ONCOLOGY ISSUES

This publication is a benefit of membership
Association of Community Cancer Centers

November | December 2015

Closing the Loop with a Post-Biopsy Breast Clinic

ACCC
Association of Community Cancer Centers

AstraZeneca

In EGFRm+ advanced NSCLC,

NEARLY 2 OUT OF 3

cases of progression with first-generation EGFR TKIs are related to the T790M mutation[1,2]

NEARLY **2 OUT OF 3**

CASES ARE RELATED TO T790M

T790M is an acquired mutation and has been identified as the most common mechanism of acquired resistance in nearly 2 out of 3 patients with advanced NSCLC.[1,2]

When patients with EGFRm+ status progress, prior to changing therapy, a biopsy is reasonable to identify mechanisms of acquired resistance, as stated in NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®).[3]

Find out how the T790M mutation could affect the future of NSCLC at: EGFRevolution.com.

AstraZeneca is conducting ongoing research to understand the science of the T790M mutation as a driver of resistance.

References: 1. Yu HA, et al. Analysis of tumor specimens at the time of acquired resistance to EGFR-TKI therapy in 155 patients with EGFR-mutant lung cancers. *Clin Cancer Res.* 2013;19:2240-2247. **2.** Arcila ME, et al. Rebiopsy of lung cancer patients with acquired resistance to EGFR inhibitors and enhanced detection of the T790M mutation using a locked nucleic acid-based assay. *Clin Cancer Res.* 2011;17:1169-1180. **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.7.2015. ©National Comprehensive Cancer Network, Inc. 2015. All rights reserved. Accessed June 12, 2015. To view the most recent and complete version of the guideline, go online to NCCN.org. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, NCCN GUIDELINES®, and all other NCCN Content are trademarks owned by the National Comprehensive Cancer Network, Inc.

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DEPARTMENTS

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Association of Community Cancer Centers

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Association of Community Cancer Centers

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FROM THE EDITOR

A Piece of the Pie

BY CHRISTIAN DOWNS, JD, MHA

One of my first experiences in healthcare was serving as an "intern" for a credentials and privileges committee at a local community hospital. While the work was often mundane, from time to time I was able to gain interesting insights into how the healthcare world really worked.

The committee was comprised of physicians from the hospital and its surrounding community. The committee's main purpose: to review the educational background and experience of physicians applying to use the hospital's services.

My memory is a little foggy on the details, but I remember a physiatrist who once applied for privileges. Physiatrists, as you may know, are physicians who work with patients on physical rehabilitation (sometimes in lieu of surgery) and it's a relatively small specialty.

As the committee was reviewing the application, two physicians were questioning whether the community had too many physiatrists. The main thrust of their argument was that the physiatrist two hours away at the academic medical center more than met the needs of the community. You don't need to be Perry Mason to see the weakness in their argument—until you understand that these two physicians were orthopedic surgeons. Now put aside the legal issues of not granting privileges to this physiatrist. Is anyone surprised the surgeons made this argument? Essentially, they viewed the physiatrist as "taking a piece of the pie" that could possibly go to them.

In cancer delivery today, we have the chance to do better. It's common knowledge that we have a shortage of providers: medical oncologists, radiation oncologists, oncology-certified nurses, and more. This shortage is only expected to increase over the next decade. Over the same time period, the number of cancer patients—primarily driven by the aging baby boomer population—is expected to grow. So what are we going to do?

In this edition of *Oncology Issues*, we offer a series of articles that focus on using advanced practice nursing to expand our workforce resources.

In "Advanced Practice in Oncology Nursing" and "The NP and CNS: Advanced Practice Nurse Roles," an experienced team of APNs look at the roles and responsibilities of their profession, and how effective use of these clinicians to the full extent of their credentials and abilities may help fill this growing workforce shortage. More, the authors highlight years of research that shows APNs offer quality of care comparable to physicians (often at a lower cost) and high patient satisfaction scores.

Does that mean APNs can (or should) replace physicians? Not at all. Instead these authors carefully build a case that shows how successful cancer programs are able to "partner" these clinicians—to the benefit of providers, patients, and the cancer program.

This type of collaborative thinking will need to continue if we are going to adequately address our cancer patients' needs. Many big thinkers in cancer delivery are going further and incorporating primary care physicians, pharmacists, social workers, and other sub-specialists, such as pulmonologists and endocrinologists, into the cancer care continuum.

To be successful in this ever-changing healthcare landscape, cancer programs must accept that some of these providers may be performing new or expanded roles in oncology. But don't worry; there's enough pie to go around, even if we have to learn a little portion control. OI

The Evolution of OPEN

BY STEVEN L. D'AMATO, BSPharm, BCOP

In 2004 the Association of Community Cancer Centers (ACCC) launched the Oncology Pharmacy Education Network (OPEN), an initiative spearheaded by an ACCC pharmacist member Ernie Anderson Jr., RPh, FASHP, who went on to serve as ACCC President 2008-2009. OPEN's goal: to engage the multidisciplinary team on issues (e.g., clinical, financial, and operational) that pharmacy providers face every day.

The practice of pharmacy, and in particular oncology pharmacy, has evolved through the years; it is no longer a discipline focused solely on drug therapy. The complexities of pharmaceutical care now encompass many domains of practice, which the clinical pharmacist must be equipped to deal with. True to its mission of advocacy, education, and multidisciplinary care, ACCC recognized the need for a platform to help pharmacy address these new complexities of evolving oncology care.

One way ACCC is meeting this need is through annual OPEN pre-conferences scheduled with the fall National Oncology Conference. These one-day programs offer sessions on cutting-edge oncology pharmacy issues and provide abundant peer-to-peer networking opportunities for pharmacists, administrators, and other cancer program staff with an interest in pharmacy concerns.

Last month's OPEN pre-conference, held in conjunction with the ACCC National Oncology Conference in Portland, Ore., had a phenomenal turnout. Session content was varied and generated some great discussions. Expert presenters led discussions on bundled payments, differences and benefits between hospital and private practice sites of service, distribution models and the challenges they present to oncology pharmacy and cancer programs, and budgetary projections for 2016 as new drugs, regulations, and technology continue to challenge all of us in the oncology community.

Recently, ACCC expanded OPEN's reach by initiating a series of regional OPEN meetings. This concept evolved from a local program, the New England Hematology Oncology Pharmacy Symposium (NEHOPS). The symposium was started nine years ago by a group of New England pharmacists with the goal of gathering the best oncology pharmacists in the nation to deliver cutting-edge talks on clinical oncology disease state management. Held annually in Massachusetts every October, this symposium has grown in attendance each year, which speaks to the program's value and quality. In 2015 ACCC partnered with NEHOPS to host three regional OPEN meetings in New Jersey, North Carolina, and Florida. In the future, ACCC looks to continue these types of collaborative opportunities for OPEN to ensure its membership and their multidisciplinary care teams across the country can gain critical insight on oncology pharmacy issues.

Today, the oncology pharmacy continues to evolve as cancer treatments become increasingly more complex and costly. As new payment models and programs develop and roll out with increasing frequency, it is now necessary for oncology pharmacists to understand the business and operational sides of oncology. Indeed, the future of cancer care in this country requires that *all* of our providers work at the top of their licenses and develop new skills to meet the challenges ahead. Thankfully ACCC has the tools and resources to help, including the white paper, "Dispensing Pharmacy: A Value Proposition for Oncology Practices," which mailed with this edition of *Oncology Issues*. Stay tuned for more as OPEN continues to evolve. OI

Coming in Your 2016 *ONCOLOGY ISSUES*

- The Cancer Care Collaborative—Where Patients are An Active Member of the Cancer Care Team
- Developing & Implementing a Patient Advisory Council
- Building Bridges, Breaking-down Barriers: One Psycho-Oncology Program's Approach to Quality Patient-Centered Psychosocial Care
- A Support Program for Providers that Prevents Burnout and Improves Care
- Everything You Need to Know about Patient Navigation Core Competencies, Training, and Certification
- Everything You Need to Know about Patient Navigation Metrics & Benchmarking
- Improve Patient Engagement, Improve Your Cancer Program
- The Oncology Nursing Fellowship Program: A Pipeline for the Future
- Health Info on the Go: Community Outreach at the Farmer's Market
- Developing an Oncology IT Strategy

more online @ accc-cancer.org

INFO

2015 Financial Advocacy Survey

Read what more than 100 of your colleagues have to say about their financial advocacy service line—including the 5 most collected metrics—as well as training needs, salary ranges, and education levels for this fast-growing profession. accc.cancer.org/FAN.

PAPER

Institute for the Future of Oncology White Paper

Read about 5 essential actions cancer programs can take today to help achieve a positive impact on patient care in today's integrated healthcare environment. accc.cancer.org/institute.

APP

ACCC-FAN-app.org

Patient assistance programs, co-pay programs, travel and housing assistance, and more are now just a click away. Because the last concern your patients should have to worry about is how to pay for their cancer treatment. ACCC-FAN-app.org.

VIDEO

2015 ACCC Innovator Award Winners

Couldn't make it to the ACCC National Oncology Conference in October? Find out why more than 600 of your colleagues attended this hugely successful meeting by watching these short videos that highlight the 2015 award-winning programs. accc.cancer.org/innovator.

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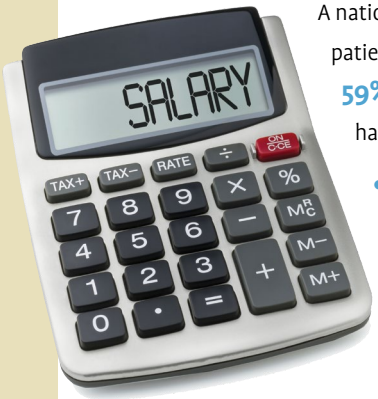
Most Cancer Patients Want to Stay On the Job—Despite Workplace Challenges



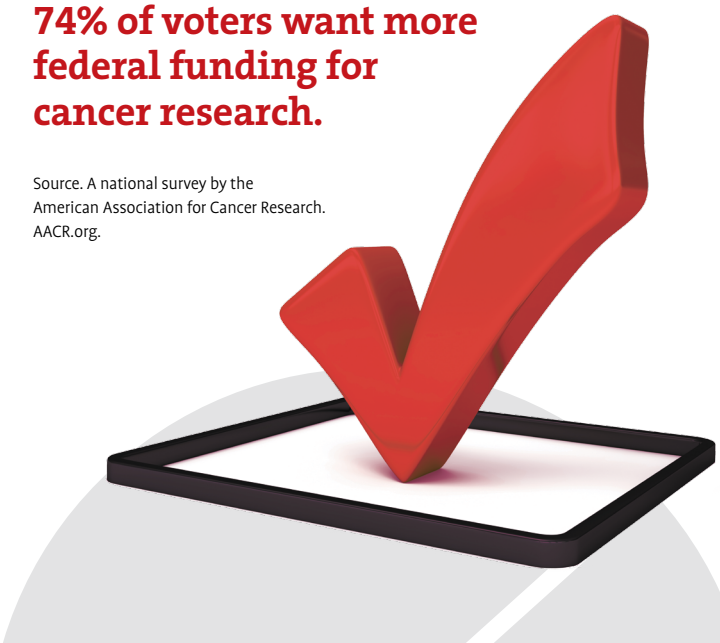
A national study finds that **73%** of cancer patients and survivors want to work—although **59%** who worked through treatment felt they had no choice. Other survey findings:

- **73%** of employed survivors reported that working during treatment helped them cope.
- **68%** of employed survivors said their primary reason for continuing to work during treatment was financial concerns.
- More employed women (**39%**) than men (**30%**) reported their work negatively impacted their treatment; however, more women (**78%**) than men (**66%**) felt working during treatment helped them cope with their cancer.
- Of those who are working and who underwent treatment, more women (**63%**) faced challenges than men (**50%**), and were more likely (**20%**) to work a reduced schedule (**13%**).

Source. Cancer and Careers. Harris Poll Survey. cancerandcareers.org.

74% of voters want more federal funding for cancer research.

Source. A national survey by the American Association for Cancer Research. AACR.org.



facts

Healing Hands

A 2014 study of patients with AML who received **50** minutes of Swedish massage **3** times per week for **7** weeks, found all participants experienced stress reduction, increased comfort, and relaxation.[1]

A recent meta-analysis of nearly **600** cancer patients found massage therapy significantly reduced pain compared to the conventional standard-of-care alone, and was particularly effective in eradicating surgery-related pain.[2]

Sources. [1]Taylor AG, et al. Gentle massage improves disease- and treatment-related symptoms in patients with acute myelogenous leukemia. *J Clin Trials*. 2014;4:1000161. [2]Lee SH, et al. Meta-analysis of massage therapy on cancer pain. *Integr Cancer Ther.* 2015;14(4):297-304.

RAC Appeals

- Hospitals have appealed **49%** of RAC denials through June 2015, and have won **64%** of the appeals that have completed the process.
- In **89%** of RAC denials appealed to the administrative law judge (ALJ) level, the judges have taken more than the 90-day statutory limit to render a decision.
- **44%** of all RAC appeals are still working their way through the five-level appeals process.

Source. American Hospital Association. Exploring the Impact of the RAC Program on Hospitals Nationwide: Results of AHA RACTRAC Survey, 2nd Quarter 2015. aha.org/advocacy-issues/rac/ractrac.shtml.

What Our Cancer Patients are Saying

- **62%** of cancer patients say that having a specific individual coordinate their care is important; however, only **32%** experienced this type of coordination while undergoing treatment.
- Among patients who currently have coordinated care, the majority (**74%**) were "completely satisfied," with their care, suggesting a direct correlation between the delivery of coordinated care and the overall patient experience.
- Less than half of patients (**46%**) and caregivers (**49%**) understand terms such as genomic testing, immunotherapy, precision cancer treatment, and molecular testing. Even fewer know the benefits, suggesting there is a lack of clear and important communication between care teams, patients, and caregivers.
- Nearly **40%** of cancer patients seek a second opinion, and these are typically younger patients. This finding suggests that younger cancer patients, in general, take a more proactive role in their treatment decisions.

Source. 2015 The Cancer Experience: A National Study of Patients and Caregivers. Cancer Treatment Centers of America. cancercenter.com.

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Worth the Wait?

LEAH RALPH

In August 2015 the Health Resources and Services Administration (HRSA) released its much-anticipated "mega-guidance" on the 340B Drug Pricing Program, proposing new limits on the program but stopping short of a complete overhaul, prompting mixed reviews from stakeholders. ACCC has long advocated for more clarity in the program—something both covered entities and drug manufacturers can agree on—and we commend HRSA for taking this important step amid legal challenges and Congressional pressure. But just how far the guidance will go remains unclear. While HRSA's directives are not legally binding, it does inform 340B participants how the agency believes the program should operate and we can expect it will be used as a basis for future audits. Stakeholders are still working to decipher the impact the guidance will have on the day-to-day operations of the 340B program, and it remains to be seen whether Congress will codify the guidance or move any other legislation related to 340B.

While HRSA's guidance addresses many of the key issues needing clarification, including hospital and patient eligibility, contract pharmacy arrangements, and audit procedures, it most notably proposes to place tighter controls on patient eligibility. For a patient to be classified as a 340B patient of a covered entity (CE), HRSA would require the 340B prescription to satisfy six new criteria:

1. Patient received a healthcare service from a registered CE.
2. The service is provided by a CE-associated provider.
3. The drug prescription is a result of the service provided by the CE and, importantly, the service is not limited to the dispensing or infusion of a drug.
4. The service is consistent with the CE's grant or contract.
5. The prescription is the result of an outpatient service, determined by how the CE bills the payer.
6. The CE maintains access to auditable health records.

Importantly, HRSA also specifies that the revised patient definition would be applied on a prescription-by-prescription basis, meaning that each individual encounter would be evaluated for eligibility and patients would not qualify for 340B drugs for all of their needs based on being treated by the CE for one medical issue.

So what does this mean? Essentially, the guidance significantly strengthens the relationship between the covered entity and patient, requiring that the CE provide a more comprehensive service for a patient to be classified as a patient of that CE and receive discounted 340B drugs. This will likely have significant implications for referrals and follow-up care, limiting the ability of patients to move between sites of care. As an example, under the guidance, in a situation where a patient sees a physician at a non-340B site as a referral or follow-up to care, even though the patient's care originated at a CE, that patient would no longer be eligible to receive a 340B discount. However, HRSA specifies that when a patient returns to the CE for ongoing care, subsequent prescriptions would be eligible for discounts. This would also mean, for example, that if an outside physician (i.e., a non-CE-physician) sends patients to a CE for an infusion, that drug would not be eligible for the 340B discount because the guidance stipulates that the service the CE provides cannot be limited to the infusion or dispensing of a drug.

Other provisions that are important from the provider's perspective include HRSA's guidance on the eligibility of an offsite, or "child site," facility. HRSA proposes to retain the current standard that the facility or clinic be listed as a reimbursable line of the hospital's Medicare cost report, but also specifies that the services provided have associated Medicare outpatient costs and charges. Notably, HRSA is soliciting alternative methodologies to this approach. While there were no major changes to hospital eligibility, HRSA does clarify how to meet certain requirements to participate, requiring more detailed documentation, which potentially could result in increased administrative burden.

The guidance is fairly quiet on contract pharmacy arrangements, declining to impose any restrictions on the number of CE contract pharmacy locations or arrangements, and instead emphasizing a CE's compliance obligations. HRSA proposes that CEs conduct a quarterly review and annual independent audit of these arrangements.

The agency may issue final guidance sometime in the following months, so stay tuned! OI

Leah Ralph is ACCC director of Health Policy.

Ordering Diagnostic Tests—Are You Providing Accurate Information?

BY CINDY PARMAN, CPC, CPC-H, RCC

Radiation and medical oncologists count on other providers for patient referrals—sometimes it is the surgeon, occasionally it is the internal medicine specialist or it may be the medical oncologist referring to the radiation oncologist (or vice versa). With the advent of ICD-10-CM, providers on the receiving end of referrals are expecting complete and accurate clinical information that may ultimately be used for diagnosis code assignment to be part of the referral process. But what if the oncologist is the physician referring a patient for a diagnostic imaging study? Will the test request have the correct patient diagnosis information with the highest degree of specificity? Unfortunately, complete and accurate orders for advanced imaging services, including CT, MRI, and PET scans, continue to challenge many healthcare organizations, regardless of which physician specialty placed the order.

The Department of Health and Human Services (HHS) recently announced goals of transferring 30 percent of Medicare payments into alternative payment models by the end of 2016 and 50 percent by the end of 2018, shifting 85 percent of Medicare payments to a model tied to quality or value by 2016 and 90 percent by 2018.[1] For any patient encounter, the CPT® procedure code(s) determines how much a provider is paid, but it is the diagnosis code(s) that determines if the service is reimbursed. The smooth, effective continuum of patient care that we want for our family members and ourselves requires clear, timely, and well-documented orders from the treating practitioners who request imaging.[2]

Medicare

It is important to remember that the Centers for Medicare & Medicaid Services (CMS) guidelines for Independent Diagnostic Testing Facilities (IDTFs) and physician offices are different from hospital ordering guidelines. In addition, commercial payer requirements for orders can also differ significantly, which means each payer policy must be obtained and reviewed. CMS has published specific rules for the ordering of diagnostic tests in the Medicare Benefit Policy Manual, Chapter 15, Section 80.6.[3] This section defines an order as a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary. For a test to be reasonable and necessary it must be ordered by the attending physician or practitioner and the ordering physician must use the result in the management of the beneficiary's specific medical problem.

The requirements for any services ordered in the hospital are detailed in the Medicare Hospital Conditions of Participation (CoP). These can be found in the Code of Federal Regulations [42 CFR §482.26(b)(4)], which states that services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.[4] And of course, all orders for diagnostic tests must be medically necessary, which means that the reason for the order (the patient's diagnosis, disease surveillance, staging, etc.) must be both documented in the medical record and accurately represented by ICD-10-CM diagnosis codes.

Non-Medicare

Most commercial payers require that advanced diagnostic imaging studies, such as CT, MRI, and PET, be pre-certified (sometimes referred to as a pre-authorization) prior to their performance. It is the referring physician's responsibility to obtain this pre-certification by contacting the payer and providing the medical reason for the exam. Upon approval, the payer issues a pre-approval number, which must be submitted by both the facility and the interpreting physician. If the payer refuses to approve the exam, neither the facility nor the physician will be paid for their services—regardless of the exam findings. Referring physicians bear the responsibility to obtain the approval because they control the patient's medical record and should have all relevant documentation to support the reason for the diagnostic test.

Required Elements for a Valid Order

For a diagnostic testing order to be valid, it must contain the following elements:

- ***Specific test to be performed.*** The referring provider may request a test with specific views or protocols (such as, chest X-ray PA and Lat, MRI T-Spine without contrast) or may request a general test (such as, CT abdomen and pelvis, ankle X-ray). Both types of requests represent valid orders.
- ***Clinical Indications.*** The referring provider must supply the diagnostic

information, signs, and symptoms or diagnosis code on the order for it to be valid. Orders received without any clinical indications or with "rule out" conditions are not valid orders for Medicare and most other payers.

- ***Referring physician/practitioner name.*** The referring provider name can be in the header of the order like on a prescription form, typed under a signature, or handwritten. If multiple provider names are on the order, it is acceptable for the name of the referring provider to be circled.
- ***Referring physician/practitioner signature.*** If the referring provider name is not typed or handwritten anywhere on the order, the provider's signature must be legible.

Clinical Indications

The challenge for referring oncologists is to provide a complete and accurate diagnosis, signs, and symptoms or other reason for the diagnostic study. The need for detailed clinical information is always driven by patient care and medical necessity. Remember that the order for the test is why the study is needed by the treating physician, not just what condition the patient has. For example, the patient may have lung cancer, but the test may be ordered for intermittent and persistent headaches. Radiology examinations are performed and interpreted in a manner that addresses the clinical reason for the test.

And remember, a "payable" diagnosis or covered medical condition cannot be listed if it is not documented in the patient chart, and there are some scenarios where an imaging study may be ordered but not reimbursed by the patient's insurance. Some policies only allow a limited number of advanced imaging studies, such as PET scans, during a single course of therapy or over the patient's lifetime. As a result, oncologists should ensure that the clinical indications for the test are thoroughly and accurately reported. Table 1, page 14, lists some problem scenarios that radiologists encounter when oncologists order diagnostic tests.

The radiology department requires details regarding the patient's condition from the referring providers, including medical and radiation oncologists. Specifically, providers must document the location, severity, and the reason for the diagnostic test as it applies to a designated medical condition or presenting patient symptoms. Although it may appear that the referring provider is being asked for a lot more information, in reality the details required for the radiology order are the same details required for the clinical assessment and patient progress note. In other words, the referring oncologist is only required to provide ordering information that should already have been documented.

Choosing Wisely®

First announced in Dec. 2011, Choosing Wisely (ChoosingWisely.org) is part of a multi-year effort led by the ABIM Foundation to support and engage physicians in being better stewards of healthcare resources. The overall goal is to help physicians and patients engage in conversations to reduce overuse of tests and procedures and help patients make smart and effective care choices. Participating specialty societies are working with the ABIM Foundation and Consumer Reports to share the lists widely with their members and convene discussions about the physician's role in helping patients make wise choices.

The mission of the ABIM Foundation: to advance medical professionalism to improve the healthcare system. The Foundation achieves this by collaborating with physicians and physician leaders, medical trainees, healthcare delivery systems, payers, policy makers, consumer organizations, and patients to foster a shared understanding of professionalism and how the tenets of professionalism can be adopted into practice. Both the American Society of Clinical Oncology (ASCO) and the American Society of Radiation Oncology (ASTRO) participate in this endeavor and below are some of the items related to testing procedures:

1. Don't perform PET, CT, and radionuclide bone scans in the staging of early prostate cancer at low risk for metastasis.
2. Don't perform PET, CT, and radionuclide bone scans in the staging of early breast cancer at low risk for metastasis.
3. Don't perform surveillance testing (biomarkers) or imaging (PET, CT, and radionuclide bone scans) for asymptomatic individuals who have been treated for breast cancer with curative intent.
4. Avoid using PET or PET-CT scanning as part of routine follow-up care to monitor for a cancer recurrence in asymptomatic patients who have finished initial treatment to eliminate the cancer unless there is high-level evidence that such imaging will change the outcome.
5. Don't perform PSA testing for prostate cancer screening in men with no symptoms of the disease when they are expected to live less than 10 years.
6. Don't routinely recommend follow-up mammograms more often than annually for women who have had radiotherapy following breast conserving surgery.

Remember that while these are specialty society recommendations, they do not constitute regulatory guidance, although some payers may reference these guidelines in policies or other publications. In addition to this specialty society information, other publications provide information on ordering diagnostic tests. For example, a large prospective trial indicates that an interim PET/CT scan following two cycles of rituximab plus cyclophosphamide, doxorubicin, vincristine and prednisone given every 14 days (R-CHOP-14) does not help guide treatment decisions in patients with diffuse large B-cell lymphoma who go on to receive six cycles of R-CHOP-14.[5]

Clinical Decision Support

The Protecting Access to Medicare Act of 2014 mandated the use of a clinical decision support tool in the ordering of every

Table 1. Problem Scenarios Radiologists Can Encounter When Oncologists Order Diagnostic Tests

ORDERING CONCERN	CORRECTION REQUIRED
VAGUE MALIGNANCY DESCRIPTION: "Breast cancer" "Bladder cancer" "Metastatic lung cancer" OR non-specific diagnosis codes	• Specific location of malignancy • Staging, including all known sites of disease • Quadrant, section, organ-specific area • Primary or secondary malignancy • Active malignancy, history of malignancy
It is essential that the imaging study be pre-authorized and/or performed for the correct diagnosis. If the patient has a history of lung cancer and an MRI of the brain is requested to determine if there are brain metastases, the correct diagnosis on the order is "personal history of lung cancer."	
SURVEILLANCE OR STAGING	• Personal history of malignancy • Prior treatment (chemotherapy, radiation therapy, surgery) • If no current conditions, report surveillance or aftercare code
There are no unique ICD-10-CM diagnosis codes for "staging." In this scenario, only those medical conditions known to be a fact about the patient can be coded and reported. For example, if the patient has no current symptoms and is post-treatment to breast cancer with no evidence of any malignancy, the diagnosis codes would include personal history of breast cancer and personal history of radiation and/or chemotherapy.	
RECURRENCE	• New presenting signs or symptoms • Active malignancy, same site as prior malignancy • Staging, including all known sites of disease
If the patient is symptomatic, then a description of the symptoms provides the reason for the study. However, if the imaging study is performed in order to determine if there is a recurrence or a new site of disease in the absence of patient symptoms, this may not be a payable imaging procedure.	
"RULE OUT"	• Patient signs, symptoms • If no conditions, report observation for suspected malignancy
Some patients present for an initial evaluation without a diagnosis of malignancy. An advanced imaging study performed to determine if there is a potential area of interest can be ordered based on the patient's current symptoms. If there are no symptoms, a screening diagnosis code can be reported, which *may not* be a payable imaging service.	
FOLLOW-UP	• Report code for follow-up care • Personal history of malignancy • Prior treatment (chemotherapy, radiation therapy, surgery) • Existing secondary sites of malignancy
Once the treatment has been fully completed, the primary diagnosis code will be the follow-up code, which also may not be reimbursed. Keep in mind that some payers will not pay for additional imaging to a known area of malignancy once treatment has been completed, unless the patient has symptoms of disease spread or new sites of disease.	

Medicare outpatient CT, MRI, nuclear medicine, and PET study performed in the U.S. Clinical decision support (CDS) is scheduled to be implemented Jan. 1, 2017, for all higher modality services (e.g., CT, MRI) reimbursed by CMS in an effort to reduce duplicate and/or unnecessary scanning and associated costs.[6] According to the 2016 Medicare Physician Fee Schedule (PFS) proposed rule, this means that oncologists ordering advanced imaging studies, such as CT, MRI, and/or PET scans, on or after Jan. 1, 2017, must consult with a listed, qualified clinical decision support mechanism and the furnishing radiologist must include specific information on the Medicare claim to identify the use of CDS by the ordering physician. When fully implemented, physicians who provide imaging services will only receive reimbursement for claims that include information about the specific CDS tool used.

The goal of CDS is to determine the range of potentially appropriate imaging procedures based on indications, such as patient symptoms, information from prior exams, the patient or family medical history, and risk factors or presenting circumstances. CDS looks to drive up the quality of care while keeping costs down. Additional benefits of CDS implementation:

- Offering real-time decision support
- Reducing patient exposure to unnecessary radiation
- Documenting appropriate medical care
- Reducing rescheduling of exams.

By Nov. 2015, the Department of Health and Human Services (HHS) must specify the applicable appropriate use criteria (AUC) for imaging services. The 2016 Medicare PFS proposed rule clarifies that only AUC developed, modified, or endorsed by organizations meeting the definition of a provider-led entity (such as national provider-led specialty societies, hospitals, or healthcare systems) would be considered applicable. According to an article by the Radiological Society of North America (RSNA):[7]

"Using the CDS tools embedded with appropriateness criteria is designed to improve the accuracy of ordering advanced diagnostic studies and ensure the appropriate studies are done for the right reason on the right patient."

During the 1990s, the American College of Radiology (ACR) recognized the need to define national guidelines for appropriate use of imaging technologies. Subsequently, the ACR Task Force on Appropriateness Criteria was created to develop nationally accepted, scientifically-based guidelines. According to the ACR:[8]

"The ACR Appropriateness Criteria® are evidence-based guidelines to assist referring physicians and other providers in making the most appropriate imaging or treatment decision for a specific clinical condition. Employing these guidelines helps providers enhance quality of care and contribute to the most efficacious use of radiology."

CMS recognizes that the number of clinicians impacted by the scope of the AUC program is massive; it will apply to every physician and practitioner who orders advanced diagnostic imaging studies. The final component of the Medicare AUC program is the Identification of Outlier Ordering Professionals, including the ability to implement a prior authorization requirement for outlier professionals beginning Jan. 1, 2020.

Although imaging has significantly improved the quality of healthcare and increased value, it is an expensive tool. Orders and medical necessity will continue to be a key factor in patient care and ultimately appropriate reimbursement. However, predictability in the determination of medically appropriate studies will promote compliance, help mitigate burdensome administrative costs, and promote the delivery of a uniformly high quality of patient care. Because these new provisions place the CDS completion burden on the referring physician, oncologists may require additional time to order diagnostic imaging studies. The investment of a little extra time will be worth it, however, to ensure performing the right study, at the right time, in the right way for each individual patient. OI

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

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spotlight

PeaceHealth St. Joseph Cancer Center, Bellingham, Washington

PeaceHealth St. Joseph Cancer Center is a Commission on Cancer (CoC) accredited hospital-based facility in Bellingham, Washington, serving the Pacific Northwest. The new cancer center is just three years old and prior to its construction, fragmentation of cancer care in the community was a challenge for patients and providers. Medical oncology was located in a multidisciplinary clinic, while radiation oncology was housed on the hospital campus, and infusion was located within the hospital. "As you can imagine this was a huge burden for patients to travel around to all of these locations to receive their care and certainly was not ideal," said Jennie Crews, MD, FACP, medical director at PeaceHealth St. Joseph Cancer Center.

Recognizing the need for consolidation of services, hospital leadership and staff led the charge for building a dedicated cancer center. Through the support of philanthropic and community funding, the PeaceHealth St. Joseph Cancer Center now houses medical oncology, radiation oncology, infusion, pharmacy, clinical trials, complementary therapies, and a wide array of support services as part of what the cancer center terms "integrated cancer care."

"The name 'integrated cancer care' came from the fact that in building our brand new cancer center we are able to bring all of these services together and integrate them to the convenience of the patient," said Dr. Crews.

Services Under One Roof

The 35,000-square-foot cancer center works to provide state-of-the-art clinical and supportive services in one convenient location.

The medical oncology department is staffed by four board-certified oncologists, and the centralized location of care delivery means that patients can schedule and see both medical and radiation oncology on the same day. Radiation oncology performs IMRT and SBRT procedures with two Varian linear accelerators and the cancer center also recently launched a stereotactic brain program.

The infusion center includes 16 private suites equipped with TV and Internet access overlooking the cancer center's healing garden.

Nurse navigation services are currently available for head and neck, lung, and breast cancer patients. Support services include:

- Nutrition counseling
- Financial counseling
- Social work
- Massage
- Acupuncture
- Support groups
- Tai Chi
- Yoga classes
- Meditation
- Art therapy.

Select artwork by patients participating in art therapy is displayed on the walls of the new cancer center.

A physician assistant (PA) serves as the survivorship coordinator for cancer patients. She sees patients completing curative therapy and compiles their treatment summary and their care plans. She also refers patients to any kind of psychosocial support they may need at the completion of their treatment. In addition, the PA spends a portion of her time seeing acute patients as the cancer center's urgent care provider.

Bringing Clinical Trials to the Community

The cancer center maintains a robust clinical trials program through an aggressive screening process. Screening is based on new pathologic diagnoses within the community; every new diagnosis of cancer gets reviewed by the clinical trials department. Members of the department proactively write letters to referring physicians to say they have identified a patient—who may not have even seen anyone at the cancer center yet—but who may be a candidate for an open clinical trial. Clinical trials staff members also participate in all of the tumor boards.

"We have this beautiful new cancer center, but our program actually extends beyond the walls of this building," said Dr. Crews. PeaceHealth St. Joseph Cancer Center offers a number of outreach programs to the community, including screenings for various cancers, educational programs, and a program called Cancer 101. Hosted at the cancer center and open to the community, speakers present on topics such as nutrition, exercise, and integrative oncology.

To further strengthen ties to the surrounding community, the cancer center's advisory committee includes physicians in the community who are not employed by PeaceHealth who assist in setting strategies that meet the cancer care needs in the community.

Multidisciplinary Lung Program

PeaceHealth St. Joseph Cancer Center partners with various outside providers and community agencies to better serve their patient population. A major initiative to come out of a recognized community need is the multidisciplinary lung program. A lung cancer conference is held weekly to review all abnormal CT scans and also discuss management of diagnosed lung cancer patients. Participants include: thoracic surgery, pulmonary, radiation oncology, medical oncology, radiology, pathology, and primary care. PeaceHealth St. Joseph Cancer Center also offers lung cancer screening in the community. This initiative has proved successful with a demonstrated reduction in time from diagnosis to treatment due to the efficiency of the navigation services.

Through this program, the cancer center works very closely with primary care physicians in the health system and community to identify:

- What is appropriate follow-up for lung cancer patients?
- What tests are needed and who should perform them?
- How can patients transition back to their primary care provider in a timely fashion?

"With the projected rise in cancer cases and the workforce shortage we're facing, we need to partner and find new ways to deliver care so that these patients aren't relying completely on oncologists for their follow-up and survivorship care," said Dr. Crews.

Reaching the Rural Population

As a comprehensive cancer center, PeaceHealth St. Joseph Cancer Center serves as a hub for a large catchment area of cancer care that includes very remote regions. "Even patients who aren't flying here from those remote areas can have difficulty getting to their appointments," said Dr. Crews. The cancer center operates two satellite clinics for chemotherapy consultations and follow-up care: one on San Juan Island and another in Ketchikan, Alaska, locations that providers can only reach by plane or boat. The navigation program is critical in assisting patients with transportation issues. The navigators work closely with social work to arrange transportation and also housing for patients undergoing prolonged treatment.

The cancer center has a patient assistance program supported by philanthropic funds that distributes taxi vouchers, gas cards, or bus coins to help patients get to the cancer center and home again. Community resources include the American Cancer Society's Road to Recovery for volunteer drivers and The San Juan Eagles Treatment Support Mission Project, which provides free flights for cancer patients from San Juan Island to nearby airports.

Select Support Services:

- Financial Counseling
- Nutrition Counseling
- Navigation
- Survivorship
- Art Therapy
- Chaplain
- Support Groups

Percentage of patients accrued to clinical trials annually: 8%

Number of new analytic cases seen in 2014: 983.

tools

Approved Drugs

- The U.S. Food and Drug Administration (FDA) approved **Adcetris® (brentuximab vedotin**) (Seattle Genetics, seattlegenetics.com) for the treatment of patients with classical Hodgkin lymphoma at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation consolidation.

- Endo Pharmaceuticals Inc., (endo.com) and BioDelivery Sciences International, Inc. (bdsi.com), announced that the FDA has approved **Belbuca™ (buprenorphine) buccal film** for use in patients with chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Belbuca is expected to be commercially available in the U.S. during the first quarter of 2016.

- The FDA approved Amgen's (amgen.com) biologics license application for **Imlygic™ (talimogene laherparepvec)**, a genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.

- The FDA granted accelerated approval for **Keytruda® (pembrolizumab)** (Merck, merck.com) to treat patients with metastatic non-small cell lung cancer (NSCLC) whose disease has progressed after other treatments and with tumors that express a protein called PD-L1. Keytruda is approved for use with a companion diagnostic, the PD-L1 IHC 22C3 pharmDx test.

- Taiho Oncology, Inc. (taihooncology.com) announced that the FDA approved **Lonsurf® (trifluridine and tipiracil)**, formerly known as TAS-102, for the treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.w

- The FDA approved **Onivyde™ (irinotecan liposome injection)** (Merrimack Pharmaceuticals, merrimack.com) in combination with fluorouracil (5-FU) and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas whose disease has progressed following gemcitabine-based therapy.

- Bristol-Myers Squibb Company (bms.com) announced that the FDA granted accelerated approval to **Opdivo® (nivolumab**) in combination with ipilimumab for the treatment of patients with BRAF V600 wild-type, unresectable, or metastatic melanoma.

- The FDA has approved **Promacta® for oral suspension (eltrombopag)** (Novartis, novartisoncology.com) for the treatment of thrombocytopenia in pediatric patients one year and older with chronic immune idiopathic thrombocytopenia who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

- TESARO, Inc. (tesarobio.com) announced that the FDA approved **Varubi™ (rolapitant)** in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy.

- Bristol-Myers Squibb Company (bms.com) announced that the FDA approved **Yervoy® (ipilimumab) 10 mg/kg** for the adjuvant treatment of patients with cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm who have undergone complete resection including total lymphadenectomy.

- The FDA approved Janssen Product's (janssen.com) **Yondelis® (trabectedin)**, a chemotherapy for the treatment of specific soft tissue sarcomas—liposarcoma and leiomyosarcoma—that are unresectable or metastatic. This treatment is approved for patients who previously received chemotherapy that contained anthracycline.

Drugs in the News

- Eli Lilly and Company (lilly.com) announced that the FDA granted breakthrough therapy designation to **abemaciclib**, a cyclin-dependent kinase 4 and 6 inhibitor, for patients with refractory hormone-receptor-positive (HR+) metastatic breast cancer.

- The FDA granted fast track designation to Pfizer's (pfizeroncology.com) **avelumab**, an investigational fully human anti-PD-L1 IgG1 monoclonal antibody, for the treatment of metastatic Merkel cell carcinoma, a rare and aggressive type of skin cancer.

- Blueprint Medicines (blueprintmedicines.com) announced that the FDA granted orphan drug designation to its novel drug candidate **BLU-554** for the treatment of hepatocellular carcinoma (HCC).

- Bionomics Limited (bionomics.com) announced that its IND submission for **BNC101** passed FDA review. Bionomics plans to initiate a Phase I clinical trial in patients with metastatic colon cancer and in patients with metastatic pancreatic cancer prior to Dec. 31, 2015.

- The FDA granted fast track designation to Can-Fite BioPharma's (can-fite.com) drug candidate **CF102** as a second line treatment for HCC.

- Janssen Research & Development, LLC (janssenrnd.com) announced that the FDA accepted for priority review the biologics license application (BLA) for **daratumumab** as a treatment for patients with multiple myeloma who are refractory to both a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who have received three or more prior lines of therapy, including a PI and an IMiD.

- The FDA accepted for priority review the BLA for **Empliciti (elotuzumab)** (Bristol-Myers Squibb Company, bms.com and AbbVie, abbvie.com). This investigational signaling lymphocyte activation molecule-directed immunostimulatory antibody is for the treatment of multiple myeloma as combination therapy in patients who have received one or more prior therapies.

- Boehringer Ingelheim (us.boehringer-ingelheim.com) announced that the FDA has accepted filing applications for **Gilotrif® (afatinib)** for the treatment of patients with advanced squamous cell carcinoma of the lung progressing after treatment with first-line chemotherapy.

- A supplemental new drug application (sNDA) for **Imbruvica® (ibrutinib)** (Janssen Biotech Inc., janssenbiotech.com) was submitted to the FDA for front-line use in patients with chronic lymphocytic leukemia.

- The FDA granted breakthrough therapy designation to Pfizer Inc.'s (pfizer.com) investigational antibody-drug conjugate **inotuzumab ozogamicin** for acute lymphoblastic leukemia.

- Amgen (amgen.com) announced that the FDA accepted for priority review the sNDA of **Kyprolis® (carfilzomib) for Injection** for patients with relapsed multiple myeloma. The sNDA is designed to expand the current indication to include Kyprolis in combination with dexamethasone for patients who have received at least one prior therapy.

- The FDA has granted orphan drug designation to **LOXO-101** (Loxo Oncology, Inc., loxooncology.com) for the treatment of patients with soft tissue sarcoma.

- Bristol-Myers Squibb Co. (bms.com) announced that the FDA granted breakthrough therapy status to its immunotherapy drug **Opdivo® (nivolumab)** as a potential treatment for kidney cancer patients.

- The FDA has granted orphan drug designation to Tocagen's (tocagen.com) lead immuno-oncology product, **Toca 511 & Toca FC**, for the treatment of glioblastoma.

Approved Devices

- EIZO Inc. (eizo.com) announced that it has received FDA 510(k) clearance for breast tomosynthesis for its 5 megapixel monochrome medical monitor, the **RadiForce GX540.**

- The FDA has granted 510(k) clearance to Orfit Industries' (orfit.com) **HP Pro Solution**, a versatile immobilization system for use in brain and head and neck treatments in proton therapy.

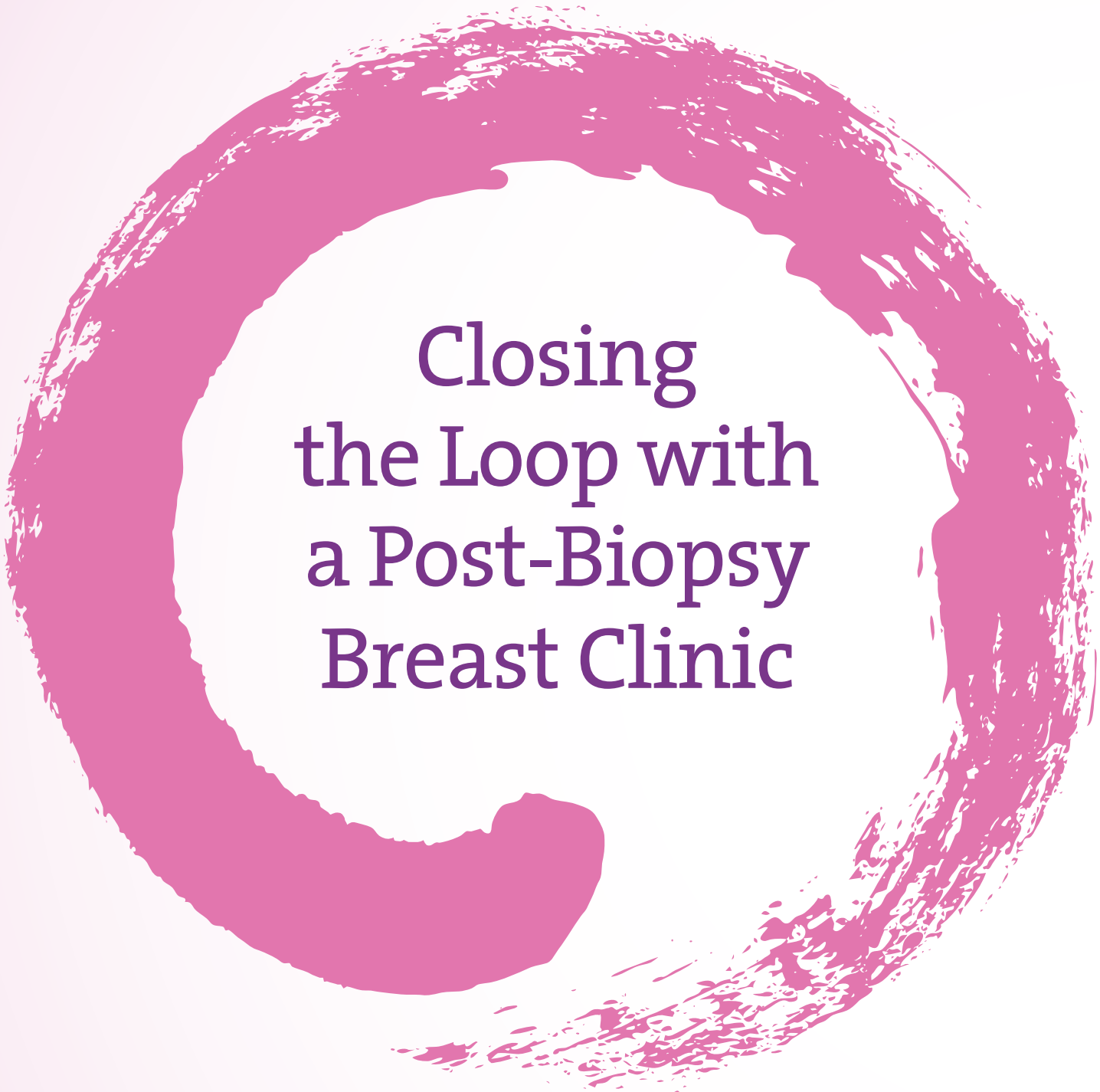
- Royal Philips (philips.com) announced that it has received 510(k) clearance from the FDA to market its **Spectral Diagnostic Suite (SpDS)**, a set of advanced visualization and analysis tools designed for the Philips IQon Spectral CT to deliver enhanced spectral viewing and advanced clinical applications capabilities.

Devices in the News

- Lightpoint Medical (lightpointmedical.com) announced that the **LightPath™ Imaging System** is now CE marked, enabling the launch of the device in Europe. The LightPath Imaging System is the first approved medical device for intra-operative molecular imaging in the world. The technology provides the potential for optical imaging of numerous cancer types. Commercial launch in the United States is planned for 2016.

Genetic Tests and Assays in the News

- Dako (agilent.com) announced that the FDA has approved the new diagnostic **PD-L1 IHC 28-8 pharmDx** that can identify PD-L1 expression levels on the surface of non-small cell lung cancer tumor cells and provide information on the survival benefit with Opdivo® (nivolumab) for patients with non-squamous NSCLC.



Closing the Loop with a Post-Biopsy Breast Clinic

BY KIMBERLY C. HUTCHERSON, MD,
AND KATHERINE S. MICHAUD, MPA

In early 2013 members of the Gwinnett Medical Center Breast Program Leadership Team voiced a need to reorganize and realign the care continuum for patients undergoing breast biopsies. The team saw an opportunity to create a more comprehensive diagnostic care pathway to include more timely results to breast biopsy patients, streamlined access to treatment specialists, and improved processes and communication with referring physicians. This vision of the Breast Program Leadership Team came at an opportune time, on the heels of great expansion and investment into the breast imaging and cancer care infrastructure at Gwinnett Medical Center (GMC), Lawrenceville, Ga., which positioned the NAPBC-accredited program to achieve a new level of service. The journey to our current patient-centered program was multifaceted.

Setting the Stage

In 2007 and 2008 GMC-Duluth opened its Center for Screening Mammography and Center for Women's Diagnostic Imaging which, like all of Gwinnett Medical Center's mammography centers, is an all-digital facility accredited by the American College of Radiology. At the new center, patients experience soothing music in a spa-like setting and relaxing environment covering just under 7,000-square-feet. But the primary benefit of GMC's all-digital technology is that diagnostic studies are completed quickly, offering clearer and faster results.

Then, in 2011, our community celebrated the grand opening of the 17,584-square-foot, all-digital, state-of-the-art Gwinnett Breast Center at GMC-Lawrenceville. The all-digital breast imaging center offers the convenience of having diagnostic and screening services in one location, as well as a 5,000-square-foot procedure suite. More importantly, the breast center has a distinctly patient-centered approach to delivering care, providing an access navigator to coordinate patient care. This process is designed to ease patient anxiety and help patients and families negotiate the multiple aspects of follow-up care.

At the same time, members of the GMC multidisciplinary support team realigned their focus on a more patient-centered program. In December 2012, the infusion centers of Suburban Hematology Oncology Associates P.C., located in Lawrenceville, Duluth, and Snellville, became the Center for Cancer Care at GMC. This newly-formed center was the result of a strengthened relationship between GMC and the physicians of Suburban Hematology Oncology Associates P.C. "The venture allows us to build on our individual strengths and together set new goals for continuing to improve our services for patients living with cancer and their families. Over time we hope this takes the form of a more seamless system of care and also additional access to services that are needed in our region," said medical director, Anthony M. Landis, DO, in a news release.

In October 2014, a new Cancer Support Center opened, adjacent to the Gwinnett Breast Center in Lawrenceville. The new


Table 1. Goals & Measure of Success
Broad Goals of the Breast Program Leadership Team
• Improve quality of care
• Increase market retention of surgical cases
• Increase breast imaging volumes
• Increase breast program integration and physician engagement
Patient-Centered Goals
• Timely service along the continuum of care: Screening-Diagnostic-Biopsy-Result-Surgery
• Personal service ✧ Personal rendering of biopsy results to patients ✧ Biopsy site evaluation and care (also helpful for American College of Radiology accreditation outcomes and complication rate calculations) ✧ Assistance with surgical consultation scheduling ✧ Scheduling of follow-up imaging
• Support increased nurse navigation to be available during the diagnostic process
Physician-Centered Goals
• Increase communication between radiologists and referring physicians
• Act as liaison between patients and referring physicians
• Support referring physicians in the care process of their patients
• Increase image-guided needle biopsy rates
• Increase market retention of surgical cases

Cancer Support Center offers patient navigation, social work, nutrition, and hereditary cancer risk assessment services. With the appropriate infrastructure in place to ensure provision of smooth coordination of care for breast cancer patients, the stage was set to take on an important process improvement initiative.

Getting Started: Post-Biopsy Breast Clinic

A multidisciplinary workgroup was convened to plan for implementing a post-biopsy breast clinic. Group members included physician leadership from radiology, primary care, surgery, medical oncology, radiation oncology, and pathology, as well as key staff members, such as the breast health nurse navigator and leadership from imaging services. The workgroup developed goals to work from and measure success (Table 1, left). Next, the workgroup set out to envision an ideal process for the timely and supportive rendering of breast biopsy results (Figure 1, right), which centered on a core principle of communication with patients and referring physicians at every step of the process. During this exercise, the post-biopsy breast clinic quickly took shape.

To reduce patients' "sleepless nights" from the point of biopsy to definitive diagnosis, the workgroup set targets: a two-day turnaround of biopsy results from pathology and a three-day turnaround from biopsy procedure to post-biopsy clinic appointment. The workgroup established routine availability for biopsy procedures on the same day as the diagnostic mammogram—for both patient convenience and to expedite care. The workgroup also made pre-scheduled appointments with a surgeon for the same day as the post-biopsy clinic or within 24 to 48 hours a priority as well.

The workgroup felt strongly that the post-biopsy visit should be a no-charge encounter, and the radiologists of North Metropolitan Radiology Associates, LLP, (a private practice affiliated with the hospital) and GMC's administration agreed. The shared commitment to ensuring optimal continuity of care through the diagnostic service rendered was easy to support. The workgroup also anticipated that a comprehensive and timely diagnostic process would likely lead to downstream market capture for breast surgery and other services.

Operationalizing the Vision

An additional .9 FTE breast nurse navigator was necessary to establish the post-biopsy breast clinic at two locations (Gwinnett Breast Center in Lawrenceville and the Center for Women's Diagnostic Imaging in Duluth). An additional key duty for the new navigator was to become a super-user of the breast imaging information system, gathering key metrics (NQMBC, ACR) to share with the Breast Program Leadership Team to measure clinical quality and aid in continued accreditation efforts.

Next, a multidisciplinary team was formed to spearhead planning efforts. Members were comprised of imaging leadership, breast center staff, nurse navigators, and radiologists representing the breast centers on the two campuses. Clinic flow and scheduling, as well as radiologist communication and dictation, were all carefully planned, trialed, and evaluated during the pilot phase. The team met for three months to iron out operational issues and fine tune the process, seeking constant feedback from patients, breast center staff, and referring physicians to create the overall flow of the diagnostic experience, including the new post-biopsy breast clinic (Figure 2, page 24).

Today, the post-biopsy breast clinic is offered at two locations, providing ease of access and a private setting in close proximity to radiologist work areas. Initially, the team planned to "soft launch" the clinic at one location and for select referring physicians, but quickly learned that serving all patients in both locations was much easier to operationalize. The team also originally envisioned that the new nurse navigator would serve as the "diagnostic navigator" staffing the clinics, while the second navigator would aid patients during active treatment and into survivorship. However, this idea evolved into both navigators providing services spanning the entire continuum of care to afford the most staffing flexibility and optimal service to patients and to avoid a navigator "handoff" after diagnosis.

The breast health nurse navigator sees all patients who return to clinic, while the radiologist sees primarily patients with a positive diagnosis or with questions that the navigator cannot effectively answer. While the post-biopsy breast clinic was initially envisioned as requiring the breast radiologist to personally render all results in the company of a breast health nurse navigator, over time this practice evolved to the radiologist rendering all positive pathology, and the breast navigators informing patients of non-cancerous findings.

"It's really been amazing to see the reaction of patients when we tell them that we will see them back in a few days to give them their results and help with any plans that may need to be made. They are so appreciative that they know what to expect and when to expect it," says Gretchen Hayward, RN, CBPN-IC, breast health nurse navigator. "What surprised us the most was

Figure 1. Initial Concept Post-Biopsy Breast Clinic & Breast Navigation Workflow

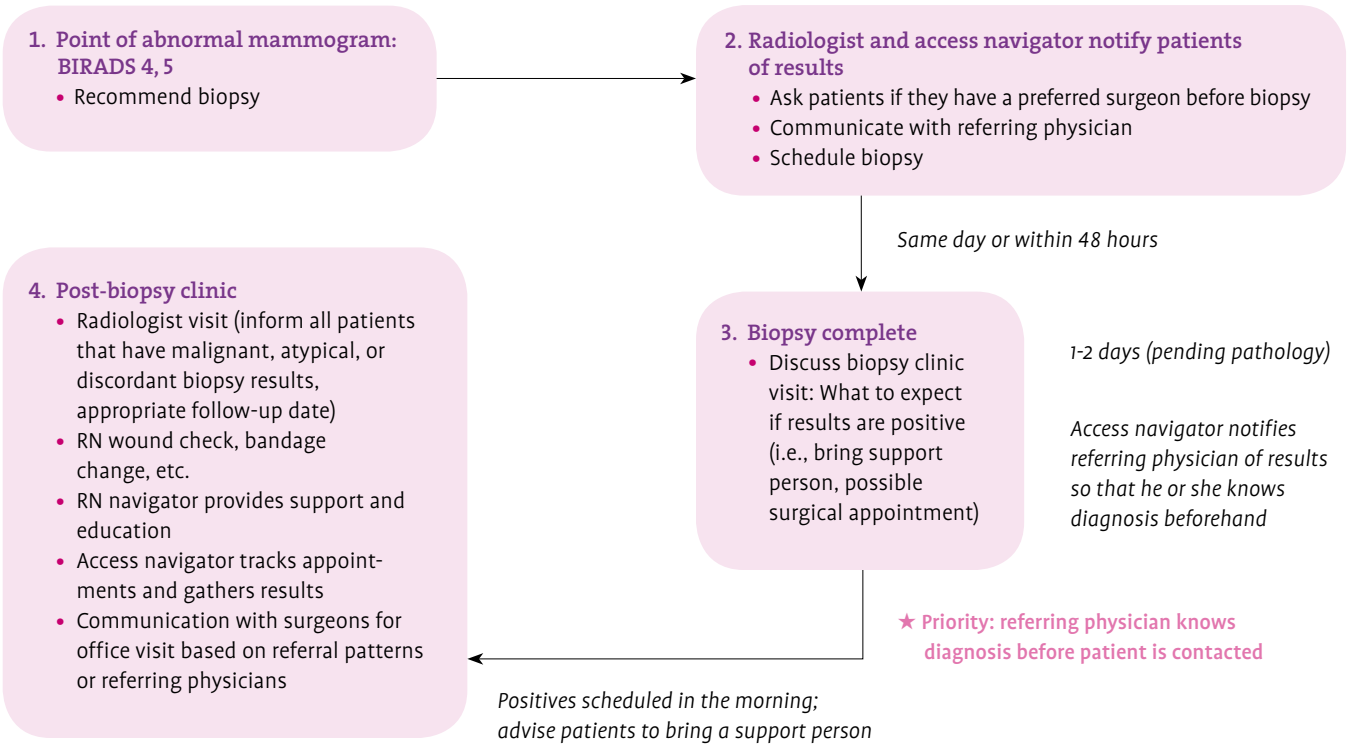
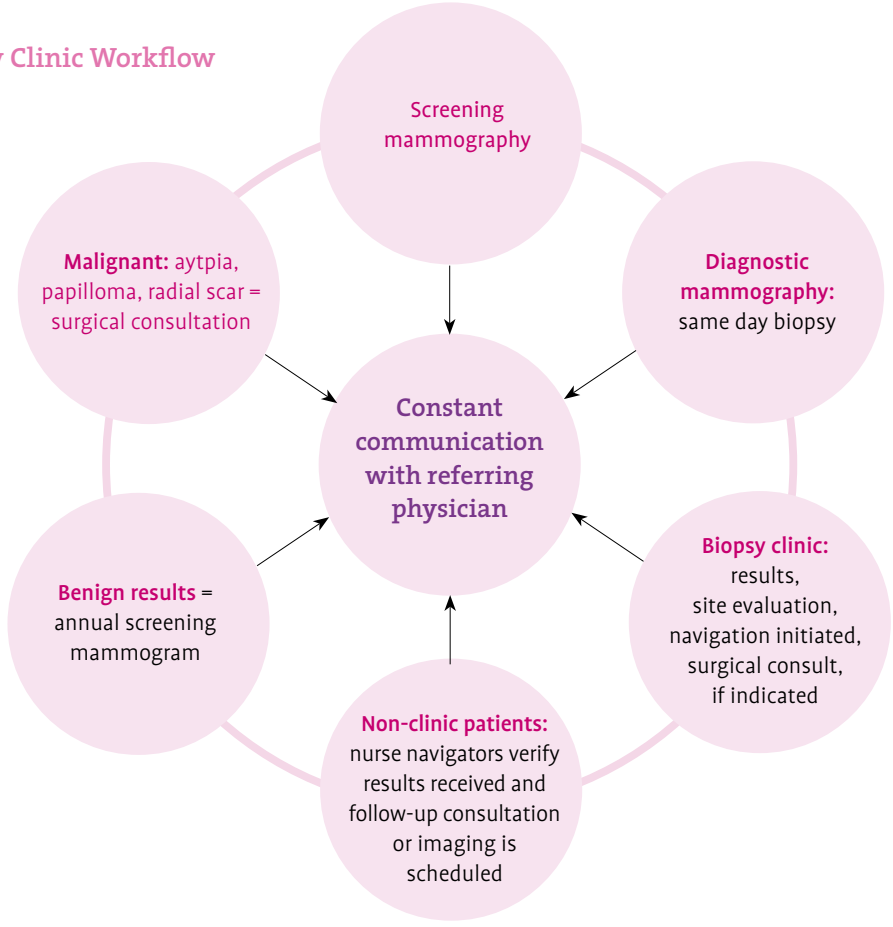


Figure 2. Post-Biopsy Clinic Workflow



> ...although patients may already know their results, they can still come to the clinic for biopsy site care and to access the supportive services...

that the patients who receive benign results from us are actually the ones who many times have the biggest emotional reaction. We are honored to be there for them, in person, to be sure that all of their questions are answered whether they receive a diagnosis of cancer or not."

Clinic Success Factors & Utilization

Ultimately, a key success factor was the flexibility of the post-biopsy breast clinic. Some referring physicians prefer to render biopsy results themselves, rather than using the post-biopsy breast clinic for their patients. The breast health nurse navigators still follow cases that do not come to clinic to ensure appropriate follow-up and identify ways to help ease any barriers to care patients may experience. Specifically, navigators call patients and, in some cases, the referring physician office. Furthermore, although patients may already know their results, they can still come to the post-biopsy breast clinic for biopsy site care and to access the supportive services, for example, to make an appointment with the American Cancer Society patient navigator or the hospital's oncology social worker or to borrow educational materials from the resource library.

Communication has been another key success factor. Initially, communication with referring physicians about the post-biopsy breast clinic was in the form of face-to-face office visits with primary care, surgical, and OB/GYN practices. GMC also developed a flier to market the program to referring physicians. Once referring physicians were made aware of the post-biopsy breast clinic, the team established processes for ensuring that referring physicians received communication about specific patients every step of the way. To meet this goal, the team developed dictation templates for the five dedicated breast imaging and interventional radiologists to employ as a cornerstone of communication—both within the breast center and to referring providers (see Figure 3, right).

The clinic is held daily at the Gwinnett Breast Center in Lawrenceville and three times weekly at the Center for Women's Diagnostic Imaging in Duluth. Across the two locations, the

(continued on page 27)

Table 2. Post-Biopsy Breast Clinic Press Ganey Survey Patient Satisfaction Results

Location	Year Prior to Clinic (FY 2013)	1st Year of Clinic (FY 2014)
Duluth diagnostic mammo	89th Percentile	93rd Percentile
Duluth screening mammo	88th Percentile	99th Percentile
Lawrenceville diagnostic & screening	84th Percentile	99th Percentile

Figure 3. Dictation Templates for Radiologists

Radiologist Communications (Procedure dictation)

Scheduled Breast Clinic

POST-BIOPSY BREAST CLINIC: The pathology results and recommendation will be reviewed with the patient in Breast Clinic. The patient has a scheduled appointment on [date] at [time].

Radiologist Communications (Procedure dictation)

No Breast Clinic

POST-BIOPSY BREAST CLINIC: The patient declined to schedule for the post-biopsy breast clinic. [Referring physician] will notify the patient of the pathology results and recommendations and evaluate the post-biopsy changes.

Radiologist Communications (Radiology/Pathology correlation)

ADDENDUM: The pathology results from the [US, ST, MRI] guided vacuum-assisted core biopsy of the [mass/calcifications] in the [o'clock] position of the [right/left] breast revealed [pathology results]. The pathology results are in concordance with the imaging findings.

The breast imaging access navigator notified [nurse] at [referring physician]'s office of these findings and recommendations on [date] at [time]. [Nurse] will notify [referring physician] when the pathology results and recommendations are available for review.

POST-BIOPSY BREAST CLINIC: The pathology results and recommendations will be reviewed with the patient in Breast Clinic. The patient has a scheduled appointment on [date] at [time].
OR
The patient declined to schedule for the post-biopsy Breast Clinic. [Referring physician] will notify the patient of the results and recommendations and evaluate the post-biopsy changes.

RECOMMENDATIONS: [Annual/Surgical consultation]. The patient has a surgical consultation scheduled with [surgeon] on [date] at [time].

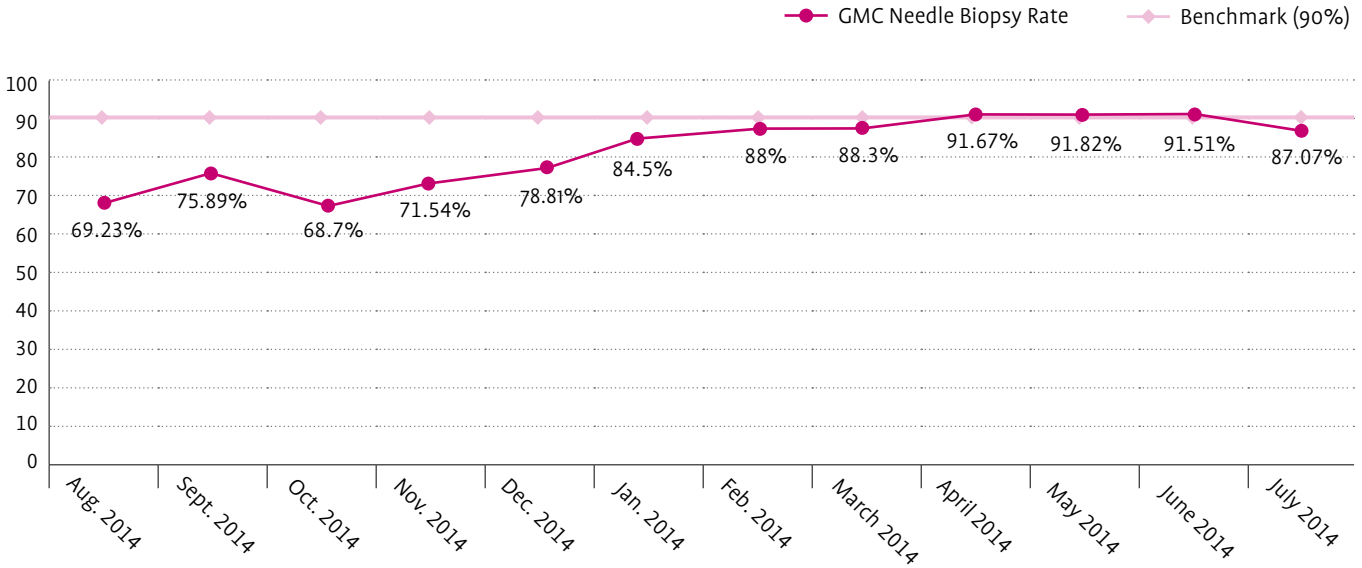
Radiologist Communications (Clinic visit dictation)

POST-BIOPSY BREAST CLINIC: The patient presented to the post-biopsy breast clinic to discuss the pathology results and to evaluate the biopsy site from the image-guided breast procedure performed on [date].

The pathology results were discussed with the patient by [radiologist] and [navigator]. Assessment of the biopsy site by the nurse navigator revealed expected post-biopsy changes. No significant hematoma or signs of infection were identified. The breast health nurse navigator provided oncology support and resource information.

RECOMMENDATIONS: Annual mamogram/Surgical referral/ Risk-reduction referral

Figure 4. Gwinnett Medical Center Needle Biopsy Rate



About Gwinnett Medical Center

Gwinnett Medical Center is a 553-bed nationally-recognized, not-for-profit healthcare network with acute-care hospitals in Lawrenceville and Duluth, Ga. Offering oncology, cardiovascular, orthopedic, and neuroscience specialty care, as well as a full continuum of wellness services, GMC's 5,000 associates and 800 affiliated physicians serve more than 400,000 patients annually. To learn more about how GMC is transforming healthcare, visit gwinnettmedicalcenter.org or follow us on at facebook.com/gwinnettmedical, twitter.com/gwinnettmedical, or youtube.com/gwinnettmedical.

- 2015 Women's Choice Award America's Best Hospitals-Obstetrics
- Georgia Trend-Top Large Hospital
- Organizational Commitment to Safety, HPI Partnership
- CoC Accredited Comprehensive Community Cancer Program
- Accredited Breast Program (NAPBC)
- ACR Breast Imaging Center of Excellence
- Certified Oncology Rehabilitation Program (Oncology Partners)
- Lung Cancer Screening Center of Excellence (Lung Cancer Alliance)
- Chest Pain Center Accreditation
- Primary Stroke Certification

- Beacon Award in Critical Care Nursing Excellence
- Best Nursing Home – *U.S. News and World Report.*

Our Community At-a-Glance

Gwinnett County is located in the northeast suburbs of the metropolitan Atlanta area and boasts the second largest county population in the state of Georgia with 859,304 residents in 2013. Home to more than 600 foreign-owned companies, Gwinnett County is very diverse, with more than 150 languages spoken at Gwinnett county public schools. Gwinnett is the 61st largest county population in the United States with a 6.7 percent population growth from April 1, 2010 to July 1, 2013.

(continued from page 24)
average monthly number of patients returning for clinic is 46 (of 81 biopsy recommendations). The Center for Women's Diagnostic Imaging, while seeing less breast biopsy volume overall, is more heavily utilized by patients and referring physicians for clinic. Roughly 70 percent of breast biopsy patients return to the post-biopsy breast clinic at the Center for Women's Diagnostic Imaging, while only about 40 percent return to the Gwinnett Breast Center. This finding is attributed to the fact that our Duluth community is more primary care driven in terms of referrals, while our Lawrenceville community is more heavily populated with surgeons who refer to Gwinnett Medical Center for breast image-guided diagnosis, but may prefer to render their own results.

Outcomes

The post-biopsy breast clinic has brought anticipated gains in patient satisfaction, as well as increased breast surgery volumes and market retention. In a study comparing a six-month snapshot one year before clinic implementation to the same six-month period during the implementation year, the program saw both a 21 percent increase in surgical breast cases overall, and a 26 percent reduction in outmigration of surgical breast cases operated on at competing hospitals. Compared to the prior year, patient satisfaction increased significantly—particularly at the Gwinnett Breast Center—the year the clinic was implemented (Table 2, page 25).

Patient satisfaction with the post-biopsy breast clinic comes as no surprise to Christopher Hagenstad, MD, medical oncologist and hematologist and medical director of the Cancer Genetics and Risk Assessment Program. "The positive impact I see is the clinic reducing the time patients spend waiting for results and, in turn, they can more quickly begin any needed steps to start cancer treatment. The clinic provides great information to patients and does an excellent job of also communicating with ordering physicians, which makes the overall process of care work well," he said.

GMC saw a major quality of care improvement from the enhanced collaboration and communication the post-biopsy clinic brought to the broader Breast Program—a 21 percent increase in image-guided core biopsy rates. This quality of care indicator was a separate but related concern that program leadership was studying at the same time that the post-biopsy breast clinic was implemented. Figure 4, left, shows the marked improvement in image-guided core biopsy rates since initiation of the post-biopsy breast clinic in the fall of 2013.

The post-biopsy breast clinic has broadly impacted Gwinnett Medical Center's cancer program and breast programs alike. It has set the bar for how a comprehensive approach to care—well communicated and coordinated—can benefit our patients in ways they can see and feel. OI

Kimberly C. Hutcherson, MD, is the medical director of Breast Imaging and Intervention at Gwinnett Medical Center in Lawrenceville and Duluth, Ga. She is an associate with North Metropolitan Radiology Associates, LLP. Katie S. Michaud, MPA, former director of Oncology at Gwinnett Medical Center, is currently director, Oncology Services, University of Vermont Medical Center, Burlington, Vermont.

Patient Education Tool

Women's Imaging Radiologists

North Metropolitan Radiology Associates (NMRA), LLP, is proud to partner with Gwinnett Medical Center. Each radiologist is board-certified and provides sub-specialty reading and interpretation to ensure that your diagnosis is made in the most accurate and timely fashion. To better assist you in identifying NMRA radiologists who are included on your insurance plan, and because insurance plans typically list individual physicians rather than physician groups, NMRA's women's imaging radiologists are listed below. Please check with your insurance plan to verify that the NMRA radiologists are participating providers on your plan. NMRA radiologists are not individually employed by Gwinnett Medical Center. Women's imaging radiologists are listed in alphabetical order by last name after Medical Director Kimberly C. Hutcherson, MD.

Kimberly C. Hutcherson, MD, is the medical director of Breast Imaging and Intervention at Gwinnett Medical Center in Lawrenceville, Ga. She is an associate with North Metropolitan Radiology Associates, LLP, and has been in her current position at Gwinnett Breast Center since 1999. Dr. Hutcherson is a frequent guest expert on breast health, and has been featured on national radio and television shows. She has also been an honorary and keynote speaker at Gwinnett's American Cancer Society Gala, in recognition of her leadership in the battle against breast disease.
Fellowship: Magee Women's Hospital–University of Pittsburgh Medical Center (Women's Imaging)
Residency: University of South Alabama
Internship: Baptist Medical Center, Birmingham, Ala.
Medical School: Meharry Medical College

Mark Ferrara, MD
Fellowship: Emory University (Breast Imaging)
Residency: Indiana University School of Medicine
Internship: Deaconess Medical Center
Medical School: University of Nevada

Jennifer Gillis, MD
Fellowship: Emory University (Breast Imaging)
Residency: University of Virginia (Radiology)
Internship: University of Virginia (Surgery)
Medical School: University of Vermont

Stephanie Roberson, MD
Fellowship: Northwestern University (Women's Imaging)
Residency: University of Texas–Houston/MD Anderson Cancer Center
Internship: Washington Hospital Center
Medical School: Howard University College of Medicine

Cynthia Robinson, MD
Residency: Michael Reese Hospital
Internship: Hennepin County Medical Center
Medical School: University of Minnesota

Gwinnett Breast Program Highlights

State-of-the-art, spa-like breast imaging centers in Lawrenceville, Duluth, and Dacula (Hamilton Mill), Ga. Services include:

- Screening and diagnostic digital mammography in five locations, including a mobile mammography unit
- Breast ultrasound
- Bone densitometry
- Breast MRI
- Imaged-guided needle localizations (for surgery)
- Image-guided biopsies
  - Stereotactic-guided core biopsy
  - Ultrasound-guided fine needle aspiration
  - Ultrasound-guided core biopsy
  - MRI-guided core biopsy
- Tomosynthesis.

Breast Clinic scheduled with the patient, radiologist, and nurse navigator to review test results within three days of diagnosis. Breast Program features include:

- Well-trained and experienced surgeons, nurses, and technologists.
- Access to the Center for Cancer Care that offers medical oncology services, including chemotherapy infusions and injections in Lawrenceville, Duluth, and Snellville, Ga.
- Weekly pre-treatment multidisciplinary breast conferences to review and discuss patient cases and develop individualized treatment plans.
- Clinical trials information and enrollment.
- Women's Cancer Support groups offered in English and Spanish.
- Chaplaincy services to provide spiritual support.
- Pain Management Center offers individualized pain treatment plans.
- Certified oncology rehabilitation services including lymphedema and occupational and physical therapy.
- Access to services at the Cancer Support Center, including:
  - Certified breast health nurse navigators dedicated to helping patients and their families every step of the way.
  - An array of information to help educate and support men and women diagnosed with cancer.
  - Hereditary Cancer Risk Assessment Services and High Risk Clinic.
  - Cancer survivorship services, including Cancer Transitions© classes focusing on topics such as nutrition and exercise.
  - Nutrition counseling with a registered dietitian.
  - Oncology social work services.
  - ACS Look Good…Feel Better® sessions and other appearance services.
  - Twisted Sisters Yoga for breast cancer survivors.

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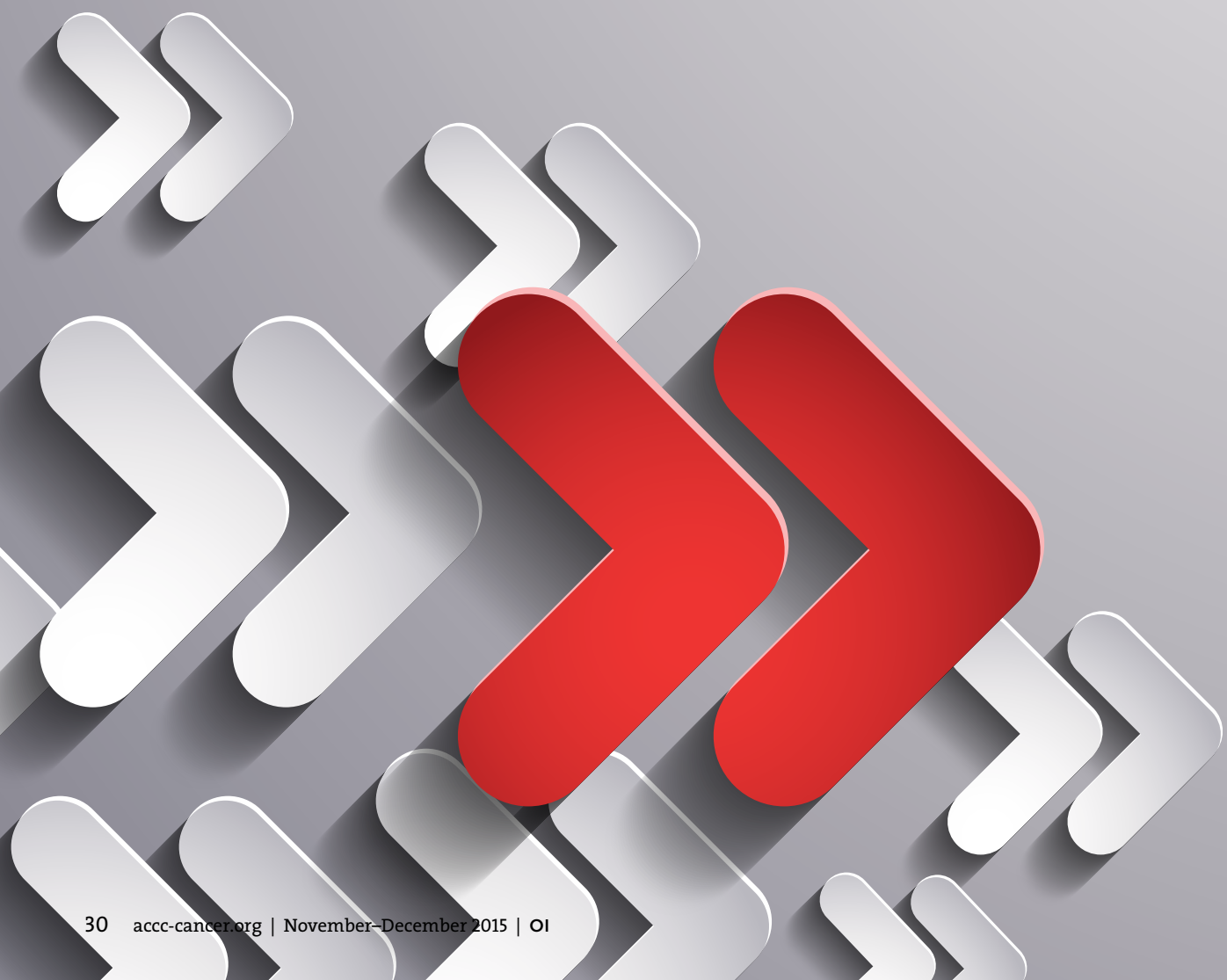
A Web-Based Patient Tracker

helps one cancer program transition to a multidisciplinary, primary care nursing model



BY MICHELLE EVANGELISTA, RN, MHSA,
AND ASTRID LENIS, BS

Locating oncology patients along the care continuum at any given time and providing individualized attention can be a challenge for large cancer programs. Critical steps in patient flow include:

- Greeting patients on arrival
- Registration completion
- Blood draw completion
- Rooming for exam
- Rooming for treatment.

In the summer of 2012 the Ruttenberg Cancer Center, New York, N.Y., developed and implemented a web-based patient tracking system to improve patient flow and enhance the patient experience. When the cancer program moved to its new location in the fall of 2012, this tool was integral in transitioning patient care to a multidisciplinary, modified primary nursing delivery model. (For more on this move and Ruttenberg Cancer Center's multidisciplinary care delivery model, see page 38.)

Mapping Our Current & Future Processes

While the concept for the tool was based on an existing patient tracker, Ruttenberg Cancer Center's patient tracker was the result of a collaborative effort between our web-based development team, operations, and nursing. Step one was mapping the current processes at the cancer center. Only then could our process improvement team begin to design the new work flow, identifying critical points in the patient flow process and strategies for minimizing delays. Next, the team mapped out the future state of patient flow (Figure 1, pages 32-33) and piloted the patient tracker prior to the cancer center's move to a new location and care delivery model.

The initial design focused on the critical steps in the process where the patient tracker would facilitate and coordinate patient visits. Using six sigma and lean methods, our process improvement team established turnaround times as the baseline metrics for evaluating the effectiveness and success of the tool.

Our Patient Tracker

The web-based tracker supports patient flow from arrival at the cancer center (greet time) to discharge (check out time).

Greeting & Registration. When they arrive, patients are greeted by front desk staff who then designate patients in the tracker as "greeted," which automatically generates an arrival time.

If a patient is not registered within 15 minutes of the greet time, the patient appointment changes to yellow on the tracker to alert staff that the patient has been waiting 15 minutes. If the patient is not registered in 30 minutes, the patient tracker appointment changes to pink. Staff quickly investigates these delays to resolve any issues and to ensure that patient wait times are not excessive. Future plans include a self-arrival kiosk where patients will be able check themselves in, as well as confirm demographic and insurance information; new patients will be able to complete forms. These enhancements to our patient tracker will further expedite the arrival and registration process.

Each morning the management team huddles to review the schedule and make any necessary staffing adjustments. In addition, the patient tracker alerts managers of potential delays by generating emails when patients have waited 15 minutes. Managers can then evaluate the reasons for the delay and make immediate adjustments to resolve these issues.

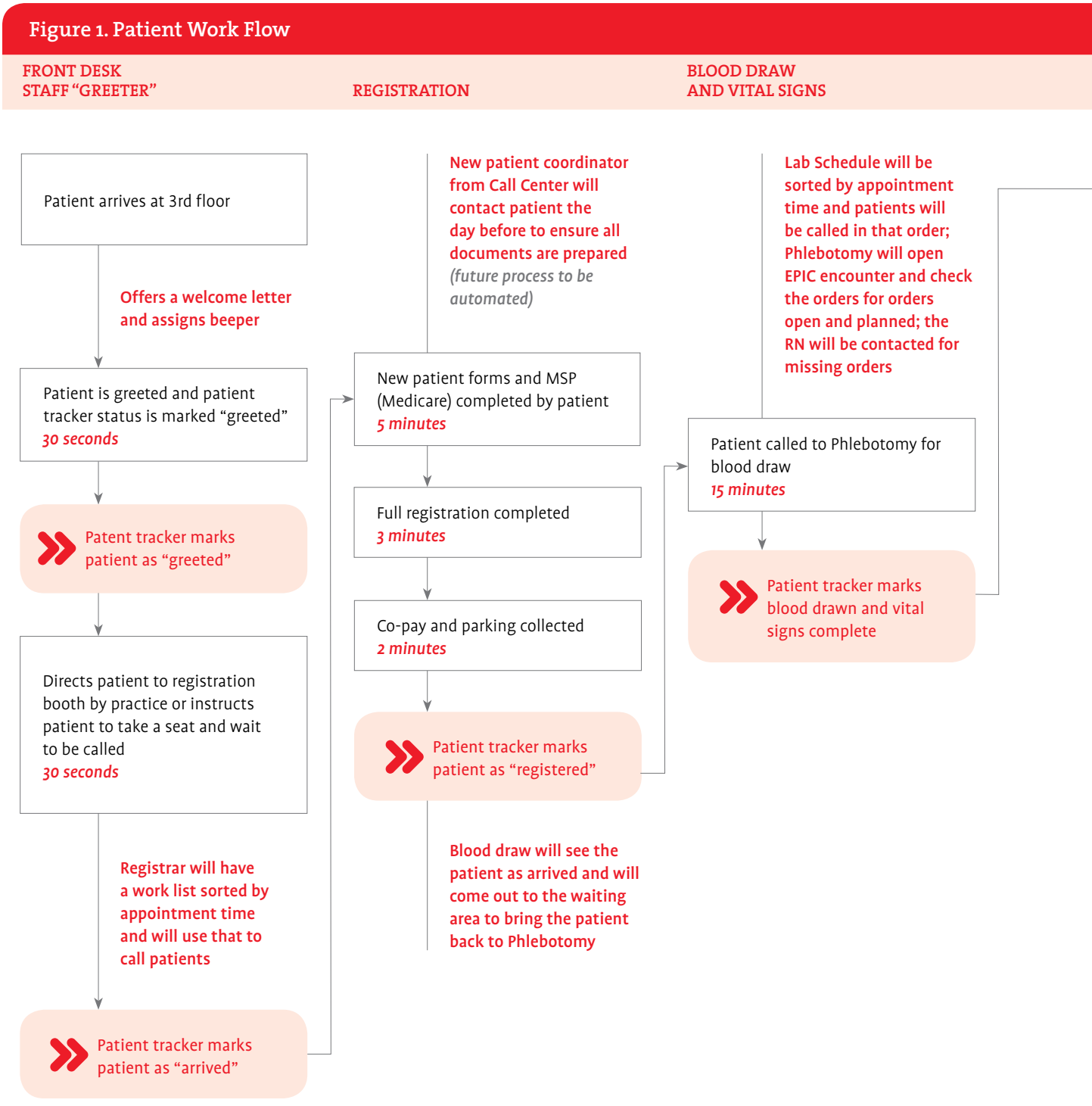
The patient tracker helps manage the registration process and reduce delays by generating a daily work list for registration staff. Once patients are greeted, they show up on a work list at each registration station computer. Registration staff then uses the work list to prioritize patient registration, comparing arrival times and scheduled visit times to identify the next patient for registration. This web-based work list eliminates the need for paper lists at the registration desk.

Blood Draw Completion. At the next critical step in the patient flow process—blood draw completion—phlebotomists use the tracker to designate when the blood draw is complete, alerting practice staff that the patient lab work was drawn and sent to

(continued on page 35)

The patient tracker helps manage the registration process and reduce delays by generating a daily work list. Once patients are greeted, they show up on a work list at each registration station computer. Staff then uses the work list to prioritize patient registration, comparing arrival times and scheduled visit times to identify the next patient for registration.

Figure 1. Patient Work Flow



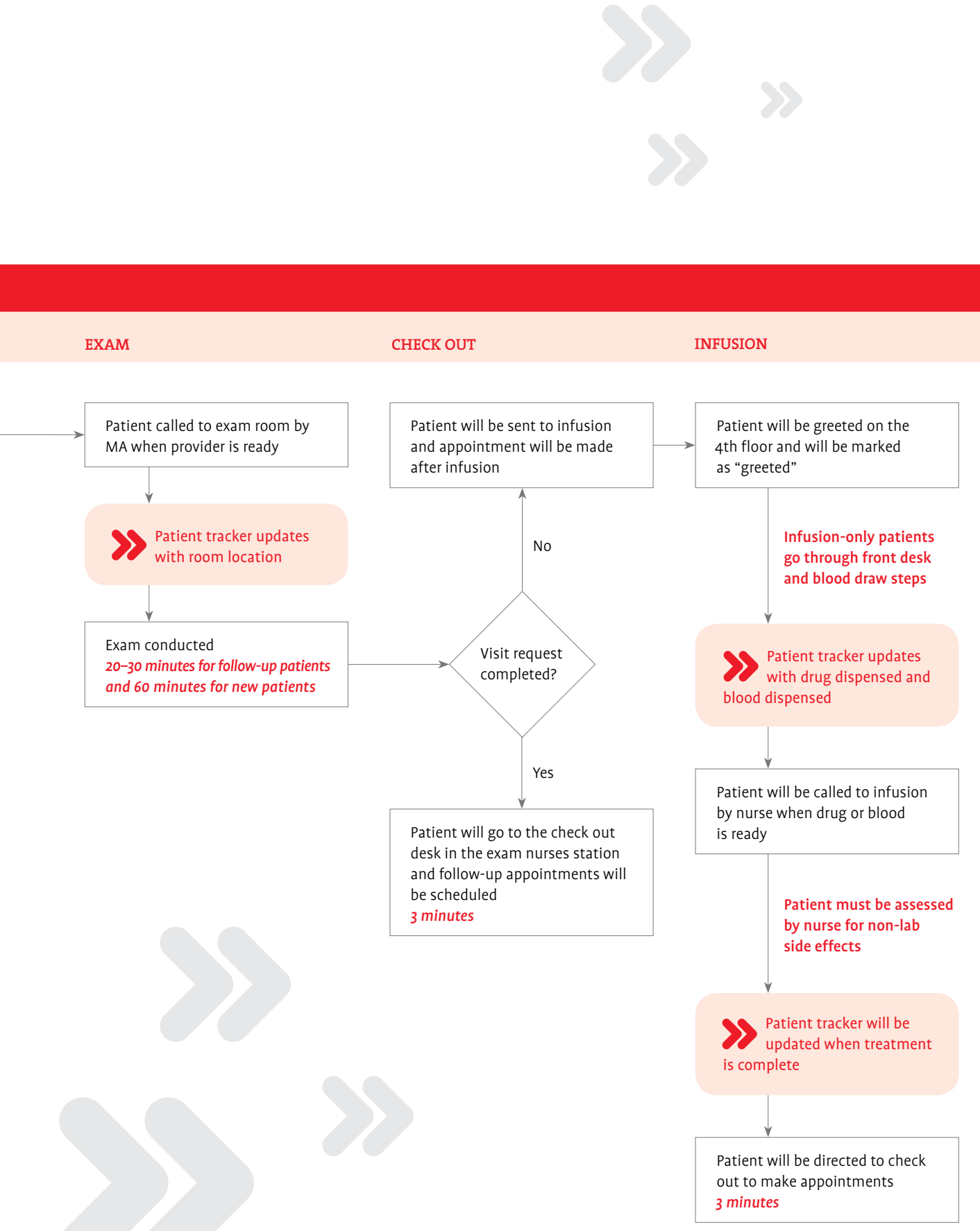

EXAM
CHECK OUT
INFUSION
Patient called to exam room by MA when provider is ready
Patient tracker updates with room location
Exam conducted
20–30 minutes for follow-up patients and 60 minutes for new patients
Visit request completed?
No
Yes
Patient will be sent to infusion and appointment will be made after infusion
Patient will go to the check out desk in the exam nurses station and follow-up appointments will be scheduled
3 minutes
Patient will be greeted on the 4th floor and will be marked as "greeted"
Infusion-only patients go through front desk and blood draw steps
Patient tracker updates with drug dispensed and blood dispensed
Patient will be called to infusion by nurse when drug or blood is ready
Patient must be assessed by nurse for non-lab side effects
Patient tracker will be updated when treatment is complete
Patient will be directed to check out to make appointments
3 minutes

Figure 2. Screenshot of Patient Tracker

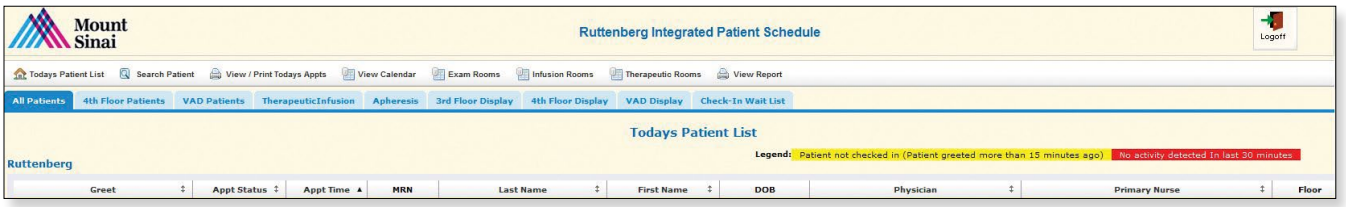


Figure 3. An Example of Patient Tracker Data Collected

VISIT DATE	DATE/TIME OF CONFIRMATION	DATE/TIME OF GREETING	DATE/TIME CHECKED IN	DATE/TIME CHECKED OUT	CHECK IN LESS GREETING
Sept. 3	Aug. 8, 11:23 am	Sept. 3, 7:28 am	Sept. 3, 7:32 am	Sept. 3, 3:51 pm	00:04
Sept. 3	Aug. 4, 5:24 pm	Sept. 3, 9:31 am	Sept. 3, 9:39 am	Sept. 3, 6:41 pm	00:08
Sept. 5	Sept. 4, 12:21 pm	Sept. 5, 9:34 am	Sept. 5, 9:50 am	Sept. 5, 12:03 pm	00:16
Sept. 5	July 9, 5:16 pm	Sept. 5, 11:13 am	Sept. 5, 11:17 am	Sept. 5, 12:04 pm	00:04
Sept. 5	Sept. 4, 4:31 pm	Sept. 5, 11:22 am	Sept. 5, 11:31 am	Sept. 5, 12:04 pm	00:09
Sept. 8	Sept. 3, 10:18 am	Sept. 8, 8:29 am	Sept. 8, 8:43 am	Sept. 8, 5:43 pm	00:14
Sept. 8	Sept. 5, 2:50 pm	Sept. 8, 9:31 am	Sept. 8, 9:43 am	Sept. 8, 5:43 pm	00:12
Sept. 17	Sept. 5, 3:45 pm	Sept. 17, 8:27 am	Sept. 17, 8:40 am	Sept. 17, 5:37 pm	00:13
Sept. 18	Sept. 18, 10:24 am	Sept. 18, 10:18 am	Sept. 18, 10:27 am	Sept. 18, 12:17 pm	00:09
Sept. 19	Sept. 19, 10:18 am	Sept. 19, 10:21 am	Sept. 19, 10:26 am	Sept. 19, 5:22 pm	00:05
Sept. 23	Sept. 23, 9:23 am	Sept. 23, 9:49 am	Sept. 23, 10:13 am	Sept. 23, 1:59 pm	00:24
Sept. 25	Aug. 28, 2:42 pm	Sept. 25, 8:34 am	Sept. 25, 8:42 am	Sept. 25, 6:16 pm	00:08
Sept. 30	Sept. 12, 10:23 am	Sept. 30, 10:33 am	Sept. 30, 10:49 am	Sept. 30, 1:42 pm	00:16
				AVERAGE CHECK IN LESS GREETING TIME	00:11

(continued from page 31)
the onsite lab. A new function is being added to the patient tracker to improve communication about manual differentials (counts done by the laboratory staff to confirm lab results). Specifically, we are establishing a process where the lab will use the tracker to identify when the blood has been drawn and to prioritize manual differentials. When the manual differential is complete, the lab technician will enter into the tracker that the test is complete and the slides are ready. This improved communication between the lab and the practice will reduce the number of phone calls and interruptions to the lab and identify delays so that managers can intervene as needed.

Pharmacy. Pharmacy staff uses the patient tracker to notify primary nurses when drugs have been dispensed, eliminating the need for nurses to call the pharmacy and allowing management to track time to dispense. Management can pull data from the patient tracker, including time stamps for the critical handoffs, into an Excel spread sheet. Management then reviews this data to identify ways to improve the patient flow process and turnaround times.

All staff has access to the patient tracker on computers located throughout the cancer center. Figure 2, left, is a screenshot of the patient tracker and the information that is available to staff. With this real-time information staff can easily locate patients.

Our Assignment Grids

Another feature of the patient tracker: assignment grids that identify unassigned patients on the left and nurses' names on the right so that physicians and pharmacy staff can easily locate their patients and their nurse. (Unassigned patients are patients that have been added to the schedule on the day of treatment.) The nursing coordinator works with nursing leads and nursing staff to assign patients to available chairs and to balance the workload. We only pre-assign patients for treatment; exam patients are assigned on arrival.

These web-based assignment grids replaced our existing paper assignment sheets. To support the new multidisciplinary care model, balance the workload of staff, and facilitate patient flow, we implemented two assignment grids. One grid assigns patients to exam rooms. The tracker allows staff to drag patient names from a patient list and drop them into an exam room. When patients are roomed, an automatic notification is sent to staff that patients are ready for assessment. This feature helps staff keep patients informed about delays and wait times.

The treatment assignment grid allows primary nurses to self-assign patients by reviewing the primary nurse assignments for the five most recent visits. If the primary nurse is not available on that day, associate nurses are assigned. The nursing coordinator is responsible for reviewing the nursing self-assignment grid and completing the assignment for a nurse who is not in on that day but who will be in the following day. To ensure optimal workload distribution, the primary nurses assign an acuity score to each of their patients; the nursing coordinator balances the nursing workload and tracks assignments for continuity of care. This pre-selection process not only balances the workload of staff, it allows primary nurses to plan for their assignment and start the process of preparing for the treatment before patients arrive.

The treatment assignment grid lets nursing management monitor patient arrival and room availability throughout the day. (The assignment grids change color when patients arrive and when they are discharged.)

These assignment grids have improved communication among staff by clearly identifying the location and primary nurse caring for each patient and have also resulted in more efficient follow-up during treatment visits. With regards to the patient experience, we have seen our patient satisfaction scores improve with the establishment of a consistent nursing assignment.

Our Outcomes

Using baseline data collected through observation and process mapping, our process improvement team identified the following improvements:

- Time from arrival to the completion of registration was decreased to 10 minutes
- Time to blood draw from completion of registration was decreased to between 10 and 15 minutes
- Drug dispense time was decreased to 30 minutes.

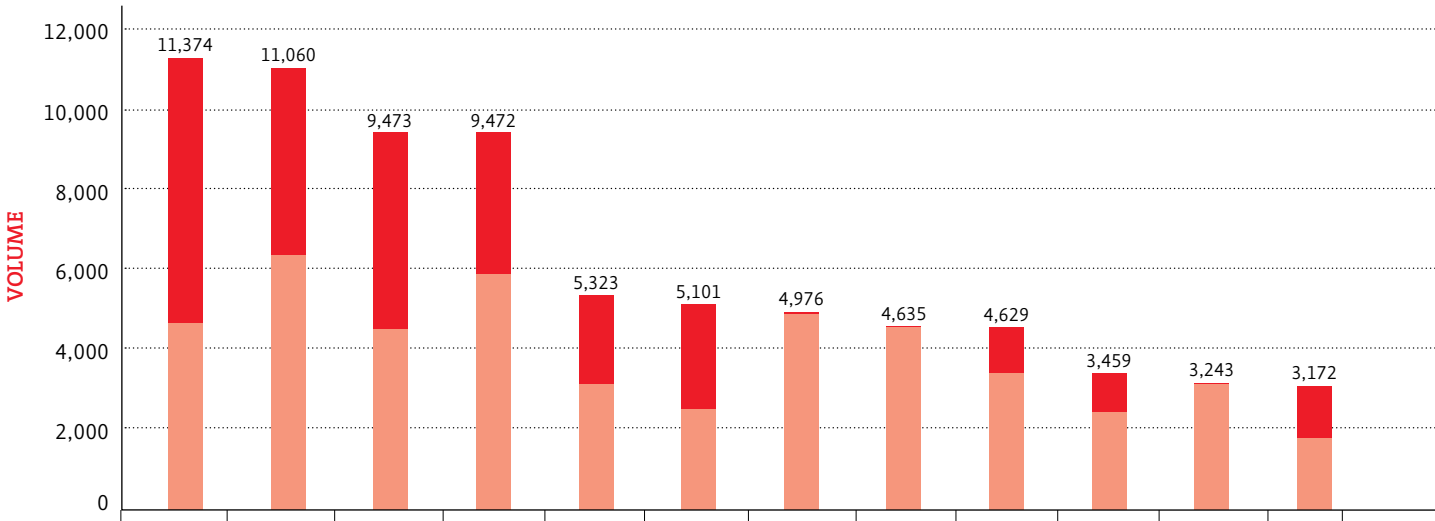
Management continually reviews data from the patient tracker and the EHR to ensure that the patient flow process is stable and to support new improvement efforts. Figure 3, left, shows the data we collect to measure patient flow from time greeted to registration complete. We have made some recent staffing and process changes, and we are using the patient tracker data to make adjustments and identify opportunities to further improve the process.

Patient satisfaction scores have continued to improve. We use a real-time satisfaction tool called Rate My Hospital to obtain daily feedback from patients, and we monitor our scores with a target score of 4.5 overall. (Following every patient visit, Rate My Hospital sends a text message with the survey.) We track multiple questions for wait time satisfaction, developing control charts to follow the stability of the patient flow process and to evaluate any process changes. Based on Press Ganey data on the implementation of the modified primary nursing model, we saw patient satisfaction with wait time in chemotherapy go from 83.6 in October 2013 to 91.7 in August 2014.

On a daily basis, management explores new opportunities to use the patient tracker to improve patient flow and the overall patient experience; the process improvement team continues to work closely with the web-based development team that has been critical to the success of this project. The cancer center is still challenged by the manual efforts required to update the patient status, but compliance with the tracker has improved. Further, continued review and quality improvement efforts by the staff and management team have made this tool valuable to staff and patients.

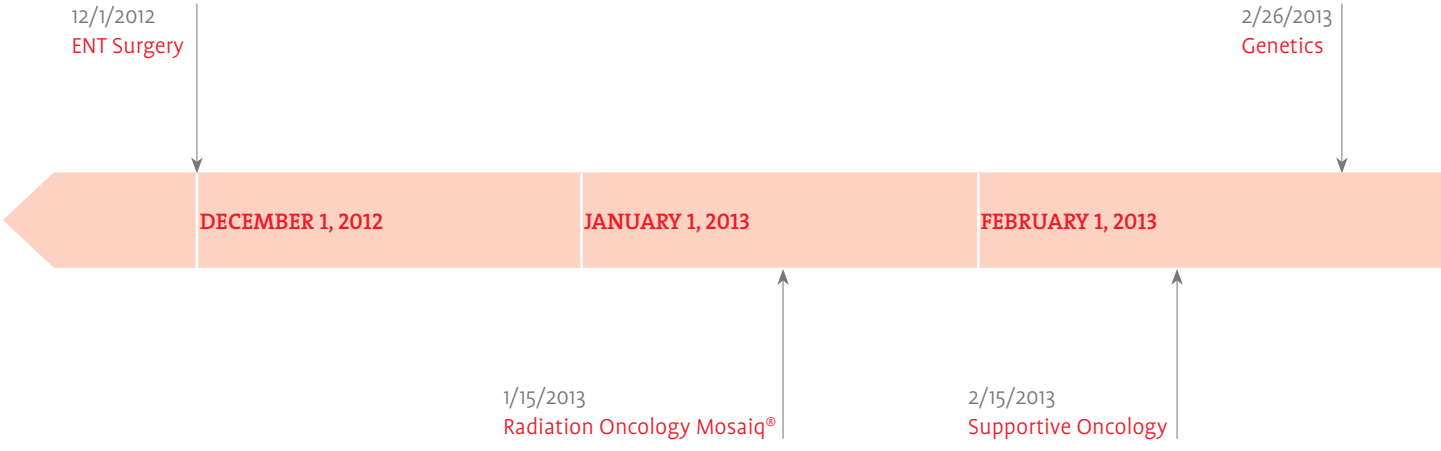
(continued on page 38)

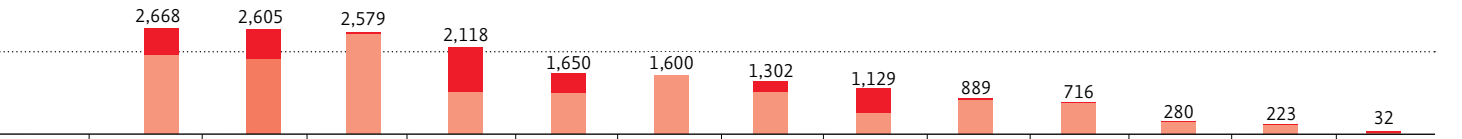
Figure 4. Comparison of Practice Volumes, (Aug. 2013 to Sept. 2014)



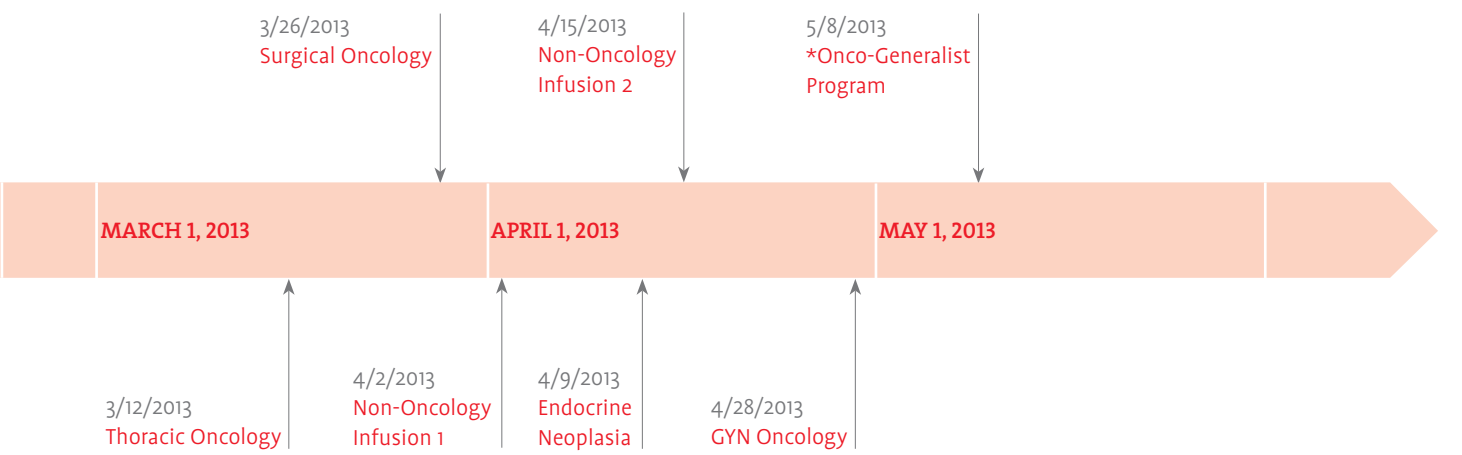
	MM	Breast (Hem-Onc)	GI/Liver	BMT	Head and Neck	MDS	Breast Surgery	EMT	MPD	GYN Surgery	Thoracic Surgery	Lung
TREATMENT VISITS	6,737	4,706	5,061	3,534	2,100	2,577	12	2	1,209	968	3	1,344
EXAMS	4,637	6,354	4,412	5,938	3,223	2,524	4,964	4,633	3,420	2,491	3,240	1,828

Figure 5. Ambulatory IT Planning Timeline





Benign Hem.	GU	Surgical Oncology	Leukemia/ Lymphoma	Sarcoma	Endocrine Neoplasia	Melanoma	Voluntary Physicians	Supportive Oncology	Psychiatry	Onco-Cardiology	Neuro-Oncology	Solid Tumor
679	864	12	1,105	593	0	255	583	49	1	4	22	16
1,989	1,741	2,567	1,013	1,057	1,600	1,047	546	840	715	276	201	16



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The enhanced patient tracker is now being implemented at both the Dubin Breast Center and the new outpatient unit of the Cardiovascular Department and will soon be implemented throughout the Mount Sinai Health System. OI

Michelle Evangelista, RN, MHSA, was the senior director for Outpatient Oncology at Mount Sinai and is currently clinical systems engineer II at NewYork-Presbyterian Hospital, New York, N.Y. Astrid Lenis, BS, was the director of operations at the Derald H. Ruttenberg Treatment Center of the Tisch Cancer Institute, New York, N.Y., and is currently administrator for Radiation Oncology at Mount Sinai Beth Israel.

The Big Move Brings a New Care Delivery Model

ON OCT. 29, 2012, the Derald H. Ruttenberg Treatment Center of the Tisch Cancer Institute moved to the third and fourth floors of the Leon and Norma Hess Center for Science and Medicine, New York, N.Y. Housed within one of the nation's top-ranked hospitals, Mount Sinai's Derald H. Ruttenberg Treatment Center offers a wide range of outpatient services for all cancer diagnoses—with the exception of breast cancer patients who are treated at the Mount Sinai Dubin Breast Center, New York, N.Y. At its new location, the cancer center has 47 exam rooms and 54 treatment rooms and sees patients Monday through Saturday from 8:00 am to 6:00 pm. The average number of exam visits per day is between 250 to 300; the average number of daily treatment visits is 100. Figure 4, pages 34-35, shows the cancer center's practice volume from August 2013 to September 2014.

Surgeons, medical oncologists, radiation oncologists, a supportive care oncologist, an onco-psychiatrist, and onco-cardiologists all work together in the cancer center to provide patients with a coordinated approach to care. This multidisciplinary model requires support for complex patient visits, including new patient visits, multidisciplinary patient visits, metastatic patient visits, follow-up visits, and treatment visits. Patients navigate not just a single visit, but often a series of visits to complete the diagnostic process and obtain a treatment plan or follow-up services. To create this multidisciplinary model, our planning team started with a timeline (Figure 5, pages 36-37) to:

1. Integrate seven practices into the hospital-based cancer center.
2. Assist two programs that were not part of the cancer center —the Therapeutic Infusion Center (for non-cancer infusions) and the Genetics Infusion Center—in adopting the primary nursing model and using the patient tracker to assist with patient flow in their treatment spaces.

To help transition the practices into the hospital-based setting, we created an IT development team comprised of representatives from scheduling, the EHR (electronic health record) team, and the web team that developed our patient tracker. One of the challenges during this time of transition was understanding and designing the patient flow for surgical and radiation oncology patients. The practice flow of these new service lines was different from our existing medical oncology model where oncologists use the patient tracker to locate patients and coordinate treatment visits, and primary nurses use the tool to facilitate follow-up visits. Surgical oncology visits, for example, are often high volume and involve many disciplines and services, including pathology and speech therapy, and procedures such as ultrasound and scoping. Accordingly surgeons look to use this tracking tool to identify patient arrivals, expedite patient visits, and improve patient satisfaction scores for surgical oncology services.

Supportive Oncology and Psychiatry also required a special approach to patient visits, which involve psychosocial support services and symptom management. The supportive programs have a different patient flow than medical and surgical oncology. Scheduling templates were developed that met the needs of these specialized services, and the patient tracker reflected these unique requirements.

Our multidisciplinary model continues to evolve as new practices and new providers are added to increase services to our patients, including a Metastasis Center that coordinates visits for metastatic patients of all cancer diagnoses, a new patient navigation program that manages patient access, and an onco-generalist program. A strategic objective for this evolving new multidisciplinary model: to provide enhanced patient navigation by using the patient tracker to monitor patient progress and provide alerts to management if delays occurred.

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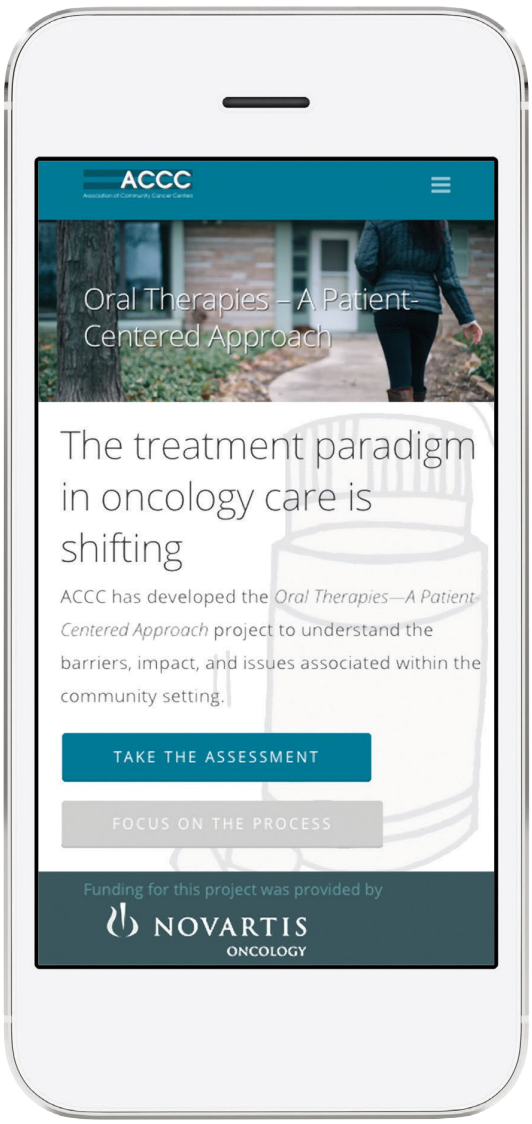

ORAL CHEMOTHERAPY
New! Patient Adherence Assessment Tool

NOVARTIS | *Funding for this project was provided by Novartis Oncology.*

Advanced Practice in Oncology Nursing

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TRACEY TATUM, RN, MS, FNP, AOCNP

Advanced practice nurses (APNs) are integral members of the multidisciplinary cancer team that provide care for this chronic patient population. In addition to their clinical skills, APNs have leadership experience that can make them instrumental partners to oncology administrators. Successful cancer programs have a complete understanding of the APN role, so they are able to fully utilize the education, individual skill, and expertise of these clinicians.[1] Perhaps the first step in this understanding is to know what APNs are not; APNs are not junior doctors, physician substitutes, physician extenders, or mid-level practitioners, nor are they defined by a narrow set of skills or credentials. Rather, APNs provide alternative and complementary components to the medical care of patients. A 2015 Oncology Nursing Society (ONS) position statement says that "advanced practice oncology nurses provide leadership to improve outcomes for patients with cancer and their families by increasing healthcare access, promoting clinical excellence, improving patients' quality of life, documenting patient outcomes, and increasing the cost-effectiveness of care."[2]

Advanced practice nursing is more a concept than a defined role and cannot be described as a specific set of skills or regulatory requirements. The regulatory term increasingly being used across the country is advanced practice registered nurse or APRN. The term APRN is intended for use in defining baseline legal and regulatory issues, but the term itself does not capture the full capacity of advanced practice nursing. For the purpose of discussing the broader concept—and not merely the regulations—advanced practice nurse, or APN, is used throughout this article.

Core Components & Competencies

A review of the core components of an APN is essential to understand how an APN functions within a cancer program. While these components may be performed in different ways based upon the type of APN, all APNs practice with expanded levels of autonomy, skill, and decision-making.[3] Advanced practice nursing constitutes more than physical assessment, pathophysiology, and pharmacology; it is the synthesis and integration of the core components below.[3]

Specific to oncology, APNs often excel in symptom management, providing interventions that are critical to patient outcomes and quality of life.

Clinical Expert. APNs are registered nurses educated at the graduate or doctoral level who have oncology expertise, often with further sub-specialization reflected in their direct patient care. Sub-specialization within oncology can be symptom management, inpatient nursing care, disease-specific patient population care, program development, etc. Through their advanced nursing skills, APNs guide the provision and evaluation of nursing care. The oncology APN conducts a thorough assessment to create a comprehensive and unique patient treatment plan. A holistic view, coupled with an understanding of risk and contributing factors, disease trajectory, and response to treatment, allows APNs to anticipate future problems, patient responses, and results in health promotion practices.[3] Specific to oncology, APNs often excel in symptom management, providing interventions that are critical to patient outcomes and quality of life.

Educator. The role of educator encompasses interactions with patients, families, the community, or other healthcare practitioners. APNs may serve as a formal educator—such as a preceptor—or in an informal role, educating staff while providing direct patient care. The education and information APNs provide to patients and caregivers is critical to informed decision-making and empowerment.

Researcher. Building an evidence basis for practice is essential to the role of the APN.[4] As such, APNs identify and develop research studies to further patient outcomes, incorporate improvements in patient care into practice, and publish outcomes to further nursing care. APNs must continuously challenge the status quo, while seeking better patient care through scientific inquiry.[5] APNs are in a prime position to conduct research on the effectiveness of nursing interventions given their clinical expertise, access to patients, and their master's or doctoral-level graduate research coursework. These clinicians are routinely aware of the need to demonstrate the effectiveness of their own practice and are often tying outcomes of their involvement to the highest level of quality care.[6]

Consultant & Coach. In these roles, APNs may facilitate problem solving and decision making; communicate and coordinate treatment plans with various disciplines; and motivate patients, team members, and caregivers about the various interventions of the treatment plan.[7] Consulting may include collaborating with other cancer program staff to conduct quality improvement projects or educational presentations. Coaching or mentoring may involve becoming adjunct faculty to undergraduate or graduate level nursing students and guiding them in becoming expert clinicians, educators, leaders, change agents, researchers, and collaborators.

Leadership. APNs are leaders within their cancer programs and, as such, routinely head up educational projects or initiatives. Through publication and within their profession, APNs often disseminate nursing and healthcare knowledge beyond their practice setting.[5] As leaders, oncology APNs may actively participate in the assessment, development, implementation, and evaluation of quality improvement (QI) programs in collaboration with hospital senior leadership. Oncology APNs possess a thorough understanding of the working environment, hospital system, and organizational structure, routinely collaborating with other department leaders and different medical disciplines to improve the professional environment. Finally, as APNs are embedded in cancer programs and aligned closely with oncology nursing and medical staff, these clinicians can respond quickly to change and successfully drive education and QI initiatives.

Practice Requirements

To understand how an APN functions within a cancer program, a review of practice requirements is also essential, including education requirements, credentialing, and reimbursement for APN services.

Education. Graduate education resulting in a master's degree includes core coursework on physical assessment and diagnosis, pathophysiology, and pharmacotherapeutics. All APN education programs preparing graduate students for advanced practice and licensure must go through a pre-approval, pre-accreditation, or accreditation process prior to admitting students. Accredited programs qualify the APN for the certification examination to ensure national competencies that entitle them for state licensures, and the resultant advanced practice registered nurse (APRN) credentials.

Requirements of graduate education support an expanded scope of practice.[8] A doctorate in nursing practice provides coursework that deepens the graduate work of a master's program in conjunction with information and systems analysis, leadership, public policy, and population health.[9] Graduate faculty and clinical preceptors serve as instrumental role models, contributing to professional development through role modeling how to operationalize programmatic components and guidance on how to fully use intuition and education in the practice setting. A minimum of 500 student clinical practice hours are required in the masters' programs and at least 1,000 hours of clinical practice are required for the doctor of nursing practice (DNP) program—regardless of the number of years the graduate nursing student has worked.[10] Fitzgerald and colleagues describe educational strategies that include intensive interprofessional collaborations and curriculum revisions in order to be the envisioned providers of healthcare reform.[10]

Scope of Practice. The scope of practice provides the parameters APNs are legally authorized to practice under and the services they can provide to patients. It is determined on the national level by professional organizations; on the state level via nurse practice acts, rules, and regulations; and at the institutional level, defining the patient population and process for physician collaboration.[11] Since scope of practice is determined by state law, there are differences in what APNs can do across states. The scope of practice can also differ for the two APN roles: nurse practitioner (NP) and clinical nurse specialist (CNS). (For more on these APN roles, see the companion article on pages 42-46.) APN scope of practice is directly linked to the competencies of direct clinical practice, coaching, and guidance, complemented by the other components and competencies.[9]

Regulatory. There is no federal regulation of APNs across the states. Each state independently determines the legal scope of practice, the criteria for entry into advanced practice, and the standards necessary for entry-level proficiency assessment. Since state licensure regulates APN practice, depending upon the state, the licensure limitations can serve as a barrier to these professionals practicing to the fullest extent of their education and training.[12]

The APRN Consensus Model. Regulatory, legal, and certifying organizations; accreditors; and educators historically made independent decisions that impacted APNs, often with differences in terminology, requirements, and regulatory approaches. In 2008 these stakeholders joined together to develop a uniform regulatory model for advanced practice nursing that aligns licensure, accreditation, certification, and graduate education (LACE). The goal: to move towards maximizing the abilities of APNs through the creation of the Consensus Model for APRN Regulation: Licensure, Accreditation, Certification & Education

(APRN Consensus Model). Endorsed by 41 nursing organizations, the APRN Consensus Model:

- Defines APRN practice
- Describes the APRN regulatory model
- Identifies professional titles to be used
- Defines specialty
- Describes the emergence of new roles and population foci
- Presents strategies for implementation.

The APRN licensure reflects the regulatory and legal groups consensus on minimum requirements and consistency in language. Learn more about the APRN Consensus Model at nursingworld.org/consensusmodel.

Credentialing. Credentialing is the paperwork and process necessary to ensure APNs meet competency and safety standards. It involves evaluating the scope of practice for the appropriate fit within healthcare settings. Requirements to practice under the title are dictated by a regulatory body or institution. It includes education, licensure, and national certification and is done at both the state level and the institutional level. Institutional credentialing is facility specific, requiring specific documentation, sometimes a physician endorser and/or collaborative practice agreement, which are reviewed by a designated credentialing committee. Licensure is two-fold: the first licensure designates the APN as an APRN and the second licensure matches up the state board of nursing criteria with the specific role declaration—CNS (clinical nurse specialist) or NP (nurse practitioner).

Certification. Certification occurs at both the state board level and through the Oncology Nursing Society (ONS). Certification ensures a basic measure of competence within the role and subspecialty. Oncology certification began in 1995 with the increasing number of graduate nurses sub-specializing in oncology. ONS currently offers two advanced oncology nursing certification credentials for nurse practitioners and clinical nurse specialists working in oncology: Advanced Oncology Certified Nurse Practitioner (AOCNP™) and Advanced Oncology Certified Clinical Nurse Specialist (AOCNS™). (Note: the AOCN is an ONS APN certification for those who achieved that certification 20 years ago and is available only for renewal of those APNs.)

Reimbursement. After meeting licensure, credentialing, and state board of nursing scope-of-practice regulations, APNs are authorized to bill Medicare using the physician payment system only if state law allows. State licensing and billing regulations are complex and often require a billing expert. Although most third-party payers follow Medicare guidelines, their decision to reimburse APNs and reimbursement requirements are unique to the insurer, varying widely from payer to payer. Medicare makes no distinction between different APNs, so differences in billing and reimbursement between nurse practitioners and clinical nurse specialists come down to individual state definitions of their respective scope of practice.[13] Medicare and some third-party payers reimburse for CNS services if the clinician meets certain criteria that are state dependent. Nursing services are defined by nurse practice acts of individual states and can be viewed by state on the Board of Nursing websites.

Hospitals can bill NP services under Medicare Part B as a physician service if the hospital is not being reimbursed under Part A for the NP's salary and if a physician of the same specialty is not billing for that service on the same day. In the acute setting, Medicare will reimburse one bill, per patient, per service, per day. Third-party payers reimburse for only one physician service, per specialty, per day. So, if a physician is performing an evaluation and management visit, the NP cannot bill for the service. When an APN and physician are not employed by the same entity, there is no opportunity for "shared billing."[14]

Physician services, unlike nursing services, are defined by federal law and include diagnosis, surgery, consultations, and home, office, and institutional calls. The ambulatory settings involve evaluation and management (E&M) services as defined by Current Procedural Terminology (CPT) codes. E&M codes require documentation of history taking, physical examination, medication decision making, counseling, and coordination of care.[15] In the ambulatory setting, "'incident to' a physician's professional service" is a Medicare billing mechanism by a CNS or NP for professional services provided and billed under the physician's national provider identification (NPI) number. Direct supervision is required with the physician in the clinical area where the care is being delivered and immediately available to provide assistance. The physician does not need to be in the examination room of the patient, but in the same area. Billing "incident to" is submitted under the physician's NPI number and paid at 100 percent of the reimbursement rate.

Medicare reimburses APN services at 85 percent of the physician rate.[16] An APN can bill as the single provider if they have a provider number. An APN can also serve as a single provider with a non-advanced practice registered nurse performing the work and billing incident to the APN.[17]

Evolving Opportunities for APNs in Oncology

Because numerous studies have demonstrated the value of integrating APNs into the clinical setting, and as the landscape of healthcare continues to evolve, advanced practice nurses are perfectly suited to meet the growing demand for healthcare services in the 21st Century.[18] This is especially true in the oncology setting where patients often have complex needs and require expert clinical care. APN potential and broad diversity can contribute to solutions for healthcare concerns including access, quality, and cost. The Institute of Medicine's 2011 "The Future of Nursing" report describes the need for sufficient advanced practice nurses in order to fulfill the vision of a new, improved healthcare system design.[19] The IOM report recommends removing scope of practice barriers, and it is making these recommendations to Congress, state legislatures, the Centers for Medicare & Medicaid Services, and the Federal Trade Commission so that APNs can practice to the fullest extent of their education and training.[19]

Since graduate education and certification is required in order to practice as an APN, these clinicians have higher critical thinking skills and a broader reach than traditional nursing roles. For the cancer program administrator, increased use of APNs can maximize productivity and help differentiate their program from

competitors. APNs are not simply task-oriented. Instead, these clinicians have the ability to flex to unique and changing competitive and patient variables. This skill makes APNs a critical partner to administrators who are looking to grow patient volume, gain programmatic efficiencies, respond to changing healthcare legislation, and incorporate new treatment paradigms.

It is well documented that APNs positively impact patient and physician satisfaction, enhance educated treatment decision making, improve the quality of care regardless of location, and simultaneously improve the overall patient experience; however, other evaluative measures are sometimes needed to measure return on investment (ROI), including:

- Participation in the creation of new programs
- Accreditation commendation
- Participation in quality outcome improvements
- Contribution to total program growth
- Contribution to reduce ER visits or readmissions
- Long-term patient retention.

The evolving roles for oncology APNs cross both inpatient and outpatient settings, affecting the radiation, medical oncology, surgical oncology, clinical trials, genetics, prevention and detection, interventional radiology, and palliative care settings. Data from APN studies and the anecdotal experiences of healthcare organizations that have increased the roles and responsibilities of nurses in patient care, such as the Veterans Health Administration, Geisinger Health System, and Kaiser Permanente, support APNs in roles that deliver safe, high-quality primary care. Given that oncology is a multidisciplinary specialty, the integration of APNs as part of the oncology care team provides a collaborative solution to growing gaps in healthcare. OI

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The NP and CNS: Advanced Practice Nurse Roles

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The nurse practitioner (NP) and clinical nurse specialist (CNS) are the advanced practice nurses (APNs) primarily working in the field of oncology. Use of the term APN does not imply a blending of the CNS and NP roles; both roles are distinct, although some knowledge and skills overlap.[1] Both roles can coordinate patient care, assist patients from diagnosis to survivorship, and navigate the patient through the complex healthcare process. The difference in how these professionals perform these duties, and at what point in the care continuum, is dependent on the individual, the role, the job they are fulfilling, and the cancer program. In a literature review of nurse practitioners and clinical nurse specialists, the emphasis on collaboration versus autonomy can help differentiate the scope of practice between the two. Generally, a CNS exhibits more intradisciplinary and interdisciplinary consultative and collaborative skills in practice, whereas an NP concentrates on developing unit- or service-based professional autonomy in a collaborative practice relationship with physicians.[2]

Generally, a CNS exhibits more intradisciplinary and interdisciplinary consultative and collaborative skills in practice, whereas an NP concentrates on developing unit- or service-based professional autonomy in a collaborative practice relationship with physicians.

The Oncology Nurse Practitioner

Since the 1990s the role of the oncology nurse practitioner has greatly evolved. Currently, nurse practitioners can be found in both the physician practice and hospital setting, working in collaboration with physicians to care for complex cancer patients. NPs provide assessment, diagnosis, and treatment recommendations to patients with an oncology diagnosis. Within their daily practice NPs have the ability to autonomously assess and evaluate a subset of cancer patients by taking comprehensive histories; providing physical examinations and other health assessment and screening activities; and diagnosing, treating, and managing the problems of the patient's cancer or treatment-induced side effects.

The scope of practice for nurse practitioners continues to evolve in response to changing social and economic healthcare necessities. As licensed independent clinicians, NPs practice both autonomously and in collaboration with physicians. Depending on the state, nurse practitioners can either practice independently or under a collaborative practice agreement with a supervising physician. The same applies for prescribing medications. Thirty-one states allow NPs to independently diagnose and treat patients without physician involvement.

Nurse practitioners are regulated according to the services they perform and the patient population they serve. The specialty practice of oncology is in addition to the formal NP education and national NP certification. Oncology NPs require additional education with oncology clinical practicum exposure. Oncology certification is through the Oncology Nursing Society with an Advanced Oncology Certified Nurse Practitioner (AOCNP) certification.

The Oncology Clinical Nurse Specialist

The 2008 APRN Consensus Model (nursingworld.org/consensusmodel) defines the clinical nurse specialist role as a clinician who continually improves patient outcomes and nursing care by using evidence and practice to mentor and empower nurses to alleviate patient distress, facilitate ethical decision-making, and respond to diversity. A CNS is intent on elevating the level of knowledge and practice. With direct care as the foundation of the CNS role and with many of these clinicians embedded in cancer programs and departments, clinical nurse specialists often identify opportunities for improvement or programmatic growth. Further, clinical nurse specialists have an interest in research, so these clinicians often update institutional standards of care and then help their fellow nurses to adhere.[3]

CNS vs. NP

Because advanced practice nurse is an umbrella term, the NP and CNS credential are sometimes mistaken for one another and/or used interchangeably. It can be challenging to understand the differentiators as these two roles share many core competencies.[4,5]

In oncology, clinical nurse specialists may be responsible for strategic growth, development, and programmatic evolution. While oncology NPs may be more clinic- or practice-based, focusing their efforts on the health evaluation and management of a specific set of patients.

Because clinical nurse specialists are embedded in the system with multiple overlapping collaborations across departments, these clinicians initiate and lead projects in response to the opportunities they identify for quality improvement or cost efficiencies. Often NPs spend the bulk of their time in a clinic or office setting and their predominant resonsibility is direct patient care, which leaves less time for influencing care in other settings or through other role components.

The NP & CNS Role in Oncology

The complexity of a cancer diagnosis creates opportunities for APNs to be involved in multiple settings throughout the continuum of patient care. APNs can be geographically-focused on an inpatient unit, outpatient clinic, or office setting, or be program-based. Unit or clinic-based positions include the more traditional jobs of evaluating a specific patient population. In our experience, aligning APNs with the programmatic goals of cancer programs maximizes the skills of these clinicians. The APN span of influence tends to cross multiple settings in close alignment with the oncology patients' disease continuum. Catania and colleagues describe the broader span of influence clinical nurse specialists have when they focus on a population across the continuum.[6] Programs can be disease-specific or service-based, such as palliative care, genetics, urgent care, symptom management/late effects, survivorship, case management, quality/accreditation, and navigation.[6]

Outcomes Associated with Advanced Practice

The bulk of outcomes research has focused on the NP role due to the defined direct-care outpatient model seen in cancer programs. Although there is limited oncology-specific research, in primary care and subspecialties, NP clinical outcomes have shown equivalency when matched to physicians practicing in the same settings. The care service provided by NPs can range from assessment and symptom management to follow-up and survivorship. A few areas stand out when looking at the impact of NPs on outcomes of care: cost effectiveness and the nurse practitioners' impact on patients, communities, and practices.

CNS outcomes research proves more challenging due to the broad range of needs the role has fulfilled—often impacting cancer programs indirectly. Anecdotally, direct impact has been observed in quality improvements, cost savings, and staff improvements. Studies of CNS interventions have found that clinical nurse specialists have greater impact noted during times of patient vulnerability, for example, in the early weeks after diagnosis and in the early weeks and months after a cancer-related hospitalization.[7] In other words, the value of care is best observed when these clinicians provide expert care, advice, support, coaching, and reinforcement as patients are first diagnosed and when they begin their recovery process.

Cost Effectiveness

A 2014 study looked at nurse-led telephone and on-demand follow-up of breast cancer patients over five years.[8] While patient outcomes were comparable to physicians, nurse-led interventions demonstrated cost effectiveness.[8] The cost per person, per year of follow-up was $490 for physicians and $385 for nurse practitioners, with no statistically significant difference in patient satisfaction.[8]

Another study looked at nurse-led follow-up versus conventional physician follow-up, randomizing patients who had undergone treatment for lung cancer.[9] In the nurse-led arm, NPs provided monthly follow-up and, as needed, contact by telephone or in the clinic.[9] The European Organization for Research and Treatments of Cancer's quality-of-life questionnaire was used to assess patients at baseline, 3 months, 6 months, and 12 months. At

3 months, the nurse-led group reported less severe dyspnea (difficult or labored breathing), with 78 percent of patients reporting a preference for the nurse-led care.[9] At 12 months, this same group reported better scores for emotional functioning and less peripheral neuropathy.[9] In addition, 40 percent more patients in the nurse-led follow-up died at home.[9] There were no differences in survival; cost was not calculated.[8] Knowing that cancer-related costs rise during the end of life, one can extrapolate the potential cost savings from this intervention had these been monitored.[10]

In 2014 Roots and McDonald evaluated nurse practitioner impact in a rural, collaborative, primary care practice with a general practitioner.[11] Subspecialty medical populations included mental health, HIV, addiction concerns, frail elderly, heart failure, diabetes, and reproductive healthcare needs. Care was provided both in the practice setting and in the community. The outcomes noted were:[11]

- Decreased use of the emergency department (ER)
- Reduced ER-directed admissions
- More time spent with each patient, resulting in improved patient engagement
- Fewer unnecessary appointments
- Decompression in the schedule so that return appointments decreased from 6 weeks to 3 days for routine appointments
- Total caseload growth between 400 to 800 per practitioner
- Staff reported improvement in communication, collaboration, and satisfaction with their job.

According to a productivity assessment at the University of Michigan Hospitals, NP activities improved efficiency in the practice, patient care, and physician satisfaction.[7] NP activities included assisting with rounds, patient education, progress notes, medical records review, discharge summaries, patient documentation, orders maintenance, medication reconciliation, and consultations.[12] The study authors thought that NP productivity and revenue were grossly underscored by physicians billing for activities that might have been provided by or influenced by the NP and/or billed "incident to" the physician.[7]

CNS case management has been associated with shorter hospitalizations and reduced readmissions in the elderly population, in a prostatectomy patient group, transitional care models, and hematologic malignancies.[12-15]

Patient & Physician Satisfaction

A 2014 study analyzed 2006 to 2011 Medicare and Medicaid data of patient health outcomes by state, along with the 2012 United Health Foundation report.[16] Of significant note was the decrease in avoidable hospitalization rates and improved health outcomes in states with unrestricted NP practice.[16] The study also correlated unrestricted NP practice with the lower readmission rates within 30 days of discharge from rehabilitation and the lower annual hospitalization rates for nursing home patients.[16]

A systematic review of 37 studies of advanced practice nurse outcomes from 1990 to 2008 revealed nurse practitioner care being equivalent to physician care in patient satisfaction, self-reported patient perception of health, patient functional status outcomes, patient glucose control, levels of blood pressure control, rates of emergency department visits, rates of hospitalizations, length of stay, and mortality rates.[17]

Challenges to the APN Role

While the literature supports the numerous benefits APNs can bring to a cancer program, challenges to the successful integration of APNs into the practice setting have been identified in nursing literature and must be addressed in order for APNs to reach their full utilization and potential. These barriers include a lack of clarity and/or ambiguity regarding the APN role and a lack of awareness and support from healthcare professionals and the general public.[18,19]

Lack of clarity and/or ambiguity. As previously stated, although the NP and CNS roles often overlap, considerable variability exists related to the time each role spends on various activities.[5] For example, the role of the CNS is known to focus on professional development, leadership within the organization, and research and education, while the NP devotes more time to providing direct patient care and less time engaging in other non-clinical activities. Another key difference is the fact that the NP has legislated authority to engage in expanded clinical tasks typically associated with physicians. This includes the ability to autonomously order and interpret diagnostic tests, diagnose, prescribe medication, and perform specific procedures. Confusion surrounding these differences has caused challenges when it comes to integrating the two roles into practice, as healthcare officials—and healthcare consumers—can have unrealistic expectations about each role.[18]

APN job titles may differ greatly based on practice setting, which also contributes to a lack of clarity surrounding the role. In a 2010 study, Donald and colleagues point out that "no two CNS or NP roles are alike."[18] For example, depending on the practice setting, the CNS can be referred to by a variety of titles, including nurse educator, nurse leader, and nurse clinician.[18] Compounding the challenge are the differences seen between APNs within the same institution. While the APRN Consensus Model is designed to provide clarity and consistency, others have found that using a one-size-fits-all title only served to blur the roles further and increase misunderstanding.[18] It remains to be seen how the APRN Consensus Model will play out.

Role ambiguity can make it difficult for key stakeholders at a cancer program to have a clear understanding of the objectives, scope of practice, and responsibilities of the APN role. When

stakeholders have conflicting ideas about what the APN role entails, it can put APNs at risk for experiencing role conflict and job overload. If those key stakeholders are responsible for making funding decisions, they may choose to support a more well-established position instead of hiring or adding an APN. The CNS role, in particular, is at risk for funding cuts because the direct impact on patient care is not as easy to see when compared to the role of the NP.[5,18]

Lack of awareness and support. It is well documented that the general public lacks awareness about the value of the APN role, the services APNs offer, and what to expect from APNs. In turn, this lack of awareness can lead to a lack of acceptance and support for the APN role.[20] Indeed, the public tends to be more familiar with physicians diagnosing problems and making decisions about medical treatment, and the idea that nurses will be overseeing care is difficult for some to accept.[21] For example, a 2005 study examined factors surrounding parents' willingness to allow their children to receive care from an NP in the emergency clinic setting.[22] The authors concluded that for the public to feel comfortable with and embrace the role of the NP, they must first comprehend and understand the scope of the role.[22] If the public understands the benefits and services APNs offer, they are more likely to advocate for and/or demand access to care provided by APNs.

Physicians also struggle to understand the full scope of the APN role, and a lack of knowledge about the role has been identified in the literature as a significant barrier to successful collaboration between APNs and physicians. Among the misconceptions physicians may hold is the belief that APNs lack the education and training required to provide safe, quality care.[23] Physician support for APNs is less likely when physicians are unclear about what the APN role entails. In addition, APNs and physicians perform many of the same activities, and if the physician does not have a clear understanding of the APN role, conflict and communication break downs can result.[24]

Legal restrictions. Lastly, variation in licensure, practice laws, and prescriptive authority also create barriers to successful integration of the APN role within a cancer program.[19,23] Only about one-third of the United States has full APN practice authority licensure and practice laws.[23] Restrictive practice laws are especially problematic in the oncology setting where APNs must address complex symptoms that often require the use of prescription medication and/or autonomous clinical decision making and expanded authority. This wide variety in legal restrictions, such as prescriptive authority and insurance, can make it difficult for APNs to provide continuous, coordinated care across all settings.[25]

Making the Business Case

As the U.S. healthcare system evolves, cost efficiencies are often recognized through staff reduction. Return on investment (ROI) is associated predominantly with high-revenue producing treatment options, such as surgery and radiation. Conducting an ROI purely on the number of patients billed to an APN is incomplete, not taking into account other non-billable activities these clinicians perform so that physicians are free to conduct other clinics, see more patients, etc. For a cancer program to fully capture the revenue generated from APNs, it must take into account referral growth based on physician and patient satisfaction, reduced readmissions, and increased patient retention.

During a four-year time period in which the authors worked together in a multi-hospital health system in Richmond, Va., we created a leadership infrastructure comprised of eight APNs, sales, marketing, and decision-support staff in order to design and align with health system programmatic growth strategies. As a group, we were responsible for driving the business plan across the healthcare system's service area and through departments in which we had formal authority. Annual strategic planning resulted in more than 15 programmatic growth strategies at each hospital, leveraging the access points and physician partners in the network that the team developed. As leaders of the various programs, these APNs engaged and influenced physician specialists and department leaders across a 75-mile network, significantly contributing to the 21 percent growth experienced in the oncology service line over four years. OI

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ONc-PoWER

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An innovative web-based education resource for oncology nurse practitioners

There is growing evidence that the nation is facing a shortage of cancer care providers needed to provide high-quality cancer care. As the population ages, the treatment options for cancer expand and cancer survival increases, yet the current oncology workforce is without proportionate replacement for expected attrition.[1,2,3] While nurse practitioners (NPs) working within the specialty field of oncology are expected to assume the cancer care provider role, some may come with limited cancer experience and knowledge. The web-based education resource discussed in this article can help ensure that these providers have a basic level of knowledge to support safe, quality cancer care.

The Nurse Practitioner Role in Cancer Care

NPs have established evidence of cost effectiveness, patient satisfaction, and quality care outcomes in multiple care settings,[4-10] prompting the rapid growth of these professionals in cancer care.[5,11-14] NPs in the field of general medicine and primary care have strong skills in patient education, communication, and adherence to evidence-based practice guidelines.[15] Additionally NPs in oncology have demonstrated patient outcomes that include:[16-19]

- Increased access to care and patient education
- Improved patient satisfaction
- Cost effectiveness
- Improved patient compliance
- Fewer hospital admissions
- Decreased lengths of stay, readmission rates, emergency care visits, and healthcare costs.

The American Society of Clinical Oncology (ASCO) Fall 2008 Workforce Statement urged the development of a workforce to ensure continuous delivery of high-quality cancer care.[20] Restrategizing oncology care delivery by increasing the numbers and expanding the roles of non-physician practitioners, such as NPs, is considered to be critically important to meet the current and potential cancer care needs of the U.S. population.[20]

While the shortage of oncology providers is seen as an opportunity for NPs to play a major role in the care of cancer patients and their families, this opportunity to utilize nurse practitioners to the full extent of their capacity is not being realized. A survey of practicing oncologists conducted in 2006 found that more than half (54 percent) of the nation's oncologists work with an NP or physician assistant, but few NPs see themselves as functioning in a truly "advanced practice" nursing role. The true scope of NP practice includes:[21,22]

- Performing comprehensive health histories and physicals
- Ordering appropriate testing
- Making differential diagnoses
- Performing procedures
- Ordering medications, including chemotherapy
- Promoting health and wellness despite the stage of illness.

This full scope of practice is not realized due to a variety of factors:

- Poor education and preparation in oncology limiting the ability of the nurse practitioner to immediately assume patient care responsibilities
- Poor physician understanding of the role potential
- NPs new to oncology assuming a more comfortable and familiar "staff nurse" role rather than advanced practice nurse role in the face of new challenges and role uncertainty
- Reluctance or unwillingness of the supervising physician to teach "Cancer 101" in the middle of other clinical responsibilities.

Standardized cancer care education for oncology nurse practitioners—that creatively includes the supervising physician as a preceptor—would help eliminate these barriers. This education would include an understanding of the full scope of the oncology nurse practitioner role; the basic preparation to assume that role with safety and quality; and a template to help achieve that potential.

Currently there are non-standardized orientation models for nurse practitioners working in specialty care. They are "on the job," learn as you go models, which may hold high variability in content, motivation of the assigned preceptor, and quality.

The Need for an Oncology-Specific Curriculum

Traditionally, NPs are educationally prepared under broad umbrellas of patient populations, not disease-specific entities.[12] Because cancer care reaches across all patient populations, the existing NP educational preparation—family, adult, acute care, women's health—is not entirely adequate for the care of the cancer patient and family. NPs who come from any of these patient population educational programs and enter oncology require additional education to be able to provide safe and appropriate care of the cancer patient and family across the cancer care trajectory.[23-27] Currently NPs without previous cancer care experience or knowledge are entering oncology positions requiring a high degree of autonomy and decision making without any additional training or education, leaving cancer programs at risk of poor patient outcomes, risk management vulnerabilities, and high clinician attrition.[28] Improving and standardizing the cancer care education available to NPs entering oncology—and their clinical preceptors—is an important and essential step in eliminating or mitigating these risks.

Factors & Information Shaping the Oncology NP Curriculum

As the nurse practitioner role in oncology care has grown, additional sources inform the need, content, and delivery mode for the "Adult Cancer Care for NPs" educational program. These sources include the Oncology Nursing Society's (ONS) entry-level competencies and a "Bridging the Gap" survey of working NPs in oncology. In 2007 a national expert consensus panel, convened through ONS, created the development of entry-level competencies for NPs entering oncology practice and conducted a national validation process from practicing oncology NPs and educators.[28] These competencies were created using established national nurse practitioner standards and through consultation with the National Organization of Nurse Practitioner Faculties (NONPF) and the American Nurses Credentialing Center (ANCC). The templates for Family, Adult, Women's Health and, and Acute Care NPs were used to develop the oncology NP entry-level competencies. Learn more at: ons.org/sites/default/files/npcompentencies.pdf and http://c.ymcdn.com/sites/www.nonpf.org/resource/resmgr/competencies/populationfocusnpcomps2013.pdf.

A working group of experienced nurse practitioners established through ONS developed a cross-sectional, descriptive 30-item electronic survey to assess learning needs at entry into and through the first year of practice for oncology NPs. In the first year of practice 90 percent of oncology NPs rated themselves as "prepared" or "very prepared" in standard nurse practitioner competencies, such as obtaining patient history, performing physical exam, and documenting findings. However, oncology NPs rated themselves as "not at all" or only "somewhat prepared" in important clinical issues of chemotherapy and biotherapy competency (77.9 percent, n=81); recognizing and managing oncologic emergencies (70.2 percent, n=77); and recognition and management of drug toxicities (60.6 percent, n=63). The primary source of oncology education for oncology NPs new to practice was almost exclusively the collaborating and/or supervising physician (80.8 percent, n=84).[29]

"Adult Cancer Care" Introductory Learning

The delivery method and timing of the educational intervention chosen for the essential introductory content was formulated based on Knowles' Adult Learning Theory[30] and Bloom's classic Taxonomy of Learning.[31] Knowles' Adult Learning Theory states that adults learn best when content can be made immediately relevant. According to Bloom's Taxonomy of Learning, content should be increasingly sophisticated, progressing from basic delivery of information to higher level educational competencies, such as synthesis and application. The NP curriculum advances from basic, essential introductory cancer care information to more clinical application in each module, with suggestions for application with the identified mentor as content is made relevant to the learner's needs. These clinical application suggestions could be made to the mentor to facilitate application of the content as it is presented. For the NP new to cancer care, the foundational content with mentored application to cancer care is necessary for safe application to clinical problem solving.

Currently there are non-standardized orientation models for nurse practitioners working in specialty care. They are "on the job," learn as you go models, which may hold high variability in content, motivation of the assigned preceptor, and quality. An

additional option may entail some basic orientation with other nursing staff, which is not appropriate for the complexity of the nurse practitioner role or there may be a random mix of web-based and on-site courses—with or without formal mentoring—and with limited insight in regards to curriculum quality and learning needs of the new NP.

To begin to better define the role and standardize knowledge and skill preparation into oncology practice, ONS published specific competencies for the entry-level oncology nurse practitioner. These 2007 competencies build on core competencies for all nurse practitioners, to meet the "unique needs of patients with a past, current, or potential diagnosis of cancer."[28] The Oncology Nurse Practitioner Competencies assume that nurse practitioners have completed graduate course work and clinical experiences to "provide advanced nursing care to meet the specialized physiologic and psychological needs of patients throughout the continuum of care, including cancer prevention and detection, cancer diagnosis and treatment, rehabilitation, survivorship, and end-of-life care."[28]

ONc-PoWER

In 2013 and in accordance with the ONS Competencies for entry to practice, a team of researchers from the University of Pittsburgh School of Nursing developed an online web-based educational tool titled "Oncology Nurse Practitioner Web Education Resource (ONc-PoWER)." Funded by the National Cancer Institute (NCI), the ONc-PoWER course consists of five modules (Table 1, right) to be completed at the learner's own pace.

Enrollment and completion of the course will qualify nurse practitioners for 30 continuing education (CE) contact hours and their mentors will receive a $1,000 honorarium. The course is offered at no charge for nurse practitioners who began their career in cancer care within the last year.

The five interactive modules use life-like characters in clinical story settings. For example, "Gina" is a recent NP graduate who is excited and nervous in her new cancer care position. Within the module Gina is assigned a mentor who provides support, direction, and encouragement. The course then "solves" Gina's challenges as a new nurse practitioner in cancer care. One challenge: how to assess a new cancer patient. Gina shares her anxiety with her mentor, who tells Gina that everyone feels nervous. The mentor then identifies resources to help Gina assess and treat her new patient; the learner taking the online course learns to use these resources alongside of Gina.

The ONc-PoWER course (nursing.pitt.edu/continuing-education/onc-power) is being disseminated and evaluated as an educational product for adoption and use by cancer programs employing nurse practitioners. The course is embedded into a university course web structure as a continuing education module. Each module is organized into Content, Challenges, and Resolution.

(continued on page 57)

Table 1. The Five Modules in the ONc-PoWER Web-Based Adult Cancer Care Course

MODULE 1 (The New Patient)
Skills and knowledge related to a new patient visiting the clinic:
- Locate and review information in a patient's record.
- Assess tumor characteristics.
- Complete a history and physical.
- Communication techniques.

MODULE 2 (Patient Presentation)
Presenting a patient to the multidisciplinary team:
- Select the appropriate amount of the patient's information to include.
- Prepare for the presentation.
- Manage challenging situations that may occur during the presentation.

MODULE 3 (Care Continuum)
Managing patients at different points on the cancer care continuum:
- Recognize the distinct visits in cancer care.
- Communication with the anxious patient.
- Symptom management.
- Support for patients during survivorship.
- Recognize oncologic emergencies.
- Share difficult or bad news with the patient.

MODULE 4 (Palliative and Hospice Care)
Incorporating palliative care into cancer care:
- Incorporate palliative care into a treatment visit.
- Manage common symptoms related to palliative care and hospice care.
- Identify the important components of hospice care.

MODULE 5 (Self-Care and Professional Development)
Taking care of yourself:
- Ways to remain physically and emotionally healthy in a demanding profession.
- Plan for your professional development (setting goals, choosing conferences and seminars, further education, professional organizations, and more).

Table 2. The 7 Principles for Good Practice in Undergraduate Education in ONc-PoWER

PRINCIPLE 1. Good practice encourages student-faculty contact.

The ONc-PoWER course was designed to encourage contact between NPs and their mentors.

Through Gina (the new NP) and her mentor (Sandra), the course models an effective NP/mentor relationship. The course encourages:

- NPs to identify a mentor and/or request a mentorship.
- NPs to learn the content independently, while the mentor assists the NP in applying the content. Mentors are required to evaluate the NP's ability to apply the content of each module to practice. For example, when the NP completes Module 1, the mentor is asked to evaluate the NP's ability to perform a history and physical by agreeing to the following statement: "The nurse practitioner was observed and critiqued while performing a History and Physical (H&P) for a patient with cancer." Student and faculty contact is primarily through email and telephone, as needed.

PRINCIPLE 2. Good practice encourages cooperation among students.

The ONc-PoWER course is taken independently by NPs new to oncology, but it was designed to encourage NPs to work within a multidisciplinary team. Specifically, Module 2:

- Introduces multidisciplinary team members, including fellows, RNs, and visiting professors.
- Presents challenges NPs may face when presenting a patient to the multidisciplinary team.
- Asks NPs to choose the best response to some challenging comments or questions from the team during a patient presentation.
- Discusses the importance of team-based support during the module on wellness and growth.

PRINCIPLE 3. Good practice encourages active learning.

- Curriculum content is provided to NP learners through interactive activities.

PRINCIPLE 4. Good practice gives prompt feedback.

- Interactive learning activities prompt instant feedback with opportunity for revision of answer.

PRINCIPLE 5. Good practice emphasizes time on task.

- The ONc-PoWER course uses the blackboard system, which allows instructors to monitor participation and interaction of NPs and mentors throughout the course. Course faculty has the ability to see how often and how long NPs and mentors work on the program.
- The course is available to NPs and mentors for 6 months.
- NPs who do not move through the course, or do not begin the course after registering, receive reminder emails.
- NP learners can work at their own pace.
- NP learners can review material as much as needed.
- NP learners can immediately apply the curriculum in their work setting.

PRINCIPLE 6. Good practice communicates high expectations.

- The expectation is that new NPs will want to learn this content and invest time in order to become more proficient with specialty content.

PRINCIPLE 7. Good practice respects diverse talents and ways of learning.

The ONc-PoWER course provides a variety of learning activities for NP engagement:

- Multiple types of interactive exercises:
  - ✧ In Module 4, the NP observes a conversation between the physician, patient, and family and is asked to assess how the conversation going.
  - ✧ In Module 4, interactive sections require NP learners to "click and drag" statements or thoughts under correct categories.
  - ✧ In Module 5, NPs engage in an interactive game. Specifically, NPs are shown a Zen Garden and asked to drag a floating rock to the appropriate effective and/or ineffective action NPs would take to protect and care for themselves.

Course includes multiple sources for content. Information is presented in text on screen, linked to text-based sources, and reiterated in course feedback during interactive exercises.

(continued from page 55)

The "Content" section features the lesson of the module with the introduction of outside resources. The "Challenges" section features interactive situations in which the NP is asked to use the content or resources just presented for patient situations with immediate feedback. Each module ends with a "Resolution."

Creating quality online educational materials requires more than knowledge translation. All online teaching aids must connect with the learner, complement their learning style, and incorporate adult learning principles. Furthermore, any instructional strategy must be supported by sound educational principles that guide the teaching and learning process. Researchers from the University of Pittsburgh School of Nursing used the Seven Principles for Good Practice in Undergraduate Education as a framework to create the ONc-PoWER course: [32]

1. Good practice encourages student-faculty contact
2. Good practice encourages cooperation among students
3. Good practice encourages active learning
4. Good practice gives prompt feedback
5. Good practice emphasizes time on task
6. Good practice communicates high expectations
7. Good practice respects diverse talents and ways of learning.

While all seven principles were implemented in the development and delivery of the ONc-PoWER curriculum, the two or three areas that the curriculum used the most were active learning, prompt feedback, and student/faculty interaction (see Table 2, left).

NPs interested in taking ONc-PoWER should consider these additional benefits:

- While NP learners must use the embedded resources within the course, these resources can also be used in the real-world setting. For example, in the New Patient module, NP learners use an embedded pathology report and outside resources to review the different sections in the pathology report and answer questions about the information in the pathology report, essentially mimicking tasks required of NPs in the practice setting.
- The ONc-PoWER curriculum provides oncology education in a measured approach. While course pace may vary, the expectation is that that NP learners will complete the course within four to six months from time of enrollment. Accordingly, course access expires six months from enrollment.
- Online learning modules allow NP learners to review course content as often as needed to fully understand the information and concepts presented. Students work at their own pace, but within the specific time frame mentioned above.

The ONc-PoWER course begins with the assumption that NPs new to oncology are motivated to learn additional content in order to provide quality, safe cancer care to their patients. Further, this course was developed with the intention that nurse practitioners will want to implement this education into routine cancer care. Finally, the course helps prepare NPs for their future. Specifically, Module 5 speaks to the professional development that is necessary for the new nurse practitioner. The module covers continuing education and professional certification, and encourages healthy lifestyle choices to prevent emotional burnout in a high-stress and high-caring work environment.

The ONc-PoWER course begins with the assumption that NPs new to oncology are motivated to learn additional content in order to provide quality, safe cancer care to their patients.

Evaluation of the curriculum by nurse practitioners new to oncology and their onsite mentors is currently ongoing. For more information about ONc-PoWER and its course curriculum go to: nursing.pitt.edu/continuing-education/onc-power. OI

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How Does Your Infusion Center Measure Up?

RESULTS OF THE 2014 NATIONAL HOSPITAL ONCOLOGY BENCHMARK FOR INFUSION

The National Hospital Oncology Benchmark Study, conducted annually by the Oncology Management Consulting Group, gathers data from respondent hospital-based outpatient infusion and radiation centers across the country. This article presents a selection of the infusion-related survey analyses from the 47 infusion centers that submitted data.

Disease Mix

Most survey respondents reported that their hospital-based infusion centers treat more than cancer patients and that the mix can have an impact on staffing, scheduling, throughput, and reimbursement. On average, 58 percent of all patients treated in the infusion center were treated for cancers, 16 percent were treated for benign hematology conditions, and 26 percent were treated for other conditions.

Ancillary Staff

Table 1, right, shows the percentage of all programs that report having "dedicated" staff, although some were not necessarily full-time staff members (e.g., one social worker working half time in infusion and half time in radiation = .5 FTE for infusion). Topping the list for ancillary staff, financial counselors—47 percent of programs report having a "dedicated" financial counselor. Interestingly, even with Commission on Cancer (CoC) Standard 3.1 that requires accredited institutions to develop and implement a patient navigation process to address disparities and barriers to care experienced by cancer patients, only 22 percent of programs report "dedicated" navigators in their infusion centers. Registry data found an adjusted mean of 452 analytic cases per FTE tumor registrar.

Table 1. Support Staff Serving Only Infusion Patients

- 47 percent of programs have dedicated financial counselors
- 40 percent have dedicated social workers
- 33 percent use licensed practice nurses/nursing assistants
- 31 percent have non-physician practitioners
- 24 percent have nutritionists
- 22 percent have oncology navigators
- 20 percent use medical assistants

For many job categories, we calculated the number of patients seen per FTEs in the infusion suite for one year. Here are the adjusted mean results:

- Total patients per financial counselor: 1,310
- Total patients per social worker: 1,506
- Total patients per licensed practice nurse/nursing assistant: 2,997
- Total patients per FTE oncology-only navigator: 3,889
- Total patients per non-physician practitioner: 866
- Total patients per nutritionist: 4,411
- Total patients per medical assistant: 732

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ELAINE KLOOS, RN, NE-BC, MBA

Oncologists/Hematologists

Across the country, there is a continuing trend towards integration and alignment between hospitals and oncologists/hematologists. In the 2014 study, 49 percent of programs report having only "exclusive" oncologists/hematologists (i.e., physicians who utilize only this institution's infusion suite because they are employed or under exclusive contract); 11 percent of programs report having only "private" oncologists/hematologists (i.e., physicians who use their own offices for most infusions). Figures 1 and 2, below, shows encounters per FTE "exclusive" and "private" oncologist/hematologist.

It is not possible to accurately report the volume of services generated per oncologist/hematologist in programs where there is a mix of "exclusive" and "private" physicians. However, by comparing the number of "initial" infusion services provided to benign hematology patients and oncology patients (because only one "initial" service may be billed for any given encounter) to the number of FTE oncologists/hematologists, we see that the

Figure 1. Encounters per FTE Employed Oncologist/Hematologist

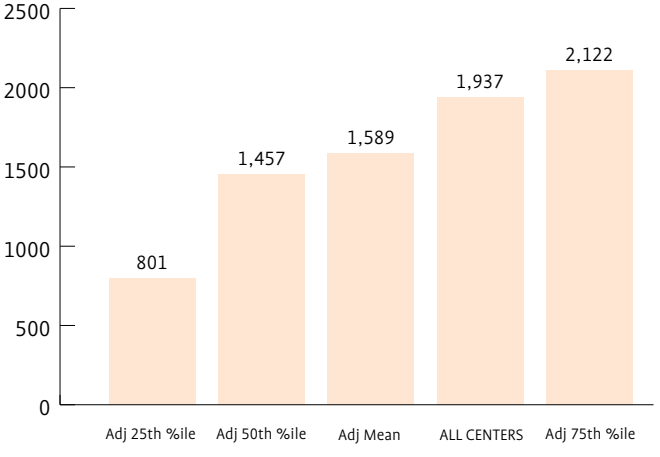
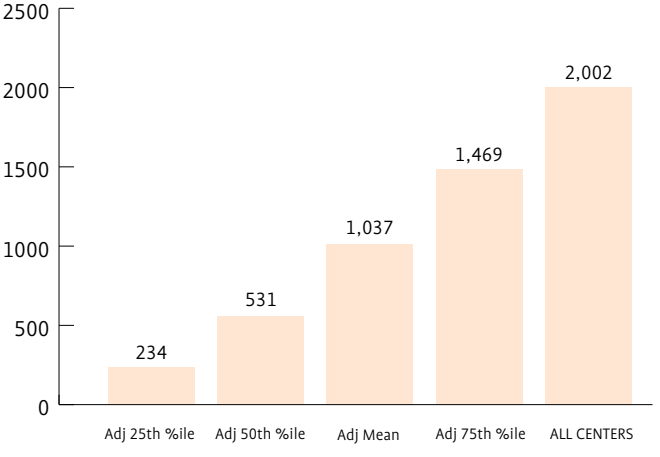


Figure 2. Encounters per FTE Private Oncologist/Hematologist



"exclusive" physicians generate 64 percent more infusions than the "private" physicians. While this is intuitively obvious, the actual number is helpful in capacity planning for programs looking to employ or contract with private practices in the future and for programs whose private physician practices are either growing or shrinking.

Infusion Nurses

Among the most commonly requested benchmarks are chairs per nurse and encounters per nurse. On average, one FTE infusion nurse handles 3.74 chairs per day and 1,162 infusion encounters per year (unique appointments—one patient on one day) (see Figures 3 and 4 below). Figure 5, below, shows the annual hours one FTE nurse spends infusing patients. Based on survey data, we calculate one FTE infusion nurse is responsible for 1,453 hours of infusions/injections per year.

Chair Utilization

While many cancer programs are facing growth in the infusion department, programs often believe that they do not have the capacity for more patients and so must plan for expansion. Before spending significant money on construction, it can be extremely valuable to look more closely at the actual utilization of those chairs. Too often, patients are seated in the infusion suite while they wait for lab results, thus taking a chair out of circulation for treatments that are ready to be given. Figure 6, below, shows that

Figure 3. Total Chairs per FTE Infusion Nurse (All Programs)

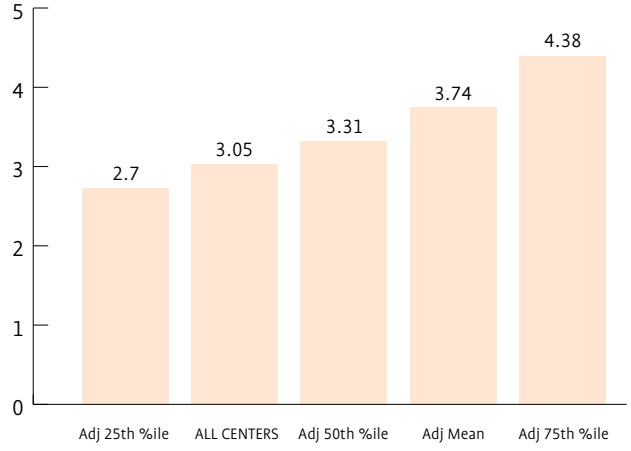


Figure 4. Encounters per FTE Infusion Nurse (All Programs)

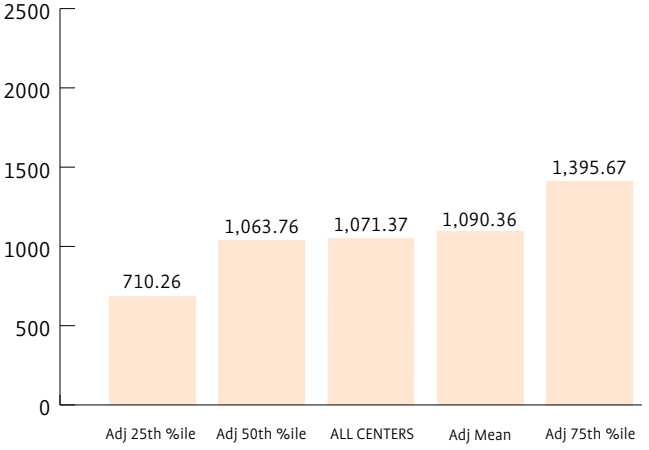


Figure 5. Infusion Hours per FTE Nurse

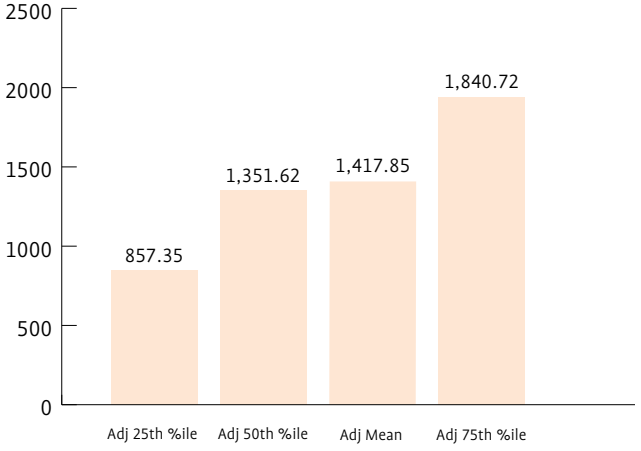
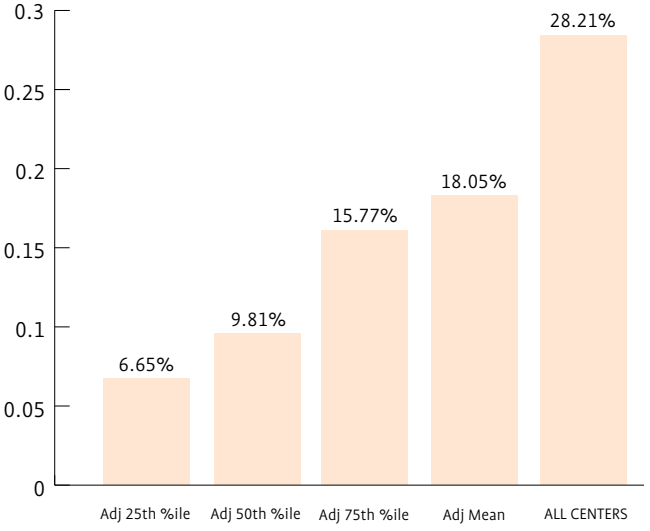


Figure 6. Chair Occupancy (Active Treatment) Rate



infusion chairs are utilized for active treatment only 18 percent of the total chair time available. Accordingly, there appear to be significant opportunities to streamline patient throughput and potentially reduce the need for costly expansion of the infusion suite. (Learn how one ACCC member program used a web-based patient tracker to streamline patient throughput on pages 30-38).

Pharmacy

Nearly all survey respondents with "dedicated" (oncology-only) pharmacy staff reported having both pharmacists and pharmacy technicians. We combined those two job categories to determine the total pharmacy FTE complement. Next, we counted all infusion/injection codes. Although many drugs do not require a substantial amount of time to prepare, we find that the average FTE pharmacy staffer prepares drugs for 5,941 infusions/injections annually (Figure 7, below). Tables 2-4, pages 63-64, show the most frequently ordered drugs for breast cancer, colorectal cancer, and lung cancer.

The full National Hospital Oncology Benchmark Study is given to each participating institution and is available for purchase at: http://oncologymgmt.com/nhobs/.

Teri U. Guidi, MBA, FAAMA, is president and CEO, and Elaine Kloos, RN, NE-BC, MBA, is senior consultant, Oncology Management Consulting Group.

Figure 7. Total Infusions/Injections per FTE Pharmacy Staff

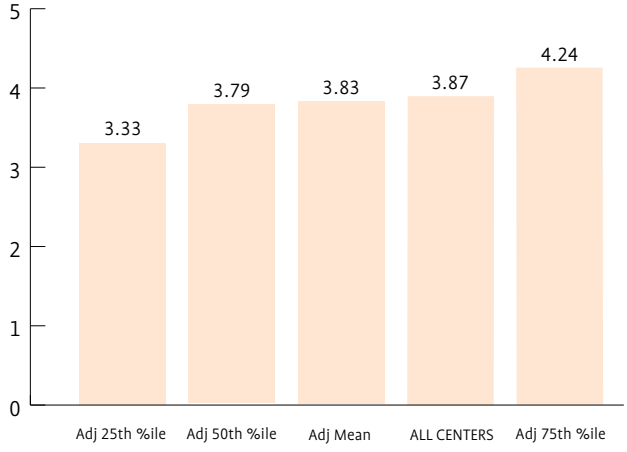


Table 2. Drug Utilization of Breast Cancer Patients

HCPCS Code	Top 10 J-Codes as a Percentage of all J-Codes		HCPCS Code	Percentage of all Breast Cancer Patients Receiving Drug		Average Number of Times Drug Given to Patient	
	All Programs	Mean		All Programs	Mean	HCPCS	# of TX
J9355	25.1%	25.8%	J9355	11.8%	15.6%	J9355	9.9
J9171	17.9%	11.6%	J9171	11.8%	11.9%	J9171	7.1
J9265	12.7%	10.8%	J9265	8.6%	10.4%	J9265	6.9
J9070	12.0%	11.8%	J9070	15.3%	18.5%	J9070	3.7
J9000	8.7%	7.3%	J9000	9.6%	9.7%	J9000	4.2
J9395	5.5%	14.0%	J9395	4.3%	6.2%	J9395	6.0
J9045	3.8%	3.9%	J9045	4.5%	5.7%	J9045	3.9
J9201	2.8%	3.6%	J9201	2.1%	3.6%	J9201	6.1
J9179	2.7%	2.0%	J9179	1.5%	1.3%	J9179	8.7
J9390	2.3%	2.0%	J9390	1.2%	1.6%	J9390	9.3

Table 3. Drug Utilization of Colorectal Cancer Patients

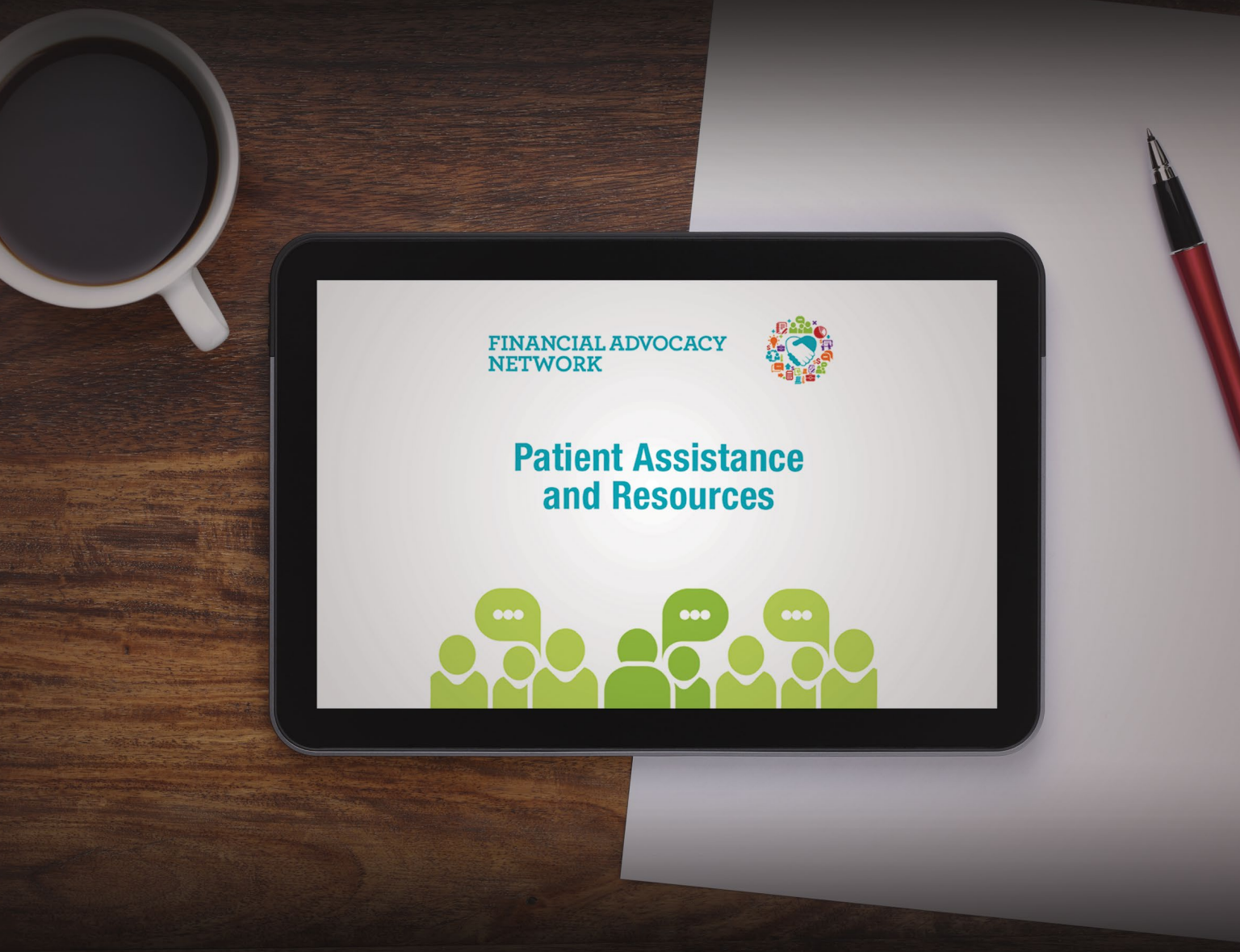
HCPCS Code	Top 10 J-Codes as a Percentage of all J-Codes		HCPCS Code	Percentage of all Colorectal Cancer Patients Receiving Drug		Average Number of Times Drug Given to Patient	
	All Programs	Mean		All Centers	Mean	HCPCS	# of TX
J9190	38.4%	44.4%	J9190	12.5%	12.7%	J9190	7.7
J9263	24.6%	25.4%	J9263	0.1%	0.0%	J9263	6.2
J9206	13.8%	10.6%	J9206	3.2%	2.2%	J9206	7.6
J9035	13.3%	13.0%	J9035	30.0%	36.1%	J9035	6.4
J9055	4.9%	2.8%	J9055	0.1%	0.1%	J9055	9.3
J9303	2.8%	2.2%	J9303	10.9%	9.5%	J9303	8.3
J9280	0.6%	0.7%	J9280	23.8%	27.4%	J9280	1.8
J9400	0.3%	0.2%	J9400	2.1%	2.7%	J9400	28.0
J9041	0.2%	0.2%	J9041	2.0%	2.1%	J9041	21.0
J9201	0.1%	0.1%	J9201	0.1%	0.0%	J9201	6.5

Table 4. Drug Utilization of Lung Cancer Patients

HCPCS Code	Top 10 J-Codes as a Percentage of all J-Codes		HCPCS Code	Percentage of all Lung Cancer Patients Receiving Drug		Average Number of Times Drug Given to Patient	
	All Programs	Mean		All Programs	Mean	HCPCS	# of TX
J9045	5.9%	10.4%	J9045	26.7%	28.6%	J9045	3.7
J9181	5.1%	5.1%	J9181	13.5%	14.2%	J9181	7.3
J9265	5.1%	6.5%	J9265	12.9%	14.6%	J9265	4.6
J9305	4.4%	3.2%	J9305	13.6%	12.6%	J9305	4.1
J9201	3.8%	2.3%	J9201	8.1%	8.0%	J9201	5.8
J9264	6.5%	7.7%	J9264	4.0%	5.7%	J9264	6.2
J9060	3.3%	3.9%	J9060	8.1%	9.5%	J9060	3.3
J9035	3.1%	3.5%	J9035	5.0%	5.6%	J9035	4.4
J9171	3.3%	3.9%	J9171	5.2%	4.2%	J9171	4.5
J9390	2.0%	2.2%	J9390	5.2%	4.0%	J9390	8.4

accc-FAN-App.org > > > > > > > >

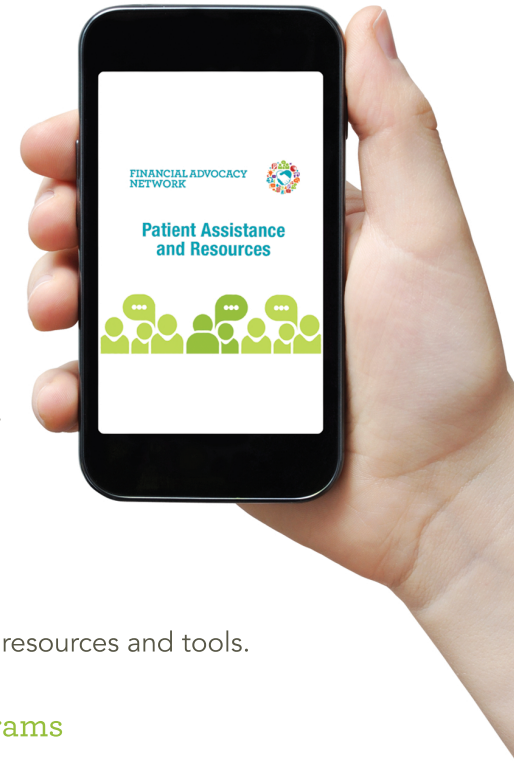
Making patient assistance resources easily accessible to cancer providers.



Because the last concern your patients should have to worry about is how to pay for their cancer treatment.

ACCC
Association of Community Cancer Centers

When your patients need financial assistance **NOW!**



With accc-FAN-App.org, critical patient assistance resources are just a click away….

Key features of the app include:

Breaking News

Stay up-to-date with the latest financial advocacy resources and tools.

Pharmaceutical Patient Assistance Programs

Search by drug name (brand or generic) or manufacturer.

Foundation & Co-pay Assistance Programs

Get help for patients with high out-of-pocket costs, including co-pays and deductibles.

Travel & Housing Assistance

Identify resources for patients who need transportation, travel, or housing assistance.

The ACCC Financial Advocacy Network (FAN)

Financial advocacy is one of the fastest growing cancer services lines, stay current with all of the latest tools and resources, including online courses and a Financial Advocacy Toolkit.

Plus, links to the ACCC Patient Assistance Guide and Oncology Drug Database appear on each individual drug page.

FINANCIAL ADVOCACY NETWORK
Resources & Tools for the Multidisciplinary Team

To access the app, go to accc-FAN-App.org.
Or, scan the QR code below!

Funding for this project was provided by Amgen, Bristol-Myers Squibb, Celgene, Genentech, Incyte, Lilly Oncology, Merck, Pfizer Oncology, and Teva Oncology.

This tool is a benefit of membership.
Association of Community Cancer Centers

BY TERI U. GUIDI, MBA, FAAMA AND
ELAINE KLOOS, RN, NE-BC, MBA

How Does Your Radiation Oncology Service Line Measure Up?

RESULTS OF THE 2014 NATIONAL HOSPITAL ONCOLOGY BENCHMARK FOR RADIATION

The National Hospital Oncology Benchmark Study, conducted annually by the Oncology Management Consulting Group, gathers data from respondent hospital-based outpatient infusion and radiation centers across the country. This article presents a selection of the radiation oncology-related survey analyses from the 27 radiation oncology programs that submitted data.

Note: in calculating data per full-time staff members, all reported staff hours were adjusted to a 2,080-hour work year. In other words, a program reporting 2,500 hours of therapist time is considered to have 1.2 full-time equivalent (FTE) therapists. Similarly, treatment equipment is adjusted to full-time equivalents. For example, a program with 2 linear accelerators (linacs) operating 50 hours per week has 2.5 FTE linacs. These calculations

Figure 1. Percentage of Radiation Oncology Treatment Modalities

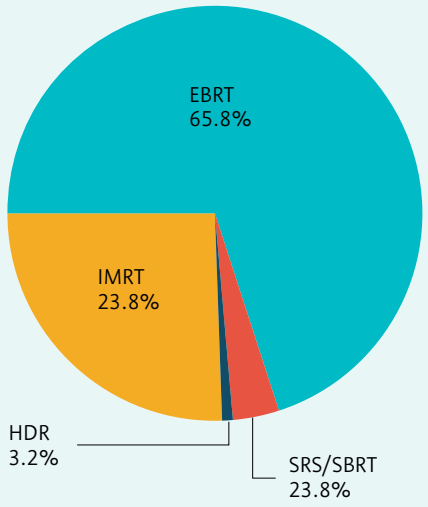


Table 1. Support Staff Serving Only Radiation Oncology Patients

- 89 percent of programs use nurses
- 56 percent have simulation therapists
- 52 percent have dedicated social workers
- 44 percent have dedicated nutritionists
- 33 percent have dedicated financial counselors
- 22 percent use non-physician practitioners
- 22 percent have navigators
- 19 percent use medical assistants
- 15 percent use licensed nurse practitioners and/or nursing assistants.

For many job categories, we calculated the number of patients seen per FTEs in the radiation center for one year. Here are the adjusted mean results:

- Total patients per nurse: 268
- Total patients per simulation therapist: 576
- Total patients per financial counselor: 861
- Total patients per social worker: 1,059
- Total patients per licensed practice nurse/nursing assistant: 552
- Total patients per FTE oncology-only navigator: 758
- Total patients per non-physician practitioner: 522
- Total patients per nutritionist: 2,697
- Total patients per medical assistant: 730

Table 2. Disease Mix for IMRT Treatments

- Prostate: 31 percent (adjusted mean)
- Head and neck: 16 percent (adjusted mean)
- Lung: 14 percent (adjusted mean)
- CNS: 7 percent (adjusted mean)
- Colorectal: 5 percent (adjusted mean).

allow us to compare data across programs that are adjusted for longer or shorter hours of operation. To define FTE physicians, we assumed that one full-time physician is scheduled to see patients for 10 half-day clinic sessions.

Disease Mix

Most cancer programs think of breast, colorectal, lung, and prostate as the top volume disease sites. For the radiation programs who reported data in our study, the top four disease sites were:

- Breast: 22 percent
- Lung: 18 percent
- Prostate: 11 percent
- Cancers of the central nervous system (CNS): 7 percent.

We calculated the mix for external beam radiation therapy (EBRT), intensity-modulated radiation therapy (IMRT), high-dose rate (HDR) therapy, and stereotactic radiosurgery/stereotactic body radiosurgery (SRS/SBRT), Figure 1, above, left.

Support Staff

We asked for hours spent serving only radiation patients: "dedicated" staff. Table 1, left, shows the percentage of all centers that report having "dedicated" staff although some were not necessarily full-time staff members (e.g., one social worker working half time in infusion and half time in radiation = .5 FTE for radiation).

Clinical Staffing

Measuring productivity can be done in numerous ways. Among the most commonly requested benchmarks is the number of patients per various clinical staff positions. On average, one FTE radiation therapist, which excludes hours for programs reporting dedicated simulation therapists, is responsible for a total of 99 patients per year. For dosimetrists that number is 323 and for physicists that number is 333. Finally, among

survey respondents, on average the FTE radiation oncologist cares for 228 patients annually.

Another commonly sought-after benchmark is the number of therapists per linac. Our survey found that there are 2.27 therapists per FTE linac (again, excluding dedicated simulation therapists). To measure the productivity of those simulation therapists, we counted the billed simulation codes to arrive at an average of 1,185 plans per year per FTE simulation therapist. Finally, to establish a productivity benchmark for physics, we applied the count of technical planning codes billed to physics staffing time—an average of 1,888 plans per year.

External Beam Treatments

Cancer programs that are facing growth in their radiation service line may find it helpful to have a grasp on the number of treatments delivered to specific disease groups, particularly if the program is engaged in strategic disease-specific initiatives. Among our findings: for patients receiving EBRT, the average number of billed codes was 20 for all diagnoses and for breast cancer patients receiving EBRT that number was 25.

IMRT

Our data found that 23 percent of all patients received IMRT. We then looked at the disease mix for IMRT and found, not surprisingly, that prostate cancer tops the list; on average, 31 percent of all IMRT patients are treated for prostate cancer. Table 2, left, shows the disease mix for IMRT treatments.

The full National Hospital Oncology Benchmark Study is given to each participating institution and is available for purchase at: http://oncologymgmt.com/nhobs/.

Teri U. Guidi, MBA, FAAMA, is president and CEO, and Elaine Kloos, RN, NE-BC, MBA, is senior consultant, Oncology Management Consulting Group.

action

FAN Process Improvement Learning Labs

As part of the its Financial Advocacy Network (FAN) education project, ACCC selected three member cancer programs to participate in on-site experiential multi-disciplinary process improvement learning labs, focusing on their financial navigation services.
The participating programs are:

- AnMed Health Cancer Center, Anderson, S.C.
- Eastern Maine Medical Center, Brewer, Maine
- Virginia Cancer Institute, Richmond, Va.

Look for learning lab participants to share their experiences in an upcoming edition of *Oncology Issues*.

Funding for this project was provided by Amgen, Bristol-Myers Squibb, Celgene, Genentech, Incyte, Lilly Oncology, Merck, Pfizer Oncology, and Teva Oncology.

Enhance Your Immuno-Oncology IQ!

Access on-demand presentations and audio podcasts from the groundbreaking Institute for Clinical Immuno-Oncology (ICLIO) conference and explore all of the ICLIO offerings at *accc-iclio.org*. Hear from experts in the field on implementing immunotherapy including:

- Administrative strategies
- Operational considerations
- Coverage and reimbursement processes
- Coordination of care
- Managing adverse side effects
- Patient access
- Clinical applications and indications.

While you explore the conference materials be sure to check out the archived ICLIO e-Courses.

ICLIO is made possible by a charitable donation from Bristol-Myers Squibb.

ICD-10 Codes Added to the ACCC Oncology Drug Database

The Oncology Drug Database is a comprehensive, timely, easily understood, and authoritative source of information on coding, billing, and reimbursement for oncology drugs. The database includes information for both provider administered ("Part B") and prescribed ("Part D") drugs commonly used in treating cancer patients in the ambulatory setting, including both therapeutics and supportive care products.

The ACCC Oncology Drug Database is easy to use. Typing the drug name (generic or brand) into a search box will direct users to a drug-specific webpage with all of the information for that drug, including:

- Billing (HCPCS, NDC) and diagnosis (ICD-9 and ICD-10) codes
- Reimbursement amounts
- FDA-approved indications
- Drug manufacturer information, including contact information for the medical affairs department and reimbursement specialists (for drugs that remain under patent protection).

You can also search for drugs alphabetically by 1) clicking on the first letter of a drug's name (brand or generic), and 2) then selecting either the "List by Brand Name" or the "List by Generic Name" tab at the top of the table. accc-cancer.org/drugdatabase.

ACCC Welcomes its Newest Members

Oregon Society of Medical Oncology (OSMO)
Executive Vice President: Liz Cleland
Website: osmo.org

Cary Medical Center
Jefferson Cary Cancer Center
Caribou, Maine
Delegate Rep: Jenn Plant, RN
Website: carymedicalcenter.org

City of Hope National Medical Center
Duarte, Calif.
Delegate Rep: Mathew Loscalzo, MSW
Website: cityofhope.org

Eisenhower Medical Center
Lucy Curci Cancer Center
Rancho Mirage, Calif.
Delegate Rep: Vicki Koceja, PhD
Website: emc.org

Littleton Adventist Hospital
(Part of Centura Health System)
Littleton, Colo.
Delegate Rep: Kelley Kovar, MSN
Website: mylittletonhospital.org

Olathe Medical Center
Oncology Services
Olathe, Kansas
Delegate Rep: Kelly McDonald, MHA
Website: olathehealth.org

Transplant in Multiple Myeloma: Peer-to-Peer Learning Webinars

Psychosocial Support & Financial Counseling
Nov. 18, 2015, 12pm - 1pm EST

Presenter: Alice D. Mullins, LCSW, OSW-C, oncology social worker, Winship Cancer Institute of Emory University, Atlanta, Ga.

Learn how programs prepare to discuss and address practical issues of psychosocial support, insurance coverage, and total cost of treatment. Discuss the psychosocial and financial support programs and tools that programs can employ and offer to their patients.

Patient Education & Engagement
Dec. 1, 2015, 12pm - 1pm EST

Presenters: Lisa Merritt, RN, nurse manager, and Kelly Lehmkuhl, RN, BSN, OCN, assistant nurse manager, Hematology and Transplant Clinic, Arthur G. James Cancer Hospital and Richard J. Solove Research Institute at The Ohio State University, Columbus, Ohio.

Review shared decision making (SDM) a collaborative process that allows patients and their providers to make healthcare decisions together, taking into account the best scientific evidence available, as well as the patient's values and preferences. Explore how transplant programs and referring centers can work together to ensure patients have access to resources, well in advance, during, and after their transplant procedure

Coordination of Care & Medical Co-management
Dec. 17, 2015, 12pm - 1pm EST

Presenter: Leona Holmberg, MD, PhD, Seattle Cancer Care Alliance, Seattle, Wash.

Explore how transplant centers and their referring programs are working together to coordinate care and co-manage patients. Learn about resources and tools to make communication easier and ensure quality care for their patients—both when they are referred for transplant and when they return to their community care provider, post-transplant.

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

Funding and support provided by Pfizer Oncology.

ACCC Board of Trustees: Call for Nominations

ACCC holds an annual election for its Board of Trustees, and we are currently accepting nominations for 2016. If you or a colleague is interested in helping to shape the future of ACCC, please send the nominee's name and program affiliation to Careen Campbell either via email: *ccamplbell@accc-cancer.org* or fax: 301.770.1949. Nominations must be received by Nov. 30, 2015.

careers

DIRECTOR OF CANCER COMMUNICATIONS
Miami, Florida

The University of Miami Miller School of Medicine-UHealth is looking for a Director of Cancer Communications who will be responsible for the creation and implementation of a strategic communications infrastructure for the Sylvester Comprehensive Cancer Center. Responsibilities include: overseeing an extensive internal communications audit; working collaboratively to develop internal communications structure that informs, engages, and connects cancer researchers, physicians, nurses, and staff to each other and to shared work; and developing an infrastructure that will promote a line-of-sight from daily work to the organization's vision and mission.

Essential requirements: Bachelor's degree in marketing, communications, PR, or related field, (Master's degree preferred); minimum of 5 years of experience in strategic organizational communications with increasing responsibilities and staff oversight (10 + years strongly preferred); healthcare and/or academic experience preferred.

Apply online at careers.med.miami.edu and reference position number P100001457. EOE.

DIVISION CHIEF OF HEMATOLOGY, ONCOLOGY & CELL THERAPY
Chicago, Illinois

Rush University Medical Center (RUMC) is seeking an experienced BC/BE Hematology/ Oncology clinician to serve as Division Chief of Hematology, Oncology & Cell Therapy. We are seeking a clinician who is committed to providing quality patient care and patient satisfaction, and possesses familiarity and experience with accreditation procedures in cellular therapies. Successful candidates will demonstrate research achievement as a physician scientist; commitment to education; and creative leadership with a strong record of collaboration and commitment to academic excellence. As a Division leader, the Chief will provide an energetic and inventive vision for maintaining and growing a departmental clinical and educational program and develop strategic interdisciplinary research teams for furthering research and coordinate care at various affiliate/satellite sites.

Nominations or letters of interest that include a CV should be sent to Courtney_Kammer@rush.edu, Director Faculty Recruitment.

DIRECTOR, AMBULATORY ONCOLOGY
Deerfield Beach, Florida

The University of Miami's Director, Ambulatory Oncology will have extensive experience with multispecialty clinics; partner and collaborate with physicians on site operations; and be a strong financial leader. Essential responsibilities: accountable for a comprehensive and effective communication strategy that promotes a common understanding of the market, vision, strategy, and accountabilities; plan future growth by assessing existing and future program needs, establish priorities and identify fiscal and human resources for development; and define goals and objectives regarding growth, fiscal plan, patient care revenue and collections, staffing support requirements, and policies. Essential requirements: bachelor's degree in business administration, finance, or accounting; 5 years of leadership experience in a large complex healthcare organization; experience developing revenues and optimizing revenue cycle in a clinical setting; and a solid understanding of the financial dynamics of a clinic site.

Apply online at: careers.med.miami.edu
Job Number: P100007886.

EXECUTIVE DIRECTOR, ONCOLOGY SERVICES
Lexington, Kentucky

Baptist Health Lexington's Executive Director for Oncology Services leads and supervises overall cancer program operations. The Director is responsible for the provision of high quality clinical services within the oncology service line. The position includes responsibility for outpatient medical and radiation oncology, as well as patient support services, including, patient navigation, genetics, multidisciplinary clinics, clinical cancer education and support services, cancer data management, performance improvement, program accreditations, and community outreach. The position has accountability for the clinical care delivery, financial performance, quality monitoring, and improvement, compliance, accreditation, and advancing the mission of Baptist Health Lexington. Qualified candidates must have a Master's degree in nursing or relevant clinical field, a minimum of 3 years oncology experience, and 3 years of management experience; certification will be required within one year from date of hire.

Apply online at: BaptistHealthLexington.com or email resume to: mmerrick@bhsi.com.

ADVERTISER'S INDEX

Rewriting the Future for Pancreatic Cancer Patients

BY ANITRA ENGEBRETSON AND NICOLE LISE FEINGOLD, MA

November is National Pancreatic Cancer Awareness Month, so it's a perfect time to shine a much-needed spotlight on the fourth-leading cause of cancer death in the U.S., and to tell you about the Pancreatic Cancer Action Network (pancan.org).

The Pancreatic Cancer Action Network is the organization rewriting the book on how to fight a deadly disease. In the 16 years since our founding, we've focused on attacking pancreatic cancer on all fronts. Early on, we put into place a strategy that includes funding private research, advocating for increased federal research funding, providing support to patients, and raising awareness in communities nationwide through the voices and activities of thousands of passionate volunteers who have joined the fight.

Using this comprehensive approach—and bolstered by our dedicated supporters, who are just as determined as we are to advance progress against the disease—we've fueled a national pancreatic cancer movement. In fact, our rallying cry, "Wage Hope," speaks to the need to take unprecedented action: to change the statistics and rewrite the future for pancreatic cancer patients. That's because despite the progress being made, the five-year survival rate for pancreatic cancer remains in the single digits at just seven percent. Although survival has increased since our efforts started (it was 5 percent in 1999), a recent study we conducted showed that pancreatic cancer will surpass colon and breast cancer to become the second leading cause of cancer-related death in the U.S. by 2020.

But we are working to change these dire statistics. Our goal: to double pancreatic cancer survival by 2020. It's an ambitious goal, and it won't be easy to achieve, but patients deserve nothing less.

Patient Central

One of our proudest achievements is becoming a trusted and important resource for pancreatic cancer patients. We encourage anyone diagnosed with pancreatic cancer to contact Patient Central, our one-to-one service that connects patients—and their caregivers—to valuable information about the disease, clinical trials, treatment options, and support resources. Our highly trained and compassionate Patient Central Associates are available without cost by phone or email, and they provide free information, resources, and hope to approximately 11,000 people each year. We feel honored to provide this service so that patients and their families can make informed decisions about their treatment and care.

The level of personalized patient support that we provide allows us to represent the patient's voice through all of our programs, and it also gives us the opportunity to implement innovative and cutting-edge initiatives. Armed with the patient's voice, we are able to drive change from the bottom-up, rather than from the top-down. We believe that is our greatest strength, and it enables us to have the most lasting impact on changing the course of history for this disease.

This month, we will serve our 100,000th individual since the program started in 2002. But to meet our goal of doubling survival by 2020, we need more patients and caregivers to contact Patient Central. We are extremely grateful for the healthcare professionals who help us reach them.

A Gateway to Progress in Research

As of 2011, an average of only 4.5 percent of pancreatic cancer patients nationwide were enrolling in clinical trials. This low enrollment rate slows progress toward new diagnostic tools and treatments. To that end, we encourage all patients to consider clinical trials as a treatment option. In fact, one of the most important aspects of Patient Central is our ability to help patients access relevant, current clinical trial information through our new online Clinical Trial Finder: clinicaltrials.pancan.org. This free tool provides patients, caregivers, and healthcare professionals around-the-clock access to the most comprehensive and up-to-date database of pancreatic cancer clinical trials in the U.S. As we sat down to write this column, approximately 155 pancreatic cancer clinical trials were underway, and it would be very difficult for any oncologist to know about all of them. Our resources allow patients and healthcare professionals access to all possible options.

Clinical trial consideration isn't only important for each patient—it's critical for the pursuit of knowledge that can lead to new research advances. A clinical trial may be a patient's best option and researchers need patients to participate in trials in order to learn about new possible drugs for patients in the future.

Of the patients who connect with our Patient Central Associates to find a clinical trial, 14 percent enroll in a clinical trial—almost three times the national average. This is accelerating research. But we want to do more.

Powerful Knowledge. Personalized Treatment.

The need to expedite progress, and also ensure that patients quickly find the right treatment for them, is the reason we created Know Your Tumor℠ (pancan.org/section-facing-pancreatic-cancer/know-your-tumor), our personalized medicine service. Know Your Tumor was designed to help double pancreatic cancer survival by increasing the number of patients enrolling in clinical trials by building on the success of our Patient Central program and empowering them with information that assists with treatment decisions.

By participating in Know Your Tumor, patients and their healthcare professionals receive coordinated assistance with facilitating tissue collection and molecular testing. At the end of the process, patients and their physicians receive an expertly-reviewed report that contains the molecular test results and a list of potentially relevant treatment options.

While there is no guarantee that the biomarkers identified in the testing process will be actionable for guiding treatment, this process can give healthcare professionals potentially helpful information about their patients. Currently, nearly 50 percent of reports have revealed an actionable finding, meaning the information gained has the potential to impact treatment choices by identifying options that may have value in treating the patient's specific tumor.

The Pancreatic Cancer Action Network has a goal to double pancreatic cancer survival by 2020.

This information may be extremely valuable to a patient as they choose a treatment to pursue and enroll in a clinical trial identified for their situation. Additionally, the fields of precision medicine and targeted therapy are growing, and Know Your Tumor will contribute vital information as it relates to better understanding their potential importance in pancreatic cancer.

These are just a few of the exemplary services we provide to pancreatic cancer patients and families. To learn more about Patient Central, Clinical Trial Finder, Know Your Tumor, and other services, please contact us at patientcentral@pancan.org. We are waiting to speak with you!

Rewriting the Story of Pancreatic Cancer

It's a revolutionary time for the pancreatic cancer scientific community, with great expectations for significant progress in treating this daunting disease. We are proud of our progress against this disease so far. We also are keenly aware that it would not have been possible without the power of our passionate and relentless supporters.

The Pancreatic Cancer Action Network is the organization rewriting the book on how to fight a deadly disease. We invite you to join us in writing the next chapter in the fight—not only for today, but for future generations. Together, we will end pancreatic cancer as we know it. OI

Anitra Engebretson is director of Clinical Initiatives and Nicole Lise Feingold, MA, is director of Patient Services for the Pancreatic Cancer Action Network. For more information about the Pancreatic Cancer Action Network or to join our movement to Wage Hope, visit pancan.org or call 877.272.6226. Because when we Wage Hope together, we make progress.

IRESSA® (gefitinib) tablets for oral use

Brief Summary of Prescribing Information.
For complete prescribing information consult official package insert

INDICATIONS AND USAGE

IRESSA is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test *[see Clinical Studies (14) in the full Prescribing Information]*.

Limitation of Use: Safety and efficacy of IRESSA have not been established in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations *[see Clinical Studies (14) in the full Prescribing Information]*.

DOSAGE AND ADMINISTRATION

Patient Selection

Select patients for the first-line treatment of metastatic NSCLC with IRESSA based on the presence of EGFR exon 19 deletion or exon 21 (L858R) substitution mutations in their tumor *[see Indications and Usage (1)* and *Clinical Studies (14) in the full Prescribing Information]*. Information on FDA-approved tests for the detection of EGFR mutations in NSCLC is available at: http://www.fda.gov/CompanionDiagnostics.

Recommended Dose

The recommended dose of IRESSA is 250 mg orally once daily with or without food until disease progression or unacceptable toxicity.

Do not take a missed dose within 12 hours of the next dose.

Administration to Patients Who Have Difficulty Swallowing Solids

Immerse IRESSA tablets in 4 to 8 ounces of water by dropping the tablet in water, and stir for approximately 15 minutes. Immediately drink the liquid or administer through a naso-gastric tube. Rinse the container with 4 to 8 ounces of water and immediately drink or administer through the naso-gastric tube.

Dose Modification

Dose Modifications for Adverse Drug Reactions

Withhold IRESSA (for up to 14 days) for any of the following:

- Acute onset or worsening of pulmonary symptoms (dyspnea, cough, fever) *[see Warnings and Precautions (5.1) in the full Prescribing Information]*
- NCI CTCAE Grade 2 or higher in ALT and/or AST elevations [*see Warnings and Precautions (5.2) in the full Prescribing Information*]
- NCI CTCAE Grade 3 or higher diarrhea *[see Warnings and Precautions (5.4) in the full Prescribing Information]*
- Signs and symptoms of severe or worsening ocular disorders including keratitis *[see Warnings and Precautions (5.5) in the full Prescribing Information]*
- NCI CTCAE Grade 3 or higher skin reactions *[see Warnings and Precautions (5.6) in the full Prescribing Information]*

Resume treatment with IRESSA when the adverse reaction fully resolves or improves to NCI CTCAE Grade 1.

Permanently discontinue IRESSA for:

- Confirmed interstitial lung disease (ILD) *[see Warnings and Precautions (5.1) in the full Prescribing Information]*
- Severe hepatic impairment *[see Warnings and Precautions (5.2) in the full Prescribing Information]*
- Gastrointestinal perforation *[see Warnings and Precautions (5.3) in the full Prescribing Information]*
- Persistent ulcerative keratitis *[see Warnings and Precautions (5.5) in the full Prescribing Information]*

Dose Modifications for Drug Interactions

Strong CYP3A4 Inducers

Increase IRESSA to 500 mg daily in the absence of severe adverse drug reaction, and resume IRESSA at 250 mg seven days after discontinuation of the strong CYP3A4 inducer *[see Drug Interactions (7)* and *Clinical Pharmacology (12.3) in the full Prescribing Information]*.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Interstitial Lung Disease (ILD)

ILD or ILD-like adverse drug reactions (e.g., lung infiltration, pneumonitis, acute respiratory distress syndrome, or pulmonary fibrosis) occurred in 1.3% of the 2462 patients who received IRESSA across clinical trials; of these, 0.7% were Grade 3 or higher and 3 cases were fatal.

Withhold IRESSA and promptly investigate for ILD in any patient who presents with worsening of respiratory symptoms such as dyspnea, cough and fever. Permanently discontinue IRESSA if ILD is confirmed [*see Dosage and Administration (2.4) and Adverse Reactions (6.1) in the full Prescribing Information*].

Hepatotoxicity

In patients who received IRESSA across clinical trials, 11.4% of patients had increased alanine aminotransferase (ALT), 7.9% of patients had increased aspartate aminotransferase (AST), and 2.7% of patients had increased bilirubin. Grade 3 or higher liver test abnormalities occurred in 5.1% (ALT), 3.0% (AST), and 0.7% (bilirubin) of patients. The incidence of fatal hepatotoxicity was 0.04%.

Obtain periodic liver function testing. Withhold IRESSA in patients with worsening liver function and discontinue in patients with severe hepatic impairment *[see Dosage and Administration (2.4), Adverse Reactions (6.1),* and *Use in Specific Populations (8.7) in the full Prescribing Information]*.

Gastrointestinal Perforation

Gastrointestinal perforation occurred in three (0.1%) of the 2462 IRESSA-treated patients across clinical trials [*see Adverse Reactions (6.1) in the full Prescribing Information*]. Permanently discontinue IRESSA in patients who develop gastrointestinal perforation [*see Dosage and Administration (2.4) in the full Prescribing Information*].

Severe or Persistent Diarrhea

Grade 3 or 4 diarrhea occurred in 3% of 2462 IRESSA-treated patients across clinical trials. Withhold IRESSA for severe or persistent (up to 14 days) diarrhea *[see Dosage and Administration (2.4)* and *Adverse Reactions (6.1) in the full Prescribing Information]*.

Ocular Disorders including Keratitis

Ocular disorders [keratitis (0.1%), corneal erosion and aberrant eyelash growth (0.2%), conjunctivitis, blephritis and dry eye (6.7%)] occurred in the 2462 IRESSA-treated patients across clinical trials. The incidence of Grade 3 ocular disorders was 0.1% [*see Adverse Reactions (6.1) in the full Prescribing Information*]. Interrupt or discontinue IRESSA for severe, or worsening ocular disorders [*see Dosage and Administration (2.4) in the full Prescribing Information*].

Bullous and Exfoliative Skin Disorders

Bullous conditions including toxic epidermal necrolysis, Stevens Johnson syndrome and erythema multiforme have been reported from treatment with IRESSA. Erythema multiforme and dermatitis bullous have been reported in two patients (0.08%) across NSCLC trials (Study 2, Study 3 and Study 4). IRESSA treatment should be interrupted or discontinued if the patient develops severe bullous, blistering or exfoliating conditions.

Embryo-fetal Toxicity

Based on its mechanism of action and data from animal reproduction studies IRESSA can cause fetal harm when administered to a pregnant woman. In animal reproductive studies, oral administration of gefitinib from organogenesis through weaning resulted in fetotoxicity and neonatal death at doses below the recommended human dose. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with IRESSA and for at least two weeks following completion of therapy [*see Use in Specific Populations (8.1, 8.3) in the full Prescribing Information*].

ADVERSE REACTIONS

The following adverse drug reactions are discussed in more detail in other sections of the labeling:

- Interstitial Lung Disease *[see Warnings and Precautions (5.1) in the full Prescribing Information]*
- Hepatotoxicity *[see Warnings and Precautions (5.2) in the full Prescribing Information]*
- Gastrointestinal Perforation *[see Warnings and Precautions (5.3) in the full Prescribing Information]*
- Severe or Persistent Diarrhea *[see Warnings and Precautions (5.4) in the full Prescribing Information]*
- Ocular Disorders including Keratitis *[see Warnings and Precautions (5.5) in the full Prescribing Information]*
- Bullous and Exfoliative Skin Disorders *[see Warning and Precautions (5.6) in the full Prescribing Information]*

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 practice.

The safety of IRESSA is based on the data from 2462 patients with NSCLC who received IRESSA 250 mg daily monotherapy in three randomized clinical studies (Study 2, Study 3 and Study 4). Patients with a history of interstitial lung disease, drug-induced interstitial disease, radiation pneumonitis that required steroid treatment or any evidence of clinically active interstitial lung disease were excluded from these studies.

Controlled Studies:

Study 2 was a randomized, multicenter, open-label trial in which 1217 patients were randomized to receive first-line treatment for metastatic NSCLC; 607 patients received IRESSA 250 mg daily and 589 patients received carboplatin/paclitaxel. The median duration of treatment with IRESSA was 5.9 months. The study population characteristics were: median age 57 years, age less than 65 years (73%), female (79%), Asian (100%), NSCLC adenocarcinoma histology (100%), never smoker (94%), light ex-smoker (6%), ECOG PS 0 or 1 (90%).

Study 3 was a randomized, multicenter, double-blind, placebo-controlled trial in which 1692 patients were randomized to receive second- or third-line treatment for metastatic NSCLC; of which 1126 patients received IRESSA 250 mg daily and 562 patients received placebo. The median duration of treatment with IRESSA was 2.9 months. The study population characteristics were: median age 62 years, age less than 65 years (60%), female (33%), Caucasian (75%), Asian (21%), NSCLC adenocarcinoma histology (48%), never smoker (22%), ECOG PS 0 or 1 (65%), PS 2 (29%), PS 3 (5%) and two or more prior therapies (51%).

Study 4 was a randomized, multicenter, open-label trial in which 1466 patients were randomized to receive second-line treatment for metastatic NSCLC; 729 patients received IRESSA 250 mg daily and 715 patients received docetaxel. The median duration of treatment with IRESSA was 2.4 months. The study population characteristics were: median age 61 years, age less than 65 years (61%), female (36%), Caucasian (79%), Asian (21%), NSCLC adenocarcinoma histology (54%), never smoker (20%), ECOG PS 0 or 1 (88%) and two or more prior therapies (16%).

The pooled safety database from the three randomized trials was used to evaluate for serious and uncommon adverse drug reactions. Common adverse reactions were evaluated in Study 3. The most frequent adverse reactions in Study 3 (incidence of >20% and greater than placebo) reported in IRESSA-treated patients were skin reactions (47%) and diarrhea (29%). The most frequent fatal adverse reactions in IRESSA-treated patients were respiratory failure (0.9%), pneumonia (0.8%), and pulmonary embolism (0.5%).

Approximately 5% of IRESSA-treated patients and 2.3% of placebo-treated patients discontinued treatment due to an adverse event. The most frequent adverse reactions that led to discontinuation in patients treated with IRESSA were nausea (0.5%), vomiting (0.5%) and diarrhea (0.4%).

Table 1 – Selected Adverse Drug Reactions Occurring with an Incidence Rate ≥5% and an Increase of >2% of IRESSA-treated Patients in Study 3

	Percentage (%) of patients			
	IRESSA (N=1126)		Placebo (N=562)	
Adverse Reaction	**All Grades**	**Grade 3 and 4**	**All Grades**	**Grade 3 and 4**
Skin and subcutaneous tissue disorders				
Skin reactions[1]	47%	2%	17%	0.4%
Nail disorders[2]	5%	0.1%	0.7%	0%
Gastrointestinal disorders				
Diarrhea[3]	29%	3%	10%	1%
Vomiting	14%	1.2%	10%	0.4%
Stomatitis[4]	7%	0.3%	4%	0.2%
Metabolism and nutrition disorders				
Decreased appetite	17%	2.3%	14%	2.0%

Table 1 – Selected Adverse Drug Reactions Occurring with an Incidence Rate ≥5% and an Increase of >2% of IRESSA-treated Patients in Study 3 (cont'd.)

	Percentage (%) of patients			
	IRESSA (N=1126)		Placebo (N=562)	
Adverse Reaction	**All Grades**	**Grade 3 and 4**	**All Grades**	**Grade 3 and 4**
Eye disorders				
Conjunctivitis/blepharitis/dry eye[5]	6%	0%	3.2%	0%

[1] Includes Acne, Acne pustular, Dermatitis, Dermatitis acneiform, Dermatitis exfoliative, Drug eruption, Dry skin, Erythema, Exfoliative rash, Folliculitis, Pruritus, Pruritus generalized, Rash, Rash erythematous, Rash generalized, Rash macular, Rash maculo-papular, Rash papular, Rash pruritic, Rash pustular, Rash vesicular, Skin exfoliation, Skin toxicity, Xeroderma
[2] Includes Ingrowing nail, Nail bed infection, Nail disorder, Nail infection, Onychoclasis, Onycholysis, Paronychia
[3] Includes Diarrhea, Feces soft, Frequent bowel movements
[4] Includes Aphthous stomatitis, Cheilitis, Glossodynia, Mouth ulceration, Mucosal inflammation, Oral mucosal blistering, Stomatitis, Tongue disorder, Tongue ulceration
[5] Includes Blepharitis, Conjunctival hyperemia, Conjunctivitis, Dry eye, Eye irritation, Eye pruritus, Eye swelling, Eyelid irritation, Eyelid edema, Eyelids pruritus

Table 2 – Treatment Emergent Laboratory Abnormalities Occurring More Frequently in IRESSA-Treated Patients in Study 3

	IRESSA		Placebo	
Adverse Reaction	**All Grades %**	**Grade 3 and 4 %**	**All Grades %**	**Grade 3 and 4 %**
Alanine aminotransferase increased[1]	38%[2]	2.4%	23%[2]	1.4%[4]
Aspartate aminotransferase increased[1]	40%[3]	2.0%	25%[3]	1.3%[5]
Proteinuria	35%	4.7%	31%	3.3%

[1] Patients were allowed to enter the clinical study with lab values of ALT or AST CTCAE grade 1 or 2
[2] 14% gefitinib patients and 10% placebo patients were CTC grade 1 or 2 ALT at baseline
[3] 15% gefitinib patients and 12% placebo patients were CTC grade 1 or 2 AST at baseline
[4] 0.2% of placebo patients were CTC grade 3 at baseline
[5] 0.4% of placebo patients were CTC grade 3 at baseline

The following adverse reactions have been reported with IRESSA across NSCLC trials (Study 2, Study 3 and Study 4) and are not listed elsewhere in Section 6: nausea (18%), asthenia (17%), pyrexia (9%), alopecia (4.7%), hemorrhage (including epistaxis and hematuria) (4.3%), dry mouth (2%), dehydration (1.8%), allergic reactions including angioedema and urticaria (1.1%), elevations in blood creatinine (1.5%), and pancreatitis (0.1%).

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of IRESSA. 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 drug exposure.

Renal and urinary disorders: cystitis, hemorrhagic cystitis

Skin and subcutaneous tissue disorders: cutaneous vasculitis

DRUG INTERACTIONS

Drugs Affecting Gefitinib Exposure

CYP3A4 Inducer

Drugs that are strong inducers of CYP3A4 increase the metabolism of gefitinib and decrease gefitinib plasma concentrations. Increase IRESSA to 500 mg daily in patients receiving a strong CYP3A4 inducer (e.g., rifampicin, phenytoin, or tricyclic antidepressant) and resume IRESSA at 250 mg 7 days after discontinuation of the strong inducer [*see Dosage and Administration (2.4)* and *Clinical Pharmacology (12.3) in the full Prescribing Information*].

CYP3A4 Inhibitor

Drugs that are strong inhibitors of CYP3A4 (e.g., ketoconazole and itraconazole) decrease gefitinib metabolism and increase gefitinib plasma concentrations. Monitor adverse reactions when administering strong CYP3A4 inhibitors with IRESSA.

Drugs Affecting Gastric pH

Drugs that elevate gastric pH (e.g., proton pump inhibitors, histamine H_2-receptor antagonists, and antacids) may reduce plasma concentrations of gefitinib. Avoid concomitant use of IRESSA with proton pump inhibitors, if possible. If treatment with a proton-pump inhibitor is required, take IRESSA 12 hours after the last dose or 12 hours before the next dose of the proton-pump inhibitor. Take IRESSA 6 hours after or 6 hours before an H_2-receptor antagonist or an antacid [*see Clinical Pharmacology (12.3) in the full Prescribing Information*].

Hemorrhage in Patients taking Warfarin

International Normalized Ratio (INR) elevations and/or hemorrhage have been reported in some patients taking warfarin while on IRESSA therapy. Patients taking warfarin should be monitored regularly for changes in prothrombin time or INR.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on its mechanism of action and animal data, IRESSA can cause fetal harm when administered to a pregnant woman. In animal reproductive studies, oral administration of gefitinib from organogenesis through weaning resulted in fetotoxicity and neonatal death at doses below the recommended human dose (*see Animal Data*). Advise pregnant women of the potential hazard to a fetus or potential risk for loss of the pregnancy.

The background risk of major birth defects and miscarriage for the indicated population is unknown; however, the background risk in the U.S. general population of major birth defects is 2-4% and miscarriage is 15-20% of clinically recognized pregnancies.

Data

Animal Data

A single dose study in rats showed that gefitinib crosses the placenta after an oral dose of 5 mg/kg (30 mg/m^2, about 0.2 times the recommended human dose on a mg/m^2 basis). When pregnant rats were treated with 5 mg/kg from the beginning of organogenesis to the end of weaning there was a reduction in the number of offspring born alive. This effect was more severe at 20 mg/kg (approximate the human clinical dose on a mg/m^2 basis) and was accompanied by high neonatal mortality soon after parturition. In rabbits, a dose of 20 mg/kg/day (240 mg/m^2, about twice the recommended dose in humans on a mg/m^2 basis) caused reduced fetal weight.

Lactation

Risk Summary

It is not known whether IRESSA is excreted in human milk. Animal studies indicate the gefitinib and its metabolites are present in rat milk at a concentration higher than those in maternal plasma. Because of the potential for serious adverse reactions in nursing infants from IRESSA, advise women to discontinue breast-feeding during treatment with IRESSA.

Data

Animal Data

Levels of gefitinib and its metabolites were 11-to-19-fold higher in milk than in blood, after oral exposure of lactating rats to a dose of 5 mg/kg.

Females and Males of Reproductive Potential

Contraception

Based on its mechanism of action and animal data, IRESSA can cause fetal harm when administered to a pregnant woman [*see Use in Specific Populations (8.1) in the full Prescribing Information*]. Advise females of reproductive potential to use effective contraception during treatment with IRESSA and for at least two weeks following completion of therapy.

Infertility

IRESSA may result in reduced fertility in females of reproductive potential [*see Nonclinical Toxicology (13.1) in the full Prescribing Information*].

Pediatric Use

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

Geriatric Use

Of the 823 patients enrolled in two randomized, active-controlled clinical trials 374 patients (45%) were 65 years and older, and 93 patients (11%) were 75 years and older. No overall differences in safety were observed between patients 65 years and older and those younger than 65 years. There is insufficient information to assess for differences in efficacy between older and younger patients.

Renal Impairment

Less than four percent (<4%) of gefitinib and its metabolites are excreted via the kidney. No clinical studies were conducted with IRESSA in patients with severe renal impairment.

Hepatic Impairment

The systemic exposure of gefitinib was compared in patients with mild, moderate, or severe hepatic impairment due to cirrhosis (according to Child-Pugh classification) and healthy subjects with normal hepatic function (N=10/group). The mean systemic exposure ($AUC_{0-\infty}$) was increased by 40% in patients with mild impairment, 263% in patients with moderate impairment, and 166% in patients with severe hepatic impairment. Monitor adverse reactions when IRESSA is administered to patients with moderate and severe hepatic impairment.

In a study comparing 13 patients with liver metastases and moderate hepatic impairment (addition of CTC grade of baseline AST/SGOT, ALP, and bilirubin equals 3 to 5) to 14 patients with liver metastases and normal hepatic function, the systemic exposure of gefitinib was similar [*see Warnings and Precautions (5.2) in the full Prescribing Information*].

OVERDOSAGE

Twenty three patients were treated weekly with doses from 1500 mg to 3500 mg, and IRESSA exposure did not increase with increasing dose. Adverse events were mostly mild to moderate in severity, and were consistent with the known safety profile of IRESSA. In the event of suspected overdose, interrupt IRESSA, institute supportive care, and observe until clinical stabilization. There are no specific measures/treatments that should be taken following IRESSA overdosing.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labelling (Patient Information).

Interstitial Lung Disease: Advise patients to immediately contact their healthcare provider for new onset or worsening of pulmonary symptoms such as dyspnea, cough and fever [*see Warnings and Precautions (5.1) in the full Prescribing Information*].

Hepatotoxicity: Inform patients that they will need to undergo lab tests to monitor for liver function. Advise patients to contact their healthcare provider to report any new symptoms indicating hepatic toxicity [*see Warnings and Precautions (5.2) in the full Prescribing Information*].

Gastrointestinal Perforation: Advise patients that IRESSA can increase the risk of gastrointestinal perforation and to seek immediate medical attention for severe abdominal pain [*see Warnings and Precautions (5.3) in the full Prescribing Information*].

Severe or Persistent Diarrhea: Advise patients to contact their healthcare provider for severe or persistent diarrhea [*see Warnings and Precautions (5.4) in the full Prescribing Information*].

Ocular Disorders including Keratitis: Advise patients promptly to contact their healthcare provider if they develop eye symptoms, lacrimation, light sensitivity, blurred vision, eye pain, red eye or changes in vision *[see Warnings and Precautions (5.5) in the full Prescribing Information].*

Bullous and Exfoliative Skin Disorders: Advise patients that IRESSA can increase the risk of bullous and exfoliative skin disorders and to seek immediately medical attention for severe skin reactions [*see Warnings and Precautions (5.6) in the full Prescribing Information*].

Embryo-fetal Toxicity: Advise pregnant women of the potential risk to a fetus or potential risk for loss of the pregnancy [*see Warnings and Precautions (5.7) and Use in Specific Populations (8.1) in the full Prescribing Information*]. Advise females of reproductive potential to use effective contraception during treatment with IRESSA and for at least two weeks following completion of therapy [*see Use in Specific Populations (8.3) in the full Prescribing Information*].

Lactation: Advise women to discontinue breast-feeding during treatment with IRESSA [*see Use in Specific Populations (8.2) in the full Prescribing Information].*

Manufactured for:
AstraZeneca Pharmaceuticals LP Wilmington, DE 19850
By: AstraZeneca UK Limited Macclesfield, Cheshire, England Product of Belgium

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NOW APPROVED!

For the treatment of metastatic NSCLC

A TKI for first-line use in EGFR mutation–positive patients

whose tumors harbor exon 19 deletions or exon 21 (L858R) substitution mutations

IRESSA®
gefitinib

Indication

IRESSA is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

Limitation of Use: Safety and efficacy of IRESSA have not been established in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

Select Safety Information

- There are no contraindications for IRESSA
- Interstitial Lung Disease (ILD) or ILD-like reactions (eg, lung infiltration, pneumonitis, acute respiratory distress syndrome, or pulmonary fibrosis) occurred in 1.3% of 2462 IRESSA patients; of these, 0.7% were Grade ≥3 and 3 cases were fatal. Withhold IRESSA and promptly investigate for ILD in any patient who presents with worsening of respiratory symptoms such as dyspnea, cough and fever. Permanently discontinue IRESSA if ILD is confirmed
- In patients who received IRESSA, 11.4% of patients had increased alanine aminotransferase (ALT), 7.9% of patients had increased aspartate aminotransferase (AST), and 2.7% of patients had increased bilirubin. Grade ≥3 liver test abnormalities occurred in 5.1% ALT, 3.0% AST, and 0.7% bilirubin of patients. The incidence of fatal hepatotoxicity was 0.04%. Obtain periodic liver function testing. Withhold IRESSA in patients with worsening liver function and discontinue in patients with severe hepatic impairment
- Gastrointestinal perforation occurred in three (0.1%) of 2462 IRESSA patients. Permanently discontinue IRESSA in patients who develop gastrointestinal perforation
- Grade ≥ 3 diarrhea occurred in 3% of 2462 IRESSA patients. Withhold IRESSA for severe or persistent (up to 14 days) diarrhea
- The most commonly reported adverse drug reactions reported in more than 20% of patients and greater than placebo, were skin reactions (47%) and diarrhea (29%)

Please see Brief Summary of complete Prescribing Information on the next two pages.

Learn more about IRESSA at www.iressa-usa.com.

AstraZeneca