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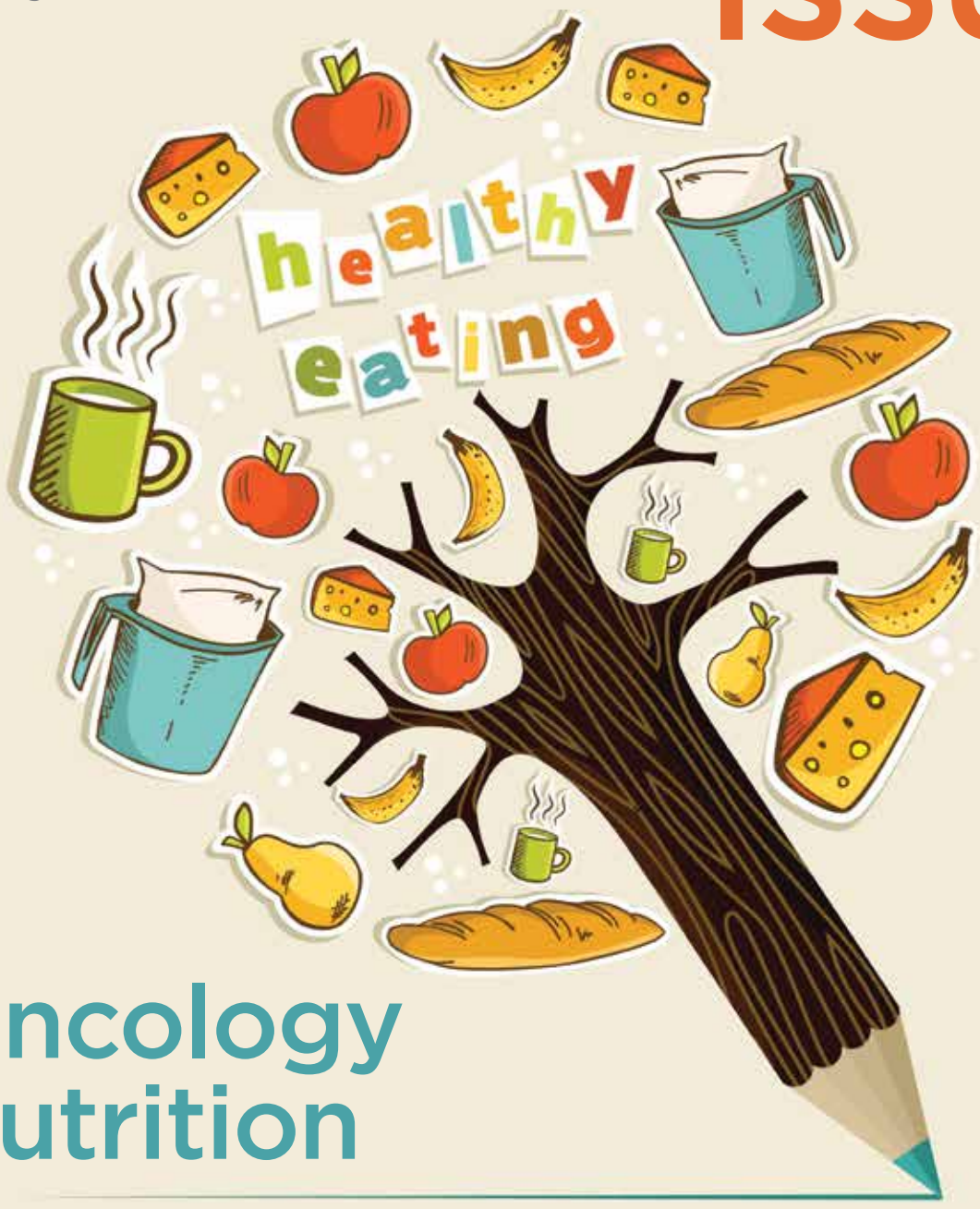
ONCOLOGY ISSUES

The Journal of the Association of Community Cancer Centers

July | August 2013



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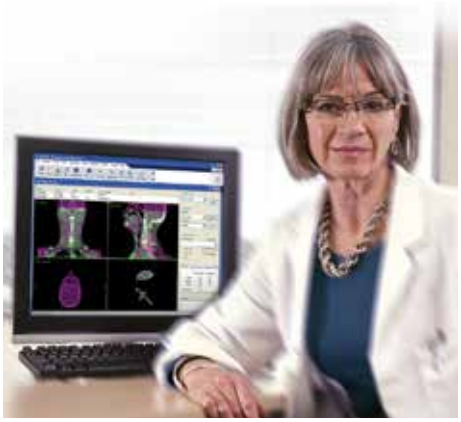

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Oncology Issues serves the multidisciplinary specialty of oncology care and cancer program management.

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

FROM THE EDITOR

Process Improvement at Work

BY CHRISTIAN DOWNS, JD, MHA

Researchers at the University of Michigan say process improvement (PI) serves as a common framework for understanding the cyclical, ongoing nature of a process. It provides a set of phased activities for analysis of an existing process for the specific purpose of identifying improvement opportunities and ensuring process alignment to customer needs and expectations. The concept of process improvement has been around in the manufacturing space since the early 1970s. While healthcare has been a little slower in its adoption, the oncology community remains at the forefront of PI efforts.

In this edition of *Oncology Issues*, we focus on four cancer programs that, in some way, used PI to better serve their patients and providers.

In our cover story, McGlinn Family Regional Cancer Center at Reading Hospital, Reading, Pa., wanted to ensure that patients at risk for malnutrition were identified early in the treatment process. Using a PI model, the cancer center developed a screening tool in 2012 to capture these at risk patients. Critical to this PI effort were strategies to reduce or eliminate financial barriers for patients needing nutrition services.

Next, Fox Chase Cancer Center, Philadelphia, Pa., developed a PI program aimed at improving patient flow and reducing hospital length of stay. As part of this PI effort, the cancer center identified and implemented a number of best practices, including a roving ADT nurse, a process for schedule "smoothing" in the OR, and performance dashboards. In 2012 Fox Chase Cancer Center was awarded an ACCC Innovator Award for this PI project.

Another 2012 ACCC Innovator Award winner, Akron General Medical Center, Akron, Ohio, developed and implemented a unique patient navigation program that reduced psychosocial distress, secured $1.35 million in direct financial assistance, and reduced institutional bad debt. This PI effort is a shining example of how an ACCC member program recognized a national trend—in this case, an increasing number of patients struggling to pay for their cancer treatment—and quickly developed strategies to address this trend. As you will read in the article, Akron General Medical Center's PI effort helped both patients and providers.

Finally, UT Southwestern Harold C. Simmons Cancer Center, Dallas, Tex., shares a blueprint for developing an integrated psychosocial oncology program. Using the examples of PI in distress screening and cancer survivorship services, the authors focus on three key programmatic areas: clinical service, research, and training.

As you will see, each of these ACCC members approached PI from a different perspective, based on the unique needs of their patient population and cancer program. And I encourage you to do the same. Start with research. Study your cancer program. What are your program's strengths and weaknesses? Are there issues or areas where improvement is needed? If so, partner with your providers and patients to develop strategies and make those improvements.

An important stop in your PI journey is to register for the ACCC 30th National Oncology Conference, Oct. 2-5, in Boston, Mass. At this meeting you will have the opportunity both to learn from ACCC's 2013 Innovator Award winners (www.accc-cancer.org/Innovator) and to share your successes and challenges with the broader oncology community. OI

PRESIDENT'S MESSAGE

Trending Now

BY VIRGINIA T. VAITONES, MSW, OSW-C

As I write this column, I'm looking at my tulips and daffodils—mindful that when you read this *Oncology Issues* many of you will be on vacation or checking off your "to do" and packing lists, getting ready to leave.

Change is a constant, whether it is the seasons or in the landscape we call "Cancer Care." Across the country our cancer programs are struggling with the changes brought about by sequestration, ongoing drug shortages, and a Congress that is seemingly unable to get much done to help our patients and our programs.

To help its members navigate through this constantly changing environment, ACCC has undertaken a multi-year survey that examines trends in community cancer centers. Key findings from the Year 4 Survey are highlighted in the eight-page gatefold, "2013 Trends in Community Cancer Centers," that mailed with this edition of *Oncology Issues*.

So what's trending now in the cancer community? The development of quality metrics and a methodology for reporting these metrics to payers and patients. The implementation of robust financial assistance programs to help our patients who struggle with high co-pays and deductibles. The consolidation of the marketplace—not only in terms of mergers and acquisitions, but also in collaborations to work on federal and state initiatives such as accountable care organizations and health exchanges.

The "2013 Trends in Community Cancer Centers" gatefold is just one of the many tools that ACCC provides its member programs to assist them with developing strategic plans, marketing to hospital leadership on cancer-specific issues, and benchmarking their program against comparable programs around the country.

For the non-administrator, results of this annual trends survey may validate what you have been hearing and reading at your specialty-specific conferences or in the news or possibly spark ideas for quality improvement projects.

The full Year 4 Survey report, as well as the Year 1 through Year 3 Survey reports, are available to ACCC members online at www.accc-cancer.org.

A cancer program's ability to successfully adapt and thrive in this evolving healthcare landscape is dependent on many groups of professionals. I'd like to call attention to two of those specialties today: oncology nurses and cancer registrars—both of whom are constantly challenged to learn and do more, often with fewer resources. Their professional organizations, the Oncology Nursing Society (ONS) and the National Cancer Registrars Association (NCRA), have just finished recognizing their members for their outstanding work. And I wanted to take a moment to say "thank you" from ACCC's multidisciplinary Board of Trustees for all that you do for our patients and programs. As I said in my first column as ACCC President, "It takes a team that works together to help our patients and our caregivers negotiate the complex world of cancer care."

With ACCC's education and advocacy support facilitating the sharing of our challenges as well as resources and solutions—all of our teams become stronger. OI

Call for Nominations

ACCC is now accepting nominations for its 2014 Annual Achievement Award and 2014 David King Community Scientist Award. For more information or to access the 2014 Awards Nomination Form online, go to www.accc-cancer.org. Completed forms should be returned to Careen Campbell either via email (ccampbell@accc-cancer.org) or by fax (301.770.1949). Deadline for nominations is August 16, 2013.

Coming in Your 2013 *ONCOLOGY ISSUES*

- A Model Rapid Access Chest & Lung Assessment Program
- Physician-Hospital Alignment: Bringing Together the PSA and MSA
- Survivor PLACE: A Multidisciplinary Approach to Survivorship Care
- A Model Outpatient Palliative Care Program
- Biosimilars: Emerging Issues for Cancer Programs?
- A Model Breast Care Center
- Establishing & Managing a Patient Assistance Fund at a Community Cancer Center
- New Advances in Genomic Testing for Breast Cancer: What You Need to Know
- Clinical Pathway Trends—Payers, Providers, and Healthcare Evolution
- Virtually There: How to Develop a Virtual Clinic
- Oncology Social Workers as Navigators

more online @ www.accc-cancer.org

TOOL

New Patient Assistance Programs

ACCC's *2013 Patient Assistance & Reimbursement* Guide now includes PAPs for patients being treated with Jakafi (ruxolitinib), Fareston (toremifene citrate), Sancuso (granisetron transdermal system), and Xofigo (radium Ra 223 dichloride injection). Learn more at www.accc-cancer.org/patientassistanceguide.

VIDEO

Get to Know ACCC's Community Resource Centers

These cancer programs serve as virtual "experts-in-residence" on small-population cancers for ACCC members. Watch their videos at www.accc-cancer.org/SPC.

TOOL

Update to ACCC's Oncology Drug Reference Guide

ACCC's guide now includes supportive care drugs. It also shows how sequestration is impacting drug payment rates under Medicare Part B. Learn more at www.accc-cancer.org/drugguide. Is your cancer program feeling the effects of the sequester? If so, we'd like to hear from you. Email mfarber@accc-cancer.org and share your story.

CALL

ACCC Members Want Information on Lung Cancer Screening

Did you miss the ACCC conference call about low-dose CT lung cancer screening programs? Access the archived call along with presenters' slides and FAQs on ACCC's MyNetwork site: mynetwork.accc-cancer.org/; search "lung cancer screening."

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

fast

Employer-Based Health Coverage Down Significantly

The percentage of Americans with employer health insurance coverage dropped from **64.4% in 1997** to **56.5% in 2010**.

Source: The Census Bureau survey report is at www.census.gov/prod/2013pubs/p70-134.pdf.

5 Facts about Hospice

1. Most hospice care is provided in the home
2. Hospice care is fully covered by Medicare, private insurance, and by Medicaid in most states
3. The hospice benefit pays for medications and medical equipment related to the illness
4. Hospice care can include complementary therapies, such as music and art
5. Hospices offer grief support to the family following the death of a loved one.

Source. National Hospice and Palliative Care Organization. www.caringinfo.org.

facts

8 Forces that Drive the Adoption of Clinical Pathways

1. Physician leadership
2. Clear communication of goals
3. A situation where everyone has a seat at the table
4. Meaningful benchmark reports
5. Alignment of provider incentives
6. Ease of use; must fit in with the clinical workflow
7. Support to other QI programs
8. Easy to go off pathways.

Source. Kathy Lokay. Presentation at ACCC's 2013 Annual National Meeting, March 2013.

Most Cancer Patients & Survivors Want To Continue Working

- **60%** of survey respondents reported taking no time off or only a few days off before returning to work after diagnosis
- **73%** felt employment gave them a sense of purpose and was tied to their identity
- **About 20%** reported feeling that cancer prevented them from carrying out professional responsibilities, reaching their true potential, or performing at the same level as their peers.

Source. Cancer and Careers. Harris Interactive Survey. Conducted Sept. 27-Oct. 3, 2012.

Why Is Congress So Interested in Quality Care?

BY MATTHEW FARBER, MA

Congress has adopted quality care as a priority goal for the Medicare program. Congress also wants to reduce the rate of spending growth, and the idea of doing so by providing quality care has truly caught on with lawmakers. From the PQRI program (now PQRS), to electronic prescribing, to meaningful use provisions for electronic health records, to the CMS Innovation Center, Congress has devoted a great deal of time and money toward improving the quality of care in this country.

The latest initiative is reworking the sustainable growth rate (SGR) formula. For many years, Congress has avoided looming SGR cuts with short-term "fixes" that did not solve the root of the problem. Congress and CMS know the SGR formula is flawed, but they have yet to devise a replacement methodology. This year, however, Congress may be on to something. It has asked specialty medical societies to help Congress develop a replacement formula based on a specialty-specific formula that would reward physicians for providing quality care to their patients.

Many say that this solution is easier said than done. First, Congress must still come up with approximately $140 billion to pay for elimination of the current formula. Then, Congress needs to develop a timeline—one that is not too ambitious so as to rush into change, but also timely enough so that the issue is not put aside in favor of other "hot-button" topics. Finally, and possibly most importantly, Congress will need the buy-in of nearly every specialty society in the medical community to develop their own set of quality metrics.

Some specialties, like oncology, are already developing measures. ASCO's QOPI program has been in practice for a few years, and more and more oncologists seem to be incorporating these measures into practice.

A great deal of work still needs to be done in order for Congress to introduce and pass a bill for the President to sign. Given the Congressional calendar, if a bill is introduced, it will likely come sometime in July through September. After hearings and debates, votes may not take place until the fall, putting the medical community at risk of yet another SGR cut that would go into effect Jan. 1, 2014. Some argue that Congress only seems to work under the pressure of a crisis, but the provider community would certainly prefer if a bill could get through the legislative body more quickly.

At the end of May, the effort to replace the SGR took a bit of a hit, as the Energy and Commerce Committee and the Ways and Means Committee decided to stop working together on SGR reform and go it alone, with each developing their own measure. While unfortunate, both efforts point in the same direction—replacing the current formula with one based on quality measures.

The oncology community must be involved in future discussions to ensure that whatever the new system looks like, it will reward true quality cancer care. ACCC will continue to work with its membership, Congress, and other key stakeholders, such as ASCO, to ensure that the voice of the community cancer center is heard.

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

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Why Everyone Needs a CDI Plan

BY CINDY PARMAN, CPC, CPC-H, RCC

While many valid reasons exist for physicians, midlevel providers, and other healthcare staff to document in the medical record, the healthcare organization can lose money when clinicians undervalue patient treatment through a lack of medical record documentation. To address this ever-present need, many cancer centers have initiated clinical documentation improvement (CDI) programs. A CDI program does not solely apply to the inpatient hospital setting; the plan is also a necessary survival tactic in both the hospital outpatient and freestanding setting.

Clinical documentation improvement has been a healthcare initiative since 1999[1] and an effective CDI plan can improve the billing cycle by ensuring that all services are coded correctly and charged promptly. In addition, a high rate of denials for services could indicate that coding and documentation are not properly aligned and that the provider could benefit from a CDI program. Last, while individual physicians are not publicly identified as quality providers by the Centers for Medicare & Medicaid Services (CMS) to date, they soon will be:[2]

In a continued effort to improve Physician Compare and to prepare the site for the eventual inclusion of quality of care information, CMS is currently in the process of completing a Physician Compare website redesign.

Better documentation leads to better care and higher reimbursement. For example, Borgess Health, a health system based in Kalamazoo, Mich., uncovered more than $6 billion in reimbursement by getting physicians to improve their documentation.[3] As part of the Ascension Health network, Borgess Health includes more than 120 care sites in 15 southern Michigan cities, as well as five owned or affiliated hospitals, a nursing home, ambulatory care facilities, home healthcare, physician practices, a cancer center, and an air ambulance service.

Defining CDI

A CDI initiative is a targeted program of producing, protecting, examining, and posting documents that contain accurate and clinically acceptable information regarding a patient's medical conditions.[4] Any deficiencies in medical record documentation can be addressed, which theoretically leads to a more complete medical record, allowing medical coders to apply concise and correct diagnosis and procedure codes.

During the past several years, CDI programs have moved from the hospital setting to a mainstream requirement for all practice settings. Current estimates find as many as two-thirds of hospitals have some type of CDI program.[5] For most institutions, CDI is an initiative of a Performance Improvement Committee or similar taskforce. This cross-departmental team holds monthly meetings, performs ongoing analysis, and ensures that there is continuing physician education on documentation requirements.

However, the cancer center itself may be organized as a freestanding facility, a remote provider-based department, or an on-campus hospital department. Regardless of the structure or physical location, the use of a unique electronic medical record (EMR) for cancer patients may require that the radiation oncology department or infusion center take full responsibility for their medical record documentation. This process includes developing a clinical documentation improvement program that supports the cancer program's unique EMR requirements.

As a CDI program takes root, those involved should gradually be able to refine their efforts, focusing only on certain diagnoses and new physicians or those individuals still having difficulties providing complete documentation. Thorough documentation supports:

1. The types of patients under treatment
2. How patients respond to a course of therapy
3. Patient acuity (by documenting and reporting diagnosis codes for comorbidities)
4. Complexity of the case.

A series of surveys conducted by 3M in August, October, and December 2012 indicated that clinical documentation improvement issues topped the list of ICD-10 concerns.[6]

Physician Engagement

For a CDI program to be successful there must be stakeholder buy-in and dedicated resources. Effective implementation of a CDI program requires showing physicians where they are missing documentation and involving medical coders or documentation

specialists to improve documentation of the clinical services performed. There is typically resistance during this phase of the process, primarily because extra physician time is required to achieve the necessary outcomes. However, physicians must be part of the team and work with medical coders or other staff to ensure that services are documented, coded, billed, and correctly reimbursed.

Since physician engagement is key, many CDI programs feature physician advisors, such as physician coaches, although there is no magic formula for success.[5] Other models employ nurses, case managers, nurse coders, and coding professionals as the primary CDI staff. Most cancer programs use a nurse reviewer or coding professional to fill the clinical documentation specialist role and these individuals have good communication skills and a basic knowledge of anatomy, oncology, and pathology.[7]

CDI programs can thrive without the benefit of outside help, such as a consulting firm, as long as the cancer center can provide the right strengths and talents internally. Both one-on-one education and group meetings may be necessary to correct any detected documentation deficiencies. At one hospital, clinicians took part in nearly 20 sessions during their specific staff meetings in order to prepare them for the coming documentation questions.[7]

A number of metrics can be used to demonstrate that clinical documentation that supports language to facilitate medical record coding can increase reimbursement. Essentially, if the extent of the patient's illness and/or multiple medical conditions is not included in the documentation, the medical record does not accurately reflect the patient care provided. Since cancer programs will likely one day be paid based on outcomes, now is the time to engage physicians in a CDI initiative.

Accurate documentation links directly to strong financial performance. Remember: a CDI program does not necessarily focus on *more* documentation; instead, the focus is *better* documentation. For example, a physician could document 10 pages of notes for a single encounter, but there may still not be sufficient documentation to code all services provided. As a result, CDI metrics can be incorporated into individual physician profile reports and management reports relating to quality and efficiency. Last, CDI also impacts data for continuity of care, regulatory requirements, accreditation, and quality scores.

1 More Reason to Document

Documentation requirements will continue to increase in complexity with ever changing rules and regulations, new reimbursement methods, and the transition to ICD-10. In addition, clinical care is judged on medical record documentation. Physician documentation is what supports or fails to support the clinician and the facility when a question arises relating to the necessity or competency of care. Medical record documentation has four primary objectives:

1. To document that the service was medically necessary for the patient
2. To demonstrate that the standard of care was met
3. To assist clinicians who will perform subsequent care
4. To justify billing the service performed.

Michelle Dougherty, AHIMA Foundation Director of Research, testified at the Office of the National Coordinator for Health IT's HIT Policy Committee meeting in February 2013; her statement included, in part:[8]

If clinical documentation was wrong when it was used for billing or legal purposes, it was wrong when it was used by another clinician, researcher, public health authority or quality reporting agency. It's crucial to address data quality and record integrity now before health information exchanges become widespread.

Establishing a CDI program will help align documentation and coding, which will enable the cancer program to withstand scrutiny during compliance audits and other regulatory actions. The overall goal of CDI is to make sure the information in the medical record accurately documents the severity of the patient's illness, as well as detailing the care provided to the patient. CDI initiatives that run smoothly not only provide quality information that can be used for a variety of purposes, but also promote cross-departmental collaboration between the CDI team, concurrent review, compliance review, and other performance improvement efforts.

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

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spotlight

Tallahassee Memorial Cancer Center

Consolidating care & expanding access

Tallahassee Memorial HealthCare is located in the Big Bend region of the Florida Panhandle, serving Leon County and beyond. In 2012 the cancer program celebrated 62 years of accreditation from the American College of Surgeons Commission on Cancer (CoC), making it the longest continually CoC-accredited Comprehensive Community Cancer Program in the state. Two years ago, Tallahassee Memorial HealthCare made a significant investment in the future of its cancer program by opening Tallahassee Memorial Cancer Center (TMCC). The new 52,800-square-foot cancer center fulfills two goals—consolidated cancer services and expanded access of care for the region.

Consolidated Care

TMCC brings radiation oncology and medical oncology services together in one convenient location with dedicated parking for patients and visitors. In January 2011 the new facility opened bringing state-of-the-art radiation oncology services to the community.

The first floor houses the radiation oncology department, research offices, tumor registry, patient navigation services, social work, and administrative and support offices. In July 2012 TMH Physician Partners Cancer & Hematology Specialists clinic and the outpatient infusion center opened on the second floor of the new cancer center. Located adjacent to the 30-chair infusion suite is a dedicated lab and pharmacy. This floor has space for 6 FTE physicians and 16 exam rooms.

Realizing the goal of consolidating oncology services has, in turn, helped achieve the goal of expanding access to care. TMCC's catchment area encompasses 10 Florida counties. Previously, this region was underserved in terms of the number of practicing medical oncologists located within the area. For some patients, this shortage meant traveling outside the region for care. With the opening of the new cancer center, additional physicians were recruited to the community, expanding patient access to care close to home.

TMCC's radiation oncology services have also expanded to meet the needs of its patient population. The new cancer center now features three linear accelerators, including a Novalis TX radiosurgery system, and offers the option of SRS and SBRT treatment. With the new technology in place, the program has seen a significant increase in the volume of SRS cases over the past year. "Having that treatment option available to patients is important to us," said Oncology Service Line Administrator, Matt Sherer, MBA, MHA, noting that previously patients were traveling outside the region for treatment. "We wanted patients to have a choice and to be able to stay here and get their cancer treatment close to home."

Patient-Centered Design

The cancer program's Patient Advisory Committee played a major role in the planning and design of the new cancer center. The committee, formed about five years ago, was tasked with making the new building patient and family friendly. The new cancer center features design elements that emphasize natural lighting and materials and warm colors, creating an inviting environment of care. Waiting areas were designed to have a cozy "living room" feel with wood-like flooring. Throughout the facility, large windows allow for plenty of sunlight. Walls adorned with artwork—from nature photographs reflecting the region's biodiversity to works by local artists—bring a soothing, peaceful ambience. Adjacent to the cancer center is a healing garden, which can be viewed by patients from the infusion suite and is tended by the Tallahassee Garden Club.

The Patient Advisory Committee continues to meet on a monthly basis, keeping patients and families updated on activities in the cancer center, advising TMCC staff on any improvements needed, and providing suggestions for additional services.

Planners also designed the building to be as easy as possible for patients to navigate, another step to reduce stress in the patient experience.

An important aspect of the new facility's design was planning for future growth. "We've done a good job of designing a building we can grow into," said Sherer. For example, the building's design and property layout will allow for the addition of two more vaults if future volumes continue to grow. Sherer said that based on patient volumes, whether an additional linear accelerator, a PET/CT, or an HDR-type treatment is needed, they can employ the additional vaults to suit their community's needs.

The infusion suite also has space to

expand to 30 chairs. "We wanted to be able to grow into this building for many years as opposed to maximizing the space immediately," Sherer said.

Commitment to Multidisciplinary Care

Another way TMCC works to expand access to care is through their affiliation with an academic medical center, UF Health Cancer Center. This partnership, announced in October 2012, increases availability of clinical research to cancer patients in the Big Bend region—both through clinical trials conducted by UF Health Cancer Center and other cooperative groups that UF Health has access to. The affiliation provides opportunities for oncology subspecialists from the academic center to participate in TMCC tumor boards via teleconferencing, furthering TMCC's mission to provide patients access to the best care available.

The breast tumor board and regular tumor board both meet weekly. A dedicated brain tumor conference meets every two weeks and a lung conference meets once a month.

The Sharon Ewing Walker Breast Center, part of the oncology service line, has two additional accreditations: NAPBC was achieved for the first time in November of 2011 and then in April of 2012 the breast center received ACR breast center of excellence designation. The program had been ACR-accredited for many years, but just recently achieved the highest designation level.

Creative Support Services

TMCC offers a wide array of support services to its patients. One service that patients specifically requested in the new cancer center is pet therapy. This service is offered two to three days a week throughout the cancer center.

In partnership with Florida State University, TMCC also offers art therapy. Two days a week, an art intern comes in and works with patients doing various types of artwork.

A writing workshop for patients occurs weekly. Offered both in the lobby and infusion area, this activity gives patients the opportunity to chronicle or write about their cancer journey.

For an in-depth look at TMCC's robust music therapy program, see its article in the November/December 2012 *Oncology Issues*.

TMCC employs three patient navigators: a dedicated breast cancer navigator, a dedicated lung cancer navigator, and a dedicated survivorship navigator. In addition to these navigators, TMCC also employs a full-time social worker and two registered dietitians.

Looking to the Future

Two areas for future cancer program growth are genetics services and palliative care. Currently TMCC has a geneticist-physician that works two days a week, with about 80 percent of her cases being cancer-related. As patient volumes and need for genetic services increase, TMCC is considering hiring a certified genetics counselor.

Currently in its third year, the inpatient palliative care program has seen phenomenal growth, which TMCC plans to accommodate by possibly adding more FTE positions and expanding the program to the outpatient setting. OI

Select Support Services

- Navigation services
- Survivorship program
- Integrative therapies
- Palliative care
- Pastoral care

- Analytic cases in 2011: 1,225
- Patients accrued to clinical trials in 2012: 4%

tools

Approved Drugs

- The Food and Drug Administration (FDA) has approved Celgene Corporation's (*www.celgene.com*) **Revlimid®** (lenalidomide capsules) for the treatment of patients with mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. This approval is the first approval of an oral therapy for the treatment of non-Hodgkin's lymphoma, enabling patients to treat their disease with minimal disruption to their lives.

- The FDA has approved **Tarceva® (erlotinib)** (Genentech, *www.gene.com*) for the first-line treatment of metastatic non-small cell lung cancer (NSCLC) patients whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. This indication for Tarceva is being approved concurrently with the cobas® EGFR Mutation Test, a companion diagnostic test for patient selection.

- The FDA approved **Xgeva®** (denosumab) (Amgen Inc., *www.amgen.com*) for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.

Expanded Coverage for Oncotype DX®

Effective May 8, 2013, Palmetto GBA has expanded its coverage policy for all qualified Medicare patients to include patients with ductal carcinoma *in situ* (DCIS) following the recent publication of the breast cancer test's DCIS Score in the peer-reviewed *Journal of the National Cancer Institute*.

- Bayer HealthCare Pharmaceuticals Inc. (*www.bayer.com*) announced that the FDA has approved **Xofigo Injection® (radium Ra 223 dichloride)** for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases, and no known visceral metastatic disease.

- GlaxoSmithKline (*www.gsk.com*) announced that the FDA has approved both **Tafinlar® (dabrafenib)** and **Mekinist™ (trametinib)**. Tafinlar is indicated as a single-agent oral treatment for unresectable melanoma or metastatic melanoma in adult patients with BRAF V600E mutation. Tafinlar is not indicated for the treatment of patients with wild-type BRAF melanoma.

  Mekinist is indicated as a single-agent oral treatment for unresectable or metastatic melanoma in adult patients with BRAF V600E or V600K mutations. Mekinist is not indicated for the treatment of patients who have received a prior BRAF inhibitor therapy. These mutations must be detected by an FDA-approved test.

Drugs in the News

- The FDA has granted breakthrough therapy designation for **daratumumab** (Janssen Research & Development, LLC, *www.janssenrnd.com*) for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who are double refractory to a PI and IMiD.

New Clinical Trial Matching Service

CureLauncher (*www.CureLauncher.com*) is a clinical trial matching service that helps determine the clinical trials that are best aligned with a person's unique goals and conditions. The personalized service is free to users and matches people to any of the 10,000 enrolling trials in the U.S. CureLauncher provides easy-to-understand information and supports people throughout the entire process—from considering a clinical trial to scheduling an appointment to meet the trial staff.

Approved Devices

- Hologic, Inc. (*www.hologic.com*), announced that the FDA has approved the use of its **C-View 2D imaging software**. C-View 2D images may now be used in place of the conventional 2D exposure previously required as part of a Hologic 3D mammography screening exam.

Devices in the News

- Olympus (*www.olympusamerica.com*) announced the commercial availability of its 510(k) cleared **BF-190 bronchoscopes**. The new BF-190 bronchoscopes offer maneuverability and flexibility through the combination of their rotary function and wider tip angulation, which will potentially allow physicians to access areas of the lung that may not be easily reached with current generation bronchoscopes. OI

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healthy
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A Quality Improvement Nutrition Program

The McGlinn Family Regional Cancer Center Experience

BY JESSICA NORRIS, MA, RD, CSO, LDN

The McGlinn Family Regional Cancer Center at Reading Hospital offers nutrition services on a subjective physician-referral basis through a billable service. Current guidelines from the American Society for Parenteral and Enteral Nutrition and the National Cancer Institute (NCI) recommend that all cancer patients be screened for nutritional risk.[1] One study of 1,453 cancer outpatients found that 32 percent of patients had a nutritional risk for poor outcomes.[2] Proactive nutrition screening and intervention are the cornerstones of success in managing cancer-related cachexia, malnutrition, and nutrition impact symptoms associated with cancer and its treatment.[3] Although oncology nutrition services are an integral part of any comprehensive cancer center, reimbursement by public and private payers has historically been problematic.[4]

Cancer patients who experience weight loss have more treatment breaks, require more and longer hospitalizations, and experience more severe side effects from their treatment. Patients who maintain their weight and nutritional status experience fewer breaks in their therapy and treatment.[4] Between 2000 and 2003, one study randomized 111 patients undergoing radiotherapy for colorectal cancer to dietary counseling, protein supplements, or ad libitum intake.[5] While both counseling and supplements improved outcomes during radiotherapy, only counseling resulted in sustained benefits three months later.[5] Registered dietitians (RDs) are highly educated nutrition experts who offer an incredible benefit to cancer patients and staff by providing timely information on symptom management, as well as resources for accurate evidence-based nutrition information.[4]

In 2012 the McGlinn Family Regional Cancer Center at Reading Hospital addressed these challenges in a quality improvement (QI) project that looked to 1) implement a screening tool to capture all oncology patients at risk for malnutrition and 2) reduce or eliminate financial barriers for patients needing nutrition services.

Screening & Assessment Tools

The terms screening and assessment are often used interchangeably. Nutrition screening by healthcare professionals is defined as the identification of cancer-related malnutrition and/or associated nutrition impact symptoms. Since cancer-related malnutrition is multifactorial, and because many of these factors may be manageable, especially when identified and treated early in the course of the disease, it is essential that nutrition issues be addressed at diagnosis and throughout the course of cancer care.[3] Nutrition screening initiates nutrition assessment, which is the first step of the nutrition care process and is defined as the:[3]

- Collection of timely and pertinent information
- Use of valid and reliable methods for data collection
- Comparison of gathered data to evidence-based standards, norms, and ideals.

Proactive nutrition screening and intervention are the cornerstones of success in managing cancer-related cachexia, malnutrition, and nutrition impact symptoms associated with cancer and its treatment.

Not all available nutrition screening tools are specific to the oncology population. For example, the Mini Nutritional Assessment (MNA) was developed as a quick and efficient tool that works well to screen for malnutrition in the elderly, but is not currently validated in the oncology population.[3] The Subjective Global Assessment (SGA) has been used in a number of patient populations and has been shown to have sensitivity and specificity over more traditional measures of nutrition assessment, although healthcare professionals often resist performing the nutrition-related physical examination. In addition, the list of nutritional impact symptoms specific to cancer is incomplete and does not include a triage component.[3]

In the mid 1990s, Dr. Faith Ottery adapted the SGA to meet

the needs of the oncology patient population. The resulting tool, the Patient-Generated Subjective Global Assessment (PG-SGA), involved patient interaction in the process.[3] The tool has been validated for use in the oncology population and has been found to correlate closely with quality of life.[3] The PG-SGA includes calculations of percent change in body weight and a nutrition-related physical exam, both of which may be time consuming to the clinical staff administering the screening tool. In order to be effective and to not merely add more responsibility to nursing and other medical staff, a screening tool must be easy-to-use and cost effective, must contain an action plan, and must be validated.[3] Therefore, individual cancer programs have been adapting and abridging the PG-SGA to facilitate its use.[3]

Our Process

Before this QI project, RD services were available by physician referral. Insured and uninsured patients face increased out-of-pocket expenses and co-payments, so they have less disposable income to pay for registered dietitian services, which are often not covered by payers in the absence of diabetes mellitus, chronic kidney disease, or obesity. To help all cancer patients at risk of malnutrition, hospital administration approved the cancer center's use of donated funds to cover a nutrition screening process for patients at risk of malnutrition.

Next, our oncology registered dietitian asked nursing staff how they could implement the PG-SGA and if barriers existed to implementing the tool. Feedback from nursing staff reported that the PG-SGA was too "cumbersome" and would take too long to administer and calculate the score, and then refer the patient to nutrition services. Taking this feedback into consideration, our oncology registered dietitian researched screening tools developed and implemented at other cancer centers and reached out to the Oncology Nutrition Dietetic Practice Group (ON DPG) of the American Academy of Nutrition and Dietetics for additional ideas and input. The result was a modified version of the PG-SGA. The M-SGA tool better met the needs of our patient population and staff members (see Figure 1, page at right).

Our oncology registered dietitian then met with radiation oncology staff to develop an implementation plan. In May 2012 radiation oncology started piloting the M-SGA tool and process. Next, our oncology registered dietitian met with supervisory staff of medical oncology to develop an implementation plan for medical oncology. In September 2012 medical oncology started piloting the M-SGA tool. The form is filled out:

- By all new cancer patients that will be undergoing treatment in the medical oncology or radiation oncology department
- At initial treatment by radiation oncology and medical oncology staff
- Once weekly during radiation oncology treatments on the day that the patient has their physician appointment
- Once monthly during treatment for medical oncology.

The form is completed multiple times during treatment to continue to monitor for nutrition-impact symptoms based on side effects that may occur at any time throughout treatment.

> Cancer patients who experience weight loss have more treatment breaks, require more and longer hospitalizations, and experience more severe side effects from their treatment.

Barriers & Challenges

During the pilot phase, our initial barrier was simply implementing a change in practice. Changes to our weekly workflow presented a new standard of care that took time to become habit. Currently, our M-SGA is a paper form. We found that radiation oncology nursing was electronically documenting the M-SGA score in its EMR in addition to using the paper form. Medical oncology was using the paper M-SGA form only due to unique EMR workflow. Duplication of referrals from medical oncology and radiation oncology is one aspect that will be eliminated when the entire cancer center begins using the same EMR in October 2013.

Currently, nutrition services receive duplicate forms for the same patient. Patients are filling out the same form more than once to prevent them from slipping by without nutrition screening. This process too will improve when medical oncology and radiation oncology begin using the same EMR. Right now, this duplication means more staff time spent administering the M-SGA and more time spent trying to schedule patients. This duplication will also be eliminated in October 2013 with the

(*continued on page 18*)

McGlinn Family Regional Cancer Center
Modified-Subjective Global Assessment (M-SGA)*

Patient Name: _____

Date of birth: _____ Date: _____ MRN: _____

Please complete all questions to the best of your knowledge in boxes 1 through 5.

1. Weight:

My current and recent weight:

I currently weigh about _____ pounds

I am about _____ feet _____ inches

One month ago I weighed about _____ pounds

Six months ago I weighed about _____ pounds

During the past two weeks my weight has:

Decreased (1) Not changed Increased (1)

2. Food Intake:

As compared to my usual intake, I would rate my food intake during the past month as:

☐ Unchanged
☐ More than usual
☐ Less than usual

I am now taking:

☐ Usual food but less than usual amount (1)
☐ Little solid foods (2)
☐ Only liquids (3)
☐ Very little of anything (4)
☐ Only tube feedings or only nutrition by vein (4)

3. Symptoms:

I have had the following problems that have kept me from eating my usual intake during the past two weeks (check all that apply):

☐ No problems eating
☐ No appetite (2)
☐ Nausea (1)
☐ Constipation (1)
☐ Mouth sores (2)
☐ Funny taste or no taste (1)
☐ Problems swallowing (2)
☐ Vomiting (2)
☐ Diarrhea (3)
☐ Dry mouth (1)
☐ Smells bother me
☐ Feel full quickly (1)
☐ Fatigue (1)

4. Supplementation:

I am using the following nutritional supplements during my cancer treatment (check all that apply):

☐ I drink more than 2 medical food supplements per day. (Example: Ensure®, Nutrashake®, Boost®, Glucerna®, etc.) (1)

☐ Vitamin/Mineral/Herbal supplements: Please list. (1)

_____

_____

_____

_____

5. Would it be okay if we refer you to the Registered Dietitian/Nutritionist based on your score? ☐ YES ☐ NO

Patient Signature: _____

Initial: _____ Follow-up: _____

Nutritional Triage Recommendations for office staff only:

Add scores from small numbers. 0-2: Low Nutrition Risk, Handout Class Flyer. ≥3: Deposit in Nutrition Folder

Total Score: _____ Cancer Diagnosis & Code: _____ Date: _____ Time: _____

Signature & Title: _____

*Modified from Dr. Faith Ottery's Scored Patient-Generated Subjective Global Assessment (PG-SGA).

adoption of one EMR. During the pilot phase, we made minor changes to the M-SGA form. Changes included:

- Adding the medical record number to the form
- Removing the statement "fill out nutrition referral form." This action did not need to take place if the M-SGA form is a 3 or higher. The M-SGA form score of 3 or higher acts as the form of communication to nutrition services.
- Adding the cancer diagnosis and code to the form
- Updating the form to include where clinical staff is to place the form once it is completed. The location is different for medical oncology and radiation oncology.

Finally, to eliminate some staff confusion, we updated our policies and procedures identifying patients that are included in the free screening program and fee-for-service patients. Our current policy can be found below.

Once the policy was updated, our oncology registered dietitian met with medical oncology nursing staff about the changes, received feedback from nursing after using the M-SGA tool for greater than six months, and responded to any staff questions. Our oncology registered dietitian then met with radiation oncology nursing staff and radiation therapists about policy changes, received feedback from using the M-SGA tool for greater than 10 months, and answered questions. This learning experience was beneficial for both the oncology registered dietitian and the staff that administers the M-SGA tool.

> By increasing the number of patients scheduled for nutrition appointments, our staff has been able to help patients better manage their nutrition-impact symptoms, which in turn will help decrease treatment breaks.

Our oncology registered dietitian has worked with the EMR builder to develop an electronic M-SGA for staff to use. The

UPDATED POLICY AND PROCEDURES FOR SCREENING PROGRAM

All patients at the McGlinn Family Regional Cancer Center that are currently receiving active treatment will undergo a nutrition screening process using the M-SGA at regularly scheduled intervals. Active treatment at the McGlinn Family Regional Cancer Center includes: chemotherapy, hormonal therapy, biotherapy, molecular targeted therapy, and/or radiation therapy that encompasses, but is not limited to: RapidArc, IMRT, IGRT, HDR, brachytherapy, SBRT, and SRS for a cancer diagnosis.

A. Patients that score according to the parameters on the M-SGA will have access to an RD, LDN.

- The M-SGA screening tool will be administered by nursing staff or medical assistant staff.
- The M-SGA is filled out by the staff, patient, or family member or individuals with power of attorney and administered by staff at regular intervals.
  - + The M-SGA will be administered at initial visit to all patients.
  - + The M-SGA will be administered once weekly for radiation therapy patients.
  - + The M-SGA will be administered once monthly for medical oncology patients.
- The M-SGA will be scored and appropriate intervention will be completed by staff.

M-SGA screening tool scoring system:

- M-SGA score of 0-2 = *At Low Nutrition Risk* = no RD, LDN intervention required. Continue to monitor.
- M-SGA score of 3 or more = *At Nutrition Risk* = refer to RD, LDN for comprehensive nutrition assessment.

B. An additional method for all patients at the McGlinn Family Regional Cancer Center that are currently receiving active treatment to have access to the RD, LDN is through a nutrition referral from their physician.

C. A patient may also be offered RD, LDN services through a fee-for-service pathway if a patient requests to see the RD, LDN without failing the M-SGA screening tool and without referral

electronic M-SGA tool will require the clinician to ask the patient the questions instead of the patient filling out the paper form; however, this process will eliminate the duplicate M-SGA forms filled out by radiation oncology and medical oncology. This next step allows us to continue to improve our care.

Metrics to Monitor Success

The metrics we use to monitor program success include brief discussions with staff members involved in the process and the data collection as shown in Tables 1-10 (pages 20-22). The administrative staff that collected the M-SGA form was responsible for the ongoing data collection and monitoring. After we made policy changes to the nutrition screening program and improved the workflow, we conducted clinical staff education in March 2013.

Our quality improvement effort was a success. The McGlinn Family Regional Cancer Center increased access to nutrition services by using the M-SGA screening tool to assess risk of malnutrition and by removing a cost barrier. These process improvements have allowed our nutrition services to reach a larger volume of patients than previously. By increasing the number of patients scheduled for nutrition appointments, our staff has been able to help patients better manage their nutrition impact symptoms, which in turn will hopefully help decrease treatment breaks. OI

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from physician. The fee-for-service pathway may include insurance reimbursement or out-of-pocket expense.

D. Oncology Nutrition Therapy as evidence-based practice will be provided for all pertinent nutrition issues. Handouts and booklets will be utilized as appropriate.

E. Nutrition assessment, education, and interventions will be documented using the Academy of Nutrition and Dietetics' Nutrition Care Process and Standardized Language. Documentation will be available in the EMR and copies provided to the referring physician and other healthcare team members per patient request.

F. An appointment will be made available to the patient within one week of receiving the failed M-SGA screening tool score or referral.

G. Appointments will be scheduled as appropriate during treatment and will allow one follow-up appointment after active treatment is completed. At that time, nutrition services will transition to Outpatient Nutrition Services and will entail a fee-for-service pathway.

H. In addition, for a nominal fee, group session nutrition lectures conducted by an RD, LDN are available to McGlinn Family Regional Cancer Center patients and the community.

I. Patients may also be made aware of opportunities to participate in additional nutrition cancer-related group lectures, disease management educational opportunities, support groups, and other integrative medicine programs as provided by Reading Hospital.

Table 1. Data Collection, July 2012

Week of July	1	8	15	22	29	Total
Forms filled out	12	9	60	54	44	179
Nutrition score < 3	9	2	39	39	27	116
Nutrition score ≥ 3	3	7	20	15	17	62
"Yes" to dietitian	7	6	28	22	22	85
Nutrition appointments	0	0	0	0	2	2
"No" to dietitian	4	3	30	30	21	88
Physician referrals	0	0	0	0	5	5
"Yes" to dietitian < 3	5	1	9	14	11	40
"No" to dietitian ≥ 3	1	1	5	6	6	19
Possible appointments	2	6	15	9	11	43

Table 2. Data Collection, August 2012

Week of August	5	12	19	26	Total
Forms filled out	27	30	20	36	113
Nutrition score < 3	14	22	12	28	76
Nutrition score ≥ 3	13	8	8	8	37
"Yes" to dietitian	16	17	11	19	63
Nutrition appointments	2	3	1	4	10
"No" to dietitian	8	10	9	17	44
Physician referrals	9	7	5	4	25
"Yes" to dietitian < 3	8	10	7	16	41
"No" to dietitian ≥ 3	4	1	4	4	13
Possible appointments	9	7	4	4	24

Table 5. Data Collection, November 2012

Week of November	4	11	18	25	Total
Forms filled out	12	15	25	13	65
Nutrition score < 3	6	12	12	8	38
Nutrition score ≥ 3	6	3	13	5	27
"Yes" to dietitian	8	8	11	8	35
Nutrition appointments	4	0	4	3	11
"No" to dietitian	4	7	14	5	30
Physician referrals	5	1	5	3	14
"Yes" to dietitian < 3	3	7	6	5	21
"No" to dietitian ≥ 3	1	2	8	2	13
Possible appointments	5	1	5	3	14

Table 6. Data Collection, December 2012

Week of December	2	9	16	23	Total
Forms filled out	17	16	13	12	58
Nutrition score < 3	10	13	9	6	38
Nutrition score ≥ 3	7	3	4	6	20
"Yes" to dietitian	7	3	7	8	25
Nutrition appointments	3	2	0	1	6
"No" to dietitian	10	7	6	4	27
Physician referrals	3	3	3	3	12
"Yes" to dietitian < 3	4	9	5	4	22
"No" to dietitian ≥ 3	4	0	1	3	8
Possible appointments	3	3	3	3	12

Table 3. Data Collection, September 2012

Week of September:	2	9	16	23	Total
Forms filled out	24	20	21	18	83
Nutrition score < 3	14	14	14	14	56
Nutrition score ≥ 3	10	6	7	4	27
"Yes" to dietitian	11	10	6	11	38
Nutrition appointments	1	3	2	2	8
"No" to dietitian	13	10	15	7	45
Physician referrals	2	4	4	4	14
"Yes" to dietitian < 3	9	6	4	6	25
"No" to dietitian ≥ 3	8	2	5	0	15
Possible appointments	2	4	2	4	12

Table 4. Data Collection, October 2012

Week of October:	1	7	14	21	28	Total
Forms filled out	10	24	13	23	11	81
Nutrition score < 3	8	17	7	14	10	56
Nutrition score ≥ 3	2	7	6	9	1	25
"Yes" to dietitian	7	14	6	16	5	48
Nutrition appointments	2	6	3	6	1	18
"No" to dietitian	3	10	7	7	6	33
Physician referrals	2	6	5	6	1	20
"Yes" to dietitian < 3	5	8	1	10	4	28
"No" to dietitian ≥ 3	0	1	1	3	0	5
Possible appointments	2	6	5	6	1	20

Table 7. Data Collection, January 2013

Week of January:	30	6	13	20	27	Total
Forms filled out	17	32	26	15	29	119
Nutrition score < 3	12	21	16	7	22	78
Nutrition score ≥ 3	5	11	10	8	7	41
"Yes" to dietitian	9	20	13	8	14	64
Nutrition appointments	3	4	2	3	5	17
"No" to dietitian	8	12	13	7	11	51
Physician referrals	4	7	6	5	5	27
"Yes" to dietitian < 3	5	13	7	3	13	41
"No" to dietitian ≥ 3	1	4	4	3	2	14
Possible appointments	4	7	6	5	5	27

Table 8. Data Collection, February 2013

Week of February:	3	10	17	24	Total
Forms filled out	30	14	31	25	100
Nutrition score < 3	28	9	22	19	78
Nutrition score ≥ 3	2	5	9	6	22
"Yes" to dietitian	12	6	19	9	46
Nutrition appointments	1	4	5	1	11
"No" to dietitian	18	8	12	16	54
Physician referrals	2	4	7	2	15
"Yes" to dietitian < 3	10	2	12	7	31
"No" to dietitian ≥ 3	1	1	2	4	8
Possible appointments	1	4	7	2	14

Table 9. Data Collection, March 2013

Week of March:	3	10	17	24	Total
Forms filled out	53	39	27	38	157
Nutrition score < 3	32	27	24	31	114
Nutrition score ≥ 3	21	12	3	7	43
"Yes" to dietitian	27	17	8	22	74
Nutrition appointments	12	5	1	6	24
"No" to dietitian	26	22	19	16	83
Physician referrals	12	6	1	6	25
"Yes" to dietitian < 3	14	11	7	16	48
"No" to dietitian ≥ 3	8	6	2	1	17
Possible appointments	13	6	1	6	26

Table 10. Patients Seen, 2012

Month	Total
January 2012	11
Febuary 2012	8
March 2012	11
April 2012	11
May 2012	27
June 2012	27
July 2012	29
August 2012	37
September 2012	39
October 2012	63
November 2012	57
December 2012	67

Our quality improvement effort was a success. Using the M-SGA, the McGlinn Family Regional Cancer Center increased access to nutrition services by removing a cost barrier.

For appropriate patients receiving highly emetogenic chemotherapy who are at risk of chemotherapy-induced nausea and vomiting (CINV)

PREVENTION BEGINS WHERE TRIPLE THERAPY STARTS

On Cycle 1, Day 1, start with Triple Therapy—EMEND® (fosaprepitant dimeglumine) for Injection, a 5-HT$_3$ antagonist, and a corticosteroid—for first-line prevention of CINV.

EMEND for Injection, in combination with other antiemetic agents, is indicated in adults for prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy, including high-dose cisplatin.

EMEND for Injection has not been studied for treatment of established nausea and vomiting. Chronic continuous administration of EMEND for Injection is not recommended.

Selected Important Safety Information

- EMEND for Injection is contraindicated in patients who are hypersensitive to EMEND for Injection, aprepitant, polysorbate 80, or any other components of the product. Known hypersensitivity reactions include flushing, erythema, dyspnea, and anaphylactic reactions.
- Aprepitant, when administered orally, is a moderate cytochrome P450 isoenzyme 3A4 (CYP3A4) inhibitor. Because fosaprepitant is rapidly converted to aprepitant, neither drug should be used concurrently with pimozide or cisapride. Inhibition of CYP3A4 by aprepitant could result in elevated plasma concentrations of these drugs, potentially causing serious or life-threatening reactions.
- EMEND for Injection should be used with caution in patients receiving concomitant medications, including chemotherapy agents, that are primarily metabolized through CYP3A4. Inhibition of CYP3A4 by EMEND for Injection could result in elevated plasma concentrations of these concomitant medications. Conversely, when EMEND for Injection is used concomitantly with another CYP3A4 inhibitor, aprepitant plasma concentrations could be elevated. When EMEND for Injection is used concomitantly with medications that induce CYP3A4 activity, aprepitant plasma concentrations could be reduced, and this may result in decreased efficacy of aprepitant.
- Chemotherapy agents that are known to be metabolized by CYP3A4 include docetaxel, paclitaxel, etoposide, irinotecan, ifosfamide, imatinib, vinorelbine, vinblastine, and vincristine. In clinical studies, EMEND® (aprepitant) was administered commonly with etoposide, vinorelbine, or paclitaxel. The doses of these agents were not adjusted to account for potential drug interactions. In separate pharmacokinetic studies, EMEND did not influence the pharmacokinetics of docetaxel or vinorelbine.
- Because a small number of patients in clinical studies received the CYP3A4 substrates vinblastine, vincristine, or ifosfamide, particular caution and careful monitoring are advised in patients receiving these agents or other chemotherapy agents metabolized primarily by CYP3A4 that were not studied.

Selected Important Safety Information *(continued)*

- There have been isolated reports of immediate hypersensitivity reactions including flushing, erythema, dyspnea, and anaphylaxis during infusion of fosaprepitant. These hypersensitivity reactions have generally responded to discontinuation of the infusion and administration of appropriate therapy. It is not recommended to reinitiate the infusion in patients who have experienced these symptoms during first-time use.
- Coadministration of EMEND for Injection with warfarin (a CYP2C9 substrate) may result in a clinically significant decrease in international normalized ratio (INR) of prothrombin time. In patients on chronic warfarin therapy, the INR should be closely monitored in the 2-week period, particularly at 7 to 10 days, following initiation of EMEND for Injection with each chemotherapy cycle.
- The efficacy of hormonal contraceptives may be reduced during coadministration with and for 28 days after the last dose of EMEND for Injection. Alternative or backup methods of contraception should be used during treatment with and for 1 month after the last dose of EMEND for Injection.
- Chronic continuous use of EMEND for Injection for prevention of nausea and vomiting is not recommended because it has not been studied and because the drug interaction profile may change during chronic continuous use.
- In clinical trials of EMEND® (aprepitant) in patients receiving highly emetogenic chemotherapy, the most common adverse events reported at a frequency greater than with standard therapy, and at an incidence of 1% or greater were hiccups (4.6% EMEND vs 2.9% standard therapy), asthenia/fatigue (2.9% vs 1.6%), increased ALT (2.8% vs 1.5%), increased AST (1.1% vs 0.9%), constipation (2.2% vs 2.0%), dyspepsia (1.5% vs 0.7%), diarrhea (1.1% vs 0.9%), headache (2.2% vs 1.8%), and anorexia (2.0% vs 0.5%).
- In a clinical trial evaluating safety of the 1-day regimen of EMEND for Injection 150 mg compared with the 3-day regimen of EMEND, the safety profile was generally similar to that seen in prior highly emetogenic chemotherapy studies with aprepitant. However, infusion-site reactions occurred at a higher incidence in patients who received fosaprepitant (3.0%) than in those who received aprepitant (0.5%). Those infusion-site reactions included infusion-site erythema, infusion-site pruritus, infusion-site pain, infusion-site induration, and infusion-site thrombophlebitis.

Please see the adjacent Brief Summary of the Prescribing Information.

An antiemetic regimen including

EMEND® (fosaprepitant dimeglumine) for Injection

Prevention From the Start

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Brief Summary of the Prescribing Information for

EMEND® (fosaprepitant dimeglumine) For Injection

INDICATIONS AND USAGE

EMEND for Injection is a substance P/neurokinin 1 (NK_1) receptor antagonist indicated in adults for use in combination with other antiemetic agents for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin.

Limitations of Use: EMEND for Injection has not been studied for the treatment of established nausea and vomiting.

Chronic continuous administration is not recommended *[see Warnings and Precautions]*.

CONTRAINDICATIONS

Hypersensitivity: EMEND for Injection is contraindicated in patients who are hypersensitive to EMEND for Injection, aprepitant, polysorbate 80, or any other components of the product. Known hypersensitivity reactions include flushing, erythema, dyspnea, and anaphylactic reactions *[see Adverse Reactions]*.

Concomitant Use With Pimozide or Cisapride: Aprepitant, when administered orally, is a moderate cytochrome P450 isoenzyme 3A4 (CYP3A4) inhibitor following the 3-day antiemetic dosing regimen for CINV. Since fosaprepitant is rapidly converted to aprepitant, do not use fosaprepitant concurrently with pimozide or cisapride. Inhibition of CYP3A4 by aprepitant could result in elevated plasma concentrations of these drugs, potentially causing serious or life-threatening reactions *[see Drug Interactions]*.

WARNINGS AND PRECAUTIONS

CYP3A4 Interactions: Fosaprepitant is rapidly converted to aprepitant, which is a moderate inhibitor of CYP3A4 when administered as a 3-day antiemetic dosing regimen for CINV. Fosaprepitant should be used with caution in patients receiving concomitant medications that are primarily metabolized through CYP3A4. Inhibition of CYP3A4 by aprepitant or fosaprepitant could result in elevated plasma concentrations of these concomitant medications. When fosaprepitant is used concomitantly with another CYP3A4 inhibitor, aprepitant plasma concentrations could be elevated. When aprepitant is used concomitantly with medications that induce CYP3A4 activity, aprepitant plasma concentrations could be reduced, and this may result in decreased efficacy of aprepitant *[see Drug Interactions]*.

Chemotherapy agents that are known to be metabolized by CYP3A4 include docetaxel, paclitaxel, etoposide, irinotecan, ifosfamide, imatinib, vinorelbine, vinblastine, and vincristine. In clinical studies, the oral aprepitant regimen was administered commonly with etoposide, vinorelbine, or paclitaxel. The doses of these agents were not adjusted to account for potential drug interactions.

In separate pharmacokinetic studies, no clinically significant change in docetaxel or vinorelbine pharmacokinetics was observed when the oral aprepitant regimen was coadministered. Due to the small number of patients in clinical studies who received the CYP3A4 substrates vinblastine, vincristine, or ifosfamide, particular caution and careful monitoring are advised in patients receiving these agents or other chemotherapy agents metabolized primarily by CYP3A4 that were not studied *[see Drug Interactions]*.

Hypersensitivity Reactions: Isolated reports of immediate hypersensitivity reactions including flushing, erythema, dyspnea, and anaphylaxis have occurred during infusion of fosaprepitant. These hypersensitivity reactions have generally responded to discontinuation of the infusion and administration of appropriate therapy. Reinitiation of the infusion is not recommended in patients who experience these symptoms during first-time use.

Coadministration With Warfarin (a CYP2C9 substrate): Coadministration of fosaprepitant or aprepitant with warfarin may result in a clinically significant decrease in international normalized ratio (INR) of prothrombin time. In patients on chronic warfarin therapy, the INR should be closely monitored in the 2-week period, particularly at 7 to 10 days, following initiation of fosaprepitant with each chemotherapy cycle *[see Drug Interactions]*.

Coadministration With Hormonal Contraceptives: Upon coadministration with fosaprepitant or aprepitant, the efficacy of hormonal contraceptives may be reduced during and for 28 days following the last dose of either fosaprepitant or aprepitant. Alternative or backup methods of contraception should be used during treatment with and for 1 month following the last dose of fosaprepitant or aprepitant *[see Drug Interactions]*.

Chronic Continuous Use: Chronic continuous use of EMEND for Injection for prevention of nausea and vomiting is not recommended because it has not been studied and because the drug interaction profile may change during chronic continuous use.

ADVERSE REACTIONS

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

Since EMEND for Injection is converted to aprepitant, those adverse reactions associated with aprepitant might also be expected to occur with EMEND for Injection.

The overall safety of fosaprepitant was evaluated in approximately 1,100 individuals and the overall safety of aprepitant was evaluated in approximately 6,500 individuals.

Oral Aprepitant: Highly Emetogenic Chemotherapy (HEC): In 2 well-controlled clinical trials in patients receiving highly emetogenic cancer chemotherapy, 544 patients were treated with aprepitant during Cycle 1 of chemotherapy and 413 of these patients continued into the multiple-cycle extension for up to 6 cycles of chemotherapy. Oral aprepitant was given in combination with ondansetron and dexamethasone.

In Cycle 1, adverse reactions were reported in approximately 17% of patients treated with the aprepitant regimen compared with approximately 13% of patients treated with standard therapy. Treatment was discontinued due to adverse reactions in 0.6% of patients treated with the aprepitant regimen compared with 0.4% of patients treated with standard therapy.

The most common adverse reactions reported in patients treated with the aprepitant regimen (n=544) with an incidence of >1% and greater than with standard therapy (n=550), respectively, are listed below:

Respiratory system: hiccups 4.6 vs 2.9

Body as a whole/Site unspecified: asthenia/fatigue 2.9 vs 1.6

Investigations: increased ALT 2.8 vs 1.5, increased AST 1.1 vs 0.9

Digestive system: constipation 2.2 vs 2.0, dyspepsia 1.5 vs 0.7, diarrhea 1.1 vs 0.9

Nervous system: headache 2.2 vs 1.8

Metabolism and nutrition: anorexia 2.0 vs 0.5

A listing of adverse reactions in the aprepitant regimen (incidence <1%) that occurred at a greater incidence than with standard therapy are presented in the *Less Common Adverse Reactions* subsection below.

In an additional active-controlled clinical study in 1,169 patients receiving aprepitant and HEC, the adverse-experience profile was generally similar to that seen in the other HEC studies with aprepitant.

Less Common Adverse Reactions: Adverse reactions reported in either HEC or moderately emetogenic chemotherapy (MEC) studies in patients treated with the aprepitant regimen with an incidence of <1% and greater than with standard therapy are listed below.

Infection and infestations: candidiasis, staphylococcal infection

Blood and lymphatic system disorders: anemia, febrile neutropenia

Metabolism and nutrition disorders: weight gain, polydipsia

Psychiatric disorders: disorientation, euphoria, anxiety

Nervous system disorders: dizziness, dream abnormality, cognitive disorder, lethargy, somnolence

Eye disorders: conjunctivitis

Ear and labyrinth disorders: tinnitus

Cardiac disorders: bradycardia, cardiovascular disorder, palpitations

Vascular disorders: hot flush, flushing

Respiratory, thoracic, and mediastinal disorders: pharyngitis, sneezing, cough, postnasal drip, throat irritation

Gastrointestinal disorders: nausea, acid reflux, dysgeusia, epigastric discomfort, obstipation, gastroesophageal reflux disease, perforating duodenal ulcer, vomiting, abdominal pain, dry mouth, abdominal distension, hard feces, neutropenic colitis, flatulence, stomatitis

Skin and subcutaneous tissue disorders: rash, acne, photosensitivity, hyperhidrosis, oily skin, pruritus, skin lesion

Musculoskeletal and connective tissue disorders: muscle cramp, myalgia, muscular weakness

Renal and urinary disorders: polyuria, dysuria, pollakiuria

General disorders and administration site conditions: edema, chest discomfort, malaise, thirst, chills, gait disturbance

Investigations: increased alkaline phosphatase, hyperglycemia, microscopic hematuria, hyponatremia, decreased weight, decreased neutrophil count

In another chemotherapy-induced nausea and vomiting (CINV) study, Stevens-Johnson syndrome was reported as a serious adverse reaction in a patient receiving aprepitant with cancer chemotherapy.

The adverse-experience profiles in the multiple-cycle extensions of HEC studies for up to 6 cycles of chemotherapy were similar to that observed in Cycle 1.

Fosaprepitant: In an active-controlled clinical study in patients receiving HEC, safety was evaluated for 1,143 patients receiving the 1-day regimen of EMEND for Injection 150 mg compared with 1,169 patients receiving the 3-day regimen of EMEND. The safety profile was generally similar to that seen in prior HEC studies with aprepitant. However, infusion-site reactions occurred at a higher incidence in patients in the fosaprepitant group (3.0%) compared with those in the aprepitant group (0.5%). The reported infusion-site reactions included infusion-site erythema, infusion-site pruritus, infusion-site pain, infusion-site induration, and infusion-site thrombophlebitis.

The following additional adverse reactions occurred with fosaprepitant 150 mg and were not reported with the oral aprepitant regimen in the corresponding section above:

General disorders and administration site conditions: infusion-site erythema, infusion-site pruritus, infusion-site induration, infusion-site pain

Investigations: increased blood pressure

Skin and subcutaneous tissue disorders: erythema

Vascular disorders: thrombophlebitis (predominantly infusion-site thrombophlebitis)

Other Studies: Angioedema and urticaria were reported as serious adverse reactions in a patient receiving aprepitant in a non-CINV/non-PONV study.

Postmarketing Experience: The following adverse reactions have been identified during postapproval use of fosaprepitant and aprepitant. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the drug.

Skin and subcutaneous tissue disorders: pruritus, rash, urticaria, rarely Stevens-Johnson syndrome/toxic epidermal necrolysis

Immune system disorders: hypersensitivity reactions including anaphylactic reactions

DRUG INTERACTIONS

Drug interactions following administration of fosaprepitant are likely to occur with drugs that interact with oral aprepitant.

Aprepitant is a substrate, a moderate inhibitor, and an inducer of CYP3A4 when administered as a 3-day antiemetic dosing regimen for CINV. Aprepitant is also an inducer of CYP2C9.

Fosaprepitant 150 mg, given as a single dose, is a weak inhibitor of CYP3A4 and does not induce CYP3A4. Fosaprepitant and aprepitant are unlikely to interact with drugs that are substrates for the P-glycoprotein transporter.

The following information was derived from data with oral aprepitant, 2 studies conducted with fosaprepitant and oral midazolam, and 1 study conducted with fosaprepitant and dexamethasone.

Effect of Fosaprepitant/Aprepitant on the Pharmacokinetics of Other Agents: CYP3A4 Substrates: Aprepitant, as a moderate inhibitor of CYP3A4, and fosaprepitant 150 mg, as a weak inhibitor of CYP3A4, can increase plasma concentrations of concomitantly coadministered oral medications that are metabolized through CYP3A4 *[see Contraindications]*.

$5\text{-}HT_3$ antagonists: In clinical drug interaction studies, aprepitant did not have clinically important effects on the pharmacokinetics of ondansetron, granisetron, or hydrodolasetron (the active metabolite of dolasetron).

Corticosteroids: *Dexamethasone:* Fosaprepitant 150 mg administered as a single intravenous dose on Day 1 increased the $AUC_{0\text{–}24hr}$ of dexamethasone, administered as a single 8-mg oral dose on Days 1, 2, and 3, by approximately 2-fold on Days 1 and 2. The oral dexamethasone dose on Days 1 and 2 should be reduced by approximately 50% when coadministered with fosaprepitant 150 mg I.V. on Day 1.

An oral aprepitant regimen of 125 mg on Day 1 and 80 mg/day on Days 2 through 5, coadministered with 20-mg oral dexamethasone on Day 1 and 8-mg oral dexamethasone on Days 2 through 5, increased the AUC of dexamethasone by 2.2-fold on Days 1 and 5. The oral dexamethasone doses should be reduced by approximately 50% when coadministered with a regimen of fosaprepitant 115 mg followed by aprepitant.

Methylprednisolone: An oral aprepitant regimen of 125 mg on Day 1 and 80 mg/day on Days 2 and 3 increased the AUC of methylprednisolone by 1.34-fold on Day 1 and by 2.5-fold on Day 3, when methylprednisolone was coadministered intravenously as 125 mg on Day 1 and orally as 40 mg on Days 2 and 3. The intravenous methylprednisolone dose should be reduced by approximately 25% and the oral methylprednisolone dose should be reduced by approximately 50% when coadministered with a regimen of fosaprepitant 115 mg followed by aprepitant.

Chemotherapeutic agents: *Docetaxel:* In a pharmacokinetic study, oral aprepitant (CINV regimen) did not influence the pharmacokinetics of docetaxel *[see Warnings and Precautions]*.

Vinorelbine: In a pharmacokinetic study, oral aprepitant (CINV regimen) did not influence the pharmacokinetics of vinorelbine to a clinically significant degree *[see Warnings and Precautions]*.

Oral contraceptives: When oral aprepitant, ondansetron, and dexamethasone were coadministered with an oral contraceptive containing ethinyl estradiol and norethindrone, the trough concentrations of both ethinyl estradiol and norethindrone were reduced by as much as 64% for 3 weeks posttreatment.

The coadministration of fosaprepitant or aprepitant may reduce the efficacy of hormonal contraceptives (these can include birth control pills, skin patches, implants, and certain IUDs) during and for 28 days after administration of the last dose of fosaprepitant or aprepitant. Alternative or backup methods of contraception should be used during treatment with and for 1 month following the last dose of fosaprepitant or aprepitant.

Midazolam: Interactions between aprepitant or fosaprepitant and coadministered midazolam are listed below (increase is indicated as ↑, decrease as ↓, no change as ↔):

Fosaprepitant 150 mg on Day 1, oral midazolam 2 mg on Days 1 and 4: AUC ↑ 1.8-fold on Day 1 and AUC ↔ on Day 4

Fosaprepitant 100 mg on Day 1, oral midazolam 2 mg: oral midazolam AUC ↑ 1.6-fold

Oral aprepitant 125 mg on Day 1 and 80 mg on Days 2 to 5, oral midazolam 2 mg SD on Days 1 and 5: oral midazolam AUC ↑ 2.3-fold on Day 1 and ↑ 3.3-fold on Day 5

Oral aprepitant 125 mg on Day 1 and 80 mg on Days 2 and 3, intravenous midazolam 2 mg prior to 3-day

regimen of aprepitant and on Days 4, 8, and 15: intravenous midazolam AUC ↑ 25% on Day 4, AUC ↓ 19% on Day 8, and AUC ↓ 4% on Day 15

Oral aprepitant 125 mg, intravenous midazolam 2 mg given 1 hour after aprepitant: intravenous midazolam AUC ↑ 1.5-fold

A difference of less than 2-fold increase of midazolam AUC was not considered clinically important.

The potential effects of increased plasma concentrations of midazolam or other benzodiazepines metabolized via CYP3A4 (alprazolam, triazolam) should be considered when coadministering these agents with fosaprepitant or aprepitant.

CYP2C9 Substrates (Warfarin, Tolbutamide): *Warfarin:* A single 125-mg dose of oral aprepitant was administered on Day 1 and 80 mg/day on Days 2 and 3 to healthy subjects who were stabilized on chronic warfarin therapy. Although there was no effect of oral aprepitant on the plasma AUC of R(+) or S(–) warfarin determined on Day 3, there was a 34% decrease in S(–) warfarin trough concentration accompanied by a 14% decrease in the prothrombin time (reported as INR) 5 days after completion of dosing with oral aprepitant. In patients on chronic warfarin therapy, the prothrombin time (INR) should be closely monitored in the 2-week period, particularly at 7 to 10 days, following initiation of fosaprepitant with each chemotherapy cycle.

Tolbutamide: Oral aprepitant, when given as 125 mg on Day 1 and 80 mg/day on Days 2 and 3, decreased the AUC of tolbutamide by 23% on Day 4, 28% on Day 8, and 15% on Day 15, when a single dose of tolbutamide 500 mg was administered orally prior to the administration of the 3-day regimen of oral aprepitant and on Days 4, 8, and 15.

Effect of Other Agents on the Pharmacokinetics of Aprepitant: Aprepitant is a substrate for CYP3A4; therefore, coadministration of fosaprepitant or aprepitant with drugs that inhibit CYP3A4 activity may result in increased plasma concentrations of aprepitant. Consequently, concomitant administration of fosaprepitant or aprepitant with strong CYP3A4 inhibitors (eg, ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir, nelfinavir) should be approached with caution. Because moderate CYP3A4 inhibitors (eg, diltiazem) result in a 2-fold increase in plasma concentrations of aprepitant, concomitant administration should also be approached with caution.

Aprepitant is a substrate for CYP3A4; therefore, coadministration of fosaprepitant or aprepitant with drugs that strongly induce CYP3A4 activity (eg, rifampin, carbamazepine, phenytoin) may result in reduced plasma concentrations and decreased efficacy.

Ketoconazole: When a single 125-mg dose of oral aprepitant was administered on Day 5 of a 10-day regimen of 400 mg/day of ketoconazole, a strong CYP3A4 inhibitor, the AUC of aprepitant increased approximately 5-fold and the mean terminal half-life of aprepitant increased approximately 3-fold. Concomitant administration of fosaprepitant or aprepitant with strong CYP3A4 inhibitors should be approached cautiously.

Rifampin: When a single 375-mg dose of oral aprepitant was administered on Day 9 of a 14-day regimen of 600 mg/day of rifampin, a strong CYP3A4 inducer, the AUC of aprepitant decreased approximately 11-fold and the mean terminal half-life decreased approximately 3-fold.

Coadministration of fosaprepitant or aprepitant with drugs that induce CYP3A4 activity may result in reduced plasma concentrations and decreased efficacy.

Additional Interactions: *Diltiazem:* In a study in 10 patients with mild to moderate hypertension, intravenous infusion of 100 mg of fosaprepitant with diltiazem 120 mg 3 times daily resulted in a 1.5-fold increase of aprepitant AUC and a 1.4-fold increase in diltiazem AUC. It also resulted in a small but clinically meaningful further maximum decrease in diastolic blood pressure (mean [SD] of 24.3 [±10.2] mmHg with fosaprepitant vs 15.6 [±4.1] mmHg without fosaprepitant) and resulted in a small further maximum decrease in systolic blood pressure (mean [SD] of 29.5 [±7.9] mmHg with fosaprepitant vs 23.8 [±4.8] mmHg without fosaprepitant), which may be clinically meaningful, but did not result in a clinically meaningful further change in heart rate or PR interval beyond those changes induced by diltiazem alone.

In the same study, administration of aprepitant once daily as a tablet formulation comparable to 230 mg of the capsule formulation, with diltiazem 120 mg 3 times daily for 5 days, resulted in a 2-fold increase of aprepitant AUC and a simultaneous 1.7-fold increase of diltiazem AUC. These pharmacokinetic effects did not result in clinically meaningful changes in ECG, heart rate, or blood pressure beyond those changes induced by diltiazem alone.

Paroxetine: Coadministration of once-daily doses of aprepitant as a tablet formulation comparable to 85 mg or 170 mg of the capsule formulation, with paroxetine 20 mg once daily, resulted in a decrease in AUC by approximately 25% and C_{max} by approximately 20% of both aprepitant and paroxetine.

USE IN SPECIFIC POPULATIONS

Pregnancy: *Teratogenic effects: Pregnancy Category B:* In the reproduction studies conducted with fosaprepitant and aprepitant, the highest systemic exposures to aprepitant were obtained following oral administration of aprepitant. Reproduction studies performed in rats at oral doses of aprepitant of up to 1000 mg/kg twice daily (plasma AUC_{0-24hr} of 31.3 mcg•hr/mL, about 1.6 times the human exposure at the recommended dose) and in rabbits at oral doses of up to 25 mg/kg/day (plasma AUC_{0-24hr} of 26.9 mcg•hr/mL, about 1.4 times the human exposure at the recommended dose) revealed no evidence of impaired fertility or harm to the fetus due to aprepitant. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: Aprepitant is excreted in the milk of rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for possible serious adverse reactions in nursing infants from aprepitant and because of the potential for tumorigenicity shown for aprepitant in rodent carcinogenicity studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness of EMEND for Injection in pediatric patients have not been established.

Geriatric Use: In 2 well-controlled CINV clinical studies, of the total number of patients (N=544) treated with oral aprepitant, 31% were 65 and over, while 5% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. Greater sensitivity of some older individuals cannot be ruled out. Dosage adjustment in the elderly is not necessary.

Patients With Severe Hepatic Impairment: There are no clinical or pharmacokinetic data in patients with severe hepatic impairment (Child-Pugh score >9). Therefore, caution should be exercised when fosaprepitant or aprepitant is administered in these patients.

OVERDOSAGE

There is no specific information on the treatment of overdosage with fosaprepitant or aprepitant.

In the event of overdose, fosaprepitant and/or oral aprepitant should be discontinued and general supportive treatment and monitoring should be provided. Because of the antiemetic activity of aprepitant, drug-induced emesis may not be effective. Aprepitant cannot be removed by hemodialysis.

Thirteen patients in the randomized controlled trial of EMEND for Injection received both fosaprepitant 150 mg and at least one dose of oral aprepitant, 125 mg or 80 mg. Three patients reported adverse reactions that were similar to those experienced by the total study population.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenicity studies were conducted in Sprague-Dawley rats and in CD-1 mice for 2 years. In the rat carcinogenicity studies, animals were treated with oral doses ranging from 0.05 to 1000 mg/kg twice daily. The highest dose produced a systemic exposure to aprepitant (plasma AUC_{0-24hr}) of 0.7 to 1.6 times the human exposure (AUC_{0-24hr}=19.6 mcg•hr/mL) at the recommended dose of 125 mg/day. Treatment with aprepitant at doses of 5 to 1000 mg/kg twice daily caused an increase in the incidences of thyroid follicular cell adenomas and carcinomas in male rats. In female rats, it produced hepatocellular adenomas at 5 to 1000 mg/kg twice daily and hepatocellular carcinomas and thyroid follicular cell adenomas at 125 to 1000 mg/kg twice daily. In the mouse carcinogenicity studies, the animals were treated with oral doses ranging from 2.5 to 2000 mg/kg/day. The highest dose produced a systemic exposure of about 2.8 to 3.6 times the human exposure at the recommended dose. Treatment with aprepitant produced skin fibrosarcomas at 125 and 500 mg/kg/day doses in male mice. Carcinogenicity studies were not conducted with fosaprepitant.

Aprepitant and fosaprepitant were not genotoxic in the Ames test, the human lymphoblastoid cell (TK6) mutagenesis test, the rat hepatocyte DNA strand break test, the Chinese hamster ovary (CHO) cell chromosome aberration test and the mouse micronucleus test.

Fosaprepitant, when administered intravenously, is rapidly converted to aprepitant. In the fertility studies conducted with fosaprepitant and aprepitant, the highest systemic exposures to aprepitant were obtained following oral administration of aprepitant. Oral aprepitant did not affect the fertility or general reproductive performance of male or female rats at doses up to the maximum feasible dose of 1000 mg/kg twice daily (providing exposure in male rats lower than the exposure at the recommended human dose and exposure in female rats at about 1.6 times the human exposure).

PATIENT COUNSELING INFORMATION

[See FDA-Approved Patient Labeling]: Physicians should instruct their patients to read the patient package insert before starting therapy with EMEND for Injection and to reread it each time the prescription is renewed.

Patients should follow the physician's instructions for the regimen of EMEND for Injection.

Allergic reactions, which may be sudden and/or serious, and may include hives, rash, itching, redness of the face/skin, and may cause difficulty in breathing or swallowing, have been reported. Physicians should instruct their patients to stop using EMEND and call their doctor right away if they experience an allergic reaction. In addition, severe skin reactions may occur rarely.

Patients who develop an infusion-site reaction such as erythema, edema, pain, or thrombophlebitis should be instructed on how to care for the local reaction and when to seek further evaluation.

EMEND for Injection may interact with some drugs, including chemotherapy; therefore, patients should be advised to report to their doctor the use of any other prescription or nonprescription medication or herbal products.

Patients on chronic warfarin therapy should be instructed to have their clotting status closely monitored in the 2-week period, particularly at 7 to 10 days, following initiation of fosaprepitant with each chemotherapy cycle.

Administration of EMEND for Injection may reduce the efficacy of hormonal contraceptives. Patients should be advised to use alternative or backup methods of contraception during treatment with and for 1 month following the last dose of fosaprepitant or aprepitant.

For detailed information, please read the Prescribing Information.

Rx only

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2012 ACCC INNOVATOR AWARDS
ASSOCIATION OF COMMUNITY CANCER CENTERS

Maximizing Patient Flow & Reducing Inpatient Hospital LOS

Incremental steps to create culture change

BY ANNE JADWIN, RN, MSN, AOCN, NE-BC

A perfect storm was brewing at Fox Chase Cancer Center (FCCC) in Philadelphia, Pennsylvania. An NCI-Designated Cancer Center and academic teaching hospital with Magnet® status, FCCC has a large ambulatory care business, as well as a 100-bed cancer specialty hospital. In 2009 we faced an increasing number of "crunch days," with a high number of scheduled admissions and an uncertain number of available beds. Staff were experiencing increasing stress stemming from the bed capacity issue.

Among the factors contributing to "crunch days" were both the hospital physical environment (semi-private rooms were often blocked due to patients with infections, terminal illness, or other issues) and the infrastructure (many manual systems in place for the admissions, discharge, and transfer processes). From the start, it was clear that the bed capacity problem was highly complex in nature, involving multiple key stakeholders and causative factors.

Our QI Efforts

In February 2009 FCCC achieved re-designation as a Magnet institution, and we turned our attention to a bed-management quality improvement (QI) project to address both patient flow and inpatient hospital length of stay (LOS) issues. Initiated as a high-profile QI project, the effort received endorsement from senior administration.

From the beginning, FCCC utilized a multidisciplinary approach to address the bed capacity issue. The project team was led by nursing and was composed of members of the medical staff, including hospitalists, surgeons, medical oncologists, admissions department, finance department,

information technology, system analysts, patient registration, social workers, and pharmacy.

Taking a best-practices approach, the team's first steps included conducting a Magnet hospital listserv query for best practices related to the office of admission, discharge, and transfer (ADT); reviewing Advisory Board webinars and publications related to ADT; and scheduling Hospital Association of Pennsylvania webinars related to hospital case management. The team then evaluated the feasibility of implementing the following best practice approaches:

- A roving ADT nurse (carved out of an existing floating RN FTE)
- A process to evaluate schedule "smoothing" in the OR
- Pre-wired discharge dates and times worked out between the healthcare team, patient, and family
- A hospitalist model of medical management
- Performance dashboards and metrics
- Daily staffing and bed huddles
- An Admitting Officer of the Day
- Streamlined discharge notification
- Online appointment notification
- Expanded case manager coverage
- Electronic bed management software implementation.

Roving ADT Nurse

This QI strategy aimed to overcome staff barriers to timely acceptance of incoming admissions and transfers. On inpatient units, nurses were often reluctant to quickly accept a new admission or a transfer because they were busy and trying to exert control over their workflow. So they would tell patients, "You can have your ride come after dinner." Or, "Why don't you stay for lunch? You can go home this afternoon." At one time, FCCC had a much more relaxed culture about admissions and discharges.

The roving ADT nurse is deployed to units with heavy admission or discharge activity. We chose to focus on admissions into the unit and not the discharge function because we wanted the nurses that had established a relationship with the patient to discharge their patients. So the ADT Nurse focused on patients being admitted or transferred into units.

We conducted the roving ADT nurse pilot for one year. The ADT nurse position was created using existing float RN hours (1 FTE). The job description essential skills included having a broad clinical background with critical care experience, exemplary interpersonal skills, and flexibility. The ADT nurse worked three 12-hour shifts (11 am to 11 pm) on high census days (usually Wednesdays, Thursdays, and Fridays) and an additional 8-hour shift per pay period. We deployed the ADT nurse based on unit activity and her hours were charged to the respective cost centers.

At approximately three-month intervals, staff evaluated the effectiveness of the role. At about the one-year mark, the ADT nurse resigned due to relocation, and we decided to eliminate the position when faced with a workforce reduction imperative. As we had some marginal success with this approach, we plan to reintroduce the position in July 2013, on two surgical units with high patient turnover.

Schedule "Smoothing" in the OR

Another factor contributing to the bed "crunch" was extreme variability in our census. Although admissions were fairly predictable for medical oncology, on the surgical side, which accounts for about 65 percent of our inpatient census, admissions

BEST PRACTICES RESOURCES

- Maximizing Hospital Capacity: Expediting Patient Throughput in an Era of Shortage, Advisory Board Company, 2002.
- Throughput Gap Analysis, Advisory Board Company, 2002.
- ADT Efficiency Toolkit: Benchmarking, Analyzing, and Managing Admissions, Discharges, and Transfers, Advisory Board Company, 2009.
- Preventing Unnecessary Readmissions: Transcending the Hospital's Four Walls to Achieve Collaborative Care Coordination, Advisory Board Company, 2010.
- Effective Interventions to Reduce Re-hospitalizations: a Compendium of 15 Promising Interventions, Institute for Healthcare Improvement, 2009.
- Patient Flow: Strategies to Improve Throughput and Control Surge Capacity, HCPro, 2009.
- Smooth the Elective OR Schedule? A Large Hospital Makes It Happen, OR Manager, April 2006.
- Schedule Smoothing: Applying Operations Management Principles in the OR, Advisory Board 2007.
- Finding the Right Flow: Smoothing Operations in the OR Leads to Success in the ED, Partners, 2009.

were extremely variable. Census variations were stressing nursing resources and straining bed capacity. In collaboration with the chief of surgery and the director of peri-operative services, we explored these issues with a goal to better manage variability in inpatient admissions from OR and PACU (post-anesthesia care unit).

One issue we identified was the scheduling of medical staff conference and vacation time. If, for example, all medical staff on a service left to attend the same conference, that entire service could be out of commission for days and the unit's census would plummet, leading to inefficient use of clinical personnel resources. Therefore, the team promoted buy-in for establishing parameters on vacation and conference attendance to ensure representation by all services at all times.

To better understand census variability, the team:

- Analyzed 16 months of data (July 2009 through October 2010), including day of the week and admission type (AM, ICU, SDS)
- Calculated percentage of inpatient admission rates by surgeon/per OR day
- Calculated percentage of inpatient days generated per OR day.

Overall, inpatient days generated per OR day were quite consistent. Variation was related more to hospital length of stay, especially in the ICU. Bottlenecks occurred when multiple patients needed critical care reservations at the same time and those beds were not available.

To improve this process, we modified the block schedule and promoted more timely transitions to the step-down level of care. We extended the number of step-down beds so that we had greater ability to move patients quickly from critical care to the step-down areas.

Pre-wired Discharge Dates & Times

This strategy was not deemed a good fit for our institution. Patients travel to FCCC from a multi-state area. For those facing a two- or three-hour travel distance, coordinating rides at certain times can be very difficult for extended family members. It is also difficult to coordinate with medical staff who may not be available to complete discharge paperwork or medication reconciliation to meet a pre-wired discharge date and time schedule.

Hospitalist Model of Medical Management

The goal was to enhance medical management and expedited patient throughput. We increased interdisciplinary team rounding to improve collaboration with case managers by enhancing day-to-day communication about where the patient was in his or her disease course and treatment. We also worked to "hard-wire" medication reconciliation processes.

To improve patient throughput, we developed a direct referral unit with medical oversight by the hospitalist service. FCCC does not have an emergency department; however, a community hospital on campus connects to FCCC via a bridge. Some of our patients use that emergency department; others go to surrounding ERs for emergency care. The direct referral unit functions similarly to an urgent care area for existing patients. It is open until 7 pm on weekdays and expanded its hours to include Saturdays in 2012.

Having a direct referral unit has created some bed capacity because a subset of patients can be treated and then discharged from the direct referral unit rather than having to be admitted as inpatients. Thus, the direct referral unit has created more capacity for those needing acute level of care.

Performance Dashboards & Metrics

Another goal was to establish quality and performance metrics related to patient flow. You can't manage what you don't measure. Developing performance dashboards and metrics has really helped in this area. Prior to 2009, we did not receive much data related to case management or patient flow. To develop our dashboards and metrics, we considered the following indicators:

- Bed turn-around times
- PACU transfer delays (by unit and reason)
- Average LOS
- Average LOS by top medical and surgical DRGs compared to Medicare and Cancer Alliance Hospitals' averages
- 24-hour stay analysis
- LOS variance analysis
- 30-day unplanned readmission analysis
- Average time to bed assigned.

We assessed these factors to determine if there were opportunities for incremental improvements. We actually developed a tool to look at how quickly beds were turned over. We assessed PACU transfer delays because we saw opportunities to improve the timeliness of moving patients out of the PACU. We developed a tool that allows us to look at where delays are by unit, time of day, and reason for the delay. For example, a unit where a nurse was always busy or at lunch or in a meeting indicated that nursing behaviors might need to change. The indicators provided some hard data that could be used to help effect those types of cultural changes on a unit.

We started looking more critically at average LOS data. We also collaborated with Finance to obtain quarterly information about our top surgical and medical DRGs and how our LOS results compared to the Medicare and Cancer Alliance Hospital averages. We developed quality-monitoring tools related to our LOS variances and unplanned 30-day readmissions. We

wanted to better understand those variations and identify opportunities to improve.

Daily Staffing & Bed Huddles

We implemented this low-cost, high-impact strategy with a goal of enhancing staff communication related to aligning and negotiating staffing resources and patient bed assignments based on projected ADT activity. While we had often held staffing huddles, we had not tried bed huddles. So we combined these into a daily staffing and bed huddle. Attendees include the inpatient managers, the OR manager or director, Admissions RN, and Staffing Office representative. The huddle allows staff to negotiate not only the admissions and transfers coming in but also to assess the staffing resources and how these might be best utilized between units.

This brief daily meeting is held at 9 am in the Chief Nursing Officer's (CNO) office. Productivity overall is much higher when we can maintain the "sweet spot" in terms of census on a given unit. If peak census or staffing issues arise, we have the option of holding ad hoc meetings throughout the day and include the CNO and Environmental Services director. Additionally, we put mechanisms in place to alert clinicians—usually by high-census alert email—that beds are needed and if there are patients that are going to be discharged that day, the process needs to be expedited.

In tandem with the daily huddle, the Admissions nurse makes rounds throughout the hospital, not only in the morning but at other times during the day when needed. This process helps units develop a rapport with this staff member and fosters a collaborative culture.

Admitting Officer of the Day

In implementing an AOD, the goal was to have a process for escalating medical decision-making when beds were tight. The AOD responsibility is rotated among senior attending physicians, including medical oncologists, hospitalists, and surgeons. The Department of Medicine creates a monthly AOD scheduling calendar. The Admitting Officer of the Day is available for consultation on weekdays from 9 am to 5 pm, and bases admission and transfer decisions on clinical criteria and priority of care. While the AOD may not be called upon often, when the hospital is at peak census, the AOD may be used multiple times a day. This position helps reduce the pressure on the Admissions Department RN.

Streamlined Discharge Notification

In the past, FCCC's discharge notification process involved multiple phone calls. The unit nurse discharging a patient called the secretary, who would call the housekeeper and the Admissions Office, and so on. Clearly, our priority was to reduce the number of phone calls.

Now notification of discharge is sent through a text page application accessible through the staff portal. The expectation is that notification is posted within 15 minutes by the unit team leader or designee. The patient's name and room number is entered and the text is then sent to the appropriate departments and staff, e.g., Admissions Office, Housekeeping, and the nursing supervisor. When the room is ready, the Housekeeping supervisor enters a notification via text pager that the room is "complete." The Admissions Office then updates the electronic bed board with this information.

The scheduling of post-hospital appointments was also holding up the discharge process. Now, through an online appointment notification application, the scheduled appointment is entered and an electronic notification is sent to the Scheduling Department. Usually within the first 24 hours after discharge, the Scheduling Department contacts the patients or their families to confirm that appointment.

Expanded Case Manager Coverage

An area with potential for improvement centered around unplanned weekend discharges. Often these discharges were being "held" until Monday so that the case manager could coordinate complex post-hospital services. In the past, weekday staff were scheduled to rotate to cover weekends, but this process had a negative impact on job satisfaction. Running "short" during the week created additional stress for staff. To address this issue, we created a 0.1 FTE position (8 hours/2-week pay period) to cover a four-hour Saturday shift. By expanding this coverage by four hours on Saturday, with minimal impact to our operational budget, we reduced the number of cases that waited over the weekend and slightly reduced the average LOS.

Electronic Bed-Management Software

Previously, physicians or clinicians in the clinic would fill out paper forms to schedule an admission. These forms would either go into an interdepartmental envelope or they would be faxed to the Admissions Department. The obvious problem was that forms would get lost. In late 2009 FCCC transitioned to Invision bed-management software.

An interdisciplinary implementation taskforce team focused specifically on the IT application. This team met biweekly and developed an application using this software that standardized bed requests so that they are all electronic. As part of this process, workflows for routine and urgent bed requests were standardized. An application to provide serial clinical updates of "Urgent Admissions or Transfers" every 6 hours was developed. If at that point, the patient is still waiting to get transferred, that nurse calls the other institution and enters an update to determine if the patient is still medically appropriate for transfer. The online bed board functionality also provides census updates that can be accessed from any PC and viewed by any clinician.

The electronic bed management system has resulted in increased efficiency for ADT staff, no "lost" requests, improved accuracy and appropriateness of admissions requests, ability to obtain data, and greater physician accountability to screen incoming transfers.

One of the most important steps was aligning bed management efficiencies with the cancer center's strategic plan and

individual and unit performance goals. Typically, inpatient units were under-reporting actual and potential discharges. "Hiding" beds was viewed as a reasonable means of controlling work flow. Achieving staff buy-in for a change in this culture was a challenge. We worked to achieve this shift by using analogies—a busy hospital is hopefully a financially prosperous hospital with more job security for existing staff. We implemented rounding by nursing supervisors, basically doing bed checks to verify actual census. We shared data with units about their census and their profitability. We also conducted one-on-one counseling with staff who were non-compliant in reporting discharges. Now several years in, we have achieved buy-in. Staff understand that if you're working on these units you will be busy every day, as we flex our resources to maximize productivity and escalate the pace operationally to ensure patients are receiving care in the appropriate setting.

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BENCHMARKING OUR LOS

In addressing bed capacity issues, our team also looked at how FCCC's LOS data compared by doing some benchmarking. Once outliers were identified, we looked for ways to improve. Our team set a goal to reduce LOS in at least three outlier DRGs in FY 2011. The case managers were charged with identifying three projects targeting selected DRGs.

1. **Decrease LOS for DRGs 393 & 394:**
   - Cycle TPN and tube feedings at home vs. hospital
   - Consider home antibiotic therapy when feasible
2. **Decrease LOS for DRGs 583, 407, 327, 734 & 656:**
   - Develop surgical resident and fellow orientation to case management
   - Develop a patient education brochure "Partners in Care–Expectations after Surgery"
   - Make a formal request to Executive Committee of Staff to include case management in new physician orientation
3. **Decrease LOS for DRGs 004, 011, 516, 013, 129 & 130:**
   - Ensure earlier de-cannulation of tracheostomies by developing a clinical pathway.

Working with medical records and coding staff on the front end, we assigned average LOS based on probable DRGs linked with the admissions diagnosis. This information is provided electronically to all of the case managers based on their census report. Initially medical staff did not completely buy in to the LOS project. Once we explained that these projections were based on data in the Medicare database and were a starting place to begin to work on this issue—buy-in improved.

We now provide LOS projections to case managers within 24 hours of patient admission. (Medical Records or coding staff assign LOS based on probable DRGs linked with admission diagnosis.) The projected LOS target is communicated to the healthcare team, patient, and family.

Case managers have access to an electronic tool called the LOS variance tool. When actual LOS varies with projected LOS at admission, the case manager uses this quality monitoring tool, which is not part of the medical chart. The case managers can pull up the patient and enter the reason for the LOS with a drop-down menu. At the end of the month, they can print out a report. As part of this process—if delays in care are occurring or the process is just not moving according to plan—case managers are encouraged to bring their cases to their case management physician liaison for possible physician coaching.

FCCC conducted several LOS projects using the FOCUS-PDCA format. The case managers primarily led these projects. Being leaders in terms of LOS reduction was a new role for these staff, who are bachelors-prepared nurses who received training and coaching on how to review outlier data and analyze some of their cases. Between FY10 and FY11, of the 14 outlier DRGs examined, 11 showed a LOS reduction and 6 were outperforming the Medicare and Cancer Alliance Hospitals' average length of stay. For the case managers, these results affirmed that it was possible to have an impact with their projects.

As FCCC has shortened LOS over time, we've been proactive in simultaneous monitoring of 30-day unplanned re-admission rates. FCCC found that these rates have been very consistent and LOS reduction does not seem to have adversely impacted re-admissions.

IN BRIEF

Psychosocial support is a significant component of comprehensive cancer care. In this article we provide information about building a psychosocial oncology program within an academic cancer center. Program development is described through the integration of three foundational components: clinical service, research, and training. We describe the importance of these components and use the examples of distress screening and cancer survivorship to illustrate their intersection. Emphasis is placed on initiating program development with existing resources and expanding as experience and resources allow.

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Growing a Psychosocial Oncology Program within a Cancer Center

The subspecialty of psychosocial oncology developed as a response to the unique psychological, social, and spiritual issues related to a cancer diagnosis and its treatment.[1] However, in 2008 the Institute of Medicine (IOM) issued a comprehensive report that indicated cancer providers often fail to adequately address the psychosocial needs of their cancer patients.[2] The groundbreaking IOM report outlined a theoretical model for providing psychosocial care built around five key elements:

1. Identification of psychosocial health needs
2. Linkage of identified patients to appropriate professionals
3. Support of cancer patients in managing illness
4. Coordination of psychosocial and biomedical care
5. Follow-up to determine effectiveness of services offered.

The IOM report also provided examples of programs that use this service delivery model. The literature has provided guidance for targeted issues, including distress screening and assessment[3,4] and interventions for specific problems such as depression[5] or patient navigation.[6] Despite this growing literature base, few resources outline the processes necessary to build a psychosocial oncology program.

This article highlights three foundational components necessary for program development—clinical service, research, and training. We discuss each component toward the goal of an integrated psychosocial oncology program. To illustrate coordination of these components, we focus on the intersection of clinical service, research, and training in efforts to enhance distress screening and cancer survivorship services within our own psychosocial oncology program at UT Southwestern Harold C. Simmons Cancer Center, an NCI-Designated Comprehensive Cancer Center in Dallas, Texas.

Program Goal 1—Clinical Service

In 1983 a multicenter, cross-sectional study demonstrated that up to 47 percent of all cancer patients experience distress at a level of intensity sufficient to meet criteria for a psychiatric diagnosis.[7] Subsequent reports have estimated that approximately 25 percent of cancer patients report significant depressive and/or anxious symptoms.[8] While cancer patients and their family members often have substantial and diverse psychosocial needs best addressed by clinician experts in psychosocial oncology, even the most integrated cancer centers are challenged to fully staff a psychosocial oncology program.

A comprehensive psychosocial oncology program must address multifaceted needs in order to treat the "whole patient" while remaining efficient and cost-effective. To do so, the psychosocial oncology team must first identify patients who need services and then have an effective process for triaging those patients to the appropriate psychosocial professional. The most efficient method to meet these goals is through distress screening. Once patients are identified through a distress screening mechanism, clinical intervention must be comprehensive yet frugal. The Psycho-Oncology Consultation Model (PCOM) is one clinical model that allows programs to achieve these often divergent goals.[9]

The PCOM is grounded in the consultation-liaison model of clinical care and assumes limited contact with the patient. The psychosocial clinician must achieve patient evaluation, treatment planning, and intervention often in a single visit.[9-11] This form of therapeutic intervention also follows a symptom management model in

which evaluation determines a specific patient concern (i.e., symptom) and interventions target that symptom. The patient returns for follow-up appointments if the intervention impact is less than desired or if a new symptom emerges.

Although single-visit efficiency may suggest a lack of treatment effectiveness, a randomized study of 100 women with gynecologic cancer demonstrated that patients who had a single meeting with a psychologist (intervention) not only demonstrated decreases in anxiety, depression, and overall distress, but had greater improvements in physical, emotional, functional, and overall well-being.[12] It is important to emphasize that the PCOM does not prohibit follow-up appointments; instead it recommends follow-up appointments based on patient need and successful completion of specific therapeutic goals.

A comprehensive psychosocial oncology program must address multifaceted needs in order to treat the "whole patient" while remaining efficient and cost-effective.

The takeaway message: when building a psychosocial oncology program you must balance comprehensive patient care with efficient use of limited resources. Efficiency can be achieved through systematic screening of all cancer patients, thus generating appropriate referrals followed by a psychosocial consultation model of care to maximize therapeutic time.

Program Goal 2—Research Integration

In recent years, psychosocial oncology literature has focused on the experiences of cancer patients and the evaluation of clinical interventions. A convergence of psychosocial oncology research training, research funding options, publication outlets, integrated cancer centers, and transdisciplinary partnerships has fostered an environment in which basic and applied psychosocial oncology research has flourished.[13]

For example, descriptive research in psychosocial oncology has addressed cancer risk and screening, psychosocial distress, and disease and treatment symptom management, often with integration of social psychological and health promotion theories. Intervention research has focused on efficacy and effectiveness of psychosocial techniques (e.g., cognitive-behavioral modalities, supportive-expressive therapy) and behavioral strategies (e.g., physical activity, yoga) for cancer patients, often integrating evidenced-based principles of psychotherapy and behavioral interventions with unique characteristics of oncology care. Although more and better interventional studies are needed, evidence-based recommendations derived from existing work are being developed for cancer patients across the diagnosis and treatment spectrum.[14,15]

Despite the growth of psychosocial oncology research, concerns exist about disconnects in the translation of empirical work to clinic practice.[16,17] To address these gaps, Jacobsen has described a "push/pull" infrastructure model focused on "pushing" evidence from research into the clinic while "pulling" the demand from clinicians and patients.[18] Within a psychosocial oncology program, a highly integrated research program allows alignment of goals that can optimize patient care through such a "push/pull" process.[19] For psychosocial oncology team members, research integration promotes scholarship and expanded recognition of member contributions through transdisciplinary collaboration, presentations at professional conferences, peer-reviewed publications, and inclusion on grant applications. In addition, psychosocial oncology research activities and intramural and extramural funding can complement clinical goals by providing support for novel or expanded service provision, additional staff members, and increased program visibility across the cancer center and the community.

On a larger scale, integration with research links a psychosocial program to greater priorities of the cancer center. Traditionally, most major cancer centers have active research programs in basic and laboratory (e.g., genetic, molecular) and clinical (e.g., therapeutic clinical trials) sciences. Over the last decade, increased focus has been placed on enhancing cancer control and population science research, particularly within NCI-Designated Comprehensive Cancer Centers. Broadly defined, cancer control and population science research focuses on epidemiology, behavioral sciences, health services, surveillance, and cancer survivorship and can take either basic or applied forms.[20] Indeed, designation as an NCI-Designated Comprehensive Cancer Center requires a commitment to population science and cancer control research, and achieving status as an NCI-Designated Comprehensive Cancer Center requires significant funded population science research and transdisciplinary collaboration.[21] Psychosocial oncology program members can facilitate these population science goals and ensure their integration with patient care and other institutional priorities.

For community cancer centers, the development of this type of research program may seem unattainable. Within a community oncology setting, psychosocial professionals' clinical and administrative demands combined with a potential lack of research expertise within the organization often limit ability to generate fundable psychosocial research. In such cases, psychosocial professionals can reach out and develop relationships with researchers at local universities, academic medical centers, and NCI-Designated Comprehensive Cancer Centers. Although these relationships may take work to initiate, they can be successful and mutually beneficial. Community cancer centers obtain the benefits of well-established research programs, such as additional funding, research expertise, and peer-reviewed publications; academic centers obtain access to an untapped oncology population for study accrual. For example, the NCI-sponsored Community Cancer Centers Program (NCCCP) explicitly seeks to align community hospital cancer centers with larger academic research partners, recognizing that most patients

are treated in community settings. Furthermore, competitive grant applications in psychosocial oncology increasingly focus on collaborative, multi-site, and multi-level research questions.

Program Goal 3—Training & Education

Growth of psychosocial oncology has been accompanied by the need for well-trained clinicians and researchers. In recent years, graduate programs in counseling and clinical psychology, psychosocial nursing, and clinical social work have partnered with cancer centers to increase depth and breadth of training within psychosocial oncology. Some programs place these opportunities within a larger framework of behavioral medicine or health psychology specialization with strong didactic preparation. Other programs provide psychosocial oncology training as "stand-alone" opportunities. More intensive training can be gained during clinical internships with psychosocial oncology rotations and during post-doctoral fellowships with a central focus in psychosocial oncology. Such specialized post-doctoral training is increasingly becoming an integral part of preparation for a position within a psychosocial oncology program.

As demands for training have grown, psychosocial oncology programs are put in the unique position of creating educational opportunities in clinical practice and research that benefit trainees but are also useful for the program and the institution. Training agreements set up without knowledge and careful planning of trainee experience, content requirements, supervisory needs, and funding obligations risk draining time and resources for all involved. However, training partnerships developed through thoughtful collaboration on these issues can provide a "win-win" scenario for trainees, institutions, and supervising professionals. The pre- to post-doctoral professional receives the necessary experience to advance skills through exposure to what is often a new population (i.e., cancer patients).

Institutions benefit by having well-trained and well-supervised additional psychosocial staff available for patient needs. Psychosocial oncology professionals stand to benefit from the presence of newly trained professionals to stimulate new clinical developments and/or new lines of research.

> Growth of psychosocial oncology has been accompanied by the need for well-trained clinicians and researchers.

When building the educational component of the psychosocial oncology program, two separate growth directions may be available. The first is to develop a post-doctoral fellowship and provide training for that level of professional. The benefit of this growth process is the training and experience level of the post-doctoral fellow. Such a trainee may quickly take on an advanced clinical load and/or provide strong research assistance, as well as play a role in pre-doctoral and intern supervision. As an added benefit, successful post-doctoral fellows may naturally progress to post-training roles as staff within psycho-social oncology programs.[18] A barrier to this growth plan is the financial commitment to provide the needed time, salary, and benefits to post-doctoral fellows. Even the most supportive and well-funded cancer center is unlikely to single-handedly and continually fund post-doctoral training within psychosocial oncology. Instead, post-doctoral traineeships may be funded through various means, including extramural training, research grants, or philanthropic funds. Any discussion of developing a sustainable post-doctoral training program will need to include funding sources and additional potential benefits to the institution.

The second growth plan for education is to begin with pre-doctoral trainees and work toward a post-doctoral fellow component by establishing relationships with a well-respected training program at one's own institution or other local universities. Many programs are eager to have another practicum site for clinical work and/or research. For pre-doctoral students with interests in behavioral medicine and health psychology, working with cancer patients may be of great interest and an essential preparation for internship and post-doctoral placement. For a psychosocial oncology program, benefits to having a strong pre-doctoral training component include a sustained relationship with quality training programs, an infusion of trainee energy, and mentorship opportunities. Inclusion of pre-doctoral trainees may also demonstrate to cancer centers the benefits of having additional psychosocial providers, supporting a program request for more staff. Despite these clear benefits, supervision of pre-doctoral trainees is time-consuming for program staff and there is often variability in students' time commitment, prior training, comfort with the oncology setting, and professional maturity. Depending on the structure of the home pre-doctoral program and the student's time commitment,

short- or long-term funding issues may also need to be addressed.

A final training issue for psychosocial oncology programs involves continuing education for already-established professionals and community members. For example, programs may develop or partner in introductory training for psychology or social work professionals interested in expanding their work to oncology patients. Continuing education may also take the form of more advanced topics geared toward one's own staff or even a national audience of psychosocial oncology professionals. Overall, these types of programs may be eligible for continuing education credits in specific fields and may attract a larger audience. Educational sessions for community members may generate new connections for program building and enhance a program's status and visibility within local areas. Such opportunities allow program staff to remain up-to-date on current practice and research and interact with other professionals and interested community members. Ultimately, a strong continuing education component can help a program and parent institution develop well-recognized specialties and elicit speaking invitations at national and international conferences and other events.

...we recommend that programs initiate development with existing resources and then expand as experience and resources allow.

Intersection of Program Goals

In our view, the three important components of psychosocial oncology programs (clinical service, research, and training) have the greatest impact when they are well integrated. However, we also recognize that few emergent psychosocial oncology programs will simultaneously have these strong, intact building blocks. Therefore, we recommend that programs initiate development with existing resources and then expand as experience and resources allow. Not all activities of an emerging program must involve all three foundational components. It is often useful to start with one foundational component and integrate other areas in a long-term plan. To illustrate these concepts, we discuss two examples from our experience as a growing psychosocial oncology program—distress screening and cancer survivorship. In the following section we describe how we focused on component integration and built off existing program strengths.

Our psychosocial oncology program is affiliated with the NCI-Designated UT Southwestern Harold C. Simmons Cancer Center (SCC). The SCC is unique in that the overall cancer program not only includes the university hospital and oncology clinics but also the county safety-net hospital (Parkland Health & Hospital System) and a private not-for-profit children's hospital (Children's Medical Center of Dallas)—primary teaching facilities for the university medical school. The SCC is also affiliated with the Moncrief Cancer Institute, a community-based cancer prevention and support center in Fort Worth. SCC is a matrix cancer center, with faculty membership from a number of academic departments. For example, faculty focused on psychosocial oncology are appointed in the Division of Psychology within the Department of Psychiatry and the Division of Behavioral and Communication Sciences within the Department of Clinical Sciences.

Despite the overall cancer program's reach across hospitals, the clinical structure of psychosocial oncology has traditionally been separate for the adult and pediatric settings. Our psychosocial team focuses on adult oncology patients and is primarily housed within the cancer center's Supportive Care Department, whereas pediatric psychosocial oncology clinicians are organized under the umbrella of the children's hospital. This results in two clinical psychosocial oncology programs (adult and pediatric) that have traditionally been independent although their goals are similar. Recent efforts have allowed us to collaborate on converging clinical issues, such as cancer survivorship. Greater integration across pediatric and adult psychosocial oncology is being achieved within research and education endeavors, project collaborations, and consolidation of several aspects of pre-doctoral training.

Distress Screening

In 2009 the International Psycho-Oncology Society endorsed psychosocial distress as the "6th Vital Sign" in oncology care.[22] NCCN has published guidelines on distress screening. Further, programs accredited by the American College of Surgeons Commission on Cancer (CoC) must meet new standards on distress screening by the year 2015.

Distress screening has an important function in oncology clinical service; it provides a real-time assessment of psychosocial and other supportive care needs and allows for prompt clinical response. At our cancer center, clinical use of distress screening has grown rapidly, building the base for emerging training and research endeavors. Our adult psychosocial oncology team developed and implemented a distress screening protocol that provides opportunity for oncology patients to report types and intensity of their psychosocial symptoms, as well as request consultation with a member of the Supportive Care team (i.e., psychologist, social worker, dietitian, financial advisor, pastoral care provider).

Consistent with NCCN guidelines, our protocol employs a screening tool that has been validated in oncology populations. Although we now use paper-and-pencil format, our goal is to integrate distress screening into our electronic medical record (EMR).

We currently only screen within our university hospital outpatient setting, but our goal is to expand screening to the inpatient setting and to the county hospital as our program grows. Outpatients are screened at each medical or surgical

oncology appointment; the screening instrument is collected and evaluated daily by a team member. Patients whose responses are above a cutoff score or who ask to speak with a team member are contacted by phone for further assessment and consult. We collect between 1,200-1,400 psychosocial distress screeners each month.

Within our program, we have begun to integrate training goals into our distress screening protocol, leveraging it as an important component of education and training. Among pre-and post-doctoral trainees, distress screening helps promote understanding of the PCOM and other relevant care models by focusing clinical attention on the most intense symptoms reported by patients. Through this focused approach, trainees learn how to integrate screening data into their evaluation process, thus reducing the time necessary for evaluation and increasing clinical efficiency.

With appropriate supervision, our trainees can follow up with low-intensity screeners, effectively increasing staff consultation hours and providing trainees with a safe patient contact experience. If during this contact it is determined that symptom intensity is greater than the trainee's clinical skills, we may use the opportunity for focused supervision or modeling of an intervention. In addition, distress screening provides an opportunity for psychosocial professionals to educate other oncology colleagues in the cancer program. Within our setting, these educational opportunities have ranged from informal (e.g., on-the-fly conversations) to more formal (e.g., presentations at grand rounds and faculty meetings) interactions. Breadth of educational topics that come from screening can include:

- Difference between screening and assessment
- Psychometric qualities of screening instruments
- Empirical basis of cutoff scores
- Ethical considerations associated with screening and follow-up.

These topics are important to all team members and oncology distress screening provides a platform for psychosocial professionals to demonstrate our unique professional knowledge.

In addition to promoting clinical goals and training opportunities, distress screening can be an important element within a psychosocial oncology research program. Although research on distress screening has grown in recent years, gaps in knowledge still exist. As noted in a recent special issue in the journal, *Psycho-Oncology*, investigations are needed to address such issues as: distress in under-represented groups, translation of findings, and measurement refinement.[22] A member of our team recently published on distress symptom frequency and intensity data from understudied patients in a community cancer center setting.[23]

Within our psychosocial oncology program, we are developing research endeavors focused on distress screening that capitalize on our large clinical screening program, our trainee involvement, and the unique features of our cancer center population. Of particular note is our cancer program's expertise in lung cancer care (as evidenced by an NCI-funded Special Program of Research Excellence and world renowned experts) and our diverse patient population. These features have allowed us to focus research projects on distress among lung cancer populations and ethnic and cultural considerations in distress screening.

Survivorship

Improvements in early detection and cancer treatment have allowed a greater percentage of individuals diagnosed with cancer to live longer. In fact, recent figures estimate almost 12 million cancer survivors (defined as living individuals ever diagnosed with cancer) live in the United States.[24] This growing survivor population has brought about a number of challenges for cancer centers in general, and for psychosocial oncology programs in particular, to broaden scope of care beyond active treatment. In addition to treatment-related side effects and physical late effects, cancer survivors may have unique psychosocial concerns, including: [25]

- Uncertainty
- Fear of recurrence
- Adjustment to physical limitations
- Sexual and fertility issues
- Existential and spiritual concerns
- Fatigue
- Cognitive impairment.

Many cancer centers are evaluating models for addressing the growing needs of cancer survivors. A recent survey of LIVESTRONG Centers of Excellence in Survivorship Care noted a number of care models, including separate survivorship clinics, integration of survivorship services into disease-oriented teams, and consultative services.[26] Within these models psychosocial clinicians have various roles, ranging from integration in multidisciplinary survivorship teams to a more consultative model of service provision. At our cancer center, the psychosocial team currently provides survivorship services to disease-oriented teams within a consultative framework. However, continuing discussions are focused on expansion of survivorship care and greater integration of supportive services. Another

psychosocial clinical goal is partnership with the pediatric oncology team at the Children's Medical Center to coordinate survivorship transition among young adult survivors of childhood cancers.

The growing number of cancer survivors reinforces the importance of understanding psychosocial needs and evaluating interventions. Facilitated in part by the NCI's Office of Cancer Survivorship and other organizations focused on survivorship funding, such as LIVESTRONG, there has been an exponential growth in cancer survivorship research in recent years.[27]As detailed by recent cancer survivorship overviews, a number of necessary inquiry topics have emerged. These include addressing psychosocial issues among aging and underserved groups of survivors, assessing economic outcomes within survivorship, and translating research into clinical care.[28]

As the clinical care for the psychosocial needs of survivors evolves within our program, we have built on our research and training infrastructure to further cancer survivorship research. Led by one member of our psychosocial oncology team, we have organized a transdisciplinary group (including both adult and pediatric researchers) to foster partnerships in research and training related to cancer survivorship issues. Monthly meetings that include both faculty and trainees (pre-doctoral and post-doctoral) allow both a discussion of projects and educational opportunities for attendees. From these discussions, collaborations have developed that have resulted in extramural funding for projects focused on lung cancer survivorship, contextual factors in treatment decision-making, and surveillance decisions among high-risk patients. In addition, pre-doctoral trainees from this group have received extramural funding and successfully conducted dissertation research focused on psychosocial issues among cancer survivors.

A number of our research endeavors have focused on patients seen at the county safety-net hospital, Parkland. Many of these patients are low-income, minority, and under- or uninsured individuals who have been traditionally under-represented in psychosocial and behavioral survivorship research. Projects focused on the needs of these individuals aim to fill a gap within survivorship research. OI

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BRIDGI

Psychosocial

A model for decreasing patient distress, while ensuring your program's financial viability.

TIMOTHY TYLER, MSW, LCSW, LISW-S, OSW-C

Most supportive care interventions are not billable, which can impact a provider's decision to provide such care. Because many public and private payers do not reimburse for these services, many providers cannot justify funding to support needed psychosocial services.[1] On the other hand, there is universal agreement among providers that cancer patients should be treated holistically and that distress in cancer patients should be recognized and addressed.[2] Responding to recommendations in the 1999 Institute of Medicine report *Ensuring Quality Cancer Care*, the Commission on Cancer (CoC) of the American College of Surgeons (ACoS) requires a 2015 phase-in for new *Continuance of Care* standards.[3] Subsequently, all CoC-accredited cancer programs must develop a patient navigation process and provide psychosocial distress screening. Both standards are critical components in efforts to provide adequate supportive cancer care. That being

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said, supportive care programs should proactively identify and address potential issues related to the economics of a cancer diagnosis.

A recent Association of Oncology Social Work (AOSW) survey found that 56 percent of patients surveyed felt they were not at all prepared to handle the financial burden of a cancer diagnosis, and only 7 percent indicated that they were completely prepared.[4] Increased medical expenditures and the potential of reduced earnings contribute to the financial hardships many patients face after a cancer diagnosis.[5] Factor in that 62 percent of all U.S. bankruptcies are initiated because of medical debt and 75 percent of that number had health insurance.[6] Accordingly, supportive care services at community cancer centers must provide support for both uninsured and underinsured populations. In addition, supportive programs should both help reduce existing or potential economic burdens for the patient and address the financial health of the institution providing medical care. Finally, a structured supportive care process should address psychosocial distress and patient navigation.

Our Model

Akron General Medical Center (AGMC), McDowell Cancer Center, developed a unique patient navigation program, which reduced psychosocial distress, secured $1.35 million in direct financial assistance to patients that would otherwise not have been available, and reduced institutional bad debt. Recognizing that patients with cancer should be treated holistically and distress should be identified and managed, we developed a structured distress management program as a component of patient navigation.

There is universal agreement among providers that cancer patients should be treated holistically and that distress in cancer patients should be recognized and addressed.

Our navigation model uses a two-person team composed of a resource counselor (an oncology social worker) and a reimbursement specialist who work together to meet the psychosocial and financial needs of our cancer patients. In brief, here's how our model works.

Our reimbursement specialist conducts a benefits investigation for all new patients receiving chemotherapy in the McDowell Cancer Center. This investigation is done prior to the start of therapy. All patients complete the National Comprehensive Cancer Network (NCCN) Distress Thermometer (DT).

Our resource counselor uses the data from the benefits investigation and distress thermometer to conduct a Brief Psychosocial Assessment (BPA) prior to initial therapy. The BPA includes a review of self-indicated stressors identified from the completed DT, the benefits investigation, and a brief assessment of emotional, practical, spiritual, financial, and medical concerns. The resource counselor then completes a comprehensive psychosocial assessment with those patients having more complex needs. Patients are assigned a case-complexity rating to help monitor those needing ongoing follow-up. The resource counselor enters data into a database and uses it to evaluate self-indicated stressors and to monitor the case-complexity rating of each patient. Our resource counselor then provides immediate and long-term interventions or makes referrals addressing the identified needs.

During their last scheduled chemotherapy sessions, patients complete the NCCN Distress Thermometer a second time. We use an ACCESS database to collect and monitor all demographic, distress, navigation, and financial data. This information is used for current and longitudinal research, to assist with program development, and for measuring program effectiveness.

For community cancer centers looking to implement a similar program, here is how we did it.

Our Experience

In 2011 McDowell Cancer Center requested and obtained a waiver of consent and approval for a study on distress screening from the AGMC Institutional Research Review Board. The title of the protocol was: Assessment of Distress Associated with Daily Life in Cancer Patients and Community Resources Available to Them. Study participants consisted of the first 106 patients who completed pre- and post-treatment distress thermometers at McDowell Cancer Center between June and November 2011. Patients completed DT One the day they started initial chemotherapy, and DT Two the day they finished their treatment regimen. We transferred all data from ACCESS to SPSS v 15 for analysis. We used an ACCESS database to monitor and track results of financial data. Study participants were:

1. Over 18 years old
2. Diagnosed with a cancer
3. Able to read standard English (i.e., the screening instrument)
4. Scheduled to receive chemotherapy at our outpatient treatment center.

As noted in Table 1 (page 43), initial DT results revealed that 25 patients starting chemotherapy were dealing with insurance and financial-related concerns and 39 percent of all patients self-indicated they were dealing with various practical problems. In the post DT screening, the number of patients indicating that they were experiencing insurance and financial concerns was significantly reduced from 25 to 13; all self-indicated practical problems were considerably reduced. However, as indicated under the Total Difference column, 6 new patients that were not experiencing insurance and financial concerns during their initial

CASE STUDY

A 34-year-old male non-citizen was admitted to the ER with no insurance, and citizenship requirements prevented him from qualifying for Medicaid. The patient then followed up with hematology oncology and was diagnosed with a blood disorder. The drug Soliris® was recommended. Our resource counselor referred the patient to our reimbursement specialist. The patient was then approved and enrolled in the Alexion patient assistance program and the drug was obtained free of charge.

It should be noted that we, as a provider, bill the drug Soliris out at $104,000 per treatment with net cost to the hospital of around $18,000. After further review by the resource counselor, the patient was also determined eligible and enrolled in the Ohio High Risk Pool insurance. The patient had managed to pay the expensive $600 a month premium, but experienced financial hardship trying to meet the additional out-of-pocket expenses required by the insurance. The patient was referred to our reimbursement specialist and was enrolled and approved for the diagnosis specific Patient Services Inc. (PSI) Foundation. Consequently, the foundation covered the entire $1,500 deductible and $3,000 maximum out-of-pocket. Because the patient would not have otherwise obtained medical coverage, all subsequent accounts are dollars generated for the hospital.

Table 1. Practical Problems (N=106)

	DISTRESS THERMOMETER ONE		DISTRESS THERMOMETER TWO		
VARIABLE	TOTAL FREQUENCY	TOTAL PERCENT	COMPARABLE FREQUENCY	TOTAL FREQUENCY	TOTAL DIFFERENCE
Childcare	2.0	1.9	1.0	1.0	0.0
Housing	3.0	2.8	2.0	3.0	1.0
Insurance & Financial	25.0	23.6	13.0	19.0	6.0
Transportation	4.0	3.8	1.0	4.0	3.0
Work & School	7.0	6.6	1.0	7.0	6.0
Total	**41.0**	**38.7**	**18.0 (17%)**	**34.0**	**(16)**

Table 2. Practical Problems: Distress Mean (N=106)

	DISTRESS THERMOMETER ONE			DISTRESS THERMOMETER TWO		
VARIABLE	M	N	SD	M	N	SD
"0" Practical Problems	2.83	75	2.708	1.88	78	2.363
"1" or more Practical Problems	5.77	31	2.918	3.96	28	2.687
All Patients	**3.69**	**106**	**3.069**	**2.43**	**106**	**2.608 P<0.001**

Table 3. Emotional Problems: Frequency & Distress Mean (N=106)

	DISTRESS THERMOMETER ONE			DISTRESS THERMOMETER TWO		
EMOTIONAL PROBLEMS	FREQUENCY	%	M	FREQUENCY	%	M
0	**30**	**28.3**	**1.87**	**53**	**50.0**	**1.15**
1	22	20.8	3.41	17	17.0	2.65
2	15	14.2	4.80	11	10.4	2.64
3	15	14.2	3.07	9	8.5	3.44
4	5	4.7	5.60	6	5.7	5.67
5	11	10.4	6.45	6	5.7	5.50
6	8	7.5	5.38	4	3.8	6.25

DT screening now reported experiencing these problems at completion of therapy.

Table 2 (above) shows that patients with zero practical problems had a significantly lower (P<0.001) mean distress level than those with one or more practical problems. When comparing first and second DT data, mean scores from respondents checking at least one practical concern was reduced from 5.77 to 3.96.

DT data showed a significant decrease in mean distress scores when comparing DT One and Two. As noted in Table 2, mean distress scores decreased significantly from 3.69 to 2.43.

DT One results from Table 3 (above) show that 72 percent of respondents self-indicated experiencing at least one emotional concern, as described by the NCCN DT checklist. Fifty-four people checked that they were experiencing more emotional problems when completing DT One. In comparison 18 respondents checked that they were experiencing emotional problems when completing DT Two—a significant reduction in self-indicated emotional problems (P<0.001).

Based on specific information from the BPA, 41 percent of cancer patients were assigned a Case-Complexity Rating of 3 or 4, thereby warranting immediate and ongoing intervention.

Table 4. Unmeasured Financial Data Variables That Can Potentially Generate Financial Hardship

	IMPACT OF POTENTIAL HARDSHIP	
	PATIENT	PROVIDER
Federal & State Programs Advocating and assisting with securing medical benefits or assistance programs, i.e., Medicaid (with or without a spend down), Medicare Savings Programs (QMB, SLMB, QI), Medicare Low-income Subsidy.	Direct	Direct/Indirect
Potential Income Gaps Patient education may include advocating and assisting with Social Security Disability, employer short- and long-term disability, FMLA, life insurance policy, employment legal issues, estate planning.	Direct	Direct/Indirect
Coordination of Benefits Providing unbiased medical coverage support and information regarding available medical coverage payer options. To include information about Medicare options, including Advantage and Supplement plan options. Explain information about private or group insurance plans. Explain insurance terminology such as deductibles, co-pays, and maximum out-of-pocket.	Direct	Direct/Indirect
Psychological Connecting patients or family with counseling, education regarding role changes, support regarding family system changes, development of communication skills, and coping strategies.	Direct	Direct/Indirect
Practical Local and national resource utilization patient education may include assisting patients and families with transportation; skilled and unskilled home health needs; emotional or mental health support and referral; diagnosis-related individual and family counseling or support; communicating with family, friends, and physicians; and individual or family crisis support.	Direct	Direct/Indirect

The Economics of Cancer

Medically speaking, to assure the best possible outcome, it is critical for a cancer patient to be diagnosed correctly and quickly. Further, to help avoid or mitigate a negative economic outcome from the cancer diagnosis and treatment, providers should offer cancer patients and their families education and assistance on many common but complex psychosocial, emotional, and financial issues.

Table 4 (above) identifies unmeasured variables that can potentially increase financial burden and negatively affect a patient's ability to adequately manage numerous complicated issues. For example, if a cancer patient does not apply for Social Security Disability at the appropriate time, the patient may experience a significant reduction in monthly income. Depending on the circumstances, the patient may experience a substantial gap in which no income is received. Often cancer patients are required to pay a substantial amount for direct medical services and indirect nonmedical necessities. These additional expenses are often incurred at a time when patients have a reduced amount of financial revenue to pay for the additional costs.[5]

Bottom line: inadequate education and support may impact the financial and emotional well-being of the patient and ultimately increase the financial vulnerability of the institution providing medical care. To help mitigate risk, providers should discuss these issues with patients and offer education on how to develop an economic game plan to reduce potential financial-related burden.[7]

At McDowell Cancer Center, we use an ACCESS database to monitor and track:

1. The costs of drugs supplied by pharmaceutical manufacturers.
2. Financial payment from co-pay or cost-sharing foundations providing financial payment of services directly to the medical provider.
3. Financial payment directly to the patient from local or national foundations to assist with practical needs.
4. Financial payment directly to the medical provider from private insurance that without intervention would have otherwise not been obtainable. (Uninsured patients without resources or patients who did not qualify for private insurance because of a pre-existing condition or for safety-net programming, such as Medicaid, were enrolled in available insurance programs, such as the Ohio High Risk Pool. We

collect insurance payment data from these programs from the hospital billing system. These patient accounts would otherwise fall under the Hospital Care Assurance Program [HCAP] or other hospital financial assistance programming in which the hospital may receive pennies on the dollar for medical services provided.)

Table 5 (below) is financial data we collected in 2012. Here is how we track this financial data.

Local foundations. We use an ACCESS database to monitor data, which is then exported into an EXCEL spreadsheet to identify monthly trends. For example, if the cancer patient is behind on his or her mortgage payment and the resource counselor verifies potential financial hardship, the patient will be referred to one or more foundations that can assist with these practical needs. In turn, the resource counselor will communicate with these local foundations and enter the appropriate financial data in the database. If patients have access to financial resources to assist with practical needs, funds will then be available to pay for direct medical services and indirect expenses. In theory, this support reduces our program's financial vulnerability to nonpayment for services provided, thus having a positive financial impact on our program.

Cost-sharing foundations. Again, we track data in ACCESS and export it to EXCEL to monitor monthly trends. Patients must have insurance to qualify for these foundations. Our reimbursement specialist completes a benefits investigation and determines if the patient has met the maximum out-of-pocket (OOP) required by the insurance provider. If not, the reimbursement specialist enrolls patients in diagnosis-specific foundations that can help cover some or all of the medical expenses until the required OOP limit is met. It should be noted that after a patient meets the maximum OOP, the insurance provider then pays for medical services at 100 percent.

Our reimbursement specialist tracks all financial assistance from these foundations. Further, our reimbursement specialist submits the patient's qualified medical expenses directly to the cost-sharing foundation. Basically, our reimbursement specialist serves as a proxy between the foundation and the patient.

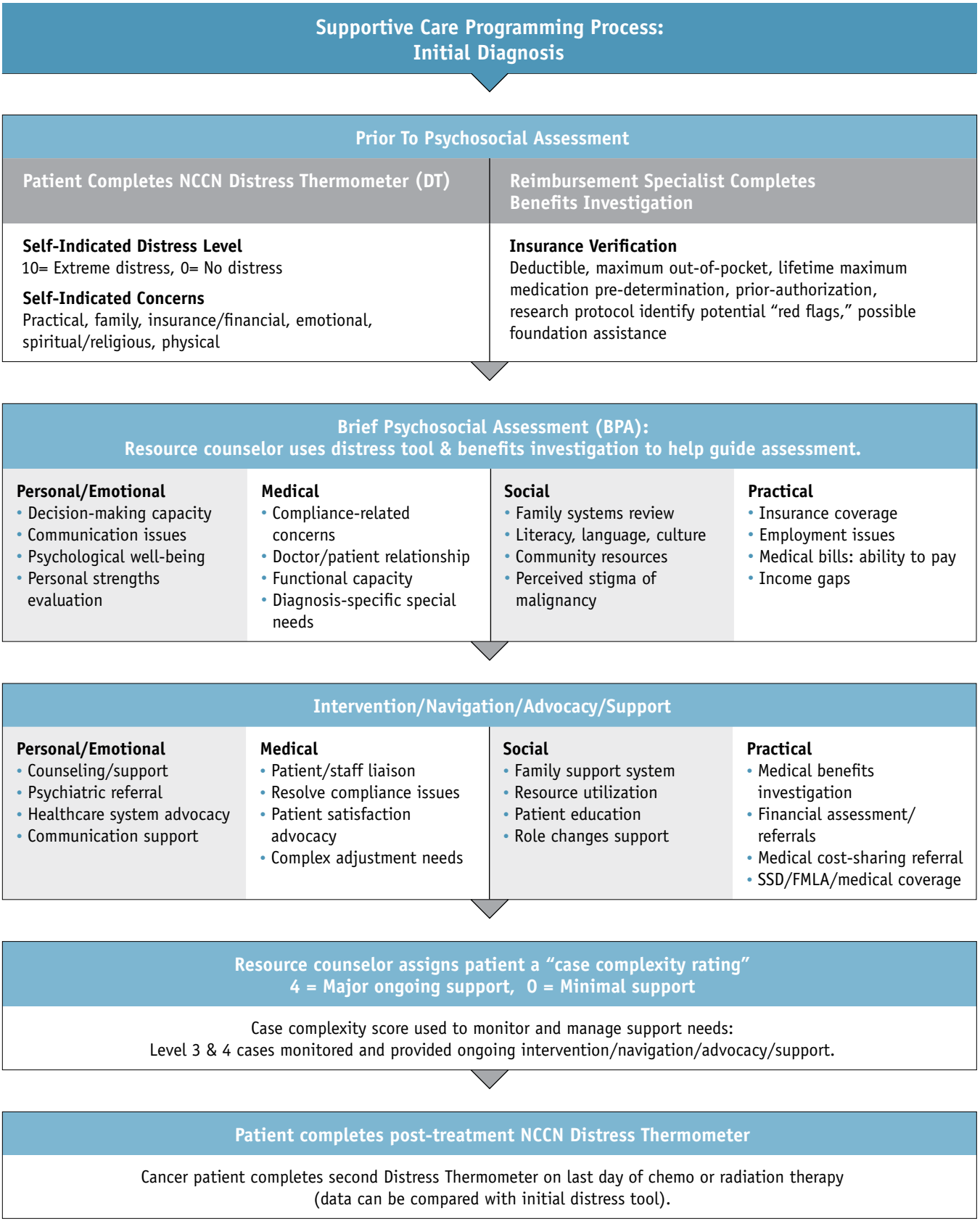
We track all co-pay amounts approved, requested, and received. With funds distributed directly from the foundation to the provider, both providers and patients benefit.

Coordination of benefits. We track and monitor data in the same way, using ACCESS and EXCEL. Our resource counselor obtains relevant financial data directly from the insurance remit form located in the provider billing system. If an uninsured patient does not meet the requirements to qualify for state or federal medical coverage, the resource counselor will evaluate and enroll the patient in other available insurance programs. For example, if a patient is not eligible for Medicaid, the resource counselor may help the patient enroll in other medical coverage options, such as the Ohio High Risk Pool insurance. If patients are experiencing financial hardship and unable to pay their COBRA

Table 5. Measured Financial Data, 2012
Variables That Can Potentially Impact Financial Hardship & Medical Provider Financial Vulnerability

	PATIENT & PROVIDER FINANCIAL BENEFIT		
	PATIENT	PROVIDER	AMOUNT
Local Foundations Helps patients with concrete needs such as mortgage or rent payment, living expenses, insurance premium, utilities, transportation.	Yes	Indirect	$119,405
Cost-Sharing Foundations Helps cover costs related to chemotherapy or other drugs—helps with medical coverage premium assistance.	Yes	Yes	$148,403
Coordination of Benefits Helps patients with medical coverage: i.e., Ohio High Risk Pool, Private Insurance, Employer Options. Assisting patients with continuance of medical coverage, i.e., Private/State/Federal Programs, COBRA, HIPPA—connect patients with premium assistance.	Yes	Yes	$2,091,252
Pharmaceutical PAP Assists patients with non-coverage or high co-pay of drugs. These programs also help with reimbursement of drugs regarding insurance denial or off-label use.	Yes	Yes	$1,040,101

Figure 1. Supportive Process Flowchart



premium, the resource counselor will connect them with hospital-based programs or foundation assistance to help cover the cost of the monthly premium.

Funds are sent directly to the provider to pay for services delivered. This arrangement benefits both patients and providers as otherwise the medical procedures would have been billed directly to the patient. These procedures are often expensive and often result in non-payment for medical services. Often the medical provider is forced to either use Ohio's HCAP (Hospital Care Assurance Program) or write-off the account.

Pharmaceutical patient assistance programs (PAPs). We monitor these data using web-based PaprxTracker software, which is then exported into EXCEL to identify monthly trends. The PAP software provides customized management of patient accounts, including reports to track demographic and financial data. This program reports drug value according to actual hospital billing, not average wholesale price (AWP). This information is important for the cancer program to determine the financial benefits of using PAPs.

Our reimbursement specialist enrolls patients in PAPs under three circumstances:

1. Uninsured, underinsured, or self-pay coordination
2. Coverage denial support
3. Off-label use of drug.

The reimbursement specialist and resource counselor work closely with Patient Financial Services and Pharmacy to assure that no payers are billed for drug(s) provided from a PAP. Again, both patients and providers benefit from the use of PAPs as the drug cost would have been billed directly to the patient, again resulting in a high potential of non-payment for medical services.

Our Process

Figure 1 (page 46) details our structured supportive care process, addressing both psychosocial distress and patient navigation as defined by CoC guidelines. Also outlined in the process are methods to help reduce the patient's existing or potential economic burden and the impending financial vulnerability of the medical provider. The resource counselor and the reimbursement specialist are necessary components needed to ensure program functionality.

Staff training & background. Our resource counselor training includes:

- MSW, LISW-S: Independent licensure with supervisor designation
- OSW-C: Certified Oncology Social Worker
- OSHIIP Certified: Ohio Department of Insurance.

Our resource counselor has expertise in 1) coordination of medical benefits issues, 2) local, state, and national resource utilization, and 3) program development and implementation.

Our reimbursement specialist has an Associate Degree in Business Administration, with expertise in:

- Medical billing and coding
- Local, state, and national resource utilization
- Coordination of medical benefits issues.

Benefits investigation. A vital element of our supportive care process is the completion of a comprehensive benefits investigation for every patient beginning therapy. Without this investigation, it is impossible to calculate the actual out-of-pocket requirements as determined by the insurance provider. All relevant information is verified and used to identify potential red flags, such as prior-authorization needs or if it is possible for the patient to reach potential lifetime or annual maximums. This information is also used to determine if a patient would benefit from cost-sharing support.

A vital element of our supportive care process is the completion of a comprehensive benefits investigation for every patient beginning therapy.

Our team. Support provided to educate patients, physicians, and staff includes 1) coordination of benefits, 2) billing concerns, and 3) payment issues specific to each patient. The goal: to maximize patient access to therapy and decrease potential patient financial burden by reducing payer-related administrative burden. A team approach is used to provide these services.

Key staff or department contributors include:

- Resource counselor
- Psychosocial coordinator
- Reimbursement specialist
- Cancer center manager
- Outpatient pharmacy
- Patient financial services.

Key services provided include:

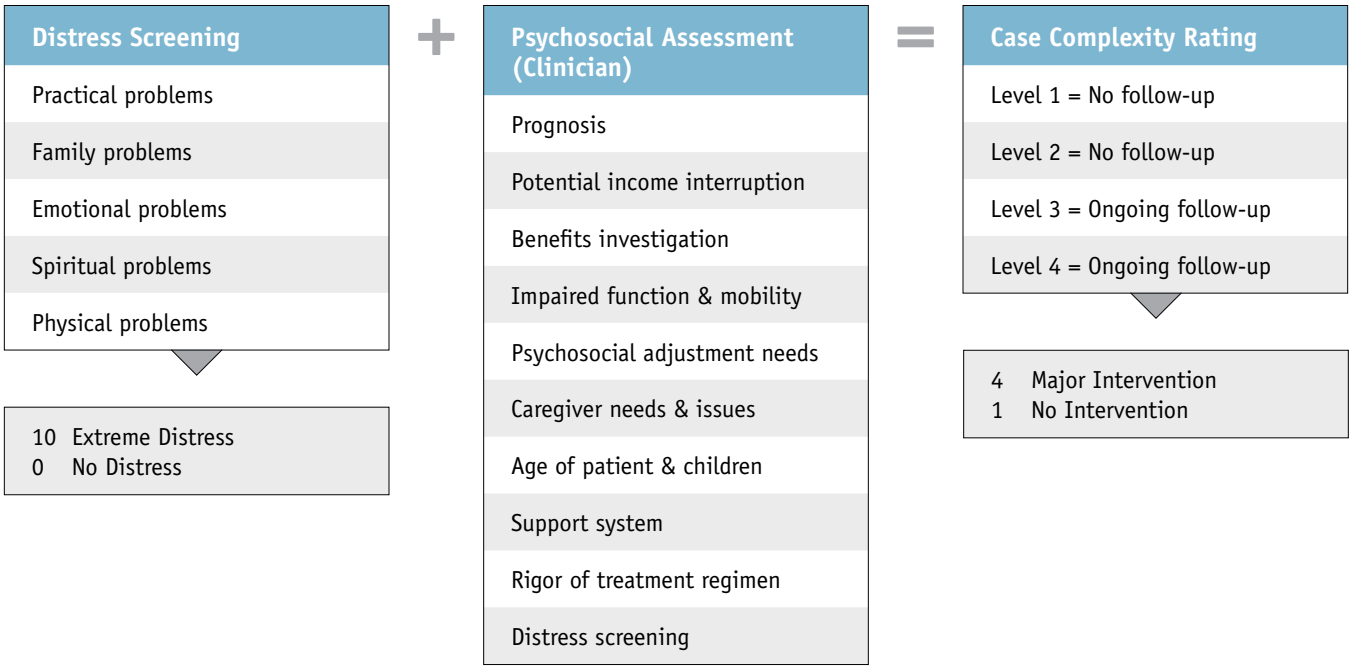
- Prior-authorization screening and tracking
- Coverage denial appeals support
- Off-label use support
- Compliance check for medical necessity on Medicare patients
- Manufacturer and foundation assistance as needed.

New CoC Standards

All CoC-accredited programs are required to phase in standards 3.1 (Patient Navigation) and 3.2 (Distress Management) by 2015. Our process (as identified in Figure 1) meets all identified requirements and criteria to meet compliance standards for CoC Continuance of Care Services.

Distress Management: CoC Standard 3.2 "requires accredited program to develop and implement a process to integrate and

Figure 2. Perceived/Actual Variables = Case Complexity Rating



monitor on-site psychosocial distress screening and referral for the provision of psychosocial care."[3] Our process meets all CoC process requirements:

1. Timing of screening
2. Method
3. Tools
4. Assessment and referral
5. Documentation.

Patient Navigation: CoC Standard 3.1 "requires each program to establish a patient navigation process, driven by a community needs assessment to address health care disparities and barriers to care for patients."[3] It is important to recognize that this standard does not require each program to hire a patient navigator, but to provide a process by which patient navigation is taking place. The process must address specific barriers identified in the required community needs assessment. We conducted a community needs assessment in collaboration with three local hospitals. (Note: new healthcare reform guidelines also require every not-for-profit hospital to complete this same community health needs assessment.)

Our team addresses the healthcare disparities identified by this assessment during the brief psychosocial assessment that is scheduled with every new cancer patient. We use program data to evaluate the effectiveness of interventions that address self-indicated stressors. Additionally, the distress tool and benefits investigation data is used to assign each patient a case complexity rating (CCR), which is used to evaluate if additional ongoing support is needed. As noted in Figure 1, subsequent to the brief psychosocial assessment, the resource counselor assigns each patient a case complexity rating from 1-4 to help monitor and connect patients having more complex needs with ongoing assistance and supportive care.

Figure 2 (above) identifies the method used by the resource counselor to tally the case complexity rating. Each patient receiving a case complexity rating level 3 or 4 is scheduled for ongoing follow-up.

Discussion & Conclusion

In addition to increased emotional concerns, as noted in Table 2 on page 43, increased distress can also be associated with financial-related burden. Both the direct cost of resources consumed (medical and nonmedical) and the indirect costs of employment-related productivity lost as a result of the disease and treatment must be considered to fully appreciate a patient and family's economic vulnerability.[8]

Distress management and patient navigation are vital components of patient care, and our outcomes support those findings. Our model for conducting psychosocial and financial assessment:

- Minimizes the financial vulnerability of our cancer program as a result of bad debt, charity care, and write-offs
- Establishes a process for making mental health referrals to patients and families in need
- Allows staff the opportunity to connect patients and families to available financial and/or supportive resources

- Offers staff the opportunity to discuss existential issues related to their perceived "cancer experience" for the patient and family.

Patients diagnosed with cancer often deal with very complex issues. Accordingly, healthcare professionals should not assume that patients understand appropriate supportive resource utilization. Interventional programming and patient education addressing the concerns related to the "person in environment" is a critical component of providing care for the "whole" patient and caregiver. Our data confirm the economic and non-monetary value of addressing financial, emotional, physical, practical, and existential concerns on the front end of patient care. When psychosocial services address the patient, caregiver, and the medical provider, it is a win-win for all stakeholders. Certainly, it is worthwhile for medical providers to invest in supportive care staff. Such staff can help develop programs that address needs regarding a patient navigation process, psychosocial distress screening, potential financial burdens experienced by the patient, and the potential economic vulnerability of the institution providing medical care. OI

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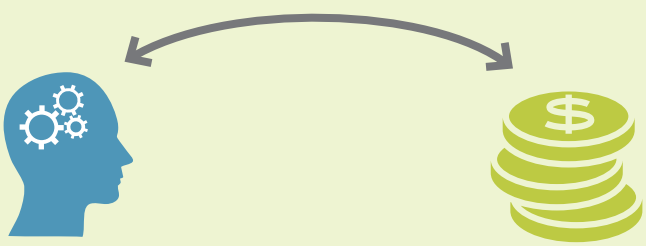

Are Your Patients Struggling to Pay for Their Cancer Treatment?

There's no need to reinvent the wheel. The *Financial Assistance Toolkit* is ACCC's newest resource to help you develop a robust patient financial assistance program, and it's filled with the information, tools, and templates you need to help your patients with their financial issues.

For more information, visit www.accc-cancer.org/filn

TOOLS

The toolkit includes:

- Worksheets to help assess benefits
- Tools to estimate the costs of chemo care plans
- Sample appeal and collection letters
- Tools to track patient assistance and drug replacement programs
- Policies for pre-authorizations, denials, appeals, and more!

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- PDF Version: Free

ACCC Non-Members

- Print Version with Binder: $149 (plus shipping)
- Print Version without Binder: $79 (plus shipping)
- PDF Version: $75

PLUS MORE!

The Financial Information and Learning Network education program has additional resources to strengthen and expand your financial assistance services.

- Video Series
- 10-Part Practical Course
- Financial Assistance Forum

ACCC Education

This project is sponsored by:
Bristol-Myers Squibb, Genentech, Lilly Oncology, Novartis Oncology, and Teva Oncology

ACCC Center for Provider Education: Overview

The Association of Community Cancer Centers (ACCC) provides community-based cancer programs with the skills necessary to increase their efficiency while maintaining the highest standards of quality care. The Center for Provider Education relies on educators with expertise in the management of hospital and office-based cancer programs, financial analysis, policy and reimbursement, marketing, and healthcare economics to achieve this goal.

Small-Population Cancers

For providers who may see just a few patients with small-population cancers, also known as low-incidence cancers, keeping up with rapidly changing treatment options can be a challenge. ACCC's Improving Quality Care in Small-Population Cancers project is here to help. Each project is designed to give providers the information they need to better care for their patients with these less common cancers. Current small-population cancer projects focus on chronic myeloid leukemia, multiple myeloma, and acute promyelocytic leukemia. A unique resource is the Small-Population Cancers Forum, which provides ACCC members with access to each project's Community Resource Centers (CRCs). These ACCC-member programs serve as virtual "experts-in-residence" on specific small-population cancers.

Learn more at www.accc-cancer.org/education/SPC

Melanoma

Unlike many other cancers, the rates of melanoma have been increasing in the U.S. over the last 40 years. Detection, diagnosis, and treatment of melanoma involves many different specialties within cancer programs-outreach and screening, surgery, dermatology, medical oncology, pathology, nursing, social work, and administration. ACCC's Melanoma: Strategies & Tools to Improve the Patient Experience project will identify effective practices in care coordination and delivery to help community cancer programs to improve the patient experience. Resources and practical tools, along with case studies of programs demonstrating effective practices will be shared with ACCC members through a special print supplement.

Learn more at visit www.accc-cancer.org/Melanoma

Multiple Myeloma

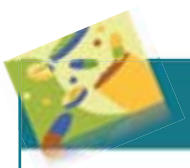
In 2013, the American Cancer Society estimates there will be about 22,350 new cases of multiple myeloma in the U.S. As with other small-population cancers, the challenge for providers in caring for patients with multiple myeloma is staying current with rapidly changing treatment options when seeing few patients with this disease each year. ACCC's Improving Quality Care in Small-Population Cancers: Multiple Myeloma project seeks to provide members of the cancer care team with the most current information on how to support multiple myeloma patients throughout their illness from diagnosis, through treatment, which might include a bone marrow transplant, and follow-up care. Project components include effective practices that cover clinical, supportive care, and programmatic elements; online resources; and access to Community Resource Centers for multiple myeloma.

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

The Financial Information & Learning Network

In its new standards, the commission on cancer (CoC) requires cancer programs to "conduct an assessment of barriers to care for patients with cancer" by the year 2015. One of the biggest barriers facing patients today: the cost of care. No longer just a problem for the uninsured, even patients with insurance need help paying high deductibles and co-pays. In response, ACCC's unique education program supports financial specialists, social workers, patient advocates, and other cancer program staff as they navigate patients through the increasingly complex ins and outs of paying for cancer treatment. The program includes a 10-part online course for providers; a toolkit with nearly 200 pages of resources, including worksheets to assess benefits, tools to estimate the cost of care, and templates to help develop a payment plan; an online community where providers can connect directly with peers to share experiences and ideas; and short videos of experienced financial specialists sharing successful strategies. Let ACCC help.

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



Oral Therapies

Increasingly, anti-cancer therapies are being developed as oral agents. In fact, estimates are that over the next decade the oncology pipeline will include up to 30% oral anti-cancer agents. Many issues surround oral therapy including cost, patient adherence, and how the shift from IV therapy to oral therapy may affect the patient experience of care. ACCC's Oral Therapies: Improving the Patient Experience education project will explore the barriers and challenges patients face when prescribed oral therapy, and develop effective practices for the use of oral therapies in the community setting. Resources will be developed to help providers and patients.

action

SAVE THE DATES!

ACCC 30th National Oncology Conference
October 2-5, 2013
The Westin Boston Waterfront
Boston, Mass.

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

Learn more and register at
www.accc-cancer.org/meetings

Seeing Beyond Age in the Management of Lung Cancer

This CME activity is intended for oncologists, nurses, and other health-care professionals who provide care to older patients with advanced non-small cell lung cancer (NSCLC).The goal of this activity is to discuss and evaluate the latest advances in the care of older patients diagnosed with advanced NSCLC. This activity is supported by independent education grants from Lilly USA, LLC, Celgene, and Genentech.

Monitoring Milestones in Patients with CML

This CME activity is intended for hematologists and oncologists involved in the diagnosis of chronic myeloid leukemia (CML) and the treatment and management of patients with this disease. This activity is designed to improve clinicians' ability to apply evidence-based guidelines and data to stratify, treat, and manage patients with CML and to assess response to treatment. This activity is supported by an independent education grant from Novartis.

For more information, go to www.accc-cancer.org/education/CCP-Overview.asp.

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Qualified Candidates: Possess an MBA, MHA, or MSN or Bachelor's degree with equivalent progressive experience in healthcare. Must have a minimum of 2-4 years of administrative management experience in a healthcare environment, including developing and implementing new programs, as well as demonstrated experience in establishing working relationships across institutional boundaries.

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Rapid City Regional Hospital is a 417-bed regional referral center located at the base of the beautiful Black Hills in Rapid City, South Dakota. Our newly-formed Palliative Care service has need of mid-level practitioners in the inpatient (Hospitalist Services) and outpatient (Cancer Care Institute) arenas.

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Rhode Island Hospital is currently hiring a full-time Nurse Practitioner I. The Nurse Practitioner I will facilitate a quality hospital experience and outcome for patients within a cost-effective time frame. The Nurse Practitioner I will be responsible to the Medical Director of Patient Services and responsible for overseeing the progress of a specific caseload of patients across the care continuum to include pre-admission and post-discharge when feasible. Acts as an educator, consultant, and liaison to healthcare providers caring for the patients across the care continuum.

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Apply online at http://jobs.lifespan.org/rhode-island/nurse-practitioner/jobid3120533-nurse-practitioner-i_infusion-center-jobs. EOE.

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Responsibilities: The Oncology Clinical Dietitian is responsible for assessing the nutritional needs of the Seacoast Cancer Center patients and implementing creative nutrition care plans with patients and family members. This includes, but is not limited to, addressing swallowing and digestive difficulties and recommending enteral and parenteral nutrition. The dietitian collaborates with the entire care team and is a part of the patient's total treatment. This position also follows inpatients with cancer related diagnoses. This position participates in the cancer center's support groups, survivorship program, anti-cancer lifestyle program, and community health-related events.

Requirements and Experience
Licensed and registered, certified in oncology nutrition, minimum 2-3 years clinical experience.

If you are a compassionate healthcare professional committed to providing the highest quality patient care, apply online at www.wdhospital.com/careers. EOE.

Take the Fight

College students serve as lay navigators, dedicated to a single patient's journey through cancer

BY DAVID WARREN AND MARCY POLETTI, RN, MSN

In November 2012 non-profit TaketheFight launched a program to train and pair leading college students one-on-one with cancer patients. These students serve as lay navigators, helping patients and families fight more efficiently and effectively, and make more informed decisions. In its first partnership, TaketheFight selected the Comprehensive Cancer Center at Wake Forest Baptist Medical Center Winston-Salem, N.C., as its inaugural site. The founders', a father-son team, initial experience with Wake Forest Baptist was for treatment of the father's glioblastoma. During that time they established a strong relationship with their forward-thinking medical team, who encouraged patients to be at the center of their care.

What Teach for America is achieving for the education system, TaketheFight aims to accomplish for the healthcare system. In the winter of 2012, TaketheFight hand-selected a corps of Wake Forest University's top undergraduate students, each of whom committed to fight alongside a cancer patient and their family for the duration of the semester. Their mission was to provide unparalleled, individual support to assist patients in navigating the cancer ecosystem of complex medical information and terminology, office visits, medical records, and resources.

Bayard Powell, MD, section chief for Hematology and Oncology, describes TaketheFight as, "Taking some very energetic, talented young folks and partnering them with patients who can benefit from some help. I see it largely as helping empower the patient to be a partner with us [providers]."

To become a "cancer strategist," students are trained through a collaborative approach of TaketheFight's unique organizational system and instruction by the Comprehensive Cancer Center's key department heads, including oncologists, patient and nurse navigators, chaplains, patient transportation staff, nutritionists, cancer program administrators, and others. Students also read assigned patient-centric cancer strategy books, written by physicians and survivors. Students are on-boarded via the Comprehensive Cancer Center's Volunteer Services, which entails additional training, including HIPAA instruction.

In its inaugural semester, oncologists, nurses, and patient navigators began referring patients to TaketheFight, which in turn paired student strategists one-on-one with motivated patients. TaketheFight's patient population is purposefully diverse, ranging from all walks of life and various diagnoses of breast, brain, pancreatic, liver, melanoma, and leukemia cancers, to additional comorbidities such as HIV,

diabetes, and sickle cell. Beginning this fall, patients will request their own strategist by reviewing strategist video introductions and résumés online in order to streamline the referral process.

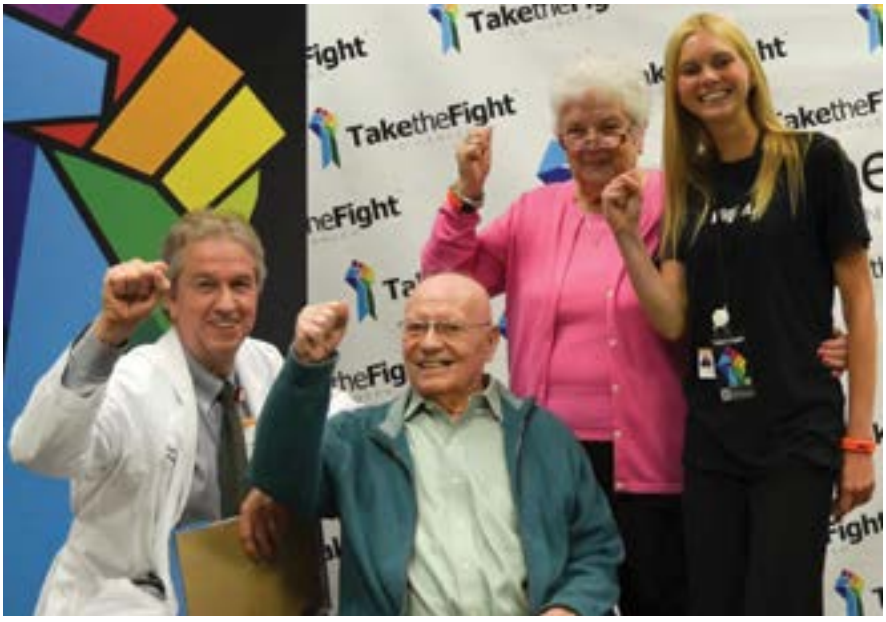
Once students and patients are paired, patients must sign releases and HIPAA authorizations so strategists can access medical records to be able to understand and discuss each patient's case with the medical team, the patient, and family, as well as other TakethеFight strategists. Students assist patients as "adopted family members," organizing their records and working collaboratively within TakethеFight's online system to develop and track patient medical histories, medication forms, and pre-visit forms prior to medical visits.

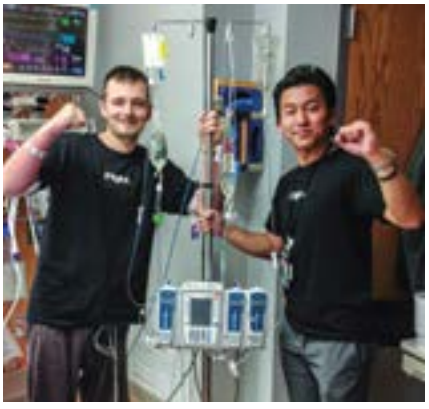
Strategists call, text, and email patients multiple times a day; some have even gone out-of-state to visit their patient and caregivers at home and slept in hospital rooms, allowing caregivers to leave the hospital to rest in their own bed so they return refreshed the next day. When class schedules allow, strategists join the patient during physician visits to help patients absorb and understand physician instructions, as well as sharing with physicians details the patient might be unable to describe or recall.

Program goals are simple:

- Maximize each patient's limited time with his or her medical team
- Ensure patients adhere to the treatment strategies
- Direct patients to appropriate resources within the cancer program
- Utilize the energy of youth to give patients an intangible boost of support.

"It not only helps your patients, it also helps the students," remarks Kerry Snyder-Husted, RT, RIT, MBA, administrative director of the oncology service line. "And in a time where fewer students are going into healthcare, it's a fabulous opportunity to give students an exposure to what it's like to work with patients."





With the upcoming projected shortage of 4,000 oncologists—15 million visits unaccounted for—over the next several years, according to the ASCO Workforce Committee, the timing couldn't be more important in improving the oncology workforce deficit. "I think that [student exposure] can really be helpful for us and where we're heading in our future in healthcare," Snyder-Husted reiterated.

Boasting 100 percent patient satisfaction, TakethеFight continues to expand its flagship chapter at the Comprehensive Cancer Center at Wake Forest Baptist. And its leadership is in active discussion with other NCI-designated cancer centers to select additional launch sites.

TakethеFight is headquartered in Bethesda, Md., and can be found online at www.takethefight.org, on Facebook at facebook.com/takethefight, or by emailing connect@takethefight.org. It's not a charity—it's an army. And no one fights alone. OI

David Warren is CEO and Founder, TakethеFight, Bethesda, Md.
Marcy Poletti, RN, MSN, is program administrator for Oncology Services, Wake Forest Baptist Medical Center, Winston-Salem, N.C.

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