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ONCOLOGY ISSUES

The Journal of the Association of Community Cancer Centers
November | December 2014

Building a Comprehensive Oncology Rehabilitation Program

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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1 Cristofanilli M, et al. *Cancer Res.* 2012;72(24 Suppl):Abstract nr P3-05-01.
2 Whitworth P, et al. *Ann Surg Oncol.* 2014 Oct.

M-USA-044-V1

mammaprint®
70-Gene Breast Cancer Recurrence Assay

blueprint®
80-Gene Molecular Subtyping Assay

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DEPARTMENTS

ACCC
Association of Community Cancer Centers

ONCOLOGY ISSUES
The Journal of the
Association of Community Cancer Centers

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

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

FROM THE EDITOR

A New Set of Wheels

BY CHRISTIAN DOWNS, JD, MHA

We all remember our first car. Mine was a Jeep CJ—huge V8 engine, full-time four-wheel drive, and painted a nausea-inducing shade of green. My parents were both *very* reluctant to let me have the car. But, being the typical teenager, I insisted that any future success I might have depended entirely on my ownership of this Jeep. (Mom never really said yes, and Dad agreed only if I paid for the gas and repairs out of my part-time job at the machine shop.)

In cancer care delivery today, we have put great focus on "quality of care." Oftentimes this brings to mind the newest technology, for example EHRs that are capable of spitting out reams of outcomes data or spray charts that show deviations from clinical pathways. But just maybe quality cancer care can actually mean something as simple as access to "wheels."

In this edition of *Oncology Issues*, we highlight two cancer programs that improved the patient experience tremendously by developing transportation programs for their patients. For Linda Bily and her colleagues at Stony Brook Cancer Center, it all started with a donated mini-school bus. In its two years of service, Stony Brook's NET (Non-Emergency Transportation) Program has improved patient adherence to treatment plans, made better use of chair time by improving "on time" arrivals, and allowed patients to receive treatment close to home. My takeaway from Bily's article: It truly takes a community to develop a successful transportation program.

Our second article describes the transportation program at the J. Phillip Citta Regional Cancer Center that also started with a donated vehicle and two volunteer-drivers. After a hugely successful pilot program, social worker Sherry Laniado proposed making the transportation program permanent. Today it includes two cars, two part-time salaried drivers, and a program coordinator who works with a support team to ensure that cancer patients are able to make their radiation treatment and outpatient infusion appointments.

Just think of all of the quality indicators these transportation programs touch on: access to care, improved time to treatment, improved patient adherence to treatment plans, increased patient satisfaction, etc.—not to mention the programmatic benefits, such as streamlined workflow.

Do these quality initiatives have the same "pop" (or cost) of some fancy hi-tech solution? No. Do they play a key role in delivering quality cancer care in the community? Absolutely.

So back to the Jeep. Mom was right to be scared of me getting behind my first set of wheels, but my Dad was too smart by half. You see, when I got the Jeep, it was about 15 years old, had 140,000 miles on it, and got about 3 miles to the gallon. Really! In the end, my meager part-time job barely covered the cost of repairs, and there was nothing much left over for the gas-guzzling engine. I drove the car maybe half a dozen times and then went off to college in August; Dad sold it that September. So much for *my* first set of "wheels." I'm happy to say, however, that the cancer programs and cancer patients featured in this *Oncology Issues* are having a much better experience with their "new set of wheels!" OI

Communication, Communication, Communication!

BY BECKY L. DEKAY, MBA

Cancer care providers are some of the best people I have known in my life, but have you ever thought about the fact that our patients do not want to see *us*? People do not want to become our patients because that means they have cancer—the Big C! So, knowing that we are likely starting off the relationship with a strike against us, how can we as cancer care providers improve the patient experience?

This question was raised often during the recent ACCC 31st National Oncology Conference in San Diego.

At Feist-Weiller Cancer Center, LSU Health Shreveport, we do everything we can to make each patient's experience as positive as possible. My cancer program provides the highest quality care with the latest therapies, but what does "quality care" mean from the patient's perspective?

I've been told by cancer patients that what they want is an experience that is as pain free as possible with the least amount of fatigue. Cancer patients want to feel good and be able to do the activities they enjoy. And even though patients rarely voice these thoughts, they want to understand *what* is going on and *how* to manage before, during, and after their cancer treatment.

The best way to meet these needs is through clear, concise communication. Our nurses and physicians do a wonderful job educating our patients throughout their cancer journey, but a huge piece of education and communication is ensuring that the intended recipient receives and *understands* the message.

In retail and real estate, the mantra is location, location, location. In oncology, I'd like to suggest the mantra: communication, communication, communication.

I grew up believing the word "remarkable" was a good word, meaning praise. My parents would say "That's remarkable!" when I brought home a good report card. When we watched Neil Armstrong land on the moon, it was "remarkable." But when my son was diagnosed with cancer, the connotation of this word dramatically changed for me. When a CT would light up, our physician said it was remarkable—not a good thing. To this day, I avoid using that word.

The words we use daily when speaking with our cancer patients—neutropenia, lesion, excision, resection—make perfect sense to those of us working in oncology, just as amicus curiae brief, eminent domain, and lis pendens make perfect sense to those in the legal field. But how many of us actually understand what this legalese means? Health literacy is not just about the uneducated patients; highly educated patients also want clear communication.

To improve patient communication I suggest:

- Slowing down
- Using "living room language" instead of jargon
- Using pictures and teaching tools
- Repeating and summarizing our conversations
- Using "teach back" and "showback" strategies
- Writing concise take-home information.

I will share another personal example of how we may be setting ourselves and our cancer patients up for communication breakdowns. When my mother had a non-smoker's lung cancer, I went with her to all of her appointments. Providers explained what was going on and why she was receiving certain treatments. I understood and thought, as a college graduate, my mother did too. Yet every drive home, she would ask me to explain what was said. And then throw in the pharmaceuticals. One person referred to my mother's oral chemotherapy as Tarceva, my sister (a nurse) continually referred to it as erlotinib, and the home health nurse would ask about her oral chemotherapy. One single pill, and my mother never could get it straight.

Bottom line: oncology providers do not need to use "big words" to prove how smart they are. Our patients know that we understand cancer—that's why they have come to us! So join me in making clear, concise communication part of our everyday conversation with patients. OI

Coming in Your 2015 *ONCOLOGY ISSUES*

- What to Do When Our Staff Becomes Our Patients
- FUN (Fitness, Understanding, Nutrition) for Life Program
- The Journey to Cultural Competence
- Cancer Clinical Trials: Enhancing Infrastructure & Accrual
- A Value-Driven Symptom Management Clinic
- Closing the Gap: An Outpatient Nutrition Clinic
- Capturing Quality Data to Improve Palliative Care
- COME HOME—A Model Oncology Medical Home
- An EMR-Driven Approach to Survivorship Care Plans
- From Distress Screening to Solutions: Patient-Centered Support
- An Innovative Patient Companion Program
- Closing the Loop with a Post-Biopsy Breast Clinic
- Implementing Oncology Inpatient Bedside Scheduling
- CoC Accreditation—The REAL Story

VIDEO

Our Story is Your Story

ACCC's new video made its debut at the ACCC 31st National Oncology Conference in San Diego. It's a powerful illustration of how ACCC is *your* community. Watch and share the video at www.accc-cancer.org/membership.

TOOL

ACCC's Oncology Drug Database

This online tool offers easy access to drug-specific information, including: billing and diagnosis codes, reimbursement amounts, FDA-approved indications, and comprehensive drug manufacturer information. www.accc-cancer.org/drugdatabase.

INFO

2014 Trends in Cancer Programs

Change in healthcare is constant. Help your cancer program stay competitive by staying educated on the latest trends in the oncology marketplace. www.accc-cancer.org/trends2014.

MEETING

One-Day Oncology Reimbursement Meeting

A 360° look at oncology reimbursement issues, tools to strengthen your program, and information to help you weather market changes. Join us Dec. 2 in Austin, Tex. Register today at www.accc-cancer.org/meetings/ReimbursementMeetings.asp.

Hiring Staff? Interview Mistakes & How to Avoid Them

Mistake—Failing to establish rapport. When this happens, the interviewer learns nothing about the applicant's priorities, expectations, or job-related needs.

Fix—Initiate a pleasant, informal conversation where the applicant can talk freely and spontaneously.

Mistake—Placing too much emphasis on technical competence. Taken alone this is a poor predictor of whether a newly-hired employee will succeed or fail. Do these skills really matter if the employee alienates coworkers (or worse, patients)?

Fix—Identify the personality traits most important for the smooth running of your practice.

Mistake—Talking too much. When interviewers do most of the talking, they often fail to learn what they need to know about job applicants.

Fix—A good rule of thumb is to let the applicant talk at least 80 percent of the time; don't rush to break a silence.

Mistake—Overselling the job. Don't make promises about salary, vacations, flexible hours, etc. that can't be kept or, if kept, would upset existing staff.

Fix—Rethink the position. Broaden the more appealing aspects of the job or trade or divide less desirable aspects among other staff or outsource them.

Mistake—Failing to check references. Eighty percent of all resumes are misleading according to Hire Right, a firm that specializes in employee background checks.

Fix—Have job applicants sign a waiver that attests to the accuracy of the information they provide and authorizes you to seek relevant background information.

Source. Levoy B. 5 Common Interviewing Mistakes Made at Medical Practices. Available online at: www.physicianspractice.com/staff/five-common-interviewing-mistakes-made-medical-practices?GUID=98EC2E34-74E0-44F8-9021-6474CB220676&rememberme=1&ts=07082014.

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

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

facts

RAC Returns

The four Recovery Audit Contractors (RACs) collected $3.65 billion in Medicare overpayments during fiscal year 2013, an increase from the $2.3 billion that was collected in FY 2012.

Source. CMS. Recovery Auditing in Medicare for Fiscal Year 2013. www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/FY-2013-Report-To-Congress.pdf.

4 Trends That Will Shape the Future of Immunotherapy in Cancer Care

1. Immune status and the Immunoscore™ emerge as important factors

Research has revealed the prognostic and predictive value of a patient's immune status for determining clinical outcomes and long-term treatment success. (Immune status is derived from a complete analysis of the number, type, and location of tumor infiltrating lymphocytes in the tumor microenvironment.) Immunoscore is a new possible approach for cancer classification that may transform immunotherapy research and clinical practice.

2. New checkpoint inhibitors hold promise for long-term results

Checkpoint inhibitors target CTLA-4 pathways, which induce the body's immune system to recognize and respond to cancer without triggering an autoimmune response. In addition to CTLA-4 inhibitors, PD-1 and PD-L1 pathways have gained significant ground as an alternative method of mitigating the ways in which cancer takes advantage of the immune system's natural checkpoints to silence the body's T cells.

3. Combination treatments to gain momentum

Research indicates that immunotherapeutic treatments may be most effective when used in combination. For example, studies at the Dana-Farber Institute examining concurrent targeting of PD-1 and CTLA-4 inhibitors for the treatment of melanoma have demonstrated positive results in a substantial number of patients.

4. Prognostic and predictive biomarkers to become the gold standard

As researchers strive to determine why some patients respond to specific types of immunotherapies while others do not, identification of immune-based biomarkers that can substantially improve patient stratification, advance the overall success of clinical trials, and drive the development of future treatments with the potential for widespread clinical adoption, remains a top priority.

Source. Definiens. www.definiens.com.

COMING SOON!
ACCC's Institute for Clinical Immuno-Oncology. Learn more at www.accc-cancer.org/ICLIO.

ACCC Association of Community Cancer Centers 40 YEARS STRONG

Happy 40th!

A Year of Celebration

In January 2014 our editorial staff made the decision to commemorate ACCC's 40th Anniversary year by creating a new column—"ACCC Fast Facts." Borrowing from the look of *Oncology Issues'* popular "Fast Facts" column, we culled through our archives and researched the Association's four decades of vibrant history to pull together interesting factoids and infographics about ACCC's past and current leaders, comprehensive education programs, advocacy efforts on Capitol Hill and with key regulatory agencies, innovative opportunities through committees and member-to-member learning, and more. This issue marks our final "ACCC Fast Facts," column, and we've saved the best for last! So without further ado, here's what your peers had to say about ACCC on its 40th Anniversary.

And remember, ACCC's anniversary year doesn't end until midnight on Dec. 31—New Year's! So it's not too late to join the celebration. Tweet on how ACCC has helped improve your cancer program through the years at twitter.com/acccbuzz using the hashtag #ACCC40th! Post your favorite ACCC anecdote or story on ACCC's Facebook page, www.facebook.com/accccancer. Share your thoughts on why ACCC is the leading education and advocacy organization for the multidisciplinary team on ACCCExchange, http://mynetwork.accc-cancer.org.

This year ACCC turned 40 Years Strong! Here's looking forward to many more years of serving the oncology community.

A Font of Knowledge

ACCC has made me a better oncology social worker. The world of oncology has changed so much over the 40 years I have worked in the field. In the beginning, the challenge was learning about the different types of cancer and their treatments and then combining them with my clinical social work skills to assist patients and caregivers with their psychosocial issues. Today's oncology social workers must combine all of the above *plus* knowledge related to reimbursement and legislative advocacy and policy at the state and federal levels. ACCC has provided me with the education and tools to successfully implement this new knowledge.

Virginia T. Vaitones, MSW, OSW-C
Oncology Social Worker
Pen Bay Medical Center
Rockport, Maine

Advocacy in Action

I first got involved with ACCC by joining the Governmental Affairs Committee. I was asked to represent my institution and testify at an APC Panel meeting. Twice a year, these meetings make recommendations regarding coverage decisions for hospital-based outpatient facilities that are then passed on to Medicare for approval. I had recently moved from a private practice to a hospital-based program, and I couldn't understand why drug administration was paid differently, depending on the practice setting. I worked with ACCC staff to present our case and testified to the importance of changing the one administration code to CPT codes that mimicked those being used in the practice setting. It is one of my most rewarding accomplishments.

Wendalyn Andrews
Practice Manager
Division of Hematology/Oncology
The University of Arizona Cancer Center
Tucson, Ariz.

fast facts

Getting a Charge from the Network

Happy Birthday ACCC! I have enjoyed the benefits of being a part of ACCC many times over, which can be summed up as the "power of network." Upon returning home from each ACCC event, both my family and clinic staff comment that I am "recharged" and once again excited about cancer care. So true! The multidisciplinary group of equals always refreshes my love of oncology and how we continually work to improve care.

Tom Whittaker, MD
Physician Advisor, Revenue Cycle Services
IU Health Central Indiana Cancer Centers
Indianapolis, Ind.

New to Oncology?

Prior to joining LSU Health, I had been in healthcare, but not oncology...big change! I needed guidance and education, and after some research, I realized ACCC filled my need better than any other professional organization. I quickly developed a list of members who I consider subject matter experts, and I've called or emailed these individuals with numerous operational questions. (Did I mention I'm non-clinical?) Fortunately ACCC represents all disciplines—physicians, administrators, nurses, social workers, pharmacists, dietitians, radiation therapists, cancer registrars, reimbursement and billing specialists, genetic counselors, patient navigators, and more. ACCC's "how to" tools and resources help me and my program prepare for and understand the changes in how we practice medicine.

Becky L. DeKay, MBA
Director of Oncology Services
LSU Health Shreveport
Feist-Weiller Cancer Center
Shreveport, La.

Reaching across all Practice Settings

In the nearly 20 years that I have been an oncologist, I have worked in a variety of practice models—private practice, academics, and hospital-based cancer centers. There are unique demands and sometimes competing agendas between each of these practice models. Yet, ACCC transcends these differences and provides relevance and value in each of these settings.

ACCC is an organization that reaches out to all members of the oncology team—in all practice environments—and effectively meets its members' needs across all disciplines and models of care. Whether through networking at meetings, using tools such as ACCC's Oncology Drug Database and *Patient Assistance and Reimbursement Guide*, gleaning best practices from ACCC's Innovator Award winners, or advocating for the needs of oncology patients, ACCC offers something for everyone in cancer care.

Jennie R. Crews, MD, FACP
Medical Director, Cancer Services
PeaceHealth, St. Joseph Medical Center
Bellingham, Wash.

Making the Connection

ACCC has given me the opportunity to view oncology through the wider lens of multiple disciplines that make up oncology care. As psychosocial care has moved more front and center, connecting with other cancer centers, sharing ideas, and developing action plans with colleagues has been invaluable...with ACCC helping to guide us, we continue to better oncology care, as well as the quality of life of the patients we serve.

Jennifer Bires, LICSW, OSW-C
Program Coordinator, Patient Support Services & Community Outreach
GW Medical Faculty Associates
Cancer Center, Washington, D.C.

Can We Really Define Quality Cancer Care?

BY MATTHEW FARBER, MA

Discussions on how to define quality cancer care and how best to deliver the highest quality care are quite frequent in the oncology community. Payers, providers, professional organizations, accrediting bodies, etc., all have a stake in ensuring the delivery of quality cancer care. But at the end of the day, what is the definition of quality cancer care?

As an example, consider the cover story of this *Oncology Issues*. The article describes how an ACCC member developed and implemented an oncology rehabilitation program. Now, although rehab programs receive little attention in quality metric discussions, I am certain that many patients would say that these services are an integral part of a quality cancer program.

While I certainly will not try to answer the question of what defines quality cancer care in this column, I do want to explore some of the ways ACCC is contributing to the quality discussion.

Throughout this year, ACCC has explored the issue of quality in cancer care as a part of ACCC President Becky DeKay's theme issue. In June ACCC held its second Institute for the Future of Oncology forum in Chicago. This year's discussion topics focused on organizational leadership and communicating quality. In October, at the National Oncology Conference, ACCC released two white papers developed from the Institute forum discussions: "Oncology Leadership: Looking to the Future in a Shifting Healthcare Environment" and "Communicating Quality in Oncology." Not surprisingly, both papers include discussions on quality care.

The "Oncology Leadership" white paper focuses on characteristics of quality leadership, ways to identify future leaders in a cancer program, and the importance of creating succession plans for the next generation of leaders, while taking into account changes in payment methodology, staffing, and marketplace consolidation. Many argue that a quality cancer program starts at the top with strategic and visionary leadership.

The second white paper looks at how cancer programs communicate that "quality care" is, in fact, being delivered. The paper reflects participants' thoughts on practical ways to identify and define quality cancer care for the three primary stakeholder groups: patients, payers, and providers. As part of this discussion, participants attempted to answer such questions as: Do cancer programs promote and market CoC accreditation or QOPI certification? Do current quality metrics cover what is essential for comprehensive care for the individual patient?

One key takeaway—the quality message needs to be communicated differently for different audiences. In other words, what is said to patients must be different from what is said to referring physicians and even payers. Bottom line: today's cancer programs must be flexible in their organization and skilled at communicating using both traditional methods (written correspondence, emails, online) and newer technology (the myriad of social media outlets).

As you seek to demonstrate the quality of care your cancer program provides, you may also want to refer back to ACCC's Institute for the Future of Oncology white papers (www.accc-cancer.org/institute). Or, if you are interested in participating in future Institute forums, contact me at mfarber@accc-cancer.org. OI

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

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Staffing Based on RVUs—The Times Are Changing

The Golden Rule of Data is: He Who Has the Data Rules! Depending on the data your cancer program captures and analyzes, you can use the resulting information for practice management, risk management, revenue enhancement, contract negotiations, and/or practice efficiency. In today's economic environment, every cancer program should be able to produce, monitor, and benchmark basic metrics to meet current business pressures for increased efficiency and efficacy of care.[1]

In addition, many cancer programs find themselves in an ongoing battle to support the number of full-time equivalent employees (FTEs) required to provide services in the hospital department or freestanding cancer center. In many facilities, annualized relative value units (RVUs) are used to determine the necessary staff allocation, but with the current increase in the number of packaged services, bundled codes, and case-rate payments, cancer programs may want to consider another method to justify staffing needs.

Non-healthcare industries have long recognized the vital importance of productivity measurement for the success of a business enterprise. The basic definition of productivity is measuring the work output per individual worker, and for healthcare this is measuring clinical productivity. In the automobile industry increased worker productivity results in the ability to build a higher number of cars with a fixed workforce. In any industry where productivity measures directly impact a worker's salary, the worker becomes more motivated to produce. Productivity measurements in healthcare tend to be more subjective, such as "everyone knows" that Dr. A is efficient and Dr. B tends to dawdle between patient encounters.

So, what is the correct number of physicians and support staff needed to meet the requirements of the cancer program? There may not be a single answer to this complex question.

What is an RVU?

The *Current Procedure Terminology (CPT®) Manual* codifies procedures and is updated annually by the American Medical Association (AMA). Prior to 1992, Medicare reimbursed physicians for their services based upon the charge billed for the code submitted. In 1992 the federal government attempted to standardize physician payments and established the resource-based relative value scale (RBRVS). The RBRVS assigns a complicated numerical value to every CPT code, referred to as the relative value unit (RVU).

It is important to note that there is significant physician involvement in setting the RVU value for each procedure code. The AMA Specialty RVS (relative value system) Update Committee (RUC) provides ongoing recommendations for annual updates to physician RVUs. There are currently three components that comprise the RVU: physician work, practice expense, and professional liability insurance (PLI). The work component includes such items as time, mental effort and judgment, technical skill, physical effort, and the stress involved in delivering the care. The practice expense (PE) component includes overhead and other expenses required to maintain the facility. In the outpatient department of the hospital, the hospital is reimbursed for the practice expense of the service or procedure under the Medicare Outpatient Hospital Prospective Payment System (OPPS). Last, PLI is the cost and value of malpractice insurance.

Each of these three components is then adjusted by the geographic practice cost index (GPCI), to correct variances in the cost of living for different regions of the country. The total RVU amount is then multiplied by a conversion factor (CF), which is updated annually, to determine the fee schedule dollar amount.

Easy, right? The bottom line, of course, is that physician compensation from Medicare (and other payers that use RVUs) is derived from the RVUs assigned to a specific procedure code. And of course the RUC is a privately-run regulatory committee that must maintain budget neutrality when modifying RVUs on an annual basis. Budget neutrality means that if the relative value is increased for one procedure, the increased amount must be taken from other existing procedures.

RVUs & Staffing

Staffing is generally driven by demand: how many and what types of patients will the cancer program expect to see in the upcoming year? Demand can then be converted to work: the specific tasks that must be performed in order to treat these patients, including that work considered to be indirect patient care.

Staffing plans address the facility's mission, structure, workforce, recruitment,

needs of the cancer program, and retention to meet current and projected patient outcomes, clinical effectiveness, and efficiency. Staffing plans should also consider performance measures, patient outcomes, and other indicators of accessibility and quality of care.

Projecting patient demand includes an analysis of historical patient utilization and determination and assessment of change factors that will affect future demand. Make certain to consider trends that could increase or decrease the number of patients that require treatment at the cancer program, such as:

- ***Population trends.*** Is the community growing or aging, are there new residents, or is there a migration away from this community?
- ***Local healthcare factors.*** Will a hospital or freestanding cancer center in the region be closing, increasing, or changing its cancer treatment offerings, or will there be more uninsured or underinsured patients?
- ***Changing referral patterns.*** Do you anticipate more or less referrals from community physicians and are these referring groups increasing or decreasing in size? Are any current referring physicians planning to initiate cancer treatment? Are physicians other than oncologists offering cancer treatments?
- ***Facility-specific factors.*** Will your cancer program have new technology or new offerings next year? Is your cancer program accredited? Will your cancer program offer clinical trials?
- ***Best practices.*** Are treatment protocols, pathways, and best practices that are under review anticipated to change in the near future? Are changes anticipated during the next five years?

"The National Practice Benchmark for Oncology, 2013 Report on 2012 Data" is a tool to measure oncology practices against others in the country in a way that allows for meaningful comparisons.[1] According to this report:

In the past, we reported HemOnc [hematology/oncology] physician productivity based on the number of new patients per year. We now report HemOnc physician productivity on the basis of work relative value units (wRVU) and use 7,000 wRVU per year as the productive capacity of a standard HemOnc physician (wRVU). When used in the aggregate, there are often only slight differences between the results expressed per FTE HemOnc or per standard HemOnc (wRVU). This is reasonable because these two measures are derived from the same aggregated data in which the number of new patients and the amount of wRVU are strongly correlated. When applying any individual benchmark to an individual practice, we encourage the conversion of the FTE HemOnc count for the practice to standard HemOnc (wRVU) and suggest using that as the standard of comparison. This provides useful comparisons both for busy practices and for those that are less busy.

For the first time, this report included radiation oncology benchmarks and tentatively introduced a new standard for the productive capacity of a radiation oncologist. The report defines a standard RadOnc

physician as one with 26 average daily treatments (on the basis of 254 working days per year). In addition, the average number of new radiation oncology patients per FTE RadOnc was listed between 250 and 300 patients. This report also states:[1]

We also measured wRVU per RadOnc physician and see an average of around 14,900 wRVU per RadOnc per year. There is, however, considerable variability in that number, which we believe reflects the ratio of complex treatments to total treatments, and we are not yet prepared to establish a standard RadOnc on the basis of wRVU.

RVUs & Physician Compensation

In some cancer programs, the physicians may receive equal compensation. In other programs, the physicians may receive an annual salary with a productivity bonus. Other compensation models may tie salary to the RVUs generated by each physician. In fact, RVU productivity is the most common form of quantitative metrics used to determine physician pay today, with "work" the behavior that is measured and rewarded.

According to a Medical Group Management Association (MGMA) 2007 survey, 61 percent of physicians were compensated based on RVU production.[2] A 2011 Merritt Hawkins (physician recruitment firm) white paper showed that salary plus a production bonus was the compensation formula offered to physician candidates in a third of physician search assignments.[3] Of importance is the fact that in most cases the productivity measurement was not based on quality of care, patient volume, a cost effectiveness metric, or revenue generated.

Arguments in favor of compensating physicians based on RVUs include objectivity, removal of distinctions between payer types, and not rewarding inefficient care. Arguments against this application of RVUs include intra-group competition for complex cases or those that have high RVUs, creation of RVUs by "slow" physicians through repetition of procedures, and not referring patients to other physicians in order to keep the RVUs in house. In addition, participation and contributions to the group or facility's overall strategic plan is not a factor in RVU bonus models.

The employment of non-physician practitioners (nurse practitioners, physician assistants) alters the RVU compensation or bonus system significantly. Each non-physician practitioner is supervised by a physician, but the RVUs for the services performed are allocated to the non-physician practitioner.

Concerns with Using RVUs

The biggest problem with tying physician compensation or staffing to RVUs is that when these relative values change, and some of these changes are significant, the model may not be sustainable. As proposed by the Centers for Medicare & Medicaid Services (CMS), radiation oncologist reimbursement is estimated to decrease by 4 percent in calendar year 2015 and payments to freestanding radiation oncology centers is expected to decrease by 8 percent. Does this mean that physician compensation or staffing levels should decrease accordingly because this monetary loss is due to a decrease in RVUs?

A standard approach when cost reduction is necessary requires reducing the payment amount for each service. With the exception of the sequestration reductions, CMS typically reduces the value for some procedures while increasing the value for other services on a year-by-year basis. This means that the RVUs for a particular service may decrease from one calendar year to the next due to budget neutrality, changes in practice expense allocations, etc. For example, at the time this article was written CMS had proposed to reduce payment for all treatment delivery services in a freestanding radiation center because the cost of the radiation vault would be removed from RVU calculation as a direct practice expense. If staffing is performed based on RVUs and the RVUs are significantly decreased while the cancer program has no change in costs, staff may be decreased inappropriately. Other issues to be considered when staffing based on RVUs include:

- ***Bundled services.*** CMS publishes its bundling guidelines, which indicate that certain codes cannot be charged on the same day by the same provider as other services. For example, a simulation (codes **77280-77290**) cannot be charged on the same day as a 3D computer plan (**77295**) for Medicare. If RVUs are only tracked for billed services (the 3D plan), there is no credit received for the bundled procedures that required physician and staff time. With respect to medical oncology, there are services such as venipuncture, nursing time, or patient chair time for infusions that may not have RVUs but contribute to patient care. Last, bundling edits are updated quarterly, so bundled services can change during the course of the calendar year.
- ***Medically unlikely edits.*** At present, the most common oncology medically unlikely edit (MUE) occurs with basic dosimetry calculations (code **77300**). Medicare contractors typically have a maximum unit allowance that will be reimbursed, although all units will be paid when medical record documentation is provided after the line item is rejected. How will RVUs be tracked in this scenario? Only those units initially paid or all units after appeal?
- ***Packaged services.*** In general, the packaging of services occurs in the outpatient department of the hospital. For example, the hospital bills for image guidance during daily radiation treatment delivery and fiducial marker placement, but this service is not separately paid. Instead, it is considered packaged into the reimbursement for the primary service (treatment delivery). And, with the advent of comprehensive APCs (C-APCs), CMS intends to package all services performed on a single service date for a number of outpatient procedures, which will expand the impact of this concern.

Exclusive use of RVU generation systems to determine staffing, distribute profit after expenses, or compensate physicians also fails to reward other behavior that is beneficial to the group or facility. Examples include:

- Willingness to take patient calls
- Regular participation in group or medical staff meetings
- Tumor board participation
- Performance of outreach services
- Achievement of quality assurance goals
- A history of positive patient and staff interaction
- Principal investigator responsibilities related to clinical trials.

Just because there is a concern with an RVU staffing or compensation system doesn't mean that there is a perfect alternate solution. In addition to billable RVUs, there are other ways to measure clinical productivity and staffing needs. The number of patient visits or the number of new patient encounters can be easily measured, but do not reflect actual collections. Gross charges are also easy to calculate, but do not reflect contractual adjustments or discounts. Charges adjusted for insurance contracts are also easy to produce, but are based on uncollected charges and do not allow for payer mix variations. Net collections reflect actual collections, but may discourage physicians from providing care to uninsured or under-insured patients.

Shifting Reimbursement Focus

According to information published in the *MGMA Connextion* July 2013, preparing for reimbursement models that place a greater share of financial risk on the provider is one of the top ten healthcare industry challenges. One of the greatest healthcare challenges of the next few years is getting control of the skyrocketing costs of treating cancer. The U.S. spends as much as $127 billion on cancer care in a year, and that is projected to grow to at least $158 billion by the end of this decade.[4] According to an article in the *Journal of Oncology Practice*:[5]

The cost of healthcare in the United States is on an unsustainable trajectory. Using current trends, economists predict that in less than 3 years, it will require 50% of the average U.S. household income to pay the costs of out-of-pocket expenses and the health insurance premium for a family.

New payment models that reward cost-effective and high-quality treatment are needed.

In a separate article, the American Society of Clinical Oncology (ASCO) states:[6]

Although 1.5% of patients develop cancer in any given year, they account for roughly 10% of all health care costs. Of the top 10 drugs that Medicare pays for as part of a beneficiary's medical benefit (the so-called Part B drugs), eight are used in the treatment or supportive care of patients with cancer. Pursuing aggressive control of expenditures, Medicare and private health insurers have increased their focus on high-cost areas, including oncology.

Oncology is a special focus because of the patient complexity, the life-threatening nature of these diseases, and headline-grabbing prices of therapies.

Medicare is accelerating plans to commit a portion of physician pay to the quality of care provided. The current payment system (fee-for-service) financially encourages physicians to perform or order more procedures and may be one of the reasons healthcare costs have escalated. The Affordable Care Act (ACA) requires Medicare to gradually factor quality into payments for hospitals, nursing homes, physicians, and other medical providers.

By 2017, the value-based modifier program will include all physicians, who stand to gain or lose one to two percent of their pay based on quality measures that vary from one specialty to another. In addition, Medicare plans to take into account how much each physician's average patient costs Medicare, to encourage more judicious use of testing and more aggressive efforts to avoid hospitalizations. Physicians will be compared against others in their specialty and those with least costly patients will be eligible for larger bonuses.

Cigna has met its goal of covering 1 million healthcare consumers under its quality and performance-based model called Cigna Collaborative Care (CCC) Arrangements.[7] This program was previously called Collaborative Accountable Care and works with healthcare professionals across the delivery spectrum that have a substantial primary care component. Regardless of practice type, the common thread is that the medical group must be willing to accept responsibility and accountability for achieving improved health, affordability, and patient experience. In this model, the medical group is rewarded through a pay-for-value structure if it meets targets for improving quality and lowering medical costs.

And Cigna is not alone; in 2014 UnitedHealthcare (UHC) announced that $27 billion of its annual reimbursements to physicians and hospitals are tied to accountable care and performance-based programs. By 2018, UHC is hoping to increase that to $65 billion. More payers are moving to risk-sharing arrangements, and they are being aggressive about strategy.

According to the *Wall Street Journal*, Americans spent $37 billion on cancer drugs in calendar year 2013, more than for any other ailment.[8]

"Oncologist reimbursement at the moment is a broken system," Richard Schilsky, ASCO's chief medical officer, told the newspaper.

Effective July 1, 2014, WellPoint initiated a program in six states to offer oncologists monthly payments of $350 for each patient treated in compliance with one of the insurer's recommended treatment pathways. The program's initial focus is on breast, lung, and colorectal cancers first and is expected to encompass the complete WellPoint network by mid-2015. The intent is to treat cancer using protocols that are supposed to be more cost effective and offer the right amount of benefits versus side effects.

While some physicians expressed concern about standardized treatment, WellPoint

expects that its treatment protocols, developed with guidance from oncology groups and outside experts and reviewed quarterly, will apply to approximately 80 to 90 percent of patients receiving chemotherapy. In addition, there are no penalties for using other treatments.

According to the WellPoint Cancer Care Quality Program Provider FAQs[9], the program will be administered by AIM Specialty Health®, a separate company. Two existing HCPCS Level II codes will be reported to obtain the enhanced reimbursement:

- **S0353**: Treatment planning and care coordination management for cancer, initial treatment
- **S0354**: Treatment planning and care coordination management for cancer, established patient.

According to the claim filing instructions, once a cancer treatment pathway regimen is selected through the program, WellPoint can be charged once for code **S0353** at the onset of treatment. Code **S0354** will then be billed no more than once a month (e.g., no more than once each 30 days of treatment) up to the maximum number of months specified by the prior approval process and program instructions.

"It's clear that our approach to cancer therapy is the answer in making a positive impact on quality and in slowing the rate of these increases to keep premiums as affordable as possible," Doug Wenners, WellPoint senior vice-president for provider engagement and contracting, said in a news release about the program.[10]

Of particular interest to medical oncology practices, UnitedHealthcare experimented by paying participating physicians a monthly allowance to cover the full course of treatment, rather than reimbursing for each individual service.[11] For the five oncology groups in the study, medical costs for 810 patients with lung, breast, and colon cancer were $65 million, versus $98 million for similar patients whose doctors received standard payments. With a savings of $33 million, cancer costs were lowered by one third and hospital stays were significantly reduced.

Oncology Medical Homes & ACOs

Other new payment models may include patient-centered medical homes and, specifically, oncology medical homes. In a medical home, each patient is managed by a physician-led care team and the practice becomes the central coordinator of care throughout all phases of treatment. This includes surgery, radiation therapy, chemotherapy, and survivorship, with communication between the oncology team and the patient's primary care team to ensure that all non-oncologic conditions are also managed. A June 13, 2011, article in *Oncology*, states, in part:[12]

In summary, the oncology medical home has the potential to be a holistic solution to improving cancer care delivery. Instead of attempting to provide individual solutions to the problems of quality, outcome measurement, avoidance of ER visits and hospitalizations, and improve care coordination, the oncology medical home can create both the structure and process to address these issues simultaneously. Furthermore, it places the responsibility for and authority over cancer care delivery where it belongs: in the hands of those who are actually accountable for the delivery of cancer care—the medical oncologists.

Accountable care organizations (ACOs) are being established in many areas. If the goal is for physicians to play a major role in reducing the cost of healthcare in the U.S., compensation models for physicians must also be aligned with incentives for ACOs. An ACO is defined as a healthcare organization characterized by a payment and care delivery model that seeks to tie provider reimbursements to quality metrics and reductions in the total cost of care for an assigned population of patients.

Increased linkage between physician compensation and value-based metrics appears inevitable, but the long-term consequences are subject to debate.[13] Excluding physicians in ACOs and patient-centered medical homes, specialists polled for the 2013 MGMA survey said about 5.7 percent of their total compensation was based on quality metrics, up from 2 percent in 2012. Healthcare payers will directly influence payment for oncology services as value-based metrics become tied to reimbursement.

Future value-based payments may be similar to capitation models of the past, but where capitation typically involved individual physicians negotiating separate deals, pay-for-value means all providers are participating in the program together. This emerging landscape of population health management includes a movement toward risk-based reimbursement.

New Staffing Models

As indicated above, there is no perfect staffing or physician compensation model, but healthcare in general and oncology in particular is rapidly outgrowing an RVU compensation and/or staffing model. According to Max Reiboldt, president and CEO of the Coker Group:[14]

We are seeing a fair amount of handwringing in terms of these deals. We are changing the paradigm of how doctors are being paid. It's not 100% (relative value unit) productivity anymore.

Rather than a pure productivity model (individual physician collections or RVUs), a salary plus productivity bonus model may be considered. Here is an example of a hybrid or composite model that incorporates several aspects of patient care:

1. ***Set on-site schedule.*** Whether it is 4 ten-hour days, 5 days per week, or another set schedule.
2. ***New patient encounters.*** The physicians have an agreed-upon schedule for new patients, including time from contact to first visit. There is also credit for inpatient hospital consultations and other off-campus or out-of-the-office patient contact.

Table 1. Staffing per Number of New Patients Annually, 8 hours per Day, 5 Days per Week

Radiation oncologists	1 per 200–300	Clerical staff	At least 1 per 200
Medical physicists	1 per 200–300*	Treatment aides	As needed
Dosimetrists	1 per 300–350*	Maintenance & service staff	1 per 3–4 MV, VT, PET/CT, MRI units
Nurses	1 per 200–300	Dietitians	As needed
Radiation therapists	1 per 100–150*	Physical or rehabilitation specialists	As needed
Simulation staff	1 per 200–250	Social workers	As needed
Brachytherapy staff	As needed		

* =25% IMRT

3. ***Downstream revenue.*** The physicians receive credit for patient care provided by other specialties or departments in the organization.
4. ***Outreach.*** Physicians are expected to participate in the cancer program's outreach activities to individuals who are not likely to access treatment independently.

According to an article in the *Journal of Oncology Practice*:[15]

We believe that the FTE HemOnc is the rate-limiting resource in oncology practice. That is to say, when the work output of the HemOnc goes up, all the other supporting assets of the practice are made more efficient because they are predominantly fixed costs. With that in mind, patient visits per FTE HemOnc is a reasonable proxy for overall practice efficiency.

Patient visits drive the demand for clinical support staff.

The National Practice Benchmark for Oncology adds:[1]

New patient volume continues to be an important measure of productivity and an essential tool for practice planning. A new patient is defined as one that has not received services in the practice in the last 3 years.

The American College of Radiation Oncology (ACRO) *Manual for ACRO Accreditation, July 2013* includes practice demographics that "will be examined to help define the nature of the patients treated and the services offered." The number of these services may also be helpful to an individual practice when staffing levels are being determined:[16]

- Number of consultations (visits)
- Number of new patients treated
- Number of patients re-treated
- Number of patients treated with curative intent, palliative intent, and for local tumor control
- Number of simulations
- Number of external beam treatments (IMRT, SRS, SBRT, electrons, and standard EBRT)
- Number of brachytherapy procedures
- Types of special procedures
- Anatomic sites and stages.

ACRO also provides general staffing recommendations as part of their *Accreditation Manual* (see Table 1, above).

These staffing numbers are similar to those listed in *Safety is No Accident*, sponsored by the American Society for Radiation Oncology (ASTRO)[17] and developed and endorsed by most radiation oncology colleges, boards, and societies. Key differences surround medical dosimetry (this reference supports 1 per 250 patients treated annually) and radiation therapists (1 per 90 patients treated annually).[17] ASTRO also puts a number to brachytherapy technologists (1 per 100 brachytherapy patients) and both references clearly state that there should be a minimum of 2 qualified individuals (e.g., therapists) present for radiation treatment delivery.[17]

The ASTRO publication provides sample worksheets for calculating medical physics and dosimetry staffing that includes equipment, sources, systems, number of patient procedures, and nonclinical estimated effort.

A Look Ahead

It can be frustrating to attempt to justify staffing levels based on flawed data, but this frustration cannot be used as justification for incorrect coding in an attempt to support maintaining staff. It is also clear that healthcare reimbursement will not continue to increase at historical rates. With operating margins decreasing and reimbursement dropping, cancer programs need a well-educated administrator and a forward-thinking reimbursement and staffing plan. In addition, physician groups or facilities that currently compensate or staff based on RVUs may want to transfer the coding function to a certified coding professional to ensure accuracy and remove the potential coding bias that may be present in an RVU-based compensation system. Last, but certainly not least, it is important to conduct regular coding and billing audits to ensure that the charges billed and paid are correctly documented in the individual patient's medical record.

Determining the right level of staffing is important because it can positively or negatively affect the cancer program. Understaffing can lead to physician burn-out and adversely affect physician and staff performance. Overstaffing can affect the program's financial performance and the credibility. At the end of the day a physician practice or cancer program, in order to survive, has to have more money coming in than going out, regardless of how many or how few RVUs are generated. OI

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spotlight

North Shore Hematology Oncology Associates,

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North Shore Hematology Oncology Associates (NSHOA), a comprehensive community oncology center, has been providing cancer care to the greater Long Island area of New York for more than 35 years.

NSHOA is comprised of six medical oncology offices, two radiation oncology offices, and one CyberKnife® location. With a goal of offering patients convenient access to care, NSHOA situated its offices throughout Suffolk County so that no patient would have to drive more than 15 minutes to reach one of NSHOA's treatment locations.

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- Flow cytometry
- Circulating tumor cell testing
- Full chemistry diagnostics
- Tumor marker testing on patients.

Infusion services are offered at all the NSHOA medical oncology offices throughout Suffolk County. NSHOA is staffed by 16 medical oncologists, 2 radiation oncologists, 12 non-physician practitioners (including nurse practitioners and physician assistants), 52 nurses, 3 full-time nurse educators, 3 navigators, and a full-service clinical research team. Many of the physicians on staff also attend at other local hospitals, where they participate in multidisciplinary tumor boards for several disease sites.

NSHOA is open 24 hours a day, 7 days a week, and keeps a "no appointment" policy for emergency patients. "If a patient doesn't feel well, they don't have to do anything but come in the door. In every one of our offices we have a physician who is assigned to treat any of the walk-in patients who don't feel well either from their underlying malignancy or from their treatment," said NSHOA CEO Jeffrey Vacirca, MD. This policy has kept NSHOA's hospitalization rate very low.

Consistent, Quality Care

To meet the challenge of keeping the standard of care consistent across multiple treatment sites, Dr. Vacirca created a management team that is responsible for day-to-day operations and ensuring uniform quality of care for every patient in every office. Each week, Dr. Vacirca meets with all site managers, NSHOA's administrator, and the CFO to cover potential issues that could arise in any office, or to discuss new technologies or processes to be incorporated into practice. "We're very proactive about patient care and making the patient experience the same in every office. A lot of this we're able to do with the incorporation of technology and our state-of-the-art EMR system," said Dr. Vacirca.

Navigation & Education

NSHOA also takes a proactive approach to patient navigation. When patients call for their first appointment, the navigator schedules the patient and begins the coordination process to ensure that the patient's first visit is a productive one.

Once the patient is scheduled, the navigator then gathers all of the pertinent information for that patient's visit, such as medical history, imaging, pathology, etc. As a practice rule, any patient diagnosed with cancer is seen within 48 hours.

"We don't want to have any burden whatsoever on the patient when they come to our office. We want them to come in and be taken care of, not running around and getting results. That, we believe, is our job," said Dr. Vacirca.

After the patient's first visit with the physician, the navigator schedules all future appointments needed including biopsies, imaging studies, follow-up appointments, and even referrals to other physicians. The goal, said Dr. Vacirca, is for patients to "leave the office not with 10 phone numbers to get things done, but with a clear, concise plan for how they're going to be taken care of."

NSHOA nurse educators also work to make sure chemotherapy patients stay on track with their treatment. Prior to treatment, nurse educators sit down with patients and go over all potential side effects and scheduling of treatment. The day following chemotherapy, every patient receives a phone call from the nurse educator checking in on how the patient is feeling. At that time, nurse educators also ensure that patients have a follow-up appointment scheduled to see their doctor within seven days of their first treatment.

Following completion of therapy, all patients can enter a survivorship program, which is also coordinated by the nurse educators.

NSHOA is currently in the process of developing a freestanding Wellness Center, which is slated to open in 2015. The Wellness Center in Stony Brook, N.Y., will be staffed by

nutritionists, psychologists, physical therapists, and additional care team members that provide complementary treatment to patients both during and after their therapy.

NSHOA also plans to open three new office locations in Suffolk County, as well as extending into Nassau County, N.Y. in 2015; two more in Suffolk County and one in neighboring Nassau County. The expansion is due to patient and physician demand. "We get a lot of calls for referrals from doctors outside of our current catchment area and really feel it's our duty to have local treatment bases where those patients can be seen and cared for," said Dr. Vacirca.

Personalized Medicine Program

In 2014, in collaboration with Caris Life Sciences, NSHOA established a personalized medicine program. NSHOA hopes to develop both a registry as well as prospective clinical trials to help determine therapies tailored to each patient for possibly better outcomes and less side effects. "One size does not fit all," said Dr. Vacirca. "We think that every patient is different and needs to be evaluated for exactly what their cancer is, and determining specifically what their treatment should be." So far the program receives a combination of physician and self-referrals. In addition to their patient community in Suffolk County, NSHOA also sees patients from Nassau, Queens, and Brooklyn coming in for a second opinion and wanting to be a part of this novel approach.

Patient Advocacy

In 2013 NSHOA teamed up with the Community Oncology Alliance's (COA) Patient Advocacy Network (CPAN) to launch a New York-based chapter for community cancer patient advocacy. Nicole Gregory, NSHOA's chief commercial officer, and the leader of the local CPAN chapter, meets quarterly with about 12 to 15 patients. In addition to being involved in legislative activities, several patients also attended the COA National Meeting in Orlando this past year and spoke about their involvement with NSHOA. OI

Select Support Services

- Patient navigation
- Benefits counseling
- Survivorship
- *Look Good, Feel Better* program

Number of analytic cases seen in 2013: 6,000

tools

Approved Drugs

• Eisai Inc. (www.eisai.com/US) announced that the Food and Drug Administration (FDA) has approved **Akynzeo® (netupitant and palonosetron)** for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Akynzeo is a combination oral agent that targets two critical signaling pathways associated with CINV (chemotherapy-induced nausea and vomiting) by combining netupitant, an NK1 receptor antagonist, and palonosetron, a 5-HT3 receptor antagonist, in a single capsule for the prevention of CINV.

• The FDA granted accelerated approval to **Keytruda® (pembrolizumab)** (Merck, www.merck.com) for the treatment of patients with advanced or unresectable melanoma who are no longer responding to other drugs. Keytruda blocks a cellular pathway known as PD-1, which restricts the body's immune system from attacking melanoma cells. The drug is intended for use following treatment with ipilimumab, a type of immunotherapy. For melanoma patients whose tumors express a gene mutation called BRAF V600, Keytruda is intended for use after treatment with ipilimumab and a BRAF inhibitor, a therapy that blocks activity of BRAF gene mutations.

• Millennium: The Takeda Oncology Company (www.millennium.com) announced that the FDA has approved **Velcade® (bortezomib) for injection** for use in previously untreated patients with mantle cell lymphoma (MCL). This approval extends the utility of Velcade beyond relapsed or refractory mantle cell lymphoma, for which it has been approved since 2006.

• Medivation, Inc. (www.medivation.com) and Astellas Pharma Inc. (www.asteallas.com/en) announced that the FDA approved a new indication for the use of **Xtandi® (enzalutamide) capsules** to treat patients with metastatic castration-resistant prostate cancer (CRPC).

Drugs in the News

• The FDA has granted multiple orphan drug designations to **aldoxorubicin** (CytRx Corporation, www.cytrx.com) in three indications: glioblastoma multiforme, small cell lung cancer, and ovarian cancer. Aldoxorubicin is CytRx's modified version of the widely-used chemotherapeutic agent, doxorubicin.

• DNAtrix, Inc. (www.dnatrix.com) announced that the FDA has granted orphan drug designation for **DNX-2401**, a conditionally-replicative oncolytic adenovirus for malignant glioma.

• FDA has granted priority review status for the new drug application for **lenvatinib mesylate** (Eisai Inc., www.eisai.com) as a treatment for progressive radioactive iodine-refractory differentiated thyroid cancer.

• Taiho Oncology, Inc. (www.taihooncology.com) announced that the FDA has granted fast track designation for **TAS-102 (trifluridine and tipiracil hydrochloride)**, an oral combination anticancer drug under investigation for the treatment of refractory metastatic colorectal cancer (mCRC).

Genetic Tests and Assays in the News

• bioTheranostics, Inc. (www.biotheranostics.com) announced that its **Breast Cancer Index℠** test has been awarded Medicare coverage. The molecular genomic test quantifies risk of breast cancer recurrence and predicts which patients have a high likelihood of benefitting from extended endocrine therapy. The Medicare policy covers use of the test to predict risk of late (5 to 10 years) distant recurrence in women with early stage, estrogen receptor-positive breast cancer who are considering extended therapy but are concerned about continuing anti-hormonal therapy because of documented toxicity or possible significant patient-specific side effects. In addition to new claims, Medicare coverage and payment for the Breast Cancer Index will be made retrospectively for previously submitted claims. OI

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- Integrating value into care
- Big data's role in quality
- Healthcare reform issues
- ROI on accreditation

Plus, get involved in Capitol Hill Day!

ACCC
Association of Community Cancer Centers

DETAILS at www.accc-cancer.org/annualmeeting

Building a Comprehensive Oncology Rehabilitation Program

BY PAULA J. BAUER, RN, MSN, OCN

Torrance Memorial Medical Center's (TMMC) Rehabilitation Department has a long history of providing physical, speech, and occupational rehabilitation services to the community. In 1999 one of the physical therapists, Sheryl Au, MPT, ATC, CSCA, CLT-LANA, became especially interested in lymphedema and its impact on the quality of life of breast cancer survivors. Au's observations about patients' struggles to control the condition led her to obtain certification in manual lymph drainage and combined decongestive therapy from the Dr. Vodder School International (www.vodderschool.com). With these credentials in hand, Au spearheaded the development of a lymphedema therapy program within TMMC's rehabilitation department.

The lymphedema treatment program provides assessment, best-practice interventions, and patient education on self-help strategies. The majority of patients who receive lymphedema therapy have iatrogenic lymphedema as a result of breast cancer treatment, although patients with lymphedema caused by treatment for other types of cancer, as well as patients with idiopathic lymphedema, are also commonly seen at the program.

Recognizing the need to provide psychosocial support, Au and a marriage and family therapist from the local Cancer Support Community began a monthly lymphedema support group in 2001. The group is free of charge and open to anyone who wants to learn more about lymphedema or meet with others dealing with similar problems. The support group serves as an important source of first-person information and emotional support for those with lymphedema and their loved ones. Because lymphedema can develop years after cancer treatment has ended and carries a lifelong risk of recurrence and complications, proactive education of at-risk patients and outreach to community physicians who care for these patients is essential.

Program Development

In 2008, after a series of discussions between the cancer center's advanced clinical nurse educator, the director of the rehabilitation department, Azmina Haji, PT, and several rehabilitation therapists, the decision was made to expand TMMC's oncology rehabilitation services beyond the lymphedema therapy program. The first step was a review of published literature on rehabilitation after cancer treatment, which revealed that cancer survivors commonly experience a wide variety of sequelae related to their malignancy and its treatment. These lingering side effects can have a profound negative impact on function and quality of life. The literature showed that cancer patients are at risk for long-term side effects due to multiple factors, including:

- Patients are usually middle-aged or older which predisposes them to pre-existing health issues
- Numerous healthy body tissues are adversely affected by cancer treatment
- Cancer treatment typically involves a multi-modality approach (chemotherapy, biotherapy, surgery, and radiotherapy) that spans months to years.

> ...more patients are surviving longer, resulting in an increasing population of individuals with cancer-specific rehabilitation needs.

The literature also showed that more patients are surviving longer, resulting in an increasing population of individuals with cancer-specific rehabilitation needs.

To meet this identified community need, TMMC rehabilitation and oncology nursing specialists developed a list of cancer sequelae that reflected unmet rehabilitation needs of oncology patients in the community and that were compatible with the rehabilitation department's mission and resources. Next, the rehabilitation specialists modified and expanded existing therapies to specifically address these identified needs of cancer survivors.

The Oncology Rehabilitation Program was formally launched in 2008 and staff includes speech pathologists Jennifer Karmelich, MA, CCC-SLP, and Lisa Kline, MS, CCC-SLP; certified lymph-

edema therapists Sheryl Au, MPT, ATC, CSCS, CLT-LANA, Mayuri Mody, OTR/L, CHT, CEAS, Tami Ramsey, MPT, OCS, CSCS, and Vicki Thornton, PTA, CLT-LANA; Domenic Bruzzese, OTD; Yolande Mavity, PT, MPT; Dirk Overturf, PT; James Vargas, MPT; and Wanda Weimer, MA, OT, CHT. In addition to lymphedema management, components of the Oncology Rehabilitation Program include:

- Exercise for overall fitness
- Strategies to help cope with ability change
- Urinary continence
- Swallowing retraining
- Adjustment tips to laryngectomy
- Cognitive strategies for "chemobrain"
- Fall prevention.

The program is a true collaborative effort between the rehabilitation department and the oncology program. For example, Miriam Sleven, RN, MS, OCN, an advanced practice nurse educator and the survivorship coordinator for the oncology program, helped the rehabilitation department conduct a patient satisfaction study related to the Oncology Rehabilitation Program. (For more on this study, see "Outcomes & Patient Satisfaction," right.) In addition, cancer program staff assists in the development of new education materials to market the Oncology Rehabilitation Program to patients and other providers.

Promoting the New Program

TMMC used a two-pronged approach to promote its new Oncology Rehabilitation Program, reaching out to both patients and providers in the community. To satisfy insurance billing requirements, physician referral is required for a patient to be evaluated by therapists at TMMC's Rehabilitation Department. Raising healthcare provider awareness of cancer late effects and the availability of effective interventions is an ongoing challenge for the program. TMMC is using a number of strategies to raise awareness of the Oncology Rehabilitation Program, including:

- Discussing the program and services offered at TMMC's Oncology Committee
- Writing articles for physician newsletters to educate and remind community healthcare providers about the program and services offered
- Reaching out to key community oncology physicians to encourage identification and referral of patients with functional late effects. These one-on-one meetings are spearheaded by TMMC's rehabilitation therapists.

To simplify the referral process, TMMC created an Oncology Rehabilitation Services referral form (Figure 1, right). The form includes check boxes for physician documentation of the patient's specific symptom or functional problem and the type of rehabilitation training that would most benefit the patient. The back of the referral form describes the service components of the Oncology Rehabilitation Program and the types of functional limitations the program can address.

Raising patient awareness of risk for late effects of cancer treatment is of equal importance. Accordingly, TMMC uses educational flyers, articles in healthcare publications, the hospital's website, and community lectures to educate the public about the Oncology Rehabilitation Program and the interventions available to improve function at work, activity tolerance, and quality of life.

TMMC is also a member of the South Bay Survivorship Consortium, a group of local oncology and primary care professionals whose goal is to improve the quality of life of cancer survivors. Consortium activities include free community events that address cancer recovery issues such as exercise, nutrition, wellness, and fatigue. In addition to bringing in national speakers who are experts in their particular field, the consortium has also used local speakers, including TMMC's chaplain and dietitian.

Outcomes & Patient Satisfaction

In 2013 TMMC's Oncology Committee conducted a process improvement study to capture data on the Oncology Rehabilitation Program, specifically, patient satisfaction and outcomes. A three-part survey was developed to assess pre-therapy expectations, post-therapy outcomes, and compliance with self-care at home post-therapy (see Figures 2-4, pages 28-30). TMMC invited all patients who received physical, occupational, or speech therapy to address an oncology-related disability to participate. Fifty patients completed surveys and were included in the data analysis.

Data revealed that satisfaction with the rehabilitation therapists was very high and that therapy successfully addressed the identified problem(s). Specifically, 90 percent of respondents said that "their expectations of therapy, as stated at the start of therapy, were completely met." Further, most patients continued with the recommended home management program. Eighty-three percent of survey respondents reported that they "were using the home management program."

On the downside, data revealed customer dissatisfaction with patient registration and appointment scheduling. To correct these issues, TMMC developed and implemented an action plan that includes:

- Front desk staff reorganization
- Customer relations training
- Clear performance expectations
- An algorithm for processing new patient paperwork (Figure 5, page 31)
- A process for triaging referrals by the rehabilitation therapists
- Increased manager oversight.

(continued on page 29)

Figure 1. Torrance Memorial Medical Center Oncology Rehabilitation Services Referral

Name ..... **Phone #** .....

Diagnosis .....

.....

.....

Date of Onset .....

Precautions & Contraindications .....

.....

.....

☐ OT/PT for lymphedema evaluation and management

☐ Occupational therapy, evaluate and treat for any of the following:

- Impaired ability to do self-care, home, or community skills (ADLs)
- Impaired activity tolerance
- Cognitive changes affecting ADLs
- Impaired upper extremity function (gross motor, fine motor, sensation)

☐ Physical therapy, evaluate and treat for any of the following:

- Generalized weakness and/or deconditioned
- Cancer-related fatigue
- Impaired range of motion and/or joint function
- Impaired balance
- Impaired mobility

☐ Speech therapy, evaluate and treat for any of the following:

- Swallowing difficulties
- Impaired speech and/or voice
- Impaired oral motor skills

☐ Frequency and duration ..... times a week for ..... weeks

Physician's Name ..... **Fax #** .....

Physician's Signature ..... **Date/Time** .....

Torrance Memorial Medical Center
3330 Lomita Boulevard
Torrance, CA 90505
310-517-4735 | Fax to: 310- 784-4978

Figure 2. Torrance Memorial Medical Center Pre-Treatment Evaluation

Patient Name ..... **MR#** .....

Date of Evaluation ..... **Evaluated by** .....

Please complete the following questions to help us evaluate the effectiveness of the Oncology Rehabilitation Program. Thank you.

1. I heard about the Oncology Rehabilitation Program/Lymphedema Program from:
   - ☐ Flyer mailed to my home
   - ☐ Flyer I picked up
   - ☐ Recommended by my physician
   - ☐ Torrance Memorial website
   - ☐ Discussion with my nurse navigator or Cancer Resource Center nurse
   - ☐ Other .....

2. My reason for coming to the Oncology Rehabilitation Program:
   - ☐ Manage my cancer-related fatigue
   - ☐ Manage my lymphedema
   - ☐ Improve my balance
   - ☐ Improve my strength
   - ☐ Speech therapy
   - ☐ Help with my swallowing
   - ☐ Treat my cancer-related wound
   - ☐ Bladder retraining
   - ☐ Start or resume the right exercise program for me
   - ☐ Return to my previous level of functioning
   - ☐ Improve my ability to complete Activities of Daily Living such as bathing, dressing and making meals
   - ☐ Manage nerve problems in my hands or feet
   - ☐ Other .....

To be completed by the therapist.

Reason for referral:

- ☐ Manage my cancer-related fatigue
- ☐ Manage my lymphedema
- ☐ Improve my balance
- ☐ Improve my strength
- ☐ Speech therapy
- ☐ Help with my swallowing
- ☐ Treat my cancer-related wound
- ☐ Bladder retraining
- ☐ Start or resume the right exercise program for me
- ☐ Return to my previous level of functioning
- ☐ Improve my ability to complete Activities of Daily Living such as bathing, dressing and making meals
- ☐ Manage nerve problems in my hands or feet
- ☐ Other .....

Source of Referral:

- ☐ Oncology Rehabilitation Program Referral Form
- ☐ Physician's prescription
- ☐ Other .....

Upon completion send to the Cancer Resource Center.

Figure 3. Torrance Memorial Medical Center Post-Treatment Evaluation

(To be completed on the last day of therapy)

Patient Name ..... **MR#** .....

Date of Evaluation ..... **Evaluated by** .....

1. My expectations of therapy, as stated at the start of therapy, have been met? (Please check one)
   - ☐ Completely
   - ☐ Partially
   - ☐ Not at all

2. I received a home management program as part of my therapy?
   - ☐ Yes
   - ☐ No

3. I am able to follow the home management self-care instructions?
   - ☐ Yes
   - ☐ No

4. Overall value of the Oncology Rehabilitation Program (Please check one)
   - ☐ Excellent
   - ☐ Good
   - ☐ Fair
   - ☐ Not useful

Suggestions on how we can improve this program .....

.....

.....

.....

Please add any additional comments you wish to share .....

.....

.....

.....

Upon completion send to the Cancer Resource Center.

(continued from page 26)

Monitoring of customer satisfaction with the new registration process is ongoing and to-date shows improvement.

Future Directions

TMMC's commitment to relieve disability and improve the quality of life of cancer survivors includes program development of exercise, diet, relaxation techniques, and numerous other rehabilitation interventions.

Further, new and improved cancer treatment modalities are allowing cancer survivors to live longer. These successes have opened up opportunities for innovative programs to facilitate recovery after cancer treatment, as well as interventions early in the disease trajectory to prevent or reduce late effects. The Torrance Memorial rehabilitation department's speech therapists have begun partnering with radiation oncology to provide pre-rehabilitation treatment planning for patients undergoing radiation therapy for head and neck malignancy, as well as ongoing swallowing therapy during treatment. OI

Paula J. Bauer, RN, MSN, OCN, is advanced clinical nurse educator, Cancer Resource Center, Torrance Memorial Medical Center, Torrance, Calif.

Figure 4. Torrance Memorial Medical Center Post-Treatment Call

Patient Name .....

Date of Call ..... **Date of Conversation (if different)** .....

1. Introduction
   a. Identify self and reason for call (evaluate the effectiveness of the oncology rehabilitation program)
   b. Answers are anonymous and confidential unless specific follow-up is requested, permission is verbally granted:

   .....

   c. Verify completion of program ☐ Yes ☐ No

2. Are you still using the home management program you received? ☐ Yes ☐ No
   Tell me why you are/are not using this program .....

   .....

3. Overall, were you satisfied with the care you received in the rehabilitation department?

   .....

   .....

   a. What was most helpful? .....

   .....

   b. What was least helpful? .....

   .....

   a. Is there anything we can do to improve our program? .....

   .....

4. Were you able to get your initial assessment appointment in a timely manner? ☐ Yes ☐ No

   .....

   .....

5. Did the program meet your expectations? ☐ Yes ☐ No

   .....

   .....

6. Would you recommend this program to someone else? ☐ Yes ☐ No

   .....

   .....

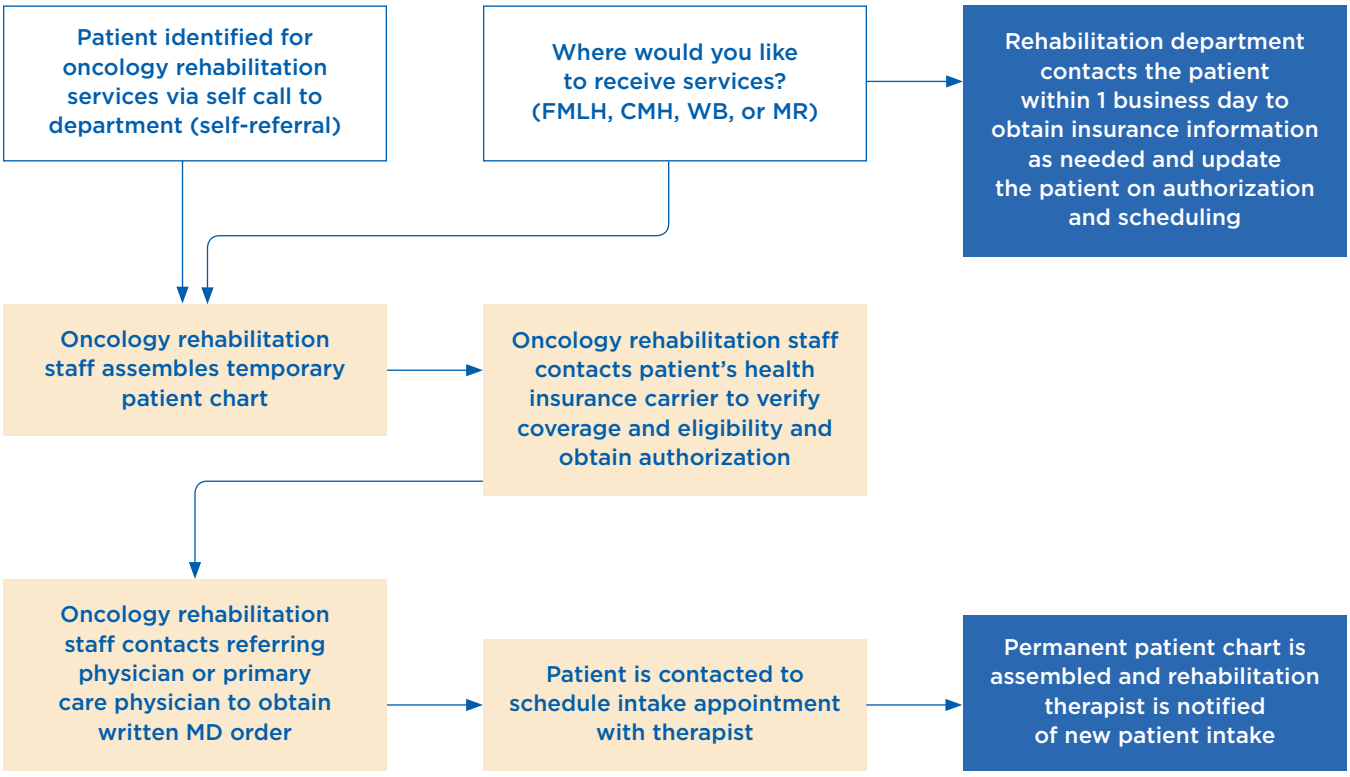
7. Other comments and suggestions .....

   .....

   .....

   .....

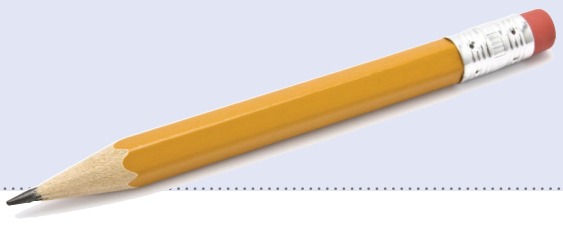
Figure 5. Torrance Memorial Medical Center Oncology Rehabilitation Program Patient Intake Form



OUR PROGRAM AT-A-GLANCE

Torrance Memorial Medical Center is a 401-bed community hospital that serves the South Bay area of Los Angeles. The TMMC service area encompasses the southwestern portion of Los Angeles County and includes several beach cities that stretch along the Pacific coast. The TMMC Hunt Cancer Institute has been accredited by the American College of Surgeons as a Comprehensive Community Cancer Center since 1980, and is one of only three facilities in California to receive the Commission on Cancer's Outstanding Achievement Award in 2012.

TMMC's oncology program is a robust service line, with more than 1,800 patients diagnosed and treated each year. Hunt Cancer Institute's multidisciplinary team prides itself on providing comprehensive care to adult patients with cancer and their loved ones across the continuum of care, including post-treatment recovery and survivorship. Assessment of community needs and identification of program development opportunities to meet those needs are ongoing and an integral part of program operations.



The NET Program

(Non-Emergency Transportation)

BY LINDA BILY, MA

How one community came together to meet the transportation needs of its cancer patients

On Long Island, transportation is a critical concern for all healthcare organizations. As Suffolk County's only tertiary care facility, Stony Brook University Medical Center provides services to patients encompassing a geographical area of more than 900 square miles within Suffolk County alone. Additional referrals come from Nassau and Queens Counties.

Research consistently cites transportation as a major barrier to successful completion of cancer treatment. "Patients, particularly minorities, may opt to forgo needed care in the absence of available and affordable means of transportation to treatment facilities."[1]

At Stony Brook Cancer Center, Stony Brook, N.Y., many of our patients consider English a second language and have difficulty navigating the state's complex transportation system. Traveling from the east end of the island to our facility by public transportation can take up to four hours and include several bus changes. Added to the physical burden of this commute to care is the cost of public transportation. Placing an immuno-compromised, fatigued cancer patient in this situation is an unconscionable burden on the physical, financial, and emotional resources of the patient and his or her family. Today—with a rising number of patients who are under- or uninsured being referred to our facility—the need for viable and cost-effective transportation is even more critical.

The Stony Brook Travel Experience

Long Island is composed of large suburban areas connected by major highways, which are arranged in a grid-like pattern. The Long Island Expressway, the Northern State Parkway, and the Southern State Parkway traverse the region in an east-west direction. In Suffolk County, the north-south routes encompass the Sagtikos Parkway, Route 111, Nicolls Road, and William Floyd Parkway. While this system of highways makes access by automobile fairly simple, the high cost of gas, health insurance, and auto repairs make personal vehicles a luxury for many of our patients. While public transportation exists, its limited location and schedule make it an unreliable option. What's more, public transportation is sparse on the east end of the island.

Today—with a rising number of patients who are under- or uninsured being referred to our facility—the need for viable and cost-effective transportation is even more critical.

When possible, local agencies such as the American Cancer Society (ACS), Fighting Chance, the Leukemia & Lymphoma Society (LLS), Cancer Care, and the Suffolk County Department of Public Works Transportation Division, provide transportation or financial assistance for travel costs to cancer patients. For example, in 2013, Fighting Chance provided 24 trips to Stony Brook Cancer Center for cancer patients coming from the east end of the island. LLS offers a one-time, $100 grant to blood cancer patients to spend on transportation as needed. Cancer Care provides $175 per calendar year, per patient for transportation (specific restrictions apply). SCAT (Suffolk County Accessible Transportation) bus service costs $4 each one-way trip. The ACS Road to Recovery program is a volunteer-driver ride service that is subject to the availability of volunteers and their location limitations.

In 2011 alone Stony Brook Cancer Center incurred a variety of transportation-related costs for its patients, including:

- Cab vouchers: $40 per cab ride for a total of 35 rides or $1,400.

- Bus vouchers: $875 for 500 bus vouchers.
- Bus transfers: $500 for 500 bus transfers.

Our oncology social workers say that they could easily triple the number of cab and bus vouchers they give to patients if Stony Brook Cancer Center had the funding to support these efforts. (Due to the increased cuts in state aid to the entire New York healthcare system, funds for patient transportation have been severely curtailed.)

Our cancer center helps patients apply for Suffolk County bus passes, including the SCAT program and the Brookhaven Jitney program. We also offer patients a list of financial resources that may be used to help pay for transportation, as well as assistance in filing Medicare, Medicaid, and Stony Brook Cancer Center financial aid forms.

Stony Brook Cancer Center treats more than 500 patients per week in medical oncology alone, currently averaging 550; more than 40 percent of these patients require some type of transportation or financial assistance.

The Dream—We Need A Bus!

Outpatient oncology social worker Darlene Kenny, LCSW, who assists surgical and medical oncology patients on a daily basis, dreams big. She was convinced that Stony Brook Cancer Center needed a bus to meet the growing transportation needs of its cancer patients. While cancer program leadership recognizes that patients are our number one priority, the cancer center simply did not have the financial resources to make such a purchase. Armed with only a "wish list," Darlene and I began our campaign. For more than a year, our mantra was, "We need a bus!" And I am proud to say that we now have the 30-second elevator pitch down to an art form.

The donation of a bus would allow Stony Brook Cancer Center to offer transportation to patients in a variety of locations. We believed that the patient benefits would significantly outweigh the cost of hiring a driver. Further, extrapolating the patient volume and the cost of outside transportation services, staff anticipated that Stony Brook Cancer Center could spend well over $20,000 per year in stopgap measures to help patients with transportation, such as bus vouchers.

Confident that we would find a donor to cover the cost of the bus purchase, we began the process of writing a proposal to hire a bus driver. This involved meeting with Long Island transportation experts, drafting policies, and mapping out bus routes.

Realizing the Dream

Sharing our dream with others would prove crucial to our efforts, and with the support of our community, our persistence paid off.

First to offer help was a member of the cancer center's Advisory Board. Her family was committed to improving the patient

experience for individuals with cancer even as their own 28-year-old son battled against AML (acute myeloid leukemia). After she told her husband about our search for a bus, he contacted We Transport, a local bus service company based in Nassau County, which agreed to donate a wheel-chair accessible mini-school bus.

News of the donation spread through our community, culminating in local media coverage, and others soon stepped up to make our dream a reality:

- Penney's North Country Car Care, located in St. James, N.Y., offered to provide free repairs for the first year of bus service.
- The GIFT (Giving Hope, Fighting Together) Foundation, a local organization that supports our cancer patients, paid for upgrades to the bus and supplies, including a first-aid kit, new batteries, and a medical gas cylinder holder.
- Splashes of Hope, a non-profit organization that paints murals for hospitals, volunteered to "splash" the bus with the cancer center's signature sunflowers and cancer awareness ribbons.
- One of Stony Brook's medical photographers donated a GPS system.
- Stony Brook University's pre-med student club washed, scrubbed, and spruced up the inside of the bus.

Stony Brook Cancer Center had its bus, now we needed a driver and money for fuel.

Next Steps

Once the bus was secured, we turned our attention to finding a driver. Stony Brook's cancer program administrator agreed to let a staff member who worked part-time as a patient advocate take time away from her daily responsibilities to serve as the driver for the pilot bus shuttle program. (This employee had an R.V. so she had experience and was comfortable with driving a large vehicle.)

At about this same time, I saw an advertisement for the Citgo "Fueling Good" competition, a social media competition that awards $5,000 in Citgo gas cards to regional winners. I completed the application, and in a few weeks we were told that Stony Brook Cancer Center had made it to the voting round. Approximately 50 applications in each of 8 geographic regions were selected to participate in the online voting campaign; one winner was selected from each region.

The entire university and medical campus participated in the online voting campaign. This social media effort drew attention to our cause and united staff, faculty, students, patients, families, and the surrounding communities with one common goal—to provide transportation help for our cancer patients. It also reinforced to Stony Brook Cancer Center the value of social media and the importance of partnering within the community. Cancer program staff shared the story of our bus campaign with their children. Local high schools voted. Local sports teams participated. Local car clubs, dance studios, and restaurants—our entire community—helped spread the word about voting.

This social media effort drew attention to our cause and united staff, faculty, students, patients, families, and the surrounding communities with one common goal—to provide transportation help for our cancer patients.

An added benefit for the cancer center was the ability to involve students from kindergarten through college in our activities and to offer them a chance for community service. These future leaders learned about altruism and community involvement, and that we all can play a role to improve life for cancer patients and their families.

In November 2012 Stony Brook Cancer Center was awarded $5,000 in Citgo gas cards. Citgo representatives came to the cancer center to present a plaque and T-shirts, and to allow staff the opportunity to meet local Citgo station owners who donate to the "Fueling Good" program. While many deserving charities win funding, Citgo said that Stony Brook Cancer Center was the first to use the gas cards for patient transportation.

Logistics: Rethinking the Process

Cancer program staff spoke to the community-based agencies that serve as resources for our cancer patients, and they were willing to coordinate efforts to make this shuttle service a viable option for our patients. Staff also met with the former director of the Suffolk County Department of Transportation to map out the shuttle bus runs that the cancer center would offer. The program started with shuttle service to patients within Brookhaven Township and then expanded to other townships outside of our core service area.

The logistics of scheduling shuttle service to coincide with treatment appointments were quite complicated. As the cancer patient advocacy and community outreach coordinator, I spent a significant part of my day working closely with the cancer center social workers and oncology medical staff to provide seamless service for our patients.

It soon became obvious that shuttle bus service was not the most expedient—nor appropriate—service. Due to limited driver availability and the large geographic area that needed to be

covered, cancer center staff determined that door-to-door service would be the best option.

Next, understanding that the need for transportation would be greater than the services available, we had to make decisions that would allow Stony Brook Cancer Center to serve those patients with the greatest need. Here is what was decided:

- Only patients with chemotherapy and/or radiation therapy appointments could request door-to-door bus service.
- Patients had to adhere to these guidelines: apply for SCAT bus service; work with their families and caregivers to provide at least some transportation; and apply for the ACS Road to Recovery program.
- Radiation oncology patients could receive bus transportation a maximum of three days a week.
- All patients using the service must be willing to adjust their travel and wait times to accommodate other patients on the bus.

Statistics: It's More Than Scheduling a Pick-Up

Stony Brook Cancer Center started its bus service in November 2012. Eighteen patient transports were made in November and December. The average roundtrip was 100 miles, and the average roundtrip time per patient was three hours. We learned quickly that you must factor the roundtrip at double the time and mileage. In other words, the driver must leave the cancer center to pick up the patient, drive to the cancer center, and then reverse the route.

In 2013 our driver logged 10,219 miles, providing 139 patient transports. Average round trip was 50 miles. Coordinating multiple

TRANSPORTATION & CANCER PATIENTS

Cancer is a life-altering experience. Patients, even those who are self-reliant, often find themselves lacking confidence, control, and the educational tools necessary to navigate the healthcare system. Costs related to cancer treatment can be significant.

Transportation to and from treatment services can have a negative effect on a patient's compliance with his or her cancer treatment regimen, which can lead to poor outcomes.

One study of 189 chemotherapy patients reinforced the impact of transportation on cancer treatment.[2] "The time spent travelling for treatment can be a potential barrier to patients' seeking treatment and keeping their medical appointments. Patients must have reliable transportation, which can be difficult if they have limited access to transportation or if long distances are involved. Transportation can be especially problematic if the patient cannot drive, does not have a car, or uses a wheelchair. Public transportation is often unreliable and time-consuming…The effects of travelling to the clinic can be so great that impaired access to transportation may cause patients to forgo treatment. In addition to the logistical inconveniences and economic hardships of travel, it [transportation] can be another source of stress and can have negative psychological effects on patients. This stress could even affect their willingness to undergo further treatment."[2]

One study of more than 600 patients over age 65 in New Mexico included "impaired access to transportation" as one of the major reasons that older patients are less likely to receive definitive therapy.[3]

Another research study of 139 participants receiving outpatient chemotherapy required patients to keep a weekly diary of nonmedical expenses related to their disease.[4] Although the study is dated, the results remain viable. The mean cost to patients for treatment weeks was almost double the cost of non-treatment weeks ($72.81 vs. $45.88).[4] Transportation and food were the largest out-of-pocket expenses.

In an annual survey of its member programs, the Association of Community Cancer Centers (ACCC) found that transportation needs continue to present challenges and barriers to cancer care.[5] Nearly 70 percent of respondents said that their cancer program has a foundation or philanthropic organization to help meet their patients' financial needs; 74 percent of those help its patients pay for transportation-related needs.[5] Or, as one survey respondent put it: "Patient affordability continues to be an issue. Co-pays, co-insurance charges, and transportation are areas of continued need."[5]

patients on the same day increased the average time per patient to approximately 3.5 hours.

That same year, Stony Brook Cancer Center's bus service allowed two patients—based on their medical conditions and residence locations—to transition from inpatient to outpatient care. The cancer center was able to decrease both patients' hospital length of stay (LOS) by more than two weeks, significantly decreasing costs to the hospital, payer, and patients.

Because the impact on our driver's other work obligations at the cancer center was greater than anticipated, cancer program leadership decided to suspend transportation for new referrals and to keep the current list of clientele operational for the last 6 months of 2014. After this trial period, we hope to hire a bus driver on a per diem basis. This new position will allow the cancer center the flexibility of scheduling bus maintenance, staff vacations, downtime for weather, and more productive driving time. A new annual budget of approximately $50,000 will pay for the driver's salary, bus repairs, fuel, and limited supplies. In the future, we hope to fund the program through an annual fundraising event and donors.

The "Pay It Forward" Effect

While the bus is a major "plus" for Stony Brook Cancer Center patients, a diesel bus consumes a greater amount of fuel and is more difficult to maneuver than a passenger vehicle. So staff soon adopted a new mantra: "We need a car!" Incredibly, the same generous family who was instrumental in obtaining the bus also donated a passenger car. (Their grandfather had recently passed away, and rather than sell his car, the family donated it to Stony Brook Cancer Center.) Their wonderful gift decreased fuel costs and allows the cancer center to use the bus more efficiently—for patients in wheelchairs or for multiple patients on the same trip.

Stony Brook Cancer Center staff and patients appreciate the bus service and what it entails: reduced travel time for patients, less fatigue for patients, a knowledgeable driver, and coordination with oncology services. In its two years of operation, our bus service has:

- Increased patient satisfaction.
- Improved patient adherence to treatment plans, vital for those at risk of recurrence or those whose stress does not allow them to complete treatment protocols. In turn, better patient compliance with treatment schedules will hopefully lead to better outcomes.
- Improved staff satisfaction based on our ability to meet the needs of the patients.
- Allowed East End patients to receive treatment at Stony Brook and forego travelling to Manhattan.
- Allowed oncology providers from the East End to offer transportation options to their patients.
- Strengthened community ties through ongoing efforts to obtain grants and community support of the bus service.

Stony Brook Cancer Center's signature sunflowers and cancer awareness ribbons.

- Improved utilization of chair time due to "on time" arrival that streamlined work flow and will likely have a positive impact on revenue flow.

Stony Brook Cancer Center's dream of a bus—and then a car—to help meet the needs of its cancer patients engaged our entire community. And together we were able to make the dream a reality and improve the lives of our cancer patients and their families. OI

Linda Bily, MA, is cancer patient advocacy and community outreach coordinator, Stony Brook Cancer Center, Stony Brook, N.Y.

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Stony Brook Cancer Center

Non-Emergency Transportation (NET) Program

- Please note that completion of this application does not guarantee transportation.
- Application response may take up to 2 weeks.
- Transportation is primarily for patients in active treatment (chemotherapy and/or radiation therapy treatment). All other requests will be evaluated on an individual basis.
- In order to use the bus service, patients must have a pre-scheduled appointment.
- Transportation will not be provided "on demand."
- It is the responsibility of the patient to be ready to depart 10 minutes ahead of scheduled pick-up time.
- To use this service, patients should try to make their appointments based on the bus schedule.
- Patients should allow at least 1 hour for travel time since the bus may make frequent stops.
- Due to limited space, patients may not be able to bring a companion on the bus.
- If patients fail to board the bus for the return trip, alternative transportation will not be provided.
- All passengers will receive a card indicating that they were transported on the Cancer Center shuttle. Please give this card to the clerk/nurse in your treatment area.
- Shuttle transportation may be provided from designated locations throughout Suffolk County.
- All patients are expected to complete a SCAT bus application, Road to Recovery referral, and (if applicable) a Brookhaven, Southampton, or Islip Jitney application.
- Note that approval for one visit does not guarantee approval for additional visits. All transportation is based on the number of patients in need, the severity of the need, location, and date/time of patient appointment(s).

Additional Resources

1. SCAT Bus: www.sct-bus.org/assets/SCAT%20APPLICATION_2012.PDF.
2. American Cancer Society Road to Recovery Program: www.cancer.org/treatment/supportprogramsservices/road-to-recovery. The ACS Road to Recovery program provides transportation to and from treatment for people who have cancer and who do not have a ride or are unable to drive themselves. Volunteer drivers donate their time and the use of their cars so that patients can receive the life-saving treatments they need.

Stony Brook Cancer Center

Non-Emergency Transportation (NET) Program

Sheet to be Completed by Referring Source

Referral Name _____ **Referring Department** _____

Phone Number _____ **Email Address** _____

Last Name _____ First Name _____

☐ Male ☐ Female Age _____

Date of Birth _____ Height _____ Weight _____

Address _____ City _____ Zip _____

Home Phone _____ Other Phone _____

Emergency Contact _____ Phone _____

Stony Brook Physician _____ Primary Language _____

Insurance _____

Do you own a car?	☐ Yes	☐ No
Do you have a N.Y. State driver's license?	☐ Yes	☐ No
Do any household member(s) have a car?	☐ Yes	☐ No
Could they drive you to your appointment?	☐ Yes	☐ No
Do you have friends who could drive you?	☐ Yes	☐ No
Do you live at a facility that has bus service?	☐ Yes	☐ No
Have you completed a SCAT bus application?	☐ Yes	☐ No
Are you disabled?	☐ Yes	☐ No
Do you use ☐ Cane ☐ Crutches ☐ Walker	☐ Leg Braces ☐ Wheelchair ☐ Oxygen	
Can you sit independently?	☐ Yes	☐ No
Can you get from your home to the curb alone?	☐ Yes	☐ No

Type of appointment _____ Appointment date/time _____

MAIL TO:

FAX TO:

INFO:

EMAIL:

STONY BROOK USE ONLY

Date Received _____ Reviewed by _____

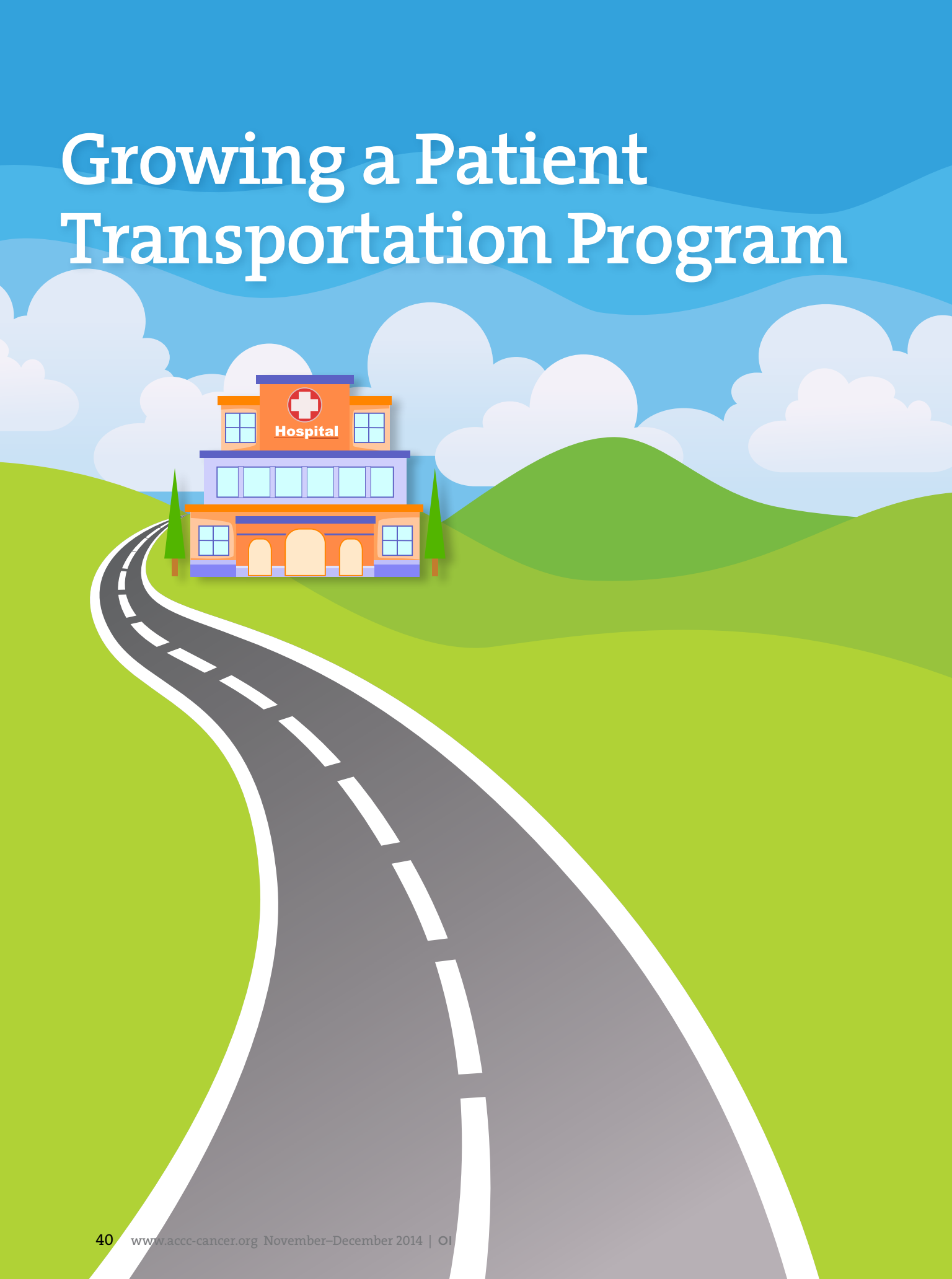
Approval ☐ for DATE _____ TIME _____ TO SB _____ FROM SB _____

☐ SCAT application given ☐ Road to Recovery application given

☐ Jitney application given ☐ Family to share transportation

Request Status _____

Growing a Patient Transportation Program



BY SHERRY LANIADO, MSW, LCSW, OSW-C

How one cancer center took a pilot program and made it permanent

Transportation is often a major barrier for oncology patients who need to receive treatment at the J. Phillip Citta Regional Cancer Center, Community Medical Center, Toms River, N.J. Radiation oncology patients, for example, need to come daily from one week to as many as nine weeks, depending on their treatment protocol. In outpatient infusion, patients have varied schedules, but still transportation is often a major obstacle. Transportation is not only a practical problem, but also an emotional impediment that can cause a tremendous amount of stress and anxiety to an already overwhelmed patient. Many regions of the country have few or no transportation services for cancer patients. And while our cancer program has used the American Cancer Society (ACS) "Road to Recovery" program, it is difficult to get a volunteer driver to commit to daily transportation for a patient for one or two months.

Increased Need, Limited Options

As an oncology-certified clinical social worker, I have spent an inordinate amount of time trying to find transportation for our radiation oncology patients. And after having worked in the cancer center for approximately two years, it became clear to me that something had to be done.

In 2001, I worked out an agreement with our county public transportation program to give cancer patients priority scheduling. Unfortunately, one year into this agreement, the transportation policy changed. New Jersey received a grant from the federal government to provide free transportation for people who participated in the Temporary Assistance to Needy Families program, which replaced welfare. This program required the head of the household to actively seek work, attend a training program or school, or actually go to work. Transportation for these activities would be provided free of charge by the county or other public transportation systems. With the arrival of "work first" federal guidelines, county transportation had to prioritize providing transportation to those recipients. This change once again left me scrambling to meet the transportation needs of our cancer patients.

My next effort involved requesting funds from our hospital's foundation to pay for taxis for those with financial need—which included many of our patients. After about one year, the costs simply became prohibitive.

Back to square one. How was I going to meet the transportation needs of our cancer patients? Was there a better solution out there?

In 2004 I learned from the vice president of Development that our hospital had received a donated 1998 Oldsmobile sedan, and with the generous support of our hospital's foundation and Volunteer Department, we proposed a pilot transportation program to assist our cancer patients. I also met with the director of the hospital's Volunteer Department to gauge the feasibility of identifying two volunteers to work part-time driving cancer patients to and from treatment appointments. Two months later, with the approval of senior administration and assistance from Risk Management with issues related to driver, vehicle, and hospital liability insurance; HIPPA compliance issues; and accident and incident reporting, we were able to establish the pilot program.

Our Pilot Program

Since our cancer center is located in the midst of many retirement communities, the majority of the population we serve is over 65. These patients represent a higher than average need for transportation services due to their increased comorbidities and disabilities. On the positive side, this population provides a much larger volunteer pool because of the number of retirees who wish to remain active.

The director of the Volunteer Department recruited two retiree volunteers to drive—a morning driver who worked from 8:00 am to 12:00 pm and an afternoon driver who worked from 12:00 pm to 4:00 pm. (Our radiation oncology department hours are from 7:30 am to 4:30 pm.)

I was responsible for scheduling, coordinating, and supervising

the pilot program. These volunteers, like the ACS volunteers, did not have any medical training. They had completed the hospital's volunteer orientation program, undergone background and employment checks, and had clean driver's license records. I also oriented our driver volunteers to the cancer patients' needs and special circumstances and gave them specific instruction. In a medical emergency, for example, drivers would call 911 and the radiation oncology department would be notified.

Because the volunteer drivers did not have a medical background or a license to perform any medical activities, drivers were told that they could not provide any medical assistance or physical assistance. All patients being transported had to be able to get in and out of the car independently. The volunteer drivers could open and close the car door and wheel patients to the radiation oncology department in a hospital-owned wheel chair at arrival, but they could not assist with any transfers or ambulation. Volunteer drivers could also assist in carrying items, such as a walker or portable oxygen tank. Working together, the oncology social worker, the risk manager, the vice president of Development, and the director of the Volunteer Department developed a list of exclusion criteria for the transportation program. Specifically, our volunteer drivers could not drive patients with the following conditions:

- Pathological fractures
- Uncontrolled seizure disorders
- Late-stage dementia
- Uncontrolled psychiatric conditions
- Infectious disease
- Bleeding
- Uncontrolled pain.

Accordingly, I carefully screened patients before accepting them into our pilot transportation program.

In addition to the two drivers from the hospital's Volunteer Department and the car donated by the hospital's foundation, the pilot transportation program included:

- An oncology social worker who spent about 5 hours per week coordinating and scheduling transportation of the cancer patients
- A risk manager who worked out issues related to insurance, licenses, background checks, and HIPAA regulations
- Key support from senior hospital administration, the director of the Cancer Center, the director of the Volunteer Department (who helped supervise the volunteer drivers), and the vice president of Development.

The pilot program was very successful. Our volunteers drove approximately 6 to 10 patients round trip each day. We transported mostly radiation oncology patients; on rare occasions, we transported outpatient infusion patients.

> ...the foundation hosted specific fundraising events where monies raised were earmarked to fund the transportation program.

Making It Permanent

In 2005, after one year of the pilot transportation program, I proposed a permanent paid program that would provide transportation for radiation oncology patients and outpatient infusion patients in need. Fortunately, I had an administrative ally—the assistant vice president for Patient Care Services. She was an oncology nurse, and had worked for many years as the oncology unit director and then as cancer center director. Both she and the vice president of Development understood the importance of and need for this program.

Together, we championed the program and presented our proposal to the hospital's chief operating officer (COO). We came armed with statistics from the pilot program, as well as the costs associated with the prior taxi program. The COO approved our proposal as long as the hospital's foundation would be responsible for the program's costs.

Fortunately, the hospital's foundation, which comes under the vice president of Development, agreed to fund a new vehicle for the program, as well as salaries for two part-time drivers. To support this effort, the foundation hosted specific fundraising events where monies raised were earmarked to fund the transportation program.

Finally! A long-term, viable solution to meet the transportation needs of our cancer patients.

I must emphasize how important it was to have senior administration champions. The assistant vice president for Patient Care Services and the vice president of Development were instrumental in making our transportation program a success. Without their support and efforts, I do not believe our transportation program would have been approved.

In 2006 the hospital's foundation purchased a Toyota Rav4. This car—along with our 1998 Oldsmobile sedan—made up our transportation fleet. We hired two part-time drivers who mainly used the Rav4. At particularly busy times, however, both drivers would occasionally work simultaneously. Drivers must have very flexible schedules because patients' schedules are always changing: emergencies arise, weather and traffic problems come up, patients' medical conditions may change, etc.

In 2013 the hospital's foundation purchased another car, a Ford Escape, which allowed us to retire the Oldsmobile. Today both the Ford Escape and the Rav4 are used simultaneously as both drivers' hours overlap at busy times in the schedule. Even better, our cancer center is now able to drive patients to both radiation oncology and outpatient infusion appointments. We average approximately 8 to 15 patients per day, round trip. While most of our patients are transported from their homes, we also provide the driver transport service to patients from nursing homes (if they are physically able), assisted living facilities, rehabilitation hospitals, and group homes.

Today the cancer center's transportation program team includes:

- Two salaried drivers who work part-time, 4 to 6 hours a day. One driver is scheduled for morning and the other for afternoon, with some overlap as needed. These drivers are also responsible for vehicle maintenance and repair. (Costs are paid for by the hospital's foundation.)
- The program coordinator (an oncology social worker) who screens and schedules patients, writes policies and procedures, and supervises the part-time drivers.
- The vice president of Development, who administers the program, funds the program, organizes fundraising events, helps to supervise the part-time drivers, and oversees vehicle purchases.
- A risk manager who handles insurance issues, vehicle and driver regulations, and compliance issues.
- Oncology nurses and radiation therapists who assist with patient scheduling.

For cancer programs looking to implement a similar transportation program, here are some practical tips to get started:

- Map out the geographical area(s) your transportation program will serve.
- Factor the number of patients your transportation program can accommodate per day.
- Determine the types of patients who need and would be eligible for the transportation program.
- Develop criteria for patient inclusion and exclusion.
- Gather credentials and conduct background checks for potential drivers.
- Identify a reliable funding source for vehicles and drivers.
- Identify personnel (staff members) to coordinate and administer the transportation program and clearly delineate their duties and responsibilities. Involve program champions who can ensure buy-in support from senior administration. OI

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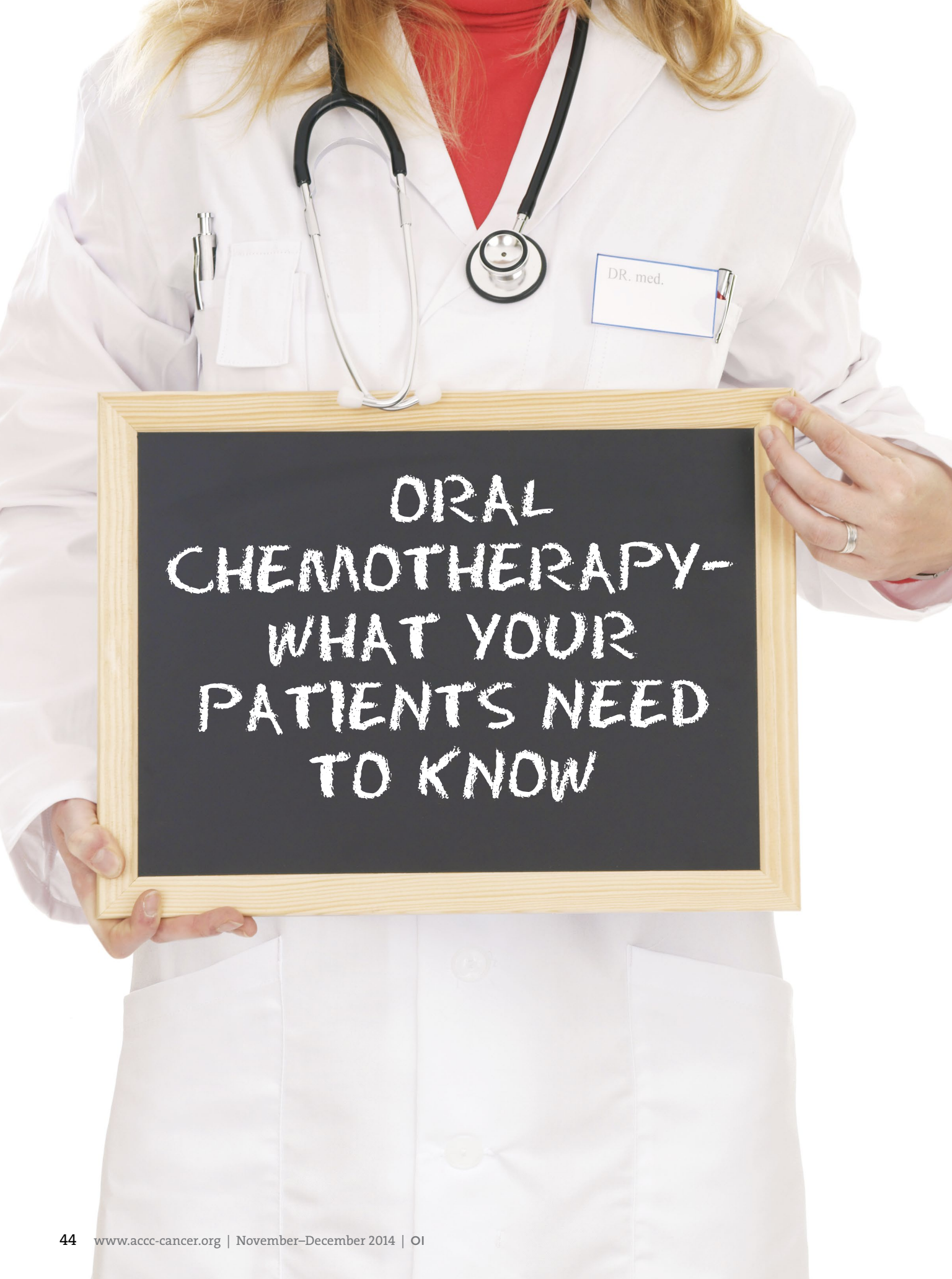
Stark Issues

With regard to Stark legislation, the cancer center does not advertise its transportation program, nor does it in any way offer the transportation program as an incentive to any patients. The transportation program is only offered to patients who have already come to the cancer center for consultation or treatment and who have expressed a need for transportation in order to make treatment appointments. In other words, patients have already made their decision to be treated at our cancer center prior to obtaining transportation service.

Our Program At-a-Glance

The J. Phillip Citta Regional Cancer Center is a community hospital with 1,500 analytic cases per year. Our cancer center has been designated as a Community Hospital Comprehensive Cancer Program by the American College of Surgeons' Commission on Cancer (CoC) since 1986. The hospital is part of the Barnabas Health System, which is the largest healthcare provider in New Jersey. The cancer center is a network partner of the Abramson Cancer Center, University of Pennsylvania.

The success of the cancer center's transportation program has been an asset to our patients *and* program, and will hopefully continue to grow with the cancer center.


DR. med.
ORAL CHEMOTHERAPY- WHAT YOUR PATIENTS NEED TO KNOW

BY ELIZABETH BETTENCOURT, RN, MSN, OCN

Cancer treatment delivery is undergoing a shift from intravenous to oral treatment. In fact, it is projected that the use of oral chemotherapy will more than double in the next several years.[1] One estimate puts 25 percent of anticancer agents in the research pipeline as "designated for oral administration."[2] This increased use of oral chemotherapy agents is moving the administration of cancer treatment from a medical facility to a patient's home. While more convenient for patients, this loss of direct medical supervision during cancer treatment administration can lead to adherence and safety issues for patients. The patient and their caregivers are now responsible for ensuring that the patient receives the right drug and the right dose, at the right time.

Many barriers can affect a patient's adherence to an oral chemotherapy regimen, including:

- Cost
- Dosing complexity
- Forgetfulness
- Distractions of everyday life
- Side effects
- Misinterpretation of the instructions.

Several studies show that patients on long-term medications geared towards decreasing mortality, such as oral chemotherapy, have a low adherence rate of 42 percent.[3] Nurses are on the front line of the medical team and must take steps to prevent or minimize non-adherence, adverse effects, and toxicities.[4] Comprehensive patient education can provide patients with the tools they need to adhere to their prescribed oral chemotherapy regimen. This article presents vital information for patients starting oral chemotherapy.

The Oral Chemotherapy Nurse Navigator Role

As the only oral chemotherapy nurse navigator (OCNN) at the Palo Alto Medical Foundation, (PAMF) Sunnyvale and Mountain View, Calif., I have implemented a process to ensure that patients on oral chemotherapy are thoroughly educated and monitored throughout the course of therapy. In brief, here is how our process works.

Comprehensive patient education can provide patients with the tools they need to adhere to their prescribed oral chemotherapy regimen.

I am notified by the physician when an oral chemotherapy agent is prescribed, and I make the initial contact with patients to discuss the prescription and begin the education process. The actual time from prescription writing to delivery of the drug to the patient can vary anywhere from two days up to as long as three weeks. Prior authorization is required for most oral chemotherapy. As copayments are unaffordable for many, additional time is often necessary to help patients obtain grants from copayment assistance organizations or financial assistance from drug manufacturers.

Once the prescription is ready for pick up at the pharmacy or ready for delivery to the patient, I meet with each patient for a teaching session specifically tailored to the patient's prescribed treatment. This teaching session can be as short as 30 minutes, but can take longer, depending on the patient needs. Education is thorough, patient and drug specific, and continuous throughout the patient's course of therapy. Three to five days after the start of treatment, I contact the patient (usually by phone) to assess side effects, reinforce education, answer questions, and provide emotional support. After that period, patients are contacted once a week for the next six to eight weeks, then monthly as needed for the length of their treatment.

Adjustments to this monitoring schedule are made based on individual patient needs. For example, patients on multiple medications for varied conditions or with complicated oral chemotherapy dosing schedules may need more frequent contact to assist with adherence to the oral chemotherapy. Patients on long-term treatment, such as imatinib (Gleevec®) and dasatinib (Sprycel®), may require less frequent monitoring, especially if no changes in the treatment plan occur.

Patient education prior to the start and during oral chemotherapy treatment is an essential part of assisting patients with adherence and should include education about:[5]

1. Storing, handling, and disposing of oral chemotherapy
2. Concurrent cancer treatment and supportive care medications and/or measures (if applicable)
3. Possible drug/drug and drug/food interactions
4. The plan for missed doses.

Other areas specific to oral chemotherapy that patients should be educated about include:

- Dosing requirements
- Monitoring parameters
- Blood testing requirements
- Side effects and management
- Drug access, which includes helping patients identify and access resources to help pay for their drug(s)
- The refill process.

Oral Chemotherapy Storage

Based on information from the FDA-approved package inserts, I educate patients and caregivers on the proper storage of their oral chemotherapy medication(s). Most oral chemotherapy agents should be stored at room temperature (68° to 77°F). Some drugs can be exposed to higher temperatures up to 86° F for a limited amount of time. Refer to the drug manufacturer for specific information about temperature exposure. Chlorambucil (Leukeran®) and trametinib (Mekinist®) require refrigeration. Regorafenib (Stivarga®) expires 28 days after the bottle is opened and requires the desiccant package to remain in the bottle. Some oral agents require protection from light. Patients must be aware of these temperature and storage requirements to ensure that these medications—some of which are delivered via specialty pharmacies directly to the patient—are not left unattended in extreme temperatures. In my education session, I tell patients to always follow the storage requirements recommended by the drug manufacturer.

Handling Oral Chemotherapy

While many of the oral chemotherapy agents currently in use and in research are targeted agents and not considered cytotoxic, there is not much known regarding the risks of handling these agents.[6] Patients and caregivers must be educated in measures to ensure their safety, as well as the safety of the environment. During my education session, I use several resources that offer guidelines for the handling of oral chemotherapy by patients and their caregivers, such as:[7,8]

- Oral chemotherapy should always be kept away from children and pets.
- Oral chemotherapy should not be chewed, crushed, cut, or dissolved.
- It is recommended that patients administer the chemotherapy agent to themselves. However, if a caregiver is preparing the medication, it is encouraged that gloves be worn. An alternative for those who may have limited financial resources would be to pour the oral chemotherapy agent into a bowl, or the lid of the pill bottle, and then pour the pills into the patient's hand or mouth. The bowl should be cleaned with soap and water. The patient does not need to avoid contact with the chemotherapy agent by wearing gloves. However, both the patient and the caregiver should wash their hands after handling the oral chemotherapy drug.
- Many patients store their oral medications in pill boxes. This can help improve patient adherence to the dosing schedule. The pill box should be used only for the oral chemotherapy, and washed with soap and water when treatment has been completed. Pill boxes are not to be used for Stivarga. Several oral chemotherapy drugs are dispensed in blister packs, eliminating the need for pill boxes.
- Patients, caregivers, pharmacists, and nurses should always wash their hands with soap and water any time contact with an oral chemotherapy agent occurs.
- Common side effects of oral chemotherapy are nausea, vomiting, and diarrhea. If a patient on oral chemotherapy soils linens with bodily fluids, launder soiled linen separately from non-soiled linen.

Patient education is key to ensuring the safe handling of oral chemotherapy agents.

Disposal of Oral Chemotherapy

Proper disposal of oral chemotherapy agents can help keep people safe and protect the environment. Oral chemotherapy agents, while not cytotoxic, are still considered hazardous and therefore must be disposed of properly. Most cities have a hazardous waste disposal policy that patients can follow, but most fire stations and retail pharmacies will *not* dispose of oral chemotherapy.

(continued on page 48)

Proper disposal of oral chemotherapy agents can help keep people safe and protect the environment.

Figure 1. Sample Calendar for Patients on Intravenous Carfilzomib (Kyprolis®) and Oral Lenalidomide (Revlimid®)

SUN	MON	TUE	WED	THU	FRI	SAT
					1 Revlimid*	2 Revlimid
3 Revlimid	4 Revlimid	5 Revlimid	6	7	8	9
10	11 Labs: CBC (complete blood count) and CMP (comprehensive metabolic panel)	12 MD Visit	13 C3D1 Kyprolis Dexamethasone IV Revlimid	14 C3D2 Kyprolis Dexamethasone IV Revlimid	15 Revlimid	16 Revlimid
17 Revlimid	18 Revlimid	19 Revlimid Labs: CBC	20 C3D8 Kyprolis Dexamethasone IV Revlimid	21 C3D9 Kyprolis Dexamethasone IV Revlimid	22 Revlimid	23 Revlimid
24 Revlimid	25 Revlimid	26 Revlimid Labs: CBC	27 C3D15 Kyprolis Dexamethasone IV Revlimid	28 C3D16 Kyprolis Dexamethasone IV Revlimid	29 Revlimid	30 Revlimid
31 Revlimid						

* Notes: Revlimid 15 mg daily for 21 days, then one week off.

Patients should be contacted within the first week of starting oral chemotherapy, and then weekly for the next few weeks.

In addition, only a few drug manufacturers provide instructions on oral chemotherapy disposal. Celgene, the maker of lenalidomide, thalidomide, and pomalidomide, provides patients with packaging material to return unused medications. Hospitals and practices must ensure that their patients are provided proper disposal instructions for these medications.

Concurrent Cancer Treatment

Oral chemotherapy can be prescribed as a single agent or as part of a multi-drug regimen for the treatment of cancer, so patients must be instructed in all aspects of the chemotherapy regimen. Many single agent regimens require the concomitant use of steroids, such as dexamethasone or prednisone. Patients receiving oral chemotherapy as part of a multi-drug intravenous chemotherapy regimen will need specific instructions about how the oral chemotherapy dosing correlates with the intravenous chemotherapy.

Patients have many different learning styles so educational tools should be tailored to support them. Also, some patients will benefit from a calendar that indicates the actual days and times to take oral chemotherapy (Figure 1, page 47). Several apps are now available for patients to use on their smartphones to help remind them to take their oral chemotherapy medications.

At PAMF, I give each patient a one-page summary of the important issues related to his or her specific drug regimen (see Figure 2 and Figure 3, right). I identify the best mechanism to educate each patient to ensure the correct dosing of oral chemotherapy.

Supportive Care Medications & Measures

Oral chemotherapy agents have side effects unique to each drug category. Hypertension, QT interval prolongation of the heart, and lab abnormalities are common side effects for many oral chemotherapy agents. Hypertension and hypertensive crises are not uncommon with pazopanib and regorafenib in the first one to three weeks of therapy. Patients may require blood pressure monitoring either daily or weekly, depending on their personal health history. Antihypertensive medications may be required.

The use of EKG monitoring of the QT interval may be required for patients receiving some oral chemotherapy (i.e., sunitinib, sorafenib, and crizotinib), with or without concomitant use of cardiac medications.

To ensure patient safety, hospitals and practices must monitor continually for potentially serious side effects. Further, patients require frequent reminders to follow through with monitoring requirements. At PAMF, I also educate patients about the prescribed drugs that treat these conditions.

Many oral chemotherapy treatments require frequent laboratory monitoring of blood counts, blood glucose, and liver enzymes. Patients need to know:

1. What testing is required
2. When to have the blood work done
3. If fasting is required.

For example, some oral chemotherapy (i.e., dasatinib, lenalidomide) can cause myelosuppression (a condition in which bone marrow activity is decreased, resulting in fewer red blood cells, white blood cells, and platelets) in the first few weeks of therapy and complete blood counts may be required weekly.

Hepatotoxicity (chemical-driven liver damage) is a potential serious side effect of many oral chemotherapy agents. Patients may require monitoring of the liver enzymes at least every two weeks for the first two to three months of treatment.

Hyperglycemia (high blood glucose) is also a common side effect of some oral chemotherapy agents.

Other common side effects of oral chemotherapy include nausea and vomiting, diarrhea, mouth sores, and skin rash, so patients must be educated on how to manage these side effects as well. An important component of this education is to discuss with the patient the need to inform the practice or hospital if these side effects occur. Many times, patients on oral chemotherapy accept these side effects as a normal part of treatment and continue on with therapy. This can result in over-adherence, a condition that can worsen the side effects and possibly result in hospitalization. At PAMF, I provide patients with their providers' contact information—not only for regular business hours, but for afterhours as well. I encourage patients to use the afterhours support if needed, since waiting over a weekend can result in severe toxicity and declining health.

Because it is not unusual for a patient to be prescribed an oral chemotherapy agent and not contact or return to see the provider for several months—especially if side effects have not occurred—follow-up care with these patients is essential. Patients should be contacted within the first week of starting oral chemotherapy, and then weekly for the next few weeks.

(continued on page 50)

Figure 2. Sample of a Patient-Specific One-Page Summary for Daily Pazopanib (Votrient®)

VOTRIENT (PAZOPANIB) PATIENT INSTRUCTIONS

MEDICATIONS
- Votrient _____ tablets (_____ mg) once a day every day.
- Take Votrient on an empty stomach, at least 1 hour before or 2 hours after food.

BLOOD MONITORING
- CMP (comprehensive metabolic panel) performed every 2 weeks for 2 months, then every month.
- CBC (complete blood counts) performed once a month.
- BP (blood pressure) performed once a week for 6 weeks, then every month.

FREQUENCY OF MD/NP VISITS
- You will see the doctor (MD) or nurse practitioner (NP) 2 weeks after starting therapy, and then every month.
- You will have blood work done 1 to 3 days prior to each MD/NP visit(s).

OTHER PRECAUTIONS
- Do not eat or drink grapefruit or star fruit juices or products while on Votrient.
- Inform your oncologist if you are prescribed an antibiotic as some antibiotics can interfere with Votrient.

DISPENSING PHARMACY

Name _____

Address _____

Phone number _____

Figure 3. Sample of a Patient-specific One-Page Summary for the V-BIRD Regimen

V-BIRD PATIENT INSTRUCTIONS ONE CYCLE = 21 DAYS

MEDICATIONS
- Revlimid _____ mg (_____ capsule) once a day for 14 days, then 7 days off.
- Dexamethasone _____ 4 mg tablets by mouth all at once on days 1, 8, and 15 (same day, every week).
- Velcade infusion on days 1, 8, and 15.
- Aspirin, 81 mg (1 tablet) every day.
- Acyclovir, 1 tablet, twice a day, every day.
- Bactrim (Septra), 1 tablet, twice a day on Saturdays and Sundays only.

BLOOD MONITORING
- CBC (complete blood counts) every week for 8 weeks, and then every 3 weeks, a few days before the cycle starts.
- CMP (comprehensive metabolic panel) every three weeks, a few days before the cycle starts.
- Pregnancy test every week for the first 4 weeks, and then 7 days prior to each cycle.

FREQUENCY OF MD/NP VISITS:
- You will see the doctor (MD) or nurse practitioner (NP) every 3 weeks prior to the start of each cycle.
- You will have blood work done prior to each MD/NP visit(s).

OTHER PRECAUTIONS
- You will take the Celgene phone and/or Internet survey every 3 weeks, 7-10 days prior to each cycle.
- The pharmacy should call every 3 weeks to arrange delivery of Revlimid to your home.

DISPENSING PHARMACY

Name _____

Address _____

Phone number _____

This follow-up lets providers:

- Assess for side effects
- Reinforce side-effect management and obtain the required laboratory monitoring
- Ensure adherence to the dosing regimen
- Answer any questions that patients and caregivers may have.

Proactively connecting with patients receiving oral medications can lead to early intervention after side effects develop, resulting in better adherence to the treatment regimen.

Drug/Drug & Drug/Food Interactions

Patient education about oral chemotherapy must include a discussion about drug and food interactions. Oral chemotherapy can be affected by prescription and over-the-counter medications, as well as supplements and food. A common group of medications that can affect the blood levels of many oral chemotherapy agents are CYP3A inducers and inhibitors. Inducers can reduce blood levels of oral chemotherapy while inhibitors can increase the blood level. CYP2D6 and CYP2C9 inducers and inhibitors are another group of medications that interact with several oral chemotherapy agents. Patients on any of these medications may require adjustment of the oral chemotherapy dose, or discontinuation of the interacting medication.

Patients on anticoagulants require close monitoring. INR (international normalized ratio) levels can be affected by some oral chemotherapy (i.e., capecitabine) and should be monitored more frequently in the first few weeks of treatment, if warranted.

Patients must be educated to inform their oncologist when they are prescribed antibiotics by another provider. Erythromycin, ciprofloxacin, and clarithromycin are not recommended or require close monitoring when taken while on some oral chemotherapy. Sometimes, it is necessary to interrupt the oral chemotherapy agent while on a course of antibiotics.

Antacids and proton pump inhibitors can interfere with the absorption of oral chemotherapy. While on capecitabine, antacids must be avoided for two hours before and after the capecitabine dose. Some oral chemotherapy agents require that proton pump inhibitors be taken at a different time of the day than the oral chemotherapy agent.

Likewise, patients must be educated on what foods should be avoided while on oral chemotherapy. Grapefruit, grapefruit juice, and grapefruit products, as well as star fruit and Seville oranges are CYP3A inhibitors and should be avoided while patients are on an oral chemotherapy agent that interacts with them. I let patients know that Seville oranges are commonly used to make orange marmalade. Patients should stop eating these fruits prior to the start of oral chemotherapy and for a few weeks after the discontinuation of the oral chemotherapy.

> Continued follow up with the patient allows nurses the opportunities to reinforce concepts previously discussed, educate about symptom management, and assess for adherence.

St. John's Wort is also a CYP3A inducer and should be avoided when on oral chemotherapy.

Food can also affect the absorption rates of chemotherapy. For example, since abiraterone (Zytiga®) taken with food can result in an increased systemic exposure to the drug, food should be avoided for two hours before and two hours after taking this oral medication. Conversely, some oral drugs must be taken *with* food, such as regorafenib (Stivarga®), which should be taken with a low-fat breakfast.

As you can see, there are many unique requirements for the safe administration of oral chemotherapy agents, so comprehensive education is essential to ensure the safety of patients taking oral chemotherapy.

Missed Doses

Patients need to know what to do if they forget a dose. In general, for oral chemotherapy taken once or twice a day, the missed dose can be taken if it is within six hours of the normal dosing time. If it is more than six hours, then the medication should be skipped. Most drug package inserts provide specific information for the patient about what to do if a dose is missed. The important factor is to avoid over-dosage.

Refill Process

Hospitals and practices that dispense oral chemotherapy should have a process for refilling these medications. Those that rely on outside pharmacies must ensure that patients are informed of the dispensing process for each particular pharmacy. Most oral chemotherapy is now dispensed by specialty pharmacies and mailed directly to the patient's home or to the physician's office. It is important that patients using specialty pharmacies plan ahead and order the refills early enough to ensure that the refill is received before they run out of their medication. At PAMF, many of our patients experienced delivery delays as a result of last year's severe winter weather. Most specialty pharmacies have plans in place to ensure that drug delivery is not affected by outside issues.

Educate, Educate, Educate

Oncology nurses have an important role in educating patients about the many facets of the oral chemotherapy treatment regimen. Education about oral chemotherapy is not a one-time event, but must be continued throughout the course of treatment. Continued follow up with the patient allows nurses the opportunities to reinforce concepts previously discussed, educate about symptom management, and assess for adherence. The end result is the safe administration of oral chemotherapy, resulting in the best clinical outcome for the patient. OI

Elizabeth Bettencourt, RN, MSN, OCN, is the oral chemotherapy nurse navigator at Palo Alto Medical Foundation, Sunnyvale and Mountain View, Calif.

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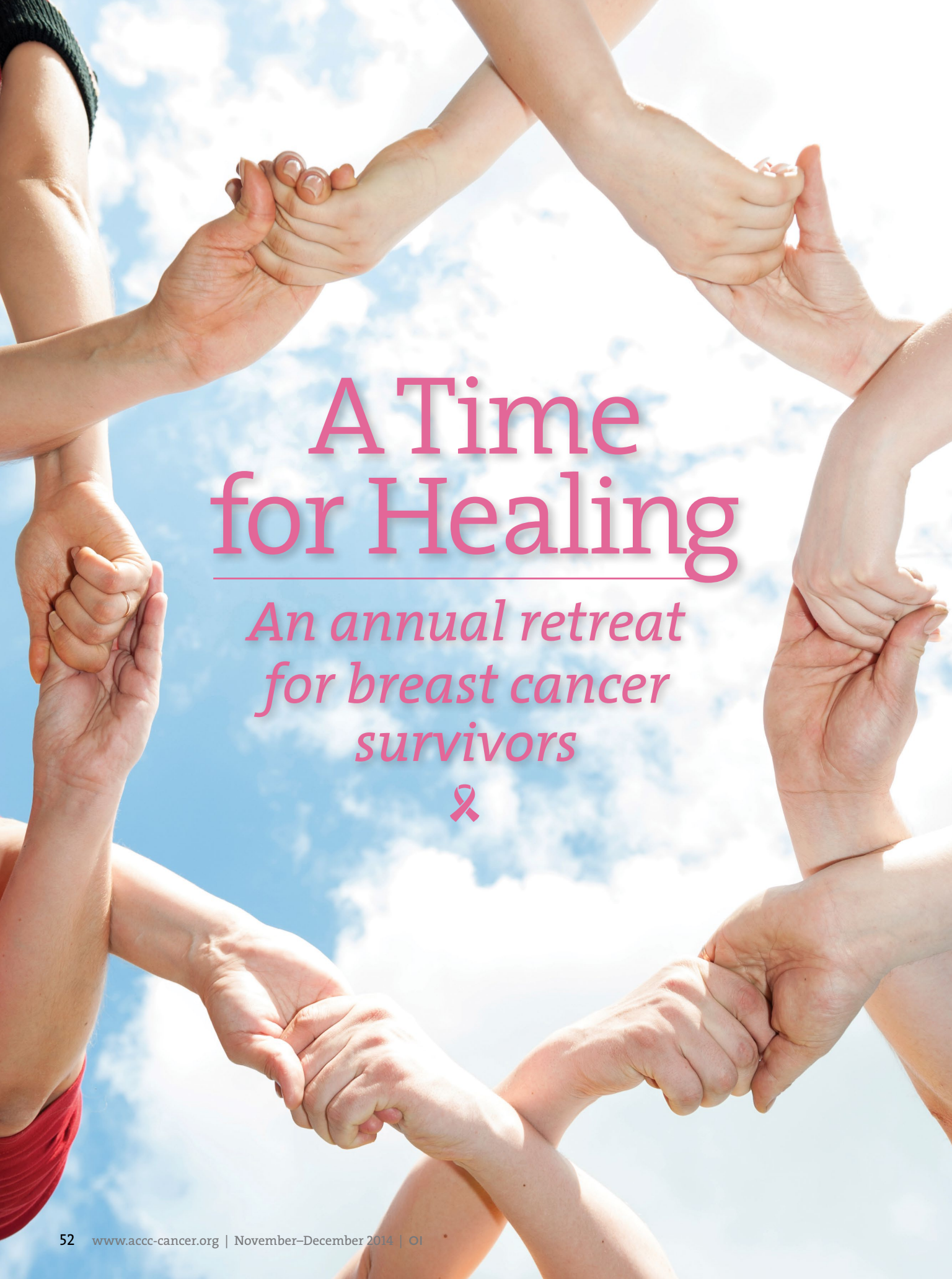

A Time for Healing

An annual retreat for breast cancer survivors

BY DEBBIE DENITTO

When breast cancer treatments end, many women struggle to make sense of their experience and how to begin the process of moving on with the rest of their life. Some breast cancer survivors feel emotionally isolated and can face psychological issues. To help meet the unique needs of its breast cancer patients post-treatment, the cancer program at Winchester Medical Center hosts an annual overnight fall retreat (Saturday-Sunday). Just as the passing seasons signal a time of change for the earth, our fall retreat is the time to address the changes in the lives of our community's breast cancer survivors. The retreat provides women an opportunity to move beyond an intellectual understanding of their disease and allows them to focus on their emotional needs.

"I kept a lot of emotions to myself because I didn't want anybody else to worry," said one of the breast cancer survivors attending our retreat.

In the Beginning

Winchester Medical Center is one of six hospitals within the Valley Health Hospital System. Winchester Medical Center is a CoC-accredited program; its Breast Care Program received NAPBC accreditation in 2009 and re-accreditation in 2013. In 2007 our community resource center, Wellspring, opened its doors, offering hope and information to anyone facing a cancer diagnosis and their caregivers. Wellspring's opening provided an excellent opportunity for Winchester Medical Center's cancer program to offer breast cancer survivors a chance to move forward after their treatment ended. Accordingly, that same year, Valley Health incorporated breast cancer survivorship as part of their cancer care continuum with this retreat.

Laying the Foundation

Our annual retreat seeks to promote healing and transformation. As breast cancer patients move into the survivorship phase of their journey, their healing and moving forward to lifelong survivorship requires reflection and support. Our time together during the retreat is aimed at that goal. The retreat provides a safe, nurturing environment for these women to express their thoughts and fears to others who have faced similar experiences. Most of our attendees are within three years of completing their cancer treatment and still processing what has happened to them and how their lives are now changed forever.

The retreat agenda has evolved over the years as we provide varied multisensory activities and healing therapies to help the women find their own path to living fully once again.

Our time together begins with a "contract of confidentiality," which seeks to put everyone at ease so they feel safe about sharing their private thoughts and feelings with one another.

Cancer program staff stress the need for attendees to be caring and compassionate listeners for all and to look at ourselves in a gentler way.

"[At the retreat] you could be open. You could talk and everyone would understand," said one attendee.

The retreat agenda has evolved over the years as we provide varied multisensory activities and healing therapies to help the women find their own path to living fully once again. For each retreat, we incorporate a variety of self-exploration activities that provide an opportunity for attendees to adopt these as lifelong coping techniques to support a high quality of life.

Fostering Engagement & Support

We keep our annual retreat small, with no more than 14 women. The intimate size of the group provides a unique opportunity for these women to fully share with each other. Many of the participants share that our retreat is the first time they have opened up about their cancer diagnosis and the fears and other feelings associated with their diagnosis and treatment. Most do not wish to burden family or friends with their thoughts, but feel a sense of comfort and openness among this small group of women.

One engaging activity retreat participants have embraced over the years is the passing of sage boughs. Sage is symbolic of helping to find one's center, awaken one's inner self, clear emotional obstructions, align group energy, and promote calmness and clarity. Retreat attendees pass the sage wand around as they begin to share their personal stories. The boughs of sage offer a sense of comfort—something to hold onto while opening up their personal lives to virtual strangers.

Our retreat is held in a beautiful natural setting conducive to reflection. This time away from their families offers an opportunity for personal reflection and a chance to discover and renew any passions that may have been put aside while going through treatment. Attendees have a chance to bond with each other—sharing their stories and fears. We see our retreat as a "pause" in these women's daily lives, a venue to put our breast cancer survivors first and acknowledge and meet their unique needs. This allows participants to take a step back, evaluate their lives, and determine what in their life is really important to them. A quote by American Naturalist John Burroughs is one we share every year, "I go to Nature to be soothed and healed and to have my senses put in order once more."

Attendees share ideas on the healing arts project.

We see our retreat as a "pause" in these women's daily lives, a venue to put our breast cancer survivors first and acknowledge and meet their unique needs.

Retreat Activities

Nutrition after a cancer diagnosis is one aspect of the recovery process that breast cancer survivors have control over and often seek as much knowledge about as possible. A healthy eating presentation with nutrition tips by either a local chef or our registered dietitian, who is also certified in oncology nutrition, is always a popular event at our retreat.

Creative therapies, such as visual arts and expressive writing, are used to promote healing during our retreat. According to one study, "The relaxation and symptom reduction produced by creative expression opens pathways to emotional healing."[1] Our retreat attendees engage in a powerful healing art expression project that involves creating a collage of pictures and words clipped from magazines. Attendees' choice of pictures and words tend to center around areas central to their emotional well-being at this point in their life and activities that they would like to start doing again or possibly try for the very first time. The collages are placed in a booklet that each attendee takes home as a reminder of what matters to her.

During our healing art expression project, we also engage attendees through the use of music to relax and entertain as we create. "In several clinical studies examining the effects of music and music therapy on healing and wellness, music has been found to be a form of relaxation and anxiety reduction."[1]

Massage therapists from the hospital's fitness center volunteer to offer seated massages for everyone. For some, our retreat is the first time they have experienced any type of massage therapy. Releasing stress and minimizing distress by manipulating neck and back muscles revitalizes participants. In fact, many go on to make massage a regular part of their health and wellness regimens.

As part of the retreat, we also offer a writing exercise titled, "Love Letter to Self." Everyone receives a blank sheet of stationery with instructions that the words they write are for their eyes only.

Social psychologist Dr. James W. Pennebaker of the University

A group photo is sent to all attendees as a lasting keepsake.

of Texas, a pioneer in the study of using expressive writing as a route to healing, has said that, "When people are given the opportunity to write about emotional upheavals, they often experience improved health. Emotional upheavals touch every part of our lives and writing helps us focus and organize the experience."[2]

Attendees are given time to write down their thoughts, wishes, dreams, or any subject important to them at that moment. Envelopes are sealed before they are handed to staff, and we mail the letters to each woman approximately 10 days after the retreat. This letter serves as a gentle reminder of what she has discovered about herself over the weekend.

Over the seven years that we've held our retreat for breast cancer survivors, events have also included sessions on yoga, Reiki, guided meditation, exercise, nature walks, and—everyone's favorite—s'mores by the campfire, a means of providing warmth and promoting social gathering. Campfires are an excellent way to foster group interaction and usually lead everyone to feeling relaxed and open for conversation. Attendees often respond to this activity as it serves as a reminder of simpler times; many of these women have not been around a campfire since they were children. For most, the crackling sounds of the fire and smoky aroma immediately invoke a relaxed state of mind.

Closure activities at our retreat include an annual group photo, which is sent to the all attendees as a lasting memento. We conclude our retreat with a circle of hands ceremony guided by one of our parish nurses who leads everyone down a non-denominational spiritual path as we begin to say good-bye to each other.

"We left there not feeling sad about anything. It's time for us to live. Time to think a little about us for a change and not feel guilty," said one attendee.

The Positive Effect

The breast cancer survivor retreat has had a positive effect on both our patients and our cancer care support team. Retreat participants can stay in touch with their new support group, if they so desire. Most of our retreat attendees continue to stay in touch with each other and with cancer program staff through our "Care to Share" email and phone list. Some of our alumni experience reoccurrence of their disease and have counted on each other for support through this trying time.

Our physicians have commented on the positive impact the retreat has had on their patients' outlook on life and have been very supportive of our efforts over the years. A separate alumni group of women (all former breast cancer patients) meet once a year for a weekend of togetherness. All of these efforts support our survivorship efforts and help our patients develop a healthy emotional outlook regarding their quality of life.

To measure the success of our annual breast cancer retreat and determine the effectiveness of the sessions and activities, we conduct an evaluation specific to each session or activity. A survey is provided at the beginning of the program and attendees are asked to complete the appropriate section as each session or activity ends. This allows retreat participants to offer real-time feedback, when the experience and their observations are fresh. We use these surveys to ensure a quality retreat and identify any areas for improvement.

Our Team

The weekend retreat is staffed and enriched by our multidisciplinary team, which includes nurses, yoga or Reiki masters, nutrition specialists, massage therapists, a social worker, a school educator and counselor, a certified cancer exercise specialist, and a regional faith community nurse coordinator. Some retreat staff are breast cancer survivors themselves, which enriches the experience for attendees as they feel an immediate sense of camaraderie and comfort with our staff. Our planning committee is made up of four survivors—three breast cancer survivors and one thyroid cancer survivor. The planning committee is the driving force behind the retreat agenda as the members have first-person knowledge of what cancer patients are seeking as they enter into survivorship.

Our Funding

Since we began hosting our annual breast cancer retreat, the Winchester Medical Center Foundation has generously funded the event. To do so, the foundation holds an annual Pink Luncheon every spring, which provides the majority of the financial support for the retreat. To help cover the cost of the over-night stay, we

request a $49 registration fee from participants; however, we do offer scholarships for those who cannot afford the registration fee.

Final Thoughts

Our annual retreat is about celebrating survivorship, becoming empowered as aspirations are rediscovered, and renewing a commitment to one's self. While retreats are not a new concept, ours has proven to be important to our rural community. This retreat was spearheaded by a breast cancer survivor who is a hospital employee and the author of this article. I attended a retreat after my treatment ended, and it inspired and energized me to pursue developing one in my own community. Interestingly, we have received calls from other hospitals seeking to send their breast cancer survivors to our retreat. Therefore, whether a patient is local or not, we are determined to empower any breast cancer patient. Our aim each year is to support our breast cancer survivors as they re-evaluate their lives and re-prioritize their goals. Restoring hope will provide the catalyst to reinstate balance as they strive for a meaningful and extraordinary quality of life. OI

Debbie DeNitto is coordinator, Oncology Community Outreach Services and breast health educator, Komen Grant, Winchester Medical Center, Winchester, Va.

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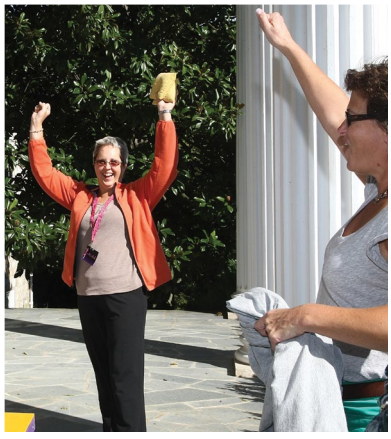

Top: Planning Committee staff members, Carol, Debbie, Colleen, and Lori, who are all cancer survivors.

Bottom: Attendees enjoy a game of bean bag toss.

IN THEIR OWN WORDS

- *It was like being in another world, one where we could just focus on ourselves and what is really important in our lives.*
- *My time and experience* [at the retreat] *will always hold a special place in my heart.*
- *It was such a blessing and inspiration for me.*
- [The retreat offered] *meaningful conversations…and allowed us to share laughter and tears.*
- [The retreat] *provided a safe accepting environment full of hope.*
- *The retreat was planned so well to make each of us feel special and grateful.*
- *I still can't stop talking about it* [the retreat]*…this weekend I had the experience of a lifetime.*
- [The retreat] *was powerful and uplifting…informative and inspiring.*
- *Lovely restful weekend for me in a gorgeous setting.*
- *Thank you for the most lovely, restful, and restorative weekend.*

careers

MANAGER, CANCER CENTER
Wausau, Wisconsin

The Manager of the Aspirus Regional Cancer Center, Aspirus Wausau Hospital, is a healthcare professional with accountability for managing and maintaining the professional and efficient day-to-day operations of the clinic.

Essential Responsibilities

The Manager provides leadership, direction, and administration and supervises, plans, organizes, and directs all aspects of the clinic's activities to ensure accomplishment of its goals as well as the continued development of both the support and clinical staff. The Manager will work closely with the Cancer Service Line Administrator, physicians, team leads, coordinators, and all staff members to assure quality service to patients, providers, and the community.

Contact: Hang McDonald, Employee Relations Specialist, Phone: 715.487.2438; Email: hangm@aspirus.org.

ONCOLOGY NURSE PRACTITIONER
Goshen, Indiana

The Nurse Practitioner (NP) at IU Health Goshen Center for Cancer Care may be primarily assigned to one of three clinical disciplines: Surgical Oncology, Radiation Oncology, and Medical Oncology, while operating comfortably within a combination of the three. NPs work directly with a physician to manage patient caseloads in both the inpatient hospital and outpatient clinic setting. They assist in the evaluation, observation, and treatment of oncology patients, ranging from chronic disease, acute illnesses, episodic disorders, symptom management, palliative care, health care maintenance, and/or survivorship.

The FTE NP receives professional medical direction from physicians. NPs proceed independently in the care and treatment of patients within the scope of practice defined and agreed to by medicine, nursing, and administration; they seek physician opinion whenever a case falls outside the scope authorized by the board of nursing, policies, and/or protocol.

At least two years of oncology practice, as either an RN or a Nurse Practitioner/Physician Assistant. Inpatient experience is preferred. A license to practice as Registered Nurse and a certificate to practice as Nurse Practitioner issued by the State Board of Registered Nursing. Physician Assistants will be considered.

Contact: Apply online at www.iuhealth.org/goshen.

ONCOLOGY RESEARCH NURSE COORDINATOR
DuPage County, Illinois

The Oncology Research Coordinator at DuPage Medical Group plans and coordinates research-related activities, making recommendations regarding the strategy and implementation of research and collaborating with the multidisciplinary team to coordinate research offerings to patients, outline the oncology research workflow, and train staff.

Requirements

- Bachelor's degree or higher in a related field (preferably nursing), public health, or research.
- 3+ years of clinical research experience.
- Achievement and maintenance of research certification preferred.
- Excellent clinical assessment skills.
- The ability to understand technical research protocol.
- The strong communication skills essential to articulating study information to patients, as well as other healthcare professionals.
- The professional demeanor to interact effectively with pharmaceutical/sponsor representatives, regulatory agents, medical-center administration, medical staff, peers, and patients.

Apply online at: www.dupagemedicalgroup.com.

VICE PRESIDENT FOR ONCOLOGY SERVICES
St. Louis, Missouri

Grant Cooper HealthCare seeks a Vice President for Oncology Services on behalf of SSM Health Care. Based in St. Louis, the SSM system is sponsored by the Franciscan Sisters of Mary and currently owns, manages, or is affiliated with 19 hospitals and numerous other care venues in Wisconsin, Illinois, Missouri, and Oklahoma. In the past year, more than 1.5 million people came to SSM for their care. SSM has about 30,000 employees, 7,000 physicians on staff, 8,500 nurses, and nearly 2,500 volunteers. It was the first healthcare recipient of the Malcolm Baldrige National Quality Award and the first large health system to go tobacco-free. The system has won numerous awards for clinical quality and patient satisfaction.

Reporting directly to the Executive Vice President /COO of Hospital Operations, this role is responsible for evaluating, developing, and implementing oncology service line growth initiatives and for ensuring the effectiveness and efficiency of oncology processes within the St. Louis region in accordance with the Philosophy and Mission of SSM Health Care. Candidates will possess a minimum of 10 years of experience in the operational, quality, and strategic business processes of a multi-site oncology service line. A Master's degree is required.

Contact: Jen Ryan, Senior Consultant, Grant Cooper HealthCare Phone: 314.449.1599; Email: ryan@grantcooper.com.

Ask ACCC's Community Resource Centers: *Gastric Cancer*

According to the National Cancer Institute, an estimated 22,220 cases of gastric cancer will be diagnosed in the U.S. in 2014 and about half of that number will die from this devastating disease. Despite an overall decline in the incidence of gastric cancer in the past few decades, it remains difficult to cure since most patients have advanced disease on presentation. The overall five-year survival rate for gastric cancer hovers around 30 percent.[1] These numbers reflect the complexity of treating this disease and thus the need for a multidisciplinary team approach to ensure the greatest chance for long-term survival. According to Martin McCarter, MD, professor of Surgery at the University of Colorado School of Medicine, Surgical Program, Director for the Esophageal and Gastric Multidisciplinary Clinic at the University of Colorado Cancer Center (UCH)—Colorado's only NCI-designated cancer center—this program brings together this kind of specialized expertise for the community at large.

Staging is Key

Accurate and timely staging is critical in determining the appropriate approach to treatment for gastric cancer. Following the initial endoscopic evaluation and biopsy confirmation for the presence of cancer, computed tomography (CT) is performed to evaluate for evidence of metastatic disease. In accordance with the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for Gastric Cancer, a PET-CT may be performed to rule out occult metastatic disease in suspected advanced cancers.[2] PET-CT combines the metabolic information using FDG (fluorodeoxyglucose) as a tracer from PET scans with the anatomic images from CT to provide increased detection of the involvement of lymph nodes and other potential metastatic sites.

Patients without evidence of metastatic disease on imaging should consider an endoscopic ultrasound (EUS). This is a critical part of the staging work-up for determining the depth of tumor invasion and thus treatment selection. In addition to the depth of tumor invasion (T-stage), EUS can detect the presence of lymph node involvement (N-assessment) and any other signs of distant spread (M-stage) in the surrounding organs. Fine needle aspiration (FNA) during EUS adds to the diagnostic accuracy of determining the N-stage. Patients found to have pre-cancerous lesions or very superficial disease that are limited to the submucosa may be eligible for endoscopic treatment with endoscopic mucosal resection (EMR) or endoscopic submucosal dissection (ESD).[3] Pathology review is an important part of the process to ensure accurate staging as studies have suggested a change in the final diagnosis which may affect up to 25 percent of patients when reviewed by expert gastrointestinal pathologists.

Other Treatment Options

Perioperative chemotherapy is considered for those patients with tumors that invade beyond the submucosa and into the muscularis propria without sign of metastatic disease. This recommendation is driven by the results of the MAGIC trial, which showed an overall improvement in 5-year survival from 23 to 36 percent in those patients who underwent chemotherapy before and after surgery. Patients were randomly assigned to surgery alone versus surgery plus perioperative chemotherapy (3 cycles both pre-operatively and postoperatively of epirubicin, cisplatin, and infusional 5-fluoruracil). The combination of perioperative chemotherapy with surgical resection offers patients the best chance for cure.[4]

Radiation therapy may be used in certain situations, pre-operatively for gastric cancers that involve the esophagogastric junction or post-operatively for gastric cancer patients with more advanced disease who did not receive pre-operative chemotherapy.

Studies have shown that institutions with higher surgical volumes specializing in the treatment of gastric cancer are

associated with improved patient outcomes.[5] While much of a patient's gastric cancer treatment may be delivered locally, it is in the patient's best interest to undergo surgery at a higher-volume cancer center. Many factors contribute to improved patient outcomes. In addition to the level of expertise and experience of specialized surgeons, a coordinated care team of nurses, nutritionists, intensivists, and dedicated physician assistants who care for these often complex patients are critical.

Our Model

Thanks to the expertise of a dedicated physician assistant who serves as the point of contact for gastric cancer patients and referring providers, most patients seen in UCCC's weekly Esophageal and Gastric Multidisciplinary Clinic are able to receive their entire staging work-up and come away with a treatment plan in place in one or two days. The first day involves a clinic visit with imaging and EUS as indicated. The following morning, each patient's case is presented in our multidisciplinary conference where the same specialists who read the PET-CT scan and performed the EUS are a part of the patient's discussion. With the collaboration of our surgeons and oncologists, this continuity enables our gastric cancer patients to receive the highest level of coordinated care. During the same conference, patients with metastatic disease or who have progressed on first line chemotherapy may receive additional molecular analysis of their tumor to determine eligibility for potential clinical trials. Because there are factors other than staging that play into determining treatment, a social worker and oncology-certified dietitian are also present to discuss any symptoms and social factors that may influence the approach to therapy. Patients are then seen by the appropriate specialists to discuss the treatment plan, which is then communicated to the referring providers. OI

Martin McCarter, MD, is professor of Surgery at the University of Colorado School of Medicine, Surgical Program and director of the Esophageal and Gastric Multidisciplinary Clinic at the University of Colorado Cancer Center, Aurora, Colo. Dr. McCarter actively participates in basic and translational science research.

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CASE STUDY

- In May 2013, a 69-year-old woman with newly-diagnosed gastric adenocarcinoma was referred by her local oncologist in Nebraska to our regularly scheduled weekly multidisciplinary clinic for further staging and treatment recommendations. Prior to the patient's visit, the clinic coordinator, also a physician assistant, gathered medical records and imaging for clinical review. Since the patient had already undergone initial staging with a CT and PET scan, an EUS was scheduled.
- In clinic, the patient was noted to have severe early satiety and nausea, with an associated 30-pound weight loss over the past several months. EUS was performed that afternoon, and she was found to have a 5 cm circumferential mass in the antrum extending to the pyloric channel with evidence of gastric outlet obstruction. With sonographic evidence of tumor invasion into the serosa and two abnormal lymph nodes in the gastrohepatic ligament, clinicians staged her disease as T3N1Mx.
- The patient's case was presented and all imaging was reviewed the following morning in our multidisciplinary conference. The endoscopist reviewed EUS findings and reported that further symptom management was imperative based on the findings of gastric outlet obstruction. However, taking the patient straight to surgery was not in her best interest for long-term survival.
- After multidisciplinary discussion, the team presented the patient with the option of proceeding directly to surgery to remove the tumor and relieve the obstruction versus ideally starting with upfront chemotherapy and enteral stent placement. The team discussed with the patient the benefits of neoadjuvant chemotherapy and risks of stent migration associated with a significant response to chemotherapy. The patient decided to proceed with enteral stent placement the following morning, which relieved her obstructive symptoms and allowed her to proceed with neoadjuvant chemotherapy with her local oncologist.
- Eating well and feeling better, she underwent three cycles of epirubin, oxaliplatin, and capecitabine in Nebraska. Then, four weeks following the completion of neoadjuvant treatment, she returned to our clinic for follow-up imaging and re-evaluation. The scan showed no evidence of new disease and the patient underwent a distal gastrectomy with curative intent. She recovered and received additional adjuvant therapy with her local oncologist closer to home.
- This case illustrates how a multidisciplinary evaluation with a team of specialists provides patients with options that might not be offered elsewhere and can ultimately improve long-term survival.

The ACCC 31st National Oncology Conference

In early October, hundreds of cancer care providers gathered in San Diego for two days of dynamic sessions focused around two track themes: **YOUR PATIENTS** and **YOUR PROGRAM**. For those of you unable to be with us in San Diego, here are some key takeaways from each track.

Your Patients Track:

- Truly patient-centered care requires conversations to first identify and then develop successful strategies to meet complex patient and family needs.
- Patients and families want to be active participants in treatment decision-making *and* have a say in how services are delivered.
- All cancer programs have a responsibility to conduct community outreach—particularly to at-risk and under-served populations.
- Proactive patient education provided *before* the start of treatment can help improve care and patient adherence to treatment recommendations.

Your Programs Track:

- To achieve the triple aim of improved quality, reduced cost, and enhanced services, providers will need to work together, collaboratively—*across all care settings and service lines.*
- The oncology community is exploring a number of new care models, including oncology medical homes and ACO's Requirements: being innovative and willing to change.
- The most successful cancer programs have access to and actively mine data to identify areas for improvement and marketplace differentiators.
- With the growing demand for services and a shrinking workforce, the oncology community will need to partner with primary care providers to meet the needs of cancer patients.

Mark your calendars today and plan on joining us in Portland, Ore., for the ACCC 32nd National Oncology Conference, Oct. 21-24, 2015. OI

Congratulations to ACCC's 2014 Innovator Award Winners

- Anne Arundel Medical Center DeCesaris Cancer Institute for its *Value-Driven Symptom Management Clinic.*
- Beaumont Cancer Institute for *Closing the Gap: An Outpatient Nutrition Clinic.*
- Duke Oncology Network, Duke Cancer Institute for *Capturing Quality Data to Improve Palliative Care.*
- New Mexico Oncology Hematology Consultants, Ltd., for its *COME HOME—A Model Oncology Medical Home.*
- Oncology Specialists, SC, for its *EMR-Driven Approach to Survivorship Care Plans.*
- University Medical Center of Princeton at Plainsboro for *From Distress Screening to Solutions: Patient-Centered Support.*

A Reminder from ACCC's Bylaws Committee

December 1, 2014, is the deadline for submission of any proposed amendments to the ACCC Bylaws. Proposed recommendations should be sent to ccampbell@accc-cancer.org. ACCC's Bylaws are available online at: www.accc-cancer.org/about/pdf/Bylaws-2008.pdf.

ACCC Welcomes its Newest Members

IU Health Bloomington, Cancer Program
Bloomington, Ind.
Delegate Rep: Wanda Katinszky, BSN, MSW, RN
Website: www.iuhealth.org/bloomington

North Shore Hematology Oncology Associates, PC
East Setauket, N.Y.
Delegate Rep: Jeffrey Vacirca, MD
Website: www.nshoa.com

Rockford Memorial Hospital Cancer Center
Rockford, Ill.
Delegate Rep: Jacqui Kudzma, RN, MS, RHIA
Website: www.rockfordhealthsystem.org

Summit Physician Services Summit Cancer and Hematology Services
Chambersburg, Penn.
Delegate Rep: Janet Daniels
Website: www.summithealth.org

ACCC would also like to welcome its newest chapter member

Premier Oncology Hematology Management Society (POHMS)
Clinton, N.J.
Website: www.pohms.com

ADVERTISER'S INDEX

My Journey to Advocacy

BY SEIJA OLIVIER, BSN, RN

In a very real sense my healthcare career began as a patient in 1999, when I was diagnosed with cancer at the age of 33. I had no experience with healthcare issues and—like many Americans—I assumed that because I had health insurance, I would be fine. I was wrong.

The words "You have cancer" were terrifying enough. I had two young children and wanted to see them grow up. But being told that I might have to pay out-of-pocket if my insurance did not cover the cost of my treatment was devastating. How would I afford my treatment?

The moment the inequality in care really hit me was when I lost my health insurance. Was my life not worth saving? The harsh reality was that without health insurance, I could no longer pay for my oral anticancer medications *and* pay my bills. In the end, I stopped taking the adjuvant oral medication, potentially sacrificing my long-term survival for my short-term needs.

I was diagnosed with cancer for the second time in September 2013. And I could not help but wonder—if I had been able to afford my medications and taken them as prescribed, would I have had a recurrence? Nobody should have to make those difficult and possibly life-threatening choices.

Making a Difference

I knew then that I needed to somehow work to create change in the way cancer patients are treated in this country. With my experience as a cancer patient as a powerful motivator, I enrolled in nursing school in 2000 to learn more about how we care for oncology patients.

I have since moved into a practice manager position, which allows me the ability to effect change at our program's policy level. However, I have found that developing better education sessions or more efficient processes in our office was not enough to meet all the needs of our cancer patients. Instead, I had to work for change at the national and state legislative level.

First Steps

I started by becoming involved with organizations that advocate for cancer patients on issues related to access and quality care. The Association of Community Cancer Centers (ACCC) was a great place to get started on my advocacy journey. For example, ACCC hosts an annual Hill Day where members visit with their representatives to talk about issues important to our cancer patients and cancer programs. Not only are these visits important in shaping the future of oncology care in this country, they are so easy to do! ACCC staff takes care of every detail—from providing information about pending legislation to scheduling appointment times with key legislators to preparing talking points and "leave-behind" materials. ACCC staff makes it simple to take your first steps as an advocate—whether by email, phone, or in person.

At the same time, I was working on advocacy issues, such as oral parity legislation, on the state and local level. The Michigan Society of Hematology and Oncology (MSHO) is a strong, state-based professional organization, which currently represents more than 93 percent of practicing hematologists and medical oncologists in Michigan. MSHO's mission is to promote exemplary care through advocacy, education, and research. Through MSHO, I have had opportunities to advocate and speak out on issues affecting cancer patients and cancer programs at the state level.

That said, I must confess that I still get nervous when I first begin to talk. Yet even as I struggle with my anxiety about public speaking, I realize that my voice truly makes a difference—nervous or not.

In 2014 I was honored with a grassroots advocacy award at the ACCC 40th Annual Meeting. Sitting next to the other award recipients, I was reminded that it is not our "perfect words" that get the world to change, but our tenacity. It's that we show up over and over again. That's how we create change. So I invite you to join me in creating change for our cancer patients—one conversation or one letter at a time. OI

Seija Olivier, BSN, RN, is practice manager, Allegiance Hematology Oncology, Jackson, Mich.

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.

Manufactured by: Catalent Pharma Solutions, LLC, St. Petersburg, FL 33716
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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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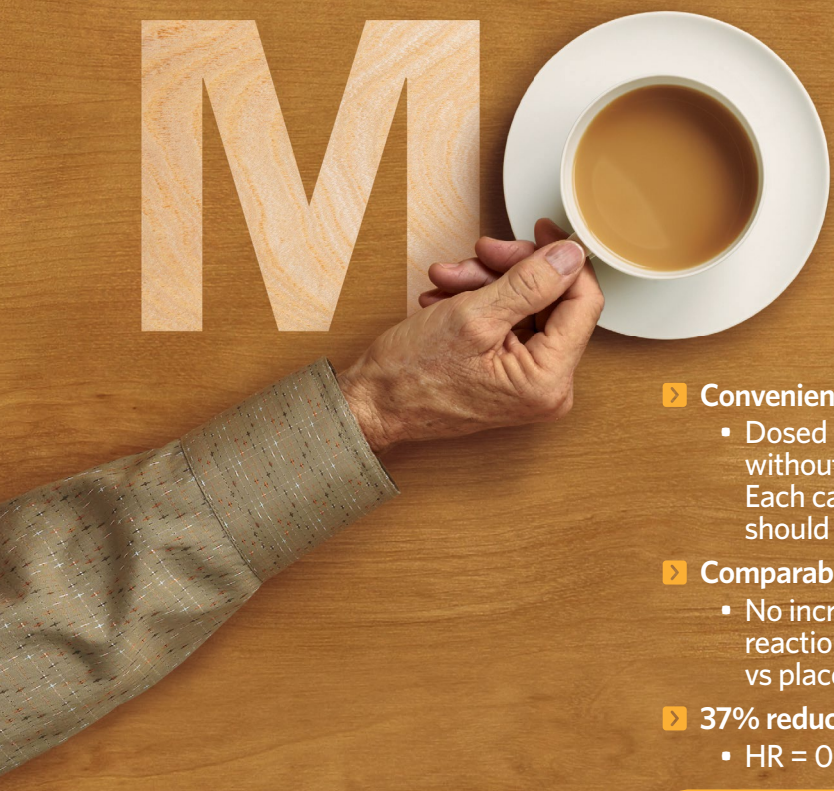
18.4 AND MORE:



- **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.