a manufacturer or GPO is reportable under the Open Payments Program.

The data collected under the Open Payments program will become part of a database that the FDA's Office of Criminal Investigations (OCI) is building to detect potentially fraudulent activity, such as off-label marketing violations.

What Information Will Be Reported?

CMS states that the standard reporting categories include:

- General Payments: payments or other transfers of value not made in connection with a research agreement
- Research Payments: payments or other transfers of value made in connection with a research agreement
- Ownership & Investment Interests.

From coffee and doughnuts to investigator grant permits, any payment or transfer must be reported under the provisions of the Open Payments program. Section 6002 provides the following limited exception:[5]

Small payments or other transfers of value, which the statute defines as payments or other transfers of value less than $10, do not need to be reported, except when the total annual value of payments or other transfers of value provided to a covered recipient exceeds $100.

Specific information reported by industry manufacturers and GPOs includes the physician's full legal name, primary specialty, primary business address, national provider identifier (NPI), state professional license number(s), and email address. In addition, there will be data relating to the name of the drug, device, biological, or medical supply and the amount, date, number, and nature of the payment(s) or other transfer(s) of value. Last, the interactions will be categorized as cash (or cash equivalent), "in kind" items or services, stock (including stock options or other ownership interest), or dividend, profit, or other return on investment.

Applicable manufacturers and GPOs will report the data for August through December of 2013 to CMS by March 31, 2014; CMS will release the data publicly by September 30, 2014. After that, a full year's worth of data will be published the following June; for example, the data from January through December 2014 will be

published in June 2015. In addition, manufacturers and other reporting entities will be required to register on a CMS website, and will submit data using templates.

According to a CMS official speaking at the annual meeting of the American Medical Association (AMA) House of Delegates in Chicago, Ill. on June 17, 2013, once data has been collected and processed, providers will have 45 days to dispute and correct manufacturer's reports.[6] After that, the data will be made public. If a discrepancy is not brought to the manufacturer's attention during the 45-day period, resolutions could take months.

If providers believe that reported data is false or misleading, they must document the disputed data elements in writing to CMS, and then work out the dispute directly with the manufacturer. The data will be flagged as "disputed" on the website, but will not be removed until the manufacturer withdraws the information. In addition, CMS will not mediate the dispute; if it is not resolved in a year, the manufacturer's data will be reported to the public.

To ensure data accuracy, CMS is required to conduct audits of the data submitted and levy civil monetary penalties against manufacturers and GPOs for failing to submit data or submitting inaccurate data. CMS can impose $10,000 fines on manufacturers for failing to report gifts, but this penalty may climb to $100,000 should a manufacturer be found to have deliberately omitted payment information.

What Should *You* Do?

There are industry concerns that this type of public database will be a target for industry critics, the press, the Internal Revenue Service (IRS), and even attorneys seeking to sue physicians or facilities. As a result, industry sources must make reporting accuracy the first priority.

Physicians, hospitals, and cancer programs should track their data. In addition, they should monitor the Open Payments website for an opportunity to register for online access to reports and dispute documents. Further, CMS recommends that physicians and teaching hospitals:

- Become familiar with the information that will be reported about physicians or teaching hospitals
- Keep records of all payments and other transfers of value received from manufacturers or GPOs
- Register with CMS and subscribe to the listserve to receive updates regarding the program
- Review the information manufacturers and GPOs submit on a physician's or hospital's behalf
- Work with manufacturers and GPOs to make sure the information submitted is correct.

Physicians and teaching facilities can register with CMS starting Jan. 1, 2014 to receive a report on their activities each June before the public report is released. CMS is also promoting its smartphone app, called "Open Payments Mobile for Physicians" that tracks payments and other value transfers from manufacturers. The physician app will work in tandem with the "Open Payments for Industry" app that allows the manufacturer to exchange information with the physician on a dynamic basis, but the apps will not be used to transmit information to CMS.

In an effort to ensure that physicians understand the details of the Open Payments Program, AMA has developed a Tool Kit, including a free archived webinar and frequently asked questions, which is available at: www.ama-assn.org/ama/pub/advocacy/topics/sunshine-act-and-physician-financial-transparency-reports.page.

Last, physicians and hospitals that will be impacted by the Open Payments program should be prepared to respond to questions from patients and other consumers once the payment results are published. This response could include disclosing the information on the provider's website, publishing frequently asked questions, and training staff to respond appropriately to questions about industry payments received during a patient encounter.

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

References

1. CMS. Open Payments. www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html. Last accessed Sept. 26, 2013.
2. Robeznieks A. Docs Fear Sunshine Act Data May be Misread. www.ModernPhysician.com. Available online at www.modernphysician.com/article/ 20130620/MODERNPHYSICIAN/306209969#. Last accessed Oct. 29, 2013.
3. Weintraub A. New health law will require industry to disclose payments to physicians. *Kaiser Health News*. Available online at www.kaiserhealthnews.org/Stories/2010/April/26/physician-payment-disclosures.aspx. Last accessed Sept. 26, 2013.
4. Amgen, Inc. Physician Payment Report 01/01/2013 to 03/31/2013. Available online at http://clearlyamgen.amgen.com/cia/pdf/Corporate_Integrity_Agreement_Physician_Payment_Report_Q1_2013.pdf . Last accessed Sept. 26, 2013.
5. HHS. *Federal Register*. 78(27):9485. Available online at www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Final-Rule.pdf. Last accessed Sept. 26, 2013.
6. Ault A. Sunshine Act: tracking of gifts, payments starts in August. *The Oncology Report*. Available online at www.oncologypractice.com/oncologyreport/single-view/sunshine-act-tracking-of-gifts-payments-starts-in-august/39ce25c0ff722d7863824588e591c466.html?tx_ttnews%5BsViewPointer%5D=1. Last accessed Sept. 26, 2013.

ACCC 40TH ANNUAL NATIONAL MEETING

Strength in Numbers

A focus on policy, economics, and business

SAVE THE DATE! ▶ March 31 – April 2, 2014

Hyatt Regency Crystal City
Arlington, Virginia

www.accc-cancer.org/annualmeeting

ACCC
Association of Community Cancer Centers

tools

Approved Drugs

• The Food and Drug Administration (FDA) has expanded the approved uses of Celgene Corporation's (*www.celgene.com*) **Abraxane® (paclitaxel protein-bound particles for injectable suspension, albumin-bound)** to treat patients with with late-stage pancreatic cancer. It is intended to be used with gemcitabine in patients with pancreatic cancer that has spread to other parts of the body.

• Genentech's (*www.gene.com*) drug **Perjeta® (pertuzumab)** was granted FDA accelerated approval as part of a complete treatment regimen for patients with early stage breast cancer before surgery. It is the first FDA-approved drug for the neoadjuvant treatment of breast cancer. Perjeta is to be used in combination with trastuzumab and other chemotherapy prior to surgery and, depending upon the treatment regimen used, may be followed by chemotherapy after surgery. Following surgery, patients should continue to receive trastuzumab to complete one year of treatment.

• The FDA has approved the first generic version of **Xeloda® (capecitabine)**, an oral chemotherapy pill used to treat cancer of the colon or rectum that has spread to other parts of the body, and metastatic breast cancer. Teva Pharmaceuticals USA (*www.tevapharm.com*) has FDA approval to market generic capecitabine in 150 and 500 mg strengths.

Drugs in the News

• Bayer HealthCare (*www.bayer.com*) and Onyx Pharmaceuticals (*www.onyx.com*) announced that the FDA has granted priority review designation to its supplemental new drug application (sNDA) for the oral multikinase inhibitor **Nexavar® (sorafenib) tablets** under evaluation for the treatment of locally advanced or metastatic radioactive iodine (RAI)-refractory differentiated thyroid cancer.

• The FDA has granted breakthrough therapy designation to Boehringer Ingelheim Pharmaceuticals' (*www.us.boehringer-ingelheim.com*) **Volasertib**, an investigational inhibitor of polo-like kinase (Plk), being evaluated for the treatment of patients aged 65 or older with previously untreated acute myeloid leukemia (AML), ineligible for intensive remission induction therapy.

Devices in the News

• Nucletron, an Elekta company (*www.elekta.com*) has launched **Esteya®**, a new approach for treating patients with skin cancer. Esteya electronic brachytherapy mimics proven high-dose rate (HDR) brachytherapy by bringing a small X-ray source very close to the cancerous site, enabling the local application of radiation for effective treatment. Esteya requires only minimal room shielding.

• The FDA has granted 510(k) clearance to Varian Medical Systems' (*www.varian.com*) **RapidPlan™**, a radiotherapy treatment planning tool designed to enhance quality, consistency, and efficiency in radiotherapy treatment planning. RapidPlan provides clinicians with knowledge-based models that generate high-quality personalized treatment plans for their patients.

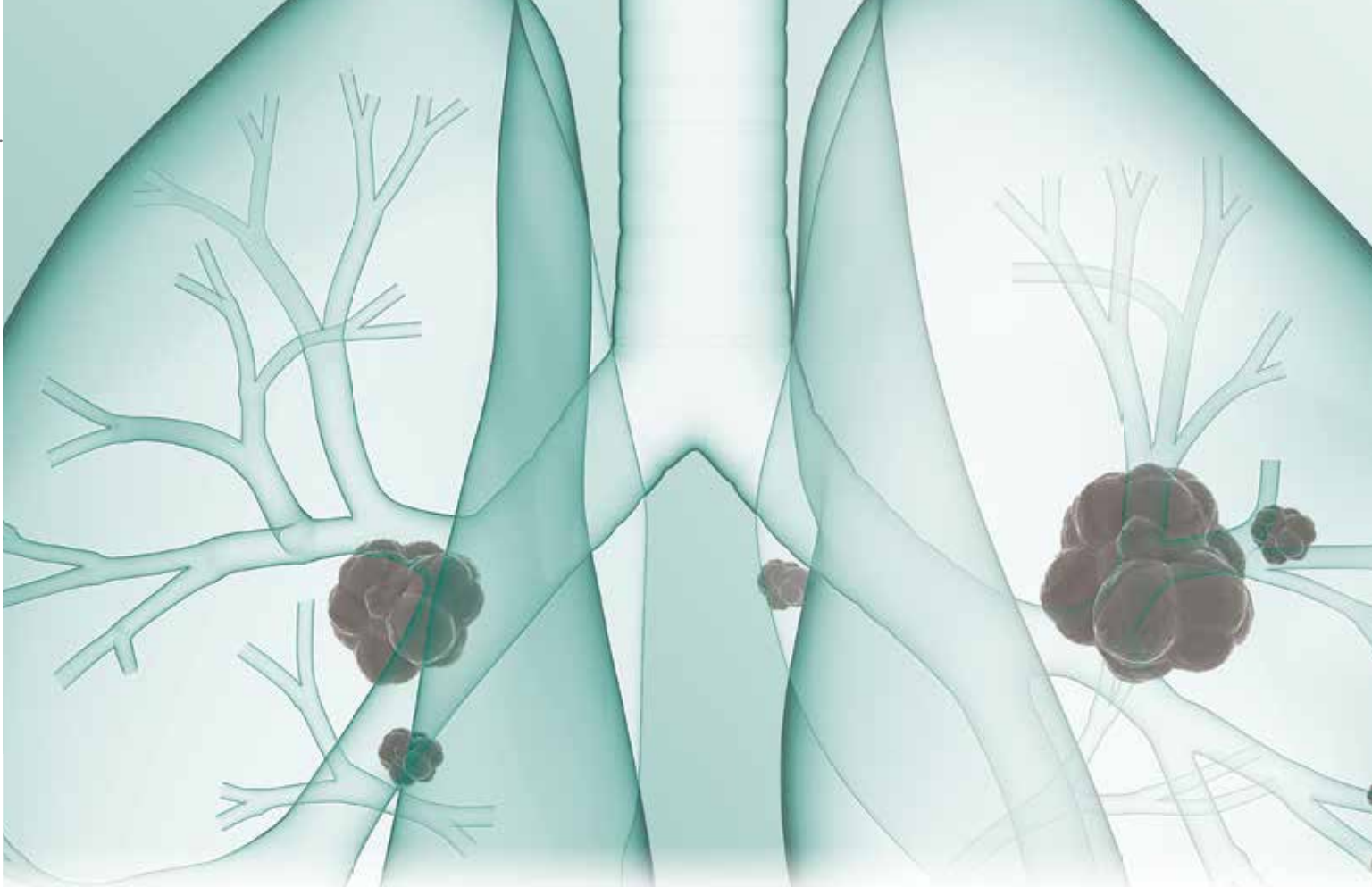
Genetic Tests & Assays in the News

• Quest Diagnostics (*www.QuestDiagnostics.com*) has announced the availability of **BRCAvantage™**, a suite of four new lab-developed genetic tests (LDT) that identify mutations in *BRCA1* and *BRCA2* genes, which are associated with increased risk of inherited breast and ovarian cancers.

• GeneDx (*www.genedx.com*) has launched **OncoGeneDx**, a suite of genetic tests for inherited cancer, including a 26-gene panel for breast and ovarian cancer that includes *BRCA1* and *BRCA2* and next generation sequencing based multi-gene panels for colorectal cancer, pancreatic cancer, and endometrial cancer.

• Ventana Medical Systems, Inc. (*www.ventana.com*) has announced the launch of the **Ventana BRAF V600E (VE1) Mouse Monoclonal Primary Antibody IHC assay**. The test is designed to detect the most frequent BRAF mutation, V600E, which has been found to play a key role in a variety of cancers including colorectal cancer.

• Trovagene, Inc. (*www.trovagene.com*) announced the availability of the first urine test for cancer mutation monitoring through the company's CLIA laboratory. Trovagene's cell-free **BRAF℠** test is a laboratory-developed test designed to detect and monitor this mutation in metastatic cancer patients with biopsy-proven V600E BRAF mutation in their tumor. OI



What if you could use the body's own T cells to combat Lung Cancer?

With Immuno-Oncology it may be possible.

Current approaches to lung cancer treatment include radiation, surgery and chemotherapy/targeted therapy, all of which are intended to target the tumor. Through our ongoing clinical program, BMS is investigating an entirely new way to treat lung cancer by targeting the immune system. Our research is focused on transforming the way tumor cells and the immune system communicate, including checkpoint pathways; we hope to find new ways to stop lung cancer from evading the immune system, thereby restoring the body's natural ability to fight it.

If you're interested in learning more about BMS investigational studies in lung cancer, including a list of study sites, please visit BMS Study Connect to search for lung cancer studies near you.

http://www.bms.com/studyconnect/Pages/Home.aspx

Bristol-Myers Squibb

Immuno-Oncology

Leading the way

Visit us at **BMS**immunooncology.com

spotlight

The Elkhart General Hospital Center for Cancer Services, Elkhart, Indiana

The Elkhart General Hospital Center for Cancer Services has been serving Elkhart County, Indiana since 1913. From 2001-2012, Elkhart General has received the Outstanding Achievement Award from the American College of Surgeons Commission on Cancer (CoC). It is one of only 13 programs in the nation to receive that honor for three consecutive review cycles.

"We are a community hospital, but we deliver the same level of care that a bigger referral center would," said Toni Klatt-Ellis, APRN, MN, AOCN, advanced practice nurse for Oncology Services.

Meeting Community Needs

When the recession began in 2008, Elkhart County was particularly hard hit. In 2009 Elkhart had the highest unemployment rate in the nation. For the cancer center, this economic downturn has meant treating an increasing number of uninsured and under-insured patients. "To provide people a level of comfort that they're going to get exceptional care here, and that they don't have to travel [to another cancer center] is important," said Klatt-Ellis, emphasizing that patients don't have to worry about incurring additional expenses involved in traveling for care.

Most of the oncology services offered by Elkhart General are housed on the hospital campus. The inpatient Oncology Care Unit is located on the fourth floor of Elkhart General Hospital. Two private medical oncology practices are close by, one adjacent to the hospital and the other, five minutes away. Patients may choose to receive chemotherapy at either the medical oncology offices or in the hospital's ambulatory infusion clinic. Almost all other oncology services are located on the lower level of the hospital, including the ambulatory infusion clinic, radiation oncology, and the interdisciplinary Breast and Thoracic clinics.

The radiation oncology department is accredited by the American College of Radiation Oncology (ACRO). The department offers state-of-the-art therapies, such as Rapid Arc and Stereotactic Body Radiation Therapy.

In 2006 Elkhart General expanded and updated their inpatient Oncology Care Unit. The 20-room unit contains all private rooms designed to feel like home with a living-room atmosphere. A spacious family area is equipped with a huge living room and a fireplace. Bathroom facilities were remodeled to accommodate family members who want to spend the night. The unit also has a full kitchen with a large dining room table for patients with many visiting family members to enjoy a meal together as if they were at home. According to Vicky Carter, CTR, cancer registry data quality control coordinator at Elkhart General, this unique space is popular for Thanksgiving and Christmas meals, and has also been used for birthday parties, anniversary celebrations, and even weddings.

The Breast Care Center, situated in the West Wing of the hospital, is recognized as a Certified Quality Breast Center of Excellence, Certification Level III – the highest certification level awarded by the National Consortium of Breast Centers National Quality Measures for Breast Centers™ Program. The Breast Care Center was also awarded the Breast Imaging Center of Excellence designation by the American College of Radiology (ACR).

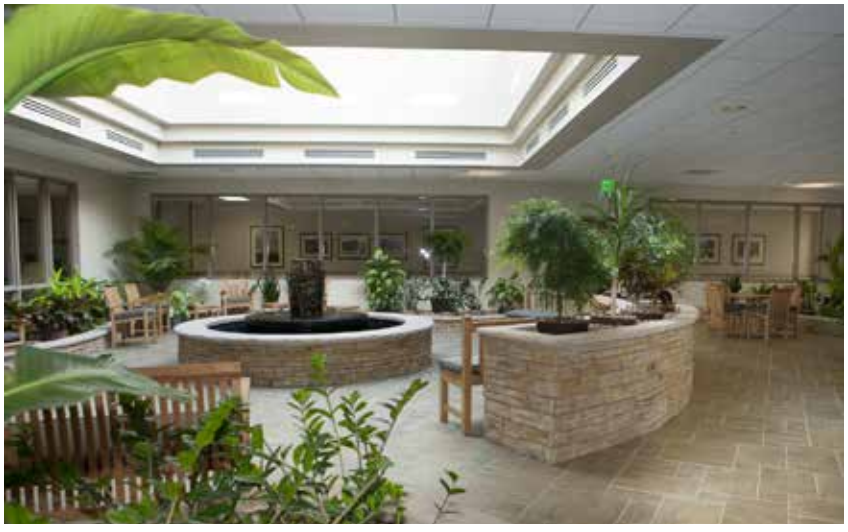
Patient navigation services are offered at Elkhart General to help coordinate care. A general navigator is available to patients treated on the inpatient unit. Nurse navigators also guide patients through the Breast and Thoracic Clinics. Navigators are also available to accompany patients to appointments and help resolve insurance issues.

To comply with the federal requirement mandating all 501(c)(3) hospitals to complete a Community Health Needs Assessment (CHNA), Elkhart General performed their CHNA in 2012. After surveying Elkhart County, the hospital identified a significant lung cancer population, obesity, and a high smoking rate as the top health issues affecting its community.

Smoking rates in Elkhart County are higher than the national rate and the percentage of patients who are diagnosed with Stage IV lung cancer is greater than 50 percent; also above the national average. With these needs identified, Elkhart General's next step was to implement programs addressing these areas.

Lung Cancer Screening Program

Based on CHNA data, as well as the National Comprehensive Cancer Network (NCCN) 2012 Guidelines and data from the



Select Support Services

- Patient navigation
- Social work services
- Survivorship program
- Patient support groups
- Nutrition services
- Number of new analytic cases seen in 2011: 711

National Lung Screening trial, Elkhart General developed a lung cancer screening program in June 2012. In addition to a need identified by the community assessment, physician champions at the hospital were also vital to the initiation of the screening program in June 2012.

First Elkhart General established a multidisciplinary thoracic oncology clinic to be able to have a disease-specific clinic for patients diagnosed with lung cancer. Staff then worked with Central Scheduling to develop a database for these patients that would facilitate scheduling and tracking of follow-up scans.

A copy of the patient's initial scan is stored in Elkhart General's database, and a copy is also sent to the patient's primary care provider. At the follow-up appointment, patients are briefed on the implications from their scan, and staff collects their smoking history, if applicable. Patients that are currently smoking are offered smoking cessation options, including classes or one-on-one clinic visits with nurse practitioners. After that, the patient receives a copy of the letter confirming that the follow-up conversation took place with hospital staff. Information on their next appointment is mailed to them by the scheduling department. The patient's primary care provider receives a copy of this letter, a copy of the NCCN guidelines, and a copy of the scan.

Since the program began, about 180 patients have been seen. According to Klatt-Ellis, the greatest number of referrals has come from cardiologists.

Engaged Patients

Elkhart General Hospital holds Breast, Thoracic, and General Cancer Conferences. Breast conferences are held weekly, and Thoracic and General take place twice a month. As with most cancer conferences, attendees include medical oncologists, radiation oncologists, surgeons, pathologists, radiologists, and other specialists. In an effort to promote patient-centered care, Elkhart General also invites patients and their families to attend the conferences. Patients are contacted by the nurse navigator prior to the conference to coordinate conference details.

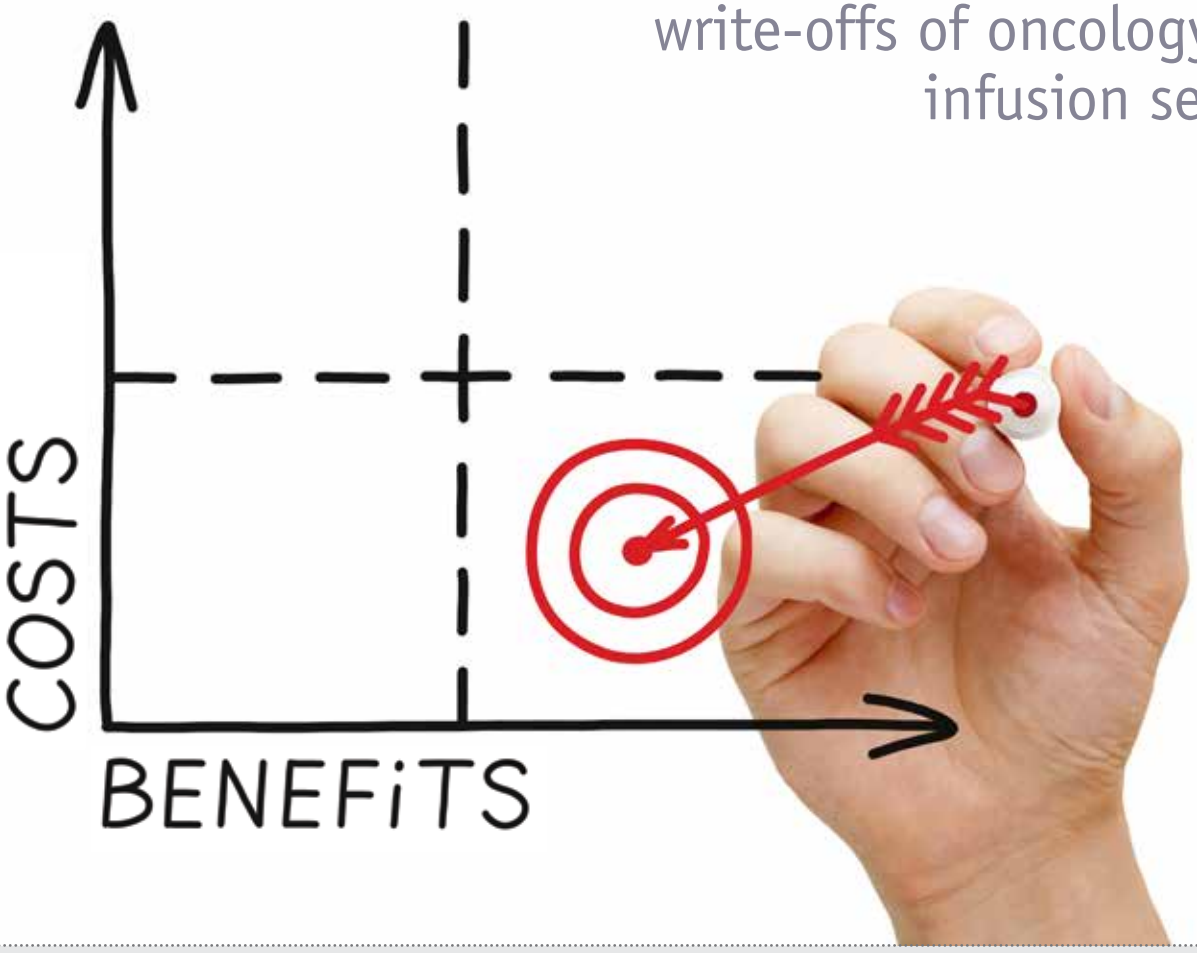
Attendance at the conference allows patients to view radiology films and pathology slides. Patients also have the opportunity to meet with clinicians, a social worker, and dietitian following their presentation to further clarify any remaining questions.

According to Klatt-Ellis, most patients take advantage of this open forum where they can ask questions and gain full knowledge of disease, staging, treatment, and prognosis along with clinical trial opportunities. Patients can even record the discussion. "The patients and families have loved this open forum. They feel like they're getting the opinion of 10 physicians in one room to work together on their plan of care," she said.

As a part of the program's theme of "Guide, Nurture, Transform," Elkhart General is committed to ensuring that every oncology patient is satisfied with their care experience every time they are seen during their cancer journey.

Improving Profitability & Service

A business case for managing financial write-offs of oncology drug infusion services



IN BRIEF Today, hospital administrators are constantly tasked with finding new ways to improve their program's bottom line. Often, the focus is on increasing revenue; however, opportunities also exist on the expense management side. Through a case study, we will illustrate how improving processes in outpatient infusion services may significantly improve a hospital's financial performance.

Infusion services typically include chemotherapy, blood transfusions, antibiotic injections, and pain management pump refills. High-volume services may be provided by a fully dedicated infusion department; infusion services may also be offered on an "as-needed basis" in the emergency room or on an inpatient unit.

Further, insurance may dictate where a patient will receive infusion services. Occasionally, private practice medical oncologists may make the decision to treat patients with private insurance—often equated with higher reimbursement—and "shift" patients with inadequate reimbursement, such as Medicare and non-insured patients, to the hospital setting. This cost-shifting can have unfortunate financial consequences for a hospital-based outpatient infusion department.

A myriad of other factors, including rising drug costs, decreased reimbursement, and stricter documentation requirements for payment, can also contribute to financial losses for hospital-based outpatient infusion services. These losses can rapidly grow out of

BY STEVEN CASTLE, JASON SARASHINSKY, REBECCA PERKINS, AND RUTH MICHAUD

Outpatient infusion departments provide comprehensive, skilled nursing services to patients who are undergoing diagnostic procedures or invasive treatments. In addition to chemotherapy administration, services may also include:

- Antibiotic therapy
- Hydration and electrolyte replacement therapy
- Transfusions of blood products
- Injections of recombinant growth factors
- Immunosuppressant therapy
- Antiviral or antifungal therapy
- Therapeutic phlebotomies
- Refill of pain pumps
- Placement of PICC or midline catheters
- Access of implanted ports
- Wound care.

Physicians can also use infusion center space to perform procedures such as simple tissue biopsies or bone marrow biopsies. In addition to a general trend towards increasing the scope of services, other factors, including a weak economy, an aging Medicare population, and longer, more complex infusions, have caused many outpatient infusion centers to extend their hours of operation.

In our case study, all of these factors were behind the hospital's decision to open a dedicated outpatient infusion department in March 2005. The infusion department grew, providing extensive services for a diverse patient population, including patients with cancer, Crohn's disease, multiple sclerosis, rheumatoid arthritis, infections, hematologic diseases, and chronic renal failure. Patient services included chemotherapy, antibiotic therapy, hydration and electrolyte therapy, transfusions of blood products, injections of recombinant growth factors, immunosuppressant therapy, refilling pain pumps, and accessing implanted ports. The outpatient infusion department was staffed by registered nurses, nursing assistants, and phlebotomists, and supported by pharmacists.

In May 2009 infusion services expanded again with a move into a newly-constructed cancer center, increasing patient capacity from 7 to 12 private chairs with hours of operation from 7:00 am to 7:00 pm, Monday-Friday. The outpatient infusion department was deliberately positioned adjacent to the office space of a large private practice medical oncology group. With this change, hospital-based infusion service volumes grew from 4,233 visits in 2009 to 5,472 in 2010. This increased volume trend continued in 2011.

Identifying & Resolving Challenges

Although the hospital's infusion department was financial viable, an internal review conducted at the time of the move into the new cancer center showed that the service line had a significant amount of write-offs—about $1.2 million annually. This finding led the hospital to create an Infusion Task Force (ITF) Committee, chaired by a hospital-employed oncology pharmacist. Committee members included: the oncology administrator, the director of Charge Capture & Compliance, the infusion director, the infusion supervisor, and the director of Patient Registration. The ITF Committee's goal: to improve the operational performance of the infusion service line and provide a guiding hand in the continual management of the service line. The committee identified multiple strategies to address the issue of write-offs, implement programmatic efficiencies, and improve quality of care. The following steps were taken:

- Create a process to review non-formulary medications (see Figure 1, page 22).
- Analyze write-offs to identify coding and process errors and less costly alternatives to reduce future write-offs.

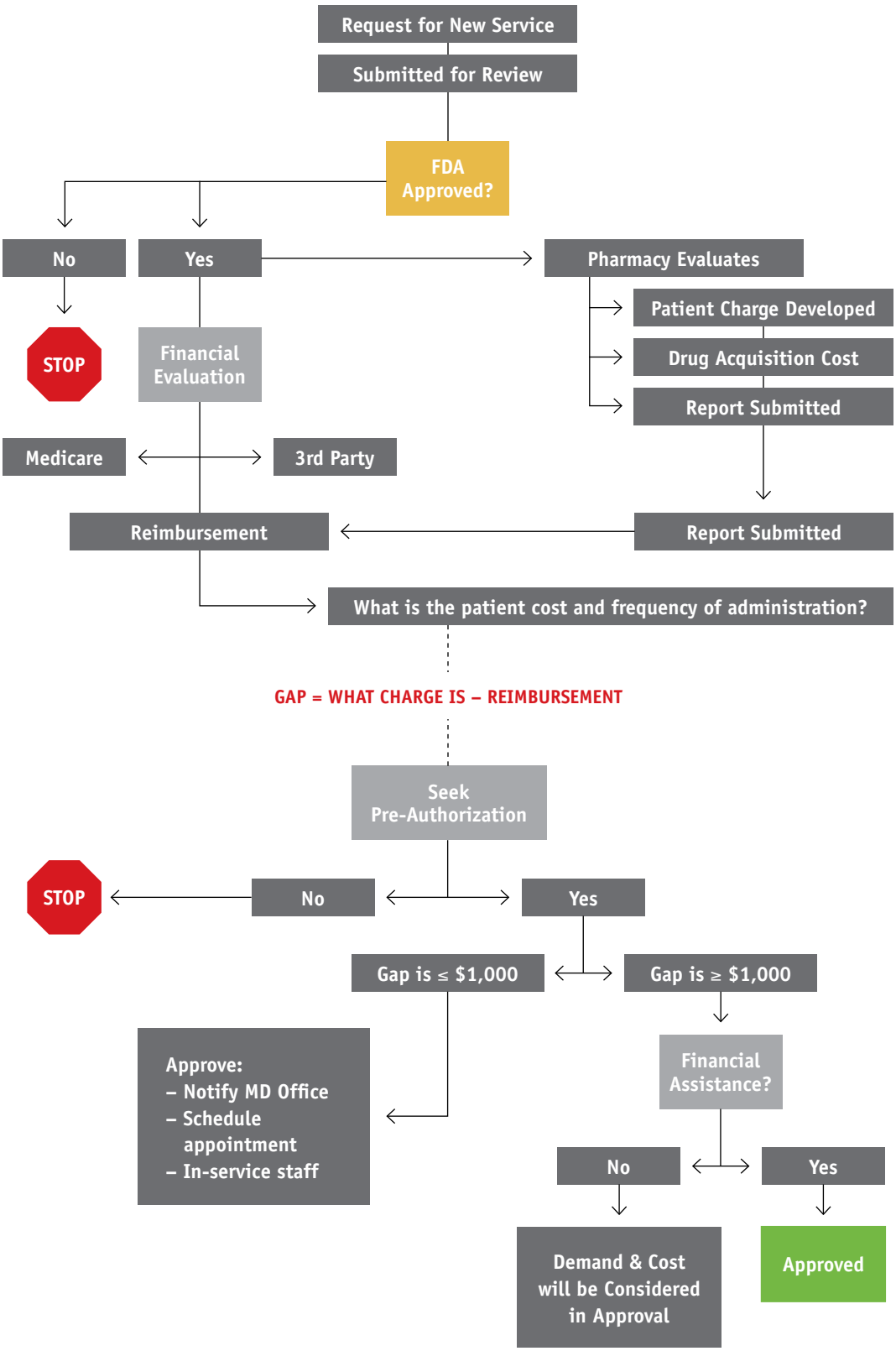
(continued on page 23)

control or even go unnoticed by busy hospital administration. For example, if not actively managed, infusion write-offs can silently grow to significant levels that adversely affect a cancer program's bottom line. Developing strategies to proactively address the issue of write-offs can help community cancer centers safeguard against such financial losses and, in turn, improve the program's financial performance.

The idea of developing a centralized process to improve reimbursement for outpatient infusion services is not new. In 2011 Norris Cancer Hospital, University of Southern California, created an in-house authorization center to monitor and improve reimbursement.[1] Detailed in a 2011 article in the *American Journal of Health System Pharmacy*, this model is just one example of how a facility can identify opportunities to improve reimbursement or, at the very least, minimize loss.

In this article we offer another model to improve the financial performance of a hospital infusion service line, including the processes used, the challenges faced, and relevant case studies. Because financial information is disclosed in this article, the name and location of the hospital has been de-identified. We hope that by sharing our experience we can help shed light on opportunities for other facilities to improve their own financial performance.

Figure 1. Process to Review Non-Formulary Medications



- Develop a proactive process to review non-covered or poorly-reimbursed medications and services.

New Drug or Service Request Form

Now, physicians requesting new or non-formulary infusion services are required to complete an Outpatient Infusion Services: New Drug or Service Request form (see pages 24-25). This form summarizes the treatment and/or medication, including indications, dose, frequency, side-effects, adverse effects, and implications for nursing. Medications that require cardiac monitoring and medications without FDA-approved indications are excluded from infusion services. With this form, the physician provides clinical evidence that the new or non-formulary treatment or medication will be equal to or better than any current treatment on formulary. If no formulary alternative exists, then the clinical evidence will include the studies that brought the treatment or medication to market. As efficiency of service and quick follow-up are important customer service goals, the ITF Committee developed a process that would allow most requests to be resolved within five business days.

Here's how the process works. Once the request form is completed by the infusion department supervisor, the ITF Committee is responsible for circulating the application through pharmacy, registration, and fiscal coding. The ITF Committee has three options for approval of new and non-formulary medications:

- Medication remains non-formulary and non-approved. The fiscal impact is too excessive or the cost of treatment outweighs any potential gains. The patient can pay out-of-pocket or be referred to an assistance program.
- Medication is reviewed on a case-by-case basis.
- Medication is added to the formulary. The benefits of providing the medication or treatment outweigh the cost and therefore support stocking the medication in the hospital pharmacy.

To help with this process, the ITF Committee created the key role of "gatekeeper." This staff person is responsible for monitoring infusion service processes that could potentially lead to write-offs. The gatekeeper identifies these cases, triggers the review process, and communicates with the ordering physician on non-formulary requests. Before the gatekeeper role was implemented to pre-review cases, physicians could order and schedule infusion services without regard for write-off potential.

Analyzing Write-offs

In addition to reviewing non-formulary medications, the ITF Committee initially met monthly to review and analyze infusion service write-offs. Standing agenda items include:

- Retrospective review of write-offs
- Outstanding requests for new drugs
- Changes in reimbursement
- Medication alerts.

Once the process flowed efficiently and results were being realized, the committee began to meet every other month. During each meeting, the ITF Committee reviews the most recent write-off report, which also includes an itemized break down of potential cases at risk of being a write-off (see Table 1, page 26). Specifically, these potential cases are claims for services that were "kicked back" from the hospital's medical necessity filter system, but have not yet been submitted to the payer. The report includes the patient name, medical record number, date of service, medication administered, referring physician, and the comment section for the cause of the "kick back." With advanced notice of potential write-offs, the ITF Committee can proactively address the issue, and identify patterns and opportunities to make improvements.

When the ITF Committee first began meeting, a write-off report was typically 12-pages long, and it was just not practical to address all items at once. Initially, the committee chose to focus on a few high-dollar write-offs each month even though these occurred much less frequently than low-dollar write-offs. When tabulated, these few cases comprised the bulk of the write-offs and often were more easily addressed. Once write-off issues were fixed, the committee monitored them closely to ensure they did not re-emerge. The ITF Committee continued to address these more costly write-offs; over time, write-offs were reduced to less than $100,000 a year.

The ITF Committee used this retrospective review to compare alternate generic drugs and drugs on formulary and review the coding of these drugs. Then, depending on the issue, the most appropriate committee member was tasked with discussing the write-off and alternatives with the prescribing physician. The gatekeeper ensured that, once identified, future cases would either meet the documentation requirement or follow the agreed on corrective action plan. Over time, this process significantly decreased the number of write-offs in reports.

Non-Covered or Poorly Reimbursed Drugs & Services

The ITF Committee developed a "fast track" process to proactively review non-covered or poorly-reimbursed infusion services.

When a physician's office contacts the hospital's outpatient infusion department to schedule a patient for a new service for non-formulary medication, the gatekeeper initiates the fast track process by filling out the Outpatient Infusion Services: New Drug or Service Request form. The gatekeeper is responsible for notifying the requesting physician of the fast track process; the ITF Committee then decides whether to approve or deny the requested service. Typically, the gatekeeper gave feedback to the referring physician; however, in some situations, it was appropriate for the pharmacist and administrator to follow up with the physician. Fortunately there was little to no physician push back; rather, physicians were understanding and supportive of the new process.

Because this review process involves a drug-based service, the ITF Committee is led by the clinical pharmacist dedicated to oncology services, with support from the cancer program administrator. Responsibilities include answering the following questions:

1. ***What is the financial cost of the new proposed service in terms of acquisition?*** This is determined based on the average wholesale price (AWP) of the new medication and the acquisition cost for the hospital to obtain the medication.
2. ***What is the cost of the service to the patient?*** This is the amount the patient must pay out-of-pocket for the medication.

(*continued on page 26*)

Outpatient Infusion Services: New Drug or Service Request

Infusion Task Force Meeting Date Presented: _____

Instructions: Fill out all areas of this form accurately and completely to avoid delays in your requests.

1. **A.** Name of requestor: _____
   B. Who took the request? _____
   C. Who will contact requestor with follow-up? _____
   D. When are we to follow-up with requestor? _____
   (Normal review time is 5 business days; however, if a prompt decision is required, indicate that here.)

2. Brief description of the service (or medication): _____

3. Drug or service provider: _____

4. Is the item on contract? ☐ Yes ☐ No If "No," who supplies the requested medication?

5. What is the indication for the medication or service? _____

6. Is this service or medication indicated for: **A.** Inpatient use? ☐ Yes **B.** Outpatient use? ☐ Yes

7. Estimated annual usage for the medication or service? _____

8. Cost of the medication or service? (May attach additional documentation to reflect actual pharmacy requisition costs, nursing infusion costs, etc.)

9. Any formulary alternatives that can be used and are in use at the cancer program? _____

10. Any other Division facilities that are currently using this medication and or service? _____

11. Recommendation of the clinical nurse coordinator of Infusion Services? ☐ Approve ☐ Deny (Indicate reason)

_____

_____

_____

12. Director's offset plan if above request approved? _____

_____

_____

13. Reimbursement:

	INPATIENT	OUTPATIENT
Anthem PPO		
Anthem HMO		
Medicare		
Medicaid		
Cigna HMO		
Cigna PPO		

CPT Code/ DRG Code: _____

APPROVALS

Pharmacy Services: _____

Administration: _____

Task Force Recommendation

☐ Approved ☐ Denied

☐ Requestor has been contacted regarding the decision of this review. Date Contacted: _____

Please note the following: If "Fast Track" is indicated, request will be examined and acted upon within 5 business days. The Committee meets on the 2nd Monday of every other month beginning with January from 3:00 pm to 5:00 pm. Please attach additional resources or references as necessary to this form if more space is needed to complete your request.

Signature Tracking for "Fast Track" Process

Pharmacy Approval: _____

Nursing Approval: _____

Finance Approval: _____

Administration Approval: _____

(Pharmacy, Nursing, Finance, and Administration must view and approve all "Fast Track" requests.)

Table 1. Sample Write-Off Report*

PATIENT NUMBER	PATIENT NAME	SERVICE CODE	ADMIT DATE	TOTAL CHARGE	PROCEDURE DESCRIPTION FROM CMS ADDENDUM B	ATTENDING PHYSICIAN NAME
123456789A	Alpha, J.	INFJ	06/23/10	$3,124	Thyrotropin injection	Adams
123456789B	Beta, M.	INFJ	07/09/10	$2,576	Iron sucrose injection	Jones
123456789C	Charlie, D.	INFJ	08/12/10	$2,273	Reclast injection	Smith

*Names, dates, and patient medical record numbers are fictitious.

(*continued from page 23*)

3. ***Who supplies the new medication if approved?*** The medication's charge information, AWP, and acquisition cost are all taken into account to make this decision.

The ITF Committee partners with a hospital-employed financial counselor to address these cases prospectively. This role became so valuable to cancer services, the financial counselor was provided dedicated space adjacent to registration and added as a member of the ITF Committee. The financial counselor compares the cost of the drug to the amount the payer will reimburse, and then develops an action plan to help the patient cover any "gaps" between what the hospital charges and what insurance will pay for the medication. This plan may include the use of financial assistance resources or even pharmaceutical cost-relief programs for patients. The financial counselor summarizes the action plan to the ITF Committee by determining:

- The reimbursement amount for the medication based on the patient's insurance.
- The patient's out-of-pocket costs (charge amount – reimbursement amount = patient responsibility).
- If the medication should be added to the formulary using payer mix (private vs. public) to calculate overall reimbursement.

Coming to a Decision

Generally, if the "gap" between cost and reimbursement is less than $1,000, the treatment is accepted and the medication is added to the formulary. If the "gap'" is greater than $1,000, then a payment plan is developed for the patient. If we are not able to develop a payment plan with the patient, the medication may not be approved. The ITF Committee does take other factors into consideration during decision-making, including; frequency of use, patient need, lack of alternatives, or possibly offsetting contributions from other ancillary services. Once a new service or medication is approved:

- The gatekeeper notifies the requesting physician
- Pharmacy acquires the medication
- Registration will post and schedule the patient.

The ITF Committee reviews the final reimbursement numbers once the service is completed. Per policy, any new treatment or medication not approved during this fast track process cannot be re-submitted by the physician for a period of at least six months, unless the patient has gained access to a program that changes his or her financial situation. Usually, the committee can make a decision on new non-formulary treatment requests within five business days. If a decision is needed sooner, the infusion supervisor communicates with the ITF Committee, which will work with the physician to help avoid any significant treatment delay.

Financial Outcomes

The ITF Committee also reviews the listing of Medicare accounts written off due to lack of medical necessity. Data is trended based on: service line, department, physician, and specific service provided. Using this review process, the ITF Committee identified major issues related to screening for medical necessity before administration of the drug epoetin alfa and two needed processes:

1. Physician education regarding standardized order sets, which ensures capture of all the diagnostic information required for the NCD/LCD
2. Pre-screening of the orders prior to providing the service.

Case Study 1. Epoetin alfa (Procrit® and Epogen®) is currently FDA-approved for the management of anemia due to chronic kidney disease and ongoing cancer chemotherapy. Cancer patients who qualify for epoetin alfa fall under a Risk Evaluation and Mitigation Strategy (REMS) protocol, and are required to follow a specific outpatient monitoring protocol. Patients with chronic kidney disease (CKD), defined as CKD stages III-V, qualify for epoetin alfa under medical necessity. These patients are screened for baseline hemoglobin (Hgb) and hematocrit (Hct) values to match standards within the drug prescribing guidelines. All patients must have a baseline Hgb/Hct of less than 10/30 g/dL to start treatment.

Once treatment begins, if the Hgb/Hct rises by greater than 1 g/dL in any two-week period, the prescribing physician must be contacted and advised to hold treatment or decrease the dose by 25 percent. For the renal population, treatment can continue until a patient's Hgb is at therapeutic levels, as defined as 11.5 g/dL. Oncology patients must follow the rules in the REMS guidelines. These patients cannot receive treatment if their Hgb/Hct is above 10/30 g/dL. At that point, treatment must be withheld, and dose adjusted to keep Hgb/Hct values between 9.5 and 10 g/dL.

In this case study, the majority of patients on epoetin alfa were

CKD patients. The NCD/LCD requires two diagnoses specifying the stage of the CKD and the type of anemia. Nephrologists were educated on the diagnosis coverage requirements and an order form was created to ensure capture of the required documentation. As a result, write-offs for these patients were virtually eliminated.

Case Study 2. The ITF Committee identified a write-off trend due to lack of medical necessity for HCPCS J9045: carboplatin injection for patients with uterine cancer. (Six patient accounts with a total of $28,620 in write-offs.)

On review, here's what was happening. A physician provided orders with a non-specific ICD diagnosis code of 179: Malignant Neoplasm of Uterus, Part Unspecified. For medical necessity coverage, the LCD requires the specific anatomical site of the uterus involved: ICD diagnosis code 182* - Malignant Neoplasm of Body of Uterus. After the review, the infusion supervisor discussed the specific LCD requirements with the ordering physician. Now infusion center staff pre-screens carboplatin orders for diagnosis specificity and obtains clarification when needed. This pre-screening process has eliminated these write-offs.

Case Study 3. After the ITF Committee addressed and remedied the infrequent high-dollar write-offs, the committee began to address the low-dollar/high-frequency write-offs, such as laboratory tests. After one such review, the ITF Committee identified opportunities for physician education related to medical necessity for magnesium CPT 83735, which is impacted by therapeutic infusion. The ITF Committee was also able to provide physician education related to NCD coverage for:

- CPT 82378 – CEA (Arcinoembryonic Antigen)
- CPT 86304 – CA125 (Tumor Antigen by Immunoassay CA 125)
- CPT 86300 – CA15-3 (Tumor Antigen, Immunoassay, CA15-3) and CA19-9 (Tumor Antigen by Immunoassay CA19-9).

Medical Necessity Write-Offs, NCDs & LCDs

On a quarterly basis, the hospital received a report with account-specific data for Medicare medical necessity write-offs. The director of Coding, Compliance & Reimbursement began reviewing these reports to identify trends for service lines, as well as opportunities for physician and coding education. From this initial analysis the hospital determined that the departments providing the services needed to be aware of their write-offs. Accordingly these reports became a monthly review and standing agenda item for the reporting departments.

The review revealed two key findings. First, the hospital as a whole needed to tap into subject matter experts to better understand the services experiencing write-offs. Second, physicians needed education on the completeness of their documentation and the interpretation of the NCDs/LCDs.

The ITF Committee became the vehicle to discuss write-offs and identify where education and process changes were needed to ensure complete documentation prior to providing services. A monthly case-by-case review allowed the ITF Committee to proactively identify strategies to decrease write-offs from patients who frequented services and to obtain complete documentation for future visits.

As a standing agenda item, any new or revised NCDs/LCDs are brought to the ITF Committee for review and discussion. The committee then identifies key individuals to provide the necessary staff and physician education. In addition, the ITF Committee researches any new infusion services prior to providing the service to ensure that:

- NCD/LCD requirements are understood and met
- Physician education is provided
- Order sets are standardized or created
- Staff education for pre-screening is provided.

Key Successes

The ITF Committee has benefitted our patients, family members, and staff, including our private practice physicians. The stress of the illness alone is significant, but when compounded with managing the financial side of treatment, patients are often overwhelmed. At a time when satisfaction is highly valued by both patients *and* payers, our outpatient infusion center provided a great service to its patients by reducing the negative incidents when patients are burdened with bills, insurance forms, and even collections.

Often the person to hear from patients about financial and billing challenges associated with treatment is the ordering physician. No hospital wants its physicians to be burdened with complaints about hospital billing. This situation only occurs after the patient has received treatment and may occur several months following treatment. We found that the ITF Committee engaged our physicians and brought them into the solution. Their feedback has been positive and contributes to patient volume growth.

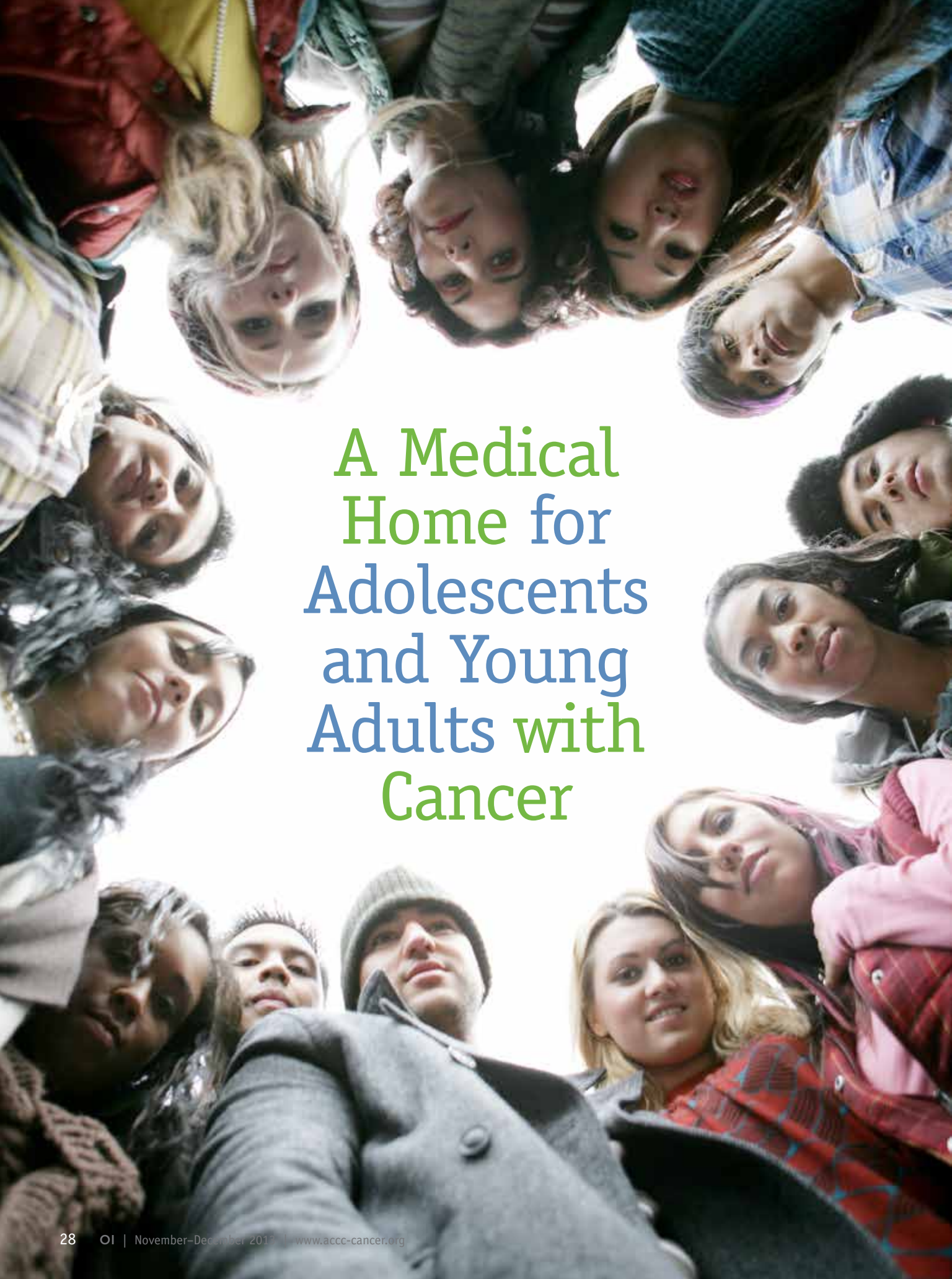
For the hospital, the benefit has been a substantial decrease in financial write-offs. Further, decisions to approve treatment with the understanding that a write-off was likely were being made in a controlled, managed, and proactive manner. Note: the hospital awarded the ITF Committee with an *Innovation Award for Finance*.

Process improvements and strategies discussed in this article are derived from a single facility. Variables, such as facility volumes and payer mix, will undoubtedly affect performance. We recommend that administrators review their own write-off reports to identify opportunities specific to their program. The solutions provided within this article are suggestions; each facility should determine their own process for reducing service write-offs. With healthcare reform, innovative, proactive processes to reduce the cost of care are now a priority and a responsibility. Although this initiative did not eliminate write-offs completely, nor should that be expected, the processes described significantly reduced the quantity of write-offs. As with quality efforts, we are constantly chasing zero. OI

Steven Castle formerly served as an oncology administrator. Jason Sarashinsky is an oncology pharmacist, Rebecca Perkins is a director of coding and compliance, and Ruth Michaud is department operations director at a community-based cancer program.

References

1. Desai SS. Inhouse authorization center to improve reimbursement for outpatient chemotherapy infusions. *Am J Health Syst Pharm*. 2011;68(9):828-834.



A Medical Home for Adolescents and Young Adults with Cancer

BY DOUGLAS S. HAWKINS, MD

Our team consists of more than 30 doctors specializing in cancers that affect newborns to young adults.

According to the National Cancer Institute (NCI), 70,000 Americans ages 15 to 39 are diagnosed with cancer each year. NCI also reports that adolescents and young adults (AYAs) are much more likely to be diagnosed with cancer than children under age 15.[1] Over the past 30 years, cancer survival has not been improving for teens and young adults as fast as it has been for children and older adults. In fact, the rates have hardly improved at all.[2] These findings obviously point to a need to focus on the unique medical needs of the adolescent and young adult patient population and to develop more effective treatment.

Research shows that, for certain kinds of cancer, teens and young adults have dramatic improvements in long-term survival when they are treated on pediatric treatment protocols. For example, teens and young adults with acute lymphoblastic leukemia (one of the most common AYA cancers) have a 25 percent improvement in survival when they are treated on pediatric treatment regimens.

Seattle Children's Cancer and Blood Disorder Center ranks as one of the top pediatric cancer centers in the nation, according to *U.S. News & World Report*. Our team consists of more than 30 doctors specializing in cancers that affect newborns to young adults. These physicians co-lead a multidisciplinary team of pediatric oncologists, hematologists, surgeons, radiation oncologists, social workers, child-life specialists, clinical dietitians, pharmacists, pain management specialists, and professionals from many other disciplines to provide the best care possible. Under the care of this team, our patients experience better outcomes than the national average (see Table 1, page 31). It's important for patients to know that, depending on their diagnosis, the location of their treatment matters and pediatric protocols can dramatically improve their outcome.

Expanding Our Program

Seattle Children's, which serves a multi-state region, including Washington, Alaska, Idaho, and Montana, treats more newly-diagnosed young cancer patients than any other institution in the region. Teens and young adults comprise a significant population of patients receiving cancer treatment at Seattle Children's, where about one-fourth of the patients are currently age 15 and older. When a lack of available beds resulted in patients being turned away, the hospital made the decision to expand to accommodate a growing patient demand.

In April 2013 the hospital opened its newly expanded facility, known as Building Hope. The new facility houses:

- The Cancer Center, with 48 new private rooms for child, adolescent, and young adult cancer patients, providing the comfort and privacy families need
- An Emergency Department
- A Critical Care Unit, with 32 new private rooms.

With this expansion, Seattle Children's became the first hospital in the United States to open an inpatient cancer unit exclusively for adolescents and young adults. The 16-bed unit is located on the top floor of Building Hope. Within one month of Building Hope's April 2013 opening, all of the new 80 beds were filled, including those in the AYA cancer unit.

Building Hope is the first phase of a four-phase approach to expanding Seattle Children's. We began the design process in 2010, with a goal of creating a patient-focused facility. From the beginning, we incorporated patients, families, and staff members in our planning advisory board to help create an environment that would support the physical, emotional, and psychological aspects of healing from the people who knew best.

The primary goal of the advisory board was to discuss ways to improve the hospital for patients and families. A secondary goal was to make our staff more efficient. To create an open and collaborative forum, we adopted a motto of "no idea is a bad idea" for the advisory board meetings.

The advisory board offered diverse perspectives and ideas on how to make Seattle Children's the best place for healing. This brainstorming led to insights into how to improve the physical space in Building Hope, as well as how to improve our services to better accommodate patients and families. For example, one parent thought it would be important for a child to have a visual assessment as soon as he or she entered the emergency department. Another suggested quiet areas where families could talk privately with hospital staff and process the events of the day.

Special consideration was given to the AYA unit's physical

Building Hope expansion

Artwork in AYA Unit

features and environment. For example, providing these patients with some control over their rooms was important given that they have little control of much else when undergoing treatment. Some of the unique features of our AYA inpatient cancer unit are listed in the box on page 33.

Meeting the Unique Needs of AYAs

Our AYA cancer unit is designed to address the particular needs of adolescents and young adults—ages 14 to 21 (and up to age 30 for certain diagnoses)—who often fall between the cracks in the healthcare system. The unit also houses the hospital's AYA oncology program, which focuses on the unique needs and treatment challenges of this age group and has a special emphasis on offering psychosocial support.

Until now, there was no medical home for this age group since cancer programs are typically divided into pediatric and adult care where teens and young adults are a distinct minority. Thus, adolescents and young adults often feel isolated when they are battling cancer because they do not have contact with people their own age that they can relate to. Peer interactions are especially important for teens and young adults because they look to one another to see what milestones they should be reaching. Healthy peers are viewed as moving forward very fast as they head toward adulthood. If cancer treatment causes patients to miss months of school, or key events like graduation and going to college, patients may feel like their whole world has moved on without them.

Creating an AYA unit in Building Hope was a top priority so that we could not only offer an age-appropriate care environment, but also so that patients could benefit from the support of their peers during one of the most challenging times in their lives. Just knowing that they aren't alone and are on a similar path as others their age can be very valuable.

Tailored Treatment & Programming

Seattle Children's has one of the leading AYA cancer programs in the country. Our program offers a multidisciplinary team that includes experts in many specialties that have a specific focus on caring for this population, such as our dedicated AYA psychologist and AYA child-life specialist.

Seattle Children's pediatric oncology and hematology experts are both scientists and physicians, who place as much emphasis on diagnosis and care planning as they do on developing new treatments. Our cutting-edge research makes the newest protocols available to patients from infancy through young adulthood. We also offer patients greater access to groundbreaking clinical trials, such as the cellular immunotherapy Phase I cancer trial currently taking place at Seattle Children's Research Institute.

We have done a lot of work to create innovative programs, as well as teen- and young-adult-focused educational materials and tools designed to help patients meet their treatment goals while also improving their quality of life.

From educational and supportive tools like the "Good Times and Bald Times" video series, to a Healing Arts Program that provides psychosocial support by helping patients share their stories through creative arts, these programs help to improve a patient's treatment experience.

Seattle Children's Healing Arts Program has been particularly beneficial to patients. The arts can be a powerful tool in helping patients and families through challenging circumstances. This program gives patients a voice in telling their stories through photography, film, music, and writing. Some of the patient-created works that have come out of the program include:

- Chris Rumble's music video "Stronger," which went viral last year and caught the attention of singer Kelly Clarkson
- "The Cat Immersion Project" starring Maga Barzallo Sockemtickem
- "The Hidden Shadows of Cancer" featuring Ruby Smith's photography
- "Haunting A Head" starring Jenna Gibson
- "Sara Takes Her Leap into the Bone Marrow Sea" by Sara Mirabdolbaghi.

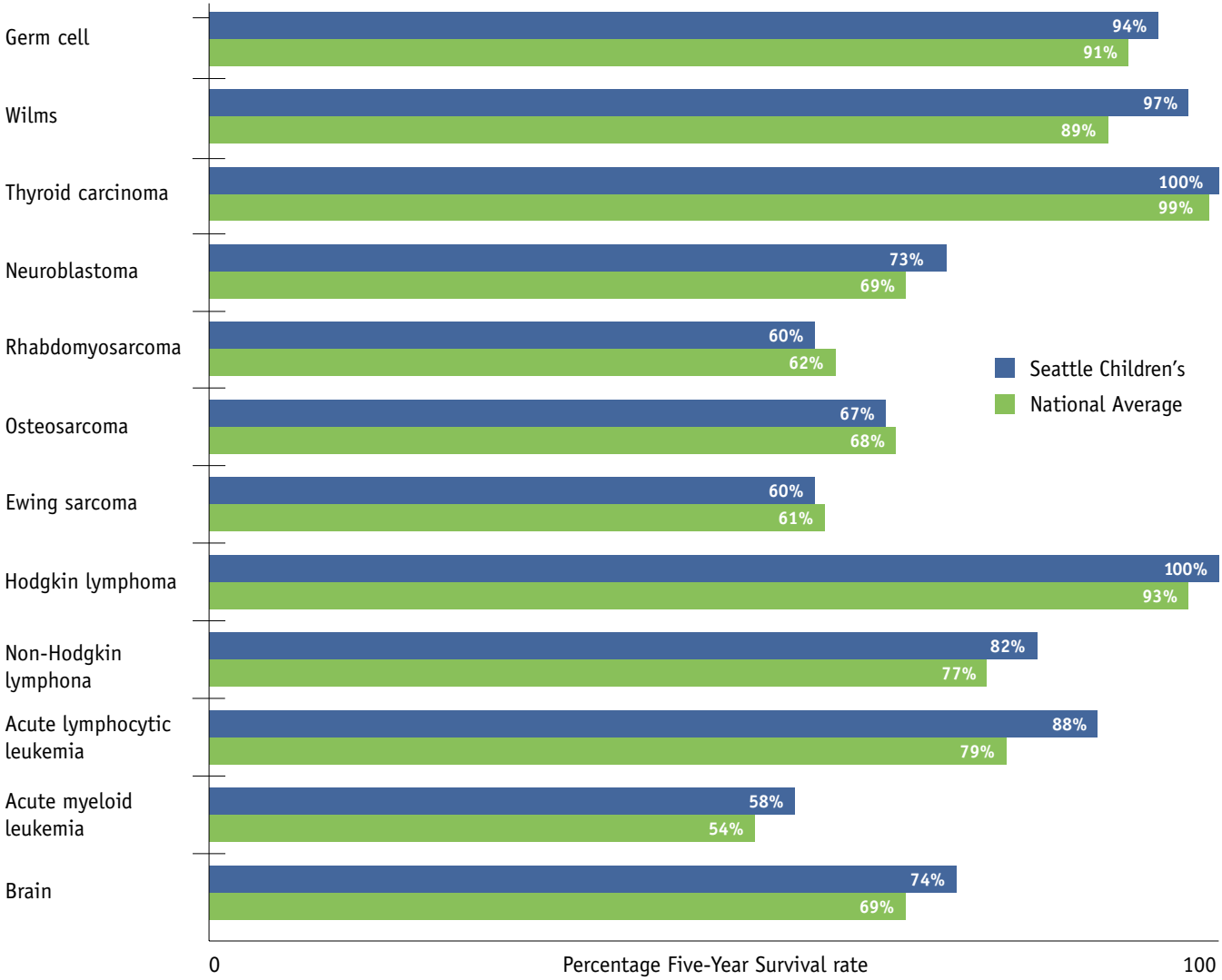
We understand missing school can also be a major issue for children, teens, and young adults while they are undergoing

(continued on page 32)

Soothing hallway in AYA Unit

AYA patient room

Table 1. Percentage of Children with Cancer between 1998 and 2005 Who Have Survived Cancer for at Least Five Years after Diagnosis*



*The blue bar shows the survival rates for Seattle Children's patients; the green bars show the national average survival rates.

AYA quiet room

Patient Lounge

cancer treatment. Because of this, we help patients continue with their education during treatment.

Another major area of focus in our AYA program is educating patients about fertility preservation. When a patient is first diagnosed as a teen, starting a family can be the furthest thing from their mind. But it's a crucial time to educate patients about how they can take steps to preserve their fertility, informing them of their options and connecting them with the necessary fertility preservation services that are available.

Becoming a Survivor

The word "remission" can be a breath of fresh air for patients and their families. However, young cancer survivors need to understand there are long-term risks to their overall health.

According to a 2006 study in *The New England Journal of Medicine*, about two-thirds of childhood survivors suffer from at least one chronic health condition and about one-third will experience another life-threatening condition.[3]

At Seattle Children's we understand that comprehensive, long-term support is crucial for cancer survivors to help prevent a relapse or other life-threatening illness. We've collaborated with the Fred Hutchinson Cancer Research Center in Seattle to create a Cancer Survivor Program that aims to keep survivors healthy throughout their lives by providing care and education about health risks.

This program is open to all survivors of childhood cancer who have completed treatment and have no signs of cancer, no matter where their treatment took place. Most survivors come to our survivorship clinic about two years after finishing therapy.

The program provides three types of services to childhood cancer survivors: education, clinical care, and research. Each survivor receives a notebook that describes the specific treatment they received, the health issues they should be aware of, and recommendations on how to stay healthy and improve their long-term outcomes. A personalized cancer treatment summary and long-term follow-up recommendations are also sent to the survivor's primary care provider.

In addition, this program helps ease the transition from pediatric to adult care and provides the opportunity to network with other cancer survivors and their families. Participants also have the option to take part in ongoing research studies about medical and psychosocial issues for long-term survivors.

Key Takeaways

While Seattle Children's was the first medical center to create a specific unit for AYAs, the concept of creating a medical home for adolescent and young adult patients is gaining interest in other parts of the country. At Seattle Children's, we have helped to pave the way for the creation of other AYA cancer units across the United States. We are excited to see other facilities follow in our footsteps and we hope that with an increased focus on this population, we can begin to move the needle on improving survival outcomes. OI

Douglas S. Hawkins, MD, is the associate hematology/oncology division chief and the associate director of the Center for Clinical and Translational Research at Seattle Children's Hospital. He is also a professor at the University of Washington School of Medicine, the principal investigator for Children's Oncology Group (COG) at Children's and chair of the COG Soft Tissue Sarcoma Committee.

References

1. National Cancer Institute. Adolescents and Young Adults with Cancer. Available online at: www.cancer.gov/cancertopics/aya. Last accessed Nov. 4, 2013.
2. National Cancer Institute. SEER AYA Monograph Available online at: http//seer.cancer.gov/publications/aya/1_intro.pdf. Last accessed Nov. 4, 2013
3. Oeffinger KC, Mertens AC, Sklar CA, Kawashmia T, et al. Chronic health conditions in adult survivors of childhood cancer. NEJM. 2006;355:1572-1582.

Patient and Family Lounge

UNIQUE FEATURES OF BUILDING HOPE'S INPATIENT CANCER UNIT

- ***Private rooms with more space.*** Rooms are approximately 330 square feet, which includes bathrooms with showers and space for two family members to stay overnight. Previously, family members needed to walk to a special area in the hospital to shower. Each of the private rooms is equipped with curtains to provide adolescents and young adults with privacy from their families as well. These patients are also no longer sharing rooms with young children, who may have different sleep patterns or, in the case of infants, may awake crying in the middle of the night.
- ***In-room conference table.*** There is now a private space in every patient room for hospital staff, patients, and families to discuss treatment plans—a design element that empowers patients and families to participate in the medical care.
- ***Medication and supply pass-through cabinets.*** Care teams deliver medication, linens, and other items to and from patient rooms through cabinets with doors on the inside and outside of the room. By using pass-through cabinets, we hope to reduce the risk of transmitting infection. The private rooms also help to eliminate what can be nearly 200 interruptions a day from physicians, nurses, aides, and others, helping our patients to rest with more privacy.
- ***Flat-screen TVs and "Get Well Town."*** Each patient room includes a 42-inch television with "Get Well Town," an interactive, internet-equipped TV entertainment system with access to live and on-demand TV programming, movies, and games. The TV system allows patients to access social media sites, such as Facebook or Instagram, to stay connected to friends and family and reduce feelings of isolation. We've already heard from patients that being able to connect to the web via their TV is one of their favorite features.
- ***Personalized rooms.*** Patients get to choose not only their room's temperature, but also the color of the lighting, which some patients call their "mood lighting." Glass door panels include multi-color LED lights, which can be tailored to fit personal preferences. This small enhancement gives patients some sense of control over their living space. Rooms also have a personal refrigerator so patients and families can keep their own food and beverages onsite, as well as a private safe.
- ***Therapy gym.*** This gym serves the fitness and rehabilitation needs of all cancer patients.
- ***Quiet rooms and family lounges.*** The AYA unit, as well as the other cancer floor and critical care floor in Building Hope, include quiet rooms and patient and family lounges that offer a space for reflection away from a patient's room. The patient and family lounges also serve as a gathering area for patients on the cancer units to come together, hang out, play games, or partake in activities like movie nights.
- ***Future rooftop terrace.*** Once completed, patients will have access to a therapeutic garden situated on the roof of the building, just outside the AYA cancer unit. The terrace will be part of a green roof and includes beautiful vistas of the area and incorporates benches and other spots for resting and healing. Glass panels will block the wind and create an unobstructed view.
- ***Care team work spaces.*** The unit includes work spaces for caregivers in the room, on porches just outside the room, and in centralized team stations within clear sight of rooms. We have also enhanced the age-appropriate environment of the new AYA unit by making changes to some of our procedures and practices to better fit teens and young adults. We extended visiting hours to midnight and our staff does rounds later in the morning.

The NCCCP Cancer Genetic Counseling Assessment Tool

How to assess your program and improve performance

BY MELANIE S. MOSHIER, MS, CGC
JENNIFER N. EICHMEYER, MS, CGC
PATRICIA D. HEGEDUS, RN, OCN, MBA
KIMBERLY C. BANKS, MS, CGC
ZOHRA ALI-KHAN CATTS, MS, LCGC

Today genetics and personalized medicine are core components of multidisciplinary cancer care. Genetic counseling is a key factor along the entire cancer care continuum from prevention to screening to treatment and into survivorship.[1] It provides education to patients and family members on hereditary and familial causes of cancer, and aims to empower individuals to make informed decisions about cancer prevention, screening, and treatment. Genetic counseling evaluations are vital for identifying those at high risk to develop cancer and recommending appropriate strategies for cancer surveillance and risk reduction. Numerous professional organizations, including the National Society of Genetic Counselors (NSGC), have identified core components of a cancer genetic counseling and risk-assessment program.[2] Essential elements often include the following:[3]

- Documentation of an individual's family, reproductive, medical, and surgical histories to aid in risk assessment.
- Collection of a three to four generation pedigree analysis and use of currently available risk-assessment models to determine an individual's risk for developing cancer and chance of having a hereditary cancer syndrome.
- Education regarding cancer genetics, hereditary cancer syndromes, and inheritance patterns.
- Genetic testing as indicated by evidence-based guidelines.
- Discussion of the risks, benefits, and limitations of genetic testing, including issues related to genetic discrimination.
- Informed consent prior to specimen collection.
- A pre-test assessment of the patient's ideas about cancer risk and etiology, as well as a psychosocial assessment.
- Post-test result counseling and re-assessment.

While it is critical for institutions to assess the strengths and weaknesses of their cancer genetic services to identify areas in need of improvement, few resources and/or tools exist to help in these efforts. To help meet this need, the National Cancer Institute Community Cancer Centers Program (NCCCP) developed a self-assessment tool to assist cancer centers in assessing their programs and developing quality improvement plans. (For more on the NCCCP and its role in improving cancer genetic services, see box on page 41).

Developing the CGCAT

NCCCP sites developed the Cancer Genetic Counseling Assessment Tool (CGCAT) to address the goal of providing enhanced genetic and molecular testing at NCCCP community cancer centers. In 2008 the Quality of Care Subcommittee formed a Genetics Working Group; the group consisted of 10 individuals from 8 of the NCCCP sites that either had existing cancer genetic services or were interested in developing an oncology genetic counseling program. Those participants with genetics programs described a variety of different methodologies for providing genetic counseling services, including:

- Onsite genetic counseling
- Referral to outside services
- Contracted genetic counselors
- Telehealth and telemedicine.

Genetic counseling services at these NCCCP sites were provided by a combination of genetic counselors, oncologists, and nurse practitioners.

With so much variety, the NCCCP Genetics Working Group recognized the need for a tool to help programs set internal goals and growth measurements. The first step in the tool development process was an extensive literature review to identify benchmarks, guidelines, and position statements. This literature review did not reveal any models for systematically evaluating a cancer genetics program.

Next, to establish key components to include in the CGCAT, the NCCCP Genetics Working Group reviewed professional position statements and guidelines regarding cancer genetic counseling and testing from several organizations, including the American Society of Clinical Oncology (ASCO), NSGC, the U.S. Preventive Services Task Force (USPSTF), the American Society of Human Genetics (ASHG), and the Oncology Nursing Society (ONS).[4-8] All position statements recommended that:

- Cancer genetic counseling and testing to be performed by a qualified healthcare provider, including certified genetic counselors as well as oncologists and advanced practice oncology nurses with specialized education in hereditary cancer genetics.

With so much variety, the NCCCP Genetics Working Group recognized the need for a tool to help programs set internal goals and growth measurements.

- Patients at risk to have a cancer-predisposing mutation are to be appropriately identified.
- Genetic testing is performed only subsequent to pre-test counseling and in conjunction with post-test counseling.

By consensus, the NCCCP Genetics Working Group selected seven clinical and programmatic components as "essential" to a successful cancer genetics program:

1. Patient Identification
2. Physician Referrals
3. Services Provided
4. Pre-Test Counseling
5. Post-Test Counseling
6. Documentation of the Cancer Genetics Consult in the Patient's Medical Record
7. Financial (billing).

As a numerical measurement, the NCCCP Genetics Working Group modeled the CGCAT after the NCCCP Multidisciplinary Care Assessment Tool. The CGCAT uses a five-level measurement system ranging from Level 1 (having few to none of the elements for a given component) to Level 5 (having all the elements for a given component).

After multiple revisions, the NCCCP Genetics Working Group finalized the CGCAT in 2009; it was subsequently approved by the NCCCP Quality of Care and Executive Subcommittees. In 2010 the NCCCP employed the CGCAT to establish a retrospective baseline at the NCCCP sites, and then to prospectively assess current program status, set goals, and identify desired program enhancements.

In 2011 the NCCCP formed a second working group to revise the CGCAT to capture incremental growth and observe effective strategies for program enhancement, which was not available in the previous tool. The updated 2011 CGCAT included the same seven component areas of performance as the 2009 version. Updates were made to the component areas of "physician referrals" and "services provided" (see specific core element below), while the other five component areas were not amended. The 2011 CGCAT can be found on pages 38-39.

The NCCCP CGCAT is intended to be used to assess individual genetics programs within the context of the unique qualities and challenges that any given institution may face. The tool can be used to look at the program as a whole or to look at specific areas (e.g., only colon cancer referrals). Additionally, cancer programs should select the core elements to include in the assessment based on their unique needs and quality improvement efforts. The goal is for cancer programs to identify areas of opportunity and to use the self-assessment tool to provide measurable outcomes based on their own strategic plan.

Component 1: Patient Identification

This component quantitatively assesses the percentage of patients for a given disease site who are referred for a genetic counseling consultation. Approximately 20 percent of cancers develop from hereditary or familial causes.[4,9] Based on this statistic, the Genetics Working Group set a 20 percent increment for appropriate referrals per disease site (primarily breast and colon) as the highest target goal. Thus, if a community cancer center were to refer 10 percent of its breast cancer patients appropriate for genetic counseling, this site would have reached 50 percent of the target goal (Level 3). A site that referred 20 percent of its appropriate breast cancer patients would have reached 100 percent of the target goal (Level 5).

The patient identification component may be used for any type of cancer for which a significant proportion of the cancer results from hereditary or familial causes. Flexibility is built into the component such that programs can choose to assess a patient population of interest or in greatest need of improvement. Additionally, there is no set time frame for analyzing the "patient identification" component. For example, if a program identifies a paucity of referrals for breast cancer and decides to implement an improvement plan over a one-year time frame, it can track the number of referrals for breast cancer using the patient identification component on a monthly basis for that year.

In addition, this component may also be used to track referrals for unaffected individuals. For example, if a program identifies a dearth of referrals for a family history of breast cancer and decides to improve on this over a one-year time frame, the program may assess the percentage of individuals seen for screening mammography that are referred for genetic counseling services using the patient identification component on a monthly basis over the course of that year. Such analysis will aid a program in determining if intervention strategies for improving patient identification and referrals are effective.

Component 2: Physician Referrals

This component quantitatively assesses what percentage of genetic counseling referrals come from a given type of healthcare provider. The percentage is analyzed by summing the number of referrals received from one type of physician specialty, such as medical oncology, and dividing this number by the total number of referrals received for genetic counseling. The physician referrals component uses a tiered system:

- Tier one: physicians who refer the most often for cancer genetic counseling services
- Tier two: physicians who refer often or occasionally
- Tier three: physicians who rarely refer.

For example, if 100 referrals are received for genetic counseling

and 75 of the referrals are made by oncologists, 20 referrals from primary care physicians, and 5 referrals from other healthcare specialties, this would correspond to Level 3 on the CGCAT.

The NCCCP Genetics Working Group determined the percentage for each tier by using the collective performance of the NCCCP sites as a reasonable standard. This tiered system allows programs to identify the most common referral source provider type and the provider that refers less frequently. This data allows programs to focus the target of their marketing efforts.

Over time, the Genetics Working Group amended the physician referrals component of the CGCAT. The 2009 CGCAT version defined the provider types for physician referrals as front line "cancer" clinicians (i.e., medical oncologists, radiation oncologists, and surgical oncologists), primary care clinicians, and specialists. Use of the CGCAT before 2011 revealed a greater diversity of front line referring providers at NCCCP cancer genetic counseling sites than previously thought. For example, one NCCCP site reported that dermatologists were a primary type of referring physician. To make the CGCAT more robust, the definition for "physician referrals" was revised in 2011 to remove specific provider types. Additionally, the 2011 revision added two more rating levels, the 2009 CGCAT had allotted only three levels by which sites could score their performance. The inclusion of five levels allows programs to more closely monitor their progress.

Component 3: Services Provided

This component assesses the diversity of the indications for which patients are referred for a genetic counseling consultation. Reasons for referral for genetic counseling are varied, but often include:[10]

- Cancer diagnosed at an unusually young age (e.g., breast or colon cancer before age 50).
- Multiple close family members with either the same type of cancer or related cancers (e.g., breast and ovarian cancer; colon and uterine cancer).
- Two or more primary cancer diagnoses in the same individual (e.g., breast cancer in both breasts, ovarian and breast cancer, colon and uterine cancer).
- Certain rare cancers or tumors (e.g., medullary thyroid cancer, male breast cancer, adrenocortical carcinoma, pheochromocytoma).
- Other features associated with a hereditary cancer syndrome (e.g., multiple colon polyps).

This component is analyzed by summing the number of referrals received for a particular indication, such as breast cancer, and dividing this number by the total number of referrals received for genetic counseling. For example, if 100 referrals are received for genetic counseling and 60 of the referrals are for a personal and/or family history of breast cancer, 30 referrals are for colon cancer, and 10 referrals are for other types of cancer this would correspond to a Level 5 on the CGCAT.

The services provided component allows programs to identify which type of cancer is the primary indication for referral. As with physician referrals, the percentage for each tier was based on what the Genetics Working Group believed was a reasonable standard, using the collective performance of the NCCCP sites with existing genetic counseling services as a guide. This component allows programs to identify if there are certain disease sites for which referrals are rarely made so that strategies may be implemented to improve these referrals.

Component 4: Pre-Test Counseling

This component assesses information from a patient's personal and family history, as well as the information that is provided to a patient. The following four elements are a critical part of quality genetic counseling:[2,3,5]

1. Ascertainment and documentation of a three to four generation family pedigree.
2. Evaluation of the personal and family history for the purpose of determining what, if any, genetic testing is appropriate.
3. Calculation of risk assessment via computer-based risk assessment models (as appropriate).
4. For patients pursuing genetic testing, discussion of all elements of ASCO-informed consent.[5]

Component 5: Post-Test Counseling

This component assesses the information provided to a patient after the initial risk assessment and evaluation of the genetic counseling session. The following six elements are essential to quality genetic counseling:[2,3,5]

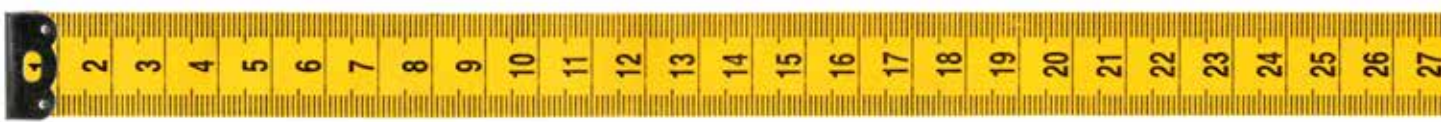
1. Cancer risk estimation based on genetic test result (if applicable) or empiric data.
2. Recommendations for cancer screening and prevention.
3. Discussion of risk-reduction surgeries, if appropriate.
4. Provision of educational resources and referrals, as needed.
5. Disclosure and interpretation of genetic test results within the context of personal and family history (if applicable).
6. Discussion of additional genetic testing options (if applicable).

Component 6: Documentation of the Cancer Genetics Consult in the Patient's Medical Record

The Genetics Working Group identified the following elements as essential components for documentation within a patient's medical record:[5]

- Personal history
- Family history

(continued on page 39)



Cancer Genetic Counseling Assessment Tool

COMPONENTS	ELEMENTS/DEFINITION	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
Patient Identification	Potential patient numbers based on 20% of applicable yearly analytic cases having hereditary and/or familial predisposition for: • Breast, breast/ovarian • Colon, colon/uterine • Other ▲ Genodermatoses ▲ Thyroid ▲ Renal/neuroendocrine ▲ Pediatric	0–20% of appropriate patients identified	21–40% of appropriate patients identified	41–60% of appropriate patients identified	61–80% of appropriate patients identified	81–100% of appropriate patients identified
Physician Referrals	Subtypes of clinicians: • Tier one top referring physician subtype (e.g., medical oncology)—always to often refers • Tier two—refers occasionally to often • Tier three—rare to few referrals	Majority (>90%) of referrals from tier one	85% tier one 15% tier two	75% tier one 20% tier two 5% tier three	70% tier one 25% tier two 5% tier three	60% tier one 30% tier two 10% tier three
Services Provided	Cancer Genetics Service Lines: • Breast, breast/ovarian • Colon, colon/uterine • Other ▲ Genodermatoses ▲ Thyroid ▲ Renal/neuroendocrine ▲ Pediatric	Majority (>90%) of cancer genetics consultations occur for one service line	85% for one service line with at least 15% occurring for a second service line	75% for one service line with at least 20% occurring for a second service line and 5% from a third service line	70% for one service line with at least 25% occurring for a second service line and 5% from a third service line	60% for one service line with at least 30% occurring for a second service line and 10% from third service line
Pre-Test Counseling	• 3-4 generation pedigree • Evaluation of the personal and family history to determine what, if any, genetic testing is appropriate • Run risk-assessment models as appropriate • Provide all elements for ASCO informed consent	0–1 components of pre-test counseling provided	2 components of pre-test counseling provided and/or components provided episodically	3 components of pre-test counseling provided routinely	All components of pre-test counseling routinely provided	Level 4 plus utilization of computer applications for pedigree drawing risk calculation
Post-Test Counseling	• Genetic test results disclosure and interpretation in the context of the personal and family history • Cancer risk estimates based on genetic test results or empiric data • Recommendations for cancer screening and prevention • Discuss risk-reduction surgeries, if appropriate • Educational resources and referrals given as needed • Discuss additional genetic testing options	0–1 components of post-test counseling provided	2–3 components of post-test counseling provided and/or components provided episodically	4–5 components of post-test counseling provided routinely	All components of pre-test counseling routinely provided with utilization of computer applications for risk calculation when available	Level 4 plus at least one of the following: • Patient is referred to long term follow-up program • Research options are reviewed • Resources are provided to assist without dissemination of information to family members

Cancer Genetic Counseling Assessment Tool (cont.)

COMPONENTS	ELEMENTS/DEFINITION	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
Documentation of the Cancer Genetics Consult in the Patient's Medical Record	• Personal history • Family history • Initial impression • Genetic testing recommendations • Test result • Result interpretation • Cancer risk estimates • Summary management recommendations	Limited to no documentation in the patient's medical record	N/A	Applicable elements documented in the patient's medical record	N/A	Level 3 plus copies distributed to the patient and his/her physicians
Financial		No billing occurs for pre- or post-test counseling sessions	N/A	Billing for pre- and post-test counseling session is episodic (e.g., only when MD is present)	N/A	Global billing for pre- and post-test counseling session

- Initial impression
- Genetic testing recommendations
- Test result(s)
- Result interpretation
- Cancer-risk estimates
- Summary of the medical management recommendations.

Both for the initial, as well as the revised version of the CGCAT, the NCCCP Genetics Working Group defined only three levels of assessment.

Note: this component does not specify whether documentation occurs in a hand-written chart or an electronic medical record. A genetic counseling program's ability to document services in an electronic medical record depends, in large part, on the ability of clerical support staff and technical support, as well as rules and regulations stipulated by state laws to protect against genetic discrimination. The Genetics Working Group felt that it was critical not to impose requirements such as documentation within a medical record so that a program's ability to score at a high level was not impacted by factors that are often not within the scope of control of a genetic counselor.

Programs should also be aware of any privacy laws on protection of genetic information and the ability to protect information in electronic medical records as some systems may not be HIPPA compliant.

Component 7: Financial

Billing for genetic counseling services is essential to a program's financial solvency. Historically, genetic counseling services have been poorly reimbursed; although there are various ways to bill for services, most have become outdated with the changes in healthcare billing policy. Reimbursement challenges may restrict the potential growth of an oncology genetic counseling program. The Genetics Working Group included the financial component in the CGCAT in order to encourage NCCCP sites to work toward billing for services to promote the sustainability of genetic counseling programs. The financial component qualitatively measures the frequency with which billing occurs for genetic counseling services on three levels (Level 1, Level 3, and Level 5).

Genetic counselors can bill using Current Procedural Terminology® (CPT) Evaluation and Management (E&M) codes 99201-99205 or 99241-99245 linked to a physician within the hospital or use CPT code 96040 for "Medical Genetics and Genetic Counseling Services." However, a 2010 survey of genetic counselors revealed that only one-third of cancer genetic counselors reported billing under the 96040 code.[11] Of the 24 respondents who participated in the survey for CPT code 96040, five (8 percent) said their facility received 10 to 30 percent of the amount they billed, ten (16 percent) received 31 to 50 percent, six (9 percent) received 51 to 70 percent, and three (5 percent) received 71 percent or more.[11] Clearly billing and reimbursement continue to be areas in need of improvement for genetic services and should be included for future assessments.

CGCAT Case Study

One NCCCP site identified a disparity in cancer genetic counseling and risk assessment in the minority population for an area that encompasses a large proportion of Hispanics and African Americans. The NCCCP site used the CGCAT to assess the healthcare system, and the initial score was Level 1 across the majority of components. It became clear that the genetics services were being underutilized. Education was needed, as well as tools to identify and refer patients.

These findings led the NCCCP site to create a pocket guide, key indicators for referral, and fax referral forms that were provided to the physician offices.

After disseminating the education materials, the NCCCP site saw an increase in the number of referrals. However, there was a high rate of patient no-shows to the appointments.

Additional research into the high rate of no-shows revealed transportation challenges, lack of health insurance, and language as the major barriers to attendance for genetic counseling. The NCCCP site partnered with the state's federally-qualified healthcare centers (FQHC) to bring genetic counseling services to the patients and the targeted community.

In addition, the NCCCP site developed a cancer questionnaire in English and Spanish and made it available to patients to help identify if they might be at increased risk for a hereditary cancer syndrome. Genetic counselors reviewed the questionnaire and contacted patients who met the referral criteria.

The NCCCP site used the CGCAT to re-assess progress monthly. Over the two-year project, the site's CGCAT scores went from Level 1 to Level 4. Referrals increased from a total of 12 annually to 9 referrals per month in the second year. This exceeded the site's goal of 8 new referrals a month for year two. The NCCCP site saw the biggest increase in the number of referrals in the second half of year two, which had an average of 14 new referrals per month. This data is primarily attributed to addressing transportation barriers and bringing the service to the FQHCs, which are in walking distance of the residents.

The cancer questionnaire allowed the NCCCP site to identify families with a variety of cancer diagnoses. Developing education for healthcare providers, fax referral forms, and the pocket guide also helped to identify patients and increase physician referrals.

Discussion & Future Implications

Community cancer centers can use the CGCAT to focus on specific core elements and develop targeted quality improvement strategies. They may also want to establish their own time frames for when to re-assess their programs with the CGCAT to help with needs assessment, goal setting, and improvement planning.

Community cancer centers should not expect to score a Level 5 in all core elements; the objective is to use the CGCAT to determine performance improvement targets and strategies to reach the level that is most realistic for each individual organization.

For NCCCP sites, use of the tool enabled progress and promoted creative strategies for quality improvement in cancer genetics programs. Some NCCCP sites are working with survivorship teams and nurse navigators to attend community events. Other sites are instituting telegenetics, chart reviews, or a tracking system.

Additionally, by using the CGCAT, the NCCCP sites were well positioned for compliance with the 2012 American College of Surgeons Commission on Cancer (CoC) Risk Assessment and Genetic Counseling Standard, which was only a draft at the time of the tool's design.[12] The CGCAT specifically addresses key competencies for a genetic counseling program as outlined by CoC, such as the need for identification of patients with indications for hereditary cancer conditions. By using the CGCAT for analysis of cancer genetic counseling services, NCCCP sites are not only able to monitor the performance of their genetic counseling services but are able to determine whether those services are in compliance with CoC standards.

Genetic counseling services for oncology play an integral role in identifying patients at high risk for developing cancer and additional primary cancer. Such identification may lead to appropriate cancer surveillance and early intervention, thereby helping individuals to prevent and/or detect cancer at earlier stages when treatment will be most effective. A comprehensive metric tool is essential to providing the necessary genetic counseling services for a site's at-risk oncology patient population. NCCCP sites designed the CGCAT to address the gap in quantifiable metrics for evaluating a cancer genetics

ACKNOWLEDGMENTS

This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, under Contract No. HHSN261200800001E. The content of this publication does not necessarily reflect the views of policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government. We are grateful to the following NCCCP sites for their contributions to this effort: the Ascension Health sites (Brackenridge Hospital, Columbia St. Mary's, and St. Vincent), Billings Clinic, the Catholic Health Initiatives sites (Good Samaritan, Penrose-St. Francis Health Services, St. Elizabeth Regional Medical Center, St. Francis Medical Center, and St. Joseph Medical Center), Helen F. Graham Cancer Center at Christiana Care, Einstein Healthcare Network, Geisinger Medical Center, Gundersen Health System, Hartford Hospital, Lehigh Valley Health Network, Maine Medical Center, Mercy Medical Center-Des Moines, Northside Hospital, Norton Cancer Institute, Our Lady of the Lake Regional Medical Center, Providence Portland Medical Center, Saint Mary's Health Care, Sanford USD Medical Center, Spartanburg Regional Healthcare System, St. Joseph Health, St. Joseph Mercy Hospital, St. Joseph's/Candler, St. Luke's Regional Medical Center, The Queen's Medical Center, and Waukesha Memorial Hospital.

program. While the CGCAT has yet to be validated, NCCCP sites have used it extensively for self-assessment and program planning. The CGCAT is the first of its kind and provides community cancer centers with a tool for assessing specific cancer genetics programs.

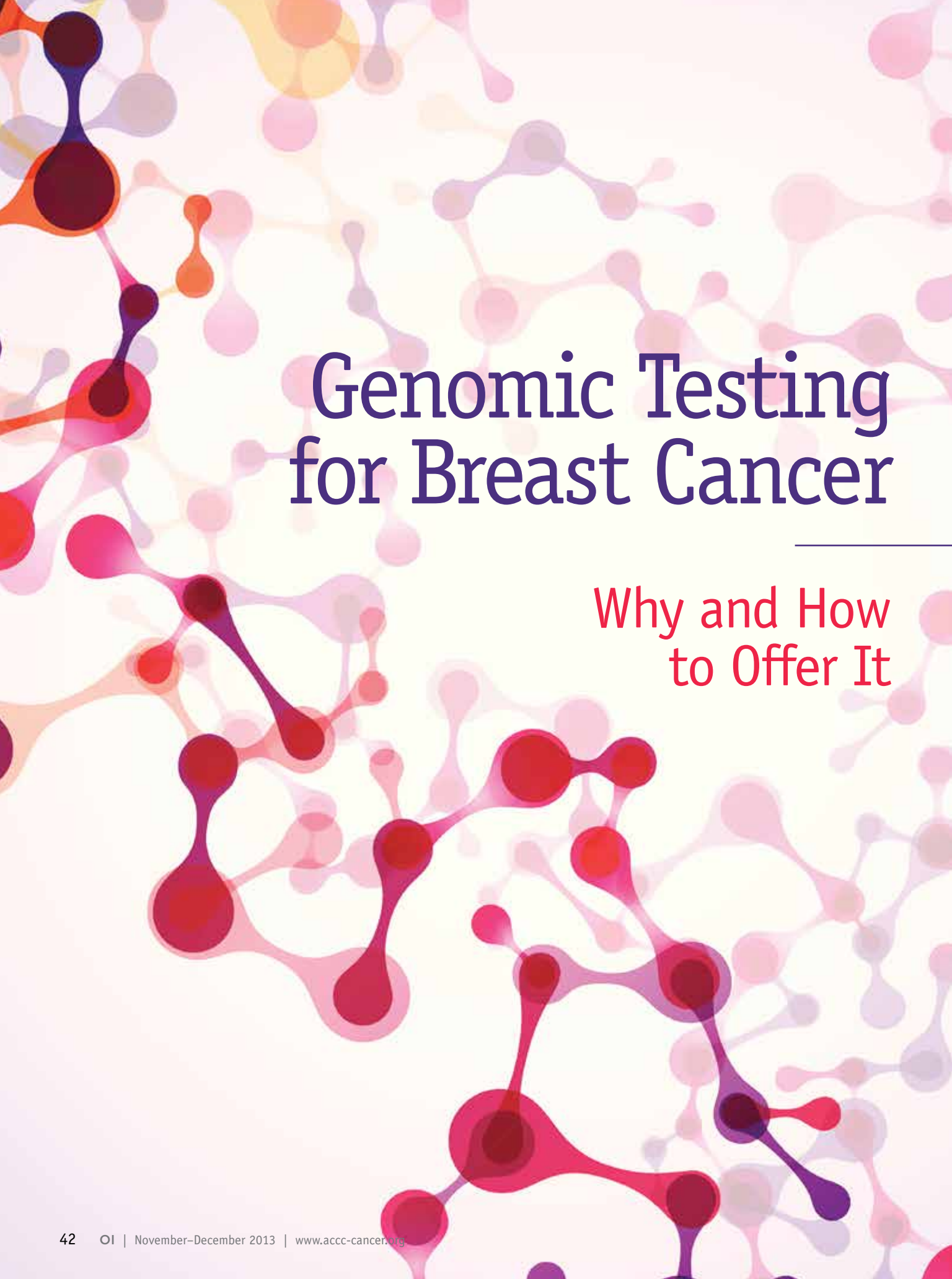
Melanie Moshier MS, CGC, is an oncology genetic counselor at Gibbs Cancer Center & Research Institute, Spartanburg, S.C. Jennifer N. Eichmeyer, MS, CGC, is a certified genetic counselor at St. Luke's Mountain States Tumor Institute in Boise, Idaho. Patricia D. Hegedus, RN, OCN, MBA, is the oncology clinical performance director at Gibbs Cancer Center & Research Institute, Spartanburg, S.C. Kimberly C. Banks, MS, CGC, was the genetics program manager at St. Joseph Hospital of Orange, Calif. Zohra Ali-Khan Catts, MS, LCGC, is director, Cancer Genetic Counseling at Helen F. Graham Cancer Center, Christiana Care Health System, Newark, Del.

References

1. Robson ME, Storm CD, Weitzel J, Wollins DS, et al. American Society of Clinical Oncology Policy Statement Update: Genetic and Genomic Testing for Cancer Susceptibility. *J Clin Oncol.* 2010;28(5):893-901.
2. Riley BD, Culver JO, et al. Essential elements of genetic cancer risk assessment, counseling, and testing: updated recommendations of the National Society of Genetic Counselors. *J Genetic Counsel.* 2012;21(2):151-161.
3. Trepanier A, Ahrens M, McKinnon W, Peters J, et al. Genetic cancer risk assessment and counseling: recommendations of the National Society of Genetic Counselors. *J Genetic Counsel.* 2004;13(2):83-114.
4. Carroll JC, Allanson J, Blaine SM, et al. Hereditary breast and ovarian cancers. *Can Fam Physician. 2008*;54(12):1691-1692.
5. ASCO. American Society of Clinical Oncology policy statement update: genetic testing for cancer susceptibility. *J Clin Oncol.* 2003;21(12);2397-2406.
6. ASHG. Statement of the American Society of Human Genetics on Genetic Testing for Breast and Ovarian Cancer Predisposition; 1994. Available online at www.ashg.org/pdf/policy/ASHG_PS_November1994.pdf. Last accessed Sept. 16, 2013.
7. USPSTF. Genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility. *Ann Intern Med.* 2005;143(5):355-361.
8. ONS. Cancer Predisposition Genetic Testing and Risk Assessment Counseling; 2006. Available online at www.ons.org/Publications/Positions/Predisposition. Last accessed Sept. 16, 2013.
9. Half EE, Bresalier RS. Clinical management of hereditary colorectal cancer syndromes. *Curr Opin Gastroenterol.* 2004;20(1):32-42.
10. National Cancer Institute: PDQ® Cancer Genetics Risk Assessment and Counseling. Bethesda, MD: National Cancer Institute. Available online at http://cancer.gov/cancertopics/pdq/genetics/risk-assessment-and-counseling/HealthProfessional. Last accessed Sept. 16, 2013.
11. Harrison TA, Doyle DL, McGowan C, et al. Billing for medical genetics and genetic counseling services: a national survey. *J Genetic Counsel.* 2010;1(1):38-43.
12. American College of Surgeons Commission on Cancer. Cancer Program Standards 2012: Ensuring Patient-Centered Care Standard 2.3 Risk Assessment and Genetic Counseling. 2012; 68-69. Available online at www.facs.org/cancer/coc/programstandards2012.pdf. Last accessed Sept. 16, 2013.

ABOUT NCCCP

The National Cancer Institute Community Cancer Centers Program is a network of community hospital-based centers collaborating to improve quality, enhance access to cancer care, and expand cancer research. Launched in 2007 as a pilot program with 16 community hospitals and expanded in 2010 with the addition of 14 more hospitals, the program currently has 21 participating community hospitals. One of the NCCCP's goals is to bring services typically only provided by large academic centers to the community setting. Genetic counseling is one such service and over the past six years the NCCCP community cancer centers have worked toward establishing or enhancing infrastructures for genetic and molecular testing services either onsite or through referrals. Program deliverables which focus on enhancing or improving genetic counseling services have been in place since the inception of the program and remain in place today.



Genomic Testing for Breast Cancer

Why and How to Offer It

BY JAMES V. PELLICANE, MD, FACS

New technologies spread in medicine roughly the same way they do in other parts of society. There are early adopters, followed by the early majority, the late majority, and then everyone else. Genomic testing for breast cancer treatment is following this predictable pattern. The approach is now established enough that both a first-generation test and a significantly more evolved second-generation test are available. Neither test is experimental; their results are well accepted in the field.[1,2] Today these tests are transforming the approach to breast cancer treatment taken by oncologists, surgeons, and multidisciplinary breast care teams.

With genomic testing, one-size-fits-all medicine is giving way to personalized medicine—diagnoses and treatments that are tailored to the individual characteristics of each patient's cancer. Cancer centers that provide genomic testing can offer many patients the choice of forgoing chemotherapy without increasing the risk of recurrence. That in itself can be an advantage for a cancer center in a competitive environment. More importantly, it is the appropriate way to provide patient care. Recent statements from a task force of the National Cancer Institute (NCI) and an international panel of breast oncology experts have underlined the growing value of genomic testing to determine both recurrence risk and molecular subtype to guide personalized treatment.

These tests are simple to adopt. They require no capital outlay and no major disruption to a cancer center's ordinary administrative processes, and yet, genomic testing for eligible patients has not reached even the "early majority" phase of adoption. This article explores the reasons for its slow diffusion in the field; details the multiple advantages of the tests for patients, providers, and the healthcare system at large; and describes the simple practical steps to provide the tests.

How Genomic Testing Changes Diagnosis & Treatment

The advantages of genomic testing for breast cancer are profound—clinically, economically and, for patients, experientially. Those advantages are available right now in certain applications, and expanded applications may be just around the corner.

The most noteworthy clinical advantage today is the ability to predict with a high degree of reliability how aggressive a tumor is—that is, how likely the cancer is to recur or metastasize. If there is a low risk of recurrence and no overwhelming factors where more aggressive therapy would be supported by the literature, the medical oncologist may offer the patient the option of not undergoing adjuvant chemotherapy and the potential side effects. Women generally find the prospect of those side effects disturbing and often for good reason.

Relatively common complications of adjuvant chemotherapy for breast cancer include nausea and hair loss, as well as compromising of memory, concentration, and motor function (in one-quarter to one-third of women).[3,4] The latter may persist long term.[3] Other potential complications include mouth sores, diarrhea, weight loss or weight gain, depression, and low blood cell counts leading to fatigue, vulnerability to infections, and easy bruising or bleeding.[3,4]

Long-term complications of adjuvant chemotherapy can include anemia, thrombocytopenia (abnormal blood clotting), liver and kidney damage, neuropathy, allergic reactions, heart muscle damage and heart failure, other heart and nervous system problems, severe joint and muscle pain, menstrual abnormalities, sexual dysfunction, and infertility.[3,4] Serious secondary cancers, such as leukemia, are a rare long-term complication.[3,4]

These complications are not a secret. Women have heard of them and dread them. With genomic testing, many patients can now choose to safely avoid all of these complications without an impact on their chances of survival.[5]

The financial impact of avoiding chemotherapy is considerable. While it is not possible to state an average cost of adjuvant chemotherapy due to the number of factors involved, costs range from tens to hundreds of thousands of dollars. The savings to the healthcare system, if genomic testing were more widely adopted, could be substantial.

The value of genomic tests is underlined in new clinical practice guidelines, published in the August 2013 edition of *Annals of Oncology* and provided by the St. Gallen panel of international breast cancer experts along with European and Japanese Oncology societies.[6] The St. Gallen guidelines emphasize the need to use genomic assays that can provide molecular subtyping to determine which patients need to undergo chemotherapy.[6]

In the U.S., an NCI taskforce has recently pointed toward the value of molecular diagnostics to reduce overtreatment such as unnecessary chemotherapy for breast cancer.[7] The taskforce noted that many patients are overdiagnosed and overtreated today. Overtreatment can have serious side effects that could be avoided,

for certain patients identified by molecular testing. "Molecular diagnostic tools that identify indolent or low-risk lesions need to be adopted and validated," the authors said, adding that "understanding the biology of individual cancers is necessary to optimize early detection programs and tailor treatments accordingly."[7]

Why is Genomic Testing Not More Widely Used?

According to Google, breast cancer patients are the number-one seeker of healthcare information on the Internet, as evidenced by almost 2 million monthly hits searching the key words "breast cancer." Breast cancer patients often arrive at the doctor's office already informed about genomic tests. In fact, both companies making genomic breast cancer tests offer patient education websites for this purpose. Should physicians be uninformed about these tests, they risk losing informed patients to cancer centers that offer these tests routinely.

While genomic testing is established enough to be covered in general practice guidelines, a significant number of clinicians have not even heard of the concept. Even among physicians who are aware of genomic testing, many have serious misunderstandings about molecular diagnostics, as revealed in "Molecular Testing the Community Setting," an education program conducted by the Association of Community Cancer Centers (ACCC).[8]

For this project ACCC conducted two informal online surveys, one of multidisciplinary team members and one of pathologists. Survey findings, along with focus group discussion and follow-up interviews, identified several barriers that stood in the way of molecular testing adoption. One of those barriers was, in the words of the ACCC survey report, "need for significant upfront capital investment and competing capital priorities."[8]

While this barrier may affect other forms of molecular testing, there is no upfront capital investment to stratify breast cancer patients with genomic testing. The tests are simply ordered online from either of the two companies that offer testing. The companies then bill the patient's insurer(s) for the cost and design an individual payment plan for the patient for any uncovered fees.

The education project also identified another financial barrier to adopting the tests: "Unwillingness on the part of administration to take risks and invest time…and staff upfront."[8] But as I will describe in more detail in the following section, it is becoming increasingly risky *not* to offer genomic testing. The staff commitments for a cancer center are also minimal.

Genomic testing is used to determine the nature of a diagnosed breast cancer patient's breast tumor. Genomic testing provides information on how that specific tumor is behaving and what is driving the growth of the tumor. With this information, a more specific treatment plan can be developed for each patient. If the genomic test shows the tumor to be at low risk for recurrence, a patient can with good confidence elect to forgo chemotherapy, because further therapy to reduce recurrence risk is unnecessary.[5]

There are two more reasons that genomic tests have not been more widely adopted: inertia and outright resistance to change. Sometimes, it is more comfortable for physicians to continue doing things as they have in the past because those things seem to work well for them in their practices. In addition, some physicians may be more cautious than others in accepting new technologies and processes.

That said, reluctance or delay in adopting genomic testing is perfectly understandable. Genomic testing is a significant paradigm shift in the way we think about breast cancer growth and metastasis and requires an equally significant shift in thinking. Physicians are also pulled in many directions at once, with constant change in all fields. They can certainly be forgiven for not having the time to review all the new literature about genomic profiling—particularly if breast cancer therapy is not their main focus. This fact alone explains why many physicians will continue with their traditional approach to the disease.

Advantages of Incorporating Genomic Testing

There are many advantages to offering genomic testing at your breast cancer treatment center or community cancer center.

Ease and benign nature of testing. Genomic testing is not an invasive test. It is performed on tissue previously removed by surgery or biopsy. It has no side effects. Genomic testing simply provides information on which to base treatment decisions. It means those decisions can be made more wisely than they could have been before the advent of genomic testing. In short, there is no clinical downside.

Improved patient care. This is of course the most important factor. Genomic testing provides the information upon which more accurate and more personalized treatment decisions can be based. Patients who are found to be at low risk of recurrence have the option of avoiding the side effects and lifestyle disruption of chemotherapy. Patients shown to be at high risk of recurrence can choose a therapy regimen, likely including chemotherapy, which is personalized to their tumor biology.

Cancer centers that do not offer genomic testing run the risk of over- or under-treating their patients. These programs are operating on information that, while necessary and helpful in the current environment, can only be described as insufficient and outdated if considered alone. Clinicians are effectively assuming that all patients have the same need for and will get the same benefit from chemotherapy. But that's not the state of objective medical knowledge today. These cancer centers may be needlessly recommending chemotherapy to some of their patients. Those patients will be exposed to risk and side effects but receive no treatment benefit because the decision to treat was based on outdated parameters.

How your cancer center is perceived. Genomic testing is well on its way to becoming the standard of care. Cancer centers that do not soon incorporate genomic testing will fall behind the mainstream, and may be viewed as such by the public and medical professionals alike. The positive side of this scenario is that if your cancer center offers genomic testing, prospective patients will perceive it as providing state-of-the-art diagnoses and treatment in a circumstance that affects their daily experience of life as well as their long-term survival. In short, it can be a strong market differentiator.

Cost. The only conceivable objection to genomic testing then could be cost: that it is not a cost-effective use of personal or healthcare system dollars. But the cost per patient to the healthcare system is about $4,000. That's far less than the typical lifetime cost of adjuvant chemotherapy, resulting in a net savings to society. Government and most private payers cover genomic testing. Both testing companies also have financial assistance programs for patients based on financial need.

As noted previously, there are no capital costs to adding genomic testing. No new medical or administrative staff need be added because the testing companies handle the billing. Because genomic testing is different from genetic testing, no genetic counselor is needed. The primary investment is brief training time for a medical oncologist or breast surgeon and a nurse or nurse navigator to better understand the test so they can knowledgeably interface with patients.

Deciding Which Test to Offer

Here are two genomic tests for breast cancer:

- A "first-generation" test, Onco*type* DX® Breast Cancer Assay, from Genomic Health, Inc.
- A "second-generation" panel called Symphony, from Agendia, Inc., which encompasses MammaPrint® and two other, closely related tests.

A cancer center must decide whether to offer both tests or just one—and if the latter, which test it wants to offer.

In my view, the wisest strategy is to offer the second-generation panel of tests alone. This decision makes sense from both a clinical and a cost-effectiveness standpoint. The three tests in the panel, which are done at the same time on one tissue sample, are the most advanced scientifically; yield the most definitive results; and are applicable to many more breast cancer patients than is the first-generation test.

The case for offering both tests does not hold up to scrutiny, in my opinion. That decision is better understood after examining the differences between the tests in detail (see "Actionable Results," at right). Those differences come down to several factors:

Foundation science. The first-generation test was developed by studying 250 genes that breast cancer experts at the time (more than a decade ago) thought might affect cancer recurrence and which genes performed well in their assay.[1] The research resulted in a 21-gene "signature."

In contrast, the second-generation test was developed using a scientific method based on the Human Genome Project. That is, the second-generation test was based on the examination of the approximately 25,000 genes mapped by the project.[2] The methodology made clear to researchers which genes were relevant to recurrence based on the difference between signatures of cancers that recurred versus cancers that did not recur, resulting in a 70-gene signature giving a dichotomous result.[2]

Prospective outcome studies. The first-generation test has been more widely used, with more than 300,000 patients tested. However, I am not aware of the publication of any peer-reviewed study in which actual treatment decisions were prospectively based on the test and reported the patients' outcomes.

The second-generation test does have prospective data validating it. A study published this year in the *International Journal of Cancer* showed that among women who were identified by MammaPrint as having a low risk for recurrence—the majority of whom chose not to receive chemotherapy—97 percent were cancer-free five years later.[5] The study also found that among women identified by the test as being at high risk—who then chose to undergo chemotherapy—91 percent were cancer-free five years later.[5] The results, which apply to women with early-stage breast cancer who are lymph-node-negative, further validated the second-generation test. They show that the second-generation test accurately stratifies patients into low-risk and high-risk groups for purposes of personalizing their cancer treatment.[5]

Applicability. While both tests are for early-stage breast cancer patients, the first-generation test is only applicable to women who are estrogen-receptor (ER) positive and HER2/Neu-negative.[9,10] The second-generation test has no such limitation. It can be used for all early-stage breast cancers.[11,12]

It is also important to understand that the first-generation test is based on research with women who had completed five years of tamoxifen therapy. Its validity is unclear if women have not completed a full course of tamoxifen.[1] That is important to note, because studies show about half of women who begin taking tamoxifen quit before the five-year point.[13] Again, there is no such limitation with the second-generation test because the test was developed and subsequently validated on untreated patients.[2]

Actionable results. The first-generation test stratifies women into three groups: low-risk, intermediate, and high-risk. Women in the low-risk group may choose to avoid chemotherapy and those in the high-risk group are advised to pursue a more aggressive approach. But those in the intermediate group, encompassing about 37 percent of results, are in treatment limbo.[14] The first-

generation test does not indicate any particular action and those patients are no better off than if they had not had the test at all. This test does not appear sophisticated enough to stratify all women. It may be helpful at either end of the spectrum, but for the significant number of patients in the middle, the test provides no help.

In contrast, all results of the second-generation test are "actionable." The test stratifies women into low- and high-risk groups only, and the implications regarding chemotherapy are clear for everyone. This difference is most likely related to the objective way in which the genomic signatures were derived. Again, the second-generation test began with 25,000 candidate genes as opposed to 250. Plus, the study design lets the tumor itself guide the gene selection, instead of researchers adding bias to the test by choosing the genes that scientists thought were relevant at the time the first-generation test was developed.

The issue of actionable results gets to the crux of whether a cancer center should offer two tests or one. Some cancer centers test women with the first-generation test, and if a woman gets an intermediate result, they then test her with the second test to determine definitively if she is at low- or high-risk for recurrence. If clinicians had simply started with the second-generation test, they would have had a definitive result to begin with and could have begun treatment earlier.

Cost-effectiveness. While both tests cost about the same ($4,000), more than one-third of women who take the first-generation test will get an intermediate, non-actionable result—meaning the test did not help with treatment decision making and insurance still must be billed. The second-generation test has no such drawback. Offering both tests potentially doubles the cost for patients in terms of co-payments, co-insurance, deductibles, and other out-of-pocket-expenses.

Looking at cost-effectiveness in a larger framework, a paper published last year in the journal *Cancer* found the second-generation test to be significantly more cost-effective for the healthcare system at-large.[15] The researchers compared "the costs and quality-adjusted life-years (QALYs) of treatment decisions guided by" the tests. In this scenario, patients who used the first-generation test to guide treatment decisions spent $27,882 and gained 7.364 QALYs. Those who based their treatment decisions on the second-generation test spent substantially less—$21,598—and gained 7.461 QALYs. Both differences were statistically significant.[15]

Patient relationships. Patients seek definitive answers from clinicians and tests. Ambiguity is upsetting to them. Yet, cancer centers that offer the first-generation test will frequently have to report ambiguous intermediate results to their patients. If clinicians then use routine clinico-pathologic guidelines to "split the difference," they may end up recommending that a majority of those patients consider chemotherapy—when in fact as many as half of patients may not benefit from it.

Molecular subtyping. The second-generation test provides quantitatively more information for treatment decision making. That's because it is actually part of a three-assay suite of tests. For instance, one of the assays (BluePrint™) classifies breast cancer into basal, luminal, and ERBB2 (HER2/Neu dominant) molecular subtypes. Each subtype is known to have a different prognosis and to respond differently to various therapies. This additional layer of information goes beyond the basic stratification of patients into low-risk and high-risk groups and can help guide—and personalize—treatment decisions.

The value of molecular subtyping will increase over time as more data is accumulated. For example, paradigm-shifting findings continue to emerge about clinically HER2-positive patients and the different subtypes they express. Studies are also revealing substantial findings about basal subtype patients. The first-generation test does not provide molecular subtyping and is therefore not really sophisticated enough to tease out these potentially relevant differences.

No need for more personnel. With both of the genomic tests, staffing considerations are quite straightforward. Administrative and office staff, plus clinicians, including nurse navigators, need to be aware that the test is being offered. The cancer center will need a relationship with a pathologist and the breast surgeon who will obtain the tumor sample, either surgically or with a core biopsy. The sample is then typically sent to the testing company as formalin-fixed, paraffin-embedded (FFPE) tissue. The medical oncologist will use the test results to help patients decide on an appropriate treatment strategy. The two main companies that offer these tests handle the billing to Medicare, Medicaid, and insurance companies.

Going Forward

Genomic testing that stratifies breast cancer patients with regard to their risk of cancer recurrence is now beginning to figuratively stratify breast cancer treatment centers, as well. Those that offer genomic testing will be seen as providing the most advanced care available. Those that do not offer genomic testing will increasingly be perceived as behind the curve.

This is particularly true when it comes to the decision process about whether or not a patient should undergo chemotherapy. The consequences of that decision are so significant that informed patients will seek the most sophisticated advice they can find. Today, that means genomic testing. OI

James V. Pellicane, MD, FACS, is director of Breast Oncology at the Bon Secours Cancer Institute in Richmond, Va. He is board certified by the American Board of Surgery, a fellow of the American College of Surgeons, and a member of the American Society of Breast Surgeons.

References

1. Paik S, Shak S, Tang G, Kim C, et al. Gene expression and benefit of chemotherapy in women with node-negative, estrogen receptor-positive breast cancer. *J Clin Oncol*. 2006;24(23):3726-3734.
2. van't Veer LJ, Dai H, van de Vijver, MJ, He YD, et al. Gene expression profiling predicts clinical outcome of breast cancer. *Nature*. 2002;415(6871):530-536.
3. American Cancer Society. Chemotherapy for Breast Cancer; 2013. Available online at www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-treating-chemotherapy. Last accessed Sept. 18, 2013.

4. Mayo Clinic. Chemotherapy for Breast Cancer: Risks; 2013. Available online at www.mayoclinic.com/health/chemotherapy-for-breast-cancer/MY01368/DSECTION=risks. Last accessed Sept. 18, 2013.
5. Drukker CA, Bueno-de-Mesquita JM, Rete VP, van Harten WH, et al. (2013). A prospective evaluation of a breast cancer prognosis signature in the observational RASTER study. *International J of Cancer.* 2013;133(4):929-936.
6. Goldhirsch A, Winer EP, Coates AS, Gelber RD, et al. Personalizing the treatment of women with early breast cancer: highlights of the St Gallen International Expert Consensus on the Primary Therapy of Early Breast Cancer 2013. *Ann Oncol.* 2013;24(9):2206-2223.
7. Esserman LJ, Thompson, Jr. IM, Reid B. Overdiagnosis and overtreatment in cancer: an opportunity for improvement. *JAMA.* 2013;310(8):797-798.
8. Association of Community Cancer Centers. Molecular Testing in the Community Oncology Setting; 2013. Available online at www.accc-cancer.org/education/pdf/MolecularTestingGatefold.pdf. Last accessed Sept. 18, 2013.
9. Paik S, Shak S, Tang G, Kim C, et al. A multigene assay to predict recurrence of tamoxifen-treated, node-negative breast cancer. *N Engl J Med.* 2004;351, 2817-2826.
10. Biroschak JR, Schwartz GF, Palazzo JP, Toll AD, et al. Impact of Oncotype DX on treatment decisions in ER-positive, node-negative breast cancer with histologic correlation. *Breast J.* 2013;19(3):269-275.
11. Mook S, Schmidt MK, Viale G, Pruneri G, et al. TRANSBIG Consortium. The 70-gene prognosis signature predicts disease outcome in breast cancer patients with 1-3 positive lymph nodes in an independent validation study. *Breast Cancer Res Treatment.* 2008;116(2):295-302.
12. Knauer M, Cardoso F, Wesseling J, Bedard PL, et al. Identification of a low-risk subgroup of HER-2 positive breast cancer by the 70-gene prognosis signature. *British J Cancer.* 2010;103(12):1788-1793.
13. Hadji P, Ziller V, Kyvernitakis J, Bauer M, et al. Persistence in patients with breast cancer treated with tamoxifen or aromatase inhibitors: a retrospective database analyses. *Breast Cancer Res Treatment.* 2013;38(1):185-191.
14. Kelly CM, Krishnamurthy S, Bianchini G, Litton JK, et al. Utility of Oncotype DX risk estimates in clinically intermediate risk hormone receptor-positive, HER-2 normal, grade II, lymph node-negative breast cancers. *Cancer.* 2010;116(22):5161-5167.
15. Yang M, Rajan S, Issa AM. Cost effectiveness of gene expression profiling for early stage breast cancer: a decision-analytic model. *Cancer.* 2012;118(20):5163-5170.

GENOMIC TESTING FOR BREAST CANCER: A PATIENT'S STORY

E.L., a physical therapist in Richmond, Va., wasn't expecting any surprises when she received the results from her first-ever mammogram in November 2011. But she got one. The radiologist found what looked like breast cancer.

Among the many fears racing through her head was the possibility that she would have to undergo chemotherapy after her surgery, to prevent a cancer recurrence. "You always hear about people being really sick, throwing up, losing all their hair," said E.L. "Then I researched it on my own and read about having long-term heart problems, getting 'chemo brain,' and other serious issues. I have a friend who had an intestinal cancer. She had chemo and got neuropathy, including numbness, in her hands. That would have been a real problem in my profession."

Before her surgery, E.L. met with her breast surgeon, who recommended that her tumor be evaluated with the second-generation genomic test. Following her January 2012 operation, her medical oncologist advised that the first-generation test be ordered, as well.

The results for both tests arrived in mid-March 2012. The first-generation test result was confusing. It was right on the border between the test's low-risk and intermediate categories, which meant there was no clear direction about whether chemotherapy would be helpful. The second-generation test result left no such questions. It placed her squarely in the low-risk category. But how should she weigh that score against her first-generation test reading?

E.L. consulted with her breast surgeon, who had first told her about the second-generation test. He said that he could not make the decision for her but made it clear that in her situation, he would not choose chemotherapy. He also assured E.L. that the second-generation test, besides providing more straightforward results, was more sophisticated than the first-generation instrument. E.L. decided she could safely choose to avoid chemotherapy and not look back.

Today, E.L. is in the midst of tamoxifen therapy, a normal recommendation for her hormone receptor-positive form of the disease. It affected her mood at first but other than that, the therapy has gone smoothly. Because there's no chemotherapy in the picture, she's back to the life she enjoys—playing tennis, taking exercise classes, and working a full schedule. She's a big believer in the benefits of genomic testing.

"It just makes sense to look at what's driving the tumor," E.L. said. "And no one should have to do chemo if they don't really have to. If a woman has breast cancer and her doctor doesn't do genomic testing, I would definitely recommend that she find another doctor who does."

The Performance Pivot

Using Theory of Constraints, Lean & Six Sigma to make breakthrough improvements

BY PAUL SCHILSTRA

> Long-term commitment to new learning and new philosophy is required of any management that seeks transformation. The timid and the fainthearted, and the people that expect quick results, are doomed to disappointment.
>
> W. EDWARDS DEMING, 1982

Cancer programs around the country are currently pursuing a number of strategies to improve their services, stay competitive, and achieve profitable growth. Unfortunately, many of these strategies fail to deliver the long-term expected benefits (see Table 1, page 50). A number of underlying factors—usually based on incorrect or incomplete assumptions—may ultimately lead to the failure of these improvement and growth efforts, including:

1. The "productivity paradox" combined with cost accounting
2. Incomplete and incorrect use of Lean and Six Sigma
3. Sub-optimization within the cancer program
4. An overall failure to create a continuously learning, improving, and growing organization.

The "Productivity Paradox"

It's every cancer program administrator's dream: everybody and everything in the cancer program working at 100 percent efficiency (read: doing more with less) and 100 percent productivity (read: be 100 percent busy all the time). But how does a cancer program achieve this outcome? And is it even realistic? Before we can answer these questions, we have to define what these terms really mean.

Efficiency is defined as the number of units of output or desired results (e.g., revenues, outcomes, etc.) generated per unit of input or resource (e.g., money, people, equipment, etc.). Ideally, efficiency should at least be equal to or greater than one.

Utilization is the one and only measurement for determining how busy a resource is. However, a resource should never and cannot ever be busy 100 percent of the time. It is mathematically impossible. Variations in demand, available capacity, treatment duration, and quality all conspire to make it impossible to achieve 100 percent utilization. Cancer programs that strive for this goal will only experience longer wait lines and wait times.

Productivity is often equated with "being busy," but that interpretation is wrong. Productivity should measure to what extent a cancer program is able to reach a specific goal—not whether somebody or something (a piece of equipment) is busy all the time. As such, productivity and efficiency are closely related. Any activities or resources that bring a cancer program closer to achieving its goals are productive; activities or resources that do not are unproductive and, therefore, wasteful.

The problem with pursuing efficiency ("doing more with less") and utilization ("being busy") is that it can lead to erroneous decisions about individual performance and staffing levels, as well as required capacity for equipment, rooms, chairs, beds, and more. Worse yet, these efforts may have a serious and negative impact on safety, quality, cost, and the overall patient experience if pursued in a vacuum.

Cost Accounting Challenges

Cost accounting, as it is usually practiced with fully-loaded cost per patient or unit of service, can cause a number of problems.

For example, the idea that it is critical to reduce the total cost per procedure or patient often leads to the desire to increase utilization at the departmental level. This goal may adversely affect the performance of the cancer program as a whole because it may unintentionally create bottlenecks and issues with patient throughput. A cancer program's goal should not be to reduce the cost per patient or procedure, but rather to provide superior outcomes and stellar patient services—at a price the market is able and willing to pay. Healthcare is a business. As such, cancer programs are expected to bring in revenue and profitable growth. Remember: no margin, no mission!

Second, the traditional fully loaded cost plus profit margin per procedure and patient approach frequently leads to inflated costs and prices. This practice, in turn, may lead cancer programs to forego valuable opportunities for profitable growth. An example of this thinking was the recent announcement by a number of physician-owned cancer clinics to turn away Medicare patients because they became "unprofitable" as a result of the reimbursement cuts caused by sequestration. Table 2, page 51, shows a simplified example of a cancer clinic affected by the sequestration cuts. In this example, the current patient volume is 100 patients per year while its maximum capacity is 140 patients per year. This example shows that accepting more Medicare patients can actually increase a program's net revenue and profit. In this example, a cancer program could actually

(continued on page 51)

Table 1. Improvement & Growth Strategies

INITIATIVE	OBJECTIVE	REASON FOR FAILURE
Stop investments and reduce operating expenses	• Improve the bottom line • Improve productivity	• Narrow, short-term focus on reducing cost • Fails to take the need for revenue growth into account
Pursue accreditation	• Improve the program's image for marketing efforts • Attract more patients • Improve the quality of care	• Focus on improving the image only
Start a marketing campaign	• Attract more patients	• Insufficient investment • Poorly-defined goals • Poorly-defined targeted audiences • Poorly-defined value propositions for each targeted audience • Ineffective or inappropriate communication channels and media
Acquire physician practices	• Secure referrals • Increase market share	• Poor integration of physicians and practices • Poorly-validated assumptions about the impact on growth
Partner with a major academic medical center or national oncology network	• Improve the program's image for marketing efforts • Attract more patients • Improve the quality of care	• Focus on improving the image only • Poor alignment of stakeholders • Poor integration of the two organizations
Invest in new cancer treatment capabilities and services	• Improve the program's image for marketing efforts • Attract more patients • Provide more value	• Focus on improving the image only • Failure to conduct the necessary research to justify purchases or additions to service line (i.e., does patient volume and patient mix support new equipment or new services) • Failure to include patients and staff in purchasing decisions • Not improving and redesigning processes
Build a new cancer treatment facility	• Improve the program's image for marketing efforts • Attract more patients • Improve the quality of care	• Focus on improving the image only • Failure to include patients and frontline staff in the design • Poor design of the new facility • Not improving and redesigning processes
Acquire or merge with another hospital or network	• Reduce operating expenses • Capture greater market share • Secure better leverage with payers	• A power struggle ensues between the two leadership teams • The two organizational cultures do not integrate well
Apply Lean and/or Six Sigma	• Eliminate waste • Reduce errors • Reduce variation • Reduce cost • Improve the quality of care	• Cost reduction is really the primary driver • Senior management is not engaged and supportive • Lean and/or Six Sigma are not applied correctly

increase its total profit from $400,000 to $440,000, even though the profit per patient decreases by $333.

The allocation of total fixed expenses—both direct and indirect—across individual procedures and patients is often where problems lie. Fixed costs typically make up most of a cancer program's total expenses so they are vulnerable to distortions. Few costs can be directly linked to an individual patient, except perhaps, for items like medication, meals, gowns, etc. In addition, many cancer programs are part of a larger organization that allocates a portion of its overall overhead to the cancer program, which further increases the total cost per patient or unit of service.

Other cost accounting challenges include:

- Cost accounting often ignores available extra capacity that can be used to increase revenues and overall profitability of a cancer program.
- Inventory, equipment, and facilities are treated as assets on the balance sheet, even though, in reality, they are liabilities that generate a host of operating expenses, e.g., maintenance, support, and upgrades. These expenses further add to the total cost of a cancer program.
- Traditional accounting metrics, such as cash flow, profit & loss, and return on investment are not easily translated into specific management actions.

Incorrect Use of Lean & Six Sigma

For some cancer programs, Lean and Six Sigma may not always consistently yield profound and sustained improvements. The reason is that few are aware of the history and context in which Lean and Six Sigma were developed or limitations to this approach. Lean has been mostly used to eliminate waste (Muda) in order to reduce cost. However, many Lean projects often overlook unevenness in patient flow (Mura) and overburdening of physicians and staff (Muri). These Lean improvement efforts tend to fail if frontline people (lower-level managers, physicians, and staff) are not properly trained, empowered, engaged, and supported. Often, these staff are already overburdened and stressed by just doing their job and sacrificing personal time in the process. Assigning yet more work to them in the form of improvement projects may very well tip the balance toward a culture of burnout, apathy, and cynicism.

A Lean project that does not take into account patient flow and overburdening of staff will often look like this:

✓ **Step 1:** Reduce inventories

Table 2. Reimbursement Example Before and After Sequestration*

	Before	After	Gain (Loss)	Decision
Maximum Capacity in Patients Per Year	120	120		
Total Patients Per Year	100	120		
Total Fixed Costs Per Year	$ 1,000,000	$ 1,000,000		
Traditional Cost Accounting Approach (Per Patient Analysis)				
Average Net Revenue Per Medicare Patient	$ 100,000	$ 98,000	$ (2,000)	
Average Cost of Drugs Per Medicare Patient	$ 86,000	$ 86,000		
Average Contribution Margin Per Patient	**$ 14,000**	**$ 12,000**	**$ (2,000)**	
Total Fixed Costs Per Patient	$ 10,000	$ 10,000		
Average Profit Per Patient	**$ 4,000**	**$ 3,667**	**$ (333)**	**Reject More Medicare Patients**
Recommended Approach (Throughput-Based Accounting)				
Total Net Revenues	$ 10,000,000	$ 11,760,000	$ 1,760,000	
Total Cost of Drugs	$ 8,600,000	$ 10,320,000		
Total Gross Margin	**$ 1,400,000**	**$ 1,440,000**	**$ 40,000**	
Total Fixed Costs	$ 1,000,000	$ 1,000,000		
Total Profit	**$ 400,000**	**$ 440,000**	**$ 40,000**	**Accept More Medicare Patients**

*Under the traditional cost accounting approach, where all fixed costs are allocated proportionally to individual patients, sequestration results in a net loss of $400 per patient. Under the recommended approach, when patient volume grows to meet its maximum capacity, profitability is reached.

Table 3. Lean and Six Sigma Strengths and Weaknesses

	LEAN	SIX SIGMA
Origin	• Henry Ford: training within industry • Edwards Deming: The Toyota Way, production system and business practices	• Walter Shewart • Edwards Deming • Motorola
Typical Goals	• Provide better value to the customer • Improve flow • Do more with less • Reduce cost	• Reduce variation • Reduce defects or errors
Strengths	• Simultaneous focus on value, flow, efficiency, speed, and quality improvement • Can be effective for solving simple ("known knowns") and complicated ("known unknowns") operational problems • Limited need for statistical analyses • Can be taught to and adopted by many levels in the organization • Prefers proven, simple, and low-tech solutions	• Scientific, quantitative, and structured methodology • Can be effective for solving simple ("known knowns") and complicated ("known unknowns") operational problems
Limitations & Potential Points of Failure	• Is a significantly diluted and westernized version of the Toyota Way, the Toyota production system, and the Toyota business practices • Focuses mostly on operations and often ignores other important functions critical to growth, such as marketing • Assumes that patient volumes and case mix are fairly stable and that fluctuations in demand can be easily smoothed • Places too much emphasis on Lean as a set of tools and tends to ignore the concept of a learning, continuously improving and growing organization • May result in too much focus on short-term cost cutting rather than increasing and improving throughput and quality • Pays little attention to the impact of Lean projects on the existing workload of physicians and frontline staff • Is often applied in limited and one-time improvement projects instead of continuous, cancer-program-wide improvement efforts • May lead to sub-optimization of individual processes, teams, or departments within the cancer program if the cancer program as a whole system is not taken into consideration • Is not effective in dealing with complex problems or significant crises ("unknown unknowns"), where there is no obvious relationship between cause and effect	• Is a significantly diluted version of Total Quality Management and Continuous Quality Improvement • Focuses on the quality of operations only and ignores other important functions critical to growth, such as marketing • May not be appropriate in environments of regular and significant changes, e.g., due to rapid innovation • Places too much emphasis on Six Sigma as a set of tools and tends to ignore the concept of a learning, improving, and growing organization • Requires a great deal of measurements and statistical prowess • Does not include a focus on improving flow and workload leveling • Pays little attention to the impact of Six Sigma projects on the workload of physicians and frontline staff • Narrow focus may lead to sub-optimization of individual processes, teams, or departments within the cancer program because the cancer program as a whole system is not taken into consideration • Is not effective in dealing with complex problems or significant crises ("unknown unknowns"), where there is no obvious relationship between cause and effect

- ✓ **Step 2:** Reduce head count
- ✓ **Step 3:** Redistribute tasks among people
- ✓ **Step 4:** Step back and wait
- ✓ **Step 5:** Results are good enough, so let's move on to something else.

In addition, Lean and Six Sigma are often used only once and in one limited area, say Lab or Pharmacy, without continuous efforts to keep improving the area. Performance improvement—including the use of Lean and Six Sigma—is like gardening: you have to continue weeding or the weeds grow right back.[1] A short-term, one-time approach to Lean and Six Sigma can result in short-lived,

less than optimal improvements. Table 3, left, lists a number of reasons for why Lean and Six Sigma often do not yield the anticipated benefits.

In many cases, individual departments within a cancer program have their own performance objectives, which usually consist of some mix of revenue growth and cost reductions. If individual departments all adopt the "do more with less" strategy, it could potentially lead to internal conflicts and adverse consequences for a cancer program as a whole. Picture the cancer program as a chain, in which each link represents a different department, team, or service. The strength of the cancer program's chain is then defined by its weakest link. Most improvement efforts with Lean are one-time activities that focus on improving one link at a time, without knowing whether they strengthened the weakest link or a stronger one, and without knowing whether they, thus, strengthened the whole chain.[2]

For example, a pharmacy— reporting to a different manager from the cancer program administrator—may be tasked to reduce waste and staff because overall patient volumes are stagnant. At the same time, the cancer program administrator is tasked with growing the cancer program. It is easy to see how the pharmacy department can quickly become a serious bottleneck if it is not equipped to handle the anticipated increase in cancer patients.

Ultimately, the failure to pursue and create a continuously learning, improving, and growing cancer program is the main reason that improvements are often sporadic, limited in scope, and short lived.

The Transformation Journey

To successfully transform a cancer program into a vibrant center of excellence, follow these six steps:

- Start with a holistic, system-wide perspective of the cancer program
- Define the system's goals and critical success factors
- Understand the physics of the cancer program
- Define the key performance indicators
- Identify the "performance pivot" of the cancer program
- Improve and learn continuously.

1—A Systems Perspective

Cancer programs are complex and dynamic systems—mostly consisting of people—that have to continuously adjust to an ever-changing environment and demand for care (see Figure 1, below). Changes in demand often differ in acuity, frequency, and magnitude throughout the day, week, and year. These constant changes "shock" a cancer program and often result in the program being out of sync with its environment.[3,4] Cancer program leadership should seek to optimize the overall performance of the cancer program in light of these constant shocks.

2—Define the Goal

The next transformation step is to develop clear and succinct definitions of the cancer program's:

- ***Purpose.*** The difference the cancer program is trying to make.
- ***Vision.*** What the world will look like after the cancer program has fulfilled its purpose.
- ***Mission.*** How the cancer program will fulfill its purpose and vision.

The purpose and vision are the goals of a cancer program, while the mission represents its critical success factors: the things that must be done or must be in place to achieve the goals. Combined, these will guide future decisions and actions. Figure 2, page 54, shows an example of a possible set of cancer program goals, along with some corresponding critical success factors and necessary conditions. Consider constructing a similar diagram using this cause and effect structure.[5]

(Continued on page 55)

Figure 1. A Holistic, System's Perspective of a Cancer Program

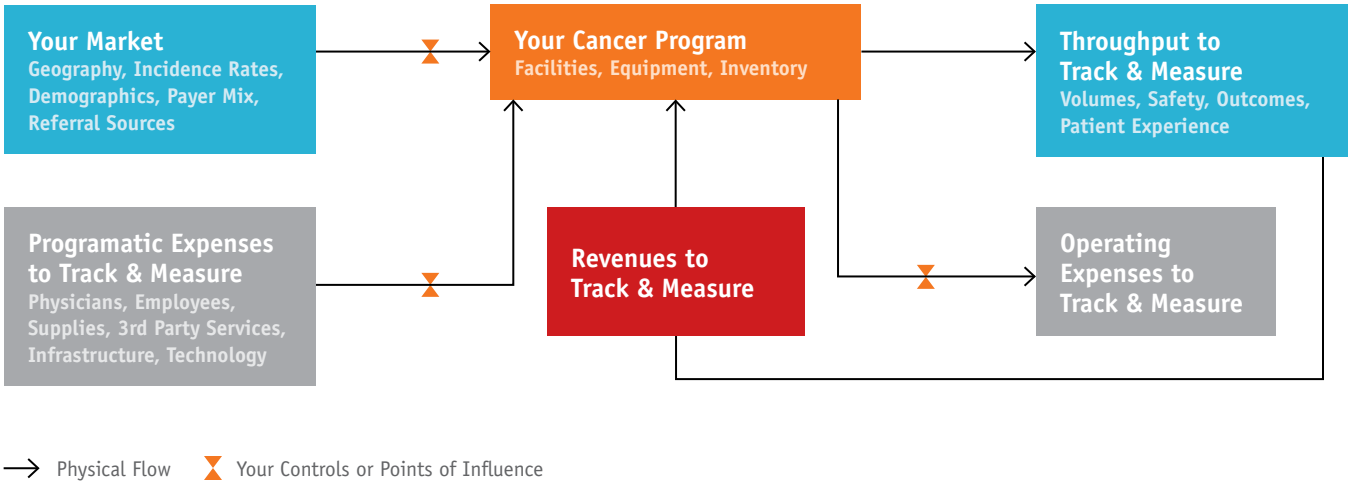


Figure 2. Cancer Program Goals, Critical Success Factors & Necessary Conditions

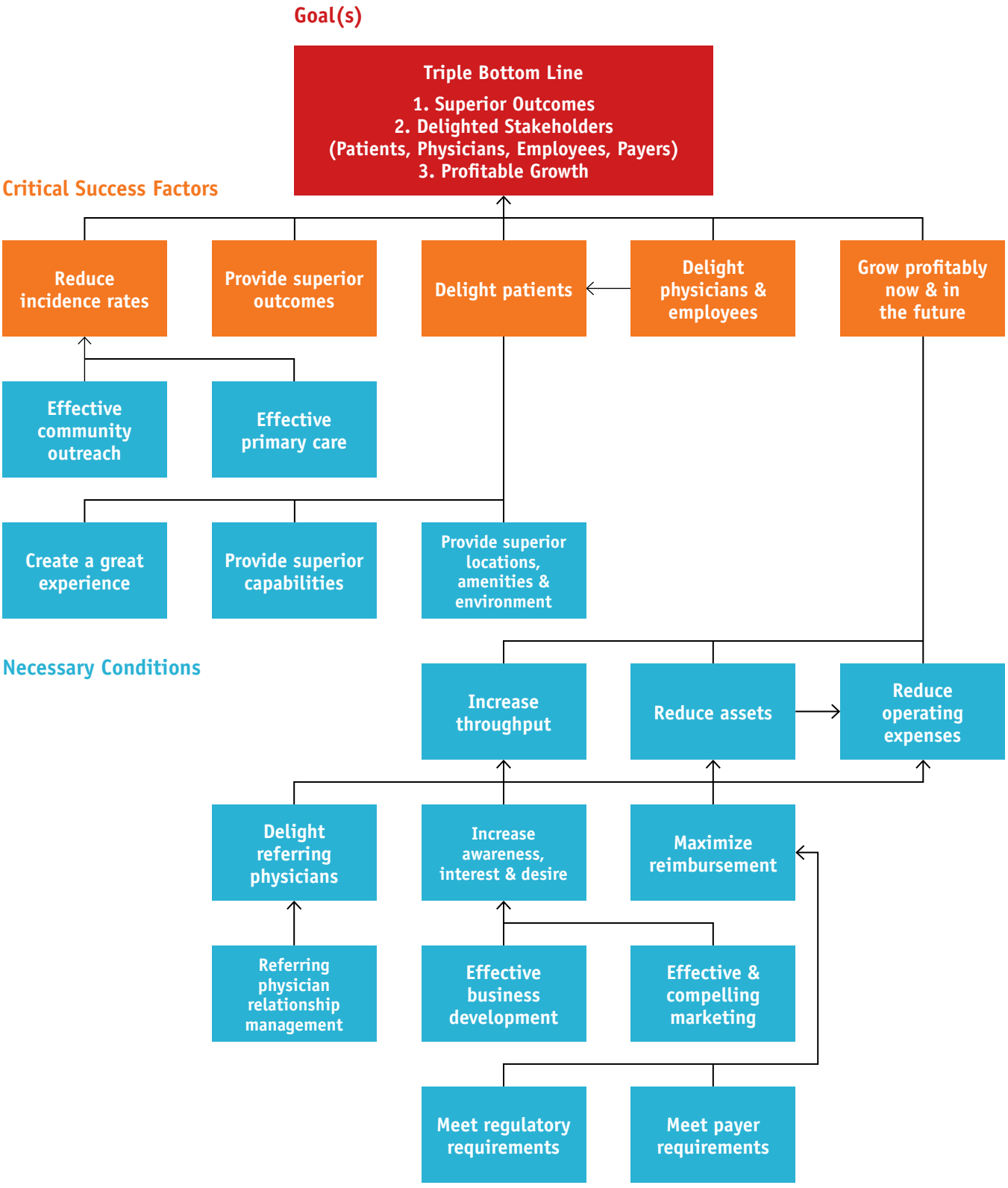
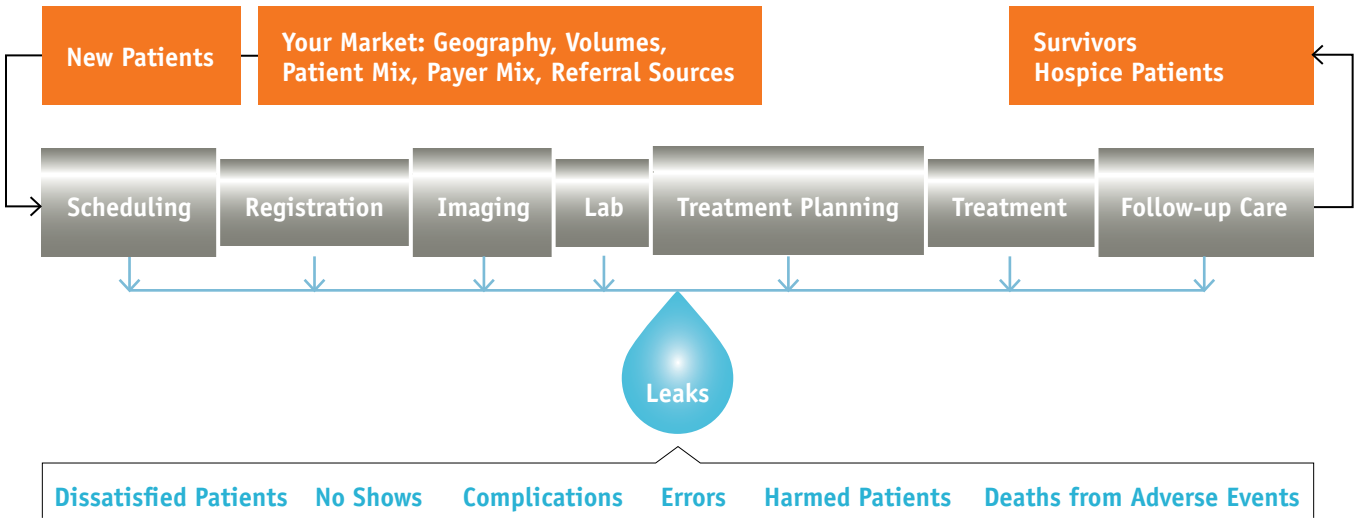


Figure 3. An Analogy of a Cancer Program as a "Pipeline"



3—Understand the Physics of the Cancer Program

Imagine a cancer program as a water pipeline that consists of different sections that represent different departments or resources (see Figure 3, above). The sections differ in diameter, representing different levels of maximum available capacity. In addition, each section of the pipeline contains leaks, representing patients experiencing complications, errors, harm, or death. In this example, water (i.e., patients) flows through this pipeline, and the rate at which the water flows through is defined as "throughput." A cancer program's throughput is determined by the narrowest section of the pipeline—the bottleneck or constraint—and by the number and sizes of the leaks along this pipeline. Constant changes in demand, bottlenecks, and leaks create turbulence and an uneven flow of patients throughout this pipeline. In turn this will lead to unevenness in the staff workload along the pipeline.

4—Define Key Performance Indicators

The next step is to use the systems-based framework and the cancer program's goals and critical success factors to determine which key performance indicators best define and measure the program's success. The task: optimize throughput—defined as the rate at which the cancer program achieves its goal(s). Throughput should be measured along five dimensions: volume, outcomes, safety, patient experience, and top line growth, i.e., revenues minus those direct variable costs that can be directly associated with an individual patient or procedure.

Once the cancer program's throughput begins to improve, focus on reducing cost—provided that such cost reduction efforts do not lead to a decrease in throughput. Two major factors drive cost:

1. ***Investments.*** All the money the cancer program has invested in assets to care for cancer patients, e.g., facilities, equipment, inventories, other assets, and liabilities.
2. ***Operating expenses.*** All the money the cancer program spends on caring for cancer patients. It is the sum of all direct fixed and all indirect expenses, i.e., those expenses that cannot be directly associated with individual patients or procedures.

Investments such as facilities and equipment often generate significant operating expenses associated with maintenance, support, and upgrades. Careful and appropriate reduction of investments will, therefore, lead to reduced operating expenses. Often, efforts to improve throughput will simultaneously lead to opportunities for reducing investments and operating expenses.

Effective Oncology Dashboards track a limited number of key performance indicators that:

- Matter to all stakeholders: the cancer program, patients, payers, employers, physicians, and employees
- Are directly related to the cancer program's goals, i.e., results
- Are well understood, valid, reliable, and easy to convert into corrective actions.

Figure 4, page 56, shows an example of an Oncology Dashboard with key performance indicators. Define concepts such as quality care, superior outcomes, and patient experience in actionable terms. For the purpose of this article, quality cancer care is defined as the combination of superior outcomes and a great patient experience. Together clinical quality and the level of service that a cancer program provides determine the patient experience as a critical success factor.

Figure 5, page 57, shows how these concepts relate to each other from the customer's point of view, i.e., patients and their families, referring physicians, employers, and payers. Note: the safety of a cancer program's services is often assumed and taken for granted by the general public. It is not a dimension of cancer care that new cancer patients will typically and explicitly consider in their choice of where to go for their treatment.

Figure 4. Example of an Oncology Dashboard

KEY PERFORMANCE INDICATOR	CATEGORY	VERSIONS OR DEFINITION	PURPOSE	FREQUENCY OF MEASUREMENT
Throughput	Volume	**Inpatients** • Admissions (scheduled, unscheduled, emergency, no shows) • Case mix (new and current patients, disease site) • Discharges **Outpatients** • Visits (scheduled, unscheduled, emergency, no shows) • Case mix (new patients, current patients, survivors, disease site) • Discharges	**Purpose** • Identify constraints • Level workload (Mura) and create flow • Prevent overburdening of physicians and staff (Muri) • Eliminate waste (Muda)	• Daily • Weekly • Monthly • Quarterly • Annually
	Safety	• Patients experiencing complications during treatment • Patients harmed as a result of errors	• Identify constraints • Strive for perfection • Improve the patient experience	• Daily • Weekly • Monthly • Quarterly • Annually
	Outcomes	• 5-year disease-free survival by cancer site and stage • 5-year progression-free survival by cancer site and stage	• Identify constraints • Strive for perfection • Improve the patient experience	• Monthly • Quarterly • Annually
	Patient Experience	• Dissatisfied patients	• Identify constraints • Improve the patient experience • Strive for perfection	• Monthly • Quarterly • Annually
	Financial	• Total net revenues—total direct variable expenses	• Identify constraints • Measure financial value added	• Monthly • Quarterly • Annually
Investment	Financial	• Total value of facilities + equipment + inventory + other assets and liabilities	• Eliminate waste (Muda)	• Monthly • Quarterly • Annually
Operating Expenses	Financial	• Total direct fixed expenses + total indirect expenses	• Eliminate waste (Muda)	• Monthly • Quarterly • Annually

5—Identify the "Performance Pivot"

In our current, dynamic, and complex healthcare environment, cancer programs require a powerful set of tools to effectively guide them towards their goal(s). The transformation process proposed in this article is adapted from three well-established and proven methods. Together, they complement each other and overcome the limitations of each:

1. ***Theory of Constraints*** (TOC) for optimizing an entire cancer program's performance as a whole.
2. ***Lean*** for continuously improving value, flow, quality, and the workload of physicians and staff, while eliminating waste.
3. ***Six Sigma*** for further reducing variation, complications, and errors.

TOC was developed by Dr. Eliyahu Godratt, an Israeli physicist who became an international manufacturing and business "guru" in the 1990s. In his book *The Goal*, he outlined his Theory of Constraints, a dynamic, systems-based and systematic approach to creating breakthrough improvements.[2] TOC enables cancer programs to focus first and foremost on the most critical factor—the constraint or weakest link—that limits the program's ability to achieve its goals. The result: the constraint becomes the

"performance pivot." By effectively leveraging the constraint, cancer programs can "pivot" towards their goals and, thus, create a breakthrough improvement. A cancer program's main constraint is often one of the following:

- Market
- Referral network
- Capacity
- Quality
- Management time
- Policies.

Improve & Learn Continuously

Constraints can and do move around over time, with or without active intervention, so it is important to establish an ongoing process of learning and improving. TOC consists of five focusing steps that enable cancer programs to effectively increase their throughput:

1. Identify the constraint
2. Exploit the constraint and generate as much throughput as possible with it
3. Subordinate everything else to the constraint to ensure a level and consistent throughput—and workload—across the entire cancer program
4. Elevate the constraint to increase throughput as needed
5. Don't stop; repeat step 1.

In many instances, the market or the referral network is the constraint, rather than current capacity or quality problems. A number of tools are available if a cancer program is looking to attract more patients.[6] Of course, cancer programs will need to have a compelling value proposition—i.e., unique selling points—to convince more patients to come to their cancer program rather than to the competition. In addition, stellar patient services and an excellent patient experience should be critical elements in the value proposition.

Figure 6, page 58, shows how to best integrate TOC with Lean and Six Sigma. TOC enables cancer programs to maintain a holistic system perspective, combined with a prioritization of key performance indicators. At the same time, Lean and Six Sigma allow cancer programs to exploit constraints, subordinate other processes and resources to the constraints, and, finally, elevate the constraint if feasible. This integrated approach focuses major efforts on addressing the constraint that most holds a cancer program back, while also learning about the many operational and clinical aspects and dynamics that ultimately drive the success of the cancer program. In addition, this approach is scalable in that it can be applied at all levels of the organization down to individual processes, departments, and teams. OI

Paul Schilstra is President of primeASCENT, LLC, an oncology management consulting firm that helps cancer programs increase their patient throughput and profitability. www.primeascent.com.

References

1. Liker JK, Franz JK. *The Toyota Way to Continuous Improvement: Linking Strategy and Operational Excellence to Achieve Superior Performance*. McGraw Hill; 2011.
2. Goldratt E, Cox JJ. *The Goal*. Second Revised Edition, Great Barrington, Massachusetts: North River Press; 1992.
3. Forrester JW. *Industrial Dynamics*. Productivity Press; 1961.
4. Forrester JW. *Principles of Systems*. Productivity Press; 1971.
5. Dettmer HW. *The Logical Thinking Process: A Systems Approach to Complex Problem Solving*. ASQ Quality Press; 2007.
6. Schilstra P. Growing your cancer program in challenging times: six critical success factors. *Oncol Issues*. 2012;27(5):38-45.

Figure 5. Quality Care from the Customer's Point Of View

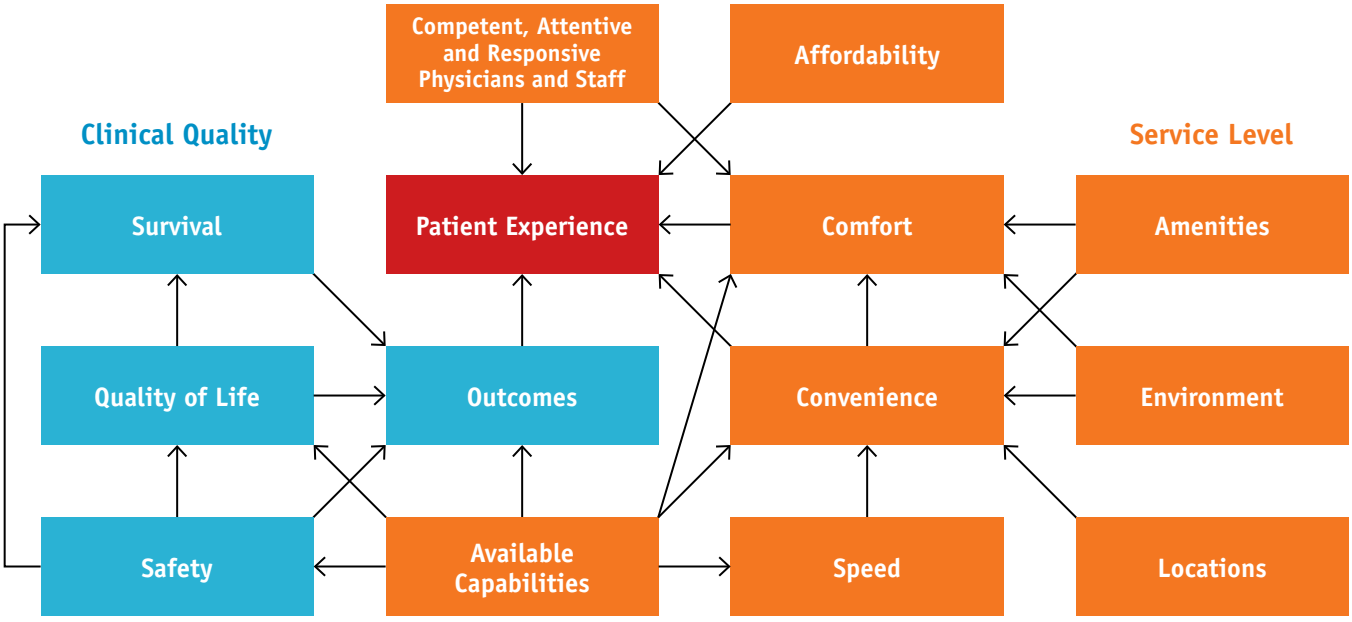
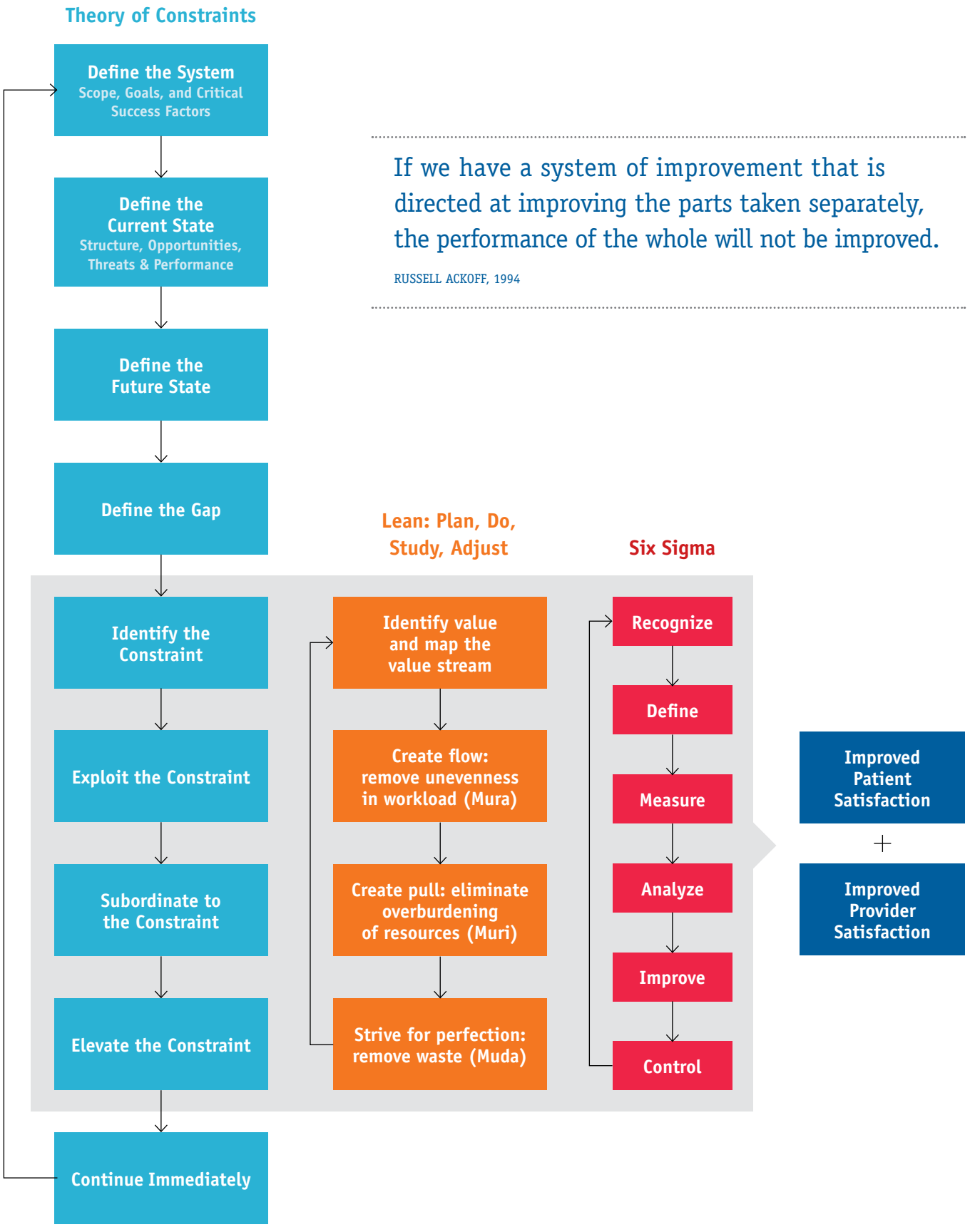


Figure 6. An Integrated Process of Ongoing Improvement



If we have a system of improvement that is directed at improving the parts taken separately, the performance of the whole will not be improved.

RUSSELL ACKOFF, 1994

careers

OPERATIONS MANAGER, RADIATION ONCOLOGY
Washington, D.C.

The Operations Manager, Radiation Oncology at MedStar Washington Hospital Center will be responsible for coordinating and managing the daily operations of the Radiation Oncology department to include:

- Oversee financial, clinical, and performance improvement objectives
- Provide leadership and guidance to the staff
- Coordinate with the physicians to assist them with their individual needs to practice radiation oncology
- Stay abreast of new technology and growth opportunities in radiation oncology
- Develop and administer operational plans and budgets to ensure financial targets are achieved
- Make recommendations towards strategic growth.

To qualify, you must have a Bachelor's degree in a healthcare-related field (Master's degree preferred or obtained within three years of employment), current radiation therapist license (certified dosimetrist, physicist, or oncology certified RN preferred), and at least three to five years of experience in an oncology field in a hospital or outpatient clinical setting (management preferred).

Learn more and apply online at:
www.medstarwashington.org.
A tobacco-free workplace. EOE/AA.

CANCER CENTER ADMINISTRATOR
Milwaukee, Wisconsin

The Medical College of Wisconsin in Milwaukee seeks a Cancer Center Administrator to help obtain NCI-designation by 2016.

Essential Responsibilities: The Administrator of the MCW Cancer Center will manage the administrative, financial, and regulatory infrastructure of the successful operation of the center. The Administrator manages the day-to-day business operations and supports the business cycle, including forecasting, strategic planning for growth, grant administration, and ways to maximize reimbursement and revenue streams.

Essential Requirements: The ideal candidate will be healthcare professional with strong business acumen and interpersonal skills. A Bachelor's degree in business, finance, or related field from an accredited institution is required; a Master's degree strongly preferred. At least 8 years of professional management experience, including experience in an academic environment is required. Successful candidates will have current or recent management responsibilities and demonstrated leadership within a cancer center that is NCI-designated or pursuing designation.

To apply or receive additional information,
contact: Jane Fischer, Tyler & Company.
Email: jfischer@tylerandco.com
or Telephone: 610-558-6100, ext. 231.

CERTIFIED MEDICAL DOSIMETRIST
Bakersfield, California

Minimum Requirements Include:

- Graduate of an AAMD-affiliated hospital or university-affiliated Medical Dosimetry Program.
- Certified by Medical Dosimetry Certification Board
- Skilled in all areas of radiation therapy
- Experienced in Eclipse treatment planning system.
- Skilled in IMRT, Rapid Arc, and 3D planning
- Knowledge of computer and experience with ARIA
- Current First Aid and BLS certification.

Responsibilities Include:

- Conduct patient treatment planning
- Calculate distribution of doses for radiation therapy treatments including IMRT using Eclipse planning system for external beam treatments and MultiPlan for CyberKnife
- Calculates plans for HDR and other brachytherapy procedures
- Provides support and problem solving with complex treatment set-ups to the simulator and therapy staff
- Assists physicists in data collection and quality checks
- Assists physicist in performing checks and calibrations.

Interested candidates can email: rmassey@cbccusa.com.

BMT HEMATOLOGY/STEM CELL TRANSPLANT ADMINISTRATOR
San Antonio, Texas

Responsibilities: The BMT Administrator provides direction and support for the ongoing development of Methodist Hospital BMT and Hematologic Malignancy services for both adults and pediatrics. Individual will be responsible for aligning multiple departments, fostering interdepartmental collaboration, and ensuring quality in a common mission across the full continuum of care. Areas of responsibility include FACT preparation, contracting, quality and compliance, program management, strategic development, marketing and outreach, and research. Reporting directly to the Vice President of Oncology, the position will have administrative authority and responsibility for BMT and the Hematologic Malignancy Program related services, as well as its financial performance.

Qualifications: Ideal candidate will support the Methodist Healthcare System mission and vision, as well as possess a Master's degree combined with a minimum of 5 years of progressive healthcare/hospital management experience. Transplant and/or oncology experience required. Preference will be given to candidates with clinical experience in Nursing or a related field.

Submit resumes to: Pamela.McDonald2@MHShealth.com
or apply online at: https://hca.taleo.net/careersection/jobdetail.ftl?job=1483374. EOE.

CME/CE Opportunities

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

www.accc-cancer.org/CME

PHYSICIANS: Maximum of 1.00 AMA PRA Category 1 Credit(s)™

Advances in Myeloid Disorders: Highlights and Analysis of Pivotal Data from the 2013 Summer Congresses

Review the most significant clinical research and trial data from the summer congresses on myeloid malignancies. Examine the implications of emerging data for the treatment of patients with myeloid disorders and how these data are applicable and relevant in the community practice setting.

James Foran, MD
Mayo Clinic

Supported by independent educational grants from Boehringer Ingelheim and Novartis Oncology

PHYSICIANS: Maximum of .25 AMA PRA Category 1 Credit(s)™

Individualizing Therapy for Patients with CLL: Focus on Age and Comorbidities

Evaluate patient-and disease-related factors to assess risk and select treatment for patients with CLL. Compare treatment approaches, their mechanism of action, efficacy in clinical trials, and their suitability for patients with CLL who are elderly and/or have co-morbidities.

Ian W. Flinn, MD, PhD
Sarah Cannon Research Institute

Supported by an independent educational grant from Genentech

PHYSICIANS: Maximum of 1.00 AMA PRA Category 1 Credit(s)™

The Evolving Treatment Landscape of Pancreatic Neuroendocrine Tumors

Review the diagnosis and treatment of resectable and nonresectable PNETs and the outcomes associated with these approaches.

Matthew H. Kulke, MD
Dana-Farber Cancer Institute

Pamela L. Kunz, MD
Stanford Cancer Center

Alexandria Phan, MD
MD Anderson Cancer Center

Jonathan S. Strosberg, MD
H. Lee Moffitt Cancer Center

James C. Yao, MD
MD Anderson Cancer Center

Supported by an independent educational grant from Novartis Oncology

ACCC Association of Community Cancer Centers | Medscape EDUCATION

action

ACCC 30th National Oncology Conference

Nearly 600 cancer care professionals attended ACCC's 30th National Oncology Conference in Boston, Oct. 2-5, 2013. Below are highlights of the meeting.

1 In the face of challenging new standards, evolving payment systems, and shifting regulatory demands, oncology providers may wonder how they'll manage to achieve innovative, high-quality cancer care. But the recent changes in the healthcare system create exactly the type of disruptive environment that fosters the most innovation, said Whitney Johnson, keynote speaker, in her session "Dare to Disrupt: Innovate from the Inside."

2 A panel discussion on "Innovation: Value, Quality, and Technology" continued the keynote theme on how to harness the synergy between disruption and innovation.

3 The ten 2013 ACCC Innovator Award Winner sessions offered during the conference provided attendees with patient-centered, data-driven, replicable solutions to real-world challenges in the delivery of quality cancer care. Look for articles from these 2013 ACCC Innovator Award Winners in *Oncology Issues*.

4 Paul F. Engstrom, MD, was presented with the ACCC Clinical Research Award on Friday, Oct. 4. In his acceptance remarks Dr. Engstrom noted ACCC's long history of support for the role of community oncology in clinical research. "I believe clinical cancer research is only relevant when it involves community patients and their oncologists," he said. Dr. Engstrom was honored for his work in advocating for cancer prevention and screening programs in research through the U.S. and around the globe.

action

ACCC Welcomes its Newest Members

Baylor College of Medicine
Dan L. Duncan Cancer Center
Houston, Tex.
Delegate Rep: John Skora
Website: www.bcm.edu/cancercenter

Covenant HealthCare
Covenant Cancer Care
Saginaw, Mich.
Delegate Rep: Marcia Rau
Website: www.covenanthealthcare.com

Kalispell Regional Healthcare
Kalispell Regional Cancer Program
Kalispell, Mont.
Delegate Rep: Lynn Andenoro
Website: www.kalispellregional.org

Mount Sinai Medical Center
The Derald H. Ruttenberg Treatment Center
New York, N.Y.
Delegate Rep: Astrid Lenis
Website: www.mountsinai.org/patient-care/service-areas/cancer/locations/ruttenberg-treatment-center

Southeast Georgia Health System
Cancer Care Centers of Southeast Georgia Health System
Bruswick, Ga.
Delegate Rep: Enzo Centofanti
Website: www.sghs.org/cancer

KentuckyOne Health
(System Membership)
Louisville, Ky.
Delegate Rep: Mark Milburn
Website: www.kentuckyonehealth.org

Cancer Center of Santa Barbara with Sansum Clinic
Santa Barbara, Calif.
Delegate Rep: Lynn Humphrey
Website: www.ccsb.org

Jewish Cancer Care
Louisville, Ky.
Delegate Rep: Mark Milburn
Website: www.kentuckyonehealth.org

Parkland Medical Center
The Lahey Center for Oncology/Hematology at Parkland Medical Center
Derry, N.H.
Delegate Rep: Laurie Tyer
Website: www.parklandmedicalcenter.com

SAVE THE DATES!

ACCC Regional Oncology Economic & Management Meeting
Dec. 10, 2013
Hilton Savannah Desoto, Savannah, Ga.
Register for this FREE meeting at: www.accc-cancer.org/regionalmeetings.

ACCC 40th Annual National Meeting
March 31-April 2, 2014
Hyatt Regency Crystal City, Arlington, Va.

ADVERTISER'S INDEX

This index is provided as an additional service.
The publisher does not assume liability for error or omissions.

Survivorship Services—We Owe it to Our Patients!

BY MARY ANN HEDDON, RN, MSN, OCN

Staff at Pearlman Cancer Center, Valdosta, Ga., is continually challenged to identify the qualities and services that set us apart from our competitors. We recognized that taking the lead in developing a cancer survivorship program was one way to distinguish our organization as an early adopter of this essential service line.

As luck (or providence) would have it, my administrator ran across a flyer for the City of Hope's upcoming *Survivorship Education for Quality Cancer Care*. The City of Hope, under a grant from the National Cancer Institute (NCI), was offering a series of courses to educate oncology providers in teams of two from across the country. The goal: to provide education on cancer survivorship that would result in the development of programs to improve the post-treatment care for cancer patients in the U.S.

As the clinical trials coordinator, I was selected along with our education coordinator to attend the second of four annual conferences at the City of Hope in July of 2007. It was an eye-opening, challenging experience that left us with a sense of urgency to develop a survivorship program for our patients.

Fueled by excitement and oblivious to the true scope of our mission, we began work on the project immediately. We discussed the need for a survivorship program with our leadership. They were on board with the concept, but realistic about the prospects for funding an FTE to run the program. Undaunted, we mapped out what we thought represented an ideal survivorship program and began developing each component in earnest. Over the next three years, we crafted a program on paper that we felt would serve the major physical and psychosocial needs of our patients as they transitioned "from cancer patient to cancer survivor."

It Takes a Village

We live in a community with a state university (Valdosta State University, VSU) that has a College of Nursing. We teamed up with one of the nursing faculty who incorporated the development of our psychosocial patient education handouts into the curriculum of her senior-level Nursing Research class. The students did a beautiful job creating these materials and, in the process, received meaningful real-world experience.

Working with our academic partner, we conducted a baseline needs assessment of our current cancer survivors, analyzed results, published several articles, and presented at several national conferences.

VSU also has a Division of Social Work that offers a Masters Program. We worked with a senior MSW student to create an evaluation plan to measure the effectiveness of educating our survivors on multiple aspects of physical and emotional well-being, as well as healthy choices in nutrition and physical activity. This work was accomplished during a year-long internship at our cancer center, during which the MSW student satisfied her course requirements, earned academic credits, and helped craft a critical component of our survivorship program. Collaborations between healthcare organizations and institutions of higher learning are mutually beneficial and stretch limited resources.

Sharing Our Knowledge

As we progressed in our program development, we were struck by the magnitude of the undertaking and the realization that other cancer centers across the country would soon face the same monumental task. We discussed the idea of assembling our survivorship program into a "kit" and offering it to other cancer centers as a blueprint for developing their own survivorship program.

We partnered with our regional cancer coalition, which underwrote the mass printing of two program brochures and the purchase of four key publications. In exchange, we would share our kit with the three other cancer centers in the region. Next, we turned our attention to making the kit available for purchase by cancer centers outside our region. We talked with our administrative leadership, and worked out the details of how to structure a commercial venture. The result is the *Pearlman Survivorship Kit*. The original files for all program elements are included, allowing each cancer center to customize the kit to fit its unique resources, capabilities, and vision. The kit is available for purchase online at www.pearlmansurvivorshipkit.com.

The Pearlman Survivorship Kit

The kit is divided into four booklets. Book 1 contains six scripted PowerPoint

presentations to educate staff, administration, physicians, survivors, and primary care providers. Photos of cancer center staff and patients can be added, along with the organization's logo. A Survey of Needs is included to allow cancer programs to survey and identify the unique needs of their patient population. The survey can be repurposed to assess the level and sources of distress in patients completing treatment. This Post-Treatment Needs Assessment serves as a baseline for transition into survivorship. If programs choose to offer a Survivorship Clinic, responses can guide the conversation and education at that appointment.

Also included in Book 1 is a template for a comprehensive, yet compact, Survivorship Care Plan and the shorter Treatment Summary, which can be paired with a care plan such as Journey Forward or the LIVE**STRONG** Care Plan. These two components can help meet the American College of Surgeons 2012 Program Standards 3.2 (Psychosocial Distress Screening) and 3.3 (Survivorship Care Planning).

For cancer centers electing to conduct survivorship education in a group setting, Book 1 includes a class syllabus and PowerPoint presentation developed by a multidisciplinary team. It's a two hour class that starts with a patient video, addresses known physical and psychosocial issues experienced by survivors, and includes a questionnaire about nutrition, physical activity, and several quality of life issues. A post-questionnaire can be administered six months to one year later to help assess the effectiveness of the class in modifying behaviors known to impact risk of recurrence.

Book 2 contains patient education handouts on 79 survivorship issues. They're color-coded by domain addressed—physical, social, psychological, spiritual, and an "other" category. Responses on the Needs Assessment, which parallels the education sheets, can guide selection of the education materials for each patient completing treatment.

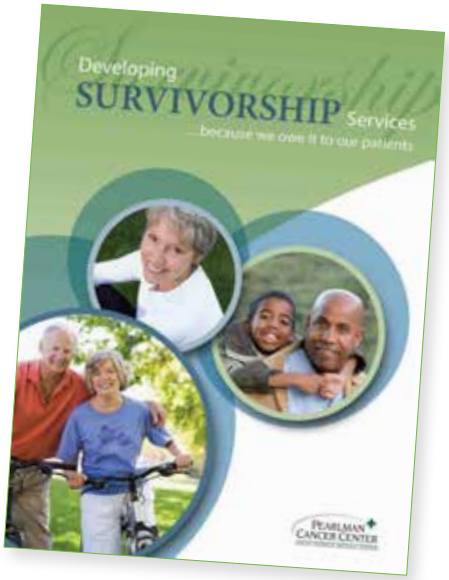
Book 3 focuses on survivorship program resources. Suggestions for organizing a series of six Survivorship Workshops for the community are included. Presenters are selected from experts in the cancer center and surrounding area, such as physicians, nurses, dietitians, exercise specialists, mental health professionals, attorneys, and Social Security personnel. Other components in Book 3 include:

- A cancer rehabilitation program that uses existing cardiac rehab facilities. Staff are cross-trained using the Cancer Exercise Specialist program or a similar program, and no additional equipment is required.
- A guide to available print and online resources to help cancer centers build their library for staff and patients.
- A budget template in *Good, Better, Best* format, which allows facilities to tailor their program to available resources.
- A selection of potential funding sources to augment the financial support of a new survivorship program.
- Tools to share with primary care providers in the community. In the shared care model, longer-term survivors are transitioned to their primary care providers as oncologists focus their efforts on the acute needs of newly diagnosed patients. These tools help primary care providers to target their assessment on the late effects associated with the specific treatment received and common health problems experienced by survivors. Recommendations from the American Cancer Society are included as the standard for educating survivors on healthy choices in nutrition and physical activity.

Book 4 contains an evaluation plan that can be used when applying for a grant to bolster program funding.

Our Survivorship Program

Pearlman Cancer Center hired a FTE nurse practitioner in 2011 and opened its Survivorship Clinic in February 2012. We chose a consultation model and used selected components of the kit to quickly get our program up and running. Briefly, here's how our program works.



Patients completing treatment are shown a video about survivorship and asked to complete the Post-Treatment Needs Assessment. We create a Treatment Summary and Care Plan for the patient and pull together education sheets related to the issues self-identified in the Needs Assessment. The patient meets with the nurse practitioner for an hour in the clinic to review the Treatment Summary and Care Plan and discuss recommendations for nutrition and physical activity in the post-treatment phase. Eligible patients are offered a free 12-week cancer rehabilitation program. Patients then see the dietitian and social worker to round out the Survivorship appointment. Follow-up appointments are made, depending on the patient's needs.

It's no surprise that feedback from the patients is very positive. We're giving them the tools and structure they need to go forward and be a successful survivor. While it's certainly true that many patients choose not to make important choices that decrease their risk of recurrence, a new cancer, or other chronic illness, we're meeting a critical need to provide the information that gives each survivor a fighting chance to experience quality of life after cancer. OI

Mary Ann Heddon, RN, MSN, OCN, is clinical trials coordinator at the Pearlman Cancer Center, South Georgia Medical Center, in Valdosta, Ga.

In a world of changing information, we're with you every step of the way.

THE VARIAN ONCOLOGY SOFTWARE SOLUTION.

In cancer care, the best medicine is often information. But what makes good information possible? Data. It's the unseen lifeblood of today's medical system. That's why Varian is cultivating an environment where images, treatment plans and patient records connect and work together securely and efficiently. It's an oncology software solution that enables better teamwork among doctors and clinicians, more efficient workflows and customized treatment delivery. As your ally in the rapidly changing world of healthcare, we're with you through it all, from patient diagnosis and treatment to survivorship*.

Learn more at:
Varian.com/OncologySoftware

VARIAN medical systems | A partner for **life**

For patients prescribed Gilotrif™ (afatinib) tablets

Tying together important **access** and **clinical** support solutions into one comprehensive program…because patient support is our priority.

Access Solutions

- **Coverage and reimbursement support**
- **Financial support**
- **Distribution options***
- **GILOTRIF Pledge™†**

Clinical Support Solutions

- **Patient support kit**
- **Nurse support**
- **24-hour specialty pharmacy support‡**
- **GILOTRIF Dose Exchange™§**

Visit us online at www.bisolutionsplus.com
Call us at 1-877-814-3915 from 8 AM to 8 PM EST

*GILOTRIF is available through our specialty pharmacy partner, Accredo, as well as through select on-site pharmacies.
†GILOTRIF Pledge provides patient and payer refund for first month of therapy if eligible patients (commercially insured through participating health plans and serviced through Accredo) discontinue before first refill.
‡For patients serviced through Accredo.
§GILOTRIF Dose Exchange offers replacement drug and eliminates an additional co-pay for the replacement drug. It is offered for up to 2 dose adjustments for patients serviced through Accredo who are exchanging ≥9 pills.

Boehringer Ingelheim

SolutionsPlus™
Patient support. Our priority.™