ONCOLOGY ISSUES

The Journal of the Association of Community Cancer Centers
May | June 2014

Implementing an Electronic Dosimetry Whiteboard

ACCC Association of Community Cancer Centers
40 YEARS STRONG

GRANIX™
(TBO-FILGRASTIM)
Injection

Take a bite out of G-CSF acquisition costs*

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

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

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

†Biologics License Application.
‡As of February 2014.

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

Indication

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

Important Safety Information

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

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

For more information, visit GRANIXhcp.com.

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

TEVA Oncology

GRANIX™ (TBO-FILGRASTIM) Injection

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

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

4 CONTRAINDICATIONS
None.

5 WARNINGS AND PRECAUTIONS
5.1 Splenic Rupture
Splenic rupture, including fatal cases, can occur following administration of human granulocyte colony-stimulating factors. In patients who report upper abdominal or shoulder pain after receiving GRANIX, discontinue GRANIX and evaluate for an enlarged spleen or splenic rupture.
5.2 Acute Respiratory Distress Syndrome (ARDS)
Acute respiratory distress syndrome (ARDS) can occur in patients receiving human granulocyte colony-stimulating factors. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving GRANIX, for ARDS. Discontinue GRANIX in patients with ARDS.
5.3 Allergic Reactions
Serious allergic reactions including anaphylaxis can occur in patients receiving human granulocyte colony-stimulating factors. Reactions can occur on initial exposure. The administration of antihistamines, steroids, bronchodilators, and/or epinephrine may reduce the severity of the reactions. Permanently discontinue GRANIX in patients with serious allergic reactions. Do not administer GRANIX to patients with a history of serious allergic reactions to filgrastim or pegfilgrastim.
5.4 Use in Patients with Sickle Cell Disease
Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disease receiving human granulocyte colony-stimulating factors. Consider the potential risks and benefits prior to the administration of human granulocyte colony-stimulating factors in patients with sickle cell disease. Discontinue GRANIX in patients undergoing a sickle cell crisis.
5.5 Potential for Tumor Growth Stimulatory Effects on Malignant Cells
The granulocyte colony-stimulating factor (G-CSF) receptor through which GRANIX acts has been found on tumor cell lines. The possibility that GRANIX acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which GRANIX is not approved, cannot be excluded.

6 ADVERSE REACTIONS
The following potential serious adverse reactions are discussed in greater detail in other sections of the labeling:
- Splenic Rupture [*see Warnings and Precautions (5.1)*]
- Acute Respiratory Distress Syndrome [*see Warnings and Precautions (5.2)*]
- Serious Allergic Reactions [*see Warnings and Precautions (5.3)*]
- Use in Patients with Sickle Cell Disease [*see Warnings and Precautions (5.4)*]
- Potential for Tumor Growth Stimulatory Effects on Malignant Cells [*see Warnings and Precautions (5.5)*]

The most common treatment-emergent adverse reaction that occurred at an incidence of at least 1% or greater in patients treated with GRANIX at the recommended dose and was numerically two times more frequent than in the placebo group was bone pain.
6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.
GRANIX clinical trials safety data are based upon the results of three randomized clinical trials in patients receiving myeloablative chemotherapy for breast cancer (N=348), lung cancer (N=240) and non-Hodgkin's lymphoma (N=92). In the breast cancer study, 99% of patients were female, the median age was 50 years, and 86% of patients were Caucasian. In the lung cancer study, 80% of patients were male, the median age was 58 years, and 95% of patients were Caucasian. In the non-Hodgkin's lymphoma study, 52% of patients were male, the median age was 55 years, and 88% of patients were Caucasian. In all three studies a placebo (Cycle 1 of the breast cancer study only) or a non-US-approved filgrastim product were used as controls. Both GRANIX and the non-US-approved filgrastim product were administered at 5 mcg/kg subcutaneously once daily beginning one day after chemotherapy for at least five days and continued to a maximum of 14 days or until an ANC of ≥10,000 x 10^6/L after nadir was reached.
Bone pain was the most frequent treatment-emergent adverse reaction that occurred in at least 1% or greater in patients treated with GRANIX at the recommended dose and was numerically two times more frequent than in the placebo group. The overall incidence of bone pain in Cycle 1 of treatment was 3.4% (3.4% GRANIX, 1.4% placebo, 7.5% non-US-approved filgrastim product).
Leukocytosis
In clinical studies, leukocytosis (WBC counts > 100,000 x 10^6/L) was observed in less than 1% patients with non-myeloid malignancies receiving GRANIX. No complications attributable to leukocytosis were reported in clinical studies.
6.2 Immunogenicity
As with all therapeutic proteins, there is a potential for immunogenicity. The incidence of antibody development in patients receiving GRANIX has not been adequately determined.

7 DRUG INTERACTIONS
No formal drug interaction studies between GRANIX and other drugs have been performed.
Drugs which may potentiate the release of neutrophils, such as lithium, should be used with caution.
Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting bone-imaging results.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Pregnancy Category C
There are no adequate and well-controlled studies of GRANIX in pregnant women. In an embryofetal developmental study, treatment of pregnant rabbits with tbo-filgrastim resulted in adverse embryofetal findings, including increased spontaneous abortion and fetal malformations at a maternally toxic dose. GRANIX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
In the embryofetal developmental study, pregnant rabbits were administered subcutaneous doses of tbo-filgrastim during the period of organogenesis at 1, 10 and 100 mcg/kg/day. Increased abortions were evident in rabbits treated with tbo-filgrastim at 100 mcg/kg/day. This dose was maternally toxic as demonstrated by reduced body weight. Other embryofetal findings at this dose level consisted of post-implantation loss, decrease in mean live litter size and fetal weight, and fetal malformations such as malformed hindlimbs and cleft palate. The dose of 100 mcg/kg/day corresponds to a systemic exposure ($AUC_{0\text{-}24}$) of approximately 50-90 times the exposures observed in patients treated with the clinical tbo-filgrastim dose of 5 mcg/kg/day.
8.3 Nursing Mothers
It is not known whether tbo-filgrastim is secreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when GRANIX is administered to a nursing woman. Other recombinant G-CSF products are poorly secreted in breast milk and G-CSF is not orally absorbed by neonates.
8.4 Pediatric Use
The safety and effectiveness of GRANIX in pediatric patients have not been established.
8.5 Geriatric Use
Among 677 cancer patients enrolled in clinical trials of GRANIX, a total of 111 patients were 65 years of age and older. No overall differences in safety or effectiveness were observed between patients age 65 and older and younger patients.
8.6 Renal Impairment
The safety and efficacy of GRANIX have not been studied in patients with moderate or severe renal impairment. No dose adjustment is recommended for patients with mild renal impairment.
8.7 Hepatic Impairment
The safety and efficacy of GRANIX have not been studied in patients with hepatic impairment.

10 OVERDOSAGE
No case of overdose has been reported.

TEVA Oncology

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Sicor Biotech UAB
Vilnius, Lithuania
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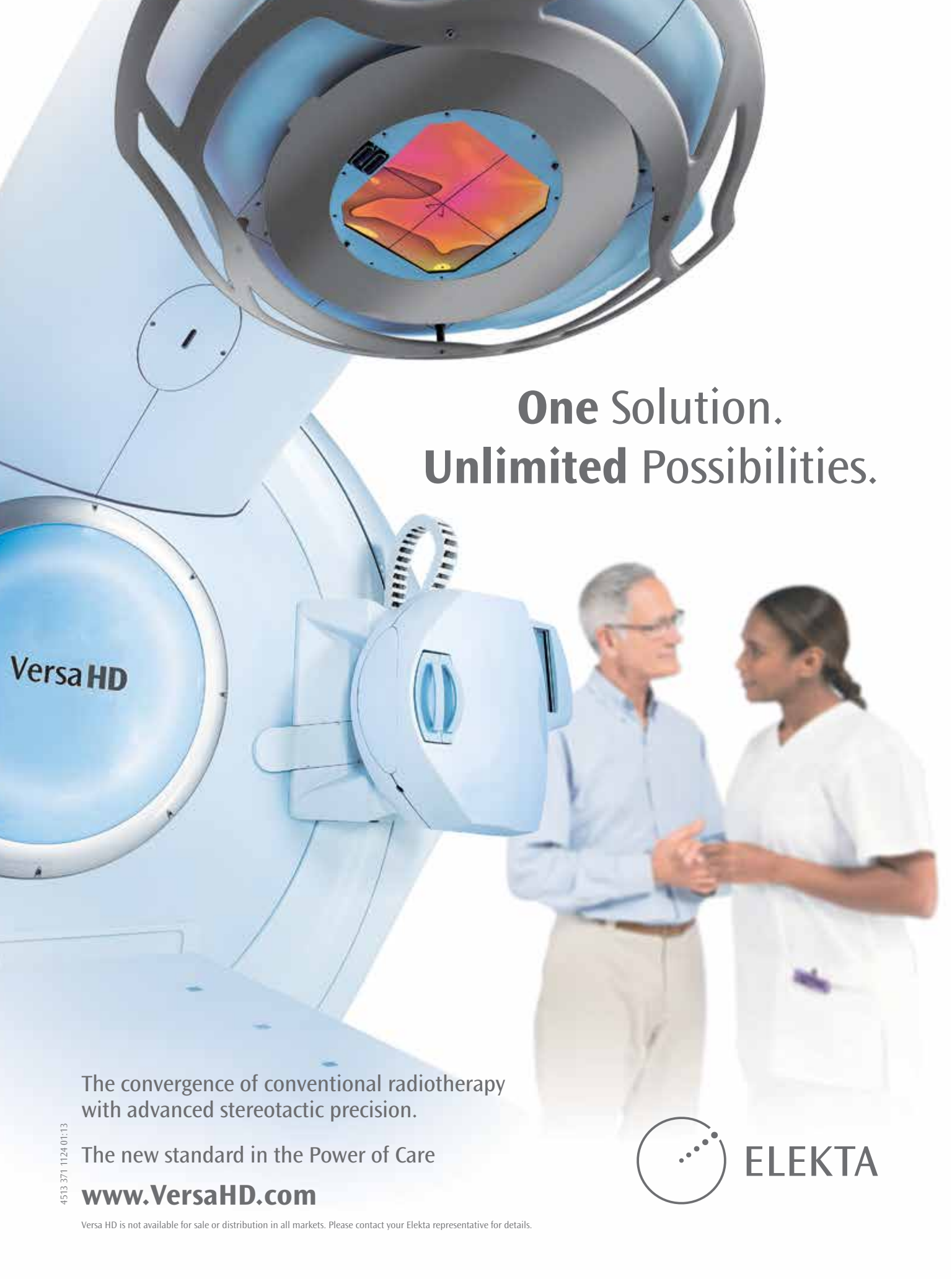
Teva Pharmaceuticals USA, Inc.
North Wales, PA 19454

Product of Israel
GRX-40188 January 2014

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



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DEPARTMENTS

ACCC
Association of Community Cancer Centers

ONCOLOGY ISSUES
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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

Don't Just Bloviate, Innovate!

BY CHRISTIAN DOWNS, JD, MHA

A few years ago I was at a meeting on the future of cancer care. We had reached the point where everything had been said about the issue, but not everyone had said it. A woman who had sat quietly in the audience while most of us bloviated (Google that one!) eventually spoke up. She said one factor we were ignoring was the cost of innovation. Not just the financial cost, but the time and energy it takes to manage innovation. Then she added that this cost is one we cannot cut or ignore. Rather we must absorb the cost to improve patient care.

Her words were on my mind as I reviewed this edition of *Oncology Issues* and thought about where ACCC, as an organization, is headed.

The theme of innovation is woven throughout this issue.

For example, the cover story features Temple University Hospital Cancer Center's electronic dosimetry whiteboard. This program received a 2013 ACCC Innovator Award for this tool, which improved a very busy radiation oncology service line by increasing transparency, improving staff communication, ensuring accountability, and streamlining work distribution. Even better, this innovative, low-cost tool improved staff morale and increased physician and patient satisfaction.

In another feature article, Hematology Oncology Associates of Central New York shared its innovative solution for patients who are prescribed oral oncolytics. This practice invested time and resources to put together a team to create, implement, and then execute a physician dispensing platform for these therapies and other supportive medications. Today, The Patient Rx Center serves medical and radiation service lines at multiple locations.

While ACCC member programs are always innovating, so is the Association itself. This year ACCC will launch three exciting initiatives.

One will be an expansion of ACCC's Oncology Pharmacy Education Network (OPEN). Many of you are familiar with OPEN and its goal of helping providers better understand the oncology pharmacy. This fall, ACCC will host a series of meetings to highlight the latest trends in oncology pharmacy—in other words all the information that providers need to know to get the most out of this service line.

The second initiative builds on ACCC's popular Financial Advocacy and Assistance education program. ACCC will host a series of regional meetings around the country, bringing together the latest tools and resources to help its member programs support their cancer patients and deal with the rising cost of cancer treatment.

Finally, this year, a group of dedicated volunteers and ACCC staff have started a new program aimed specifically at the Association's office-based practice members. This group is developing programs around communication, integration, and practice management that will look to preserve the country's cancer care delivery infrastructure.

If you are interested in discovering how community providers are innovating every day, you must secure a place at the upcoming ACCC 31st National Oncology Conference in San Diego, Oct. 8–11. In addition to presentations from the 2014 ACCC Innovator Award winners, you will find dozens of sessions offering the tools and resources your program needs to take on the challenge of innovation and succeed.

The cost of innovation is something we cannot ignore. Instead we must invest the time, resources, and energy to be successful—for our programs and our patients. Luckily, ACCC is here to help. OI

Goooooood Morning, ACCC!

BY BECKY L. DEKAY, MBA

It is with great honor that I serve you, the membership, as ACCC President, 2014–2015. I must admit, however, to experiencing a bit of trepidation at writing my first President's Message. I've read many informative and inspirational ACCC presidential columns throughout the years from many great thought leaders, and I am grateful for the opportunity to add my "voice" to the oncology discussion.

ACCC is an incredible organization for all members of the cancer care team. As my predecessor and mentor, Ginny Vaitones, MSW, OSW-C, so eloquently stated during her presidency, "It takes a team that works together to help our patients and their caregivers negotiate the complex world of cancer care." Each of you reading this edition of *Oncology Issues* is a member of that team—as are all of your colleagues. So it is my sincere hope that you share valuable ACCC resources with them and include them in ACCC activities and programs.

Each ACCC president is given the opportunity to develop a theme for his or her presidential term, and I've chosen to focus on quality in cancer care. The first step is to understand that quality is a journey—not a destination. Delivering quality care takes buy-in from every member of the cancer care team, and especially from the physicians who must serve as champions for quality initiatives.

We all practice quality care; no one enters this field to not do their very best for our patients. But many times we fail at providing the best care simply because outdated processes stand in our way. We're accustomed to doing things a certain way because that's how it's always been done. Have you ever found yourself manually completing monthly statistical reports (census, no shows, LOS, etc.) for administration, only to find out that administration has been pulling the same reports via the EHR installed years earlier? I have! You'll remember that Albert Einstein defined insanity as "doing the same thing over and over and expecting different results." Recognizing these "because it's always been done this way" traps and resolving to overcome them is precisely where quality improvement comes into play.

Discussions of quality care inevitably will involve decisions around data collection and metrics. If you attended ACCC's 40th Annual National Meeting in March, you heard Dr. Kavita Patel of the Brookings Institution talk about an increased focus from public and private payers on data for contracting and value-based payment. Wouldn't *you* rather develop and drive the appropriate measures in cancer quality than be told what to do by your payers? *I* would.

ACCC will not create new quality measures. Our member programs all participate in quality-related initiatives—whether it's QOPI, PQRS, RQRS, or any of the other "alphabet soup" measures. But ACCC can play a role in some of the following issues:

- How does your program use data to make changes in care provision?
- How and to whom does your program present its data? To payers? To patients? To hospital or health system leadership? To your community at large?
- When and how do you bring in the voice of the patient?
- How do you identify appropriate and easily demonstrated quality measure to your payers? How do you identify measures valued by your patients and their caregivers?

In the next 12 months be on the lookout for ACCC projects related to quality, and participate! My hope is that ACCC's wonderful education programs, networking opportunities, and advocacy efforts can spread the science of quality nationwide. The "alphabet soups" are necessary reporting, but we know that measuring only retrospectively is like driving a car while looking in the rearview mirror. Rapid turnaround studies with concurrent measures are needed to create true change and improvements. I look forward to traveling on the quality journey with you this year!

Coming in Your 2014 *ONCOLOGY ISSUES*

- Integrating Palliative Care into a Medical Oncology Practice
- Improving Oncology Genetic Counseling
- Developing a Community-Based Program for Cancer Survivors & Caregivers
- A Model for Improving the Care of Very Immunocompromised Patients
- Skin Cancer Screening Clinic: A Creative Business Model
- Biosimilars: Emerging Issues for Cancer Programs?
- Clinical Pathway Trends—Payers, Providers, and Healthcare Evolution
- New Patient Coordinator: Streamlining a Cancer Center's Phone Lines
- Completion of a Community Health Needs Assessment
- SIR-Spheres Microspheres as a Treatment Option for Patients with Metastatic Colorectal Cancer
- Cancer Clinical Trials: Enhancing Infrastructure and Accrual
- Patient Education and Consent for Oral Chemotherapy

more online @ www.accc-cancer.org

fast

TOOL

Access New Pancreatic Cancer Tools

We're rolling out practical resources for providers treating pancreatic cancer patients, including effective practices in use at ACCC member programs, a patient education booklet on Whipple surgery, and more. www.accc-cancer.org/pancreatic.

VIDEO

Town Hall on Value in Cancer Care

How do we define value and quality in cancer care? Panelists at ACCC's 40th Annual National meeting explored this question from the payer, patient, and provider perspectives. The wide-ranging conversation touched on the forces driving the high cost of care; the potential for reform; and the struggle to reach consensus. www.accc-cancer.org/resources/TownHall.asp.

BLOGS

ICD-10-CM Delay: What Next?

ACCC asked *Oncology Issues*' Compliance columnist Cindy Parman, PC, CPC-H, RCC, for her views on the ICD-10 implementation delay and next steps for cancer programs. http://acccbuzz.wordpress.com/2014/04/11 icd-10-cm-delay-what-next/.

AWARD

Meet the 2014 Innovators!

Now in their fourth year, ACCC's Innovator Awards recognize and honor pioneering strategies for the effective delivery of cancer care in the community setting. See what this year's award winners have done to advance quality care. www.accc-cancer.org/innovator.

Oncology Remains Most Restrictive Specialty in 2013

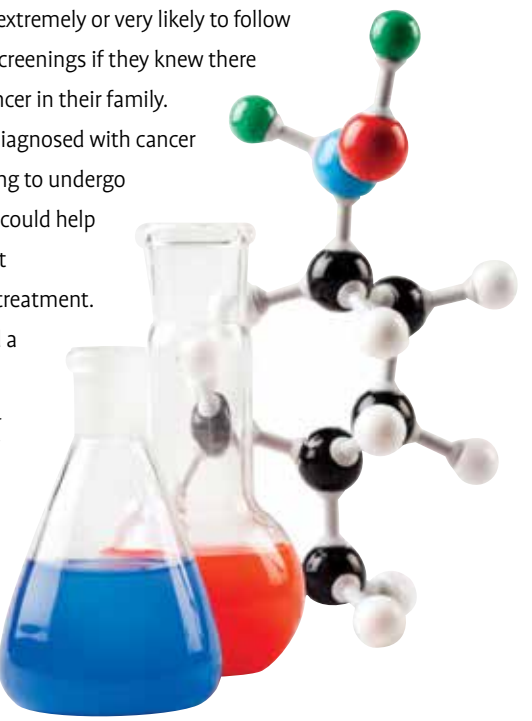
About **65%** of oncologists in the U.S. placed moderate-to-severe restrictions on visits from pharma sales reps. (**58%** of cardiologists and **47%** of primary care physicians restrict rep access to the same degree.) By comparison, only **17%** of oncologists restricted access to reps in 2008.

Source. Spring 2013 AccessMonitor™ report from global consulting firm ZS Associates.

Survey Finds Public Divided on Genetic Testing to Predict Cancer Risk

- **34%** of respondents would not seek genetic testing to predict their likelihood of developing a hereditary cancer—even if cost was not an issue. Concerns about employment and insurability were cited as the primary reasons.
- **35%** would be extremely or very likely to seek aggressive prophylactic or preventive treatment, such as a mastectomy, if they had a family history of cancer and genetic testing indicated a genetic pre-disposition to cancer.
- **63%** report being extremely or very likely to follow all recommended screenings if they knew there was a history of cancer in their family.
- **85%** state that if diagnosed with cancer they would be willing to undergo genetic testing if it could help determine the most effective course of treatment.
- Only **8%** have had a genetic test.

Source. Huntsman Cancer Institute at the University of Utah.



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

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

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

facts

7 Growth Pathways for Hospitals & Health Systems

1. Recruitment or acquisition of medical groups already in-market, but not fully aligned with the hospital.
2. Clinical program development and service expansions, including recruiting new physicians, expanding existing groups, or "leasing" physicians from a nearby academic or tertiary center.
3. Geographic market expansion through the deployment of medical practices and/or ambulatory resources to establish additional locations of care and system access points.
4. Targeting emerging clinical technologies (robotics, new surgical instrumentation, imaging devices, nanotechnology, etc.) as opportunities for new revenue streams.
5. Ambulatory care development, including freestanding urgent care, surgery and imaging centers, strategically located medical office buildings, and emergency care centers.
6. Primary care development, including residency programs, academic affiliations, employment, use of mid-level health professionals, and medical home practices.
7. Preferred arrangements with health plans where members can reduce out-of-pocket costs by remaining in-network with the hospital and its affiliated physicians.

Source. Stephen Gelineau, MS. The Camden Group. August 2013.

Taking the "Temperature" of Prostate Cancer Patients & Their Caregivers

PATIENTS

- **41%** percent do not feel like people understand what they are going through in terms of managing and treating their prostate cancer. Of these, **78%** wish people better understood the stress of coping with prostate cancer, and more than half wish others understood the inconvenience caused by prostate cancer (**59%**) or the side effects of treatment (**59%**).
- While **66%** said that the level of discomfort they will experience is important or very important to them when choosing therapies, only **45%** believe that this factor is important or very important to their physicians.

CAREGIVERS

- **73%** said they are concerned or very concerned about their ability to continue providing care over a long period of time. The top area of concern (**83%**) is their ability to help their patient cope with the physical and emotional effects of the disease.
- **93%** report experiencing troublesome feelings as a result of caregiving, such as stress, sadness, and fear.

Source. Advanced Prostate Cancer Patient and Caregiver Burden of Illness Survey. Commissioned by Astellas Pharma US, Inc., and Medivation, Inc., through Harris Interactive.

Provider Resources

www.accc-cancer.org/resources

ACCC offers a range of resources to help cancer programs learn practical strategies for meeting the challenges of providing cancer care today. Webinars, publications, toolkits, and more are available on a variety of topics designed to meet the needs of the multidisciplinary oncology team.

Cancer Types

Acute Promyelocytic Leukemia (APL)
Chronic Myeloid Leukemia (CML)
Gastric/GE Junction Cancer
Melanoma
Multiple Myeloma
Myelofibrosis
Pancreatic Cancer

Supportive Care

Cancer Nutrition
Financial Advocacy & Assistance
Patient Navigation
Survivorship

Practice Improvement

ACCC Cancer Program Guidelines
Molecular Testing
Payment Systems (Town Hall)
Trends in Community Cancer Centers

Pharmacy

Dispensing Pharmacy
Oncology Pharmacy Education Network (OPEN)

CME/CE

Web-based CME/CE Opportunities

ACCC Leads the Charge for Survivorship Services

In 2007 ACCC launched an education project to raise awareness about the importance of comprehensive survivorship programs. The very next year, ACCC added survivorship services to its *Cancer Program Guidelines*, stating that "an optimal comprehensive cancer program should make available information and programs specific to survivorship issues to cancer patients and their families." By comparison, the CoC standard on survivorship care does not go into effect until 2015. Learn more at www.accc-cancer.org/survivorship.

fast facts

Cancer Nutrition—Back by Popular Demand!

In 2002 ACCC published "Integrating Nutrition into Your Cancer Program."

Ten years later ACCC launched a comprehensive education program, which included:

- An update of the nutrition services guidelines in ACCC's *Cancer Program Guidelines*
- A supplement with practical strategies, model nutrition programs, tools and resources, and more
- A series of nutrition-specific webinars
- Podcasts on symptom management and meeting the unique nutrition and supportive care needs of patients with head and neck cancer.

Learn more at www.accc-cancer.org/nutrition.

Members Spoke, ACCC Listened!

In 2013 ACCC's listserv was flooded with requests for information, tools, and resources around low-dose CT screening for lung cancer. ACCC responded with a webinar that offered practical tips for establishing a lung cancer screening program, a session at the ACCC 30th National Oncology Conference, and a cover article in the March-April 2014 *Oncology Issues*. The webinar and meeting session are archived on ACCC's website. View the article online at www.accc-cancer.org/oi/MA2014.

ACCC Embraces Patient Navigation Efforts

ACCC's 2009 education program had four key goals:

1. Identify barriers to access to care that patient navigation can address
2. Increase successful implementation of patient navigation services
3. Refine staffing models
4. Establish effective metrics for measuring and benchmarking patient navigation services.

To meet these goals, ACCC offered members a wide variety of tools and resources, including publications, one-day training sessions, online virtual lectures, webinars, and more. Learn more at www.accc-cancer.org/patientnavigation.

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Data, Data, Everywhere… But What are We to Think?

BY MATTHEW FARBER, MA

In early April, the Centers for Medicare & Medicaid Services (CMS) released claims information that showed how much each physician billed the Medicare system in 2013. This news comes on the heels of hospital charge data for certain procedures that the agency released last year. And in September, CMS will be releasing data that pertains to contributions made to physicians from manufacturers. (The release of this data is mandated under the Sunshine Provision of the Affordable Care Act.) So we should be asking ourselves—why is CMS releasing all of this information, and what does it all mean for the oncology community and its patients?

There are multiple reasons driving CMS's release of these data. One is the agency's desire to be more transparent with the public. The thought is that making these data available will help consumers in making better, more informed choices about their healthcare. CMS is also using these data to draw attention to certain providers to stop fraud and abuse of the Medicare system.

While ACCC supports efforts to better inform the public and to reduce fraud, the methods CMS is using to accomplish these goals are actually more of a disservice than a service. Why? Because data provided without context does not provide the full picture. The delivery of cancer care is complex and costly. To truly understand the business of oncology care, consumers and the general public need to see the entire picture. In April, ACCC and other stakeholders expressed concerns to CMS about the release of Medicare physician payment data without providing context on how these payments are used in treatment and the complexity of cancer care delivery.

So what does this mean for the oncology community? Taken at face value, these data could be harmful to certain physicians. Patients may see these claims data, or cost data, and assume that they are being unfairly billed, or over-treated. Without an understanding of our reimbursement system—including how costs are negotiated with payers—patients are missing the big picture. For example, many oncology treatments are delivered in the office setting, so much of the money that physicians bill Medicare for actually passes on to drug distributors and drug manufacturers to pay for the drugs and biologicals used in treatment. Therefore, ACCC and other stakeholder organizations within the oncology community must do a better job of informing the public about exactly what these numbers mean.

In addition, CMS released physician payment claims data in April without offering physicians the opportunity to review for accuracy. There may be reporting errors, or claims may have been unfairly attributed to certain physicians simply because they may be the head of an oncology or pathology department. If so, patients will again be getting an incomplete or inaccurate picture of how physicians are paid by Medicare.

Of note, the Sunshine disclosures will allow physicians to review the data before they are published later this year.

At this stage, it is incumbent on the oncology community to provide the missing context to give a full picture of what these data mean. If we do not do a good job of educating the public and decision makers, the effects may be detrimental to certain physicians. Second, the oncology community must work with CMS to weed out fraud and abuse. Finally, we must also continue to communicate to the agency that if it is going to release data, it needs to paint the whole picture of how care is delivered and paid for in this country.

If you have any questions about the data released so far, or how CMS plans on moving forward, please email me at mfarber@accc-cancer.org. OI

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

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

mammaprint

Copy & Paste—CMS To The Rescue!

BY CINDY PARMAN, CPC, CPC-H, RCC

Electronic health records (EHRs) can help providers correctly document and code the services they provide. Yet physicians struggle to use EHRs to help ease documentation burdens. Further, providers must ensure that their EHR notes do not take on a problematic uniformity.[1] In the same way that medical coders want their codes to tell the patient's story, physician documentation should provide an accurate picture of the patient's medical condition(s), treatment provided, and response to care.

According to Medicare, the problem arises around documentation that is worded exactly like or similar to previous entries in the same patient chart or across medical records for patients with the same medical conditions.[2] This may include pre-printed templates, fill-in-the blank forms, check-off boxes, copy and paste, or information defaulted (brought forward) from other medical record documents. An article in *FierceEMR* states:[3]

Most physicians are taking advantage of their copy and paste function in their electronic health records and copying progress notes rather than creating new, original ones, according to a new study published in the journal Critical Care Medicine.

The study examined 2,068 progress notes by 62 residents and 11 attending physicians of 135 intensive care unit patients in a medical center in Cleveland, using plagiarism detection software. The researchers found that more than four-fifths (82 percent) of the residents and three-fourths (74 percent) of the attendings' notes contained at least 20 percent of copied information. While the residents authored more copied notes, they copied a bit less information than the attendings (55 percent to 61 percent).

After a day or more off, a whopping 94 percent of the attendings copied from their own prior notes, and two-thirds (66 percent) of the residents did so.

Documentation short-cuts can create difficulty in supporting medical necessity, determining the complexity of care provided, or differentiating treatment from one patient to another. Unlike a note written on paper, a note written in the EHR can be generated by using information that was recorded elsewhere and is imported from either within or outside the EHR, such as when sections of a document are copied from one file and pasted into another.

Fraud Concerns

According to *The Intersection of EHRs and Fraud and Abuse*, national dialogue surrounding EHRs has turned toward the potential for fraud and abuse:[4]

If not used correctly, computers have given us the power to make mistakes in large quantities at the speed of light. So, depending on the design of an EHR and how it is used by the provider, the electronic environment can certainly make it much easier to generate the amount of documentation required to support a higher-level code or to make medical necessity appear to be met when, in fact, neither case can be supported.

Since the idea is to lessen the crushing workload that many doctors are under by letting the system "do the work," the potential exists to lose a crucial level of controls, i.e. the vast majority of providers who would never abuse the system on purpose.

In September 2012 the Department of Health and Human Services (DHHS) and the Department of Justice (DOJ) issued a joint letter stating that there were indications some healthcare providers were using EHRs to clone medical record documentation on Medicare claims to boost payments. The letter, signed by Secretary Kathleen Sebelius and Attorney General Eric Holder, states in part:[5]

A patient's care information must be verified individually to ensure accuracy. It cannot be cut and pasted from a different record of the patient, which risks medical errors as well as overpayments.

This letter followed a *New York Times* article that detailed how the use of EHRs may be a contributing factor in higher Medicare billings. Rich Umbdenstock, chief executive of the American Hospital Association (AHA), responded on behalf of the AHA, "We agree that the alleged practices described in your letter, such as so-called 'cloning' of medical records and 'upcoding' of the intensity of care, should not be tolerated."[6]

2012 CMS Instructions

On Dec. 10, 2012, CMS issued revised instructions stating that while template use is not prohibited, the agency does not approve or endorse any templates. In addition, CMS discourages the use of templates that provide limited options for the collection of information, such as check boxes or predefined answers, or limited space to enter information. According to CMS:[7]

Some templates provide limited options and/or space for the collection of information such as by using "check boxes," predefined answers, limited space to enter information, etc. CMS discourages the use of such templates. Claim review experience shows that that limited space templates often fail to capture sufficient detailed clinical information to demonstrate that all coverage and coding requirements are met.

Physicians should be aware that templates designed to gather selected information focused primarily for reimbursement purposes are often insufficient to demonstrate that all coverage and coding requirements are met. This is often because these documents generally do not provide sufficient information to adequately show that the medical necessity criteria for the item/service are met.

If a physician chooses to use a template during the patient visit, CMS encourages them to select one that allows for a full and complete collection of information to demonstrate that the applicable coverage and coding criteria are met.

Add to the audit factor the concern that as EHRs become more interconnected, errors resulting from their use can be amplified and affect a larger group of individuals.[8] Once EHR information is transmitted using health information exchanges, any incorrect, incomplete, or templated information entered into the record will be widely distributed. As a result, the scale of the problem has changed; what used to be a single data entry or incorrect statement can now cascade into multiple records.

In addition, risks of cloned or copied medical record information include the possibility that a note will be populated with outdated, conflicting, incomplete, or inaccurate information. Cloned notes may also be repetitive, inconsistent, or identical; these notes do not assist in the care of the patient and over time may be ignored by other staff due to the presence of outdated or stagnant information.

Last, notes that continue to build over time with the constant addition of information become cluttered; in this situation, new or pertinent information may be overlooked or may not be easily accessible by other service providers.

2013 OIG Report

The next chapter in the documentation saga was triggered by a December 2013 Office of Inspector General (OIG) report, "Not All Recommended Fraud Safeguards Have Been Implemented in Hospital EHR Technology."[9] While the OIG report focuses on hospital EHRs, physicians and freestanding centers will likely be bound by the documentation policies that result from this study. The OIG states, in part:[9]

EHRs replace traditional paper medical records with computerized recordkeeping to document and store patient health information. Experts in health information technology caution that EHR technology can make it easier to commit fraud.

This study determined how hospitals that received EHR Medicare incentive payments, administered by the Centers for Medicare & Medicaid Services, had implemented recommended fraud safeguards for EHR technology.

For this study, the OIG administered an online questionnaire to the 864 hospitals that received Medicare incentive payments as of March 2012 and received a 95 percent response rate. The questions focused on the presence of safeguards related to audit functions, user authorization, access, and data transfer. In addition, the OIG conducted onsite structured interviews and observed an EHR demonstration in eight hospitals. Last, the agency conducted surveys with four EHR vendors and asked them "the extent to which they had incorporated the recommended fraud safeguards into their products."

As a result of this study, the OIG determined that nearly all hospitals with EHR technology had the recommended audit functions in place, but that hospitals might not be using these functions to their full extent. In addition, only about one fourth of hospitals had policies regarding the use of copy-paste features; which, if used improperly, could pose a vulnerability for fraud. According to the OIG:[9]

Copy-pasting, also known as cloning, allows users to select information from one source and replicate it in another location. When doctors, nurses, or other clinicians copy-paste information but fail to update it or ensure accuracy, inaccurate information may enter the patient's medical record and inappropriate charges may be billed to patients and third-party healthcare payers. Furthermore, inappropriate copy-pasting could facilitate attempts to inflate claims and duplicate or create fraudulent claims.

Although the copy-paste feature in EHRs can enhance efficiency of data entry, it may also facilitate attempts to inflate, duplicate or create fraudulent healthcare claims.

In 2006 the Office of the National Coordinator (ONC) for Health Information Technology contracted with RTI International to develop recommendations to enhance data protection, including increasing data validity, accuracy, and integrity as well as strengthening fraud protection in EHR technology. The resulting recommendations addressed several types of vulnerabilities, including copy-paste and overdocumentation. RTI recommendations require:

1. The use of an audit log function and specify audit log operation and content for tracking EHR updates.
2. The methods (i.e., copy-paste, direct entry, import) for any EHR update be documented and tracked.
3. The user ID of the original author be tracked when an EHR update is entered "on behalf" of another author (i.e., distinguish between entries made by an assistant and a provider).
4. That original EHR documents be retained after they are signed off and modifications be tracked as amendments.
5. That EHR technology not prompt an EHR user to add documentation, but be able to alert a user to inconsistencies between documentation and coding.

All four EHR vendors surveyed by the OIG

indicated that they provided standard product implementation training, but that hospitals do not commonly request additional audit log training. Of note, 49 percent of the hospitals responding to the OIG survey indicated that they track the date, time, and user ID of the original author when data are copied. In addition, 44 percent of hospitals already track the method used when data are entered into the EHR (such as direct text entry, speech recognition, automated, or copy-paste). However, none of the hospitals surveyed analyzed their audit logs to prevent or detect fraud, for example, by identifying duplicate or fraudulent claims and inflated billing. Last, only 24 percent of hospitals had policies in place regarding the use of copy-paste in the EHR.

The OIG stated that CMS must do more to ensure that all hospital EHRs contain safeguards and that hospitals use them to protect against electronically enabled healthcare fraud. Recommendations from the OIG included development of a comprehensive plan to address fraud vulnerabilities in EHRs. In addition, the OIG made a specific recommendation that CMS develop guidance on the use of the copy-paste feature in EHR technology, and CMS stated that it will develop guidelines to ensure that this feature is appropriately used. The CMS response states, in part:[9]

- CMS is planning to work with ONC to develop a comprehensive plan to detect and reduce fraud in EHRs.
- CMS is conducting audits as a method to reduce fraud, waste, and abuse in the EHR Incentive Programs. Some of these pre-payment audits will be random and some will target suspicious or anomalous data.
- CMS will develop appropriate copy-paste guidelines to ensure that this feature is used appropriately for enhancing clinical efficiency.

Last, the OIG stated that it will release a companion report to the December 2013 document that describes the program integrity practices CMS implements in response to these recommendations.

What Should Providers Do?

First, identify the documentation shortcuts, including copy and paste, used in the EHR at all practice or hospital locations. Additional recommendations for facilities and physicians to consider include:

1. Ask the hard questions when a vendor states that the EHR will increase reimbursement, such as how will that happen? Will it be through increasing accuracy and detail or some other mechanism?
2. Implement strong compliance controls to constantly monitor the bills submitted, track coding trends, etc. For example, it may be prudent to audit documentation for inconsistencies or similarities to prior notes.
3. Include compliance training for all staff members in every meeting, whether the practice or facility is in the process of implementing the EHR or for purposes of ongoing review.
4. Establish written policies for automatic field population, copy and paste, the use of templates, and other documentation shortcuts.
5. Ensure that there is a method for EHR users to communicate documentation concerns and errors in the medical records.

The following publicly available resources from the American Health Information Management Association (AHIMA) will help with establishing specific internal guidelines:

- *The Legal Health Record: Copy and Paste Guidelines*. (http://campus.ahima.org/audio/2009/RB111709.pdf)
- *Auditing Copy and Paste*. (http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_042416.hcsp?dDocName=bok1_042416).

Continually monitor medical record documentation—whether performed via dictation, dynamic documents, or other electronic method—to ensure that any templates in use are correct, complete, and compliant. Further, educate physicians and other staff on the proper use of templates, the difference between a template and a cloned note, and the need for complete and accurate medical record documentation. OI

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spotlight

Southcoast Centers for Cancer Care

Fairhaven and Fall River, Massachusetts

Southcoast Centers for Cancer Care is part of a comprehensive health system comprised of three hospitals and a variety of ambulatory centers known as Southcoast Health. Southcoast Centers for Cancer Care, a certified member of the MD Anderson Cancer Network™, serves the southeastern coastal communities of Massachusetts.

Oncology services are provided at two sites: a free-standing facility in Fairhaven, and on the Charlton Memorial Hospital campus in Fall River. The two locations are 22 miles apart. Both sites provide radiation and medical oncology services. Between both locations, Southcoast is staffed by three radiation oncologists, seven medical oncologists, and provides genetic counseling. Each center has one linear accelerator on site. Outpatient medical oncology services are delivered at both locations.

Inpatient oncology care is provided in designated inpatient oncology units staffed with a core group of chemotherapy certified nurses. Southcoast strives to provide the same standard of care across all their settings. "Our policies for oncology cross over both outpatient and inpatient. For example, patients are receiving chemotherapy in-house under the exact same policies and standards as the outpatient setting," said Carme Tripp, RN, MHA, OCN, director of Oncology Patient Care Services.

In the infusion centers at both locations, all treatment bays are private or semi-private with flat screen TVs, recliners, and gliders. Patients are provided snacks or lunch and warm blankets by volunteer staff. Fairhaven has 16 treatment bays with infusion suites and Fall River has 13. To ensure infusions are prepared and delivered in a timely fashion, an embedded oncology pharmacy is adjacent to each treatment room, staffed by dedicated oncology pharmacists and pharmacy technicians.

Southcoast Centers for Cancer Care in Fall River is on the Charlton Memorial Hospital campus with a dedicated entrance and parking lot for cancer patients and their families. The cancer center is linked to the main hospital building by a tunnel.

Select Support Services

- Nutritionist
- Oncology rehabilitation
- Social work
- Navigation
- Support groups
- Genetic counseling

Number of analytic cases seen in 2010: 1,190

Thoracic Multidisciplinary Clinic

Offered exclusively at this site and entering its fourth year, is Southcoast's thoracic clinic. At the bi-weekly clinic, a multidisciplinary team of thoracic surgeons, medical and radiation oncologists, pulmonologists, oncology nurses, radiation therapists, social worker, nutritionist, and patient navigator reviews all newly diagnosed lung cancer cases. A pre-clinic conference is held where the patient's clinical results and information are reviewed by the team and a plan of care formulated. The physicians then meet with the patient and family. Other members of the team are introduced to the patient and family based on the patient's specific needs. Patients leave the clinic with a treatment plan and an appointment for their next visit. Physicians are encouraged to refer patients to the clinic as soon as a lung cancer diagnosis is suspected and clinic staff coordinate all diagnostic testing.

As the process has significantly shortened time from diagnosis to treatment, Southcoast is looking to expand this clinic model to head and neck patients at the Fairhaven location. In addition to the thoracic clinic, Southcoast holds weekly breast, colorectal, and general tumor boards at both sites.

Wraparound Care

Southcoast strives to provide "wraparound care" which, according to Tripp means engaging patients even before they arrive for their first appointment and maintaining that engagement through survivorship. A dedicated patient intake coordinator handles all new patient referrals. With a process in place to centralize referrals and collect health information before a first visit, Southcoast providers can have more meaningful initial appointments with patients.

Patient navigators are also available to patients before they begin cancer treatment. Southcoast coordinates with referring primary care physicians and specialists in the community, and if they have a patient in the office experiencing high distress, a Southcoast nurse navigator can intervene. The navigators can either meet with patients at their doctor's office, or call the patient

and begin a discussion on next steps for treatment.

Southcoast's navigator policy is to provide this service to any patient identified as having a barrier to care (financial, emotional, educational, etc.). Patients receiving dual modality treatment (both chemotherapy and radiation therapy), head and neck patients, and brain tumor patients are also followed by a navigator.

In addition Southcoast employs a dedicated nutritionist two days a week at each site and two full-time social workers (one at each site).

Wraparound care also means putting measures in place to ensure that regardless of site of service, patients are, according to Tripp, "getting the right treatment in the right place at the right time."

One of these wraparound measures aims to keep patients out of the emergency department. Southcoast created a special "Fever Card" for neutropenia patients. Patients are taught that if they have a fever of 100.4 degrees or above during office hours, they are to immediately call or come in and be seen. At that point, Southcoast conducts a series of tests, including blood cultures and chest x-rays, and begins the appropriate antibiotic. The goal is to have patients receive the antibiotic within 60 minutes of presenting. If a patient has a fever after hours or on weekends, they are taught to go to their local emergency or urgent care facility and present their Fever Card to the triage nurse. Key to this Fever Card program is emphasizing to patients that they must keep the Fever Card with them at all times. Patients with a high fever present this red, white, and black card to their local emergency department or urgent care. The card gives very specific, simplified instructions for these departments to begin the appropriate care promptly. The card includes phone numbers for both cancer centers, as well as the treating physician.

Since implementing the Fever Card program, Southcoast has decreased the amount of time from when the patient presents to when they receive antibiotics from over 4-5 hours to 90 minutes.

Quality and Accreditation Specialist

As mentioned previously, Southcoast Centers for Cancer Care is a certified member of the MD Anderson Cancer Network™. Southcoast is also accredited by the American College of Surgeons Commission on Cancer, certified by QOPI, and has earned The Joint Commission's Gold Seal of Approval.

To maintain and sustain the standards that must be in place for these distinctions, Southcoast has a full-time Quality and Accreditation Specialist on staff. The specialist is dedicated to the oncology program and, according to Tripp, "having a full-time, in-house quality and accreditation specialist, is really key. We've had this position for four years and she is focused not only on the accreditations but also on the day to day quality with staff and the physicians."

Community Outreach & Education

As part of its survivorship services, Southcoast partners with LIVE**STRONG** to provide a free reconditioning program.

Offered at three local YMCAs, this 12-week program is oncology-specific. Staff from Southcoast meet with YMCA staff regularly to review the effectiveness of the program and how to enhance participation.

A majority of Southcoast's patient population reside in the coastal towns that comprise the southeastern coast of Massachusetts. According to Tripp, reliable transportation is a significant barrier to care for many. To counter this, the cancer centers make use of the Southcoast Health System Mobile Van Services to bring screening events (head and neck and skin are the two most popular) to their patients in their own communities.

Southcoast vans park in local drug store lots, or sometimes right by the docks, to bring their screening and awareness services directly to the large population of commercial and transient fishermen who are often representative of an underserved population. Each van is equipped with two or three exam rooms. Every screened patient leaves with information about the cancer center and the warning signs for cancer in Portuguese, Spanish, or English. OI

tools

Approved Drugs

• Eli Lilly and Company (www.lilly.com) announced today that the U.S. Food and Drug Administration (FDA) has approved **Cyramza™ (ramucirumab)** as a single-agent treatment for patients with advanced or metastatic gastric cancer or gastroesophageal junction (GEJ) adenocarcinoma with disease progression on or after prior fluoropyrimidine- or platinum-containing chemotherapy. With this approval, Cyramza becomes the first FDA-approved treatment for patients in this setting.

• Guerbet (www.guerbet.com) announced that **Lipiodol® (ethiodized oil) Injection** was approved by the FDA pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act indicated for selective hepatic intra-arterial use for imaging tumors in adults with known hepatocellular carcinoma (HCC). As previously announced in October 2013, Lipiodol has received an orphan-drug designation for management of patients with known HCC.

• The FDA has approved GlaxoSmithKline's (www.gsk.com) **Arzerra Injection (ofatumumab, for intravenous infusion)** in combination with chlorambucil, for the treatment of previously untreated patients with chronic lymphocytic leukemia (CLL), for whom fludarabine-based therapy is considered inappropriate. The approval was based on the results of a multi-center, randomized, open-label trial comparing ofatumumab in combination with chlorambucil to single agent chlorambucil.

• Novartis (www.novartis.com) announced that the FDA has approved **Zykadia™ (ceritinib)** for the treatment of patients with anaplastic lymphoma kinase-positive (ALK+) metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib. Zykadia is an oral, selective inhibitor of ALK, an important therapeutic target in lung cancer. ALK is a gene that can fuse with other genes to form an aberrant "fusion protein" that promotes the development and growth of cancer cells.

Drugs in the News

• Advanced Accelerator Applications (www.adacap.com) announced that the FDA has granted orphan drug designation status to their radiopharmaceutical **Gallium-68 Dotatate**. The orphan drug designation has been granted for use of Gallium-68 Dotatate as a diagnostic agent for the management of gastro-entero-pancreatic neuroendocrine tumors (GEP-NETs). Gallium-68 Dotatate is a radiopharmaceutical used in PET/CT imaging of GEP-NETs.

• Janssen Research & Development, LLC (www.janssenrnd.com) announced the submission of a supplemental new drug application for **Imbruvica™ (ibrutinib)** to the FDA by its collaboration partner Pharmacyclics, Inc. (www.pharmacyclics.com). This regulatory submission is based on data from the Phase III RESONATE™ study in relapsed or refractory chronic lymphocytic leukemia (CLL). Imbruvica is being jointly developed and commercialized by Janssen and Pharmacyclics. In February 2014, Imbruvica received FDA approval to treat patients with CLL who have received at least one prior therapy.

• The FDA has granted orphan drug designation to MEI Pharma, Inc.'s (www.meipharma.com) investigational drug **Pracinostat** for the treatment of acute myeloid leukemia (AML). Pracinostat is an orally available histone deacetylase (HDAC) inhibitor that has been tested in a number of Phase I and Phase II clinical trials in advanced hematologic disorders and solid tumor indications in both adult and pediatric patients.

• Boehringer Ingelheim Pharmaceuticals, Inc. (www.boehringer-ingelheim.com) announced the FDA has granted orphan drug designation to **volasertib** for acute myeloid leukemia (AML). Volasertib is currently being evaluated in a Phase III clinical trial for the treatment of certain patients with AML. Volasertib has not been approved by the FDA; its safety and efficacy have not been established.

Genetic Tests and Assays in the News

• Roche (www.roche.com) announced that the FDA Microbiology Devices Panel of the Medical Devices Advisory Committee recommended unanimously that the benefits of the **cobas HPV (Human Papillomavirus) Test** as a first-line, primary screening tool in women 25 years and older to assess their risk of cervical cancer based on the presence of clinically relevant high-risk HPV DNA outweigh the risks.

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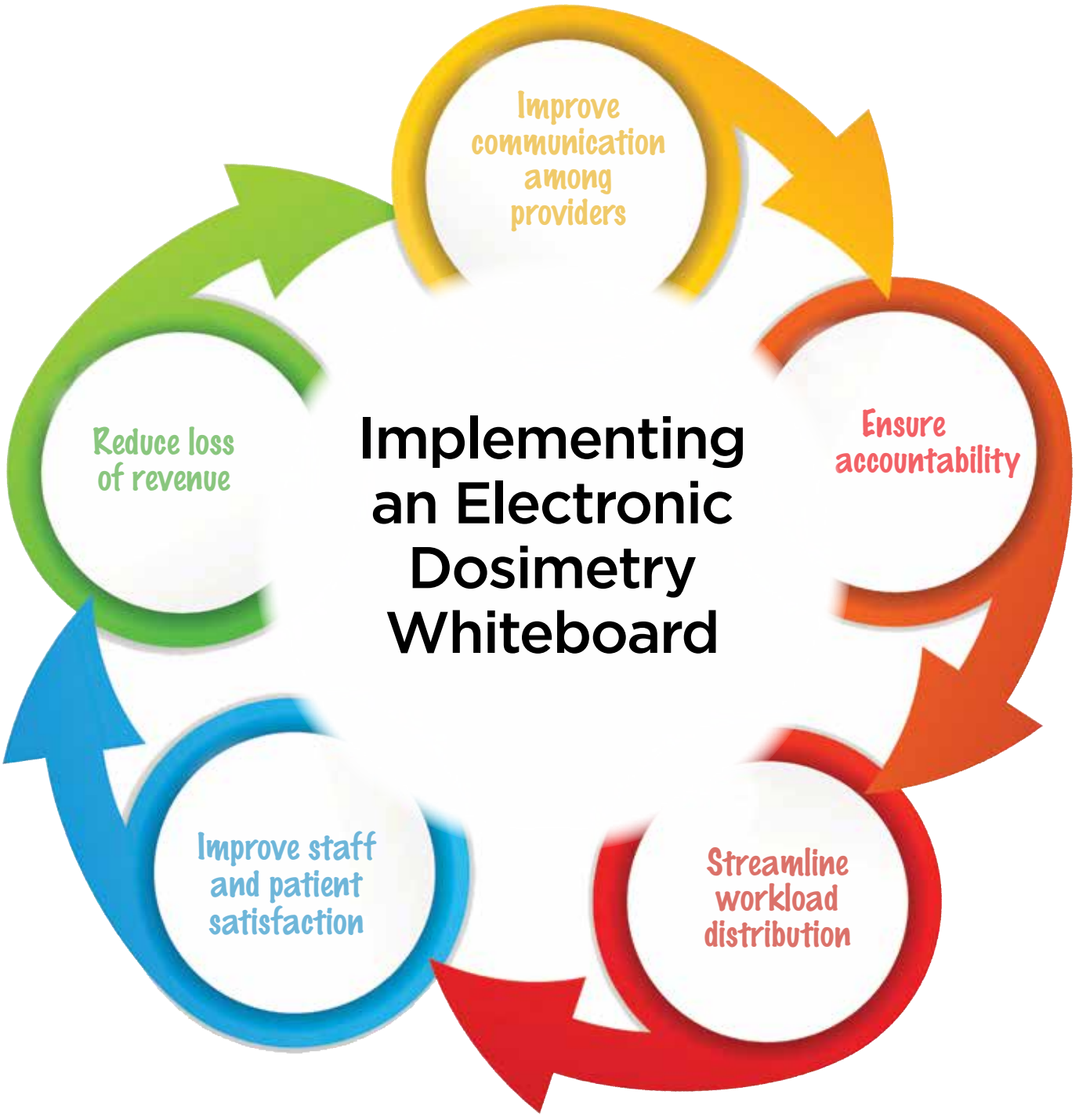
Improve communication among providers
Ensure accountability
Streamline workload distribution
Improve staff and patient satisfaction
Reduce loss of revenue
Implementing an Electronic Dosimetry Whiteboard

BY ROXANA TAVEIRA, MHSA, CMD, RT(T)(R)
AND ROBERT BEECHER, MBA, RT(T)(R)

How this tool improved processes and patient care at Temple University Hospital Cancer Center

At Temple University Hospital Cancer Center's Radiation Oncology Department, Philadelphia, Pa., patients are seen first as a consult by the radiation oncologist who reviews the patient's studies, pathology reports, labs, etc. After the decision is made for the patient to be treated with radiation therapy, a CT simulation appointment is scheduled. Once the CT simulation is completed, patients are tattooed to aid in proper alignment during treatment. Once the CT simulation is completed, the treatment planning phase is initiated. The goal of treatment planning: to deliver 100 percent of the radiation to the target area so that structures around the target area (organs at risk) are spared.

For many years, this treatment planning process was relatively simple. CT therapists came into the treatment planning area and wrote the date, the name of the new patient, the treating physician, and the tumor site (i.e., lung, brain, prostate) on a dry erase board. The CT therapists might also add a few other comments, such as if the patient needed to fuse to a PET/CT or a previous MRI.

However, radiation oncology has changed dramatically over the past several years—making the dry erase board an antiquated way of communicating among staff. For example, in addition to the CT simulation, the treatment planning process may now include previously performed diagnostic CTs, MRIs (both with and without contrast), PET/CTs, and CTs with contrast. These modalities are fused to the planning CT so that physicians can better delineate the target volume. From the time of CT simulation to the time of treatment, many tasks must now take place. These tasks are carried out by multiple staff members, including the radiation oncologist, the medical dosimetrist, and the medical physicist. Bottom line: the process of writing information on a dry erase board was not meeting the needs of this busy Radiation Oncology Department.

What Went Wrong?

In the past several years, some of the challenges the Radiation Oncology Department at Temple Cancer Center encountered, included:

- Transparency concerns
- Ineffective communication
- Accountability issues
- Uneven treatment planning workload distribution
- Decreased employee morale
- Decreased patient satisfaction
- Potential loss of revenue.

Transparency concerns. Physicians would come into the treatment planning area and want to know who was working on their treatment plan. They had to ask this question verbally as there was no process in place to easily access the information. Physicians had other questions such as, "Who can I talk to about my patient?" or "Have my volumes been contoured yet?" or "Has the fusion been completed, because I'm ready to draw my targets?" But it was sometimes difficult to get answers because the information was not readily available.

Communication. Physicians see their patients in clinic—not always in a location adjacent to the treatment planning area. So when radiation oncology staff needs information from the physicians, they generally call or page them. At Temple Cancer Center, some of the physicians were so busy at clinic that radiation oncology staff would leave sticky notes to tell them that their

Figure 1. Tiered Categorization System for Treatment Planning

	TIER 1	TIER 2	TIER 3
TREATMENT SITE	SIMPLE PORT PLANS, NO FUSION	SINGLE IMRT PLANS OR MULTIPLE CONFORMALS	RE-TREATMENTS, IMRT PLANNING, AND "UNKNOWN"
GU	Simple plans, with field and blocks done on day of simulation	Conformal with previous treatment, IMRT, VMAT	IMRT/VMAT re-treatments, special procedures
GI			
GYN			
Lung			
Mycosis			
Brain			
Breast	None	Single ISO breast tangential, Sclav tangential	Other (i.e., bilateral, IMboosts), chest wall
Prostate	None	IMRT, VMAT	None
Head and Neck	None	None	ALL
SBRT	None	Lung and spine without prior treatment	If prior treatment
Palliative Care (i.e., bone metastasis, whole brain irradiation)	If NO previous treatment	If previous treatment	None
	3 DAYS	7 DAYS	10 DAYS

plan was ready for review or that they needed to review the fusion. Most of the communication taking place between physicians and treatment planning staff was verbal—not all of it effective.

Accountability. Today many different disciplines are involved in the treatment planning process: the radiation oncologists, the dosimetrists, the physicists, and the radiation therapists. Since we did not have a process in place that allowed us to see the real-time status on each patient, sometimes staff was unsure about exactly where we were in the treatment planning process. Worse, staff began to experience instances of "He said, She said." For example, a staff member was not informed that it was time to complete a certain task or a staff member did not know that others in the treatment planning process were waiting for them to complete a task. In short, our Radiation Oncology Department was having accountability issues.

Treatment planning workload distribution. Under the old process, only new patients were written on the dry erase board. This approach was not optimal, as new patients are only a part of the work that is done in our Radiation Oncology Department. Staff also performs additional tasks, such as cone downs and re-plans. Physicians who came into the treatment planning room had no idea of all the other tasks assigned to treatment planning staff. The physicians only saw the dry erase board with a list of 9 or 10 new patients.

The Radiation Oncology Department has three FTE dosimetrists; so on the surface it might appear that staff was not as productive as possible. The situation resulted in frustration—for both physicians and treatment planning staff. Sometimes physicians had the impression that the dosimetrists and physicists did not have much to do, so they wanted their treatment plans completed more quickly. The dosimetrists and physicists—who were working on tasks unrelated to new patients—were frustrated that every treatment plan was being treated as an "emergency." The old process did not allow us to track the staff's workload and productivity or even know what task each staff member was doing.

Decreased employee morale. All of the challenges discussed above created a number of inefficiencies in our workflow. Ineffective communication among our team members sometimes led to instances of "finger-pointing." For example, a physician telling a dosimetrist: "You didn't tell me that it was time for me to draw my target and volumes." Or a physicist telling a physician: "I didn't know the plan was done and that I needed to check it." This type of uncertainty and turmoil had an adverse affect on employee morale.

Decreased patient satisfaction. Unfortunately, our Radiation

Oncology Department also experienced instances where treatment plans were not completed in a timely manner and patients had to change their appointment instances, or worse, treatment plans were not completed when a patient arrived for treatment. Imagine a radiation therapist having to tell a patient that the treatment plan wasn't ready and that the appointment would need to be rescheduled. Staff was not happy to deliver that message; patients were *really* not happy to hear that message. Patients are already very worried, and a delay in treatment only increases their anxiety. They start to question if there is something else wrong or if the tumor grew or the cancer spread. Additionally, Temple Cancer Center is an inner city program, and many of our patients need transportation assistance. For patients to struggle to get to an appointment and be told that their treatment plan was not ready was simply not acceptable.

Potential revenue loss. Finally, our Radiation Oncology Department was experiencing some loss of revenue. For example, if a treatment plan was not completed in advance, sometimes the dosimetrist had to finish and print the treatment plan on the day the patient came for treatment or a verification simulation. If that happened, we could not bill for the treatment plan and the verification simulation on the same day. In other words, we would lose the charge for the verification simulation. In today's reimbursement climate, no cancer program wants to lose charges.

Addressing the Challenges

Faced with these challenges, our first order of business was to put together a workgroup to look at all of these issues. The workgroup included:

- The administrative director of Oncology Services
- The director of Radiation Oncology
- Radiation oncologists
- A medical physicist
- The chief dosimetrist
- The chief therapist
- The Radiation Oncology Department's dedicated IT manager.

Nurses were not included in this workgroup, as they were not part of the radiation treatment planning process we were trying to improve. And while we did experience some communication gaps between our nurses and our radiation therapists, the hope was that these issues would improve organically when we improved our processes.

The workgroup had five key objectives:

- To improve communication
- To improve accountability
- To address the workload distribution
- To increase transparency in the treatment planning process
- To be cost-effective.

The workgroup believed that accomplishing these objectives would improve both patient satisfaction and staff morale, while minimizing the potential loss of revenue.

Take One

The workgroup first looked to the current EMR to help meet its objectives. The EMR option was low-cost; the cancer program already had the technology in place. The EMR also had a quality checklist functionality, which basically serves as a "to-do" list. Using this quality checklist, treatment planning staff can enter data, such as the patient's name, the study that the patient is having done, and the date the patient is returning for treatment. Additional notes, for example, if the patient is getting chemotherapy, can be entered in the comment section. Treatment planning staff was trained on how to use this EMR functionality, and the decision was made to pilot this new process for three months. Then, the workgroup would meet again to measure the effectiveness of the intervention.

Three months later, here's what the workgroup found. On the positive side, the EMR solution was definitely low cost and it did improve staff communication—but not to the level that the workgroup wanted. Specifically, treatment planning staff was constrained by what information they could enter into the EMR. If this solution were to truly work as the workgroup wanted, the EMR would need to be customized for our Radiation Oncology Department. With regards to transparency, the EMR allowed everyone to access the information, but it did not offer the visual transparency the workgroup wanted. The goal was for the entire department to be able to see all of the treatment plans at the same time.

On the negative side, the EMR option did not help with the accountability issues we were experiencing. The Radiation Oncology

(continued on page 25)

Table 1. Treatment Planning Tasks & Staff Responsible

TASK	STAFF RESPONSIBLE	DATE COMPLETED
CT simulation	CT simulation therapist	
Fusion	Staff member who performs this task	
Volumes	Physician	
Planning	Dosimetrist and physicist	
Approval of plan	Physician	
Print plan	Planner	
Physics check	Physicist	
Transfer of images	Physicist	
Treatment	Chief therapist	

Figure 2. Tiered Treatment Planning Schedule

	DAY 0	DAY 1	DAY 2	DAY 3
SCHEDULE 1	CT simulation fields done, treatment intent contour done	Planning, physics support, submit for MD approval, MD approval	Physics approval, transfer data to MOSAIQ, image transfer	Setup
Patient receives appointment slip on day of simulation	Monday	Tuesday	Wednesday	Thursday
	Tuesday	Wednesday	Thursday	Friday
	Wednesday	Thursday	Friday	Monday
	Thursday	Friday	Monday	Tuesday
	Friday	Monday	Tuesday	Wednesday

- Treatment intent represents the planning guidelines.
- Emergencies are done on an as-needed basis, and are not subject to these guidelines.
- If cases are completed before the scheduled start date, we will call the patient to come in earlier for his or her set up.

	DAY 0	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
SCHEDULE 2	CT simulation	Fusion, MD volumes, treatment intent, physics review	Dosimetry contours, previous treatment reconstruction, treatment intent (for re-treatments)	Planning, physics support, plan submitted to MD for review by the end of Day 4		MD plan iterations, MD approval by the end of Day 5	QA, physics approval, transfer data to MOSIAQ, image transfer	Setup
Patient receives appointment slip on day of simulation	Monday	Tuesday	Wednesday	Thursday	Friday	Monday	Tuesday	Wednesday
	Tuesday	Wednesday	Thursday	Friday	Monday	Tuesday	Wednesday	Thursday
	Wednesday	Thursday	Friday	Monday	Tuesday	Wednesday	Thursday	Friday
	Thursday	Friday	Monday	Tuesday	Wednesday	Thursday	Friday	Monday
	Friday	Monday	Tuesday	Wednesday	Thursday	Friday	Monday	Tuesday

	DAY 0	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
SCHEDULE 3	CT simulation	Fusion, MD volumes, treatment intent, physics review	Dosimetry contours, previous treatment reconstruction, treatment intent (for re-treatments)		Planning, physics support, plan submitted to MD for review by the end of Day 6			MD plan iterations, MD approval by the end of Day 7
Patient receives appointment slip on day of simulation	Monday	Tuesday	Wednesday	Thursday	Friday	Monday	Tuesday	Wednesday
	Tuesday	Wednesday	Thursday	Friday	Monday	Tuesday	Wednesday	Thursday
	Wednesday	Thursday	Friday	Monday	Tuesday	Wednesday	Thursday	Friday
	Thursday	Friday	Monday	Tuesday	Wednesday	Thursday	Friday	Monday
	Friday	Monday	Tuesday	Wednesday	Thursday	Friday	Monday	Tuesday

Department was still not able to identify where in the process any given patient's treatment plan was sitting. The EMR also could not address the workload distribution. Leadership was still not able to identify which staff member should be assigned to the next patient case coming out of simulation or even the actual workload of each staff member. For example, there was the perception that one dosimetrist was routinely getting the more complicated cases. So leadership wanted to streamline the workflow and distribute it evenly across all three of the certified dosimetrists.

Back to the Drawing Board

As the workgroup continued to meet, another issue became apparent. Treatment planning staff was experiencing a "bottleneck" of patient cases—mostly attributed to physicians who wanted their patients started on radiation therapy immediately. Of course, treating every patient as "emergent" often means that radiation oncology staff does not have the time or resources for actual emergencies. The workgroup believed that development and implementation of processes to improve patient flow would also bring standardization to the treatment planning process, thus reducing bottlenecks.

Accordingly, the workgroup created a system to categorize the types of treatment plans and to estimate how long each of these treatment plans should take from the time of CT simulation to the start of treatment (see Figure 1, page 22). Treatment plans are categorized into three tiers by treatment site:

- Tier 1. Simple port plans, no fusion. Treatment plan would take 3 days to complete.
- Tier 2. Single IMRT plans or multiple conformals. Treatment plan would take 7 days to complete.
- Tier 3. IMRT planning, re-treatment plans, and unknown (other complex) plans. Treatment plan would take 10 days to complete.

DAY 8	DAY 9	DAY 10
QA, physics approval, transfer data to MOSIAQ, image transfer		Day 10
Thursday	Friday	Monday
Friday	Monday	Tuesday
Monday	Tuesday	Wednesday
Tuesday	Wednesday	Thursday
Wednesday	Thursday	Friday

This system helps supervisors assign the next case coming out of dosimetry. Supervisors add up the category numbers (tiers) of the plans that each dosimetrist is currently working on; the dosimetrist with the lowest number is assigned the next case. This process has helped ensure that treatment planning cases as they come out of CT simulation are evenly distributed among the three dosimetrists.

With these tiers in place, the workgroup was able to go a step further and identify the tasks involved in each treatment planning process and the day that each task should be completed (see Figure 2, left). For example, the tasks and timeline for a 3-day treatment schedule are:

- Day 0. CT simulation fields and treatment intent contour
- Day 1. Planning, physics support, submission to MD for approval, MD approval
- Day 2. Physics approval, data transferred to MOSAIQ, images transferred
- Day 3. Treatment planning setup.

While this schedule is not followed rigidly, it serves as an important guide. The tool's real value is that it allows staff to know how far out to schedule patients for their return appointment. This schedule also allowed us to track and solve bottlenecked areas. By mapping treatment plans to the timeline created, we were able to stop this type of bottlenecking. Of course there are always instances when true emergent situations arise and the work on other treatment plans is slowed down.

Once the workgroup developed these tools, it was time for implementation. The workgroup wanted a way to display this information so that all the physicians and treatment planning staff could see it. Further, the workgroup wanted to use this information as a checklist to make sure that the steps (tasks) were being completed in a timely manner (see Table 1, page 23). Finally, the whole process had to be done at minimal cost.

The Electronic Dosimetry Whiteboard

The ultimate solution was surprisingly simple: use an Excel spreadsheet to enter and track the necessary data and then display the spreadsheet on a 46-inch monitor in the treatment planning area. The whiteboard is a shared Excel file, so anybody can access it from any computer in our department. Again, the solution was low cost—only the cost of the monitor, approximately $600. Further, the Excel functionality allowed the workgroup to customize and edit it on an "as-needed" basis. It is continually evolving to meet the changing demands of the department. Figure 3, page 26, is a representation of the electronic dosimetry whiteboard that is now displayed in Temple Cancer Center's Radiation Oncology treatment planning area. The populated fields are:

- Patient name
- Treating physician name

Figure 3. Representation of Electronic Dosimetry Whiteboard

PATIENT	PHYSICIAN	PLANNER	CATEGORY	AUTHORIZATION NEEDED	DUE DATE	LINAC	INITIAL/CONE DOWN/ RE-PLAN	DESCRIPTION
1. John Doe	VV	AE	2	N	07.09.2013	A	CD	3D breast boost plan
2. Jane Smith	CM	AE	2	N	07.12.2013	A	CD	VMAT boost prostate
3. Bob Jones	VV	ST	2	Y	07.23.2013	B	Initial	Lung, fuse PET scan from 11.30.2013 & CT from 06.20.2013
4. Dave Johnson	MIC	YD	2	N	07.15.2013	A	Initial	Neck, fuse with PET, IMRT-IGRT
5. Sarah Connor	MIC	YD	1	N	07.18.2013	B	CD	CD, scalp, re-simulation
6. Arthur Doyle	CM	ST	2	N	07.22.2013	B	CD	VMAT, boost
7. Daisy Dalyrmple	MIC	DP	2	Y	07.22.2013	B	Initial	Pelvis, prone (ON HOLD per MD dp 07.15.2013)
8. Ed Smith	MIC	YD	1	N	07.22.2013	A	CD	Re-scan post neck
9. Will Shakespeare	MIC	AE	3	N	07.23.2013	A	Initial	Clinical E-set up
10. Frank Martin	MIC	AE	1	N	07.23.2013	A	Initial	Left hip
11. Carol Peters	CM	ST	3	Y	07.24.2014	C	Initial	Prostate, MRI, 07.12.2013 at NE Hospital
12. Buffy Summers	CM	ST	2	N	07.25.2013	C	Initial	T7-T9
13. Anne Sanders	MIC	KD	2	N	07.25.2013	B	CD	Rescan pelvis
14. Mina Harker	MC	DP	2	N	07.26.2013	B	Initial	Pelvis
15. Jay Gatsby	CM	KD	2	N	07.26.2013	C	CD	VMAT, CD, prostate
16. David Lorel	MIC	DP	1	N	07.30.2013	A	Initial	Left breast
17. Johnny Utah	VV	PC	3	N	07.31.2013	C	Initial	SBF lung, 07.31.2013 at 2:30 on C
18. Dean Murphy	CM	KD	2	N	08.01.2013	C	CD	VMAT, CD, prostate
19. Stephanie Plum	VV	DP	1	N	08.02.2013	B	Initial	Patient cancelled (not to be treated per VV 07.22.2013)
20. Elle Woods	CM	DP	2	N	08.05.2013	C	Initial	Prostate, MRI, 07.19.2013
21. Edward Frankel	CM	YD	2	N	08.05.2013	C	Initial	Prostate
22. John Matheson	VV	YD	3	N	08.07.2013	C	Initial	HN larynx, IMRT, fuse PET+diagnostic CD
23. Matthew Kerns	CM	KD	2	N	08.21.2013	B	CD	VMAT, CD, prostate
24. Adam Santini	CM	DP	2	N	08.12.2013	A	CD	Prostate, VMAT, boost

- Tier category (1, 2, or 3)
- If a pre-authorization is needed (Yes or No)
- Date patient is due back for treatment
- Linac assigned
- Type of treatment (initial, cone down, re-plan)
- Description of treatment
- Date orders are received
- Date CT simulation is completed
- Date fusion is completed
- Date volumes are done
- Date planning is completed
- Date MD approves treatment plan
- Date treatment plan is printed
- Date physicists approve treatment plan
- Date images are transferred
- Date treatment is initiated.

As mentioned previously, we consider the electronic dosimetry whiteboard a work in progress. For example, the original whiteboard did not include the pre-authorization field. We began to experience issues with a specific payer that required a pre-authorization prior to IMRT treatment. Occasionally the dosi-

ORDERS	SIMULATION	FUSION	VOLUMES	PLANNING	MD APPROVAL	PLAN PRINTED	PHYSICS APPROVAL	IMAGE TRANSFER	THERAPY
			X	06.14.2013	06.14.2013	07.05.2013	07.05.2013	07.05.2013	
			X	07.01.2013	07.02.2013	07.08.2013			
06.19.2013	06.19.2013	06.24.2013	06.26.2013	07.01.2013	07.02.2013	07.09.2013			
07.08.2013	07.08.2013	07.09.2013	07.09.2013	07.10.2013	07.10.2013	07.11.2013			
			07.14.2013	07.14.2013	07.14.2013				
			X	07.01.2013	07.01.2013	07.11.2013			
	07.12.2031								
07.18.2013	07.18 3012	X	07.18.2013	07.19.2013	07.19.2013	07.22.2013			
X	X	X	X	07.22.2013	07.22.2013	07.22.2013			
07.19.2013	07.19.2013	X	07.19.2013	07.22.2013	07.22.2013	07.22.2013			
07.08.2013	07.08.2013	07.15.2013	07.15.2013	07.16.2013	07.17.2013	07.18.2013			
07.22.201	07.23.2013	X	07.23.2013						
07.18.2013	07.18.2013	X	07.18.2013	07.19.2013	07.19.2013	07.23.2013			
06.26.2013	07.16.2013	X	07.16.2013	07.17.2013	07.17.2013	07.18.2013	07.18.2013	07.18.2013	
	06.11.2013	X	06.11.2013	07.16.2013	07.16.2013	07.17.2013	07.17.2013	07.17.2013	
07.19.2013	07.19.2013	X	07.19.2013						
	07.17.2013	07.18.2013	07.18.2013						
06.06.2013	06.18.2013	06.18.2013	06.19.2013						
07.10.2013	07.10.2013	07.11.2013	X	X	X	X	X	X	
07.15.2013	07.18.2013		07.22.2013	07.22.2013	07.22.2013	07.23.2013			
06.24.2013	07.22.2013								
07.11.2013	07.18.2013	07.19.2013							
06.20.2013	06.25.2013	07.01.2013	07.03.2013						
06.26.2013	07.02.2013		07.05.2013						

metrists did not realize that a patient had that particular insurance coverage when they developed the treatment plan, and we lost some charges. To eliminate this issue, the workgroup added the pre-authorization column. Now staff must verify the patient's insurance plan and then check either "Yes" or "No" for pre-authorization required.

Because the Excel spreadsheet is a shared file, we also had instances where multiple people were making multiple entries at the same time, causing discrepancies within the file. To fix this problem, we now have three designated sections at the bottom of the spreadsheet—new simulation, cone down, and physics—where any new information is entered.

Briefly, here's how our electronic dosimetry whiteboard works. When a patient comes in for a CT simulation, the therapist doing the simulation starts the process by entering the patient's name, the treating physician, the treatment category (Tier 1, 2, or 3), the date the treatment is scheduled, the machine the patient will be treated on, the type of plan, etc. Rows are highlighted: blue for initial plans, green for cone downs, pink for physics plans, red for emergency plans, and yellow for re-plans. By the end of the day, the chief dosimetrist assigns the case to the dosimetrist who currently has the lightest workload. As each task is

completed—either by the dosimetrist, physicist, or physician—the person responsible for that task updates the corresponding field with the date the task was completed. The information is available in real time, and treatment staff can easily see where in the process every patient case is sitting.

At the end of each day, two designated "Super Users" (the director of Radiation Oncology or the chief dosimetrist) "sort" the electronic dosimetry whiteboard by date so that the next patient coming in for an appointment is at the top of the whiteboard. On the first day of treatment, one of the Super Users enters the date that treatment was initiated, and then moves that patient's information into the Completed Tab on the electronic dosimetry whiteboard. This requires copying all of the patient's information and pasting it into the Completed Treatment Tab and then deleting the information from the whiteboard. The functionality of Excel has it limits. For example, it is fairly easy to make a mistake and clear content. That is why only the two Super Users are responsible for sorting the whiteboard each day and moving patient information from the whiteboard and into the Completed Treatment Tab.

Implementation Challenges

Implementing the electronic dosimetry whiteboard required a change in staff work habits and workflow, which is always a challenge. To ensure that the process worked, the workgroup had to get 100 percent user buy-in. For staff, the whiteboard is just one more task they need to do. Our physicians are actually the biggest promoters of the whiteboard because they can now easily see the status of each patient's treatment plan.

Probably the greatest challenge involved the dosimetrists and the physicists. With the electronic dosimetry whiteboard, their work is out there in front of everyone. The workgroup received some feedback that staff felt like "Big Brother" was watching. However, staff soon understood that the benefits outweighed these concerns. Bottom line: the whiteboard increased the accountability of the department as everyone could now see the status of any given treatment plan.

As a shared file, the whiteboard had multiple benefits, but it also brought challenges. Any radiation oncology staff, including physicians in remote locations, can pull the whiteboard up on any computer. So if they leave the file open or do not refresh the file, they may not be seeing the most up-to-date information. To help mitigate this issue, we've asked staff to close the whiteboard down as soon as they are finished reviewing the schedule or entering information into the spreadsheet.

Measuring the Tool's Effectiveness

After implementation of the electronic dosimetry whiteboard, the workgroup assessed whether its original objectives were being met:

- ***Improve communication.*** The workgroup believed that the whiteboard had definitely improved communication in the Radiation Oncology Department. In fact, the whiteboard had a "water cooler effect" in that it became a meeting place where staff gathered to see what was going on with each patient.
- ***Improve accountability.*** The whiteboard improved accountability simply by the fact that the information was now displayed publicly for staff to see. Treatment staff could readily see when patients were coming in for treatment and ensure that everyone was on time with the treatment plans.
- ***Increase transparency in the treatment planning process.*** The electronic dosimetry whiteboard basically provides a one-stop, "big-picture" look at treatment plan progression. Any physician or staff member can easily see where we are in the treatment planning process for any given patient. Before the whiteboard, physicians and staff did not know when dosimetrists were working on tasks unrelated to new patients, such as cone downs and re-plans. Now that information is readily available to everyone. The whiteboard allows the department to understand its true patient volume—not just new patient volumes.
- ***Address the workload distribution.*** Workload distribution definitely improved with implementation of the whiteboard. It is now policy that patient cases must be assigned by the end of the day. With the new categorization system, supervisors can ensure that patient cases are evenly distributed when they come out of CT simulation.
- ***Be cost-effective.*** As our department already had Excel in its software suite, the only expenditure was the cost of the monitor to display the electronic dosimetry whiteboard.
- ***Minimize loss of revenue.*** Now that treatment planning is being carried out according to the schedule created by the workgroup, the incidence of lost charges has decreased.

Meeting their objectives allowed the workgroup to improve the efficiency of Temple Cancer Center's Radiation Oncology Department. For example, we reduced wasted steps, such as physicians having to leave clinic to come down to the treatment planning area to check on the status of a patient. Now physicians simply pull up the information they need on the shared file while in their own offices or clinics.

Quality of care and patient satisfaction has also improved. After implementing the categorization system, staff now knows how many days it should take from CT simulation to treatment. Patient scheduling has also improved; about 90 percent of our patients now leave the CT simulation with a return appointment. There are some instances where it's not possible to make a return appointment, for instance, if a patient is getting another diagnostic study that needs to be fused to the CT. In these cases, staff tells patients that if they don't hear from us within two weeks, they should call.

Today, treatment plans are completed on time, and the number of instances where patient appointments have been rescheduled or canceled has been greatly reduced. When staff does have to reschedule a patient, the whiteboard allows for more advanced notice. If patients are given ample notice and an explanation, such as the need for the patient to have an additional test, like a PET/CT and that treatment staff did not get the new image soon enough to fuse to an earlier image, patients understand the change.

Since the electronic dosimetry whiteboard was implemented, our Radiation Oncology Department had only two instances when a patient showed up for an appointment and had to be rescheduled. Both times were due to human error. For this to happen even once to a patient is unacceptable; our goal is to eliminate those instances altogether.

Finally, the electronic dosimetry whiteboard has greatly improved the morale of our staff. Communication is better and the use of the whiteboard has promoted a true team approach to care. Staff understands that they must work together to ensure that treatment plans are completed on time. Further improving accountability and transparency has improved provider satisfaction with their job and with their team members. OI

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OUR PROGRAM AT-A-GLANCE

Temple University Hospital, Philadelphia, Pa., is an academic medical center with more than 700 beds. The Temple Cancer Center is housed within the hospital. Here's a snapshot of our Radiation Oncology Department:

Our Equipment

- 3 linear accelerators
- A 16-slice CT simulator
- A high-dose rate brachytherapy unit
- Leksell Gamma Knife
- A hyperthermia unit
- Treatment planning system (Philips Pinnacle)
- An oncology electronic medical record (EMR) (Elekta Mosaiq)
- An Active Breathing Coordinator (ABC) for motion management

Services

- 3-D conformal radiation treatments
- Intensity-modulated radiation therapy (IMRT)
- Total skin electron beam that is used to treat a large population of patients with mycosis fungoides, the most common form of cutaneous T-cell lymphoma
- Image-guided radiation therapy (IGRT)
- Stereotactic radiosurgery (SRS)
- Stereotactic body radiation therapy (SBRT)
- Volumetric-modulated arc therapy (VMAT)
- I-guide with 6-D hexapod table
- High-dose rate (HDR) and low-dose rate (LDR) brachytherapy
- Gamma Knife radiosurgery
- Hyperthermia treatment
- 4-D symmetry organ reconstruction
- 4-D CT simulation.

Our Team

- 3 radiation oncologists
- 4 certified medical physicists
- 3 certified medical dosimetrists
- A chief therapist
- 12 certified radiation therapists
- 3 registered nurses
- 1 medical assistant
- An oncology social worker
- A nutritionist
- Clerical support
- A dedicated IT systems manager


medicine
pills
Health
Px

BY SUSAN M. SHIELDS, MBA, RN, NE-BC

Mobile Health Outreach

A community & corporate collaboration

As the healthcare community focuses more on wellness, prevention, and population health, the idea of taking services outside institutional walls has been embraced by providers. Mobile health units address two significant barriers to access for preventive and primary prevention services: transportation and time.

Texas Health Harris Methodist Hospital Fort Worth is part of Texas Health Resources, a private, not-for-profit health system in north Texas. Its mission: "To improve the health of the people in the communities we serve." The facility has 726 licensed inpatient beds. The cancer program at Texas Health Harris Methodist Hospital Fort Worth, including outpatient services based at its Klabzuba Cancer Center, had 1,852 analytic cases in 2012 and is a CoC-Accredited Community Hospital Comprehensive Cancer Program. It was awarded the CoC's Outstanding Achievement Award in 2006, 2009, and 2012.

Texas Health Harris Methodist Hospital Fort Worth's cancer program has operated a mobile health screening program since 1993. Over two decades, it has grown from providing only mammography to a service that provides a number of preventive and screening activities and education. Throughout this growth, partnerships and collaborations with a variety of organizations were critical. What follows is a brief history of the program's inception, expansion, operations, and community impact.

Growing the Program

Because Texas Health Harris Methodist Hospital Fort Worth is a not-for-profit entity built on faith-based traditions, community partnerships have always been a foundation of the care that is provided. The hospital frequently participates in health fairs, screenings, and other community health-related events. We collaborate with local and national organizations to provide services and fundraise and are proud of our ongoing partnership with the American Cancer Society. A robust volunteer force regularly contributes to the hospital's outreach efforts.

The Doris Kupferle Women's Health Advisory Board supported the 1993 purchase of Harris Methodist Hospital's first mobile mammography unit.

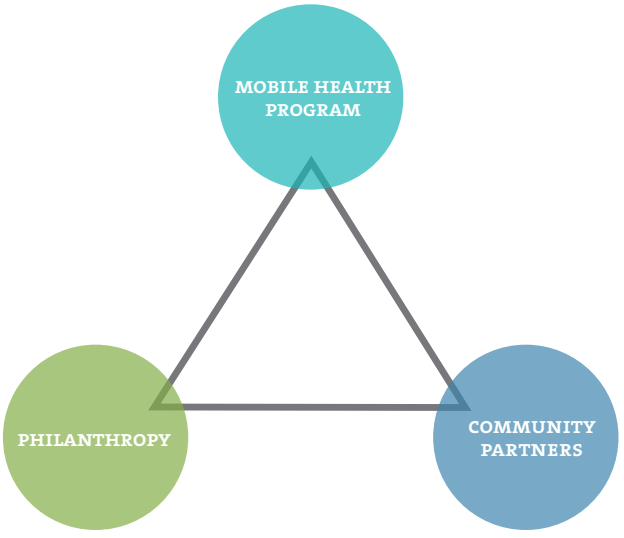
The Doris Kupferle Women's Health Advisory Board was established in 1990 as part of the Harris Methodist Health Foundation to promote women's health, and was the driving force behind funding the hospital's first full service breast center. In 1993 the advisory board assisted in the purchase of Harris Methodist Hospital's first mobile mammography unit.

From the beginning, the mobile mammography program served uninsured or underinsured women who were eligible for mammography screening. The Fort Worth Housing Authority, United Community Centers, and several churches in underserved neighborhoods were among the hospital's first partner organizations. Texas Health Harris Methodist Hospital Fort Worth also established relationships with three of the city's largest employers: General Dynamics, Alcon, and Bell Helicopter. One of the hospital's largest collaborative partnerships began in 1999 with the Tarrant County Hospital District and its public hospital, John Peter Smith (JPS). The mobile mammography vans—which looked similar to U-Haul moving trucks in those days—performed screening mammograms at the network of primary care clinics in the JPS Health System.

Beyond Pink! In 1999 the decision was made to expand the mobile screening program beyond mammography. The hospital obtained funding from the Kupferle Women's Health Advisory Board (part of the Harris Methodist Health Foundation) to provide cervical cancer screening at events that included the mobile unit. Family nurse practitioners who were employed in other departments of the hospital performed these screenings. Because the mobile units did not have space for examinations, nurse practitioners set up portable exam tables in buildings adjacent to or near where the mobile units were parked.

A Full Service Vehicle. With tremendous philanthropic support from the community, the hospital built and put into operation a full-service vehicle in 2000. The 40-foot mobile coach contained a mammography suite on the front end, a registration area in the middle, and an examination room in the rear. With consistent exam space and generous funding from the Kupferle Women's Health Advisory Board, a part-time family nurse practitioner was hired specifically to staff the mobile unit.

Figure 1. Our Three-Part Collaborative



The 2006 "Cruisin' for a Cure" event provided screening and education to qualified men in the Fort Worth community.

Wellness for LifeSM. In 2001 the hospital chose the program name *Wellness for Life* to reflect the scope of services beyond mammography. Screenings at area businesses began to grow in popularity. Multiple screenings at work sites, such as the City of Fort Worth, became more popular as time and transportation barriers were eliminated for employees.

Men Get Screened, Too! In 2002 a survivor-led coalition partnered with *Wellness for Life* to host the first "Cruisin' for a Cure" classic car show and prostate awareness event in downtown Fort Worth. Urologists volunteered their time working with Harris Medical Lab staff to perform education, PSA blood tests, and digital rectal examinations at the hospital's mobile units. Proceeds from the event supported the costs of screening and also the Prostate Cancer Resource Center located in the Klabzuba Cancer Center, which opened in 2003. Over the years, the event has steadily grown in popularity. In 2013 "Cruisin' for a Cure" celebrated its 12th anniversary; 176 men met screening criteria, received appropriate education, and were screened on September 21, 2013.

The coalition has grown, too. The initial core group of survivors has become the North Texas Prostate Cancer Coalition (www.ntxpcacoalition.org), with five area medical facilities collaborating in the care of men with prostate cancer and their families.

Second Full-Service Mobile Unit. Again, with outstanding philanthropic support, the hospital was able to purchase a second mobile health coach, which was put into service in 2004. In addition to the mammography suite and the examination room, additional space was allocated for processing laboratory specimens. With the capacity gained through adding the second full-service unit, the program was able to hire its first full-time (FTE) family nurse practitioner to provide additional screenings and education. The first screenings for colon cancer (FOBT), skin

cancer, and bone density were performed on the mobile units at the 2004 Fort Worth Stock Show and Rodeo.

Additional Services. In 2007, through a grant from Minyard Food Stores, cardiovascular risk assessment (physical examination, biometrics, cholesterol, glucose) was added to the menu of services.

In 2010 the *Wellness for Life* program and UT Southwestern Moncrief Cancer Institute partnered to create the Breast Screening and Patient Navigation project. Funded through a grant from CPRIT (Cancer Prevention and Research Institute of Texas), this mobile outreach project brings breast screening to rural counties surrounding Fort Worth. The project initially began with a 5-county focus that was expanded to 12 counties in 2012.

The hospital purchased its third full-service mobile coach as part of an 1115 Waiver project. (1115 Waivers give states flexibility to design and improve their Medicaid and CHIP programs; they let states test new or existing ways to deliver and pay for healthcare services.) At 45 feet long, this coach is the largest in the fleet. The project will bring breast, cervical, and colon cancer screening to 9 rural counties in Texas District 10.

Two Essential Collaboration Models

Because the operational needs at community sites and workplace sites vary widely, the program required two different partnership models. Both models require processes for scheduling patients, parking the mobile health units at the sites, performing services, and following patients who require further referral. However, issues such as the need for language interpreters, applications for funding assistance, global payment arrangements, and contracting issues with corporations mean that separate processes are needed for each site.

Community Collaborations. To effectively operate a mobile health program in the community, a solid three-part collaborative must be in place (Figure 1, left):

1. Mobile Health Program: provides services and tracks outcomes of services provided.
2. Philanthropic support: provides funding for capital requirements and services to underserved populations.
3. Community organizations: provide scheduling opportunities at sites and help coordinate activities at screenings.

Key community partners for the program currently include:

- Catholic Charities, Diocese of Fort Worth
- Susan G. Komen, Greater Fort Worth
- Moncrief Cancer Institute
- Cornerstone Clinic
- Muslim Community Center for Human Services
- Elrod's Cost Plus Supermarkets

Work Site Collaborations. These partnerships rely on excellent relationships with the individual(s) responsible for employee wellness programs at the organizations where services are provided. Often responsibility rests with the Human Resources Department, but occasionally falls under another functional group. An under-

The second full-service mobile health unit was put into service in 2004.

Table 1. 2012 Patient Volumes for Two Mobile Health Units

SCREENING ACTIVITY	NUMBER OF PATIENTS SCREENED
Screening mammograms	4,784
Prostate cancer screening and education	182
Skin cancer screening, risk assessment, and education	225
Colon cancer screening, risk assessment, and education (FOBT kits distributed)	178
Cervical cancer screening, clinical breast examination, and health education	951
Bone density screening (heel ultrasound) and education	166

Table 2. Referrals for Follow-up Appointments from Screenings

SERVICE	NUMBER OF REFERRALS
Diagnostic mammograms, ultrasounds, and biopsies	397
Prostate cancer referral for further evaluation	73
Skin cancer referral for further evaluation	22
Colon cancer FOBT kits returned	130 (73%)
Referrals for further evaluation	20
Cervical cancer referral for further evaluation	122

standing of the benefits covered under the employees' insurance plans is critical. Services are billed in several ways:

- Directly to the employees' insurance carriers
- A global bill generated to the company for some or all services
- Self-payment by employees for services not covered by either insurance or the company.

Because of the variety of payment methods, individual contracts are frequently required for work site customers. Key work site partners currently include:

- Alcon Laboratories
- Bell Helicopter
- Burlington Northern Santa Fe Railway
- JP Morgan Chase
- Galderma Laboratories
- Mouser Electronics
- XTO Entergy
- Pier 1 Imports
- Lockheed Martin
- The City of Fort Worth
- The City of Grapevine
- Southwest Airlines
- Northwest Independent School District.

Infrastructure for a Mobile Health Program

With the addition of the 1115 Waiver Project, the equipment and personnel needs of the operation grew substantially. Now with three full-service mobile health units that travel to 9 surrounding counties, the department grew from 9 to 15 FTEs in 2013.

Mobile Health Unit. Over the 20 years of the program's operation, purchasing top-quality equipment became a critical necessity. Any time the hospital purchased a "second best" option, the program suffered. Attention to service providers is also important because no single service center can maintain and repair every component of these complex vehicles. For example, the company that services the generators is unlikely to be an expert in cabinet repair or satellite communications systems.

Mammography Equipment. Because all of the mammography equipment is digital, adequate facilities for downloading the images into the PACS system at the end of the day are important. Close collaboration with the breast center is critical to ensure that all quality and licensing requirements are met.

Staffing Model

The 15-person mobile health program staff includes the following:

- ***Manager.*** This 1.0 FTE oversees the entire operation. The manager is involved with strategic planning, selection and development of personnel, and budgeting.
- ***Team Lead/Operations Coordinator.*** This 1.0 FTE supervises daily operations of the program, including site planning, supervision of drivers/admissions clerks, and supplies.
- ***Drivers/Admissions Clerks.*** Three FTEs drive the vehicles to the sites and admit patients to the hospital on site. These staff members must be proficient in the hospital's EMR, scheduling, and admissions systems and have a current commercial driver's license.
- ***Interpreters.*** These are contract personnel who provide language interpretation for non-English speaking patients; languages vary by site visited.
- ***Mammography Technologists.*** These 2.8 FTEs perform screening mammograms on site.
- ***Family Nurse Practitioners.*** These 2.8 FTEs provide well woman exams, prostate screening education and examination, cardiovascular risk assessment, skin cancer screening and education, and colon cancer screening and education.
- ***RN Patient Navigator.*** This 1.0 FTE guides patients who are referred for further services to appropriate providers and offers patient education. The goal of the navigator is to direct patients to providers near their homes, if possible, and to connect them to primary care services if they do not already have them. The navigator also evaluates patients who are un- or underinsured for eligibility for local or government resources.
- ***Administrative Assistant.*** This full-time staff member supports the departments' administrative needs, processes group billing, and oversees contracts.
- ***Community Outreach Coordinator.*** This 1.0 FTE serves as liaison between the mobile health program and community organizations. This staff member evaluates sites for suitability, books the sites, and assists site coordinators in organizing mobile health visits.
- ***Data Analyst.*** This full-time staff member analyzes outcomes of all screening activities and constructs reports for administration and funding organizations. This staff member also assists with grant writing.

In-House Departmental Collaborations

The following inter-departmental collaborations have been critical to the success of the mobile health program.

Breast Center. The breast center supplies the mammography technologists who perform mammograms on the mobile health units. These staff members download the images into PACS at the end of the day. The breast center then assumes the responsibility for processing, reading, and reporting mammograms according to MQSA (Mammography Quality Standards Act) standards. The mammography equipment on the mobile health units is part of the breast center's license and all accreditations are managed through the breast center.

Engineering. Designated engineering personnel are responsible for maintenance and repair of the mobile health vehicles, as well as the electrical and information technology connections they require.

Radiology Engineering Services. This department maintains and repairs the mammography equipment on the vehicles.

Centralized Scheduling. Mobile health unit patients are directed to the hospital's centralized scheduling department to make appointments for services. Walk-in patients can occasionally be accommodated, but the preferred process is for individuals to schedule an appointment before the screening day.

Admissions. These specialists complete the admissions processes that cannot be completed in the field after the mobile health unit's return to the hospital.

Laboratory. The hospital laboratory processes blood and tissue specimens for screenings.

Program Capacity & Volume

On average the mobile health units can handle 22 mammograms and 11 well woman or other complex visits per day. The daily patient volume varies depending on the distance the units must travel to the sites. The goal is to limit the staff to a maximum 10-hour work day.

Scheduling must allow for such variables as downtime for preventive maintenance and repairs, as well as adverse weather and road conditions, all of which may affect capacity.

Table 1, left, shows 2012 patient volumes for our mobile health program. Referrals for follow-up appointments are reflected in Table 2, left.

Follow-up after Screening

One of the biggest challenges for any screening program is the issue of follow-up when screening results indicate that it is needed. The RN navigator assesses each patient's situation to put each individual on the optimal path for further care. For those in need

of financial support, she assesses eligibility and assists in the application process for those funds. For example, in many cases we assess eligibility for BCCCP (Breast and Cervical Cancer Control Program) at the time of screening mammograms.

A unique source of follow-up funding is the Kupferle Health Board. Each year the board produces a fashion show and luncheon; part of the proceeds is used to fund diagnostic procedures for women who need follow-up from their screening mammograms. These funds will support care through biopsy, if necessary. The members of the community who attend this event enthusiastically support this mission. In 2013 more than $70,000 was raised during the event's three-minute challenge alone.

A Brighter Future

Thanks to the vision and support provided by a unique group of high-energy women in 1992, the *Wellness for Life* mobile health program at Texas Health Harris Methodist Hospital Fort Worth was initiated and over two decades has grown from providing screening mammograms in the community a few days per month to a full-time, full-service education and primary prevention operation serving a multi-county area. Development of robust partnerships to reach targeted populations and to support delivery of appropriate services has been the critical factor in the program's success. In addition, the ongoing support of the hospital's administration allowed the mobile health program to become a fundamental component of the hospital's cancer program.

The mobile health unit benefit has benefited the cancer program by creating ongoing awareness in the community of the importance of appropriate prevention and screening for a variety of cancers. The program has also increased the visibility of the hospital's commitment to quality cancer care in Fort Worth and surrounding communities. In part because of aggressive promotion of screening, 67 percent of the analytic breast cancer cases seen at the hospital in 2011 were stage 0 or 1. These are cancers where the outcomes are expected to be favorable.

Generous funding from the Kupferle Advisory Board paid to build a full-service 40-foot mobile coach that was put into service in 2000.

Operating a mobile health program is complex and expensive, with many day-to-day challenges and uncertainties not found in a static hospital or clinic; however, the rewards are great. The benefits to the community, the cancer program, and the hospital more than justify its nourishment and growth. OI

Susan M. Shields, MBA, RN, NE-BC, is the cancer program director at Texas Health Harris Methodist Hospital Fort Worth, Klabzuba Cancer Center.

OUR COMMUNITY AT-A-GLANCE

Fort Worth is the 16th-largest city in the U.S. and the fifth-largest city in Texas. Located in north central Texas, the city is a cultural gateway into the American West and covers nearly 350 square miles in Tarrant, Denton, Johnson, Parker, and Wise counties—serving as the seat for Tarrant County. According to the 2010 census, Fort Worth had a population of 741,206.

According to the 2006–2008 American Community Survey, the racial composition of Fort Worth was as follows:

- White: 63.0 percent (Non-Hispanic Whites: 43.4 percent)
- Hispanic or Latino (of any race): 33.8 percent
- Black or African American: 18.0 percent
- Native American: 0.5 percent
- Asian: 3.5 percent
- Native Hawaiian and Other Pacific Islander: <0.1 percent
- Persian: 1 percent
- Other race: 13.2 percent
- Two or more races: 1.8 percent

The diverse nature of the population creates many opportunities to explore innovative ways to deliver care. Over the last 20 years, the mobile health program has addressed community disparities and barriers to care that are unique to segments of its population.

BY MICHAEL J. REFF, RPH, MBA

Physician Dispensing

Adding value to patients and the practice

While oral oncolytics are serious medications prescribed to help patients with serious ailments, there can be misconceptions that medicines in "pill" form do not require the same level of diligence from patients and providers. Instead, patients and providers should fully understand and appreciate the risks and benefits *before* an oral oncolytic is prescribed. For example, oral oncolytics allow patients enhanced autonomy and freedom from traveling to the oncology clinic to receive infused therapies; however, they come with the potential of less than robust adherence, which can lead to compromised efficacy and unique side effect management concerns.

Today's increasingly competitive oncology marketplace coupled with the tremendous increase in the number of FDA-approved (and pending) oral oncolytics has created a unique opportunity for community and hospital-based practices to consider physician dispensing of oral oncolytics. Physician dispensing allows physicians to give the oral medications directly to their patients, resulting in the same high level of care as infused medications—instead of having to send the prescription to an outside specialty pharmacy. Still, the decision to open a physician dispensing business should not be made lightly. Instead, oncology practices need to critically evaluate the financial viability of a physician dispensing platform and the feasibility of successful implementation.

The first stop on our journey was a comparison of business models; physician dispensing vs. a retail pharmacy. We evaluated the pros and cons of both in terms of implementation time, cost, and potential constraints due to state-specific regulations.

For all of these reasons Hematology/Oncology Associates of Central New York (HOACNY), a multi-site, private practice with more than 30 providers, located near Syracuse, N.Y., made the decision to embrace physician dispensing. The Patient Rx Center, the name given to the physician dispensing space, opened in April 2013, three and a half months after considerable up-front planning, process creation, and construction were completed. We share our story so that other physician practices may learn from our experience.

Physician Dispensing vs. Retail Pharmacy

The first stop on our journey was a comparison of business models; physician dispensing vs. a retail pharmacy. We evaluated the pros and cons of both in terms of implementation time, cost, and potential constraints due to state-specific regulations. Other factors that went into the decision included:

- The evolving regulatory environment
- Sourcing constraints; i.e., the ability to source specific medications from GPOs, distributers, and pharmaceutical companies
- The reimbursement landscape (i.e., the potential for reimbursement differences from payers that may exist between the two options).

After thorough evaluation, HOACNY believed that the physician dispensing option best suited the practice's long-range goals by providing flexibility, easier (and timelier) implementation, and minimal sourcing and reimbursement challenges.

In January 2013 the practice's Board of Directors endorsed this option and hired a team to create, implement, and then execute a physician dispensing platform for oral oncolytics and supportive medications that are part of an oncology protocol for its medical and radiation oncology businesses. A pharmacist manager, nurse navigator, and pharmacy technician made up this three-person team.

Our Team

When putting together the team that would implement physician dispensing, HOACNY felt it was critical to identify individuals

who could support the long-term goals of the practice and who had the necessary skills to create and then drive a tremendous amount of change across all departments. With that in mind, HOACNY selected a pharmacist with extensive oncology, retail, and continuous improvement and project management experience to lead the team.

Next, HOACNY created an oral oncology nurse navigator position, which was staffed by a certified oncology registered nurse (OCN). This individual was a current practice employee who possessed a wealth of oncology and practice-specific experience.

The nurse navigator was accountable for implementing and maintaining several important project components. For example, using standard oncology reference materials and partnering with pharmaceutical company representatives, she created folders for each oral oncolytic that might potentially be prescribed to our patients. If pharmaceutical manufacturer materials were deemed useful for patient education, the nurse navigator highlighted the relevant information for use during future one-on-one patient education teaching appointments. Depending on the perceived value of a specific piece, some or all of the pharmaceutical company materials are provided directly to the patient.

> Employing team members with experience in a retail pharmacy setting was invaluable in terms of the project's design, construction, formulary disposition, implementation, and execution.

The nurse navigator also spearheaded the team's review of all the available information for each medication and the development of concise teaching points. This one-page document is reviewed in detail with patients at the time of dispensing.

Additionally, the nurse navigator is accountable for consistent messaging and meeting with advanced practice providers (nurse practitioners, physician assistants) to review, improve, and then refine patient information related to oral oncolytics.

Finally, the nurse navigator follows up with patients as part of our oral adherence and persistence program.

The nurse navigator provides a unique value to our practice. Patients who utilize physician dispensing at the practice receive knowledgeable answers—regardless of their oncology protocol. The nurse navigator assists patients who have questions not only related to their oral oncology regimen but also patients receiving oral supportive medications for their infused therapies. In addition, the nurse navigator's clinical knowledge and ability to navigate through the complex EMR system allow her to assist the certified pharmacy technician with prior authorizations for the oral medications.

A certified pharmacy technician (CPhT) with strong retail and institutional pharmacy experience rounded out our team. The pharmacy technician organizes inventory and supplies for The Patient Rx Center. She interfaces with insurance companies to obtain prior authorizations and collaborates with the nurse navigator to procure co-pay and foundation assistance for patients. Additional responsibilities include:

- Maintaining proper inventory levels
- Purchasing products from suppliers
- Adjudicating payments
- Sourcing all the operating supplies (labels, prescriptions bags, tape, etc.)
- Maintaining the department's standard operating procedures
- Acting as subject matter expert on our prescription filling software; the pharmacy technician is HOACNY's lead trainer for the software.

Our pharmacy technician led the development of a practice-wide "Recognition in the Development of Pharmacy Technician Excellence Program." Further, senior management has endorsed the document that outlines the career steps a CPhT may pursue at our practice.

Our Planning Process

The team followed a simple yet effective project management approach—Plan, Do, Review. Project milestones were initially driven by the construction schedule and by the team's sense of urgency to provide a critical value-added benefit to patients and the practice. Construction lasted just over one month and entailed collaboration with many internal and external stakeholders. Once the scope and prescription volume for The Patient Rx Center was ascertained, the size of the space could be determined. One of the biggest hurdles was obtaining town construction permits and gaining consensus regarding proposed changes with the lessor of our building.

The readiness tracker. Beginning with the end in mind,[1] the team identified project milestones and developed a readiness tracker. The team populated the readiness tracker with each milestone and its associated tasks, assigning a target completion date and the team member who would be accountable for meeting that date.

Team mission. In parallel with developing the readiness tracker, the team created a team mission statement (see box at right). The process helped team members focus and fostered an environment of cooperation. The mission statement provided a roadmap for

The Patient Rx Center Team. (L to R) Hannah B. Peabody, CPhT; Michael J. Reff, RPh, MBA; and Deborah R. Walters, RN, OCN.

the new enterprise. It is a litmus test for all current and future activities. In other words, everything the team does must meet or exceed the principles contained within the mission statement.

This mission statement is prominently displayed on a large poster board adjacent to the prescription pick-up window. Patients and caregivers read the poster board and then experience first-hand the embodiment of the mission statement principles through interactions with the staff.

Infrastructure needs. Physical space, prescription dispensing flow, and formulary decisions, including storage, were all important considerations. Employing team members with experience in a retail pharmacy setting was invaluable in terms of the project's design, construction, formulary disposition, implementation, and execution.

During the initial design phase, the team calculated anticipated prescription volumes and defined formulary scope. The team recognized that using existing space can have a domino effect when work space and people are displaced for the new enterprise. A proactive, strategic evaluation of workflow for all affected staff and departments is critical to help mitigate these challenges. To optimize workflow, the team outlined how equipment is used during the prescription filling process (i.e., computers, printers, refrigerator, cash register, etc.), taking into consideration any space constraints. As with any construction project, no matter how well the construction scope is defined, challenges arise. Appointing a project lead who would also be the future "owner" of the physician dispensing space helped keep the project on-scope, on-budget, and on-time.

Project deliverables. Next, the team worked to prioritize and classify project deliverables. Placing these deliverables in a matrix, with one axis quantifying cost and/or time and the other axis quantifying necessity (ranging from "not needed" to "nice to haves" to "must haves") helped the team's focus during the design phase. We concentrated on the deliverables identified in the upper right quadrants in the nine box grid—designated in green in Figure 1, page 42.

State law, practice treatment pathways, patient demographics, medication carrying costs, medication storage space, and storage requirements are all important considerations when deciding on a formulary. Our team employed a "start small and grow" approach, piloting physician dispensing with one prescriber who practices at HOACNY's main site. We then expanded to additional prescribers at the main site, eventually recruiting prescribers who treat patients at the four satellite locations. This approach works well as long as you have planned for the anticipated increase in

Team Mission

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

prescription volume; we advise a similar approach for practices with multiple prescribers and practice locations. Recruiting a small number of prescribers at one site and then enrolling additional prescribers allows a practice to learn and adapt to the new workflow. Another approach would be to start exclusively with oral oncolytic prescriptions and then gradually increase the focus to include the supportive medications that are part of an oncology protocol.

Recruiting existing practice couriers to help deliver prescriptions to satellite locations helps the physicians dispense the medications to patients in a convenient and timely manner. The Patient Rx Center staff quarterbacks this process with the office employees at each practice location to ensure a smooth and seamless handoff to the patient.

Process flow maps. Our team then developed a process flow map to help the practice better understand the whole prescription process—from start (writing the prescription) to finish (prescription disposition). We actually created two process flow maps: the "As-Is" model and the "To-Be" model. The As-Is process flow map outlines the current process, fostering team building, elevating awareness for the new enterprise, and identifying opportunities for efficiency gains. These efficiency gains are then captured on the To-Be process flow map. Developing the To-Be process flow map further contributes to the team building aspects, while augmenting awareness and excitement for the new patient-centered service.

Our team recruited staff from all departments and from all satellite locations to participate in process flow mapping exercises. With the support of management, we hosted "Brown Paper Fairs" where the team led a discussion on the As-Is process, then actively solicited feedback and input from other staff. Employees were empowered to place comments directly on the process flow chart outlined on brown paper. Colored Post-It Notes were used to capture comments that fit into three specific buckets:

- Pink identified a potential opportunity for improvement and/or a problem
- Yellow was a comment and/or clarification about the process
- Green identified strengths in our current process.

After the Brown Paper Fairs, the team collated all comments. Pink Post-It Notes generated an action plan with an accountable stakeholder and target completion date. The team organized the Yellow Post-It Notes by topic and then addressed staff comments and points of clarification by email and at all-employee staff meetings. A similar approach was used to communicate the existing "strengths" back to all the employees.

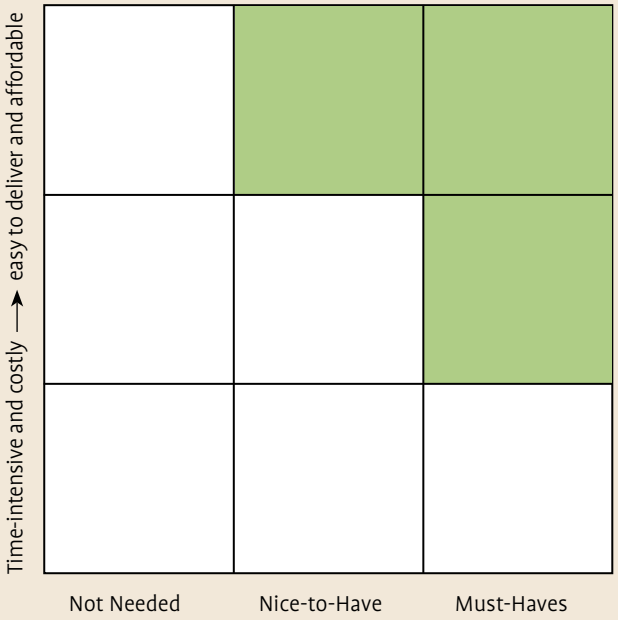
Implementation

The prior pharmacy retail experience of two of our team members was helpful during the implementation phase. We used EMR data to help quantify the volume of prescriptions the physician dispensing pharmacy could be expected to generate. EMR data can be sorted in many ways, by prescriber, by location, by diagnosis, by medication, etc. Collaborating with the EMR manager and prescribers, our pharmacist created and maintained an electronic database representing the current formulary for dispensing. This list (formulary) of medications builds confidence with the prescribers about what medications are on hand, and ready for patients. Additionally, our pharmacist established "favorites" for each prescriber within the EMR. This pre-populated list of e-prescriptions saves prescribers time and helps them more fully use the EMR for e-prescribing, which in turn supports the practice's meaningful use data.

We used the EMR to develop care plans for specific diseases and treatment pathways. These care plans helped standardize prescribing while promoting adherence to treatment guidelines.

We use EMR data to measure the success of The Patient Rx Center. Our team established S.M.A.R.T. (specific, measurable, achievable, relevant, and time-bound) goals to help track, gauge, and report successes. Based on their process flow, other practices may want to group these goals into separate categories, for example, goals that support activities prior to, during, and after dispensing.

Figure 1. Matrix for Project Deliverables



Below are a few examples of current and future key performance indicators our team identified:

- Percent of prescribers trained on e-prescribing to The Patient Rx Center
- Rx prescribed by provider (normalized by month).
- Total Rx (normalized by month).
- Rx by department and location (normalized by month).
- Medications available for prescribing. (We collect data on formulary growth to meet the demands of the rolling implementation and of our growing oncology protocols.)
- Percent of Rx oncolytics vs. total Rx volume (normalized by month).
- Rx interventions (quality metrics).
- Persistence and patient adherence measures.
- Co-pay and foundation assistance (number of patients and dollar amounts normalized by month).
- Percent of Rx refills vs. total Rx volume.
- Percent of patients proactively asked if they would like counseling regarding their medication; our goal is 100 percent.

Our team tracks and communicates the successes realized by physician dispensing to all stakeholders:

- CEO
- Administration
- EMR team
- Nurses
- Prescribers
- Couriers (to transport medications, supplies, etc., between practice locations)
- Finance
- Social workers
- Billing
- Radiation technicians
- Clinical assistance staff
- Building maintenance
- Information technology.

Sharing this information is critical to the successful implementation of any new entity, including physician dispensing. Some practices may realize capacity gains, or shifts in capacity, by reallocating responsibilities. For example, oral prescription prior-authorization responsibility was removed from nursing and administrative staff and re-allocated to The Patient Rx Center staff. Having a dedicated team focus exclusively on this important task streamlined the process and increased efficiencies, while allowing for capacity gains with other stakeholder groups (i.e., nursing). As our physician dispensing team gains experience, additional opportunities to improve the process will become apparent. Constantly reviewing these improvement opportunities will help ensure the continued success of this important patient-centered enterprise.

Key Takeaways

A practice that is dedicated to the physician dispensing platform is the single most important ingredient for success. All stakeholders must embrace the changes that are created by this new venture. Lack of adoption by prescribers and lack of support by administration are two of the biggest reasons behind the failure of physician dispensing.

HOACNY leadership devoted the time and resources to establish a solid foundation prior to filling its first prescription and staffed the enterprise with the right team to create and then drive the necessary change across the organization. Adoption by prescribers has been very favorable at our practice with a steady month-over-month increase in prescription volume.

As our physician dispensing team gains experience, additional opportunities to improve the process will become apparent.

The Patient Rx Center team regularly receives positive feedback from patients, and patient comments continue to reflect every aspect of the team mission statement. Patients are overwhelmed by the convenience, the supportive and thorough medication counseling, and the herculean effort demonstrated in securing financial assistance.

Proactively identifying and defining what success looks like and clearly establishing roles and responsibilities charts the clearest course. Planning, doing, then reviewing (with a built-in continuous improvement component) is a simple yet effective project management methodology. Practices interested in physician dispensing should strongly consider the management principles outlined above. OI

Michael J. Reff, RPh, MBA, is the manager of The Patient Rx Center, Hematology/Oncology Associates of Central New York.

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BY DIANE ST. GERMAIN, RN, MS; EILEEN DIMOND, RN, MS; KRISTI OLESEN, CHRISTIE ELLISON, RN, BSN, OCN, CCRP; LIANNE NACPIL, MPH, CTR; LUCY GANSAUER, RN, MSN, OCN; ANGELA CARRIGAN, MPH; KATHLEEN IGO; AND MARIA GONZALEZ, MPHC

The NCCCP Patient Navigation Project

Using patient navigators to enhance clinical trial education and promote accrual

Patient navigation has been a significant component of the National Cancer Institute Community Cancer Centers Program (NCCCP), which seeks to explore the best methods to enhance access to quality care and research in community hospitals, with a focus on minority and underserved populations.[1] (The NCCCP was established in 2007 as a pilot program with 16 sites, expanded to 30 sites in 2010, and currently has 21 sites.) To address these aims, the program established six major focus areas: Disparities, Clinical Trials, Biospecimens, Information Technology, Survivorship and Palliative Care, and Quality of Care, with an additional requirement to address disparities in each of these areas. Patient navigator roles at the NCCCP sites vary based on local needs, though navigator interventions span the cancer care continuum and could include community outreach, screening, early detection, care coordination, and multidisciplinary conferences and clinics.

Since navigation is a barriers-focused intervention,[2] NCCCP sites considered how the navigator's role could naturally extend to address barriers to clinical trial enrollment for minority and underserved populations. Through their educational and advocacy activities, navigators are familiar with the communities where their patients live; they have an established, trusting relationship with patients after months of coordinating care, and an intimate understanding of the barriers to cancer care and overall healthcare needs for the underserved populations in their service area. Thus, the navigator is uniquely poised to help with patient- and system-related barriers[3] to enrolling minority and underserved populations to clinical trials.

The NCCCP Patient Navigation Project

Starting in 2009, patient navigators from the 30 NCCCP sites met monthly as part of a working group designed to help the network hospitals enhance their patient navigation programs. Collectively, they identified core measures essential to a successful cancer navigation program and created a tool to help the sites measure progress with their individual navigation programs. The NCCCP Navigation Assessment Tool included 16 core indicators, each with five assessment levels to show increasing competence and program maturity.[4] One of these indicators— Engagement with Clinical Trials—was a novel area of involvement for navigators at community hospitals and one that this working group felt warranted inclusion based on the NCCCP's programmatic goals.

The hospitals rated their navigation programs in this area from a Level 1, where navigators simply share a basic understanding of cancer clinical trials with patients, to a Level 5, where navigators are engaged with research teams and assist with specific trial referrals for underserved populations. To further assess the effectiveness of engaging patient navigators to increase minority and underserved accrual to clinical trials, the NCCCP developed a demonstration project in 2010—the NCCCP Patient Navigation Project.

Site participation in the NCCCP Patient Navigation Project was voluntary, and 15 sites chose to participate. The non-participating sites chose to opt out due to physicians' desire to be the first to discuss clinical trials, time commitment, data collection challenges, and/or the need to change staff and patient flow and procedures. Of the 15 sites that implemented the project, several did not participate for the entire duration given the challenges associated with the project's data collection requirements.

The core concept of the NCCCP Patient Navigation Project was to determine the feasibility of integrating navigators with research teams at NCCCP sites in an effort to remove barriers to clinical trial enrollment for underserved populations. The sites self-selected clinical trials for cancer types of high incidence in their service area for the targeted minority and underserved population and then trained patient navigators to assist with accrual. This training involved educating navigators to equip them with the tools necessary to discuss clinical trials as a treatment option with patients. The level of discussion depended on

the navigator's experience and educational background. The navigators' role in the project included:

Planning

- Identifying, with the research team, a minority and underserved population to target.
- Identifying, with the research team, a barrier to accruing this population to relevant clinical trials and planning strategies that address the barrier.
- Focusing on clinical trials for cancers with high incidence in the chosen target minority/underserved population.

Implementation

- Providing educational materials to patients about clinical trials with the aim to empower patients to ask their providers about clinical trials.
- Linking patients to the clinical trials research team.
- Ensuring that a clinical trial is provided as an option when treatment decisions are discussed.
- Identifying strategies to address barriers.

Navigators at the participating NCCCP sites used a spreadsheet, called the Patient Navigator Data Collection Tool (Figure 1, below), to document key data items, such as the number of patients educated and/or provided educational materials, the number of patients referred to the clinical trials research team, barriers to clinical trial accrual encountered, and strategies to overcome these barriers. Process measures included the number of minority patients screened for clinical trial eligibility and the number of minority and underserved patients informed about or offered clinical trials. The working group hoped that engaging navigators with the clinical research teams would lead to increased patient awareness and education about clinical trials before meeting with their care providers to discuss treatment options. The group also hoped that early engagement with navigators would allow earlier identification of clinical trial participants and earlier referral to the research team, and ultimately result in enhanced enrollment of minority and underserved populations to clinical trials.

Research nurse and nurse navigator review patient cases and trial options after a MDC conference.

This article describes how, through implementation of the NCCCP Patient Navigation Project, three NCCCP sites successfully integrated navigators and clinical research teams. The description of their experience includes their challenges, successes, and program sustainability.

Sanford USD Medical Center

Sanford USD Medical Center (SMC), Sioux Falls, S.D., is the largest tertiary hospital in South Dakota and a teaching hospital

Figure 1. Image of Patient Navigator Data Collection Tool

NCCCP PATIENT NAVIGATION INFORMATION

	Patient ID	Race	Ethnicity	Age	Did you discuss clinical trials? YES	NO	If clinical trials were not discussed, please indicate reason
1							
2							
3							
4							
5							
6							
7							

for Sanford School of Medicine at the University of South Dakota. SMC is part of Sanford Health, an integrated healthcare system that is the largest rural not-for-profit healthcare system in the nation. It has a presence in 126 communities in 9 states. SMC serves mainly a rural, Caucasian population within a 250 mile radius. Table 1, page 48, provides a brief overview of Sanford's research program.

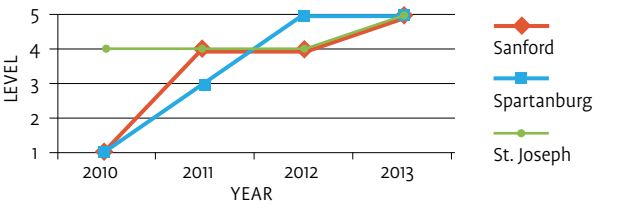
Although Sanford already had a few nurse navigators in place, in December 2010, with funding from the NCCCP to support additional navigators and to better meet the program's research and quality of care goals, Sanford established a nurse navigation department. Sanford chose a disease-specific navigation model because the large volume of analytic cases by disease site could support a full-time nurse navigator in each area. A navigator coordinator directs the navigation efforts with leadership from the Vice President of Cancer Services.

Within the department, the six professional nurse navigators are registered nurses (RNs); the breast navigators are certified breast care nurses (CBCNs), and the lung and GI navigators are oncology certified nurses (OCN®). The nurse navigators are located in their disease-site clinics but can meet with patients and caregivers anywhere on campus. The navigators identify barriers to care, refer patients to appropriate resources, and answer patient questions related to cancer and treatment. Overall, these nurse navigators provide another level of support and add to the quality of care patients receive. They are advocates for clinical trials, providing clinical trial education to patients, as well as referring patients to the clinical research team.

In addition, a lay navigator works with the refugee and immigrant population to provide cancer screening and prevention education, coordinate cancer screening appointments, and provide follow-up. Upon diagnosis, a disease-specific nurse navigator takes over navigating the patient. An on-site American Cancer Society lay navigator also assists patients with financial, transportation, lodging, and support group resources after diagnosis.

Prior to the NCCCP Patient Navigation Project, nurse navigators had limited involvement in clinical trials advocacy. Sanford's navigation team used the different building blocks of the project's guidelines and the NCCCP Navigation Assessment Tool to enhance its navigation program and increase nurse navigation engagement with clinical trials. This new focus helped Sanford move from a Level 1 in 2010 to a Level 5 in less than three years in terms of "level of engagement with clinical trials" (Figure 2, above).

Figure 2. Level of Engagement with Clinical Trials



KEY

Level 1: Navigator shares basic understanding of clinical trials in cancer.

Level 2: Navigator has greater depth of understanding of clinical trials and has completed specific training (NCI, ONS, etc.).

Level 3: Navigator shares information regarding the availability of clinical trials in their community cancer center with patients.

Level 4: Navigator engages with research team in providing general referrals.

Level 5: Navigator engages with research team and assists with specific trial referrals for underserved populations.

Source: NCCCP Navigation Assessment Tool

NCCCP PATIENT NAVIGATION INFORMATION

	Did you provide clinical trial education? YES	NO	Did you refer the patient to the clinical trials research team? YES	NO	Barriers and challenges encountered	Strategies to overcome these barriers and challenges	Partnerships and resources used for outreach and clinical trial recruitment
1							
2							
3							
4							
5							
6							
7							

To implement the NCCCP Patient Navigation Project, Sanford's nurse navigators had to be educated on clinical trials. Initially, navigators were uncomfortable about discussing clinical trials with patients; however, education and use of a script to guide discussions helped them to become more at ease.

Now, three years later, the clinical research department and nurse navigators work as a team to accrue patients to clinical trials. Clinical research staff and nurse navigators attend tumor board conferences where the patient's course of treatment is discussed, including eligibility for clinical trials. Clinical research coordinators operate under a model consistent with therapeutic area assignments (non-oncology and oncology). At times, however, coordinators must cross-train, depending on the portfolio of available trials. Coordinators are assigned to industry-funded, federally-funded, and investigator-initiated trials within their respective area of non-oncology or oncology.

For the NCCCP Patient Navigation Project, Sanford selected clinical trials for each navigated tumor site and identified the underserved target population, considered barriers to trial enrollment, and developed strategies to overcome these barriers (see Table 2, right, for an example).

Sanford created a script to help navigators introduce general information about clinical trials to patients and answer common questions to minimize patient concerns. Still in use, the script emphasizes that clinical trials may be one of many treatment options—empowering patients to make informed decisions about their treatment. Additionally, the navigators provide materials to assist with educating patients about clinical trials, such as the NCI's *Taking Part in Cancer Treatment Research Studies* brochure. Sanford also created a clinical research brochure that is given to patients, and the cancer resource library includes informative videos, such as the NCI's Understanding Cancer Clinical Trials DVD that are available for patient viewing. (This complimentary DVD can be ordered online at https://pubs.cancer.gov/ncipl/detail.aspx?prodid=Q021.)

Table 1. Sanford Research Program Overview

Hospital beds	545
New cancer cases annually	1,500
Management (director, manager) FTEs	2
Clinical research nurses (CRNs) FTEs	6
Clinical research associates (CRAs) FTEs	2
Research program support FTEs (e.g., regulatory specialists, trial coordinators, insurance, budget, finance, Quality Assurance, etc.)	4
TOTAL FTEs dedicated to clinical research	**14**

Completing the project's Patient Navigator Data Collection Tool was a time consuming aspect of project implementation. The navigators documented if clinical trials were discussed, if education was provided, and if patients were referred to the clinical research team. During the project time frame, navigators provided a clinical research brochure and general clinical trial information to nearly 75 percent of the patients seen with a highly suspicious finding or positive diagnosis, referring more than half (i.e., 56 percent) of navigated patients to the clinical research team. If navigators refrained from clinical trial discussions, the main reasons were that the patient had already started treatment, the physician preferred to have the conversation, or there was not time during the appointment.

The project was a catalyst to developing a strong partnership

Table 2. Sanford Patient Navigation Project

CLINICAL TRIAL FOCUS EXAMPLE

Trial: Phase II Study of DCA (dichloracetate) vs. placebo in combination with Cisplatin and definitive radiation in Stage 3–4 squamous cell carcinoma of the head and neck (Sanford Health DCA 2010). Trial aim: To evaluate the safety and effectiveness of giving an investigational study medication (DCA) to patients diagnosed with squamous cell head and neck cancer that is either recurrent or newly diagnosed advanced (Stage 3 or Stage 4).

Target Population: Native American and rural populations (patients within specific zip/RUCA codes).

BARRIER	STRATEGY
Some Indian Health Services (IHS) doctors do not support research due to risks of side effects.	Show how research benefits Native Americans and the general population. Follow up with those who enroll and tell them the outcome of the trial. Start with other CTs such as baby formula studies so they get used to research. Place research topic segments on TVs in IHS waiting rooms to prompt patients to ask their doctors about CTs.
Transportation costs.	Provide gas cards and telemedicine services.
Meal costs.	Provide all cost-related details when trial is introduced to minimize cost concerns. Some trials offer a meal stipend.
Lodging logistics and costs.	Inform patients about available lodging programs.
Lack of insurance coverage.	Collaborate with IHS to address coverage of routine patient care costs in clinical trials.

between nurse navigators and the clinical research team. For the first time, all the nurse navigators became more informed about how research processes are carried out in the clinical setting and they became advocates for research. In addition, a study on navigation in partnership with the American Cancer Society recently opened.

After three years of participating in the project, nurse navigators now routinely refer patients to the oncology clinical research department; the head and neck nurse navigator also assists in screening patients for a clinical trial developed by one of Sanford's head and neck cancer surgeons and researcher.

St. Joseph Hospital

St. Joseph Hospital of Orange is a values-based Catholic healthcare provider founded by the Sisters of St. Joseph in 1929 and one of 14 healthcare ministries within the St. Joseph Health System, the tenth largest not-for-profit health system in the U.S. Its comprehensive cancer program, the Center for Cancer Prevention and Treatment (CCPT), serves as a centralized location, catering to the unique needs of cancer patients and their families Table 3, below, provides a brief overview of the St. Joseph research program.

At St. Joseph, patient navigation was initiated in 2004 when a professional nurse navigator was hired to assist cancer patients who come from a diverse population base in Orange County. In 2005 the cancer program added five navigators and began a disease-site specific navigation model to coordinate the care of patients diagnosed with breast, melanoma, lung, urologic, colorectal, and head and neck cancers as they move through the different phases of cancer care from diagnosis, treatment, follow-up, and survivorship. All navigators are highly skilled, disease-site-specific OCN certified nurse navigators.

The navigation program continued to evolve through St. Joseph's active participation in the NCCCP. With NCCCP funding to support the hiring of additional navigators and the NCCCP's

Table 3. St. Joseph Research Program Overview

Hospital beds	525
New cancer cases annually	1,655
Management (director, manager) FTEs	1
Clinical research nurses (CRNs) FTEs	4
Clinical research associates (CRAs) FTEs	2
Research program support FTEs (e.g., regulatory specialists, trial coordinators, insurance, budget, finance, Quality Assurance, etc.)	3
TOTAL FTEs dedicated to clinical research	**10**

Members of the St. Joseph Hospital navigation program.

Table 4. St. Joseph Patient Navigation Project

CLINICAL TRIAL FOCUS EXAMPLE

Trial: NSABP P-5: Phase III Statin Polyp Prevention Trial in Patients with Resected Colon Cancer. Trial Aim: To determine if rosuvastatin (Crestor) compared to placebo can help prevent the return of colon cancer and the development of new cancers or polyps for patients with Stage 1 or 2 colon cancer that has been removed by surgery.

Target Population: Hispanic.

BARRIER	STRATEGY
Ineligibility of many patients due to statin use.	Re-educate stakeholders to ensure that patients are screened for statin use upfront.
Limited referrals to clinical trials.	Use research coordinators for physician outreach and education and community events. Collaborate with the colorectal program and surgeons to improve screening efforts. Have colorectal navigator support screenings.
Cultural considerations and language barriers.	Use a community spokesperson to enhance the credibility of the trial and research in question. Use short forms to obtain consent from non-English speaking patients. Use certified interpreters employed by the hospital, phone interpreters, or Nextalk laptop translating system. Have patients self-report race and ethnicity. Research database working effectively and with financial information incorporated.
Lack of educational materials.	Develop trial fact sheets (English and Spanish). Partner with the NSABP and the NCCCP network to provide clinical trials information during community outreach events and health fairs.

overarching quality of care and research goals, St. Joseph restructured processes to encourage use of and collaboration with navigators during patient treatment. The navigators are a blend of registered nurses, allied health professionals, and non-nursing staff that are introduced to patients at various points of their cancer care; however, it has been the goal of the cancer program to influence patient care as early as possible—at the time of diagnosis. This phase is critical, especially for access-challenged patients, yet education and social support are also needed to navigate the complex process of treatment planning and decision making. Navigators help cancer patients overcome barriers to care and open doors by introducing them to a wide variety of available resources—including community programs, local and national agencies, support groups, social workers, genetic counseling services, and research participation opportunities.

When the NCCCP Patient Navigation Project was launched, the St. Joseph navigators increased their focus on building clinical trial awareness to empower patients to ask their physicians whether a clinical trial might be a treatment option for them. The process began by matching clinical research associates and disease-site-specific cancer research nurses with disease-site-specific navigators. St. Joseph selected several breast, colorectal, and urologic trials as specific areas of focus to track patient education by the navigator and referral to research. The metric tools provided by the Patient Navigation Project were integrated into the home-grown navigator and cancer research databases to facilitate data tracking and reporting.

Completing the Patient Navigator Data Collection Tool presented challenges, as gathering the data was time consuming and not always the navigator's priority. Accordingly, St. Joseph found that accurately tracking the total number of patients referred by a navigator to the clinical trials team—along with the number of patients accrued as a result of the referral—was not always possible. Both databases could potentially produce reports showing these data; however, most reports came from the cancer research database, which relied on the information gathered and entered by the cancer research personnel. While attempts to refine data collection are ongoing, the increased interaction between the navigation program and the research team is a direct result of the NCCCP Patient Navigation Project. Table 4, page 49, provides an example of a trial selected for the NCCCP Patient Navigation Project along with the target population, barriers to enrollment, and strategies developed to overcome the identified barriers.

Today, through the shared cancer conference responsibility of the navigators and research coordinators, St. Joseph has increased awareness in clinical trial availability and eligibility, which facilitates the screening and referral process. A clinical trials algorithm, with each study linked to its eligibility requirements and schema, is readily available during the cancer conferences.

When the NCCCP Patient Navigation Project ended, stakeholders continued to track data albeit inconsistently as there was no longer a requirement to do so. In 2012, however, the navigation-research collaboration at the Center for Cancer Prevention and Treatment was re-launched using the tools and guidelines developed during the NCCCP project. St. Joseph focused on defining the role of the navigator as an advocate for clinical trials to conduct high-level screening and encourage referrals of potentially eligible patients to research for more in-depth screening. The disease-site-specific navigators coordinate with disease-site-specific research coordinators for training and education to assist with specific trial referrals with special attention to underserved populations. Navigators and research staff consider the metrics recommended by the NCCCP Patient Navigation Project; they meet monthly to discuss protocol updates, barriers to screening and research, and patient treatment updates to ensure more effective communication. Through this collaborative method, screening and referral processes have improved, duplication of efforts has decreased, and navigators ensure that cancer patients are informed about clinical trials as a treatment option.

St. Joseph used the NCCCP Navigation Assessment Tool to monitor and enhance its navigation program. Over the course of the project, St. Joseph's rating for the "Engagement with Clinical Trials" evolved from the navigators working with the research team by providing general referrals to assisting with specific trial referrals—with particular interest in serving patients typically under-represented in cancer clinical trials. The endeavor was largely supported by the community outreach nurse navigator with the assistance of the financial coordinator as appropriate. Clinical trials are a top priority at St. Joseph, and clinical trial accrual updates are shared in the Cancer Committee on a quarterly basis.

Table 5. Spartanburg Research Program Overview

Hospital beds	341
New cancer cases annually	1,664
Management (director, manager) FTEs	2
Clinical research nurses (CRNs) FTEs	9
Clinical research associates (CRAs) FTEs	5
Research program support FTEs (e.g., regulatory specialists, trial coordinators, insurance, budget, finance, Quality Assurance, etc.)	9
TOTAL FTEs dedicated to clinical research	**25**

Spartanburg Regional HealthCare

Spartanburg Regional HealthCare is a three-hospital system in South Carolina; the medical center is located in a rural area of the state's northwest region. In 1999 the hospital built a comprehensive cancer center, housing all cancer services in one building, including inpatient oncology. Table 5, above, provides a brief overview of Spartanburg's research program.

When the cancer center opened, a multidisciplinary model for

breast care was implemented with a multidisciplinary clinic and two nurse navigators to support the program. A lung cancer program started several years later with a lung navigator as the program coordinator. In 2007 Spartanburg Regional became a NCCCP site and worked to enhance the disease-site navigation program; it quickly grew as Spartanburg focused on creating an evidenced-based model for navigation with metrics, including return on investment that could support expansion. The navigation program added a prostate/GI navigator, a head and neck navigator, and hematology/CNS navigators. Today Spartanburg has 8 navigators for 10 disease-site programs.

Spartanburg's navigation program is linked to disease-site multidisciplinary conferences (MDCs) and uses both nurses and a social worker in a collaborative team-based supportive model. The navigation department is structured under the Cancer Support Division along with all of the other support services that span the cancer care continuum. In addition to traditional navigation services, the program is responsible for MDC coordination, case presentation, and supporting the physician lead in quality and disease-site program goals.

As part of its NCCCP participation, Spartanburg used the NCCCP Navigation Assessment Tool to assess the navigation program and focus on key elements to guide development of a stronger program. When the NCCCP Patient Navigation Project began in 2010, Spartanburg's navigators did not see research interface as their role and had minimal comfort level in that area. Additionally, the clinical research nurses were not aware of the potential value of navigators' support in increasing accruals.

As Spartanburg prioritized clinical trial accruals and required every patient to be screened for an available clinical trial at each disease-specific MDC, the value of the navigator's role increased. Navigators began to educate patients on clinical trials, refer appropriate patients, and track the interventions; the perspective of the research staffs slowly changed. Initially research staff was somewhat resistant to collaborating with the navigation team, viewing the navigators' clinical trial efforts as duplicative of other referral sources and not valuing the education that the navigators provided to patients.

Spartanburg began to pair each navigator with a disease-site research nurse. The navigators were required to attend the investigator meetings and monthly research and navigator staff meetings. It took nearly a year for the research staff and navigators to embrace the new model and roles. Becoming more informed about clinical trials and the importance of providing clinical trial education to patients helped the navigators become very engaged in the process. Once research staff was partnered with navigators, they were able to identify ways in which the navigators could benefit accrual. The research nurses and navigators now work hand-in-hand to dispel myths and educate patients about clinical trials as a potential treatment option. The navigators are responsible for addressing accrual barriers, such as transportation, access to screening, and trial education. The nurse navigators receive education regarding the cancer type they navigate and the relevant clinical trials. Because of this education, several nurse navigators have become quite comfortable pre-screening patients for eligibility, including looking at the stage and molecular markers, following evidence-based guidelines, and educating patients about specific trials.

The navigator works closely with the research team to best address issues that impact eligibility. For example, the navigator coordinates referrals to primary care physicians and specialists for management of co-morbid conditions. This capacity for care coordination is one of the primary advantages to Spartanburg's disease-site model for its navigation program.

For the NCCCP Patient Navigation Project, Spartanburg selected clinical trials for each navigated tumor site and identified the underserved target population, considered barriers to trial enrollment, and developed strategies to overcome these barriers (see Table 6, below, for an example).

NCCCP participation and work over the course of the NCCCP Patient Navigation Project have been catalysts to the evolving role of Spartanburg's navigators. Navigation responsibilities now include, but are not limited to:

- Demystifying clinical trials by addressing myths and fears about cancer research
- Answering questions about clinical trials
- Communicating with physicians and research nurses
- Educating patients on the availability of specific trials
- Screening patients for trial eligibility
- Referring patients to the clinical research team.

Helping patients and families develop a comfort level about considering trial participation as a treatment option is an

Table 6. Spartanburg Patient Navigation Project

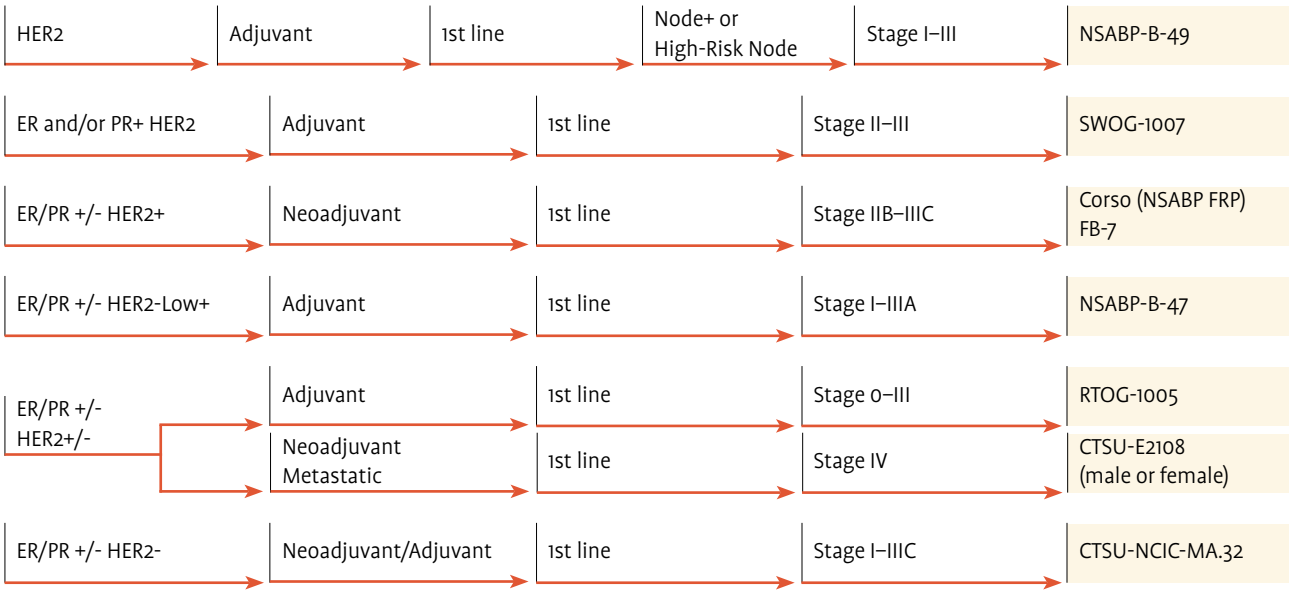
CLINICAL TRIAL FOCUS EXAMPLE

Trial: Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Adding New Drug TAK700 (RTOG 1115).
Trial aim: Compare the effects of hormone therapy and TAK-700 plus radiation therapy with hormone therapy and radiation therapy to find out which is better.

Target Population: High-risk African American (AA) males with prostate cancer.

BARRIER	STRATEGY
Travel and transportation.	Provide gas cards.
Educational level.	Educate AA males about clinical trials in general and this trial specifically.
Lack of trust.	Provide culturally relevant information regarding the risks/benefits of the trial.
Decisional choices.	Pre-educate patient about the multiple treatment options prior to provider consult.

Figure 3. Spartanburg Trial Matching Tool



important aspect of the navigator's role. Two phrases to assist in this process are:

- *Clinical trials help us* [providers] *answer questions about how we can improve outcomes* [for the patient's specific cancer type]. *This research may even benefit a family member in the future.*
- *I will help you through your treatment and this study.*

Requiring navigators to become actively involved with clinical trial accrual was a paradigm shift for the cancer center. The process was complex and took the commitment of leadership to encourage increased interactions between two traditionally separate departments. Although the process took time, Spartanburg attributes these additional factors to the successful shifts in processes and roles:

- The navigators' strong core advocate role
- Data collection on navigator interventions, which helped track progress and celebrate successes
- Navigator attendance at investigator meetings
- The practice of partnering each navigator with a research nurse
- Collaboration between the directors of research and navigation.

The navigator's expertise in laying the ground work for increasing patient comfort levels about enrolling in clinical trials continues to grow and is helping to increase accruals. Patients and families look to the navigator as the one who can guide them through their cancer journey, which may include a clinical trial. Navigators use resources, such as the Trial Matching Tool (Figure 3, above), to look for available trials. This tool provides an easy method for the navigator to identify and discuss trials for which the patient may be eligible.

Going Forward

While experiences varied for the community hospitals that participated in NCCCP Navigation Project, the three programs described in this article have demonstrated that—despite some challenges—educating patient navigators and engaging them with research staff result in navigators who are better prepared to discuss clinical trials with patients. In turn, this education led to increased navigator awareness of treatment options and helped navigators decrease patient anxiety during treatment discussions with their providers, realizing one of the project's aims: to empower patients to discuss relevant clinical trials with their physicians.

The sites who participated in the NCCCP Navigation Project value patient navigation and recognize the important role navigators can play in clinical trials. The programs continue to collect, share, and discuss the following metrics:

- Navigators' level of engagement in clinical trials, including provision of clinical trial education or information
- The number of referrals by the navigator to the clinical research team
- The number of these referrals who are accrued to clinical trials.

These metrics help measure the impact of the navigators' efforts, potentially justifying their use in this area and supporting the navigation program's return on investment. Though the NCCCP Patient Navigation Project's focus was on feasibility, demonstration of navigator interventions on increasing clinical trial accrual, particularly in underserved and minority populations, is important to pursue in a controlled setting. The NCI-ASCO Clinical Trial Accrual Symposium recommended future studies to evaluate patient navigation and its impact on enhancing trial participation.[5]

In addition to studying navigation and its role in clinical trial accrual, the experiences of the three NCCCP sites described in this article demonstrate the need for the development of well-designed randomized clinical trials to study navigator interventions and determine optimal roles and the effectiveness of professional and lay navigators. These studies align with the expanded research agenda of the new NCI Community Oncology Research Program (http://prevention.cancer.gov/ncorp), which will include cancer care delivery research. Future research may also include the impact of navigation on healthcare utilization, cost, and patient satisfaction.

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Nurse navigator confers with radiation oncologist about a patient's case.

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Productivity Benchmarks for Outpatient Cancer Programs

Results from a national study

Many outpatient cancer programs struggle to measure productivity and answer questions such as, how many staff members are required in a given department and how many chairs are needed in an infusion suite. Even when data are available, are benchmarking data the same for all outpatient cancer programs or are there are important differences depending on program size and other variables? In 2013 the Oncology Management Consulting Group solicited volunteer ACCC-member cancer programs to contribute data for a pilot analysis of productivity in hospital-based infusion and radiation centers. This article reports highlights of this hospital oncology benchmarking study. (The full study is available online at: http://mynetwork.accc-cancer.org.)

Methodology

Data was submitted by 32 infusion centers and 19 radiation oncology departments. Each participating program was assigned a unique Hospital ID to maintain confidentiality. Data included information about the cancer program (Table 1, page 56), as well as billing information. The billing information included a report of all items billed to any patient who received services in the infusion and/or radiation department(s). Respondents submitted data in spreadsheet format with each row of data representing a single billed item by CPT and HCPCS code. The columns were:

- Unique patient identifier
- Date of service
- Code billed
- Units of code billed
- Revenue center
- The first three ICD-9 diagnosis codes associated with the billed service.

One year of data was requested, either the most recently complete 12 months or the most recently ended fiscal year. Cancer registry data was not reported or was reported in a format that could not be interpreted by six infusion and six radiation oncology centers and those centers are excluded from the cancer registry analysis. Four infusion and two radiation oncology centers reported less than a full year of billing data due to significant program changes that would skew the analysis. For these centers, data was annualized. Four infusion and three radiation oncology centers did not report diagnosis or reported diagnosis in a format that could not be utilized; those centers are excluded from the diagnosis-specific analysis.

For this analysis, several assumptions were made: all contributors are coding and billing correctly, diagnosis coding places a cancer diagnosis in the first three of the diagnosis code fields on each claim, and all centers interpreted the questionnaire in a consistent manner. In a few cases, we elected to disregard a program data point because responses were inconsistent or unclear (e.g., percent of curative versus palliative radiation treatments). In other cases, we realized that the question was not clear and therefore did not provide value (e.g., number of other radiation equipment units) and we excluded those from the analysis.

Data Contributor Profiles

Thirty-two infusion centers submitted data, of which four self-identified as "academic." Nineteen radiation oncology departments submitted data, of which four self-identified as "academic." For both infusion and radiation, an encounter is defined as one unique patient with services on one unique date of service. Thus, one patient who receives multiple infusions or multiple radiation fractions at a single encounter counts as one encounter. Table 2 (page 57) profiles the infusion centers, ranked by size. Small centers are those with fewer than 3,500 annual encounters, medium centers see between 3,500 and 5,500 annual encounters, and large centers have over 5,500 encounters each year. The average number of annual encounters is as follows:

- Small centers: 1,667
- Medium centers: 4,502
- Large centers average: 9,615.

Treated Patients vs. Registry Cases

The study looked to identify if a correlation exists between treated patients and cancer registry cases. In most cases, the registry data time periods did not parallel the billing data time periods. In addition, a patient receiving treatment in the current year may actually be a cancer registry new analytic case in the prior year.

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Still, a comparison of the number of patients treated to the number of analytic cases holds some interest as a secondary indicator of market share (second to Class of Case in the registry data). This is true in large part because while a Class of Case 1 patient received "all or most of the first course of treatment" at the hospital, that first course could consist of infusion elsewhere and radiation treatment at the institution. Few registries abstract to that level of detail. In addition to serving as a secondary market share view, this comparison can help to project capacity needs when a hospital is working to increase volumes through various strategic initiatives, as well as purchasing new radiation technology.

For infusion, data found that the number of breast cancer patients treated compared to registry cases is approximately 60 percent of the number of analytic breast cancer cases. For colorectal cancer that number is 55 percent. Lung is nearly 60 percent; however, prostate is only 30 percent. Intuitively these data seem logical as the major treatment options for prostate cancer are surgery and/or radiation.

The comparison of registry data to radiation patients revealed:

- The number of breast cancer patients treated is roughly 60 percent.
- The number of lung cancer patients is 58 percent.
- The number of colorectal cancer is 28 percent (again not surprising given the typical treatment options).
- The number of prostate cancer patients is substantially—and logically as noted above—higher at 85 percent.

Infusion: Oncology vs. Non-Oncology

Few infusion centers treat only oncology patients; however, the mix varies widely from one institution to another in part because when private physician offices provide infusions, the volume of oncology infusions is likely lower. By comparing the number of infusion patients with oncology-related diagnoses (ICD-9 codes 140-249.99, 285.22, 288.1, 787.01-03, 790.6, C71.9, V58.0, V58.1, and V58.11-12) to the number of patients with non-cancer diagnoses, we see that smaller centers have a slightly higher proportion of non-oncology than medium and larger centers: 48 percent, 39 percent, and 35 percent respectively. This finding might be because larger centers have sufficient volume to segregate oncology and non-oncology infusions into separate departments.

Infusion Hours

To construct various benchmarks around activity and productivity, we calculated the number of hours of actual treatments. For many infusion codes, the duration of the procedure is part of the description. For example, 96413 is defined as an initial infusion of one hour and 96375 is defined as a therapeutic push of up to 15 minutes. Where code descriptions do not have times, we estimated the following:

- Bone marrow aspiration or biopsy, all blood products (per unit), and "other" infusions, such as therapeutic phlebotomy, were all counted as one hour procedures.
- Vaccines were estimated at 10 minutes.
- Initiation of a prolonged infusion was estimated at 30 minutes.

Across all hospitals and for all types of patients, the average "time in a chair" is 1.5 hours. The mean times are consistent with this numer—1.4, 1.6, and 1.5 for small, medium, and large centers respectively.

Next, we determined that it would be useful to know how long patients with specific diagnoses receive active treatment in a chair. Specifically, we calculated these times for breast, colorectal, prostate, lung, and non-oncology patients. Colorectal treatments run the longest: 2.1 hours average for all centers with slightly shorter times in small centers (1.6 hours average compared to 2.3 hours average at medium centers and 2.1 hours at large centers.) Breast treatments average 1.5 hours and lung treatments average 1.8 hours with almost no variation across center size groupings for either disease. Treatment for prostate cancer is the shortest with an average of 1.1 hours for all centers and again virtually no variation across center size groupings. The differences between the various disease groups are likely the result of different treatment regimens as some drugs must run over many hours while others are short infusions. Finally, for non-oncology infusions, the average time is 1.2 hours for centers of all sizes.

Infusion Nursing Productivity

Perhaps the two most commonly requested benchmarks are the number of chairs per infusion nurse and the number of encounters per infusion nurse. Another extremely valuable benchmark is the number of hours of actual infusion time each nurse performs on an annual basis. We measured chairs in terms of available chair hours (i.e., hours of operation multiplied by the number of chairs). We measured worked hours of infusion nurses by multiplying the percent of FTE nurses reported by 2,080 (the standard measure for one year of full-time effort). Here's what we found:

- The number of chairs per FTE nurse averaged 3.2 for small centers, 4.3 for medium centers, and 3.4 for large centers. More interesting is the range—from 2 to more than 5 chairs per nurse.
- The number of annual encounters for a full-time nurse was 438.9 for small centers, 652.7 for medium centers, and 628.4 for large centers.
- The number of active infusion hours for one full-time nurse was 1,182 for small, 1,654 for medium, and 1,446 for large centers. Curiously, some centers show more than 2,080 hours of infusion time per nurse. Since 2,080 hours is considered "full time" this number seems impossible. Recognize, however, that nurses are treating several patients at the same time in the nurses' assigned chairs.

Other factors affect this benchmarking data, such as other duties the infusion nurses perform and whether support staff is assigned in the chemo suite to perform non-nursing tasks. In addition, it is possible that staff at smaller centers is simply not as efficient with processes, such as chemo double checks, checking for potential drug reactions, and coverage for breaks even when the volumes are low. Still, centers with particularly low chair-to-nurse ratios may wish to delve into staff productivity, particularly as it is affected by task assignments. Conversely, those centers with particularly high ratios might want to review their operations to ensure that they are not adversely affecting safety by over-loading staff with too many patients.

Physician-Related Infusion Benchmarks

The final benchmarks in the infusion section cover the number of nurses needed for each full-time oncologist and the number of encounters generated by a full-time oncologist. The former is a very valuable data point for centers that anticipate adding or losing physicians since those changes will obviously have an impact on the number of staff needed in the infusion suite. The data was segregated for centers that reported having only "employed" oncologists, those that reported having only "private practice" oncologists, and those that reported a mix of the two staff models.

The results are not surprising in that intuitively we would expect "employed" physicians to require more nurses and to generate more encounters because the hospital infusion suite is their only venue for treating their patients. What is extremely interesting here is the difference between what "employed" physicians require and generate and what "private practice" physicians require and generate. For centers with only "employed" oncologists, the average number of full-time nurses required is 2.26 while "private" oncologists only require 0.7 FTE nurses to care for their referred patients. Perhaps one of the most valuable infusion-related benchmarks is the number of encounters that one full-time oncol-

Table 1. Program Data Points

STAFFING (FTEs budgeted for the fiscal year)
Infusion non-physician practitioners
Infusion nurses
Infusion LPN/NAs
Infusion (other)
Radiation non-physician practitioners
Radiation physicists
Radiation dosimetrists
Radiation therapists
Radiation nurses
Radiation LPN/NAs
Radiation MAs
Radiation (other)
EQUIPMENT & RESOURCES (for the fiscal year)
Number of outpatient infusion chairs and beds
Number of linear accelerator units
Number of Cyberknife® units
Number of Gamma Knife® units
Number of other radiation equipment units
Standard hours of treatment operations in each department
MEDICAL STAFF (only clinical FTEs for the fiscal year)
Number of FTE hematologists/oncologists using only the hospital infusion center
Number of FTE hematologists/oncologists using another infusion center in addition to the hospital's
Number of FTE radiation oncologists (excluding any time spent using non-hospital equipment)

ogist will generate as this has tremendous importance when planning for expansion through growth or through acquisition of a practice. On average, one full-time "employed" oncologist orders 1,177 infusion visits per year; "private" oncologists order 72 percent fewer encounters at 331 per year.

Radiation Daily Treatments

To define treatments, we counted all billing codes that define treatment delivery. This includes all types and modalities, such as external beam, stereotactic radiosurgery, stereotactic body radiation therapy, high-dose rate radiation, MammoSite, Gamma Knife, and more. To calculate daily treatments, we summed the number of billed treatment codes and divided by the number of dates on which any treatment code was billed (Table 3, page 58).

Among the most commonly requested benchmarks are those relating to the number of treatments per patient. We calculated those numbers for all diagnoses as well as for breast, colorectal, prostate, and lung cancers. Of note, these figures include both curative and palliative treatments. Unfortunately, the variability of diagnosis coding practices among data contributors makes it impossible to segregate the two because some centers may code the metastatic site in the first or second diagnosis code slot while others may code the initial site of disease first or second.

Prostate cancer patients lead the way with an average of 22.5 treatments, which is not surprising since radiation is among the most common approaches in treating this disease. Breast cancer patients follow closely with 21.8, while colorectal cancer patients receive 18.3, and lung cancer patients average 14.5 treatments (Table 4, page 58).

IMRT & IGRT

Cancer centers often ask what proportion of treatments is intensity-modulated radiation therapy (IMRT) and/or image-guided radiation therapy (IGRT). Payers often develop policies regarding the "acceptable" indications for these modalities, and centers do not want to find that their utilization of these modalities is high enough to spur an audit. To measure the proportion of IMRT to IGRT, we compared the number of IMRT and IGRT codes billed to the total number of treatments billed. On average, for all centers, 33.7 percent of all treatments are IMRT (see Table 5, page 59). Here is the data by the four major disease sites:

- Prostate cancer leads the way at 27.3 percent of all IMRT treatments
- 4.3 percent of all IMRT treatments are for lung cancer
- 2.8 percent of all IMRT treatments are for breast cancer
- 2.1percent of all IMRT treatments are for colorectal cancer.

Several of the small and medium centers do not have IGRT capabilities, but for those that do, IGRT represents 22.6 percent of all treatment codes for small centers and 37.1 percent of all treatment codes for medium centers. At large centers, IGRT represents 28.1 percent of all treatment centers.

Table 2. Infusion Center Profiles

HID	SIZE	ACAD/ COMM	INFUSION ENCOUNTERS	INFUSION PATIENTS
H17	S	C	985	110
H36	S	C	1,141	222
H35	S	C	1,177	274
H8	S	C	1,202	315
H11	S	C	1,436	571
H30	S	C	1,473	172
H5	S	C	1,705	642
H13	S	C	2,823	383
H19	S	C	3,064	619
H31	M	C	3,501	376
H15	M	C	3,587	485
H3	M	C	3,632	328
H37	M	C	3,694	382
H33	M	C	4,053	968
H18	M	C	4,268	481
H21	M	C	4,818	827
H12	M	C	5,107	623
H10	M	C	5,125	988
H23	M	C	5,367	749
H14	M	C	5,418	891
H27	M	C	5,453	765
H25	L	A	6,428	2,419
H24	L	C	6,531	1,536
H4	L	C	6,532	1,141
H7	L	A	6,842	889
H29	L	C	6,993	637
H1	L	C	7,197	907
H6	L	C	7,526	868
H22	L	C	11,996	1,667
H9	L	A	12,020	1,646
H2	L	A	15,544	2,712
H26	L	C	18,158	2,864

Small = <3500 annual encounters; Medium = 3,500–5,500 annual encounters; Large = >5,500 annual encounters

Table 3. Radiation Center Profiles

HID	SIZE	ACAD/ COMM	DAILY TREATMENTS	PATIENTS
H36	S	C	4	216
H13	S	C	9	90
H5	S	C	11	405
H23	S	C	16	216
H37	S	C	20	284
H33	S	C	22	326
H7	M	C	26	290
H10	M	C	28	331
H27	M	C	29	446
H21	M	C	35	625
H1	M	C	36	422
H22	M	C	37	508
H4	M	C	46	701
H26	L	C	55	802
H20	L	C	56	660
H2	L	A	60	1,423
H24	L	C	64	972
H25	L	A	66	2,045
H9	L	A	69	1,080

Small = <25 daily treatments; Medium = 25-50 daily treatments; Large = >50 daily treatments

Radiation Staffing Productivity

We calculated the number of hours of linear accelerator (linac) operation and compared that to the number of hours reported for therapists, dosimetrists, physicists, and radiation oncologists. Note that these data report all therapists, including simulation therapists. Here, large centers average 3.7 therapists per linac which is somewhat higher than small centers at 2.9 therapists per linac and medium centers at 3.0 therapists per linac. Likely this variation is the result of higher complexity and more modalities of radiation services in the large centers.

Dosimetry is less varied across institution sizes (.78 dosimetrists per linac for small centers, .82 dosimetrists per linac for medium centers, and 1.0 dosimetrists per linac for large centers). Physics showed some small differences (small centers have an average of .77 physicists per linac, medium centers have an average of 1.0 physicists per linac, and large centers have an average of 1.25 physicists per linac). This data seems logical since the larger centers generally have more complex technologies.

The Centers for Medicare & Medicaid Services (CMS) have specific requirements regarding the supervision of outpatient therapeutic services including radiation. Those rules require that there be a properly qualified, trained, and credentialed provider present during the delivery of treatments. The rules do permit the supervising provider to be a non-physician practitioner (NPP) although in many states, the scope of practice for NPPs may not cover radiation, and the state radiation safety regulations may require a physician's presence. In our survey, we find that while the average number of radiation oncologists per linac is 1.0 for small and medium centers and 1.3 for large centers, the range is from .5 to 2.0. A center with .5 radiation oncologists per linac might have two machines, which is acceptable, but for those with less than a full-time physician for full-time linac operations, there may be a need to explore other means of coverage to remain compliant.

The last benchmark data point analyzed is the number of patients per staff category. Here we found that, on average, small centers handle 77 patients per therapist, 355 patients per dosimetrist, 371 patients per physicist, and 243 patients per radiation oncologist. For medium centers, those numbers are 86 patients per therapist, 328 patients per dosimetrist, 244 patients per physicist, and 30 patients per radiation oncologist. Data for large centers found 122 patients per therapist, 454 patients per dosimetrist, 418 patients per physicist, and 350 patients per radiation oncologist. The numbers for large centers are somewhat higher than we expected although not alarmingly so. We also note that it appears that the learning curve for dosimetrists with IMRT seems to have eased, making them more productive than noted in previous years' anecdotal observations.

The 2014 Survey

The response this survey was remarkable and OMC plans to repeat and expand on the study in 2014. We expect to release the call for data in mid-2014 for data from calendar year 2013. For that study, we plan to expand not only the number of centers to a goal of at least 100, but to expand the data points and to

Table 4. Average Radiation Treatments per Patient

DISEASE GROUP	ALL CENTERS
Prostate cancer patients	22.5
Breast cancer patients	21.8
Colorectal cancer patients	18.3
Lung cancer patients	14.5
All patients	17.4

Table 5. IMRT Utilization

INSTITUTION	BREAST CANCER AS % OF IMRT	COLORECTAL CANCER AS % OF IMRT	PROSTATE CANCER AS % OF IMRT	LUNG CANCER AS % OF IMRT	IMRT AS % OF TOTAL TREATMENTS
OVERALL	2.8%	2.1%	27.3%	4.3%	33.7%
H1	1.7%	3.3%	54.3%	8.9%	35.2%
H10	12.8%	1.8%	41.5%	4.7%	48.3%
H13					28.5%
H2					46.6%
H20	0.0%	5.1%	49.5%	2.3%	22.9%
H21	0.0%	4.4%	42.5%	12.5%	34.5%
H22	2.0%	4.2%	36.6%	10.8%	29.8%
H23	0.6%	0.0%	31.5%	13.6%	25.6%
H24					35.4%
H25	0.0%	4.6%	27.4%	0.4%	22.8%
H26	7.3%	1.9%	48.4%	4.6%	34.2%
H27	0.7%	6.9%	44.2%	0.8%	28.9%
H33	7.2%	0.0%	10.8%	12.6%	6.7%
H36	0.0%	0.0%	71.2%	0.0%	28.0%
H37	0.0%	0.0%	24.6%	1.1%	14.7%
H4	0.0%	2.5%	60.8%	0.0%	17.1%
H5					29.4%
H7	11.0%	3.1%	37.6%	9.2%	71.6%
H9	2.0%	0.8%	11.2%	5.4%	51.2%

No data = hospitals without diagnosis data or without IMRT

work on the granularity of several of those data points. We hope to add staffing benchmarks for pharmacy, social work, navigators, tumor registrars, genetic counselors, financial counselors, non-physician practitioners, and radiation nurses. We will also drill down on various categories of staff (e.g., infusion nurses versus LPNs and treatment therapists versus simulation therapists), as well as on data such as disease groups for non-oncology infusions and various radiation modalities and hours of operations for detailing staffing benchmarks. We will look for ways to match up tumor registry cases to treated patient cases if this can be done without placing an onerous burden on our data contributors. And finally, we welcome any suggestions from cancer center administrators to help us continue to build a more robust data set as we move forward to bring these valuable productivity benchmarks to oncology administrators across the country. OI

Teri U. Guidi, MBA, FAAMA, is the president and CEO of Oncology Management Consulting Group based in Pa. For more than 12 years, OMC Group has provided professional consulting services to oncology providers across the U.S. With solutions tailored to each client's precise needs, OMC Group offers the leadership, vision, and collaboration that oncology organizations need to adapt and succeed in the rapidly changing healthcare industry. Elaine Kloos, RN, NE-BC, MBA, is senior consultant at Oncology Management Consulting Group. Additional information on this benchmarking survey can be found on OMC Group's website: www.oncologymgmt.com.

Ask ACCC's Community Resource Centers

Even with the advent of novel agents and autologous peripheral blood stem cell transplants therapy (ASCT), multiple myeloma (MM) is still an incurable disease; most patients relapse, even those patients placed into complete remission (CR). In the absence of a high curative potential, long-term disease control remains the most important part of MM treatment. Clinicians have disagreed on whether standard-risk patients who will survive a long time need to be treated as aggressively as high-risk patients, but all agree that high-risk patients require a complete remission for long term overall survival (OS) and an aggressive strategy to reach that goal.[1] Leona A. Holmberg MD, PhD, Fred Hutchinson Cancer Research Center, discusses current standard of care and what the future holds for patients with MM post-ASCT.

THOUGH UNDERUTILIZED FOR treating MM, ASCT remains the most common reason for transplant. Unfortunately, relapse of MM remains a major problem after transplant. Possible explanations for relapse include: incomplete eradication of endogenous disease or infusion of tumor contaminated stem cell products.[2,3] Attempts to improve outcomes by further dose intensification of conditioning to date with a single ASCT have led to an increase in transplant-related morbidity and mortality without a significant reduction in both relapse rates and improvement in OS.[4]

Clinicians also face challenges determining minimal residual disease (MRD) status in MM patients. Molecular and multi-parameter flow cytometry techniques have not yet been standardized in MM and the most sensitive assays are not well accepted by providers. In addition, determining PCR (polymerase chain reaction) status is time consuming and requires specific primers from patients. Although other diseases have seen the advent of deep sequencing, its role in MM has still to be addressed.

Genetic profiling also plays an important role in treating MM patients. Unfortunately, standardization and easy use of gene expression profiling signature to help identify those patients with more indolent MM that may require less aggressive therapy does not yet exist. MRD must be combined with genetic assessment to develop a powerful medical risk-assessment tool. In other words, before using MRD to make clinical decisions, providers need to standardize the tests and the criteria used to determine response and then validate their relevance in clinical outcomes.

Clinicians have commonly used additional therapy post-ASCT to try to improve outcomes for MM patients. These therapies have fallen into different approaches of consolidation with or without maintenance therapy or maintenance therapy alone. Consolidation therapy has been defined as improving on response and accepting more toxicity; maintenance therapy has been defined as maintaining response with less toxicity (see table 1, page 61).

In the era of novel agents, improved outcomes after ASCT and induction therapy have been realized. ASCT followed by consolidation therapy and maintenance therapy appears to be the standard approach to induce remission status in MM patients.[5–8] While thalidomide works best in good-risk disease, peripheral neuropathy has made it hard for patients to comply with this therapy.[9]

Optimal duration of maintenance therapy may be drug specific. For example, the optimal use of lenalidomide may be for as long as tolerated or until disease progression. Newer agents, such as carfilzomib, are being studied, looking at not only the combination of agents, but giving them alone or sequentially.

ACCC's Community Resource Centers for Multiple Myeloma

- **The Nebraska Medical Center, Omaha, Nebraska**
- **Seattle Cancer Care Alliance, Seattle, Washington**
- **Winship Cancer Institute of Emory University, Atlanta, Georgia**

Contact them at: www.accc-cancer.org/resources/MultipleMyeloma-CRC.asp.

For future studies as effective salvage therapies continue to come on board, overall survival (OS) is going to be problematic as an endpoint. So, as a community, we need to decide whether TTP (time to progression) and EFS (event free survival) are reasonable endpoints for future studies of consolidation and maintenance therapy after ASCT.

Additionally, clinicians have not yet answered the question as to whether all patients need therapy post-ASCT or if there are groups of patients that do not need to be treated. A standardized clear definition of MRD and a process to identify accurately who still has the disease may help clinicians make that choice.

Current studies have not yet clearly delineated good-risk and bad-risk patients or the role of additional therapy post-ASCT in patients who require more than one induction regimen to get good response before ASCT or patients who are undergoing ASCT in the relapsed delayed transplant setting.

Still, it is premature to say that all patients should not be offered therapy if in CR (complete remission) after ASCT. Data shows that patients with bad-risk parameters at diagnosis, such as elevated beta 2 microglobulin or bad-risk cytogenetics, or those who require more than one induction regimen may benefit from additional therapy post treatment—even if they are in complete remission.

Our old definitions of CR still have high-relapse rate; the median TTP (time to progression) from ASCT for sCR (stringent complete remission) is 50 months vs. 20 months for CR and 19 months for near CR.[10] Thus, if clinicians maximize the use of sCR after ASCT, we may—with the current standard technology and use of clinical information, such as good-risk factors at presentation—identify a group of patients who (with adequate counseling) do not need additional therapy post-ASCT.

In the future, clinicians need to assess the best therapy to use post treatment based on previous therapy and cytogenetic and other risk factors. In other words, we need to learn how to choose therapy based on toxicity of drugs and underlying toxicity that patients have from previous therapy, especially in a setting where we are not curing disease but treating it as a chronic illness.

Future studies should address risk stratification approaches, and we need to do head-to-head comparisons of different regimens to determine the best treatment with specific MM patients post-ASCT.

Finally, clinicians must establish the appropriate duration of treatment with different agents. We need to standardize MRD criteria and design studies to address this question appropriately with other risk factors to maximize the use of additional post transplant therapy. But, for patients with bad-risk factors at presentation and even those in good-risk category that do not achieve sCR after ASCT, the strategy of non-cross resistant therapy to induce deeper remissions and sustain them over time is the goal and currently is reached by novel agent combination induction therapy, ASCT, and additional novel agent therapy post treatment.

Table 1. Consolidation vs. Maintenance Therapy

Consolidation Therapy	Maintenance Therapy
Accept more toxicity	Well tolerated with easily manageable toxicity
Limited time use	Long term use
Effective	Effective
Need not be simple to give	Simple to give
Deepen response	Maintain response

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action

Wrap-up of the ACCC 40th Annual National Meeting

ACCC's meeting, March 31–April 2, Arlington, Va., took place during an exciting week in the nation's capital, coinciding with a vote on the SGR on Capitol Hill and the end of marketplace open enrollment. On March 31 more than 50 ACCC members from 27 states walked the halls of Congress for ACCC's Capitol Hill Day. Read about their experience at http://acccbuzz.wordpress.com/2014/04/01/accc-on-the-hill-timing-is-everything. On April 1, keynote speaker Kavita Patel, MD, told attendees that providers will likely face some form of risk-sharing as reimbursement moves from volume-based to value-based models. Read a summary of Patel's keynote speech at acccbuzz.wordpress.com/2014/04/02/alternative-payment-models-risk-sharing-ahead-says-accc-keynoter. A photo album from the meeting has been posted on the Association's Facebook page at https://www.facebook.com/accccancer/photos_stream.

ACCC Annual Achievement Award recipient, Paula Kim, Founder, CEO and Chairman, Translating Research Across Communities.

SAVE THE DATES!

ACCC 31st National Oncology Conference
October 8–11, 2014
Sheraton San Diego Hotel & Marina
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ADVERTISER'S INDEX

Project Violet

BY JIM OLSON, MD, PHD

Every animal, every plant in nature has a way of protecting itself so it can survive.

Sunflowers are able to keep their bright yellow petals from being completely devoured by bugs by manufacturing a trypsin inhibitor, a peptide that neutralizes the enzyme insects spit on their food to break it down so they can eat it. Spiders and scorpions, over millions of years, have developed powerful toxins that enable them to paralyze their prey, ensuring a leisurely, trouble-free meal—and the survival of their species. Even that ball of starch we know as a potato is able to protect itself from being completely consumed by insects and grubs and whatever else lives underground because of a substance—a protective drug—produced in the potato skin.

Nature's medicine chest is both imaginative and boundless. Luckily for us, it's also malleable.

For the past 10 years, our lab at Fred Hutchinson Cancer Research Center in Seattle has been working with the mini proteins or peptides produced by various organisms—drugs that are encoded into the DNA of plants and animals and passed from generation to generation—with a mind toward using these amazing molecules to obliterate cancer cells without harming healthy tissue.

Our first candidate for investigation was a chlorotoxin peptide produced by the Israeli deathstalker scorpion. This peptide is useful to the scorpion because it's able to travel through the bloodstream of prey to hit its target. It's useful to us because that same tough little peptide also happens to bind to cancer cells but not to normal tissue.

When we first started working with scorpion chlorotoxin, we didn't know why it bound itself exclusively to cancer cells. Now we do—it has to do with a protein target that is usually inside cells but gets flipped to the outside of cancer cells, making it available to chlorotoxin. But that's not the amazing part of the story. The amazing part is that we were able to think creatively and optimize the scorpion venom peptide by binding it to a safe fluorescent dye to create a sort of molecular flashlight that illuminates cancer cells under near-infrared light.

In 2004, a colleague and I injected this optimized peptide—optide, for short—into the tail of a mouse that was growing a human brain tumor under its skin. That optide traveled through the mouse's bloodstream and an hour later, its brain tumor was glowing brightly while the rest of the mouse was not. My colleague and I were dancing around in our white lab coats because we'd just come up with a drug that could clearly—brilliantly, even—differentiate healthy tissue from tumor.

This drug, which we call a Tumor Paint imaging agent, is currently in clinical trials in Australia. It got there in a very reasonable amount of time—10 years—thanks to research that was funded in an unconventional way. I'd written grants to the National Institutes of Health—six of them, in fact—but each was rejected because the idea seemed "too speculative" or "overly ambitious."

My colleagues and I believed in the incredible potential of Tumor Paint molecules, however, as did the families of the pediatric brain cancer patients in our practice. These are families who've seen their children die or suffer debilitating consequences because it is so difficult for surgeons to distinguish brain cancer from normal tissue. These families—along with their friends and neighbors and colleagues—began fundraising and eventually brought in more than $8 million to fund the research at Fred Hutch. Subsequently, we created Blaze Bioscience, a new biotech company spun out of Fred Hutch, specifically designed to efficiently and expediently advance our discoveries to human clinical trials and eventual FDA approval.

Along with thinking creatively in the lab, we're also trying to think creatively about how to fund and develop our cutting-edge research.

That's where ProjectViolet.org comes in. Inspired by my patients, the crowdfunding success of Tumor Paint and the idea of a new class of anti-cancer compounds derived from nature, Project Violet allows everyday individuals—bus drivers, beauticians, database managers—to adopt new drug candidates for as little as $100. These candidates, derived from the DNA of everything from spiders and scorpions to potatoes and cone snails to sunflowers and violets, will become part of a larger library that we plan to share with other scientists around the world, to collaborate on diseases long considered incurable.

We created Tumor Paint with pediatric brain cancer patients in mind. As a pediatric neuro-oncologist, I've seen far too many children lose healthy tissue during brain surgery. I've seen far too many children come out of surgery only to have MRIs reveal

Clockwise from above:
Dr. Jim Olson with Carver Faull, a former patient.

Dr. Jim Olson hugs Carver Faull, a former patient, as Carver's family looks on.

Blitz (the official mascot of the Seattle Seahawks) comes to cheer on brain cancer patients and Dr. Jim Olson and team.

that their brains still house remnants of a tumor. I've seen far too many children die. We desperately need a way to make cancer cells light up so surgeons can see them while operating. We hope that Tumor Paint will do just that.

Tumor Paint also has potential well beyond brain cancer. In pre-clinical studies, it's been found to light up prostate, colon, breast, skin, and other cancers. We believe that if it's as successful in humans as it is in animals, this powerful little peptide—borrowed from nature and bettered through science—has the potential to help over a half million cancer patients a year.

And Tumor Paint is just the beginning. Over the past few years, we've been able to boost the number of optides we can develop from about 12 a year to 10,000 a month. Each of those optides is a potential key to turn the lock of a particular disease. Our team is working to uncover better treatments for a variety of cancers, along with autism, Alzheimer's, and other rare diseases unlikely to receive attention from pharmaceutical companies. We intend to share libraries of optide therapeutic candidates with other scientists around the world provided that Project Violet is successful.

Every animal, every plant in nature has a way of protecting itself so it can survive. Human beings are no different except we protect ourselves through science, through innovation, through creativity and, in this case, the generosity and vision of "citizen scientists" who've lost friends, neighbors and loved ones to cancer and other debilitating diseases. We protect ourselves with hope and heart and inspiration and, yes, a few amazing tricks borrowed from nature. OI

Jim Olson, MD, PhD, is a pediatric brain tumor specialist and researcher at Fred Hutchinson Cancer Research Center and Seattle Children's in Seattle, Wash.

careers

NURSE MANAGER
Warwick, Rhode Island

Major Responsibilities: Management of the daily operations of The Cancer Center Memorial Hospital of Rhode Island, ensuring smooth patient flow through both the Infusion Center and the Hematology and Oncology practice. Ensure staff competencies and make certain that The Cancer Center's processes and systems support the operation of the hospital, patient care and staff performance. Promote a culture of safety and excellence and ensure full compliance with all regulatory and accreditation requirements. Work collaboratively with physicians and nursing staff to deliver high quality patient care in both venues in an efficient and effective manner.

Education: Graduate of NLN School of Nursing required. Masters preferred. Rhode Island nursing license required. OCN certification required. Chemo-biotherapy required.

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DIRECTOR, ONCOLOGY SERVICES
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Olathe Health System, Inc. is looking for dedicated and caring professionals to join our system! Olathe Medical Center, Inc., a 300-bed general acute care facility is currently looking for a Director of Oncology Services to join our team. The Director of Oncology Services will oversee, direct, plan, market, and implement the oncology service line with direct responsibility for the overall staff of the cancer center in conjunction with the oncology service line Medical Director. This includes the functions of oncology outpatient infusion services, radiation oncology services, psychosocial services, cancer screening programs, the cancer committee, tumor registry, research program, and cancer center facilities with liaison/collaborative responsibility to the inpatient oncology unit.

Education: Master Nursing Administration, Master Hospital Administration or related field required.

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2-3 years oncology experience preferred.

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CERTIFIED NURSE PRACTITIONER (Breast Surgery)
Oakland, California

We are seeking a certified nurse practitioner to work alongside our dedicated team of healthcare providers at Epic Care, a surgical office based in Oakland.

Responsibilities include:

- Perform new surgical patient evaluations for pain, lumps, and other examination issues.
- Perform breast ultrasounds and preliminary evaluations of results.
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- Perform IP and OP post-op visits, along with providing inpatient care.
- Remove drains, aspirate Seromas, cysts.

Required Certification Requirements:

- California registered nursing license (current).
- Certified nurse practitioner (current).
- American Association of Nurse Practitioners (AANP).
- American Nurse Credentialing Center Board Certified (ANCC).

Education Requirements:

- B.S. Nursing required. Post graduate degree preferred. A minimum of 2 years' experience with an EMR system is required and 2 years minimum clinical oncology experience is preferred.

Apply online at epic-care.com
Click on the Career Opportunities tab to apply.

ONCOLOGY ARNPS
Auburn & Tacoma, Washington

MultiCare Health System is searching for two full-time oncology—advanced registered nurse practitioner (ARNPs)—one at our Auburn location and one at our Tacoma location to work with our established and expanding comprehensive cancer program. This position requires one weekend a month coverage in our infusion center. The MultiCare Regional Cancer Center is a network affiliate of the Seattle Cancer Care Alliance.

Competitive salary, a full array of benefits and a great location makes this an ideal choice for the provider who is looking to experience the best of Northwest living; from big city amenities to the pristine beauty and recreational opportunities of the great outdoors.

Apply online at http://blazenewtrails.org, email your CV to blazenewtrails@multicare.org, or fax your CV to 866.264.2818.

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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Issued: August 2012
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astellas ONCOLOGY

MEDIVATION

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

Xtandi (enzalutamide) capsules

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

Important Safety Information

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

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

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

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

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

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

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

Xtandi (enzalutamide) capsules

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

18.4 AND MORE:

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

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

Select Important Safety Information

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

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

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