ONCOLOGY ISSUES

The Journal of the Association of Community Cancer Centers
July | August 2014

An Outpatient Palliative Care Program Improves the Patient Experience

ACCC Association of Community Cancer Centers 40 YEARS STRONG

GRANIX™
(TBO-FILGRASTIM)
Injection

Take a bite out of G-CSF acquisition costs*

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

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

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

†Biologics License Application.
‡As of February 2014.

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

Indication

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

Important Safety Information

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

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

For more information, visit GRANIXhcp.com.

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

TEVA Oncology

GRANIX™
(TBO-FILGRASTIM)
Injection

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

SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Splenic Rupture

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

5.2 Acute Respiratory Distress Syndrome (ARDS)

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

5.3 Allergic Reactions

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

5.4 Use in Patients with Sickle Cell Disease

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

5.5 Potential for Tumor Growth Stimulatory Effects on Malignant Cells

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

6 ADVERSE REACTIONS

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

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

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

6.1 Clinical Trials Experience

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

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

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

Leukocytosis

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

6.2 Immunogenicity

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

7 DRUG INTERACTIONS

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

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

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

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

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

8.3 Nursing Mothers

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

8.4 Pediatric Use

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

8.5 Geriatric Use

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

8.6 Renal Impairment

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

8.7 Hepatic Impairment

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

10 OVERDOSAGE

No case of overdose has been reported.

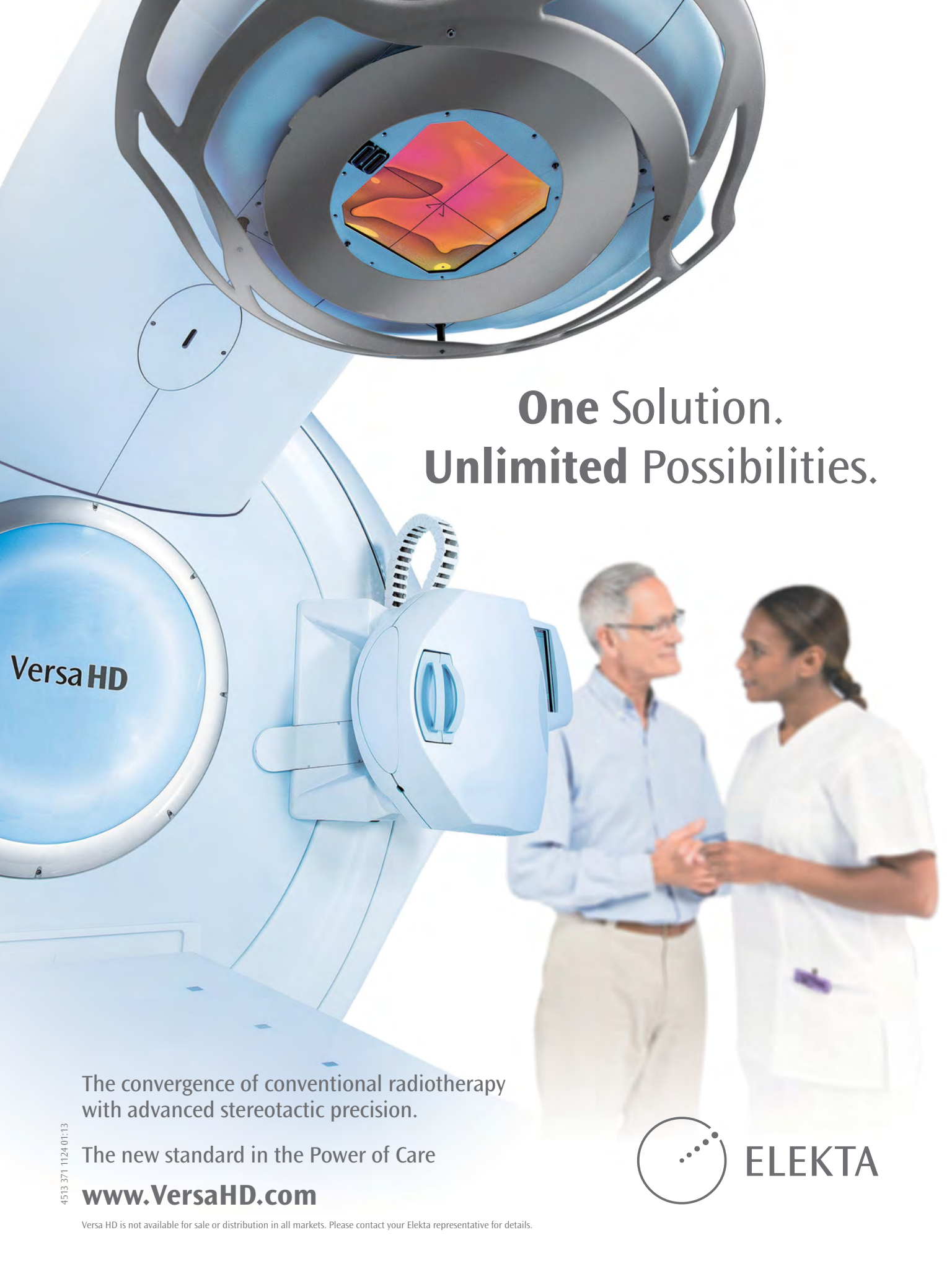
TEVA Oncology

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

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

Product of Israel
GRX-40189 January 2014

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



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DEPARTMENTS

ACCC
Association of Community Cancer Centers

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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 Good, the Fast, and the Affordable

BY CHRISTIAN DOWNS, JD, MHA

When I was doing my graduate work in health administration, one of the first lectures I heard was on the economics of healthcare delivery. The professor presented an interesting axiom. He said that in healthcare you can have good, you can have fast, and you can have affordable—but you can only have two of the three at the same time. I'm amazed at how we continue to struggle with this same scenario today.

Moreover, there is a good argument to be made that this axiom is most relevant to the delivery of cancer care. Much of the excitement around cancer care delivery has focused on the "good"—the myriad of initiatives that measure and/or identify quality of care. At the same time, the issue of "affordable" has also taken center stage. In cancer care, we tend to define "affordable" in terms of "value," i.e., is our cancer program providing services of "value" to patients and payers?

And then there's "fast." (In the community cancer program context, "fast" is taken to mean "access" to care.) So what has the oncology community done to ensure that "fast" is not overlooked in our efforts to deliver "good" and "affordable" care?

This edition of *Oncology Issues* illustrates how important "fast" (access) is to our cancer patients. Take, for example, the efforts of Gibbs Cancer Center & Research Institute to integrate palliative care into its medical oncology practice. As the authors point out: the best possible care means that "cancer patients should receive palliative care *concurrently* with curative care." To date, this program's half-day supportive care clinic has increased patient satisfaction, reduced distress symptoms, and increased supportive clinic visits.

Next, St. Luke's Mountain States Tumor Institute (MSTI) addressed barriers to delivering genetic counseling services to patients in rural areas. To ensure that these patients had timely access to qualified genetic specialists, MSTI implemented an innovative telehealth program and weekly chart review. The result: improved convenience and access, cost savings, and improved quality of care.

In our third example, Winship Cancer Institute partnered with the Metro Atlanta YMCA to develop *Winship at the Y*—an innovative program where patients receive a discount and have access to wellness coaches with special training in cancer survivorship. To date, more than 350 cancer patients have been referred to the *Winship at the Y* program.

And finally, also in this issue, learn how Methodist Hospital focused its attention on a specific patient population: very immunocompromised patients. For these patients, "fast" access can actually mean the difference between life and death. To improve the care of these patients, a multidisciplinary physician-led team developed and implemented a VIP (Very Immunocompromised Patient) Program that functions like existing cardiac or stroke alerts. If these patients experience fevers and/or chills outside of normal office hours, they present at an emergency department where an "Onc Alert" immediately triggers a VIP Protocol.

These four ACCC member programs received 2013 ACCC Innovator Awards for their efforts to improve access and care for their cancer patients. The 2014 ACCC Innovator Award winners will be honored at the ACCC 31st National Oncology Conference, October 8–10, in San Diego. We're making some exciting changes to our meeting this year, so I urge you to check out the agenda at: www.accc-cancer.org/oncologyconference. I am confident that the dozens of educational sessions we offer—as well as the opportunity to network with your peers from across the country—will deliver ideas and strategies for bringing "good," "fast," and "affordable" all together to benefit your patients and program. OI

PRESIDENT'S MESSAGE

40 Years Strong!

BY BECKY L. DEKAY, MBA

As you all know, this year ACCC is celebrating 40 years as the leading education and advocacy organization for the multidisciplinary cancer care team. A key component of the Association's advocacy efforts continues to be ACCC's Capitol Hill Day. This year, on March 31, ACCC members visited more than 100 congressional offices and shared the following ACCC messages:

- Permanently replace the SGR (sustainable growth rate) formula with responsible policy that emphasizes value over volume
- Eliminate the 2 percent Medicare sequester or, at a minimum, exempt cancer drugs from this sequester
- Pass oral parity reform
- Eliminate the Prompt Pay Discount from Medicare's drug reimbursement calculations.

The advocacy efforts of today's 20,000+ ACCC members represent nearly 2,000 hospitals and physician practices. Together, we lead efforts to coordinate care, reduce costs, and improve quality through innovative initiatives aimed at enhancing the patient experience and outcomes. If you missed ACCC's 2014 Capitol Hill Day, I strongly urge each of you to participate in future Capitol Hill Days.

In addition to our legislative efforts, ACCC staff has shared these messages with key regulatory agencies, including the Centers for Medicare & Medicaid Services. As we heard from the keynote speaker at ACCC's 40th Annual National Meeting this spring, "more clinical voices are needed in the policy setting." Congress and our regulatory bodies want and need to know what works and does not work in oncology and how they can improve policy to help us provide value and quality to our cancer patients. We hope our messages will be reflected in the 2015 proposed rules for the Hospital Outpatient Prospective Payment System (HOPPS) and the Physician Fee Schedule (PFS), which will likely have been released by the time you read this edition of *Oncology Issues*.

Looking to the future, we will extend our discussions about value and patient-centered cancer care during sessions at the ACCC 31st National Oncology Conference, October 8–10, in San Diego. These conversations about "value" truly exemplify how ACCC's unique networking opportunities help foster dialogue on pivotal issues shaping future care delivery. Where else can you reach out to your oncology peers from around the country and share perspectives on quality and value in cancer care? And those conversations don't have to stop when the meetings end. After you go back to your program and have taken some time to reflect on everything you've learned at the meeting, post your comments and questions on ACCC's online discussion forum, ACCCExchange. Become a part of the solution by sharing your strategies for adding value while staying focused on your patients.

If there is one lesson I have learned as a cancer program administrator and active ACCC member it is this: oncology providers must be proactive—not reactive! We must be at the forefront, developing ways to demonstrate value; exploring new payment models; and partnering more collaboratively with payers, other providers, and resources within our communities. Let's not allow these discussions to happen without us! Remember, it is you—the members—who truly make ACCC 40 years strong! OI

Coming in Your 2014 *ONCOLOGY ISSUES*

- Skin Cancer Screening Clinic: A Creative Business Model
- Clinical Pathway Trends—Payers, Providers, and Healthcare Evolution
- New Patient Coordinator: Streamlining a Cancer Center's Phone Lines
- SIR-Spheres Microspheres as a Treatment Option for Patients with Metastatic Colorectal Cancer
- Cancer Clinical Trials: Enhancing Infrastructure and Accrual
- Patient Education and Consent for Oral Chemotherapy
- Oncology Financial Navigators: A Closer Look at Their Role within the Multidisciplinary Team
- What to Do When Our Staff Becomes Our Patients
- The N.E.T. (Non-Emergency Transportation) Program
- Improving the Patient Experience with the Chemotherapy Process

fast

MEETING

Attend Today, Improve Tomorrow

Exciting changes are happening at ACCC's 31st National Oncology Conference! New this year: two session tracks that lead to one destination—the delivery of quality cancer care. Learn more and register today at www.accc-cancer.org/oncologyconference.

VIDEO

Got Questions? Get Answers

Watch our video to learn how ACCC's Community Resource Centers can benefit the patients you serve, offering a pathway to increased collaboration and a network of providers willing to share their knowledge and expertise. www.accc-cancer.org/CRC.

INFO

Updated Patient Assistance Guide

New content includes patient assistance programs for Fentora® (fentanyl buccal tablet), Gilotrif™ (afatinib), Imbruvica™ (ibrutinib), and Xofigo® (radium Ra 223 dichloride injection). www.accc-cancer.org/PatientAssistanceGuide.

MEETING

One-Day Financial Advocacy Meetings

Interactively discuss case studies, successful strategies, and practical solutions related to financial advocacy and assistance. Join us in New Brunswick, N.J. (Sept. 16); San Diego, Calif. (Oct. 8); Schaumberg, Ill. (Nov. 6); and Seattle, Wash. (Dec. 9). Register today at www.accc-cancer.org/financialadvocacy.

6 Smart Purchases that Will Change Your Practice

1. **Fish tanks** can help reduce anxiety and entertain waiting patients.
2. **Single-serve coffee makers** reduce the expense of wasted pots of coffee.
3. **Scanners** eliminate paper use and allow for all information to be saved electronically.
4. **Speech recognition software** eliminates the cost of paying someone to type up information.
5. **In-house billing systems** can save time and money and allow for greater physician control.
6. **Real-time locating systems** improve staff efficiency and patient flow.

Source. www.physicianpractices.com.

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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.

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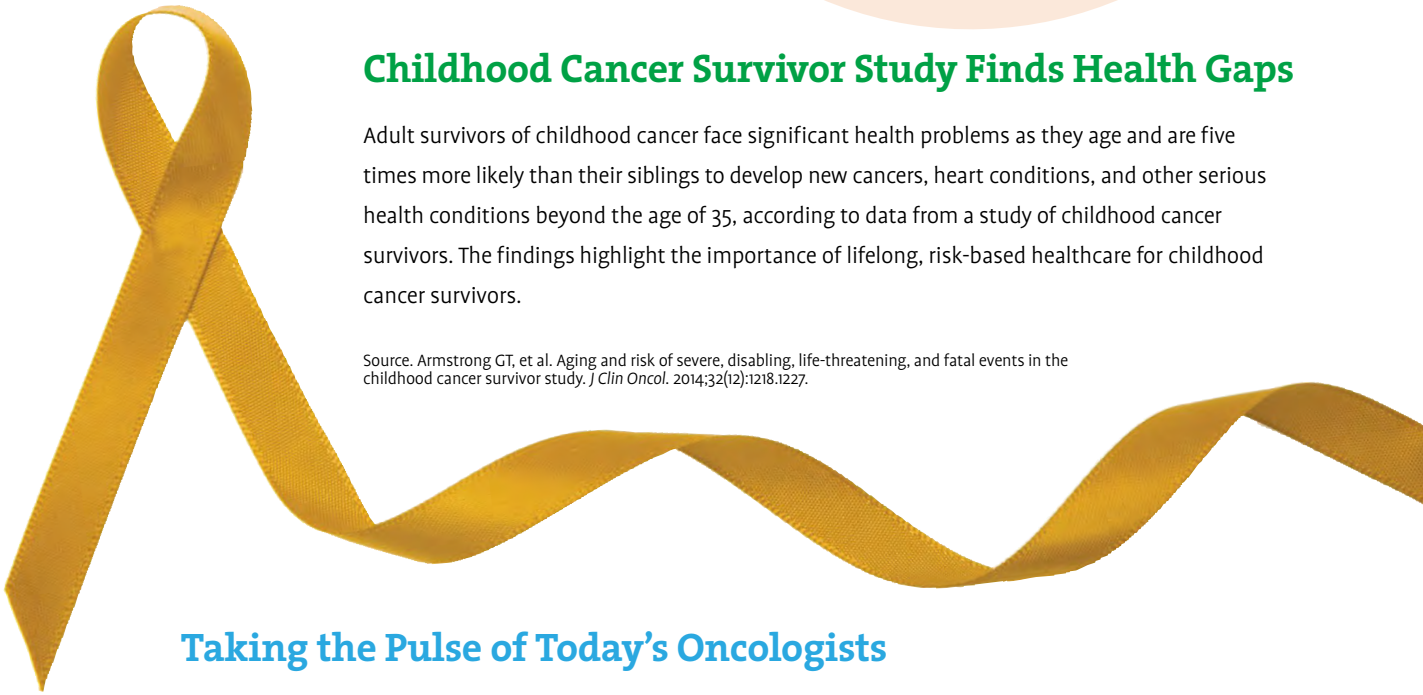
facts



Childhood Cancer Survivor Study Finds Health Gaps

Adult survivors of childhood cancer face significant health problems as they age and are five times more likely than their siblings to develop new cancers, heart conditions, and other serious health conditions beyond the age of 35, according to data from a study of childhood cancer survivors. The findings highlight the importance of lifelong, risk-based healthcare for childhood cancer survivors.

Source. Armstrong GT, et al. Aging and risk of severe, disabling, life-threatening, and fatal events in the childhood cancer survivor study. *J Clin Oncol.* 2014;32(12):1218.1227.

Taking the Pulse of Today's Oncologists

- In 2013 the average salary for an oncologist was $290,000—a **4%** increase from 2012.
- **60%** of oncologists spend more than 40 hours a week seeing patients.
- **58%** of oncologists said they would choose to practice oncology again if they had the choice.
- **52%** of oncologists feel that they are "fairly compensated" for their services.
- **19%** of oncologists have started to offer ancillary services.

Source: Medscape 2014 Physician Compensation Survey. www.medscape.com/features/slideshow/compensation/2014/public/overview#2.

Mixed Outlook for 2014 Capital Expenditures

Hospital CEOs and CFOs report medical equipment purchasing and new construction as areas most likely to experience a decline; those hospitals spending money are looking to purchase robotic surgery systems and 3D mammography systems.

Source. A survey conducted by MedPanel, LLC. www.medpanel.com.

New Cancer Program Members in 2013-2014

Adventist Hinsdale Hospital, Adventist Cancer Institute, Hinsdale, Ill.

AnMed Health Cancer Center, Anderson, S.C.

Associates in Oncology and Hematology, P.C., Rockville, Md.

Baptist Healthcare Systems, Baptist Cancer Center, Memphis, Tenn.

Baylor College of Medicine, Dan L. Duncan Cancer Center, Houston, Tex.

California Cancer Associates for Research & Excellence, Inc., San Diego, Calif.

Cancer Center of Santa Barbara with Sansum Clinic, Santa Barbara, Calif.

Centura Health Cancer Network, Englewood, Colo.

Community Medical Center, Community Cancer Care, Missoula, Mont.

Covenant HealthCare, Covenant Cancer Care, Saginaw, Miss.

DuPage Medical Group Integrated Oncology Program, Lisle, Ill.

Einstein Medical Center Montgomery, East Norriton, Pa.

Inova Comprehensive Cancer and Research Institute - Fair Oaks, Falls Church, Va.

Jewish Cancer Care, part of Jewish Hospital and Saint Mary's Healthcare, Louisville, Ky.

Kalispell Regional Healthcare, Kalispell Regional Cancer Program, Kalispell, Mont.

KentuckyOne Health, Louisville, Ky.

The Lahey Center for Oncology and Hematology at Parkland Medical Center, Derry, N.H.

Loyola University Health System, Cardinal Bernardin Cancer Center, Maywood, Ill.

Marin General Hospital, Marin Cancer Institute, Greenbrae, Calif.

Massachusetts General Hospital Cancer Center, Boston, Mass.

Mayo Clinic Health System, Andreas Cancer Center, Mankato, Minn.

Memorial & St. Elizabeth's Healthcare Services, LLP, Swansea, Ill.

Mills-Peninsula Health Services, Dorothy E. Schneider Cancer Center, San Mateo, Calif.

Mount Sinai Medical Center, The Derald H. Ruttenberg Treatment Center, New York, N.Y.

Parker Adventist Hospital, The Cancer Center at Parker Adventist Hospital, Parker, Colo.

Southeast Georgia Health System, Cancer Care Centers, Brunswick, Ga.

St. David's Healthcare System, Austin, Tex.

St. David's Medical Center, St. David's CancerCare, Austin, Tex.

St. David's North Austin Medical Center, St. David's CancerCare, Austin, Tex.

St. David's Round Rock Medical Center, St. David's CancerCare, Round Rock, Tex.

St. David's South Austin Medical Center, St. David's Cancer Care, Austin, Tex.

St. Joseph Hospital Cancer Care Program, Eureka, Calif.

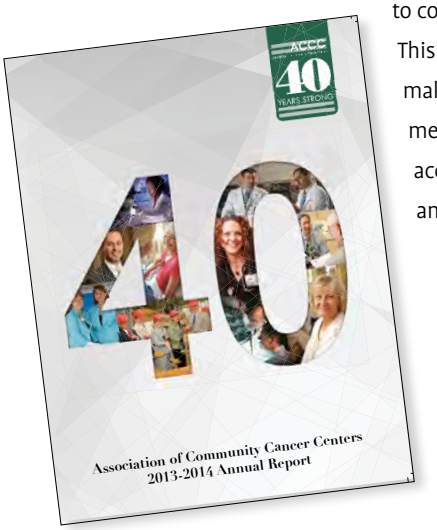
St. Joseph Mercy Oakland Hospital, SJMO Cancer Center, Pontiac, Mich.

St. Vincent Frontier Cancer Center, Billings, Mont.

University of Cincinnati Medical Center, Barrett Cancer Center, Cincinnati, Ohio

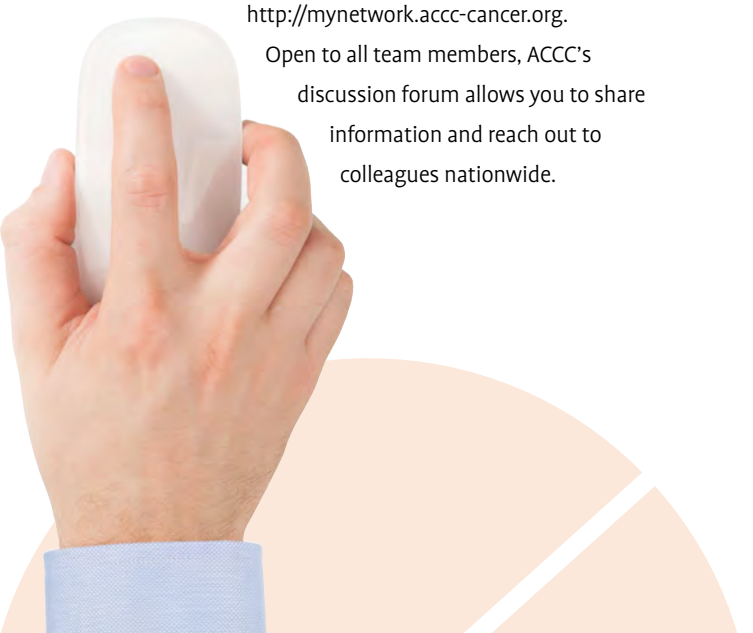
40 Years of Celebrating & Serving the Multidisciplinary Cancer Care Team

Take a look back at ACCC's rich 40-year history. Plus, see how ACCC has created and enhanced tools that help its members foster collaboration, address changes in care delivery, and implement leading-edge practices to continually improve care. This practical guide helps you make the most of your ACCC membership. www.accc-cancer.org/about/pdf/annualReport-2014.pdf.



Answers Are Just a Click Away!

For ACCC members, finding the information and answers you need is quick and easy! Questions about medical oncology staffing or how to achieve ROI on accreditations? Post them on ACCCExchange: http://mynetwork.accc-cancer.org. Open to all team members, ACCC's discussion forum allows you to share information and reach out to colleagues nationwide.



fast facts

You've Got Mail!

Look for a brochure in the mail highlighting your ACCC member benefits, and requesting that you verify and update your contact and demographic information. The more accurate our database, the better we can meet your needs!

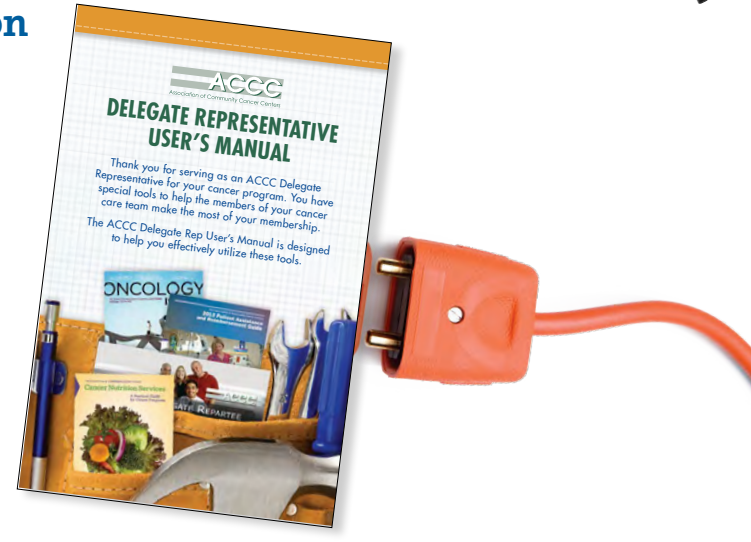
Put Your Cancer Program in the Spotlight

Don't be shy—share your success! Each edition of *Oncology Issues*, features a "Spotlight" article profiling an ACCC member cancer program. It's an opportunity to share your program's story, describe new initiatives, and more. To take advantage of this ACCC member benefit, email jkornak@accc-cancer.org.

Delegate Reps—Making the Connection

Every ACCC Cancer Program Member has one Delegate Representative—Delegate Rep for short! Today 680 Delegate Reps are the connectors between their colleagues and ACCC. These designated individuals:

1. Vote in ACCC Leadership Elections and on changes to ACCC bylaws
2. Participate in ACCC surveys
3. Encourage colleagues to use ACCC resources & participate in ACCC activities
4. Process the annual dues invoice
5. Display & update the ACCC Membership Plaque.



New ACCC Membership Category

In 2014 the ACCC House of Delegates voted unanimously to implement the newly proposed membership category known as System Membership. This membership category extends Cancer Program Membership benefits to individuals throughout a health system's oncology service line, and provides an opportunity for discount pricing for hospitals in a participating health system. To learn more contact: jwilson@accc-cancer.org or 301.946.5069.

The Future Is Now

BY MATTHEW FARBER, MA

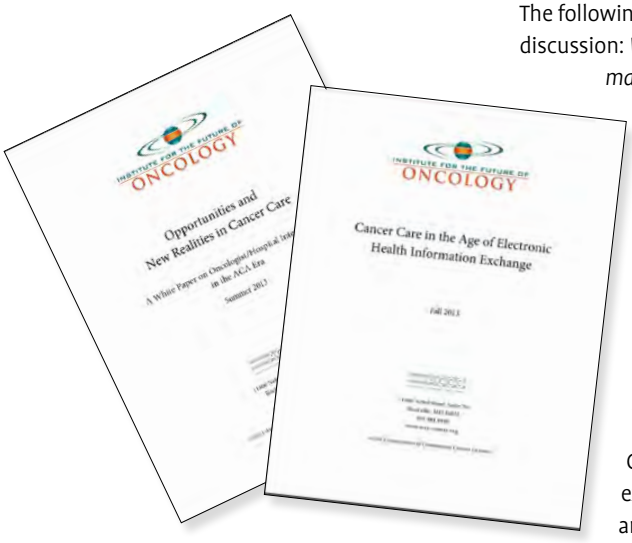
Last year ACCC launched its new Institute for the Future of Oncology initiative. The ultimate goal is to grow the Institute into a clearinghouse of information and resources designed to help ACCC members tackle issues they will face over the next 5–10 years. On any given day, oncology providers face challenges related to market consolidation and shifts in site of service, reimbursement and regulatory changes, implementation of new technology into community practice, and more. ACCC's Institute for the Future of Oncology is one resource that can help.

In June 2013 ACCC held the inaugural Institute forum, which helped to generate two white papers that delineated key challenges in the oncology landscape and possible next steps—"Opportunities & New Realities in Cancer Care: Oncologist & Hospital Integration in the ACA Era" and "Cancer Care in the Age of Electronic Health Information Exchange." Both are available online at www.accc-cancer.org/institute.

This year's Institute forum, held in June 2014, built on last year's discussion, focusing on two vital areas for the future of oncology care: Organization Leadership and Communicating Quality.

At the June forum, participants discussed:

- Planning for the future success of an organization and oncology leadership's role in decision making regarding services offered to patients
- Analyzing future needs and assimilating new and evolving technologies and treatment trends (e.g., oncolytics, immunotherapy, molecular testing, genetics, advances in radiation therapy)
- Addressing leadership succession planning and mentoring tomorrow's leaders.



The following questions helped frame the discussion: *Who are the current decision makers and, looking ahead, who are the future decision makers likely to be? How will new and evolving therapies be evaluated for inclusion in service lines offered in the community? What strategic planning approaches will lead to successful adoption of new therapies and protection of patient access?*

In the conversation on Communicating Quality, we examined how expectations vary among different stakeholders (patients, payers, and providers) and explored how quality is being communicated to these diverse groups by brainstorming the following questions:

- *How is quality successfully communicated to various stakeholders (payers, patients, other providers)?*
- *What are the key takeaways for stakeholders in discussing quality care?*
- *How do cancer care providers successfully demonstrate that they are providing quality care to their patients?*
- *What measures and metrics are being used to communicate quality in oncology?*
- *How can we use health information exchange, patient portals, and other emerging technologies to communicate quality?*

From these discussions, as in 2013, ACCC will develop two white papers that will provide unique perspectives on these areas of critical importance to the future of oncology care. In the meantime, ACCC's Institute for the Future of Oncology is seeking to identify future topics of interest to the greater oncology community. If you have thoughts on what these future topics should be or if you are interested in learning more about this initiative, contact me at: mfarber@accc-cancer.org. OI

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

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1 Drukker CA, et al. Int J Cancer. 2013 Aug 15;133(4):929-36.
2 Documents available in the public domain.

mammaprint

Chemotherapy Teaching

BY CINDY PARMAN, CPC, CPC-H, RCC

In general, cancer patients meet with a medical oncologist, hematologist, or other specialist who will order and supervise the medically necessary treatment. Once patients and physicians have agreed on a course of care, patients will receive some form of education prior to starting the course of therapy. Some cancer programs perform this service during a separate patient encounter (e.g., not on the same day as a patient visit with the attending physician or on the day the patient will receive treatment) and incorrectly believe that it can be separately charged. In general, patient and caregiver education includes, but is not necessarily limited to:

- Introduction to and duties of the multidisciplinary cancer care team (physician, midlevel practitioner, nurse, navigator, medical assistant, etc.).
- Cancer description, including staging, grade, etc.
- What to expect during treatment.
- Potential side effects of the medications to be administered.
- Tips for proper nutrition during treatment.
- Tips for management of pain and fatigue.
- Skills and coping mechanisms to better care for themselves.
- Techniques to empower patients and caregivers to make informed decisions. (This may include initial distress screening.)
- Overview of available resources and community support services, such as support groups, financial aid, etc.
- Financial information, including patient cost-share and payment schedule.
- Office, physician, or facility emergency contact information.

This education may be a combination of self-study (via video, computer-based learning, or reading material) and instruction by the nurse, midlevel provider, or physician. Some cancer programs perform group education; others provide individual patient education. Finally, education time varies from 20 to 90 minutes, depending on the type of malignancy and the specific education program.

Provider Performing Service

A great deal of variation exists among cancer programs that perform this type of education in terms of which healthcare professional provides the educational session. Some cancer programs have oncology nursing staff that meets patients and/or caregivers to perform the education, while other programs employ midlevel providers (physician assistant or nurse practitioner) who perform this function. Some physicians prefer to do all or part of the drug administration education themselves.

It is important to remember that the credentials of the healthcare professional performing the service do not impact whether this education can be separately billed to the patient. For example, chemotherapy education is not considered a billable event simply because a midlevel provider personally performs the education session.

The following definitions are provided in the *CPT® Manual*:[1]

When advanced practice nurses and physician assistants are working with physicians they are considered as working in the exact same specialty and exact same subspecialties as the physician. A "physician or other qualified health care professional" is an individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who performs a professional service within his or her scope of practice and independently reports that professional service. These professionals are distinct from "clinical staff." A clinical staff member is a person who works under the supervision of a physician or other qualified health care professional, and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a specific professional service, but does not individually report that professional service. Other policies may also affect who may report specific services.

Integral Service

It is inappropriate to bill separately for a service that is considered integral to another procedure. According to ASCO's frequently asked questions:[2]

Physician time spent on treatment planning and management is considered to be captured under the E/M codes. Chemotherapy management cannot be billed separately. Time spent by nursing staff and other health professionals on nutrition counseling, therapy management, and care coordination is also not separately billable.

In addition, APC (Ambulatory Payment Classification) allowances for hospital drug administration payment and RVUs (Relative

Value Units) for freestanding cancer center drug administration reimbursement include nursing time for education on the drug administration service. If patient education is removed from the drug administration codes and billed separately, reimbursement for *all* drug administration services would be decreased to permit reimbursement of a separate education session.

For example, the practice expense component of the RVU chemotherapy administration allowance includes the cost to operate the medical practice and is related to the general overhead expenses of the practice.[3] This includes non-physician clinical and non-clinical labor of the practice, as well as expenses for building space, equipment, and office supplies.[4] In addition, RVUs for a procedure, such as drug administration, include clinical staff time required to complete the service.

The CPT Editorial Panel meets three times each year to consider changes to existing procedure codes, the need for new procedure codes, and related issues. After each CPT Editorial Panel meeting, a document is prepared showing a summary of the actions that were taken by the Panel on each of the code applications. The February 2014 Summary of Panel Actions included an application for a code to describe "vaccine counseling by RNs" that was withdrawn.[5] There are currently no codes for counseling or education provided by nursing staff and it appears that the CPT Panel will not approve any codes for these services in the near future.

Not Billed as E/M

Before discussing potential codes for educational services, it is important to recognize what chemotherapy or other drug administration education is *not*. For example, patient education would not be reported with evaluation and management codes (**99201**–**99205**, **99211**–**99215**)—regardless of which individual performed the education. By definition, an evaluation and management (E/M) service includes acquisition of patient history, examination, and medical decision making. The exception to the three key elements is code **99211**, which is defined as:

- **99211:** Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified healthcare professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.

As indicated above, there is no procedure code for a "nurse visit." Procedure code **99211** represents an evaluation and management service ordered by a physician and documented as medically necessary that potentially does not include the presence of the physician. However, even though there are no requirements for patient history, examination, and medical decision making, there is still a requirement that there be a relevant and medically necessary exchange of information that constitutes patient evaluation and an impact on medical decision making. Based on the definition of this code, it would not be reported for chemotherapy education performed by a member of the physician's staff.

Some cancer programs believe that the patient education visit can be billed by a physician or non-physician practitioner as an evaluation and management service based on the time required for the education. According to authoritative coding guidance:[6]

The content of the service is used to select the appropriate level of E/M service. In the case where counseling and/or coordination of care dominates (more than 50%) the face-to-face physician/patient encounter, then time is considered the key or controlling factor. The extent of counseling and/or coordination of care must be documented in the medical record.

However, before a service can be reported based on visit time, it is important to understand the term "counseling," which is significantly different from a visit solely to educate the patient on the provision of the selected treatment. The counseling referred to in the context of selecting the patient visit level is that discussion with the patient performed as part of the medical decision-making component. This may include educating the patient on the various treatment options available (listed as "patient and/or family education" in the current edition of the *CPT Manual*), such as explaining the differences in side effects and outcomes between radiation therapy, surgery, and chemotherapy administration.

In addition, the *1995 Documentation Guidelines for Evaluation and Management Services* state that counseling includes:[7]

- A discussion of management and/or treatment options
- A review of imaging, laboratory, or other diagnostic data with the patient
- A dialogue with the patient surrounding risks, complications, and other factors relating to the treatment options under consideration.

The *1997 Documentation Guidelines for Evaluation and Management Services* add that counseling documentation will include co-morbidities, underlying diseases, or other factors that increase the complexity of medical decision making.[8] As a result, patient education relating to potential side effects of the service to be performed, nutrition tips, coping mechanisms, etc., would not be considered counseling for the purposes of patient visit code assignment. At this point, the patient has already selected the treatment option(s) to pursue.

Hospital Outpatient Department

Hospitals were initially instructed to use the existing CPT procedure codes for patient visits, but established their own criteria to reflect facility resource consumption. However, the 2014 Outpatient Prospective Payment System (OPPS) Final Rule changed this instruction:

While we [CMS] *agree that the proposed clinic APC* [Ambulatory Payment Classification] *encompasses a range of visits for*

Table 1. Procedure Codes to Track Resources Associated with the Provision of Educational Services

Code	Descriptor
99499	Unlisted evaluation and management service
99071	Educational supplies, such as books, tapes, and pamphlets, for the patient's education at cost to physician or other qualified healthcare professional
99078	Physician or other qualified healthcare professional qualified by education, training, and/or licensure/regulation (when applicable) to provide educational services rendered to patients in a group setting (e.g., prenatal, obesity, or diabetic instructions)
98960	Education and training for patient self-management by a qualified non-physician healthcare professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes, individual patient
98961	Education and training for patient self-management by a qualified non-physician healthcare professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes, 2–4 patients
98962	Education and training for patient self-management by a qualified non-physician healthcare professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes, 5–8 patients
S9445	Patient education, not otherwise classified, non-physician provider, individual, per session
S9446	Patient education, not otherwise classified, non-physician provider, group, per session

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

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

As a result, effective Jan. 1, 2014, CMS finalized its proposal to replace the current five levels of visit codes for hospital technical clinic visits with a single new Level II HCPCS code representing a single level of payment for new patient or established patient clinic visits:

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

According to the *Medicare Benefit Policy Manual*, Chapter 6:[9]

A hospital outpatient "encounter" is a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient.

The Centers for Medicare & Medicaid Services (CMS) adds:[10]

Billing a visit code in addition to another service merely because the patient interacted with hospital staff or spent time in a room for that service is inappropriate.

This means that the hospital will not report HCPCS code **G0463** for a technical clinic visit service unless there is also a professional patient visit service billed by the physician or a qualified non-physician healthcare professional who can bill the professional visit under his/her National Provider Identifier (NPI). As a result, procedure code **G0463** should not be routinely charged whenever the patient sees a nurse or other member of the hospital staff, including for chemotherapy education services; if there is no professional patient visit, the hospital will not report a technical clinic visit code.

Potential Codes

While chemotherapy education and teaching is generally not charged or separately reimbursed, Table 1, above,

identifies several procedure codes that may be appropriate for tracking the resources associated with the provision of educational services.

In addition to ensuring that the correct procedure code is captured for patient education (when appropriate), it is also important to report the correct diagnosis code for the educational service. Remember that the patient's cancer diagnosis (or other medical reason for treatment) will not be reported as the primary diagnosis code; the code for education will be the first-listed code, followed by other diagnosis codes that classify the patient's medical condition(s). Table 2, below, identifies these ICD-9 and ICD-10 diagnosis codes.

In Closing

Chemotherapy or other drug administration cannot be performed without patient instruction; as a result, the education or teaching service provided to the patient and/or caregiver is not a separately billable service. This patient interaction is considered part of the practice expense of the drug administration codes. The exception would be if there is an insurance payer that has a written policy that instructs the provider on coding and billing separately for the educational service. Make sure to review insurance payer coverage information carefully and question the payer for guidelines before billing for patient education. OI

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Table 2. Diagnosis Codes

ICD-9-CM Code	Descriptor
V65.19	Other person consulting on behalf of another person
V65.3	Dietary surveillance and counseling
V65.40	Counseling, not otherwise specified
V65.49	Other specified counseling (includes medication explanation)
ICD-10-CM Code	**Descriptor**
Z71.0	Person encountering health services to consult on behalf of another person
Z71.3	Dietary counseling and surveillance
Z71.9	Counseling, unspecified
Z71.89	Other specified counseling

spotlight

Mount Carmel Cancer Services
Columbus, Ohio

Mount Carmel Health System's comprehensive cancer program is accredited as a Network Cancer Program by the American College of Surgeons' Commission on Cancer. Mount Carmel is also a member of CHE-Trinity Health, the second largest Catholic healthcare system in the U.S. Serving the greater Columbus, Ohio, area, Mount Carmel delivers cancer care at three acute care facilities: Mount Carmel East, Mount Carmel West, and Mount Carmel St. Ann's.

The medical oncologists work out of an independent treatment center (the Zangmeister Center) located about six miles from the Mount Carmel East campus. The Zangmeister Center also houses the radiation therapy department for Mount Carmel East.

Infusion services, outpatient treatment, and survivorship services are available at all three acute care locations and at the Zangmeister Center.

When patients undergo concurrent therapy, Mount Carmel staff makes every attempt to schedule those patients either at the Zangmeister Center or at the St. Ann's facility; St Ann's radiation therapy and outpatient infusion department are in one suite.

Select Support Services

- Resource library
- Palliative care
- Oncology rehabilitation
- Social work
- Navigation
- Support groups
- Genetic counseling

Number of analytic cases seen in 2013: 2,876

A Virtual Care Delivery Model

According to Dodie Johnson, VP, Oncology and Surgery Service Line, Mount Carmel functions as a virtual cancer center. "Because it is a virtual program we do have a one-call access number. A patient navigation coordinator answers that phone and works with the patients to connect them with community services or refer them to the navigator, dietitian, or the social worker, depending on what they need," said Johnson.

Patient navigators are available to all cancer patients diagnosed within the hospital system. Mount Carmel has dedicated navagators for breast imaging, lung, and pancreatic cancers, as well as general navigators.

In addition, Mount Carmel has location-based patient navigators in each of the acute care settings. All patient navigators are oncology-certified nurses.

Multidisciplinary general, breast, colorectal, and GYN/oncology tumor boards meet weekly.

Breast cancer services at Mount Carmel are accredited by the NAPBC (National Accreditation Program for Breast Centers). The imaging centers and radiation therapy centers are American College of Radiology (ACR)-accredited. Mount Carmel uses Rapid Arc® technology and offers stereotactic radiosurgery at all three acute care locations. High dose rate (HDR) brachytherapy and hypo-fractionation can be performed at any Mount Carmel location, but HDR therapy is only offered at Mount Carmel St. Ann's and Mount Carmel West. All GYN malignancies are seen at Mount Carmel West. CyberKnife services are also site-specific and are delivered at Mount Carmel St Ann's.

"While patient convenience is very important, we also make certain that we've got the best expertise available," said Johnson. "For example, we don't see many prostate cancer patients. Our urologists have their own center and are able to treat prostate cancer at one location. We consolidate our prostate cancer patients for treatment. We use the same model for pancreatic surgery; all of our pancreatic hepatobiliary surgeries are performed at our Mount Carmel West campus because that is where the expertise is. We try to co-locate services that are low volume, high-risk."

Currently Mount Carmel works through the local Columbus CCOP (Community Clinical Oncology Program) to offer clinical trial options to patients. Additionally, the medical oncologists have a research department within their practice at the Zangmeister Center. Patients that do not qualify for available CCOP or Zangmeister Center trials can be referred to the NCI-designated James Cancer Hospital of the Ohio State University Medical Center.

Cancer Risk Program

The Mount Carmel Cancer Risk Program helps patients determine and reduce their risk of developing cancer. Physicians and patient navigators can refer patients to the program, or patients may self-refer. The

risk-assessment team includes physicians, certified genetic counselors, and an intake coordinator. Together, this multidisciplinary team performs a comprehensive assessment of a patient's personal and family medical history and offers genetic testing when appropriate. Mount Carmel has worked hard to establish processes to develop a robust risk-assessment program that is free to patients. Patient navigators provide education on genetic testing throughout the treatment journey, and radiologists are taught to pay close attention to a patient's family history.

Survivorship Services

While survivorship services are offered at all the acute care facilities, the new Cancer Survivorship Center is located at Mount Carmel East. The center is a 3,000-square-foot dedicated space that acts as the hub for all Mount Carmel survivorship care. Opened in November 2013, the center is dedicated to Dr. Chung Yin, the "original" radiation oncologist at the Mount Carmel East campus who died from cancer prior to the department relocating to the Zangmeister Center.

"It is a fitting tribute to him," said Kathy Grassman, system director for Radiation Therapy. "He always addressed the psychosocial needs of the patients, families, and staff." Readying the space to offer survivorship services was not without its challenges. "It is not a typical office space or even a typical survivorship center. It is quite a unique space and has a lot of room for patient activity, but it can be challenging from an office perspective," said Michael Uscio, manager of Survivorship Services.

Top: The Cancer Survivorship Center provides patients and family members a one-point access to a variety of services, programs, and staff. Above: Available in the Center, *Images for Women* cancer boutique offers a wide assortment of breast prostheses, bras, swimwear, and other items.

Renovation challenges included gutting exam rooms to make room for staff offices, and transforming radiation vaults into a patient exercise room and a conference room. To preserve some of the history of the space, the one-ton door remains on one of the former radiation vaults.

Survivorship services are free to all patients, with funding for the center and renovations provided by the Mount Carmel Foundation.

Mount Carmel envisions the center as a one-stop-shop for cancer survivors. "A patient could come in, meet with their navigator, get fitted for a surgical bra, and meet with the genetics counselor all in one visit," said Uscio. An *Images for Women* boutique sells surgical bras and prostheses onsite.

Patients have access to lung and colorectal screening through the one call-access number at the survivorship center. These programs screened 308 patients and 91 patients in 2013, respectively.

tools

Approved Drugs

• The Food and Drug Administration (FDA) has approved **Aloxi® (palonosetron HCl) injection** (Eisai Inc., www.eisai.com/US) for the prevention of acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including highly emetogenic cancer chemotherapy, in children aged 1 month to less than 17 years.

• Eli Lilly and Company (www.lilly.com) announced that the FDA has approved **Cyramza™ (ramucirumab)** for use as a single agent for the treatment of patients with advanced or metastatic, gastric or gastroesophageal junction (GEJ) adenocarcinoma with disease progression on or after prior treatment with fluoropyrimidine- or platinum-containing chemotherapy.

• The FDA has approved a 20 mg/ml oral suspension of **Purixan™ (mercaptopurine)** (NOVA Laboratories Limited, www.novalabs.co.uk). Purixan is indicated for the treatment of patients with acute lymphoblastic leukemia as part of a combination regimen.

• Teva Pharmaceutical Industries Ltd. (www.tevapharm.com) announced that the FDA has approved **Synribo® (omacetaxine mepesuccinate)** for injection, for subcutaneous use, to include home administration; the agency also approved a related Medication Guide and Instructions for Use.

• The FDA has approved a new indication for **Vectibix® (panitumumab)** (Amgen, www.amgen.com) for use in combination with FOLFOX, as first-line treatment in patients with wild-type *KRAS* metastatic colorectal cancer (mCRC). The FDA also approved the **Therascreen® KRAS RGQ PCR Kit** (Qiagen, www.qiagen.com) as a companion diagnostic for Vectibix. Vectibix is not indicated for the treatment of patients with *KRAS*-mutant mCRC or for whom *KRAS* mutation status is unknown.

• Novartis (www.novartisoncology.com) announced FDA approval of **Zykadia™ (certinib)** for patients with a certain type of late-stage non-small cell lung cancer.

Drugs in the News

• The FDA has granted orphan drug designation to **ADXS-HPV** (Advaxis, Inc., www.advaxis.com) for the treatment of Stage II-IV invasive cervical cancer. ADXS-HPV is an immunotherapy that is designed to target cells expressing the HPV gene E7.

• OncoMed Pharmaceuticals Inc., (www.oncomed.com) announced that **Demcizumab (anti-DLL4, OMP-21M18)** has received FDA orphan drug designation for the treatment of pancreatic cancer.

• The FDA has granted orphan drug designation to **Selinexor (KPT-330) oral** (Karyopharm Therapeutics Inc., www.karyopharm.com) for the treatment of acute myeloid leukemia.

Approved Devices

• Olympus (www.medical.olympusamerica.com) announced the commercial availability of its 510(k) cleared, next-generation **Endocapsule 10 System** for small bowel capsule endoscopy procedures; **BF-P190 and BF-XP190 bronchoscopes** for peripheral and small anatomy bronchoscopy; and **GIF-1TH190 gastrointestinal videoscope** for endoscopy or endoscopic surgery use within the upper digestive tract.

• GE Healthcare (www.gehealthcare.com) announced FDA approval and the U.S. launch of their new breast imaging technology, the **Invenia™ ABUS**.

Generic Version of Paraplatin® Injection Launched

Mylan Inc. (www.mylan.com) has launched **Carboplatin Injection**, 50 mg/5 ml, in multi-dose vials, a generic version of Bristol-Myers Squibb's Paraplatin Injection.

Genetic Testing Registry

In response to continued advances in genomic technology and genetic medicine, the National Institutes of Health has developed the Genetic Testing Registry, a free online resource, to provide physicians, researchers, and patients with detailed and accurate information about genetic and genomic tests. www.ncbi.nlm.nih.gov/gtr.

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Integrating Palliative Care into a Medical Oncology Practice

BY BRIAN BELL, MD;
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PATRICIA HEGEDUS, RN, OCN, MBA;
AND KATHY LINDSEY, DNP, CHPN

In recent years, the importance of integrating palliative care into standard oncology care has received increased attention. The 2012 American Society of Clinical Oncology (ASCO) Provisional Clinical Opinion on the integration of palliative care into standard oncology care states that substantial evidence demonstrates "palliative care—when combined with standard cancer care or as the main focus of care—leads to better patient and caregiver outcomes. These include improvement in symptoms, QOL [quality of life], and patient satisfaction, with reduced caregiver burden. Earlier involvement of palliative care also leads to more appropriate referral to and use of hospice, and reduced use of futile intensive care."[1]

Professional societies endorse the incorporation of palliative care services into oncology practice. For example, the National Comprehensive Cancer Network (NCCN) recommends screening every cancer patient for palliative care needs. NCCN recommends palliative care for uncontrolled symptoms, moderate-to-severe distress associated with cancer diagnosis, serious co-morbid physical or psychosocial conditions, life expectancy of less than one year, and/or patient and family concerns about the course of disease and decision-making.[2] ASCO has incorporated supportive care measures into its Quality Oncology Practice Initiative (QOPI®); QOPI measures focus on pain, psychosocial concerns, and end of life (see Table 1, page 22).[3] Finally, the Commission on Cancer has added palliative care requirements into its accreditation standards.[4]

Despite this, as noted in the 2013 IOM report Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis "…many patients do not receive palliative care to manage their symptoms and side effects from treatment. Most often this occurs because the clinician lacks knowledge of how to provide this care (or how to make referrals to palliative care consultants) or does not identify palliative care management as an important component of high-quality cancer care."[5]

Understanding the Role of Palliative Care

Palliative care, as defined by The Center to Advance Palliative Care, is "…focused on providing patients with relief from the symptoms, pain, and stress of a serious illness whatever the diagnosis. The goal is to improve quality of life for both the patient and the family. Palliative care is provided by a team of physicians, nurses, and other specialists who work with a patient's other physicians to provide an extra layer of support. Palliative care is appropriate at any age and at any stage in a serious illness, and can be provided together with curative treatment."[6]

Palliative care is appropriate at any age and at any stage in a serious illness, and can be provided together with curative treatment.

Cancer patients should receive palliative care concurrently with curative care. Figure 1, page 23, shows how palliative care should be delivered in the community setting. When patients are first diagnosed with cancer (gray area on the far left of the figure),

Table 1. QOPI Measures That Focus on Palliative Care[4]

Core Measure	Description of Core Measure
3	Pain assessed by second office visit
4	Pain intensity quantified by the second office visit
5	For patients with moderate to severe pain, documentation that pain was addressed
6	Effectiveness of pain medication assessed on visit following new narcotic medication
7	Constipation assessed at time of, or at first visit following, new narcotic medication
21	Chart documents patient's emotional well-being was assessed within 1 month of first visit to office
22	For patients identified with a problem with emotional well-being, the chart documents that action was taken within 1 month
End of Life Measure	**Description of End of Life Measure**
35	Pain assessed on the second to last or last visit before death
36	Pain intensity quantified on second to last or last visit before death
37	Dyspnea assessed on second to last or last visit before death
38	Action taken to ease dyspnea on the second to last or last visit before death
39	Patient enrolled in hospice before death
40	Patient enrolled in hospice or referred for palliative care services before death
41	Patient enrolled in hospice within 3 days of death
42	Patient enrolled in hospice within 1 week of death
43	For patients not referred in last 2 months of life, hospice or palliative care discussed
44	Chemotherapy administered within last 2 weeks of life

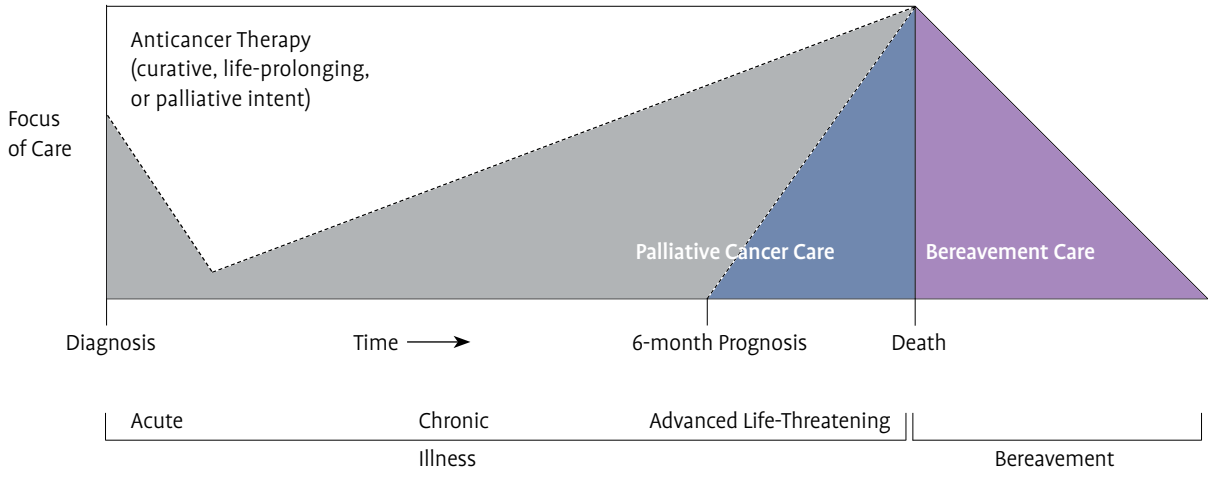
they may have a number of palliative care needs, including symptom-related issues. Once these patients enter into active or curative treatment (represented in white), their palliative care needs often decline. But, as Figure 1 illustrates, curative and palliative care are provided together, based on specific patient needs. If the disease progresses and if there is not a cure, the life-prolonging treatments diminish and palliative care treatment increases until a patient may need hospice care (represented in blue) and/or the patient passes away and the family members and caregivers enter into bereavement (represented in purple).

Our Supportive Care Clinic

The development of our Supportive Care Clinic began in 2012 when the Cancer Care Committee identified implementation of an outpatient palliative care clinic as a quality improvement initiative. The committee recognized that an outpatient palliative care clinic that followed a patient from the moment of diagnosis until the time of an appropriate hospice referral offered opportunities to improve patient care and quality of life—especially for patients diagnosed with late-stage disease. (Prior to 2012, Spartanburg Regional's palliative care program consisted only of inpatient consultation services.)

Medical and administrative leadership from Gibbs Cancer Center & Research Institute met with members of Spartanburg Regional's palliative care program to discuss how the two departments could collaborate on an innovative design for the new outpatient Supportive Care Clinic. The clinic name was carefully chosen based on MD Anderson data that reported

Figure 1. How Palliative Care is Delivered in the Community Setting



that use of the name "Supportive Care" resulted in increased and earlier referrals to palliative care, as well as decreased clinician distress.[7] After much discussion, it was also decided that the marketing materials of the new Supportive Care Clinic would mirror the look and feel of the Gibbs Cancer Center. The results are an innovative design for the outpatient Supportive Care Clinic.

Planning the Clinic

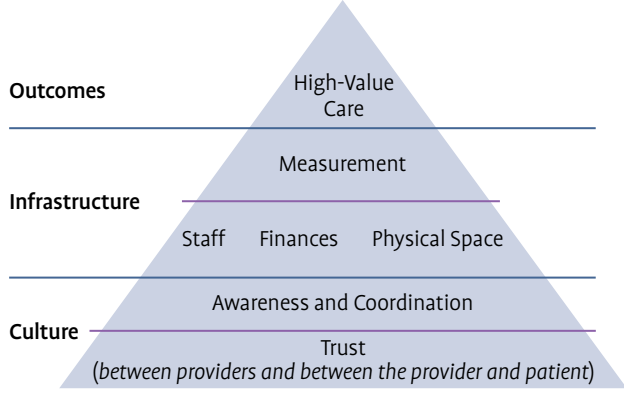
The next step was to put together a multidisciplinary development team whose members included a licensed clinical social worker, a registered nurse, two nurse practitioners, and a palliative care physician. The team's design process used a conceptual model of a successful palliative care program that incorporated culture, infrastructure, and outcomes (see Figure 2, right).[7]

The decision was made to embed the Supportive Care Clinic right into the private medical oncology practice at Gibbs Cancer Center & Research Institute. The practice agreed to provide physical space for the Supportive Care Clinic and to staff the clinic with two of its experienced Advanced Practice Registered Nurses (APRNs). The clinic would be held one half-day each week on Friday during the practice's regular business hours. The Supportive Care Clinic would use the practice's EMR for registration, documentation, and billing, which would allow all providers to access the most current medical record.

Staffing the Clinic

An APRN from the medical oncology practice and a palliative care registered nurse (RN) from Spartanburg Regional's palliative care team coordinate the weekly clinic, with oversight from the medical director of Spartanburg Regional's Palliative Care Program. A medical social worker (MSW) from the Gibbs Cancer Institute & Research Clinic rounds out the clinic staff. Two APRNs from

Figure 2. Conceptual Model of a Successful Palliative Care Program[7]



the medical oncology practice were asked to fill the APRN role at the Supportive Care Clinic, and they alternate weeks staffing the clinic. Involving two APRNs from the oncology practice has been key to building a trusting relationship between the medical oncologists and the Supportive Care Clinic. The APRNs are available for immediate consultation at the medical oncology practice and help facilitate referrals to the Supportive Care Clinic. Both the Palliative Care medical director and an APRN attend site-specific multidisciplinary planning conferences with a focus on identifying appropriate referrals to the Supportive Care Clinic.

Training Clinic Staff

In June 2012, approximately three months before the opening of the Supportive Care Clinic, the Palliative Care and Hospice Program medical directors provided 32 hours of palliative care education for the two APRNs who would help to staff the clinic. In addition to completing a communication workshop, the APRNs worked with the inpatient palliative care team and a hospice RN. Didactics included:

- Prognosis
- Palliative care theory
- Advanced symptom management
- Outpatient palliative care
- Spiritual care
- Palliative care billing.

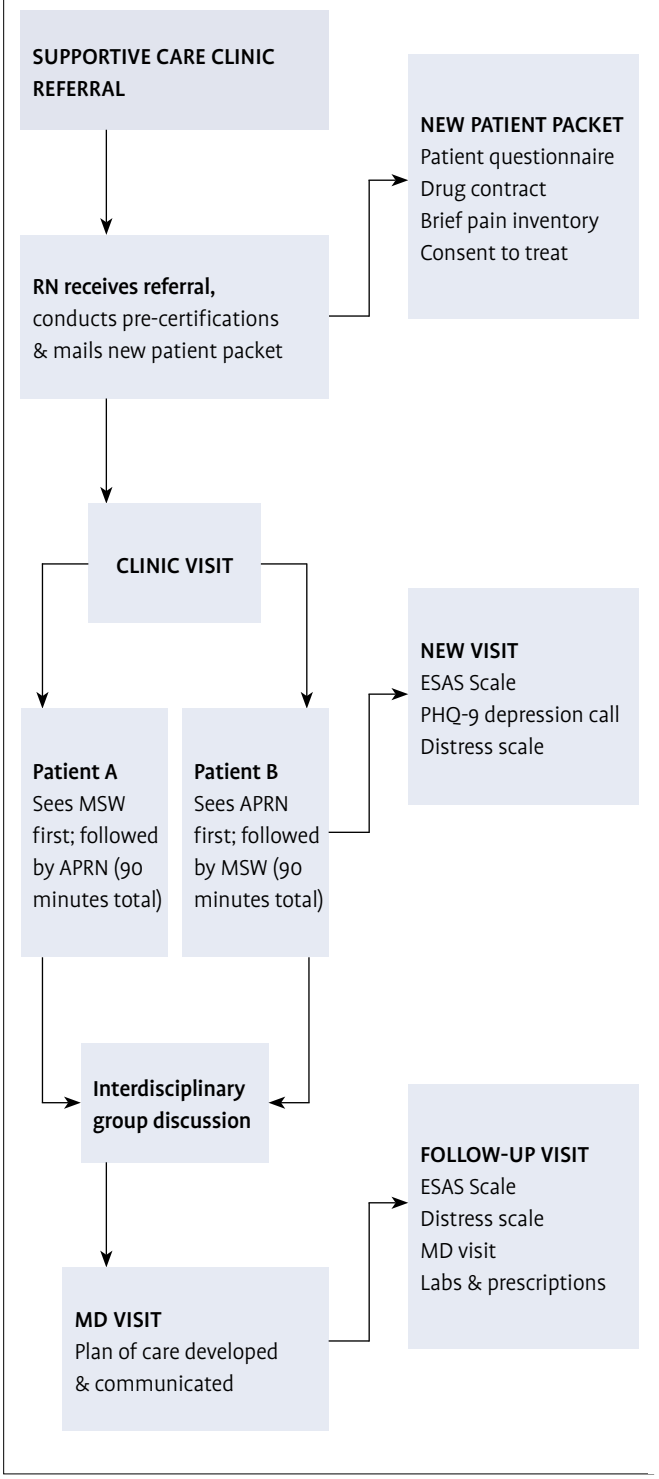
Patient Visit Flow Process

Our Supportive Care Clinic saw its first patient in September 2012. The clinic is structured so that the palliative care RN sees patients first, interviewing them and updating and completing their history and medication profile. The medical social worker follows, gathering additional information from patients and family members. Next, the APRN sees the patient and dictates the history and physical. Then the team huddles to discuss the patient and plan next steps. The appointment concludes with the patient seeing the Palliative Care medical director who performs a medical assessment and then discusses the care plan with the patient. The palliative care physician dictates the assessment and the plan, based on the following five domains:

- Prognosis
- Domain 1: Understanding Goals of Care & Prognosis
- Domain 2: Physical Symptoms
- Domain 3: Psychosocial & Practical Issues
- Domain 4: Spiritual & Cultural Issues
- Domain 5: End of Life, Advanced Care Planning & Hospice.

The palliative care RN closes the patient's clinic appointment by reviewing any medication changes, providing copies of signed paperwork, and making follow-up appointments. In three days,

Figure 3. Supportive Care Clinic Workflow



(Left to right) Supportive Care Clinic Team: Amy Sanders, NP; Chad Dingman, LISW-CP, OSW-C; Ashleigh Pintoff, RN; Brian Bell, MD; and Melissa McCarter, NP.

the palliative care RN follows up by phone with patients with excessive symptoms (symptoms with a score of four or above on the Edmondton Symptom Assessment Scale [ESAS]). All patients are given a phone number that they can call to contact a palliative care provider, seven days a week, through the Spartanburg Regional Call Center. Figure 3, left, illustrates the clinic's patient visit flow process.

Outcome Measures

The first nine months of the Supportive Care Clinic saw 71 patient referrals. Of these, a total of 49 patients were seen in the clinic. Of all appointments scheduled during this period, 22 percent resulted in no shows. Many of the "no show" patients reported later that they felt too poorly to attend the clinic. To help improve this no-show rate, the palliative care RN now contacts each referred patient by phone to initiate the relationship with the Supportive Care Clinic staff and to encourage patients to keep their appointments. Patients receive a second phone call two days before their clinic appointment, encouraging them to keep the appointment. The average age of clinic patients has been 56.7 years, and 53 percent have been male. Eighteen percent of the clinic patients have made three or more visits to the Supportive Care Clinic.

... the APRNs have been receptive to palliative care principles and philosophy, and the hope is that they will now be able to share this information within their medical oncology practice.

We have realized enormous benefits from our staffing model. Palliative care staff has learned from the medical oncology APRNs' cancer care expertise; the APRNs now serve as enthusiastic liaisons for the Supportive Care Clinic. In turn, the APRNs have been receptive to palliative care principles and philosophy, and the hope is that they will now be able to share this information within their medical oncology practice.

During the first nine months of the Supportive Care Clinic, patients have demonstrated a 13 percent decrease in pain scores from the first visit to the last visit, and a 17 percent decrease in ESAS scores during the same time frame.

Supportive Care Clinic goals for the next six months will measure:

- Volume: 80 new patients total for the 12-month period.
- Productivity: 8 patient visits per half-day clinic (2 new and 6 follow-up visits).
- Quality: A 15 percent decrease in pain scores from average first visit score to average last visit score.
- Quality: A 25 percent decrease in distress scores in the highest distress group from average first visit score to average last visit score.
- Quality: A 20 percent decrease in total ESAS score from average first visit score to average last visit score.

Palliative care in both inpatient and outpatient care settings is integral to high-quality patient-centered care.

Business Plan

In our model, the new Supportive Care Clinic used existing staff and space. The clinic generated only minimal additional expenses, e.g., fees related to additional licensure and billing services. Our team secured a grant from Spartanburg Regional Foundation to underwrite planned expenditures for patient and family educational materials and to host a Palliative Care Regional Medical Conference, which was held in Spartanburg, S.C., May 1–2, 2014. Future plans include expansion of the half-day Supportive Care Clinic from once a week to twice a week; the medical oncology practice has agreed to continue to provide the APRN, MSW, and clinic space.

Palliative care in both inpatient and outpatient care settings is integral to high-quality patient-centered care. Currently, our clinic is the only outpatient Supportive Care Clinic in the region. We continue to evaluate the success of the Supportive Care Clinic and plan to replicate this model to address similar needs for other chronic diseases. OI

Brian Bell, MD, is Palliative Care medical director, Spartanburg Regional Hospital, Gibbs Cancer Center & Research Institute, Spartanburg, S.C. Linda Harris, RN, MPH, is the Hospice director at Spartanburg Regional Hospice. Patricia Hegedus, RN, OCN, MBA, is the Oncology Clinical Performance & Support Services director at Gibbs Cancer Center & Research Institute. Kathy Lindsey, DNP, CHPN, is the Compliance manager at Spartanburg Regional Hospice.

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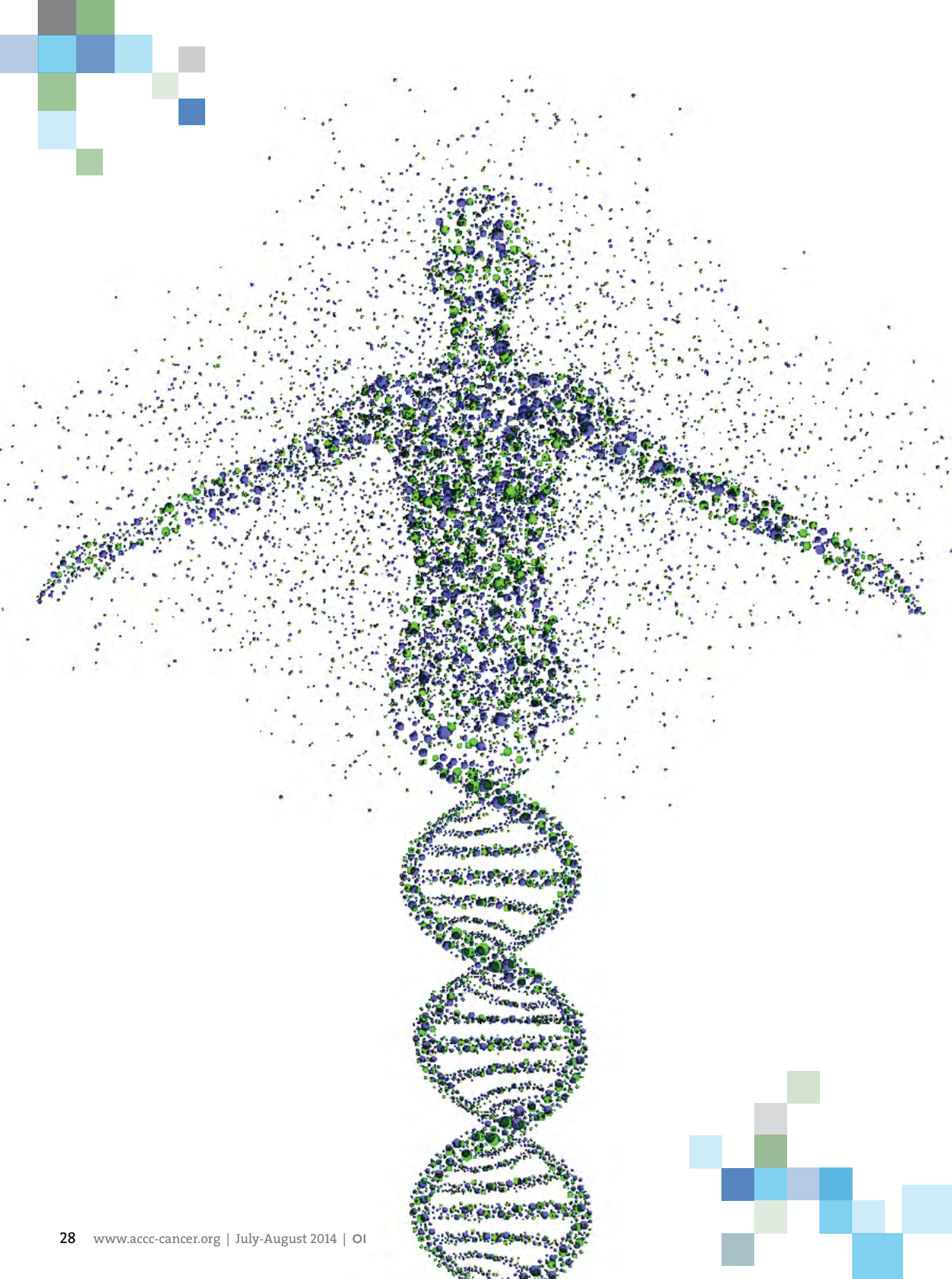


BY JENNIFER N. EICHMEYER, MS, CGC

Improving Access to Oncology Genetic Counseling

While only 5 to 10 percent of cancer diagnoses are associated with a hereditary syndrome, many of these syndromes have an alarmingly high lifetime risk of cancer—approaching 80 to 100 percent, with development of disease at younger ages than in the general population.[1-3] Recent advancements in genetic testing have led to a rapid growth in the knowledge of hereditary cancer syndromes. Options for families facing these risks may include prophylactic surgery, such as mastectomy; earlier cancer screening; and chemoprevention.[1, 2, 4] The key to providing appropriate prevention and medical management is identification of at-risk individuals and access to genetics experts for a thorough assessment. In 2011-2012, St. Luke's Mountain States Tumor Institute (MSTI) implemented two quality improvement projects for its genetic counseling program: telehealth and chart review.

Our Program At-a-Glance

Idaho is the 14th largest state with a population of more than 1.5 million; approximately 40 percent live in rural settings. MSTI is Idaho's largest provider of cancer care services, serving more than 3,000 new patients yearly in Boise, Fruitland, Nampa, Meridian, and Twin Falls. The MSTI Hereditary Cancer Assessment Clinic opened its doors in 2004. Staffed by a genetic counselor two days per week, services were originally only available at the Boise location. Since that time MSTI's genetic counseling department has seen tremendous growth. Today genetic counseling services are provided at all five MSTI sites.

Why Telehealth?

With so much mileage to cover over mountainous terrain and a steady increase in the demand for services during an economic downturn, MSTI had to find a creative solution to address the issue of access to genetic counseling services. Telehealth had been proposed for several years with more and more literature supporting it as a successful option for oncology clinics in rural settings. However, the investment expense, as well as the sheer volume of healthcare providers who would potentially demand telehealth services, was daunting. To avoid the risks inherent in a large-scale rollout and to gain the buy-in of executives and stakeholders within St. Luke's, MSTI employed small-scale "proofs of concept" (POCs) that could be rapidly implemented. POCs were a low-risk option that would allow MSTI the opportunity to test and refine ideas, while developing competencies.

> ...with providers now using video conference technology, the telehealth POC [proof of concept] would realize some cost-savings related to travel expenses.

Additionally, with providers now using video conference technology, the telehealth POC would realize some cost-savings related to travel expenses.

Telehealth POCs

Genetic counseling and nutrition counseling—both part of MSTI's supportive services—were selected for the first telehealth POCs.

Figure 1. Telehealth Patient Satisfaction Questionnaire

Circle one answer in the box below per question	EXCELLENT	VERY GOOD	GOOD	FAIR	POOR	N/A
Rate your satisfaction using the telehealth audio and visual cart.	5	4	3	2	1	0
Rate your overall satisfaction with the telehealth cart set up.	5	4	3	2	1	0
Rate the timeliness of getting connected to the outside clinician and/or service through the telehealth cart.	5	4	3	2	1	0
Rate the likelihood you would use the telehealth service for future patients.	5	4	3	2	1	0
Rate the likelihood you would recommend telehealth to your friends or family as an effective way of receiving care.	5	4	3	2	1	0

Tell us what worked well and what did not work well (audio, visual, clarity, distractions).

What could we do better to meet your care needs through this experience?

This decision was based on the fact that these service lines do not require the use of peripheral devices, such as stethoscopes and/or examination cameras, and would only need a quality audio visual connection between patient and provider for content sharing. MSTI chose Fruitland as the recipient telehealth site, as this location had the staffing resources and physical space to accommodate the POC project. The city of Fruitland is a small rural community of just over 4,500 residents in southwest Idaho, located 60 miles west of Boise near the Oregon border. Prior to telehealth, patients in Fruitland and the surrounding areas had access to a cancer genetic counselor twice a month on Fridays and the average wait time for an appointment was 23 days.

Based on budget constraints, MSTI chose Microsoft Lync as the video communications platform for the POC project. MSTI already owned the platform, and it was compatible with Microsoft Outlook, which had been recently deployed system-wide as the

Given the time constraints that oncologists are under during an initial consultation, genetic counselors can help identify patients who are appropriate for a genetics evaluation.

email platform. Equipment needs included a desktop computer, an HD web camera, a USB speaker and microphone, and dual monitors for the transportable cart in Fruitland. Initially, providers used a laptop computer equipped with a camera in the hope that telehealth visits could occur wirelessly. However, MSTI quickly found that the video and audio quality was suboptimal. To address that issue, MSTI built a provider unit that included a desktop computer, the HD web camera, the USB speaker and microphone, dual monitors, a document camera, and wired network ports in all rooms where the cart and provider workstation would be used. Equipment costs, including the telehealth cart, were $7,200.

A certified assistant personnel (CAP, the equivalent of a certified medical assistant) was trained to operate the transportable cart at the Fruitland site, including connecting with the transmitting provider and troubleshooting any problems that arose, including issues with the equipment. This staff member also performed blood draw (or sample collection), obtained signed consent forms, and administered a patient satisfaction questionnaire. Patients were asked to complete the new Telehealth Patient Experience Questionnaire (Figure 1, left) immediately following the genetic counseling telehealth visit.

At the Boise site, the genetic counselor used PowerPoint slides during the telehealth visit to demonstrate key concepts. These slides mimicked the same visual aids used during in-person counseling. A document camera allowed the patient to see the pedigree and actively participate in the pedigree assessment. The genetic counselor was able to switch between these cameras to show all aspects of the genetic counseling session as necessary.

Engaging patients through video is quite different from an in-person meeting. Providers had to learn and incorporate "Telehealth Etiquette" (small talk, longer pauses, camera placement, more verbal descriptions of thought processes, etc.) to enhance communication and comfort for both providers and the patients. MSTI created several tools to assist staff, including:

- A telehealth point-of-care script and telehealth process flowchart for introducing a patient to the telemedicine cart (Figure 2, page 32)
- A telehealth genetic counseling process flowchart (Figure 3, page 33)
- A telehealth visit etiquette checklist.

Outcomes of the Telehealth POC

MSTI selected the following metrics to measure the success of the POC:

- Provider travel time and costs (cost savings)
- Elapsed time from referral to first scheduled appointment (improved access)
- Comparison of patient volumes (increased use of services).

During the three-month telehealth POC, 23 genetic counseling appointments were conducted. These appointments resulted in a savings of $1,050 in mileage and travel wages and 13.5 travel hours. MSTI estimated return on investment for 12 months to be 28 percent for genetic counseling and nutrition telehealth usage (see Figure 4, page 35).

Wait times for genetic counseling appointments dropped from 23 days to 16 days; appointment volumes increased from 6 appointments per month to 8 appointments per month. Patients had a greater variety of appointment scheduling options, with 16 hours per month to choose from on variable days as opposed to 8 hours per month on only Fridays. (Same day appointments were available for urgent needs.)

Most patients had not experienced a telehealth visit before, and yet they were satisfied with the service. Patient scores (N=12) demonstrated "Excellent" ratings (5/5) in the following:

- 83 percent satisfaction using the telehealth cart
- 83 percent likelihood to use telehealth again
- 92 percent would recommend telehealth to a friend.

For two appointments, MSTI had to use interpretation services—both received high patient satisfaction scores. Figure 5, page 36, shows all patient satisfaction scores.

The Chart Review Process

Often the first barrier to patient access to genetic counseling is awareness that genetic services are an option and/or are recommended. Guidelines for patient referral for a cancer genetics evaluation are well established.[1-6] National Comprehensive Cancer Network (NCCN) *Clinical Practice Guidelines in Oncology* provides criteria for genetics referrals that are continuously amended and updated.[7] Unfortunately, low rates for genetic risk assessment continue, suggesting that perhaps more than half of patients who qualify for genetic counseling are not referred to these services.[8-15] Baseline data from 2010 indicated that of total eligible patients at MSTI, 58 percent (n=152) were offered genetic counseling—data that is similar to national numbers.

Genetic counselors are uniquely qualified to identify appropriate patients, as well as provide improved understanding of significant features in a family history.[1,3,15,16] Given the time constraints that oncologists are under during an initial consultation, genetic counselors can help identify patients who are appropriate for a genetics evaluation. In an effort to improve referral rates to genetic counseling services, MSTI implemented a project

(continued on page 34)

Figure 2. Telemedicine Point-of-Care Script & Process Flow
Certified Assistant Personnel (CAP) Communication with Patient

INTRODUCTION

Hello _____ I am _____. I understand your clinician recommended a video-conference consultation with our genetic counselor who is located at another site. The video-conference allows immediate connection to our providers when they're not in the clinic, so you don't have to wait for an appointment—reducing the delay in your care.

_____ (Name of the genetic counselor) will appear on the left hand screen and important education information will appear on the right hand screen. I will get you started and then leave the room for your privacy. I will check in after a couple of minutes to make sure everything is working okay. Do you have any questions?

Thank you.

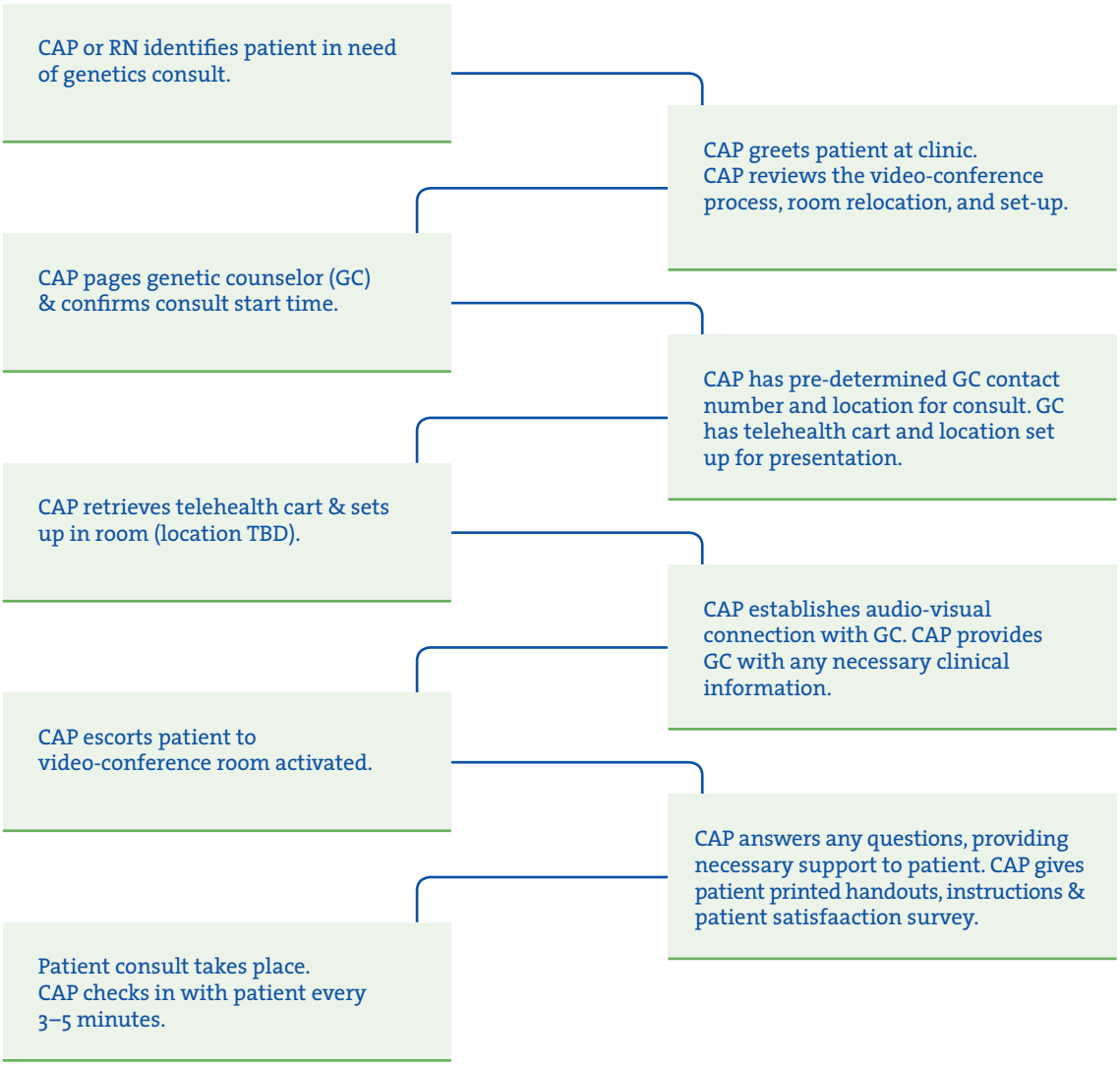
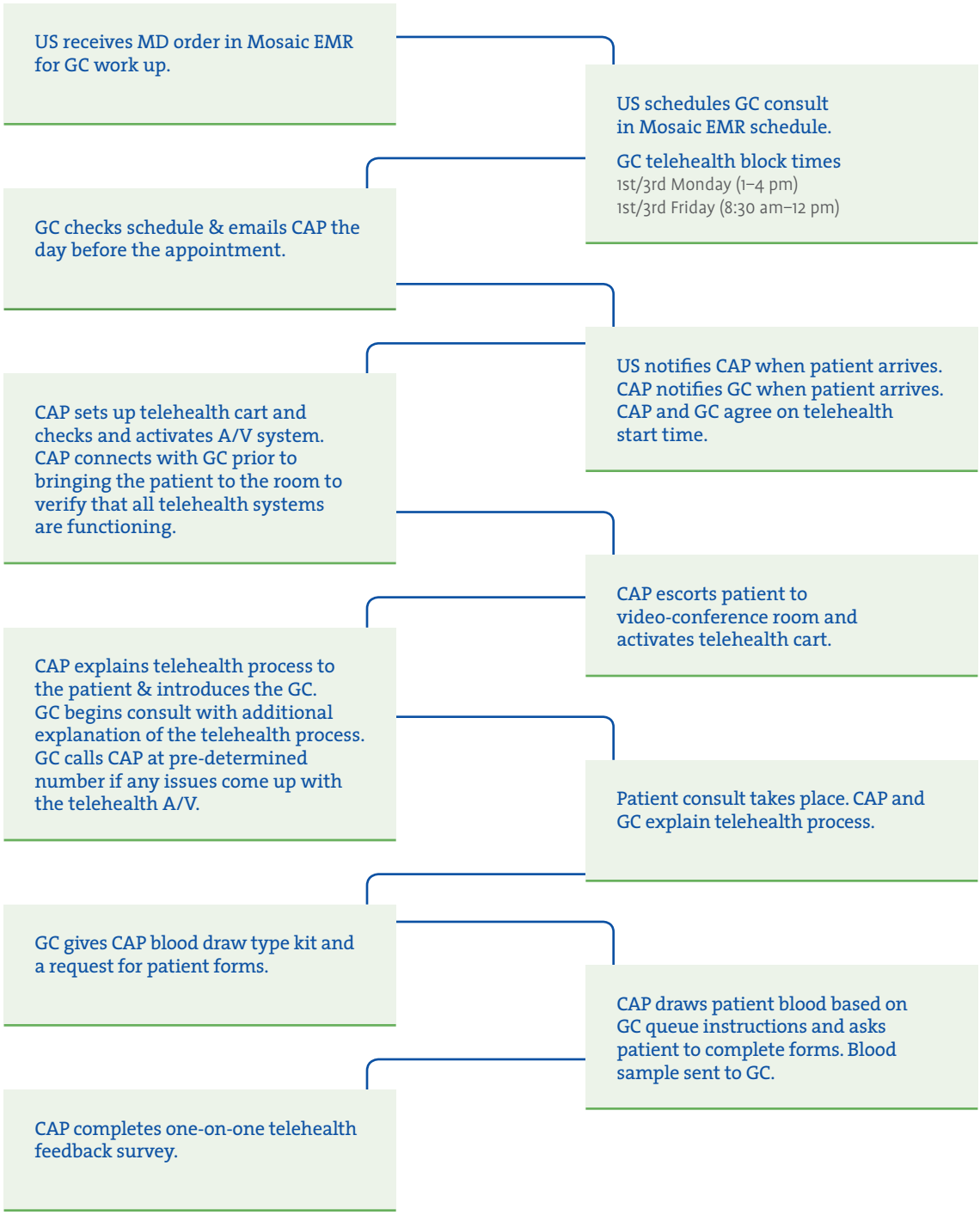


Figure 3. Telehealth Genetic Counseling Process Flow

GC = Genetic Counselor **TH** = Telehealth **US** = Unit Scheduler **CAP** = Certified Assistant Personnel (in clinic with the patient)



(continued from page 31)
where a genetic counselor would review the charts of all new oncology patients.[17]

To obtain support and input, MSTI's medical director, a medical oncologist, acted as physician champion. He brought the project to MSTI leadership meetings and took the genetic counselor to meet with the management council. Additionally, support staff met with each oncologist involved in the chart review prior to launch to determine which electronic communication method would be most effective and address any questions or concerns.[17]

> Increasing access to genetic counseling can lead to better preventive care for patients with hereditary cancer syndromes, cost savings, and improved outcomes.

MSTI uses the MOSAIQ EMR system for charting, scheduling, and communications between staff and providers. Support staff generated weekly reports of all patients with a specific appointment type (New Patient, 1-hour). Each patient chart was reviewed focusing on pathology, age, and family history. Eligibility for a genetics referral was based on NCCN guidelines: patients diagnosed with ovarian cancer at any age and patients diagnosed with breast, colon, and uterine cancer under the age of 50. If an eligible patient was not referred for genetic counseling, or if the oncologist did not provide documentation of genetics discussion, the genetic counselor flagged the patient's chart and provided an explanation of why the patient had been identified. The assigned physician determined if referral to genetics was approved and sent orders to scheduling. Support staff then generated weekly reports of identified patients for tracking and follow-up purposes.[17]

Outcomes of the Chart Review

The chart review project took two months to launch. MSTI put chart review into operation in September 2011, and the project lasted 10 months. The genetic counselor identified a total of 129 patients as candidates for genetic counseling who had not been referred or whose chart did not document discussion with the oncologist. After the project was implemented 70 percent (n=167) of eligible patients were offered genetic counseling or documentation of a genetics discussion was provided in the chart. This is a significant increase over baseline data. Patient identification for ovarian cancer was also statistically significant; improvements in breast and colon cancers were noted but were not significant.[17]

On average the genetic counselor conducted 73 chart reviews a week (60 to 80 minutes of work). Over one year, this added approximately 52 hours, or a 2.5 percent increase to a 40-hour work week. After streamlining the chart review process, MSTI's genetic counselor was able to incorporate chart review into her daily job responsibilities without impacting other patient care and management duties. In the end, the addition of slightly more than one hour of work per week for the genetic counselor improved the referral of eligible patients and facilitated the identification of three families with a hereditary cancer syndrome who might otherwise have been missed.[17] As a greater variety of genetics referrals were noted during the study period, data suggests that genetic counselors can provide expert support to oncologists beyond traditional referral indications. The recurring interaction between the genetic counselor and the oncologists allowed for educational opportunities; as oncologists became more aware, there was an increase in referrals of more complex family histories. Project data also suggests that the reminder of genetics on a regular basis improved the oncologist's attention to family history, as well as documentation in the chart.[17]

Although a chart review may appear an overwhelming undertaking, the task was deemed worthwhile to include in the job responsibilities of MSTI's genetic counselors and was easily implemented at the busy genetic counseling clinic. In 2013 MSTI decided to expand chart review to all five MSTI sites. With the additional workload plus the increased patient volumes, administration used the chart review project as justification for adding a part-time genetic counselor on staff.[17]

Improved Care

Increasing access to genetic counseling can lead to better preventive care for patients with hereditary cancer syndromes, cost savings, and improved outcomes.

The main goal of the telehealth and chart review projects was to improve patient access to cancer genetic counseling services. While cost savings alone justified the expense required to get MSTI's telehealth program up and running, telehealth also improved care by decreasing wait times and increasing access to genetic counseling appointments. The Fruitland telehealth project received executive buy-in and expansion to additional outreach sites was subsequently approved. Because some of these rural locations are even farther from the Boise site, genetic counselors will be able to save even more on travel time and mileage expenses, while devoting valuable time to direct patient care.

MSTI's chart review project achieved similar results as more patients who qualified for genetic assessments were offered an evaluation. With specialized training to recognize significant family histories, genetic counselors were able to help oncologists

Figure 4. Return on Investment on MSTI Telehealth POC

INPUTS

Travel reimbursement rate ..... $ 0.55 per mile
Average travel distance..... 120 miles
Provider time (cost)..... $ 45.00 per hour
Percentage of travel time qualifying for overtime..... 75 percent
Average round-trip travel time..... 2.25 hours

Pre-Telehealth Implementation

	Travel Days Per Month	Travel Miles Per Month	Mileage Reimbursment	Travel Time Per Month	Travel Wages Per Month	Total Monthly Cost	Total Yearly Cost
Dietitian	4	480	$ 264.00	9	$ 556.88	$ 820.88	$ 9,850.50
Genetic Counselor	2	240	$ 132.00	4.5	$ 227.81	$ 359.81	$ 4,317.75
TOTALS	6	720	$ 396.00	13.5	$ 784.69	$ 1,180.69	$ 14,168.25

Post-Telehealth Implementation

	Travel Days Per Month	Travel Miles Per Month	Mileage Reimbursment	Travel Time Per Month	Travel Wages Per Month	Total Monthly Cost	Total Yearly Cost
Dietitian	2	240	$ 132.00	4.5	$ 278.44	$ 410.44	$ 4,925.25
Genetic Counselor	0	0	$ --	0	$ --	$ --	$ --
TOTALS	2	240	$ 132.00	4.5	$ 278.44	$ 410.44	$ 4,925.25

Travel-Related Savings One Year ..... $ 9,243.00
Telehealth Equipment Cost ..... $ 7,200.00
One Year ROI 28%

identify patients who may benefit from genetic assessments and improve the patient experience.[17]

Jennifer N. Eichmeyer, MS, CGC, established the first cancer genetic counseling clinic for the state of Idaho in 2004, and now serves as the lead genetic counselor for St. Luke's Mountain States Tumor Institute.

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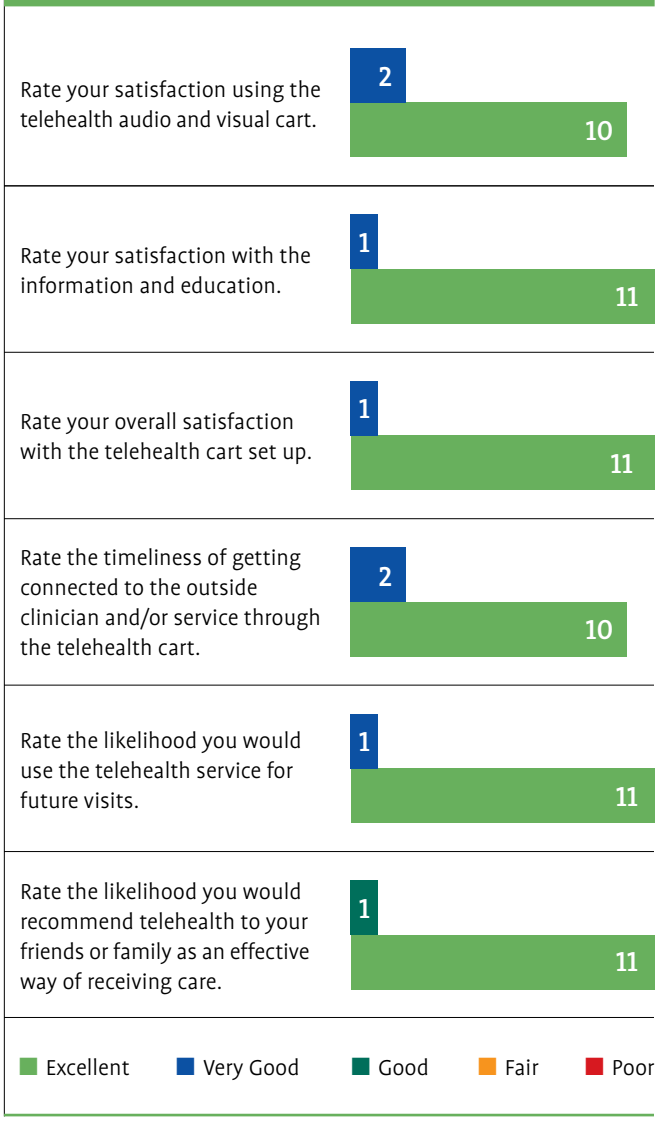
Figure 5. Telehealth Patient Satisfaction Scores



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The VIP Program

BY PAUL SHAUGHNESSY, MD, AND
JONATHAN TINKER, MHA, MBA

How Methodist Hospital improved the care of its very immunocompromised patients

After chemotherapy and/or bone marrow transplants, patients have very low blood counts and are at risk of developing febrile neutropenia, a "condition marked by fever and a lower-than-normal number of neutrophils (white blood cells), which help fight infection."[1] When white blood cells go below 500 neutrophils per cubic millimeter of blood, these patients are at very high risk of life-threatening infections. Clinicians are most concerned about the clinically important infections, such as the gram-negative bacteria. While these infections are fairly uncommon, they can progress rapidly, causing sepsis and even death if not treated very quickly—sometimes within hours. Even the more common infections, such as gram-positive bacteria from skin infections or catheter and port infections, can be quite problematic and turn into serious infections. For these reasons, febrile neutropenia is an important oncologic emergency.

To help improve the care of these patients, Methodist Hospital developed and implemented a VIP (Very Immunocompromised Patient) Program in 2012. Methodist Hospital's VIP Program received a 2013 ACCC Innovator Award. For cancer programs across the country looking to implement a similar quality improvement project, here's how it was done.

The VIP Program

As with many quality improvement initiatives, the journey started with an index (primary) case where a patient presented in the emergency department (ED) with febrile neutropenia. The ED physicians did not yet know the patient was neutropenic and because the patient looked okay, care was delayed. Bottom line: this patient (and several others) was not properly triaged and sat for too long in the emergency room.

Recognizing that improvements were necessary, Methodist Hospital brought together a physician-led team that included:

- Community oncologists and hematologists
- Oncology nurses
- Bone marrow transplant physicians
- Infectious disease physicians
- ED physicians and nurses
- Representatives from the hospital's marketing, administration, and business development departments.

This multidisciplinary team met several times to brainstorm ways to improve the care of patients with febrile neutropenia. These brainstorming sessions identified:

- Barriers to change
- Ideas to help improve assessment and decrease time to evaluation
- Ways to elevate the issue and make staff understand the importance of the condition and the necessary changes
- A process to coordinate efforts between different disciplines across multiple sites of service and programs.

The end result was the VIP Program, specifically geared towards patients undergoing chemotherapy or a bone marrow transplant in an outpatient setting. In brief, this program would function similar to existing cardiac or stroke alerts. When these patients—who are instructed to report to an ED if they experience fevers and/or chills outside of normal office hours—present at the ED,

an "Onc Alert" would immediately trigger a VIP Protocol. The VIP team knew that buy-in from ED physicians and nurses was critical to the successful implementation of the VIP Program, and that staff and patient education was key.

Developing the Onc Alert & VIP Protocol

One of the main components of the VIP Program is the Onc Alert Protocol (Figure 1, below). In this protocol, the VIP team identified the steps they wanted to see happen when a patient with febrile neutropenia showed up in an emergency room. These included:

- Triage patient
- Identify patient as an oncology patient with fever
- Immediately bring patient back for blood cultures and an assessment to make sure patient is stable
- Rapidly start the patient on antibiotics.

To help in the first step of the Onc Alert Protocol (Patient Registration), the VIP team developed an identification card for patients called the VIP Card (Figure 2, right). The card includes the name and contact information of the treating oncologist(s) so that the ED physician can easily update them about the patient's status. The VIP Card is one component in what ultimately became the VIP Kit, which also includes a thermometer and hand sanitizer. Methodist Hospital pays for the cost of making these kits; the hospital's business development department is responsible for educating community oncology practices about the VIP Kit. When kits are delivered to practices, hospital staff also provide education on what patients should do if they have a fever after office hours—namely present their VIP Card at the ED as soon as they arrive. If patients do not have their VIP Card or if they lose their VIP Card, they are instructed to tell ED staff that they are an oncology patient with a fever, which will also trigger the Onc Alert.

Figure 1. Onc Alert Protocol

PATIENT REGISTRATION	• VIP Card • Obtain name of oncologist
TRIAGE	• Onc Alert • Obtain vitals, pulse oximetry, allergies • Neutropenic precautions
WORK UP	• STAT labs • Blood culture • Antibiotic IV STAT • IV of normal saline, 100 ml per hour
ACTION PLAN	• ED physician to call oncologist • Determine admission or other plan of care

> The VIP team knew that buy-in from ED physicians and nurses was critical to the successful implementation of the VIP Program ...

The VIP team then developed a VIP Protocol, or standing order set (Figure 3, page 42), that it wanted to implement at Methodist Hospital. One of the first challenges encountered during implementation involved the name of the identification card. The ED nurses did not want to go into the waiting room and ask for the "VIP" patient. It was an easy fix. Instead the ED nurses ask for the patient with the Onc Alert. And once that Onc Alert is triggered, the following steps are supposed to happen:

- The patient's vital signs are taken
- The patient is triaged
- The necessary labs are ordered
- The patient is started on the appropriate antibiotic
- The ED physician calls the oncologist and gets the patient admitted.

All of these steps are on the standing order set and the protocol is designed to move very rapidly.

Evaluating the VIP Program

Methodist Hospital implemented the Onc Alert and VIP Protocol in June 2012. By May 2013 the hospital had more than one year of data to analyze. A retrospective review identified 206 patients who met the criteria for being an oncology patient with neutropenic fever. A little more than half of these patients (116) had the VIP Protocol initiated in the ED; the other patients did not. The VIP team had already learned its first lesson: the VIP Protocol was not being implemented uniformly. Data did reveal that rates were improving over time. For example, first quarter data showed that out of the 33 patients with febrile neutropenia only 8 were started on the VIP Protocol. By the fourth quarter, that number had reversed; out of the 32 patients that presented at the ED with febrile neutropenia, the protocol was initiated for 28 patients (see Figure 4, page 43).

Figure 2. VIP Card

Methodist Hospital also looked at time-to-start patients on antibiotics—the measure that sparked this quality improvement project. Data showed that the median door-to-antibiotic time had decreased from an average of 120 minutes (2 hours) in the first quarter to less than an hour in the last quarter. It was a significant improvement in initiating patients on antibiotics. Even better, data showed that the time-to-antibiotics was decreased even when the VIP Protocol was not ordered. In other words, just by implementing the VIP Protocol and educating the ED nurses and physicians about the protocol, the hospital was able to change behavior, culture, and the thought process behind how to treat these patients. Regardless of whether or not the Onc Alert was called, emergency departments were analyzing and triaging these patients more rapidly than before.

When the VIP team made the VIP Protocol into a pre-printed order set, the hospital realized additional improvements. Now, triage nurses and physician assistants in the ED were empowered to treat patients with febrile neutropenia. Making the VIP Protocol a pre-printed, standing order set is what really reduced and kept the time-to-antibiotics down. Figure 5, page 44, shows how the VIP team was able to increase the percentage of patients receiving antibiotics within 60 minutes from 10 percent to 45 percent. Of course, the team would like to see this number at 100 percent, so work must still be done.

The VIP Program has resulted in success for numerous stakeholders. For example, the ED nurses and physicians have found the program successful because they are now able to appropriately triage and diagnose patients with febrile neutropenia when they come into the ED. The oncologists and the transplant physicians find the program successful because it provides an additional level of support for individuals undergoing treatment in an outpatient setting. Most important, patients and families are very satisfied with the VIP Program because it provides them with a level of assurance about what to do after hours (or at any time) and where they can be connected to appropriate care in case of an emergency.

Lessons Learned

When Methodist Hospital first implemented the VIP Protocol in June 2012, it did not see an immediate decrease in the time-to-antibiotics and the VIP team wanted to understand why. So members of the VIP team went back to the ED nurses and physicians. They attended their staff meetings and communicated to them that the VIP Protocol was not being initiated consistently and that the time-to-antibiotic was not being reduced as much as the VIP team wanted. These clinicians asked the ED nurses and physicians how to improve. This is what they learned.

First, the ED clinicians had concerns that the VIP Protocol was not an appropriate use of their resources. From their perspective, many of these patients looked fine when they presented at the ED with a fever. If patients were not hemodynamically unstable, the ED physicians did not want to start them on an antibiotic. And that's good practice: physicians do not want to

(continued on page 43)

Figure 3. Onc Alert Order Set

EMERGENT FEVER IN THE PATIENT WITH BONE MARROW SUPPRESSION HEMATOLOGY AND ONCOLOGY VIP PROGRAM

PRESENTING CHIEF COMPLAINT

Fever (101° or greater), shaking chills, and 1 or more of the following:

- Chemotherapy treatment within the past 6 weeks.
- History of allogeneic bone marrow transplant.
- Patient presents hematology and oncology VIP Card.

TARGET WITHIN 10 MINUTES OF PATIENT ARRIVAL TO THE ED

Patient registration:

1. Request Methodist Healthcare VIP Card.
2. Obtain name of treating hematologist or oncologist.

Triage:

3. Confirm name of treating hematologist or oncologist.
4. Triage to Level II and page Onc Alert.
5. Obtain vitals, pulse oximetry, and allergies.
6. Take neutropenic precautions.

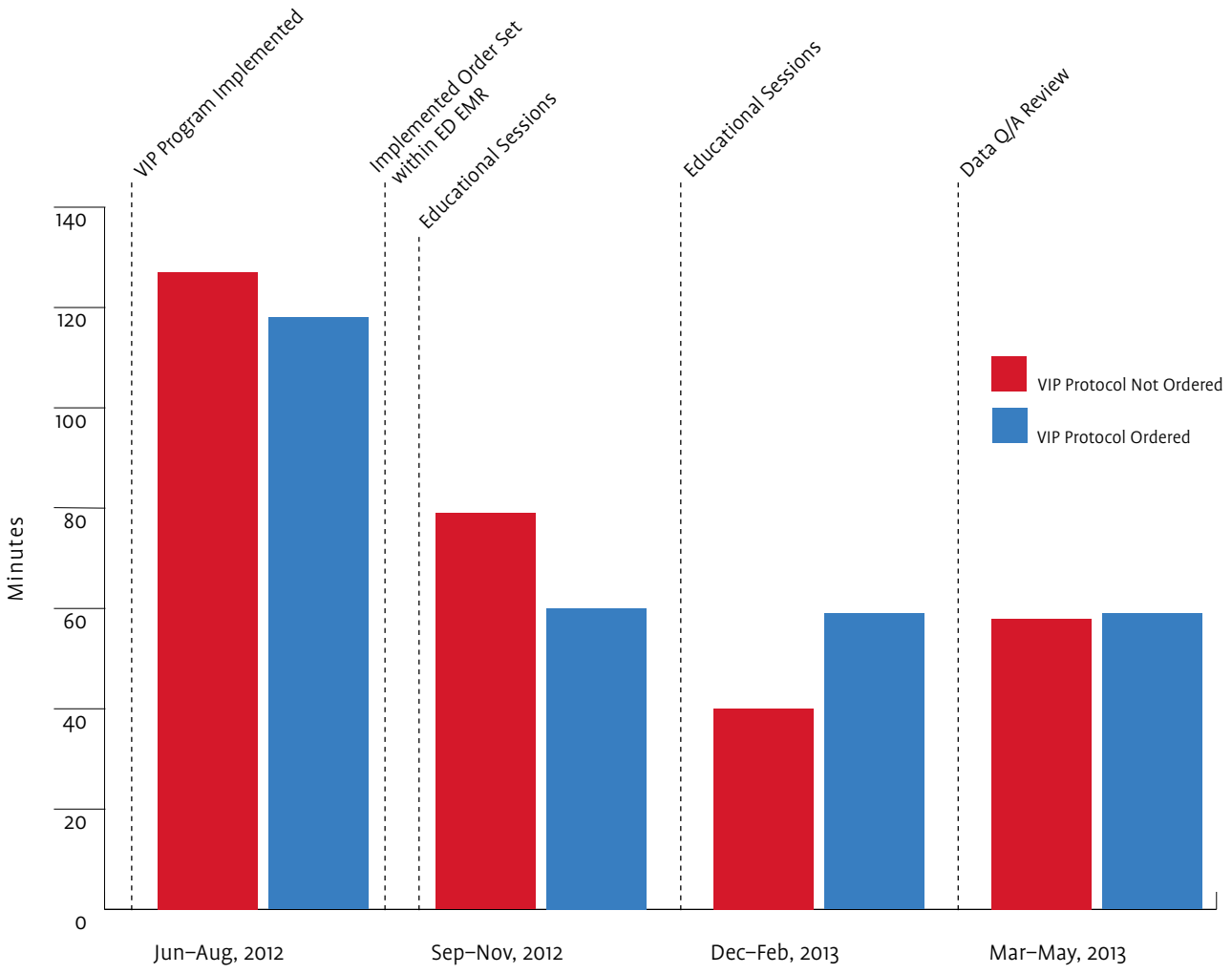
TARGET WITHIN 30 MINUTES OF PATIENT ARRIVAL TO THE ED

7. Weight and allergies.
8. STAT point of care venous lactate.
9. STAT lab: CBC with automated differential and basic metabolic panel; blood culture X 2 (if patient has a central line, obtain 1 central line BC and 1 peripheral line BC; label each correctly); LFT, LDH, Magnesium, PT, PTT.
10. If able to void, UA (urinary analysis) with micro and culture.
11. Give cefepime/maipime, 1 gram IV STAT (after blood cultures are drawn). Admitting MD to re-order on admit for every 8 hours. If allergic to cefepime/maipime and penicillin, give merrem, 1 gram IV STAT (after blood cultures are drawn). Admitting MD to re-order on admit for every 8 hours. If allergic to cefepime/maipime, but not penicillin, give zosyn, 3.375 grams IV STAT (after blood cultures are drawn). Admitting MD to re-order on admit for every 6 hours.
12. Start IV if normal saline, 100 mL per hour.

TARGET WITHIN 60 MINUTES OF PATIENT ARRIVAL TO THE ED

13. Review STAT labs.
14. Call hematologist or oncologist after patient is evaluated to discuss treatment plan.
15. If patient is to be admitted, communicate that patient is a VIP patient and request 8S or BMT bed. If ANC (absolute neutrophil count) less than 1,000, request private room.
16. Target to transport patient within 30 minutes of obtaining MD order to admit. If IP bed not available within 30 minutes, transfer to ED Clinical Admitting.

Figure 4. Mean Time from ED Presentation to Antibiotics



Notes: Patients with FN, n=206. 116 Patients (or 56%) had VIP Protocol initiated, 90 patients (or 44%) did not have the VIP Protocol initiated (p=0.03)

(continued from page 41)
use antibiotics unnecessarily.

This feedback was useful for the VIP team, signaling that more education was needed. Accordingly, VIP team members went back to the ED nurses and physicians and provided additional education on how patients with febrile neutropenia were an "oncologic emergency." For these patients the standard of care is to start the patient on the antibiotic first—before the labs come back. This was a different mindset for the ED physicians. They had to understand that there were probably some cancer patients who came to the ED with fever and who were fine. Maybe these patients weren't neutropenic. Maybe some of these patients did not even have a fever. But the ED physicians needed to err on the side of over-treating, so that they did not miss those patients who

Figure 5. Percent of Patients Receiving Antibiotics within 60 Minutes

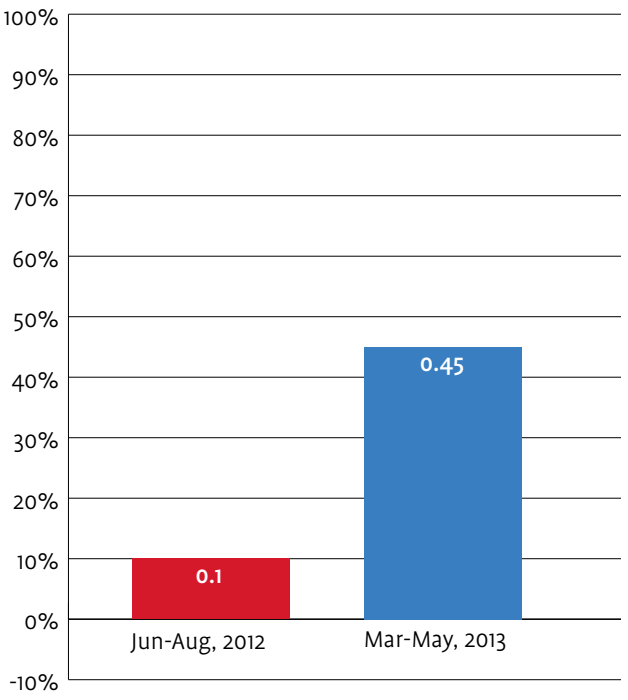


Table 1. Seven-Step Action Plan

1. Bring together a multidisciplinary team spearheaded by a physician champion
2. Establish metrics to measure and a process to capture the necessary data
3. Outline the process map of the VIP Protocol
4. Develop a VIP Kit
5. Market and promote the VIP Program and the VIP Kit to the community
6. Educate (and re-educate) community oncologists, ED physicians, and ED nurses.
7. Review data and evaluate outcomes for programmatic improvements.

were truly febrile neutropenic and about to become septic. When the oncologists explained their standard of care and the logic behind the treatment decisions to the ED nurses and physicians, change started to happen.

Second, the VIP team learned that education on the VIP Program would have to be ongoing—not a one-time event at each emergency department. Because of issues, such as staff turnover, the VIP team would need to educate and re-educate ED nurses, physicians, and administrators, as well as staff at the community oncology practices, about the VIP Program.

Third, the VIP team learned that implementing the VIP Protocol would be different at every hospital. Take, for example, the issue of electronic medical records (EMRs), which can vary from hospital to hospital. The VIP team even ran into a situation where an emergency department used a different EMR from the rest of the hospital departments. So embedding the VIP Protocol as a pre-printed order into each of these EMRs was not a simple task. The VIP team had to work with each ED—the physicians and the IT staff—to put the VIP Protocol into their template as a pre-printed set order. The VIP Program has now been rolled out to five emergency departments within the Methodist Healthcare System; there is one more hospital to go. In addition, Methodist Hospital has leveraged best practices and its relationship with the Sarah Cannon Network to assist in implementing the VIP Program at hospitals in Austin, Denver, Oklahoma City, and Nashville.

Finally, the VIP team found that the process in one emergency department was not necessarily the same process in another. So it's important to be able to adapt and to show how the VIP Program fits into each specific care setting. The VIP team uses its data to show how improving the care of patients with febrile neutropenia fits into each hospital's overarching plans of treating patients. Today, with the Affordable Care Act (ACA) and other payer-driven efforts, hospitals want to measure quality. So, the VIP team feeds the data about this quality improvement program back to the EDs and hospitals, so they can use it to show patients and payers that they are indeed providing quality care. The VIP Program is a great measure of quality as it is based on national standards and guidelines on how to provide appropriate outpatient care for patients with neutropenia.

The Challenges Ahead

The biggest challenge facing the VIP team is to understand why the VIP Protocol is still not being ordered for some patients. Recognizing that stakeholders and physician champions are the driving force behind this quality improvement initiative, the VIP team is asking community oncologists to take time away from their clinic to meet with hospital administration, hospital-based physicians, and ED nurses and physicians and provide consistent education for these clinicians about the importance of the VIP Program. The most important reason: it is the best care for patients.

Another challenge is how to expand the VIP Program outside of the Methodist Healthcare System. How does the VIP team take this program and implement it at other hospitals in the community? As stated previously, every hospital is different. Every hospital has a different way of communicating with its physicians and nurses. Every hospital has a different process for admitting patients. And the VIP team believes the key to resolving these challenges is constant (and repeated) communication and education.

Implementing a Similar Program

Methodist Hospital has had great success in implementing the VIP Program in San Antonio and would like other communities to be able to achieve similar successes. For cancer programs looking to implement a similar quality improvement program, the VIP team developed a seven-step plan (see Table 1, left).

First, bring together a multidisciplinary team that includes all key stakeholders—especially a physician champion.

Second, begin the VIP Program with an end goal in mind. What is the objective? What metrics does the program want to measure? For Methodist Hospital, the key metric was the time of entry to the ED department to antibiotic. And develop and implement a process for capturing that information.

Next, outline the process map for the ED so that hospitals understand how the VIP Program fits into their overarching plans of treating patients.

Consider developing a VIP Kit. It is a tangible education tool that community oncologists can give to their patients. Then get the marketing department involved to promote the VIP Program (and VIP Kits) to the community.

Reserve time for education and re-education. There is turnover within emergency departments and community oncology practices. Continuing to educate all stakeholders is key.

Finally, review the data from the quality improvement program and continually seek ways to improve. OI

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The authors of this article were part of the initial multidisciplinary team that developed and implemented the VIP Program. They would like to thank their fellow VIP team members: Fred LeMaistre, MD, physician chief Hematology, Sarah Cannon; Carlos Bachier, MD, director Stem Cell Transplant, Methodist Hospital; Roger Lyons, MD, Cancer Care Centers of South Texas/US Oncology; Joseph Holahan, MD, The START Center for Cancer Care; Dale Crockett, MD, chairman, Emergency Department, Methodist Hospital; Roberta Tremper, RN, ED director Methodist Hospital; Hannah Sowell, RN, clinical nurse; Carole Elledge, RN, MSN, AOCN, nurse educator; Ann Kelley, RN, BSN, Quality/Risk Management ED nurse, Methodist Hospital; Jill MacPherson, RN, clinical nurse; JoDee Kerestes, director Physician Initiatives; JoAnn King, director Marketing and Public Relations; Daniele Passatieri, RN, administrator, BMT Program, Methodist Hospital; Mary Krivoy, RN, director, BMT Program, Methodist Hospital; Marla Brady, RN, VP, Nursing, Methodist Hospital; and Charlotte Stambaugh, RN, BMT coordinator, Methodist Hospital.

About Methodist Healthcare

Methodist Healthcare System – San Antonio is the largest provider of healthcare in South and Central Texas, with 26 facilities, including 9 hospitals serving 90,000 inpatients and 390,000 outpatients annually. The Methodist Healthcare team is comprised of 8,000 employees, making Methodist Healthcare the second largest private employer in San Antonio. In 2012 Methodist Healthcare was one of only two hospitals in Texas recognized by the Texas Medical Foundation with a Gold Award for Quality. Methodist Healthcare has won the National Research Foundation's Consumer Choice Award for 13 consecutive years, more times than any other healthcare provider in Texas. For the past four years, Methodist Healthcare has received the "Best Hospital" Gold Award by the San Antonio Express-News' Readers' Choice Awards. With more than 2,700 credentialed physicians, Methodist Healthcare provides the largest array of medical services in the region including neurosurgery, cardiovascular services, oncology and women's services. Visit www.SAHealth.com to learn more.


2013 ACCC INNOVATOR AWARD
ASSOCIATION OF COMMUNITY CANCER CENTERS

BY JOAN GIBLIN, MSN, FNP-C, AOCN

Winship at the Y

Developing a community-based program for cancer survivors and caregivers

I have been a nurse practitioner for almost 30 years and a nurse for almost 44 years. I have taken care of cancer patients across the continuum beginning with diagnosis and treatment and transitioning to survivorship and/or hospice. As a family nurse practitioner, I have always viewed my patients as members of a family system and this was never more apparent to me than when I transitioned into cancer survivorship care. Recognizing the role that patients and their families (and families can be defined broadly—the spouse, the child, the grandchild, the neighbor, the church community, or the wider community) play in cancer survivorship is the mantra that guides what I do on a daily basis.

When I first took over the cancer survivorship program at Winship Cancer Institute in 2011, I thought I would spend most of my time on symptom management and palliative care (see "Essential Elements of Survivorship, page 51). I was mistaken. Instead, I spent a good portion of my time and resources on health education. For example, one 73-year-old patient came into our survivorship clinic 10 years after his cancer diagnosis. When I asked him the date of his last colonoscopy, the patient said that he'd never had a colonoscopy. He'd always assumed that he would die of his lung cancer, so he didn't see the need to get a colonoscopy. Of course, I made the patient a colonoscopy appointment immediately. The last outcome I want is for a patient to survive one type of cancer and then develop a second cancer that can be prevented through a screening test. Heart disease is another area where I spend a lot of time educating cancer survivors. I take a family history of not only cancer but any major causes of death or illness, including heart disease. I work closely with the Emory Cardiology Department, and we hope to establish a formal cardio-oncology program in the near future. Cancer survivorship is not just about cancer—it involves all forms of wellness education.

As a family nurse practitioner, I have always viewed my patients as members of a family system and this was never more apparent to me than when I transitioned into cancer survivorship care.

Getting Started

One of the challenges with developing and implementing a cancer survivorship program is that you must often start from the ground up. While survivorship programs do not all look the same, they must all address common questions:

- What kind of a survivorship care model is the best for the program (i.e., community-based shared care, academic-based comprehensive program, nurse practitioner–led shared care, multidisciplinary programs for high-risk populations)?[1]
- When should survivorship care begin?
- Who should coordinate survivorship care?
- What services should survivorship care include?
- Where should survivorship care be given?

There are also common factors to consider before implementing a cancer survivorship program.

- Setting.
- Organizational structure, key stakeholders, and program champions.
- Staffing considerations. Which providers will staff the survivorship clinic and what will their responsibilities be?
- Payment considerations. Certain providers can bill for

WHY SURVIVORSHIP SERVICES?

The oncology community, as a whole, has done a phenomenal job getting patients to the point of survivorship. But when active treatment ends, many patients feel like they've been "dropped" by their oncology providers. At this stage, cancer survivors face the question: "*What do I do now?*" And they often say: "*Give me something to do that I can control.*" Throughout their cancer journey, survivors lose much of their control. When active treatment is over, survivors want and need to get some of that control back. A comprehensive survivorship program can help do just that.

In addition, cancer survivors often face significant physical and psychosocial issues (Table 1, right), as well as practical and financial challenges. Some may have difficulty working due to the physical and/or emotional after effects of their cancer treatment. Often, these survivors are considered disabled; yet they are capable of and want to work if they have the tools and resources to help. All cancer survivors deal with financial stressors, such as lost wage earnings and high co-payments and deductibles. Right now, as a whole, the oncology community is not doing a great job addressing these practical and financial issues. Again, a comprehensive survivorship program can help in these efforts.

Table 1. Issues that Can Affect Cancer Survivors Post-Treatment

Physical Issues	Psychosocial Issues
Osteonecrosis	Body image changes
Fatigue	Sexuality changes
Cataracts	Insomnia
Early menopause	Depression
Infertility	Chronic fatigue
Heart disease	Anger
Lung disease	Anxiety
Increased risk of secondary cancers	Fear of recurrence
Cavities and tooth decay	
Muscle weakness	
Bone and joint problems	
Hearing Loss	
Osteoporosis	
Problems with memory	
Pain	
Intestinal problems	
Dysphagia	
Stomatitis	
Xerostomia	
Hypothyroidism	
Stroke	
Pituitary dysfunction.	

survivorship services. For example, nurse practitioners and physician assistants can bill incident-to a physician or independently as defined by insurance carriers when they see patients in a clinic and provide services covered. Will a fee-for-service model be used? If so, how will the program provide survivorship care for patients who cannot afford to pay for services?

- Patient characteristics, such as age, race and ethnicity, cancer type, stage of disease, and other risk-stratification issues.
- The number and type of survivors being served.
- The available healthcare providers, services, and resources.
- Patient population risk of recurrence and level of symptoms following cancer treatment.
- Patient preference regarding the type and source of survivorship care. Do patients want to come back to the cancer program for a survivorship visit after active treatment is completed? Some patients would rather see their primary care provider or oncologist.

No matter the model, the survivorship program should 1) have a positive impact on morbidity, mortality, and quality of life, 2) be able to be implemented across a variety of settings, and 3) be

A two-time survivor of head and neck cancer, Barry exercises under the guidance of his wellness coach, Leila, to combat the de-conditioning he experienced after treatment.

supported by an evidence base or—when an evidence base does not exist—consideration of the express needs of the cancer survivors the program seeks to serve.

Winship Wellness for Living

In 2011 Winship Cancer Institute implemented its *Winship Wellness for Living* program to help patients and their families move from cancer diagnosis, through treatment, and beyond. The program is aptly named because it is not just about surviving—it's about living and enjoying the best quality of life possible in whatever time patients have. The survivorship model for *Winship Wellness for Living* is evidence-based, providing follow-up care that aligns with Winship's academic model and improving care coordination with primary care providers (PCPs), as well as with patient preferences and lifestyle. Our survivorship program conducts data collection on measurable outcomes, including:

- The number of referrals to the cancer survivorship program
- The number of patients seen, including data on how survivorship services have positively impacted referring providers' ability to see more newly diagnosed cancers and fewer follow-ups
- Health outcomes
- Compliance with follow-up care plan
- Self-reported patient satisfaction.

The survivorship program provides education, social support, and medical care for patients and families within the clinical environment and within our local community.

Winship for Wellness has a survivorship clinic visit that is integrated into a long-term survivorship plan using a "shared-care" or "blended" delivery model where survivorship staff works directly with oncologists and primary care providers. The survivorship clinic is held in one of Winship's four clinical sites in the greater Atlanta area. The survivorship clinic is staffed by a nurse practitioner or physician assistant, as we have found this best meets the needs of the unique patient population served in our academic cancer center. Physicians, physician assistants, dietitians, social workers, and chaplains round out the *Winship Wellness for Living* survivorship care team.

The survivorship team conducts community outreach on topics related to cancer survivorship and prevention, and is heavily involved in survivorship-related research activities.

A Unique Gift

After their daughter was diagnosed and treated for breast cancer in her 20s, the Glenn family established the Glenn Family Fund at Winship Cancer Institute, donating a tremendous amount of money towards breast cancer research. In 2010 the family requested that a small portion of that grant money be used to develop and implement an exercise program for breast cancer

survivors. In considering how best to use this unique gift to the benefit of survivors, we had to assess whether providing an onsite exercise facility—in addition to our comprehensive *Winship Wellness for Living* survivorship program—made sense.

One practical consideration was geographical convenience. Winship Cancer Institute is located close to downtown Atlanta and is in the center of a daily traffic nightmare. Many area cancer survivors do not live in Atlanta. They reside in the surrounding communities, such as Woodstock, Canton, and Newnan. Our survivors expressed that they were not willing to travel to Atlanta for any additional services. So, while patients will come into Atlanta for cancer treatment, they are not going to come into Atlanta to exercise. We knew that any exercise facility had to be close to where our cancer survivors lived. In addition to these geographical challenges, including parking issues, childcare also presented a challenge.

Clearly an onsite exercise facility was not the answer. But the solution was right in our backyard.

Winship at the Y

Winship at the Y—a special program within Winship Cancer Institute's larger cancer survivorship program, *Winship Wellness for Living*—received a 2013 ACCC Innovator Award.

Winship at the Y is a relatively simple program that can be easily replicated in other communities. It is a formal collaboration (with written letters of agreement) between Winship Cancer Institute and the YMCA of Metro Atlanta, which allows us to reach cancer patients and cancer survivors at home and in their own communities.

When I first reached out to the YMCA about a potential partnership, I fortuitously found that the YMCA already had a program in place called THE COACH APPROACH®, an exercise support process that includes goal setting, overcoming obstacles, and ongoing support. Developed by Jim Annesi, PhD, FAAHB, director of wellness advancement at the YMCA of Metro Atlanta, THE COACH APPROACH is an evidence-based, customized, and comprehensive system of support. While the program had not yet been implemented specifically with cancer patients, it had been applied in work related to disparities and obesity.

The YMCA also had a program through which it could track members, how often they come in, and what services they use or what activities they participate in. (We asked our cancer survivors to participate in that program during their trial membership.)

Another bonus—the YMCA of Metro Atlanta had 18 locations throughout our community.

Our Clinical Trial

Using the Glenn Family grant, in June of 2012 we initiated a clinical trial to examine the effects of physical activity on cancer survivors over a six-month period from 2012–2013. The clinical trial aimed to identify the:

1. Feasibility of a coach-assisted and community-based exercise intervention targeting breast cancer survivors.
2. Psychological, social, and biological effects of an exercise intervention targeting breast cancer survivors, who have been shown to have high rates of depression, fatigue, and other issues affecting quality of life.
3. Effectiveness of an exercise program for breast cancer survivors for improving physical activity.

The clinical trial enrolled 50 breast cancer survivors from the Winship Cancer Institute into THE COACH APPROACH program. Again with funds from the Glenn Family grant, we paid for all 50 study participants to receive a six-month trial membership at one of 18 YMCA locations in metropolitan Atlanta.

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A participant in Winship's exercise study, Ellen works out on the treadmill while her wellness coach, Leila, observes.

ESSENTIAL ELEMENTS OF SURVIVORSHIP

On September 15–16, 2011, LIVE**STRONG** convened the Essential Elements of Survivorship Care Meeting in Washington, D.C. The goal: to build consensus among key stakeholders on the essential elements of survivorship care that any cancer survivorship program must provide to post-treatment survivors. It is important to note that the goal of the meeting was *not* to identify specific guidelines or standards for delivering care, such as surveillance for recurrence conducted at particular time points.

I was privileged to be part of the group that developed these essential survivorship elements. We started with about 250 different elements. It was a fascinating process, with participants from the U.S. and Canada. We identified 20 elements that we considered "essential" to survivorship care delivery (Table 2, right). The 20 elements are organized into tiers. Tier 1 includes five consensus elements defined as those elements that all medical settings *must* provide—either through direct access or referral:[2]

1. Survivorship care plan, psychosocial care plan, and treatment summary.
2. Screening for new cancers and surveillance for recurrence.
3. Care coordination strategy that addresses care coordination with PCPs and primary oncologists. (At Winship Cancer, I identify a primary care provider for every patient that comes through our survivorship clinic. If patients do not have a PCP, I find them one.)
4. Health promotion education.
5. Symptom management and palliative care.

Table 2. Essential Elements of Survivorship Care Delivery[2]

Tier 1. Consensus Elements (All medical settings *must* provide direct access or referral to the following elements of care.)
1. Survivorship care plan, psychosocial care plan, and treatment summary
2. Screening for new cancers and surveillance for recurrence
3. Care coordination strategy that addresses care coordination with PCPs and primary oncologists
4. Health promotion education
5. Symptom management and palliative care
Tier 2. High-Need Elements (All medical settings *should* provide direct access or referral to these elements of care for high-need patients and to all patients when possible.)
6. Late effects education
7. Psychosocial assessment
8. Comprehensive medical assessment
9. Nutrition services, physical activity services, and weight management
10. Transition visit and cancer-specific transition visit
11. Psychosocial care
12. Rehabilitation for late effects
13. Family and caregiver support
14. Patient navigation
15. Educational information about survivorship and program offerings
Tier 3. Strive Elements (All medical settings should *strive* to provide direct access or referral to these elements of care.)
16. Self-advocacy skills training
17. Counseling for practical issues
18. Ongoing quality improvement activities
19. Referral to specialty care
20. Continuing medical education

Winship Cancer Institute's Survivorship Team, pictured here in 2014.

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Before enrolling patients, in my role as Winship's survivorship program director, I went to each location and presented an education program to the wellness coaches on cancer survivorship. I oriented these coaches to what it would be like to work with cancer survivors. Today, this education on cancer survivorship is part of the annual training required for all wellness coaches.

Although we have not yet formally analyzed study data, I would estimate that about 50 percent of the participants on the breast cancer study (or about 25 cancer survivors) took advantage of the YMCA membership and made lifestyle changes by extending their YMCA membership, enrolling at another facility, or continuing to exercise on their own. Publication of the results of the study will be released sometime in early fall 2014.

Growing the Program

Based on the success of the initial clinical trial, we expanded the program to all 18 YMCA locations and began to actively market it in our community. For example, every location now displays a *Winship at the Y* banner. Because my contact information is included on these banners, I receive a number of phone calls from people who are not patients at Winship Cancer Institute, but who are interested in participating in the program. After obtaining their basic information and telling them to let their physician know they are enrolling in the exercise program, I will refer these individuals to the YMCA of their choice. *Winship at the Y* participants receive a 20 percent referral reduction on YMCA membership. To date, I have referred more than 400 people to the *Winship at the Y* program, the majority of these referrals are Winship patients, but many are from the wider community.

When a cancer survivor is referred into the program, I send an email informing the wellness coach who then contacts the patient to come in to the YMCA for a consult. I do not provide any additional information to the YMCA other than the contact information of the cancer survivor being referred into the program. I do not tell the wellness coaches that the patient has breast cancer or head and neck cancer. When I have a very de-conditioned patient, like some of the head and neck patients after their combined chemo-

therapy and radiation, I may suggest in the email that the wellness coach "start slow" with this particular cancer survivor. I do not share details about the patient's condition or symptoms. Patients are free to reveal this to the coach at the time of their first visit.

Implementation Tips

One factor that has contributed to the success of our partnership is the fact that the YMCA is a non-profit entity—similar to Winship Cancer Institute and many other ACCC member programs. Cancer treatment can take a big toll on the finances of a family. The practical issues of treatment and survivorship can leave a patient and family financially devastated and the last expense they can think of adding is a gym membership. It doesn't happen often, but the YMCA has been very gracious and able to extend scholarships to many of our cancer survivors. For-profit facilities might not be so generous.

> With increasing numbers of cancer survivors, the oncology community will need to develop survivorship programs that address surveillance and screening needs...

Any cancer program can replicate our success with *Wellness for Living* and specifically, *Winship at the Y*. Here are some tips to help you get started:

- Solicit the input of your cancer survivors and their caregivers.
- Engage the same survivors and caregivers in your vision for the program.
- Start with an operating committee and then consider adding a community advisory group. We used a steering committee that met weekly for many, many months and now meets quarterly.
- Explore the most cost-effective way of delivering survivorship care and programs.
- Set some short- and long-term goals with realistic timelines.
- Look to resources that are already in your community (gyms, YMCAs, church groups, etc.). Some churches have great facilities for their members. Explore all possible partnerships, if you don't have a YMCA close by.
- Look for opportunities for financial support (if needed) and manage your cost expectations. Do not assume that this type of survivorship program will be resource and time intensive. We were able to get *Winship at the Y* up and running with the initial seed money from the Glenn family. The only resource needed now is my time, which is paid for under the umbrella of our larger survivorship program.
- Start small and be willing to change direction if your first idea doesn't work. I have found with cancer survivorship, the program champion must often act as a change agent.

Today, Winship Cancer Institute has become a true partner with the YMCA of Metro Atlanta. Our connection through *Winship at the Y* led us to partner on various cancer awareness initiatives. Last summer we provided more than 1,000 summer campers with "Sun Safety Awareness" programs with the assistance of summer interns at Winship and at the YMCA. This summer we will partner with Project Open Hand and their *Good Measure Meals Program* to reach even more summer campers with activities and snacks that stress eating for wellness and cancer prevention through our *Winship at the Y Cooking with Color for Cancer Prevention* program.

Going Forward

The oncology community does not know everything it needs to know about cancer survivorship. More evidence-based research is needed in survivorship care planning and implementation.

With increasing numbers of cancer survivors, the oncology community will need to develop survivorship programs that address surveillance and screening needs, as well as the monitoring of long-term treatment effects. These survivorship programs do not have to be complex or expensive. Survivorship models will look different, depending on the practice setting, resources available, and the patient population. After effects of cancer therapy may be life-long and vary greatly with individuals and their specific cancers and treatments. Many cancers are now being treated as chronic conditions. So the question really becomes: how do you help these patients live with their chronic conditions? OI

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Navigating the GE Junction

New insights and best practices

GASTRIC/ GE JUNCTION CANCER

Resources & Tools for the Multidisciplinary Team

This article is part of ACCC's "Improving Quality Care in Gastric/GE Junction Cancer" education program. For this project, ACCC is pleased to partner with Debbie's Dream Foundation: Curing Stomach Cancer, a non-profit organization dedicated to raising awareness about stomach cancer; advancing funding for research; and providing education and support to patients, families, and caregivers. Financial support of this project is provided by Lilly Oncology. ACCC is solely responsible for content. Additional tools and resources are available online at www.accc-cancer.org/gastric.

BY ALEXANDRA HOWSON, MA, PHD

Fast Fact At the GEJ, the lower esophagus divides from the proximal stomach, and esophageal squamous epithelium changes into the columnar epithelium of the gastric cardia. The GEJ is the predominant site for adenocarcinomas of the upper GI tract.

Community cancer centers are seeing an increasing number of patients with gastroesophageal cancers, including tumors of the gastroesophageal junction (GEJ). GEJ tumors are rare but highly aggressive, with low overall survival rates.[1] GEJ tumors are characterized by two distinct histologic subtypes: squamous cell carcinoma and adenocarcinoma. The incidence of squamous cell esophageal carcinoma—associated with cancer of the distal stomach—is decreasing in Western Europe, Australia, and North America, whereas the incidence of adenocarcinoma—associated with cancers of the lower esophagus and gastric cardia—is rising rapidly.[2]

In the U.S., the incidence of adenocarcinoma is rising fastest among white men (4 to 10 percent annually since 1976),[3] and is especially prevalent in certain geographical areas, such as coastal South Carolina, Washington, D.C., and Baltimore, Md.[4] GEJ cancers comprise more than 90 percent of all esophageal adenocarcinomas.[5–8]

What Causes GEJ?

Esophageal adenocarcinomas, including those at the GEJ, can develop from multiple interactions between environmental and genetic factors (Table 1, page 56).[8] Chronic irritation from gastroesophageal reflux is considered the strongest individual risk factor for esophageal adenocarcinoma and Barrett's esophagus, a precursor to GEJ tumors.[2,8] Although reasons for rising reflux rates are unclear, increasing obesity, body mass index, and central and intra-abdominal adiposity (body fat) may play a role.[8] Exposure to *heliobacter pylori* infection increases the risk for gastric cancer; however, this bacterium is thought to protect against developing esophageal adenocarcinoma.[8]

Although early stage esophageal and GEJ cancers are generally asymptomatic, patients can experience dyspepsia (indigestion), or gastrointestinal bleeding if ulcerated lesions are present. However, most patients present at an advanced stage, commonly with dysphagia (difficulty swallowing), although odynophagia (painful swallowing), regurgitation, and weight loss can also occur.[1,9] Table 2, page 56, compares symptoms in gastric and GEJ cancer.

Community cancer centers are seeing an increasing number of patients with gastroesophageal cancers, including tumors of the gastroesophageal junction.

Classification & Staging

Until recently, GEJ tumors were treated as esophageal or gastric tumors. In the 1990s, GEJ tumors were classified into three anatomical types defined by proximity to the epicenter of the tumor (Table 3, page 57).[10] But the anatomical origins of GEJ adenocarcinomas are not always readily distinguishable between gastric cardia or lower esophageal adenocarcinomas.[11]

While GEJ tumors share some ontological characteristics with both esophageal and gastric cancers, insights into the epidemiology

Table 1. Epidemiology of Risk Factors for GEJ Tumors

Squamous Cell Carcinoma	Adenocarcinoma
Southeastern Africa, Iran, Asia	North America, Western Europe
Black ethnicity	White ethnicity
Smoking	Genetics
Alcohol	Obesity
Upper and middle esophagus	Lower esophagus
High-salt and processed-food diet	Esophageal inflammation
Low SES (socio-economic status), non-urban location	Male gender
Precursor pathological conditions (e.g., pernicious anemia, achlorhydria atrophic gastritis, gastric ulcers, adenomatous polyps)	Gastroesophageal reflux
Epstein-Barr virus	Barrett's esophagus
Gastric colonization with *H. pylori*	Chronic irritation

and biology of GEJ tumors have led to their reclassification as a heterogeneous clinical entity, with different outcomes based on primary tumor location, regional lymph node involvement, the presence of distant metastases, and histologic (tissue) grade.[1,5,12]

In addition to anatomy, the staging recommended by the 2010 American Joint Committee on Cancer (AJCC) is based on pathological data from three continents and 4,627 patients who underwent esophagectomy alone with no induction therapy.[13] This data-driven resource harmonizes clinical and pathologic staging for GEJ, and includes some important changes with implications for staging workup. Nodal staging is defined by the number of pathologically involved nodes rather than by location. For planning and prognosis purposes, all tumors arising at the GEJ, or adenocarcinomas arising in the proximal 5 cm of the stomach and crossing into the GEJ, are staged according to the TNM system for esophageal adenocarcinoma.[2,13]

In clinical trials, patients with both adenocarcinoma and squamous cell carcinoma have often been treated together, potentially obscuring differences in outcomes associated with histology-based treatment.[6] However, when compared stage-for-stage to patients with distal gastric cancers, patients with GEJ and cardia adeno-

Table 2. Symptoms in Gastric and GEJ Cancer

Gastric Cancer	GEJ Cancer
Weight loss	Dysphagia (progressing from solids to liquids)
Dysphagia	Weight loss
Dyspepsia	Hoarseness
Vomiting	Odynophagia
Anorexia	Anemia
Early satiety	Chest pain in the absence of myocardial infarction
Hematemesis	
Iron deficiency anemia	

Table 3. GEJ Cancer Siewart Classification
Type I: Esophageal
Distal esophageal adenocarcinomas with an epicenter 1-5 cm above the cardia: these tumors have similar epidemiological and histological characteristics to esophageal adenocarcinoma.
Type II: Cardia
Adenocarcinomas with the epicenter within 1 cm above and 2 cm below the cardia: complex etiology with epidemiological and histological characteristics sitting between Type I and II.
Type III: Subcardial
Noncardia gastric adenocarcinomas with an epicenter 2-5 cm below the cardia, with or without extension into the esophagus: may be similar to distal noncardia gastric cancers.

carcinomas carry a worse prognosis, with lower survival and higher rates of local and distal recurrences.[13] Notably, adenocarcinomas and squamous cell carcinomas at the GEJ are distinct entities that may benefit from different treatment approaches, and that respond differently to systemic chemotherapies and targeted agents.[5] Therefore, accurate tumor diagnosis and staging are key to effective management of GEJ cancer.

Precise local staging helps to determine the depth of tumor spread, eligibility for resection, and presence and extent of lymph node metastasis to determine the likelihood of regional control.[14] In addition to clinical examination; blood count; liver, pulmonary, and renal function tests; several complementary imaging modalities provide pathological and anatomic data to support tumor staging (see Table 4, page 58).

How is GEJ treated?

For esophageal cancer patients with localized disease, including GEJ tumors, surgery remains the gold standard for patients who are medically fit for resection (e.g., transhiatal and transthoracic esophagectomy).[8] Because locally advanced disease is associated with a high risk for recurrence, adjuvant therapy has emerged as a strategy that appears to improve survival for patients undergoing surgery; however, there is considerable debate over the advantages of dual modality therapy (chemotherapy plus surgery) over multimodality therapy (chemoradiation and surgery) for this patient population.[18]

Pre-operative Chemotherapy. Several clinical trials in the U.S. and in Europe have investigated pre-operative chemotherapy followed by surgery, with or without post-operative chemotherapy. For instance, the British MAGIC trial compared three cycles of epirubicin, cisplatin, and 5-FU followed by surgery and three cycles of post-operative chemotherapy in 503 patients with esophageal cancer, 26 percent of whom had GEJ cancer.[19] This clinical trial demonstrated improved five-year survival for the perioperative chemotherapy group compared with surgery alone (36 percent vs. 23 percent).

Multimodal Pre-operative Therapy. A landmark multicenter Phase III study found neoadjuvant chemoradiation superior to surgery alone.[20] Using endoscopic ultrasound and laparoscopic staging, the CROSS trial randomly assigned 364 patients with carcinoma of the esophagus (75 percent of whom had adenocarcinoma of the lower esophagus or GEJ) to surgery alone vs. pre-operative chemoradiotherapy (carboplatin and paclitaxel plus 41.4 Gy of external beam radiotherapy). Pathologic complete response occurred in 23 percent of the patients with adenocarcinoma who had chemoradiation and median five-year survival was also superior for this group vs. the surgery-alone arm (49 months vs. 24). Operative mortality was <4 percent in both groups.

> For esophageal cancer patients with localized disease, including GEJ tumors, surgery remains the gold standard for patients who are medically fit for resection.

Table 4. Recommended Imaging Modalities in Staging Workup[1,15]

Flexible endoscopy with biopsy is recommended to assess mucosal and submucosal penetration and confirm histologic classification. Endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) can precisely define the presence or absence of submucosal invasion and guide therapy.[16]
Baseline CT scan of chest and abdomen to evaluate for local, nodal, intra-abdominal, and thoracic metastatic disease.
Fluoride-18 fluorodeoxyglucose (FDG) positron emission tomography (PET) imaging is a standard of care for node staging and detection of metastases to determine patient eligibility for surgical resection. Functional imaging may also identify early responders to chemotherapy.[17]
Endoscopic ultrasonography with fine needle aspirate of lymph nodes is an additional staging study to confirm nodal status, improve accuracy of clinical staging, and guide therapy in the absence of metastatic disease.[1]
Laparoscopy is considered optional in GEJ cancer patients with no evidence of M1 disease.
HER2 testing for all patients with metastatic GEJ cancer at the time of diagnosis.

Current Practice Recommendations. Although there has been conflicting evidence regarding the effects of perioperative chemotherapy on survival and other outcomes, a recent systematic review that evaluated data from 14 Phase III clinical trials comparing surgery alone to surgery and perioperative chemotherapy (alone or in combination with radiotherapy) found that treatment with perioperative chemoradiation in patients with GEJ adenocarcinomas was significantly associated with longer survival compared with surgery alone (HR 0.81, CI 0.73-0.89; p<0.0001).[21] For patients with localized node negative/node positive adenocarcinoma and no metastases (i.e., T1b, T2-T4a), National Comprehensive Cancer Network (NCCN) guidelines favor pre-operative chemoradiotherapy, and recommend many other treatment options combined with surgery, including definitive chemoradiation for patients who decline surgery or with T4b tumors, and pre-operative chemotherapy.[15]

Improving Treatment of GEJ

The following are key strategies for improving the care and treatment of patients with GEJ cancer.

Upfront multidisciplinary team planning and pre-treatment counseling is essential to optimize patient outcomes. Patients with GEJ tumors require clinical expertise from several disciplines, including:

- Surgical oncology
- Medical oncology
- Radiation oncology
- Gastroenterology
- Pathology
- Oncology nurses
- Dietitians
- Social workers
- Cancer program administrators and office managers
- Patient navigators
- Data managers.

This multidisciplinary team is essential in caring for patients with GEJ cancer throughout the clinical pathway. A primary contact (e.g., nurse specialist) can ensure continuity of care, help patients navigate interventions in a timely fashion, and coordinate pre- and post-operative nutritional and psychological support, post-operative follow-up, and, if necessary, specialized rehabilitation.

Prior to treatment, GEJ tumor histology and location must be staged via AJCC staging classifications.[11]

With GEJ cancer, only 11 to 21 percent of patients will present with potentially resectable disease and have the physiologic capacity to tolerate surgery.[11] To determine whether patients will be able to tolerate pre-operative chemoradiation, providers must assess their physiologic status.[18]

Treatment of GEJ cancer can negatively impact health-related quality of life (HRQoL) due to the development of dyspnea, fatigue, and eating restrictions. Providers should recognize that acute post-operative complications, comorbidities, and advanced tumor stage are predictors of risk for deterioration in HRQoL.[8]

Providers can improve outcomes in patients with GEJ cancer by modifying risk factors before surgery, optimizing nutritional status, and educating patients about what to expect.[9]

The last decade has witnessed a trend toward consolidating

Table 5. ICD Code Changes Related to Treatment of GEJ Cancer

ICD-9 150 Malignant Neoplasm of Esophagus	ICD-10 C15 Malignant Neoplasm of Esophagus
• 150.0 malignant neoplasm of cervical esophagus	• C15.0 cervical part of esophagus
• 150.1 malignant neoplasm of thoracic esophagus	• C15.1 thoracic part of esophagus
• 150.2 malignant neoplasm of abdominal esophagus	• C15.2 abdominal part of esophagus
• 150.3 malignant neoplasm of upper third of esophagus	• C15.3 upper third of esophagus
• 150.4 malignant neoplasm of middle third of esophagus	• C15.4 middle third of esophagus
• 150.5 malignant neoplasm of lower third of esophagus	• C15.5 lower third of esophagus
• 150.8 malignant neoplasm of other specified part of esophagus	• C15.8 overlapping lesion of esophagus
• 150.9 malignant neoplasm of esophagus, unspecified	• C15.9 esophagus, unspecified
151.0 malignant neoplasm of cardia	C16.0 malignant neoplasm of cardia
230.1 carcinoma *in situ* of esophagus	D00.1 carcinoma *in situ* of esophagus
235.5 neoplasm of uncertain behavior of other and unspecified digestive organs	D37.7 neoplasm of uncertain or unknown behavior of other digestive organs (including esophagus)

high-risk cancer resections at high-volume hospitals, which can achieve perioperative mortality of ≤5 percent.[6] Fewer complications occur in high-volume settings and, if they do occur, are likely to be handled more effectively.[8,22] Community providers can partner with providers at these high-volume hospitals to ensure continuity of care as GEJ cancer patients transition between care settings.

> To determine whether patients will be able to tolerate pre-operative chemoradiation, providers must assess their physiologic status.

Accurate documentation of procedures in the patient's medical record is important for effective reporting and timely reimbursement. As International Classification of Diseases (ICD) codes migrate from ICD-9 to a more specific ICD-10, healthcare providers need to document the correct treatment and sequencing codes across the patient trajectory (see Table 5, above).[23]

The Future of GEJ Treatment

Even with perioperative chemotherapy or pre-operative chemoradiation, outcomes for patients with GEJ cancer remain poor. But there is hope on the horizon. Multiple molecular pathways involved in the pathobiology of GEJ cancer may serve as the basis for novel therapeutic agents. For instance, human epidermal growth factor receptor-2 (HER2)-positive tumors are overexpressed in esophageal and GEJ tumors. As a result of the Trastuzumab for Gastric Cancer (ToGA) trial,[24] in which 20 percent of enrolled patients had GEJ adenocarcinoma, trastuzumab presents an option in combination with chemotherapy as a first-line treatment for HER2-neu positive patients with inoperable GEJ cancer.[15] Several Phase III studies are ongoing that signal potential refinements in standards of care for patients with GEJ, as well as research to identify predictive and prognostic biomarkers. OI

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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

Single vs. Dual HER2 Blockade for Metastatic HER2-Positive Breast Cancer

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

Discuss the changing standard of care for patients with metastatic HER2-positive breast cancer.

Howard A. Burris III, MD
Sarah Cannon Research Institute

George Somlo, MD
City of Hope National Medical Center

Supported by an independent educational grant from Genentech

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

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

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

James Foran, MD
Mayo Clinic

Supported by independent educational grants from Boehringer Ingelheim and Novartis

Personalizing Treatment for NSCLC: Going Beyond the Ordinary

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

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

Alice T. Shaw, MD, PhD
Massachusetts General Hospital

Supported by an independent educational grant from Genentech

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

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

Evaluate patient and disease characteristics—such as age, performance status, comorbidities, and hepatic and renal function—in older patients with chronic lymphocytic leukemia (CLL) and select the optimum treatment approach.

Ian W. Flinn, MD, PhD
Sarah Cannon Blood Centers

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careers

CLINICIAN/SCIENTISTS AERODIGESTIVE AND GU MALIGNANCIES

Shreveport, Louisiana

The Feist-Weiller Cancer Center (FWCC) at LSU Health Sciences Center (LSUHSC) is seeking clinicians/scientists for tenure track positions in its Aerodigestive and GU Malignancy Programs. The positions—available at all academic levels—offer unique opportunities to lead or participate in active multidisciplinary teams of clinicians and scientists, allowing the opportunity to create and build clinical or translational cancer research programs.

FWCC is the most active tertiary cancer care and cancer research facility in Louisiana, serving over 80 percent of the state. FWCC has a state-of-the-art research facility, a new 60,000-square-foot multidisciplinary outpatient clinical building, and a faculty of over 50 clinicians and scientists.

FWCC's Division of Basic Cancer Research, Clinical Cancer Research, and Cancer Prevention and Control maintain active NCI-funded clinical research programs, multiple strongly funded programs in various aspects of the molecular biology of cancer, and innovative translational research projects. A new state-of-the-art cancer genome sequencing laboratory has been established. Generous start-up packages are available for translational and clinical research faculty. A mentored research development program is in place for junior faculty in both basic and clinical translational arenas.

Shreveport is a progressive modern city with excellent schools, numerous family activities, and a very low cost of living. LSU Health Shreveport is an equal opportunity employer and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability status, protected veteran status, or any other characteristic protected by law.

Interested individuals should send a CV with a letter describing research or clinical interests and with three letters of reference to: Glenn Mills, MD, Professor of Medicine, Chief, Section of Hematology and Oncology, Director, Feist-Weiller Cancer Center, LSU Health Science Center, 1501 Kings Highway, Shreveport, LA 71130-3932 or email: gmills@lsuhsc.edu.

For more information, email: gmills@lsuhsc.edu.

DIRECTOR STEM CELL TRANSPLANT PROGRAM

Shreveport, Louisiana

The Feist-Weiller Cancer Center's (FWCC) Stem Cell Transplantation (SCT) program is seeking a Director. The position—available at associate or full professorship level—offers unique opportunities to participate in an active SCT and leukemia program, interacting with established multidisciplinary teams of clinicians and scientists, allowing the opportunity to create and build clinical or translational cancer research programs. FWCC's SCT program has an active autologous transplantation program. The new Director is expected to re-activate our allogeneic transplant program.

FWCC is the most active tertiary cancer care and cancer research facility in Louisiana, serving over 80 percent of the state. FWCC has a state-of-the-art research facility, a new 60,000-square-foot multidisciplinary outpatient clinical building, and a faculty of over 50 clinicians and scientists. FWCC's Division of Basic Cancer Research, Clinical Cancer Research, and Cancer Prevention and Control maintain active NCI-funded clinical research programs, multiple strongly funded programs in various aspects of the molecular biology of cancer, and innovative translational research projects. A new state-of-the-art cancer genome sequencing laboratory has been established. Generous start-up packages are available for translational and clinical research faculty. A mentored research development program is in place for junior faculty in both basic and clinical translational arenas

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For more information, email: gmills@lsuhsc.edu.

MEDICAL CENTER CANCER CENTER DIRECTOR/ VICE PRESIDENT CANCER SERVICES

Chicago, Illinois

Rush University Medical Center, located in downtown Chicago, is seeking a Cancer Center Director/Vice President of Cancer Services. This key physician leader will be responsible for all aspects of the interdisciplinary Cancer Center, including clinical programs, strategic development, growth, operations, clinical trials, basic and translational research, and cancer informatics. This physician executive will lead the development of a detailed strategic plan around cancer services by collaborating with department chairpersons, key members of the Cancer Center, and the Cancer Center Executive Committee.

The Director will promote clinical and research activities on local, regional, and national levels and expand the center's programs and reputation. The Director will be expected to spend the majority of time on these administrative tasks, but will also continue a part-time practice and/or research program in the area of their primary expertise. The Cancer Center Director will manage the strategic, financial, and operational plans of the Cancer Center and will report to the Dean of Rush Medical College and the Executive Vice President for Clinical Affairs.

This recruitment is part of a key strategic growth initiative and generous resources are being dedicated to this enterprise. Candidates should be Board Certified in a cancer-related discipline, be eligible for faculty appointment at the full Professor level, and have demonstrated outstanding leadership capabilities. Experience in leading a large complex enterprise is necessary. Salary will be commensurate with qualifications and experience. Rush is an Equal Opportunity Employer.

Rush is home to the oldest medical college in Chicago and one of the nation's top-ranked nursing colleges, as well as graduate programs in allied health, health systems management and biomedical research.

Interested candidates should contact: Courtney Kammer, Director, Faculty Recruitment, Rush University Medical Center. Phone: 312.942.7376 or email: Courtney_Kammer@rush.edu.

For more information, email: Courtney_Kammer@rush.edu.

ONCOLOGY SERVICE LINE DIRECTOR

Wyandotte, Michigan

The Henry Ford Wyandotte Hospital, a 401-bed acute care hospital in Wyandotte, Michigan, is recruiting an oncology service line director. The oncology service line director will work collaboratively with Senior Hospital Leadership, the Oncology Medical Director, Josephine Ford Cancer Institute leadership, private practice and employed medical staff members, Cancer Care patient care team, and outside agencies to provide state of the art cancer care services.

Responsibilities include planning, implementing, directing, monitoring and promoting oncology programs and services. The oncology service line director will lead oncology strategic and business planning initiatives. Budget development for the oncology service line and insuring profitability are key responsibilities for the service line director. Managing oncology program human resources in a cost effective and supportive manner is a core component of the position.

Learn more about this position, at www.henryfordcareers.com, Job ID 85615.

SERVICE LINE ADMINISTRATOR, ONCOLOGY SERVICES

Langhorne, Pennsylvania

St. Mary Medical Center, a financially-strong, high performing 374-bed hospital and Level II Trauma Center, affiliated with CHE Trinity Health, is seeking a Service Line Administrator, Oncology Services.

We are seeking an experienced leader who can bring strategic planning, program development, and operations experience. Business planning experience and a track record of executing growth strategies are essential. A clinical background is desirable. Experience collaborating with both employed and private physicians is preferred.

Requirements: MHA, MBA, MSN, or Master's degree in a related field is required. A minimum of 8 years of progressively responsible experience in healthcare leadership. A minimum of five 5 years of leadership in oncology services, with a quantifiable track record of program development and market share growth is required.

Interested candidates should contact: John Kiernan, Managing Director, Management Pathways, 5 Great Valley Parkway, Suite 276 Malvern, PA 19355. Phone: 610.415.0888 or email: jkiernan@managementpathways.com.

For more information, email jkiernan@managementpathways.com.

action

CALL FOR NOMINATIONS

ACCC is now accepting nominations for its 2015 Annual Achievement Award and the 2015 David King Community Clinical Scientist Award. To nominate an individual or individuals for either award, complete the 2015 Awards Nomination form (www.accc-cancer.org/about/Awards.asp) and return it to Careen Campbell via email (ccampbell@accc-cancer.org) or fax (301.770.1949). Nominations must be received by August 31, 2014.

ACCC Welcomes its Newest Members

Advocate Lutheran General Hospital Lutheran General Cancer Institute
Park Ridge, Ill.
Delegate Rep: Jennifer Clayton, MSN, ACNP
Website: www.advocatehealth.com

HCA VA Cancer Network Spotsylvania Regional Cancer Center
Fredericksburg, Va.
Delegate Rep: Amy Meleason, BSN, RN, OCN, Website: www.hcahealthcare.com

New Mexico Oncology Hematology Consultants, Albuquerque, N.M.
Delegate Rep: Julie Nickerson MBA
Website: www.nmcancercenter.org

UCSF Helen Diller Family Comprehensive Cancer Center
San Francisco, Calif.
Delegate Rep: Laurel Bray-Hanin
Website: www.ucsfhealth.org

ACCC would also like to welcome its newest chapter member

Georgia Society of Clinical Oncology (GASCO)
Atlanta, Ga.
Website: www.gasco.us

ADVERTISER'S INDEX

Teen Cancer America—All Aboard!

BY SIMON DAVIES

I was a six-foot and five-inch 16-year-old and they had to make an extension to my hospital bed on the children's ward. Steve, 18, Los Angeles

I had a type of bone cancer called Ewing's Sarcoma, and I looked up the drugs they were giving me. They were 30 years old. Nothing new in 30 years! I couldn't believe it. Emily, 17, Boston

I had just turned 18 and the average age of patients on my ward at the adult hospital must have been about 60. I felt strange and isolated. Daniel, 21, Chicago

The doctor in my hospital said that he had only ever seen one other patient with my type of cancer and that he wasn't sure how to treat it. There was a bigger hospital with more expertise, but my insurance company said they wouldn't pay for me to go there. My Dad ended up taking out a loan to pay for my treatment. Ellie, 16, Daytona

These are just some of the stories voiced by teenage and young adult cancer patients in the United States.

Teenage Cancer Trust

For more than 20 years the U.K. (United Kingdom) charity Teenage Cancer Trust has single handedly battled for specialist services for this sometimes "forgotten tribe" of patients. Such that now the British National Health Service (NHS) has standards and measures that require every major cancer center to provide age appropriate facilities and expert multidisciplinary teams specifically for teenagers and young adults. Furthermore there is a national research group focused solely on this patient population and a national intelligence service that clearly marks these patients in comprehensive data collection.

And now the movement has come to the United States.

Teen Cancer America

After acting as CEO of Teenage Cancer Trust for 13 years, I was recently appointed executive director of Teen Cancer America, a charity founded by Roger Daltrey and Pete Townshend, legendary frontmen of The Who. Daltrey has been a passionate patron of Teenage Cancer Trust and, with the help of Chairman Rebecca Rothstein, Daltrey and Townshend set up the charity and brought me in to build on the U.K.'s success.

Teen Cancer America has big ambitions. We want to work in partnership with all of the major cancer centers in the U.S. to develop both facilities and multidisciplinary teams to meet the unique needs of this patient population. We work specifically with young people aged 13 to 25 because that is where all the "action" happens—late onset pediatric cancers, early onset adult cancers, growth spurts, hormonal activity, acute psychological challenges, educational and employment issues, and most significantly, a lack of medical and scientific understanding about many of the rare cancers that affect those in this age group.

The charity has hit the ground running. I have a list of more than 30 hospitals in 20 states that are in communication with Teen Cancer America about developing services. This list includes some of the top teaching hospitals in the world, such as UCLA, the Dana-Farber Cancer Institute, and MD Anderson.

There is a lot of interest and enthusiasm out there demonstrated by a small but

Left: Young people with cancer at the Long Beach Grand Prix where TCA launched Hernan's (in the driving suit and wheelchair) Road Rebellion tour. Above: Teen lounge within the specialist AYA facility at UCLA. Below: Teen Cancer America logo.

growing number of champions. The American health system is, of course, complex and different from the U.K., but the challenges are by no means insurmountable. In fact the natural entrepreneurialism of the American culture is what should make our goals achievable. It will take courage, investment, collaboration, and communication. For example, meeting the needs of teenagers and young adults with cancer requires pediatric and medical oncology to combine their efforts.

A Time for Change

The message from the U.K. and increasingly here in the U.S. is that these specialist services are what teenage and young adult patients and families want. Or, as Daltrey so succinctly puts it, "[this type of care] is the right thing to do for the young people who are our future." So, let's make this a time for change.

How do we do this? In addition to the larger, academic teaching centers, I truly believe that community programs have an important part to play in bringing about success for this patient population. While Teen Cancer America believes in centralizing complex treatments in major cancer centers that see enough of these patients to conduct clinical trials and deliver the best outcomes, the organization has a commitment to seeing well-developed partnerships with community programs that can deliver some of the most important aspects of care and support.

Rare disease requires specialist input and teams that treat young people and understand their needs. These programs need to be the coordinators of the cancer pathway. But we are increasingly able to treat cancers in outpatient settings, and the less complex aspects of medical support can be effectively given closer to home in community programs. These community programs can deliver first-class treatment by collaborating closely with their academic and tertiary counterparts.

Imagine a hub and spoke arrangement where the specialist cancer centers "design the treatment packages" and then share the delivery of these treatments with community cancer programs and primary care physicians. At the center of this hub are the multidisciplinary cancer care teams who have specific expertise with teenagers and young adults and the cancers that affect them.

Get Involved!

I recently met a young American woman who had survived cancer and is now training to become an oncologist. She told me that the isolation she felt during her cancer treatment at both the pediatric and adult cancer programs—not meeting one other person her own age—had been the single motivating factor in her desire to study medicine and bring about change. She is now determined to be a part of changing cancer treatment for those young people.

Teen Cancer America is embarking on a major initiative to draw attention to these issues. And we are joined by some amazing individuals. Hernan Barrangan survived two episodes of cancer in his teens. The last treatment (not the cancer) caused him to be paralyzed from the waist down. Undaunted, Barrangan has become an expert filmmaker and he has developed a specialty in telling the story of young cancer survivors. I have seen a thousand charity films but none compare to the quality of Hernan's. He is an exceptional talent.

Teen Cancer America is sending Hernan to every state in the U.S. to capture the stories of young people with cancer. We will then have the voice of the nation captured on film, and Teen Cancer America will use this to influence and bring about change. You can follow Hernan's "Road Rebellion" journey on the Teen Cancer America website, www.teencanceramerica.org/hernan/the-plan.

The teenage and young adult cancer train is here and healthcare professionals need to get onboard or be left behind. Find out more at www.teencanceramerica.org or contact me at simon@teencanceramerica.org if you want to help make a difference. OI

Simon Davies is executive director of Teen Cancer America, Los Angeles, Calif.

Xtandi (enzalutamide) capsules

XTANDI® (enzalutamide) capsules for oral use
Initial U.S. Approval: 2012

BRIEF SUMMARY OF PRESCRIBING INFORMATION
The following is a brief summary: please see the package insert for full prescribing information.

INDICATIONS AND USAGE

XTANDI is indicated for the treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel.

CONTRAINDICATIONS

Pregnancy
XTANDI can cause fetal harm when administered to a pregnant woman based on its mechanism of action. XTANDI is not indicated for use in women. XTANDI is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus and the potential risk for pregnancy loss *[see Use in Specific Populations]*.

WARNINGS AND PRECAUTIONS

Seizure
In the randomized clinical trial, 7 of 800 (0.9%) patients treated with XTANDI 160 mg once daily experienced a seizure. No seizures occurred in patients treated with placebo. Seizures occurred from 31 to 603 days after initiation of XTANDI. Patients experiencing seizure were permanently discontinued from therapy and all seizures resolved. There is no clinical trial experience re-administering XTANDI to patients who experienced seizures.
The safety of XTANDI in patients with predisposing factors for seizure is not known because these patients were excluded from the trial. These exclusion criteria included a history of seizure, underlying brain injury with loss of consciousness, transient ischemic attack within the past 12 months, cerebral vascular accident, brain metastases, brain arteriovenous malformation or the use of concomitant medications that may lower the seizure threshold.
Because of the risk of seizure associated with XTANDI use, patients should be advised of the risk of engaging in any activity where sudden loss of consciousness could cause serious harm to themselves or others.

ADVERSE REACTIONS

Clinical Trial Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.
In the randomized clinical trial in patients with metastatic castration-resistant prostate cancer who had previously received docetaxel, patients received XTANDI 160 mg orally once daily (N = 800) or placebo (N = 399). The median duration of treatment was 8.3 months with XTANDI and 3.0 months with placebo. All patients continued androgen deprivation therapy. Patients were allowed, but not required, to take glucocorticoids. During the trial, 48% of patients on the XTANDI arm and 46% of patients on the placebo arm received glucocorticoids. All adverse events and laboratory abnormalities were graded using NCI CTCAE version 4.
The most common adverse drug reactions (≥ 5%) reported in patients receiving XTANDI in the randomized clinical trial were asthenia/fatigue, back pain, diarrhea, arthralgia, hot flush, peripheral edema, musculoskeletal pain, headache, upper respiratory infection, muscular weakness, dizziness, insomnia, lower respiratory infection, spinal cord compression and cauda equina syndrome, hematuria, paresthesia, anxiety, and hypertension. Grade 3 and higher adverse reactions were reported among 47% of XTANDI-treated patients and 53% of placebo-treated patients. Discontinuations due to adverse events were reported for 16% of XTANDI-treated patients and 18% of placebo-treated patients. The most common adverse reaction leading to treatment discontinuation was seizure, which occurred in 0.9% of the XTANDI-treated patients compared to none (0%) of the placebo-treated patients. Table 1 shows adverse reactions reported in the randomized clinical trial that occurred at a ≥ 2% absolute increase in frequency in the XTANDI arm compared to the placebo arm.

Table 1. Adverse Reactions in the Randomized Trial

	XTANDI N = 800		Placebo N = 399	
	Grade 1-4 (%)	Grade 3-4 (%)	Grade 1-4 (%)	Grade 3-4 (%)
General Disorders				
Asthenic Conditions[a]	50.6	9.0	44.4	9.3
Peripheral Edema	15.4	1.0	13.3	0.8
Musculoskeletal And Connective Tissue Disorders				
Back Pain	26.4	5.3	24.3	4.0
Arthralgia	20.5	2.5	17.3	1.8
Musculoskeletal Pain	15.0	1.3	11.5	0.3
Muscular Weakness	9.8	1.5	6.8	1.8
Musculoskeletal Stiffness	2.6	0.3	0.3	0.0

(continued) **Table 1. Adverse Reactions in the Randomized Trial**

	XTANDI N = 800		Placebo N = 399	
	Grade 1-4 (%)	Grade 3-4 (%)	Grade 1-4 (%)	Grade 3-4 (%)
Gastrointestinal Disorders				
Diarrhea	21.8	1.1	17.5	0.3
Vascular Disorders				
Hot Flush	20.3	0.0	10.3	0.0
Hypertension	6.4	2.1	2.8	1.3
Nervous System Disorders				
Headache	12.1	0.9	5.5	0.0
Dizziness[b]	9.5	0.5	7.5	0.5
Spinal Cord Compression and Cauda Equina Syndrome	7.4	6.6	4.5	3.8
Paresthesia	6.6	0.0	4.5	0.0
Mental Impairment Disorders[c]	4.3	0.3	1.8	0.0
Hypoesthesia	4.0	0.3	1.8	0.0
Infections And Infestations				
Upper Respiratory Tract Infection[d]	10.9	0.0	6.5	0.3
Lower Respiratory Tract And Lung Infection[e]	8.5	2.4	4.8	1.3
Psychiatric Disorders				
Insomnia	8.8	0.0	6.0	0.5
Anxiety	6.5	0.3	4.0	0.0
Renal And Urinary Disorders				
Hematuria	6.9	1.8	4.5	1.0
Pollakiuria	4.8	0.0	2.5	0.0
Injury, Poisoning And Procedural Complications				
Fall	4.6	0.3	1.3	0.0
Non-pathologic Fractures	4.0	1.4	0.8	0.3
Skin And Subcutaneous Tissue Disorders				
Pruritus	3.8	0.0	1.3	0.0
Dry Skin	3.5	0.0	1.3	0.0
Respiratory Disorders				
Epistaxis	3.3	0.1	1.3	0.3

a Includes asthenia and fatigue.
b Includes dizziness and vertigo.
c Includes amnesia, memory impairment, cognitive disorder, and disturbance in attention.
d Includes nasopharyngitis, upper respiratory tract infection, sinusitis, rhinitis, pharyngitis, and laryngitis.
e Includes pneumonia, lower respiratory tract infection, bronchitis, and lung infection.

Laboratory Abnormalities
In the randomized clinical trial, Grade 1-4 neutropenia occurred in 15% of patients on XTANDI (1% Grade 3-4) and in 6% of patients on placebo (no Grade 3-4). The incidence of Grade 1-4 thrombocytopenia was similar in both arms; 0.5% of patients on XTANDI and 1% on placebo experienced Grade 3-4 thrombocytopenia. Grade 1-4 elevations in ALT occurred in 10% of patients on XTANDI (0.3% Grade 3-4) and 18% of patients on placebo (0.5% Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of patients on XTANDI and 2% of patients on placebo.

Infections
In the randomized clinical trial, 1.0% of patients treated with XTANDI compared to 0.3% of patients on placebo died from infections or sepsis. Infection-related serious adverse events were reported in approximately 6% of the patients on both treatment arms.

Falls and Fall-related Injuries
In the randomized clinical trial, falls or injuries related to falls occurred in 4.6% of patients treated with XTANDI compared to 1.3% of patients on placebo. Falls were not associated with loss of consciousness or seizure. Fall-related injuries were more severe in patients treated with XTANDI and included non-pathologic fractures, joint injuries, and hematomas.

Hallucinations
In the randomized clinical trial, 1.6% of patients treated with XTANDI were reported to have Grade 1 or 2 hallucinations compared to 0.3% of patients on placebo. Of the patients with hallucinations, the majority were on opioid-containing medications at the time of the event. Hallucinations were visual, tactile, or undefined.

DRUG INTERACTIONS

Drugs that Inhibit or Induce CYP2C8

Co-administration of a strong CYP2C8 inhibitor (gemfibrozil) increased the composite area under the plasma concentration-time curve (AUC) of enzalutamide plus N-desmethyl enzalutamide in healthy volunteers. Co-administration of XTANDI with strong CYP2C8 inhibitors should be avoided if possible. If co-administration of XTANDI with a strong CYP2C8 inhibitor cannot be avoided, reduce the dose of XTANDI *[see Dosage and Administration (2.2) and Clinical Pharmacology (12.3)]*.

The effects of CYP2C8 inducers on the pharmacokinetics of enzalutamide have not been evaluated *in vivo*. Co-administration of XTANDI with strong or moderate CYP2C8 inducers (e.g., rifampin) may alter the plasma exposure of XTANDI and should be avoided if possible. Selection of a concomitant medication with no or minimal CYP2C8 induction potential is recommended *[see Clinical Pharmacology]*.

Drugs that Inhibit or Induce CYP3A4

Co-administration of a strong CYP3A4 inhibitor (itraconazole) increased the composite AUC of enzalutamide plus N-desmethyl enzalutamide by 1.3 fold in healthy volunteers *[see Clinical Pharmacology (12.3)]*.

The effects of CYP3A4 inducers on the pharmacokinetics of enzalutamide have not been evaluated *in vivo*. Co-administration of XTANDI with strong CYP3A4 inducers (e.g., carbamazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine) may decrease the plasma exposure of XTANDI and should be avoided if possible. Selection of a concomitant medication with no or minimal CYP3A4 induction potential is recommended. Moderate CYP3A4 inducers (e.g., bosentan, efavirenz, etravirine, modafinil, nafcillin) and St. John's Wort may also reduce the plasma exposure of XTANDI and should be avoided if possible *[see Clinical Pharmacology]*.

Effect of XTANDI on Drug Metabolizing Enzymes

Enzalutamide is a strong CYP3A4 inducer and a moderate CYP2C9 and CYP2C19 inducer in humans. At steady state, XTANDI reduced the plasma exposure to midazolam (CYP3A4 substrate), warfarin (CYP2C9 substrate), and omeprazole (CYP2C19 substrate). Concomitant use of XTANDI with narrow therapeutic index drugs that are metabolized by CYP3A4 (e.g., alfentanil, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus and tacrolimus), CYP2C9 (e.g., phenytoin, warfarin) and CYP2C19 (e.g., S-mephenytoin) should be avoided, as enzalutamide may decrease their exposure. If co-administration with warfarin cannot be avoided, conduct additional INR monitoring *[see Clinical Pharmacology]*.

USE IN SPECIFIC POPULATIONS

Pregnancy- Pregnancy Category X *[see Contraindications]*.

XTANDI can cause fetal harm when administered to a pregnant woman based on its mechanism of action. While there are no human or animal data on the use of XTANDI in pregnancy and XTANDI is not indicated for use in women, it is important to know that maternal use of an androgen receptor inhibitor could affect development of the fetus. XTANDI is contraindicated in women who are or may become pregnant while receiving the drug. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus and the potential risk for pregnancy loss. Advise females of reproductive potential to avoid becoming pregnant during treatment with XTANDI.

Nursing Mothers

XTANDI is not indicated for use in women. It is not known if enzalutamide is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from XTANDI, a decision should be made to either discontinue nursing, or discontinue the drug taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness of XTANDI in pediatric patients have not been established.

Geriatric Use

Of 800 patients who received XTANDI in the randomized clinical trial, 71 percent were 65 and over, while 25 percent were 75 and over. No overall differences in safety or effectiveness were observed between these patients and younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Patients with Renal Impairment

A dedicated renal impairment trial for XTANDI has not been conducted. Based on the population pharmacokinetic analysis using data from clinical trials in patients with metastatic castration-resistant prostate cancer and healthy volunteers, no significant difference in enzalutamide clearance was observed in patients with pre-existing mild to moderate renal impairment (30 mL/min ≤ creatinine clearance [CrCL] ≤ 89 mL/min) compared to patients and volunteers with baseline normal renal function (CrCL ≥ 90 mL/min). No initial dosage adjustment is necessary for patients with mild to moderate renal impairment. Severe renal impairment (CrCL < 30 mL/min) and end-stage renal disease have not been assessed *[see Clinical Pharmacology]*.

Patients with Hepatic Impairment

A dedicated hepatic impairment trial compared the composite systemic exposure of enzalutamide plus N-desmethyl enzalutamide in volunteers with baseline mild or moderate hepatic impairment (Child-Pugh Class A and B, respectively) versus healthy controls with normal hepatic function. The composite AUC of enzalutamide plus N-desmethyl enzalutamide was similar in volunteers with mild or moderate baseline hepatic impairment compared to volunteers with normal hepatic function. No initial dosage adjustment is necessary for patients with baseline mild or moderate hepatic impairment. Baseline severe hepatic impairment (Child-Pugh Class C) has not been assessed *[see Clinical Pharmacology]*.

OVERDOSAGE

In the event of an overdose, stop treatment with XTANDI and initiate general supportive measures taking into consideration the half-life of 5.8 days. In a dose escalation study, no seizures were reported at ≤ 240 mg daily, whereas 3 seizures were reported, 1 each at 360 mg, 480 mg, and 600 mg daily. Patients may be at increased risk of seizures following an overdose.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been conducted to evaluate the carcinogenic potential of enzalutamide.

Enzalutamide did not induce mutations in the bacterial reverse mutation (Ames) assay and was not genotoxic in either the *in vitro* mouse lymphoma thymidine kinase (Tk) gene mutation assay or the *in vivo* mouse micronucleus assay.

Based on nonclinical findings in repeat-dose toxicology studies, which were consistent with the pharmacological activity of enzalutamide, male fertility may be impaired by treatment with XTANDI. In a 26-week study in rats, atrophy of the prostate and seminal vesicles was observed at ≥ 30 mg/kg/day (equal to the human exposure based on AUC). In 4- and 13-week studies in dogs, hypospermatogenesis and atrophy of the prostate and epididymides were observed at ≥ 4 mg/kg/day (0.3 times the human exposure based on AUC).

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (PATIENT INFORMATION).

- Instruct patients to take their dose at the same time each day (once daily). XTANDI can be taken with or without food. Each capsule should be swallowed whole. Do not chew, dissolve, or open the capsules.
- Inform patients receiving a GnRH analog that they need to maintain this treatment during the course of treatment with XTANDI.
- Inform patients that XTANDI has been associated with an increased risk of seizure. Discuss conditions that may predispose to seizures and medications that may lower the seizure threshold. Advise patients of the risk of engaging in any activity where sudden loss of consciousness could cause serious harm to themselves or others.
- Inform patients that XTANDI may cause dizziness, mental impairment, paresthesia, hypoesthesia, and falls.
- Inform patients that they should not interrupt, modify the dose, or stop XTANDI without first consulting their physician. Inform patients that if they miss a dose, then they should take it as soon as they remember. If they forget to take the dose for the whole day, then they should take their normal dose the next day. They should not take more than their prescribed dose per day.
- Apprise patients of the common side effects associated with XTANDI: asthenia/fatigue, back pain, diarrhea, arthralgia, hot flush, peripheral edema, musculoskeletal pain, headache, upper respiratory infection, muscular weakness, dizziness, insomnia, lower respiratory infection, spinal cord compression and cauda equina syndrome, hematuria, paresthesia, anxiety, and hypertension. Direct the patient to a complete list of adverse drug reactions in PATIENT INFORMATION.
- Inform patients that XTANDI may be harmful to a developing fetus. Patients should also be informed that they should use a condom if having sex with a pregnant woman. A condom and another effective method of birth control should be used if the patient is having sex with a woman of child-bearing potential. These measures are required during and for three months after treatment with XTANDI.

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astellas ONCOLOGY

MEDIVATION

FOR THE TREATMENT OF PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (mCRPC) WHO HAVE PREVIOUSLY RECEIVED DOCETAXEL

Xtandi® (enzalutamide) capsules

XTANDI (enzalutamide) capsules is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) who have previously received docetaxel.

Important Safety Information

Contraindications XTANDI can cause fetal harm when administered to a pregnant woman based on its mechanism of action. XTANDI is not indicated for use in women. XTANDI is contraindicated in women who are or may become pregnant.

Warnings and Precautions In the randomized clinical trial, seizure occurred in 0.9% of patients on XTANDI. No patients on the placebo arm experienced seizure. Patients experiencing a seizure were permanently discontinued from therapy. All seizures resolved. Patients with a history of seizure, taking medications known to decrease the seizure threshold, or with other risk factors for seizure were excluded from the clinical trial. Because of the risk of seizure associated with XTANDI use, patients should be advised of the risk of engaging in any activity where sudden loss of consciousness could cause serious harm to themselves or others.

Adverse Reactions The most common adverse drug reactions (≥ 5%) reported in patients receiving XTANDI in the randomized clinical trial were asthenia/fatigue, back pain, diarrhea, arthralgia, hot flush, peripheral edema, musculoskeletal pain, headache, upper respiratory infection, muscular weakness, dizziness, insomnia, lower respiratory infection, spinal cord compression and cauda equina syndrome, hematuria, paresthesia, anxiety, and hypertension. Grade 1-4 neutropenia occurred in 15% of XTANDI patients (1% grade 3-4) and in 6% of patients on placebo (no grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of XTANDI patients and 2% of patients on placebo. One percent of XTANDI patients compared to 0.3% of patients on placebo died from infections or sepsis. Falls or injuries related to falls occurred in 4.6% of XTANDI patients vs 1.3% of patients on placebo. Falls were not associated with loss of consciousness or seizure. Fall-related injuries were more severe in XTANDI patients and included non-pathologic fractures, joint injuries, and hematomas. Grade 1 or 2 hallucinations occurred in 1.6% of XTANDI patients and 0.3% of patients on placebo, with the majority on opioid-containing medications at the time of the event.

Drug Interactions: Effect of Other Drugs on XTANDI Administration of strong CYP2C8 inhibitors can increase the plasma exposure to XTANDI. Coadministration of XTANDI with strong CYP2C8 inhibitors should be avoided if possible. If coadministration of XTANDI cannot be avoided, reduce the dose of XTANDI. Coadministration of XTANDI with strong or moderate CYP3A4 and CYP2C8 inducers can alter the plasma exposure of XTANDI and should be avoided if possible. **Effect of XTANDI on Other Drugs** XTANDI is a strong CYP3A4 inducer and a moderate CYP2C9 and CYP2C19 inducer in humans. Avoid CYP3A4, CYP2C9, and CYP2C19 substrates with a narrow therapeutic index, as XTANDI may decrease the plasma exposures of these drugs. If XTANDI is coadministered with warfarin (CYP2C9 substrate), conduct additional INR monitoring.

Please see adjacent pages for Brief Summary of Full Prescribing Information.

References: 1. XTANDI [package insert]. Northbrook, IL: Astellas Pharma US, Inc; 2012. **2.** Scher HI, Fizazi K, Saad F, et al. Increased survival with enzalutamide in prostate cancer after chemotherapy. *N Engl J Med*. 2012;367:1187-1197. **3.** Referenced with permission from The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.2.2013. © National Comprehensive Cancer Network, Inc 2013. All rights reserved. Accessed March 11, 2013. To view the most recent and complete version of the guideline, go online to www.nccn.org. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, NCCN GUIDELINES®, and all other NCCN Content are trademarks owned by the National Comprehensive Cancer Network, Inc.

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MEDIVATION
Driven by science. Focused on life.

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Xtandi® (enzalutamide) capsules

18.4 MONTHS MEDIAN OVERALL SURVIVAL
VS **13.6 MONTHS** WITH PLACEBO[1]

18.4 AND MORE:

- **Convenient, oral, once-daily administration**
  - Dosed as four 40 mg capsules (160 mg) without food restrictions or steroid requirements. Each capsule should be swallowed whole. Patients should not chew, dissolve, or open the capsules[1,2]
- **Comparable overall rate of grade 3-4 adverse reactions**
  - No increased overall rate of grade 3-4 adverse reactions with XTANDI (enzalutamide) capsules vs placebo (47% vs 53%, respectively)[1]
- **37% reduced risk of death**
  - HR = 0.63 (95% CI, 0.53-0.75); $P < 0.0001$[1]

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) include enzalutamide (XTANDI) with a category 1 recommendation for use following docetaxel in patients with mCRPC.[3]

Select Important Safety Information

In the randomized clinical trial, seizure occurred in 0.9% of patients on XTANDI versus none on the placebo arm.

The most common adverse drug reactions (≥ 5%) were asthenia/fatigue, back pain, diarrhea, arthralgia, hot flush, peripheral edema, musculoskeletal pain, headache, upper respiratory infection, muscular weakness, dizziness, insomnia, lower respiratory infection, spinal cord compression and cauda equina syndrome, hematuria, paresthesia, anxiety, and hypertension. Grade 3 and higher adverse reactions were reported among 47% of XTANDI-treated patients and 53% of placebo-treated patients. Discontinuations due to adverse events were reported for 16% of XTANDI-treated patients and 18% of placebo-treated patients.

Please see adjacent pages for Important Safety Information and Brief Summary of Full Prescribing Information.