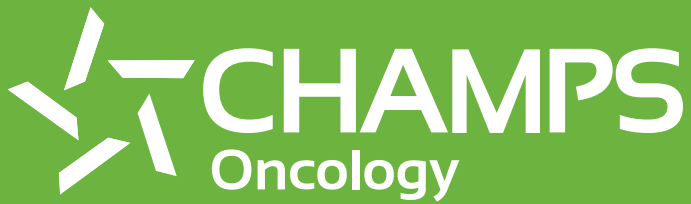# ONCOLOGY
ISSUES

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

March | April 2016

An Embedded Psycho-Oncology Program Improves Patient Care

ACCC
Association of Community Cancer Centers

contents

The Act of Action

BY CHRISTIAN DOWNS, JD, MHA

In any situation, the best thing you can do is the right thing; the next best thing you can do is the wrong thing; the worst thing you can do is nothing.

—Theodore Roosevelt

I've always found this Roosevelt quote stirring because it places the emphasis on action. Many of us went into healthcare, not only to help our fellow man, but because there is always some kind of action that needs to be carried out. As we put together this edition of *Oncology Issues*, I noticed an emerging theme: Build*ing*. Develop*ing*. Investigat*ing*. Explor*ing*. Simply put: Action. What distinguishes ACCC members is not only their commitment to action in the service of delivering quality cancer care, but their willingness to share their experiences with others.

For example, in "Building Bridges, Breaking Down Barriers," Elizabeth Archer-Nanda and colleagues describe how one ACCC member program in Louisville, Ky., developed the Norton Cancer Institute Behavioral Oncology Program, a comprehensive, embedded psychiatric program with an emphasis on integrating high-quality psychiatric care to medically complex patients. At the other end of the spectrum, Lori McNulty and former ACCC Board Member Faye Flemming demonstrate how another member program, Southside Regional Medical Center, Petersburg, Va., was able to add navigation services and distress screening with very limited resources. In their article, "Building a Navigation and Psychosocial Support Program from the Ground Up," they describe how their oncology nurse navigator partners with a local community agency to help meet higher than expected referrals and patient demand. More, they show how adding navigation services and distress screening has helped this small community program both improve patient care and meet multiple accreditation standards.

Our next "action article" centers on information technology (IT). With the understanding that data and information are power, co-authors Ryan Langdale and Alex Glonek share the keys to developing a successful, oncology-specific IT strategy in a continuously changing IT environment, including a process description, common pitfalls, and best practices.

"Investigating" is the action word that drives our next feature article. The oncology community is enjoying an almost unprecedented surge of technology and treatment breakthroughs. In "Investigating Radiodynamic Therapy to Treat the Untreatable" author Sarah Hall shares how Fox Chase Cancer Center, Philadelphia, Pa., is working to bring a new technology to the U.S.—a specialized accelerator known as a Racetrack Microtron. This technology delivers radiation at very high energies, offering treatment to a patient population with limited treatment options, including those who are only receiving palliative care. With Fox Chase currently pursing FDA approval to open clinical trials for this new technology, I look forward to seeing how it will be implemented in the community setting.

And finally, Tracy Wyant, an oncology clinical specialist in the Oncology Nursing Society Education Department, gives us a look into the policy world in her article, "Exploring the Issue of Cancer Drug Parity." She recaps what's been achieved to date in terms of efforts to ensure that patients have equal access to oral drugs—and at a cost that they can afford. As you know, this issue has been at the forefront of ACCC advocacy efforts for a number of years. Read about ACCC's successes and our continued efforts to effect change at the federal level in "Oral Parity: When Modern Medicine Outpaces Policy," page 11.

The final article in this issue, "Bike Loud," is a powerful and moving first-person account of inspiring action by a group of Boy Scouts who biked across the country to honor a young girl who lost her battle with germ cell cancer. The Hero of San Juan Hill would be proud of their efforts—and of *your* efforts on behalf of the patients and families you serve every day. OI

The Year in Review

BY STEVEN L. D'AMATO, BSPharm, BCOP

I have truly enjoyed my year as ACCC President and the opportunity to travel to different areas of the country and learn about the issues we all face. ACCC has had an exciting year, with the launch of a number of vital new programs, meetings, and resources for its membership.

As you know, my President's Theme this year has been the Oncology Medical Home and Integrated Healthcare Delivery. Exploring this theme, ACCC released a white paper on "Five Essential Actions to Achieve a Positive Impact on Patient Care in the Integrated Healthcare Environment." The paper reflected insights gleaned from the ACCC Institute for the Future of Oncology June 2015 forum. ACCC also addressed this theme during panel sessions at the ACCC 2015 National Oncology Conference and the ACCC 2016 Annual Meeting.

Immuno-oncology had a breakout year—not only in terms of new and expanded indications—but also with the launch of the Institute for Clinical Immuno-Oncology (ICLIO), an Institute of ACCC. Over the past months, the ICLIO website (accc-iclio.org) has continued to grow, providing tools, e-courses, and articles geared toward advancing immunotherapy in the community setting and working to ensure coverage and payment. The first Annual ICLIO Conference was held in October 2015, followed by the release of the first ICLIO white paper, *Advancing Immuno-Oncology in the Community Setting.* For those of you just starting your immuno-oncology journey, look to ICLIO to help you arrive prepared with its robust offerings of e-courses and e-newsletters.

Oncology pharmacy continues to be a focus of ACCC, including four regional Oncology Pharmacy Education Network (OPEN) meetings in 2015. Essential new resources for the oncology pharmacy were developed in recent months, including an online patient education tool, "What Cancer Patients Need to Know About Oral Medications," a white paper titled, *Dispensing Pharmacy: A Value Proposition for Oncology Practices,* and a well-attended member conference call on the 340B Drug Pricing Program.

Patient-centered care, a key tenet of healthcare reform, continues to be another area of focus for ACCC. This fall ACCC released white papers on *Psychosocial Distress Screening: Lessons Learned from Three ACCC Member Programs* and *The Transplant Treatment Path: Optimizing Patient-Centered Care for ASCT in Multiple Myeloma Patients.* Continuing to address issues related to the financial burden of cancer on patients, ACCC held five regional Financial Advocate Network (FAN) meetings. Members also benefited from two new tools: the metrics published in the FAN Benchmark Survey highlights infographic and the FAN patient assistance app (accc-FAN-app.org).

Molecular testing is an area of growing interest for diagnosis and treatment. ACCC provided real-world process improvement insights for its membership through a series of learning labs that informed a white paper, *Ongoing Advances & Improvements in Molecular Testing,* and three peer-to-peer learning webinars.

Reimbursement issues—always on everyone's radar screen—were front and center at six regional Oncology Reimbursement Meetings and during ACCC members-only conference calls on the proposed and final 2016 HOPPS and MPFS rules. Reimbursement is also an integral feature of one of the most popular ACCC tools, the *2016 Patient Assistance and Reimbursement Guide.*

And ACCC honored six member programs with 2015 Innovator Awards—recognizing creative initiatives as varied as a family program for parents with cancer and their children to the use of location technology to improve the patient experience.

I encourage all of you to stay involved and volunteer for positions within the organization that help with programming, membership, education, and advocacy. And I would be remiss if I did not acknowledge the staff at ACCC who have made my presidency a joy. They—like you—are family. Thank you for allowing me to serve as your 2015–2016 president. OI

more online @ accc-cancer.org

BLOG | **USP Chapter 800 — Readiness is All**
With Chapter 800, for the first time a USP standard addresses hazardous drug administration, bringing nurses—and not just pharmacists—under its purview. Healthcare facilities have a little more than two years to conform to these new requirements. Read more at: accc-cancer.org/ACCCbuzz/?p=3418.

SURVEY | **ACCC 2016 Trends in Cancer Program Survey**
ACCC's annual survey is now comprised of four separate survey instruments geared towards: cancer program administrators, oncology nurses, pharmacists, and medical directors/physician leaders. The cancer program administrator and oncology nurse surveys opened in March. Emails with links to each survey were sent to a targeted audience. If you didn't receive an email but would like to participate in one of these surveys, go to: accc-cancer.org/trends2016.

INFO | **Immunotherapy in Community Settings: There's No Referring It Away**
In this interview, Sigrun Hallmeyer, MD, an oncologist in private practice with Illinois-based Oncology Specialists, SC., and an early adopter of immunotherapy, talks about how she sees immunotherapy growing as the fourth pillar of oncology in community settings. accc-iclio.org/resources/immunotherapy-theres-no-referring-it-away.

APP | **ACCC-FAN-App.org**
Access patient assistance and reimbursement programs from your desktop, tablet, or mobile device. Find resources by drug name (brand or generic) or manufacturer. Plus, foundation and co-pay assistance programs. Access information from the ACCC *2016 Patient Assistance and Reimbursement Guide* and link directly to the ACCC Oncology Drug Database. accc-FAN-app.org.

nice work

6 Tips to Provide Effective Positive Acknowledgement to Staff

1. Look for positive staff behaviors and outcomes.
2. Make your acknowledgement genuine.
3. Make your acknowledgement specific.
4. Make your acknowledgement timely.
5. Give your acknowledgement in person.
6. Acknowledge often.

Source. Hambley C. *Keeping Medical Practice Staff Happy.* physicianspractice.com/staff/keeping-medical-practice-staff-happy?GUID=98EC2E34-74E0-44F8-9021-6474CB220676&rememberme=1&ts=09042015.

The High Costs of Claims Follow-Up

Industry estimates have pegged the average cost of following-up on late payments from insurance companies at about **$3** per claim. However, in a survey of healthcare financial professionals, **70%** of respondents said their organization's actual cost is **$4** per claim—**33%** higher. The difference is significant. U.S. healthcare providers submit an estimated **3.1 billion** claims annually, meaning claims follow-up could be costing providers **$3.1 billion** more than is commonly believed. Claim follow-up is traditionally done over the phone by back-office staff, who can review no more than three or four claims at a time, depending on payer rules.

Source. Recondo Technology's November 2015 online survey conducted during a Recondo-sponsored Healthcare Financial Management Association webinar. recondotech.com.

facts

March is National Kidney Month—5 Tips to Protect Your Kidneys!

1. Get Tested! Ask your doctor for an ACR urine test or a GFR blood test annually if you have diabetes, high blood pressure, are over age 60, or have a family history of kidney failure.

2. Reduce NSAIDs. Over-the-counter pain medicines, such as non-steroidal anti-inflammatory drugs, may alleviate aches and pains, but they can harm the kidneys. Reduce your regular use of NSAIDs and never go over the recommended dosage.

3. Cut the Processed Foods. Processed foods have been linked to cancer, heart disease, and kidney disease. Try adopting the DASH diet to guide your healthy eating habits.

4. Exercise Regularly. Regular exercise will keep your bones, muscles, blood vessels, heart, and kidneys healthy. Getting active for at least 30 minutes a day can also help you control blood pressure and lower blood sugar.

5. Stay Well Hydrated. Staying well hydrated helps your kidneys clear sodium, urea, and toxins from the body. Drinking plenty of water, and avoiding sugary beverages, is also one of the best ways to avoid painful kidney stones.

Source. National Kidney Foundation. kidney.org.

Survey Says: Many Healthcare Organizations Unprepared for Precision Medicine

Responses from Academic Programs

- **71%** said precision medicine **WILL** play a significant role in their organizations in the next **5** years.
- **64%** said they **PLAN** to integrate genomic data into their EHRs.

Responses from Non-Academic Programs

- **59%** percent of respondents said precision medicine **WILL NOT** play a significant role in their organizations in the next **5** years.
- **63%** of respondents said their organizations had **NO PLANS** to integrate genomic data into their EHRs.

Source. Health Catalyst nationwide survey of healthcare executives. healthcatalyst.com.

67% of people say age 50 is too late to begin mammograms; 73% of women believe breast cancer screenings should start earlier.

Source. A January 2016 HealthMine, Inc., survey of 501 consumers enrolled in a 2016 health plan. healthmine.com.

issues

Oral Parity: When Modern Medicine Outpaces Policy

BY LEAH RALPH

Oral oncolytics can offer a better quality of life for patients undergoing chemotherapy treatment, including less travel time, fewer work absences, often fewer side effects, and the convenience and comfort of at-home administration. For some cancer patients, an oral anti-cancer medication is the only option for treatment. Yet insurance coverage has not kept pace with medical innovation. Outdated insurance benefit designs continue to cover oral medications under the pharmacy benefit, which often mean high, burdensome out-of-pocket costs for patients. (Traditional IV chemotherapy is covered under a plan's medical benefit, resulting in minimal co-pays or no cost for patients.) This coverage disparity creates financial burdens for patients prescribed an oral anti-cancer medicine, leaving them less likely to adhere to treatment and often unable to fill their prescription. The number one reason a patient does not take his or her medication appropriately is cost. According to a 2011 study published in the *Journal of Oncology Practice* and the *American Journal of Managed Care*, 10 percent of cancer patients failed to fill their initial prescriptions for oral anti-cancer medications due to high out-of-pocket costs.

ACCC has been a longtime champion of oral parity, the legislative effort to equalize patient cost sharing for IV and oral chemotherapy drugs. We have mobilized members to state and federal legislatures, developed educational materials, coordinated fly-ins and letter campaigns, and walked the halls of Congress every year for a federal fix. In 2014 ACCC awarded an Oncology Grassroots Champion for Patient Access Award to four individuals for their advocacy efforts to pass oral parity legislation in their states.

We've come a long way—40 states plus the District of Columbia have passed oral parity legislation. These laws are not a mandate to cover oral chemotherapy, but rather require that if an insurance plan covers chemotherapy treatment, a patient's out-of-pocket costs must be the same, regardless of how the therapy is administered. As a member of the State Patients Equal Access Coalition (SPEAC), ACCC has partnered with several state oncology societies—including Virginia, West Virginia, and Arizona in recent years—to pass oral parity laws, and this year we're focusing our efforts on Tennessee and South Carolina. (If you are a provider in either of these states, and you'd like to be an advocate, email: lralph@accc-cancer.org.)

Even as these laws pass, our work is not done. ACCC has been working with coalition partners to create education materials for the clinical setting. These laws will have minimal impact if patients and providers are not aware of the coverage cancer patients are entitled to. We also continue to monitor states as they implement these laws; in some cases, an administrative or legislative fix may be needed. If you live in a state that has passed oral parity legislation and believe a health insurance company is not complying with the law, contact your state's Department of Insurance.

And even though a majority of states have now passed state-level oral parity legislation, federal legislation is still needed. A federal law would ensure that new cost-sharing restrictions are implemented consistently across the country, and that plans that fall outside state regulation, such as those covered under the federal ERISA law (usually large, multi-state health plans), must comply with the same equitable coverage requirements. In September, an ACCC member spoke at a Congressional briefing on the Cancer Drug Coverage Parity Act of 2015 (S.1566/H.R.2739), helping gain critical momentum to move the bill forward. At the ACCC Capitol Hill Day in March, we held nearly 100 meetings with Congressional offices about the importance of this bill to cancer patients and the providers who care for them.

We hope that you will join our efforts, and continue to monitor opportunities to weigh in with your state and federal legislators. For more on this issue, turn to page 58 to read our feature article, "Exploring the Issue of Cancer Drug Parity." ◼

Leah Ralph is ACCC director of Health Policy.

compliance

Coding & Billing Telehealth Services

BY CINDY PARMAN, CPC, CPC-H, RCC

The year is 2016, and we live in an age of technology. Instead of sending a letter and waiting for a written response (now called "snail mail"), we can email, text, tweet, snapchat, facebook, or otherwise immediately share information, pictures, opinions, activities, and our current location on earth. The world of medicine has been altered by the advent of electronic health records (EHRs), patient portals, and the transfer of data from one program to another. It is only natural that the next step in this process is the implementation of telehealth or telemedicine programs. According to the American Telemedicine Association:[1]

"Formally defined, telemedicine is the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status. Telemedicine includes a growing variety of applications and services using two-way video, email, smart phones, wireless tools, and other forms of telecommunication technology."

Patient consultations via videoconferencing, transmission of still images, and e-health, including patient portals, remote monitoring of vital signs, continuing medical education, consumer-focused wireless applications, and nursing call centers, among other applications, are all considered part of telemedicine and telehealth.

However, in order to be reimbursed for telehealth services, specific criteria must be met and unique procedure codes and modifiers must be appended to identify the services performed.

Medicare Coverage

On May 5, 2011, the Centers for Medicare & Medicaid Services (CMS) published a Final Rule (76 FR 25550) that was effective July 5, 2011, governing the agreements under which a hospital or Critical Access Hospital (CAH) may provide telemedicine services to its patients.[2] CMS defines "telemedicine" in this context to mean the provision of clinical services to patients by physicians and qualified practitioners from a distance via electronic communications.

According to CMS, Medicare Part B pays for a limited number of services furnished by a physician or qualified nonphysician healthcare practitioner to an eligible beneficiary via a telecommunications system.[3] The agency adds that when the telehealth service is eligible for payment, the telecommunications system substitutes for an in-person encounter.

There has been a long-standing hope that telehealth could be used to reduce rural patients' travel time to specialty physicians. Medicare covers telehealth services provided through live, interactive videoconferencing between a beneficiary located at a certified rural site and a distant practitioner. Medicare beneficiaries are eligible for telehealth services only if they are presented from an originating site located in:

- A Rural Health Professional Shortage Area (HPSA) located either outside a Metropolitan Statistical Area (MSA) or in a rural census tract; or
- A county outside of an MSA.

The Health Resources and Services Administration (HRSA) determines HPSAs, and the U.S. Census Bureau determines MSAs. A web-based tool, cms.gov/Medicare/Medicare-General-Information/Telehealth/, can help determine a potential originating site's eligibility for Medicare telehealth payment.

The term "originating site" means the location of the eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. Each calendar year, the geographic eligibility of an originating site is established based on the status of the area as of December 31 of the prior calendar year; the eligibility then continues for the full calendar year. The one exception is healthcare entities that participated in a federal telemedicine demonstration project approved by (or receiving funding from) the Secretary of the Department of Health and Human Services as of Dec. 31, 2000; these locations qualify as originating sites regardless of geographic location. The originating sites authorized by law are:

- The office of physicians or practitioners
- Hospitals
- Critical Access Hospitals
- Rural health clinics
- Federally qualified health centers
- Hospital-based or CAH-based renal dialysis centers (including satellites)
- Skilled nursing facilities (SNFs)
- Community mental health centers (CMHCs).

The term "distant site" means the site where the physician or practitioner providing the professional service is located at the time

CODE	DESCRIPTOR
Table 1. Sample Write-Off Report	
90791	Psychiatric diagnostic evaluation
90792	Psychiatric diagnostic evaluation with medical services
90832–90838	Psychotherapy with patient and/or family
90845	Psychoanalysis
90846, 90847	Family psychotherapy
90951, 90952, 90954, 90955, 90957, 90958, 90960, 90961	Monthly ESRD-related services
90963–90966	ESRD home dialysis services
96116	Neurobehavioral status exam, per hour
96150–96154	Health and behavior assessment and/or intervention
97802	Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes
97803	Medical nutrition therapy; reassessment and intervention, individual, face-to-face with the patient, each 15 minutes
97804	Medical nutrition therapy; group (2 or more individuals), each 30 minutes
99201–99205	Evaluation and management of new patient
99211–99215	Evaluation and management of established patient
99231–99233	Subsequent hospital care
99307–99310	Subsequent nursing facility care
99354–99357	Prolonged services
99495–99496	Transitional care management
G0108–G0109	Diabetes outpatient self-management training
G0270	Medical nutrition therapy, reassessment, and subsequent interventions following second referral in same year for change in diagnosis, medical condition, or treatment regimen, group (2 or more individuals), each 30 minutes
G0396, G0397	Alcohol and/or substance abuse structured assessment
G0406–G0408	Follow-up inpatient consultation, communicating with the patient via telehealth
G0420, G0421	Chronic kidney disease educational services
G0425–G0427	Telehealth consultation, emergency department or initial inpatient
G0436, G0437	Smoking and tobacco cessation counseling, asymptomatic patient
G0438, G0439	Personalized prevention plan of service
G0442	Annual alcohol misuse screening
G0443	Brief face-to-face behavioral counseling for alcohol misuse
G0444	Annual depression screening
G0445	Semiannual high-intensity behavioral counseling to prevent STIs
G0446	Annual intensive behavioral therapy for cardiovascular disease
G0447	Behavioral counseling for obesity
G0459	Inpatient telehealth pharmacologic management

the service is provided via the telecommunications system.[4] Practitioners at the distant site who may furnish and receive payment for covered telehealth services (subject to state law) include:

- Physicians
- Nurse practitioners (NPs)
- Physician assistants (PAs)
- Nurse midwives
- Clinical nurse specialists (CNSs)
- Certified registered nurse anesthetists (CRNAs)
- Clinical psychologists (CPs)
- Clinical social workers (CSWs)
- Registered dietitians (RDs) or other nutritional professionals.

Of note, CPs and CSWs cannot bill for psychiatric diagnostic interview examinations with medical services or medical evaluation and management services under a Medicare telehealth program (CPT codes **90792**, **90833**, **90836**, or **90838**). In addition, for End Stage Renal Disease (ESRD)-related services, a physician, NP, PA, or CNS must furnish at least one face-to-face "hands on" visit each month to examine the vascular access site.

As a condition of payment, the provider must use an interactive audio and video telecommunications system that permits real-time communication between the provider at the distant site and the beneficiary at the originating site. (Asynchronous "store and forward" technology is permitted only in federal telemedicine demonstration programs conducted in Alaska or Hawaii.)

Medicare Claims

Professional claims for telemedicine are submitted to Medicare in the same manner as claims for face-to-face services, with the appropriate modifier appended. Medicare then reimburses the fee schedule amount for the service performed, with the exception that physicians who have assigned their billing rights to a CAH will receive 80 percent of the fee schedule amount for telehealth services. In addition, CMS publishes additions or deletions to the services defined as covered for telehealth effective Jan. 1 each calendar year. For calendar year 2016, professional telehealth services are billed using one of the CPT® procedure codes included in Table 1, page 13, along with the following telehealth modifier:

- **GT:** Via interactive audio and video telecommunications systems.

By coding and billing a service with the GT modifier, the provider is certifying that the beneficiary was present at an eligible originating site while the billing provider furnished a telehealth service. For federal telemedicine demonstration programs conducted in Alaska or Hawaii, the modifier is:

- **GQ:** Via asynchronous telecommunication systems.

By reporting modifier **GQ**, the provider is certifying that the asynchronous medical file was collected and transmitted to the distant site from a federal telemedicine demonstration project conducted in Alaska or Hawaii.

Originating sites bill their Medicare contractor as well and are paid an originating site fee for telehealth services using the following HCPCS code:

- **Q3014:** Telehealth originating site facility fee.

If a hospital enters into an agreement for telemedicine services with a distant-site hospital or telemedicine entity, the agreement must be in writing. According to Appendix A of the State Operations Manual:[5]

"The hospital's governing body must grant privileges to each telemedicine physician or practitioner providing services at the hospital under an agreement with a distant-site hospital or telemedicine entity before they may provide telemedicine services. The scope of the privileges in the hospital must reflect the provision of the services via a telecommunications system. For example, a surgeon at a distant-site hospital may provide telemedicine consultation services at a hospital under agreement, but obviously would not be able to perform surgery by this means and must not have surgical privileges in the hospital as part of his/her telemedicine services privileges. If the surgeon also periodically performed surgery on-site at the hospital, then he or she would have to have privileges to do so, granted in the traditional manner provided for at §482.12(a)(1) through §482.12(a)(7) and §482.22(a)(1) and §482.22(a)(2)."

The Medicare & Medicaid Research Review 2013: Volume 3, Number 4, a publication of the CMS Office of Information Products and Data Analysis, includes the following comments regarding telehealth services:[6]

"Of the relatively few telehealth services provided to Medicare beneficiaries, the most common services are mental health services, including pharmacological management.

While telehealth can improve access for isolated rural beneficiaries, it has also been used to provide in-home care for urban individuals who could not travel for face-to-face care. For some of these patients who are in close proximity to a provider who can provide face-to-face visits, the additional costs associated with telehealth visits may not be justified."

Other Insurers

State laws surrounding telehealth or remote consultations are convoluted at best, with many states failing to weigh in on mandated third-party coverage. Some insurers that provide payment for telehealth services do so through partnerships with companies such as TelaDoc, RelayHealth, and MDLive in order to control expenses. As a result, providers may find it necessary to review state laws and regulations, as well as private payer policies relating to telehealth services.

Not Telehealth—Electronic Patient Encounters

Even if the facility or office does not meet the requirements for a telehealth program,

procedure codes exist for telephone and telephone/internet encounters. The following telephone services codes report care provided by a physician or nonphysician healthcare professional to an established patient, at the request of the patient:

- **99441:** Telephone assessment and management service provided by a physician or other qualified healthcare professional who may report evaluation and management services to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment: 5-10 minutes of medical discussion
- **99442:** 11-20 minutes of medical discussion
- **99443:** 21-30 minutes of medical discussion.

In addition to the codes listed above, the following set of procedure codes are reported for telephone assessments performed by healthcare professionals that do not separately bill insurance, such as social workers or dietitians:

- **98966:** Telephone assessment and management services provided by a qualified nonphysician healthcare professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion
- **98967:** 11-20 minutes of medical discussion
- **98968:** 21-30 minutes of medical discussion.

Medicare does not pay separately for these telephone assessment and management services and many non-governmental payers consider these services to be bundled into any face-to-face care provided.

In addition, there are a set of procedure codes for telephone/internet assessment and management services between the patient's treating physician and a physician with specialty expertise:

- **99446:** Interprofessional telephone/internet assessment and management service provided by a consultative physician, including verbal and written report to the patient's treating physician or other qualified healthcare professional: 5-10 minutes of medical consultative discussion and review
- **99447:** 11-20 minutes of medical consultative discussion and review
- **99448:** 21-30 minutes of medical consultative discussion and review
- **99449:** 31 minutes or more of medical consultative discussion and review.

As with the codes for telephone discussion, Medicare does not pay separately for these electronic consultative services. However, other payers may reimburse for these services. In addition, providers may also be able to use this information to negotiate alternative payment arrangements for services. These interprofessional services are typically provided in complex or urgent situations where a timely face-to-face service with the consultant may not be possible. When the sole purpose of the telephone/internet communication is to arrange a transfer of care or otherwise refer the patient, these codes are not reported.

The Future of Telehealth

An example of current telehealth activities is the Cleveland Clinic mobile stroke treatment unit (MSTU) that provides treatment faster than patients receive in the Emergency Department (ED).[7] MSTU is equipped with a mobile CT system and staffed by a registered nurse, paramedic, EMT, and CT technologist. In addition, a vascular neurologist is available to evaluate patients via telemedicine and a neuroradiologist immediately reviews images transmitted from the mobile CT. Time from the door to thrombolysis (breakdown of blood clot) was 32 minutes for the MTSU, as opposed to 58 minutes in the ED. If it is feasible to perform prehospital stroke evaluation and treatment using a telemedicine-enabled mobile unit, the only limit to telemedicine's use may be the availability of insurance payer reimbursement. **OI**

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

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spotlight

Hematology-Oncology Associates of the Treasure Coast
Port St. Lucie, Florida

For more than 30 years, Hematology-Oncology Associates of the Treasure Coast has provided medical oncology services to Port St. Lucie and surrounding counties in southern Florida. The physician group specializes in hematology and oncology, and includes three additional satellite locations to the Port St. Lucie office. The practice has 92 employees and 5 hematologist-oncologists across all locations.

"We are first and foremost a medical practice focused on patient health, safety, and quality of life. Our practice has been here for 30 plus years," said Christine Gerdes, RN, BSN, OCN, CCRP, research director for Hematology-Oncology Associates of the Treasure Coast.

Serving the Community

Practice physicians also participate in local cancer lectures to the community and serve on tumor boards at several of the area hospitals. Patients requiring radiation oncology services or any other service are referred to local hospitals or other specialty groups. These referrals are usually based on where the patient lives.

"When patients are diagnosed with cancer, they are devastated emotionally and financially making it difficult to travel even to surrounding counties for treatment. Therefore we try to refer to the closest facility in proximity to their home. Some centers offer transportation services to assist patients with traveling to their appointments," said Gerdes.

The practice offers a "one-stop-shop" for its medical oncology patients. On-site services include:

- Infusion Suites (available at all four offices with recliners and TV access)
- Laboratory
- Imaging (PET/CT)
- Financial counseling
- Oral dispensing for medications
- Research program with clinical trials.

The convenience of an in-house oral dispensary is greatly appreciated by patients. "Our patients are able to get a lot of their oral medications right here while they're in the office. They like the benefit of not having to make an additional stop to take their script down to the local pharmacy to wait," said Gerdes.

Financial Counseling

"Patients tell me about the different obstacles they endure when they're first learning that they have cancer and a big question is usually: 'What do I do next?'" said Gerdes.

The financial burden of cancer can take a toll on many patients. To help patients through the insurance process and possibly locate foundations for assistance, Hematology-Oncology Associates of the Treasure Coast employs full-time financial counselors in each office and one patient assistance coordinator.

These staff members take on the task of navigating the complex world of insurance and financial assistance—something that is often daunting to newly-diagnosed cancer patients. Financial counselors will reach out to pharmaceutical companies to find out whether they offer co-pay assistance or other financial programs and guide patients through the application process. Financial counselors can also help uninsured patients select insurance plans or enroll in Medicaid or other assistance programs.

Department of Clinical Research

Hematology-Oncology Associates of the Treasure Coast began conducting clinical cancer research in the late 1990s. The clinical research program evolved from a pre-existing outpatient stem cell transplant program with an outside company.

"I came here as a stem cell transplant nurse, and we performed stem cell transplants on an outpatient basis. Unfortunately the outcome of the stem cell transplant results limited the types of cancers that could be treated therefore the unit was disbanded. But before the transplant unit was dissolved, we had already started participating in standard dose studies in our practice so we closed the transplant unit on Friday and continued with our own research division on Monday," said Gerdes.

The Department of Clinical Research, which started in 2001 with three studies, has since expanded to more than 25 ongoing studies, including Phase I trials. Practice physicians alternate the role of principal investigators (PIs), taking on the responsibility of reporting to the FDA, the trial sponsor, or the Institutional Review Board (IRB). Practice physicians also participate as sub-investigators on all other studies.

Department staff includes three dedicated research nurses, three clinical RNs to perform all in-office drug administration, four study coordinators, three

Hematology-Oncology Associates of the Treasure Coast Office Locations

FORT PIERCE

PORT ST. LUCIE

STUART

dedicated medical assistants, and a financial administrator.

Physicians are the first line of contact for recruiting patients to clinical trials. The Department of Clinical Research holds weekly meetings with practice physicians and staff regarding enrolling trials to discuss potential patients, and specific inclusion and exclusion criteria for these studies. This keeps research at the forefront of providers' minds when seeing newly-diagnosed patients.

If a trial is available and the patient agrees, the physician submits the patient's name to the research department to perform a medical history evaluation and chart review. Patients then meet with their physician and Gerdes to go through the consenting process and ensure the patients understand their rights and what trial participation will entail.

Offering clinical trials on-site eases the travel burden for the practice's patients and provides access to new, innovative treatments for patients. "The doctors have put a lot of time and effort in to making sure their patients have this opportunity locally, since many cannot afford to travel far or leave their support system for treatment. Our site is located only 10 to 12 miles from each of our satellite offices," said Gerdes.

Gerdes has also noticed the significant impact clinical trial offerings have had on their patients with locally advanced disease or stage IV. "They may run out of treatment options so clinical trials have played a big role in their lives. Quality of life is also very important to us and our patients as well as sponsors who develop the drug. We have patients who still work during their
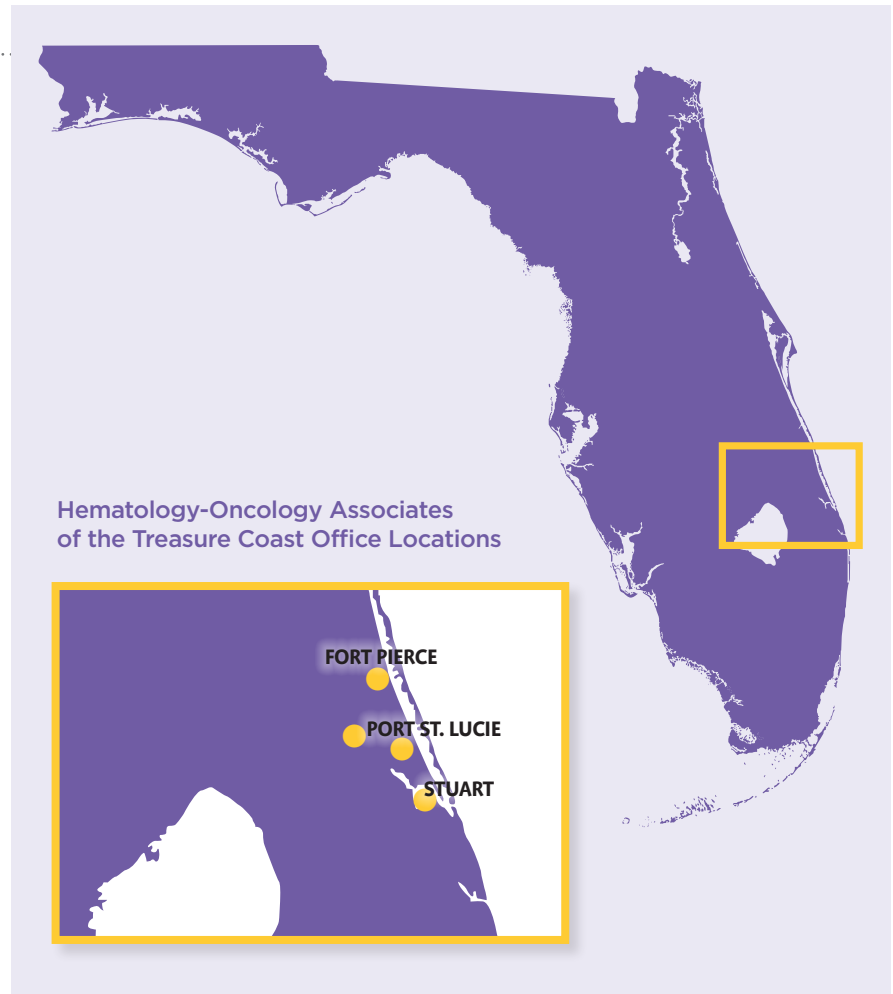
treatment on clinical trials with good quality of life."

Gerdes and colleagues have seen the evolution of cancer treatment and how important clinical trials are in the development of new therapies over the past 20 years. No longer considered the last option available to patients, qualified patients may now access state-of-the-art treatments via clinical trials earlier in their disease progress, which hopefully results in a better response without the debilitating side effects that can prevent activities of daily living or good quality of life.

Hematology-Oncology Associates of the Treasure Coast has made their Department of Clinical Research a cornerstone of their care as they believe it benefits their patients, as well as the future treatment of cancer.

The department is currently studying immunotherapies, both alone and in combination with chemotherapy. "The

more patients who participate in clinical trials, the better chance on finding a cure," said Gerdes. OI

Select Support Services:

- Financial counseling
- *Look Good, Feel Better*
- Support groups
- Physician dispensing of oral medications

Number of new analytic cases in 2014: 1,600

tools

Approved Drugs

• The U.S. Food and Drug Administration (FDA) has approved **Arzerra® (ofatumumab) Injection** (Novartis Pharmaceuticals Corporation, novartis.com) for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive chronic lymphocytic leukemia (CLL). Arzerra was previously approved for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy was considered inappropriate and also for patients with CLL refractory to fludarabine and alemtuzumab.

• Teikoku Pharma USA, Inc. (teikokuusa.com) announced that the FDA has approved **Docetaxel Injection, non-alcohol formula** for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer.

• The FDA has approved NextSource Biotechnology's (nextsourcebio.com) **Gleostine® (lomustine) 5 mg capsules**, and it is now commercially available in the U.S. Gleostine is approved for use as a single agent treatment or in combination with other approved chemotherapeutic agents. Gleostine is indicated to treat brain tumors—both primary and metastatic, as well as Hodgkin's disease.

• Eisai Co., Ltd. (eisai.com) announced that the FDA has approved **Halaven® (eribulin) Injection** for the treatment of patients with unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.

• The FDA has approved **Ibrance® (palbociclib) Capsules** (Pfizer, Inc., pfizer.com) in combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.

• Amgen (amgen.com) announced that the FDA has approved the supplemental new drug application (sNDA) of **Kyprolis® (carfilzomib) for Injection** in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy. The FDA also approved Kyprolis as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.

• Bristol-Myers Squibb (bms.com) announced that the FDA has granted accelerated approval to **Opdivo® (nivolumab)** in combination with Yervoy® (ipilimumab) for the treatment of patients with BRAF V600 wild-type and BRAF V600 mutation-positive unresectable or meta-static melanoma.

Drugs in the News

• Boehringer Ingelheim (us.boehringer-ingelheim.com) announced that the FDA has granted breakthrough therapy designation to its investigational third-generation epidermal growth factor receptor (EGFR) mutant-specific tyrosine kinase inhibitor (TKI), **BI 1482694 (HM61713)**.

• Merck (merck.com) announced that the FDA has approved its sNDA for single-dose **Emend® (fosaprepitant dimeglumine) for injection**, in combination with other antiemetic medicines, for the prevention of delayed nausea and vomiting in adults receiving initial and repeat courses of moderately emetogenic chemotherapy.

• AstraZeneca (astrazeneca.com) announced that the FDA has granted breakthrough therapy designation for **durvalumab (MEDI4736)**, for the treatment of patients with PD-L1 positive inoperable or metastatic urothelial bladder cancer whose tumor has progressed during or after one standard platinum-based regimen.

• The FDA has granted breakthrough therapy designation to **PKC412 (midostaurin)** (Novartis, novartis.com) for adults with newly-diagnosed AML who are FLT3 mutation-positive, as detected by an FDA-approved test, and who are eligible to receive standard induction and consolidation chemotherapy.

• The FDA has granted priority review to the new drug application (NDA) for **venetoclax** (AbbVie, abbvie.com) for the treatment of CLL in adults who have received at least one prior therapy, including patients with 17p deletion. ◼

A NEW TREATMENT OPTION
FOR PATIENTS WITH METASTATIC EGFR T790M MUTATION-POSITIVE NSCLC, AS DETECTED BY AN FDA-APPROVED TEST, WHO HAVE PROGRESSED ON OR AFTER EGFR TKI THERAPY

TAGRISSO™
osimertinib

INDICATION

TAGRISSO is indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, who have progressed on or after EGFR tyrosine kinase inhibitor therapy.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

- There are no contraindications for TAGRISSO

- Interstitial Lung Disease (ILD)/Pneumonitis occurred in 3.3% and was fatal in 0.5% of 813 TAGRISSO patients. Withhold TAGRISSO and promptly investigate for ILD in any patient presenting with worsening of respiratory symptoms indicative of ILD (e.g., dyspnea, cough and fever). Permanently discontinue TAGRISSO if ILD is confirmed

- QTc interval prolongation occurred in TAGRISSO patients. Of the 411 patients in two Phase II studies, 0.2% were found to have a QTc greater than 500 msec, and 2.7% had an increase from baseline QTc greater than 60 msec. Conduct periodic monitoring with ECGs and electrolytes in patients with congenital long QTc syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval. Permanently discontinue TAGRISSO in patients who develop QTc interval prolongation with signs/symptoms of life threatening arrhythmia

- Cardiomyopathy occurred in 1.4% and was fatal in 0.2% of 813 TAGRISSO patients. Left Ventricular Ejection Fraction (LVEF) decline >10% and a drop to <50% occurred in 2.4% of (9/375) TAGRISSO patients. Assess LVEF before initiation and then at 3 month intervals of TAGRISSO treatment. Withhold TAGRISSO if ejection fraction decreases by 10% from pretreatment values and is less than 50%. For symptomatic congestive heart failure or persistent asymptomatic LV dysfunction that does not resolve within 4 weeks, permanently discontinue TAGRISSO

- Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during TAGRISSO treatment and for 6 weeks after the final dose. Advise males with female partners of reproductive potential to use effective contraception for 4 months after the final dose

- The most common adverse reactions (>20%) observed in TAGRISSO patients were diarrhea (42%), rash (41%), dry skin (31%) and nail toxicity (25%)

Please see Brief Summary of complete Prescribing Information.

AZD9291 is...

NOW APPROVED!

...now **TAGRISSO**

Visit TAGRISSOhcp.com for more information

AstraZeneca

TAGRISSO™ (osimertinib) tablet, for oral use

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

INDICATIONS AND USAGE

TAGRISSO is indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.

This indication is approved under accelerated approval based on tumor response rate and duration of response [see Clinical Studies (14) in the full Prescribing Information]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

DOSAGE AND ADMINISTRATION

Patient Selection

Confirm the presence of a T790M EGFR mutation in tumor specimens prior to initiation of treatment with TAGRISSO [see Indications and Usage (1) and Clinical Studies (14) in the full Prescribing Information]. Information on FDA-approved tests for the detection of T790M mutations is available at http://www.fda.gov/companiondiagnostics.

Recommended Dosage Regimen

The recommended dose of TAGRISSO is 80 mg tablet once a day until disease progression or unacceptable toxicity. TAGRISSO can be taken with or without food.

If a dose of TAGRISSO is missed, do not make up the missed dose and take the next dose as scheduled.

Administration to Patients Who Have Difficulty Swallowing Solids

Disperse tablet in 4 tablespoons (approximately 50 mL) of non-carbonated water only. Stir until tablet is completely dispersed and swallow or administer through naso-gastric tube immediately. Do not crush, heat, or ultrasonicate during preparation. Rinse the container with 4 to 8 ounces of water and immediately drink or administer through the naso-gastric tube [see Clinical Pharmacology (12.3) in the full Prescribing Information].

Dose Modification for Adverse Reactions

Table 1   Recommended Dose Modifications for TAGRISSO

Target Organ	Adverse Reaction[a]	Dose Modification
Pulmonary	Interstitial lung disease (ILD)/Pneumonitis	Permanently discontinue TAGRISSO.
Cardiac	QTc[†] interval greater than 500 msec on at least 2 separate ECGs[b]	Withhold TAGRISSO until QTc interval is less than 481 msec or recovery to baseline if baseline QTc is greater than or equal to 481 msec, then resume at 40 mg dose.
Cardiac	QTc interval prolongation with signs/ symptoms of life threatening arrhythmia	Permanently discontinue TAGRISSO.
Cardiac	Asymptomatic, absolute decrease in LVEF[c] of 10% from baseline and below 50%	Withhold TAGRISSO for up to 4 weeks. • If improved to baseline LVEF, resume. • If not improved to baseline, permanently discontinue.
Cardiac	Symptomatic congestive heart failure	Permanently discontinue TAGRISSO.
Other	Grade 3 or higher adverse reaction	Withhold TAGRISSO for up to 3 weeks.
Other	If improvement to Grade 0-2 within 3 weeks	Resume at 80 mg or 40 mg daily.
Other	If no improvement within 3 weeks	Permanently discontinue TAGRISSO.

[a] Adverse reactions graded by the National Cancer Institute Common Terminology Criteria for Adverse Events version 4.0 (NCI CTCAE v4.0).
[b] ECGs = Electrocardiograms
[c] LVEF = Left Ventricular Ejection Fraction
[†] QTc = QT interval corrected for heart rate

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Interstitial Lung Disease/Pneumonitis

Across clinical trials, interstitial lung disease (ILD)/pneumonitis occurred in 3.3% (n=27) of TAGRISSO treated patients (n=813); 0.5% (n=4) were fatal.

Withhold TAGRISSO and promptly investigate for ILD in any patient who presents with worsening of respiratory symptoms which may be indicative of ILD (e.g., dyspnea, cough and fever). Permanently discontinue TAGRISSO if ILD is confirmed [see Dosage and Administration (2.4) and Adverse Reactions (6) in the full Prescribing Information].

QTc Interval Prolongation

The heart rate-corrected QT (QTc) interval prolongation occurs in patients treated with TAGRISSO. Of the 411 patients in Study 1 and Study 2, one patient (0.2%) was found to have a QTc greater than 500 msec, and 11 patients (2.7%) had an increase from baseline QTc greater than 60 msec [see Clinical Pharmacology (12.2) in the full Prescribing Information].

In Study 1 and 2, patients with baseline QTc of 470 msec or greater were excluded. Conduct periodic monitoring with ECGs and electrolytes in patients with congenital long QTc syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval. Permanently discontinue TAGRISSO in patients who develop QTc interval prolongation with signs/symptoms of life threatening arrhythmia [see Dosage and Administration (2.4) in the full Prescribing Information].

Cardiomyopathy

Across clinical trials, cardiomyopathy (defined as cardiac failure, pulmonary edema, ejection fraction decreased or stress cardiomyopathy) occurred in 1.4% (n=11) of TAGRISSO treated patients (n=813); 0.2% (n=2) were fatal.

In Study 1 and Study 2, Left Ventricular Ejection Fraction (LVEF) decline >10% and a drop to <50% occurred in 2.4% (9/375) of patients who had baseline and at least one follow up LVEF assessment.

Assess LVEF by echocardiogram or multigated acquisition (MUGA) scan before initiation of TAGRISSO and then at 3 month intervals while on treatment. Withhold treatment with TAGRISSO if ejection fraction decreases by 10% from pretreatment values and is less than 50%. For symptomatic congestive heart failure or persistent, asymptomatic LV dysfunction that does not resolve within 4 weeks, permanently discontinue TAGRISSO [see Dosage and Administration (2.4) in the full Prescribing Information].

Embryo-Fetal Toxicity

Based on data from animal studies and its mechanism of action, TAGRISSO can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, osimertinib caused post-implantation fetal loss when administered during early development at a dose exposure 1.5 times the exposure at the recommended human dose. When males were treated prior to mating with untreated females, there was an increase in preimplantation embryonic loss at plasma exposures of approximately 0.5-times those observed in patients at the 80 mg dose level.

Advise pregnant women of the potential risk to a fetus.

Advise females of reproductive potential to use effective contraception during treatment with TAGRISSO and for 6 weeks after the final dose. Advise males with female partners of reproductive potential to use effective contraception for 4 months after the final dose [see Use in Specific Populations (8.1), (8.3) and Clinical Pharmacology (12.3) in the full Prescribing Information].

ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:
Interstitial Lung Disease/Pneumonitis [see Warnings and Precautions (5.1) in the full Prescribing Information]
QTc Interval Prolongation [see Warnings and Precautions (5.2) 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 data described below reflect exposure to TAGRISSO (80 mg daily) in 411 patients with EGFR T790M mutation-positive non-small cell lung cancer who received prior EGFR TKI therapy, in two single arm studies, Study 1 and Study 2. Patients with a past medical history of ILD or radiation pneumonitis that required steroid treatment, serious arrhythmia or baseline QTc interval greater than 470 ms were excluded from Study 1 and Study 2. Baseline patient and disease characteristics were: median age 63 years, 13% of patients were ≥75 years old, female (68%), White (36%), Asian (60%), metastatic (96%), sites of brain metastases (39%), World Health Organization (WHO) performance status of 0 (37%) or 1 (63%), 1 prior line of therapy [EGFR-TKI treatment only, second line, chemotherapy-naïve (31%)], 2 or more prior lines of therapy (69%). Of the 411 patients, 333 patients were exposed to TAGRISSO for at least 6 months; 97 patients were exposed for at least 9 months; however no patient was exposed to TAGRISSO for 12 months.

In Studies 1 and 2, the most common (>20%) adverse reactions (all grades) observed in TAGRISSO-treated patients were diarrhea (42%), rash (41%), dry skin (31%), and nail toxicity (25%). Dose reductions occurred in 4.4% of patients treated with TAGRISSO. The most frequent adverse reactions that led to dose reductions or interruptions were: electrocardiogram QTc prolonged (2.2%) and neutropenia (1.9%). Serious adverse reactions reported in 2% or more patients were pneumonia and pulmonary embolus. There were 4 patients (1%) treated with TAGRISSO who developed fatal adverse reactions of ILD/pneumonitis. Other fatal adverse reactions occurring in more than 1 patient included pneumonia (4 patients) and CVA/cerebral hemorrhage (2 patients). Discontinuation of therapy due to adverse reactions occurred in 5.6% of patients treated with TAGRISSO. The most frequent adverse reactions that led to discontinuation were ILD/pneumonitis and cerebrovascular accidents/infarctions.

Tables 2 and 3 summarize the common adverse reactions and laboratory abnormalities observed in TAGRISSO-treated patients.

Table 2   Adverse Reactions (>10% for all NCI CTCAE* Grades or >2% for Grades 3-4) in Study 1 and Study 2

Adverse Reaction	TAGRISSO N=411	
	All Grades	Grade 3-4[f]
	%	%
Gastrointestinal disorders		
Diarrhea	42	1.0
Nausea	17	0.5
Decreased appetite	16	0.7
Constipation	15	0.2
Stomatitis	12	0
Skin disorders		
Rash[a]	41	0.5
Dry skin[b]	31	0
Nail toxicity[c]	25	0
Pruritus	14	0
Eye Disorders[d]	18	0.2
Respiratory		
Cough	14	0.2
General		
Fatigue	14	0.5
Musculoskeletal		
Back pain	13	0.7
Central Nervous System		
Headache	10	0.2
Infections		
Pneumonia	4	2.2
Vascular events		
Venous thromboembolism[e]	7	2.4

* NCI CTCAE v4.0.

a Includes cases reported within the clustered terms for rash adverse events: Rash, rash generalized, rash erythematous, rash macular, rash maculo-papular, rash papular, rash pustular, erythema, folliculitis, acne, dermatitis and acneform dermatitis.
b Includes dry skin, eczema, skin fissures, xerosis.
c Includes nail disorders, nail bed disorders, nail bed inflammation, nail bed tenderness, nail discoloration, nail disorder, nail dystrophy, nail infection, nail ridging, onychoclasis, onycholysis, onychomadesis, paronychia.
d Includes dry eye, vision blurred, keratitis, cataract, eye irritation, blepharitis, eye pain, lacrimation increased, vitreous floaters. Other ocular toxicities occurred in <1% of patients.
e Includes deep vein thrombosis, jugular venous thrombosis, and pulmonary embolism.
f No grade 4 events have been reported.

Additional clinically significant adverse reactions occurring in 2% or more of patients treated with TAGRISSO included cerebrovascular accident (2.7%).

Table 3   Common Laboratory Abnormalities (≥20% for all NCI CTCAE Grades) in Study 1 and Study 2

Laboratory Abnormality	TAGRISSO N=411	
	Change from Baseline All Grades (%)	Change from Baseline to Grade 3 or Grade 4 (%)ᵃ
Clinical Chemistry		
Hyponatremia	26	3.4
Hypermagnesemia	20	0.7
Hematologic		
Lymphopenia	63	3.3
Thrombocytopenia	54	1.2ᵃ
Anemia	44	0.2
Neutropenia	33	3.4

ᵃ The only grade 4 laboratory abnormality was 1 patient with grade 4 thrombocytopenia.

DRUG INTERACTIONS
Drug interaction studies with inhibitors, inducers or substrates of CYP enzymes and transporters have not been conducted with TAGRISSO.

Effect of Other Drugs on Osimertinib
Strong CYP3A Inhibitors
Avoid concomitant administration of TAGRISSO with strong CYP3A inhibitors, including macrolide antibiotics (e.g., telithromycin), antifungals (e.g., itraconazole), antivirals (e.g., ritonavir), nefazodone, as concomitant use of strong CYP3A inhibitors may increase osimertinib plasma concentrations. If no other alternative exists, monitor patients more closely for adverse reactions of TAGRISSO *[see Dosage and Administrations (2.4) and Clinical Pharmacology (12.3) in the full Prescribing Information].*

Strong CYP3A Inducers
Avoid concomitant administration of TAGRISSO with strong CYP3A inducers (e.g., phenytoin, rifampicin, carbamazepine, St. John's Wort) as strong CYP3A inducers may decrease osimertinib plasma concentrations *[see Clinical Pharmacology (12.3) in the full Prescribing Information].*

Effect of Osimertinib on Other Drugs
Avoid concomitant administration of TAGRISSO with drugs that are sensitive substrates of CYP3A, breast cancer resistance protein (BCRP), or CYP1A2 with narrow therapeutic indices, including but not limited to fentanyl, cyclosporine, quinidine, ergot alkaloids, phenytoin, carbamazepine, as osimertinib may increase or decrease plasma concentrations of these drugs *[see Clinical Pharmacology (12.3) in the full Prescribing Information].*

USE IN SPECIFIC POPULATIONS
Pregnancy
Risk Summary
Based on data from animal studies and its mechanism of action, TAGRISSO can cause fetal harm when administered to a pregnant woman. There are no available data on TAGRISSO use in pregnant women. Administration of osimertinib to pregnant rats was associated with embryolethality and reduced fetal growth at plasma exposures 1.5 times the exposure at the recommended human dose *[see Data].* Advise pregnant women of the potential risk to a fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically-recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data
Animal Data
When administered to pregnant rats prior to embryonic implantation through the end of organogenesis (gestation days 2-20) at a dose of 20 mg/kg/day, which produced plasma exposures of approximately 1.5 times the clinical exposure, osimertinib caused post-implantation loss and early embryonic death. When administered to pregnant rats from implantation through the closure of the hard palate (gestation days 6 to 16) at doses of 1 mg/kg/day and above (0.1-times the AUC observed in patients at the recommended dose of 80 mg), an equivocal increase in the rate of fetal malformations and variations was observed in treated litters relative to those of concurrent controls. When administered to pregnant dams at doses of 30 mg/kg/day during organogenesis through lactation Day 6, osimertinib caused an increase in total litter loss and postnatal death. At a dose of 20 mg/kg/day, osimertinib administration during the same period resulted in increased postnatal death as well as a slight reduction in mean pup weight at birth that increased in magnitude between lactation days 4 and 6.

Lactation
Risk Summary
There are no data on the presence of osimertinib in human milk, the effects of osimertinib on the breastfed infant or on milk production. Administration to rats during gestation and early lactation was associated with adverse effects, including reduced growth rates and neonatal death *[see Use in*

Specific Populations (8.1) in the full Prescribing Information]. Because of the potential for serious adverse reactions in breastfed infants from osimertinib, advise a lactating woman not to breastfeed during treatment with TAGRISSO and for 2 weeks after the final dose.

Females and Males of Reproductive Potential
Contraception
Females
Advise females of reproductive potential to use effective contraception during treatment with TAGRISSO and for 6 weeks after the final dose *[see Use in Specific Populations (8.1) in the full Prescribing Information].*
Males
Advise male patients with female partners of reproductive potential to use effective contraception during and for 4 months following the final dose of TAGRISSO *[see Nonclinical Toxicology (13.1) in the full Prescribing Information].*

Infertility
Based on animal studies, TAGRISSO may impair fertility in females and males of reproductive potential. It is not known if the effects on fertility are reversible *[see Nonclinical Toxicology (13.1) in the full Prescribing Information].*

Pediatric Use
The safety and effectiveness of TAGRISSO in pediatric patients have not been established.

Geriatric Use
One hundred eighty-seven (45%) of the 411 patients in clinical trials of TAGRISSO were 65 years of age and older, and 54 patients (13%) were 75 years of age and older. No overall differences in effectiveness were observed based on age. Exploratory analysis suggest a higher incidence of Grade 3 and 4 adverse reactions (32% versus 25%) and more frequent dose modifications for adverse reactions (23% versus 17%) in patients 65 years or older as compared to those younger than 65 years.

Renal Impairment
No dedicated clinical studies have been conducted to evaluate the effect of renal impairment on the pharmacokinetics of osimertinib. Based on population pharmacokinetic analysis, no dose adjustment is recommended in patients with mild [creatinine clearance (CLcr) 60-89 mL/min] or moderate (CLcr 30-59 mL/min) renal impairment. There is no recommended dose of TAGRISSO for patients with severe renal impairment (CLcr <30 mL/min) or end-stage-renal disease *[see Clinical Pharmacology (12.3) in the full Prescribing Information].*

Hepatic Impairment
No dedicated clinical studies have been conducted to evaluate the effect of hepatic impairment on the pharmacokinetics of osimertinib. Based on population pharmacokinetic (PK) analysis, no dose adjustment is recommended in patients with mild hepatic impairment [total bilirubin <upper limit of normal (ULN) and AST between 1 to 1.5 times ULN or total bilirubin between 1.0 to 1.5 times ULN and any AST]. There is no recommended dose for TAGRISSO for patients with moderate or severe hepatic impairment *[see Clinical Pharmacology (12.3) in the full Prescribing Information].*

17 PATIENT COUNSELING INFORMATION
Advise the patient to read the FDA-approved patient labeling (Patient Information).

Interstitial Lung Disease/Pneumonitis
Inform patients of the risks of severe or fatal ILD, including pneumonitis. Advise patients to contact their healthcare provider immediately to report new or worsening respiratory symptoms *[see Warnings and Precautions (5.1) in the full Prescribing Information].*

QTc Interval Prolongation
Inform patients of symptoms that may be indicative of significant QTc prolongation including dizziness, lightheadedness, and syncope. Advise patients to report these symptoms and to inform their physician about the use of any heart or blood pressure medications *[see Warnings and Precautions (5.2) in the full Prescribing Information].*

Cardiomyopathy
- TAGRISSO can cause cardiomyopathy. Advise patients to immediately report any signs or symptoms of heart failure to their healthcare provider *[see Warnings and Precautions (5.3) in the full Prescribing Information].*

Embryo-Fetal Toxicity
- TAGRISSO can cause fetal harm if taken during pregnancy. Advise pregnant women of the potential risk to a fetus.
- Advise females to inform their healthcare provider if they become pregnant or if pregnancy is suspected, while taking TAGRISSO *[see Warnings and Precautions (5.3) and Use in Specific Populations (8.1) in the full Prescribing Information].*

Females and Males of Reproductive Potential
- Advise females of reproductive potential to use effective contraception during treatment with TAGRISSO and for 6 weeks after the final dose *[see Use in Specific Populations (8.3) in the full Prescribing Information].*
- Advise males to use effective contraception during treatment and for 4 months after the final dose of TAGRISSO *[see Use in Specific Populations (8.3) in the full Prescribing Information].*

Lactation
Advise women not to breastfeed during treatment with TAGRISSO and for 2 weeks after the final dose *[see Use in Specific Populations (8.2) in the full Prescribing Information].*

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Building Bridges, Breaking Down Barriers

An embedded psycho-oncology program improves patient-centered care

One in ten individuals has someone in his or her family dealing with cancer.[1] In addition, it is projected that 40 percent of the United States population will receive a cancer diagnosis at some point in their lifetime.[1,2] After a cancer diagnosis, patients and families struggle to adapt to "a new normal" while simultaneously facing a number of challenges, including financial, emotional, and knowledge-based stressors.[1] Patients may also face many barriers to treatment, which can have an adverse impact on health outcomes.[1] Among the most significant barriers cancer patients report are financial problems, inadequate or a lack of health insurance, poor communication with their healthcare providers, and lack of psychosocial care.[1]

The 2008 IOM report, *Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs*, underscored the importance of integrating mental health specialists into the care of cancer patients. As many as one-third of cancer patients experience persistent distress, which can interfere with treatment.[3,4] Fewer than half of cancer patients receive the psychiatric care they need.[5]

Further, preliminary secondary analysis of the National Health and Nutrition Examination Survey (NHANES) 2003-2008 data revealed these significant findings:[6]

- 9.5 percent of individuals with cancer meet criteria for major depression compared to 7.5 percent of non-cancer patients
- More cancer patients report moderate symptoms of depression (10.2 percent versus 7.1 percent, respectively)
- Cancer patients express more depressive symptoms (3.3 percent compared to 2.9 percent).

From an epidemiological perspective, enhanced understanding of the risks that depression and other psychological sequelae pose to cancer patients may propel the inclusion of mental health interventions as a standard part of care onto the national agenda.

> As a fully embedded psychiatric program, NCIBOP offers a spectrum of services to help medically complex patients and their families deal with cancer and associated quality of life issues.

The landscape of cancer care has changed dramatically over the past several decades. An illness that was often fatal now represents both an acute life-threatening illness and a chronic condition.[1] While there have been tremendous advancements in treating the physiological aspects of cancer, management of related psychosocial and emotional issues has lagged behind.[1] Although psychological distress is common in cancer patients, it often goes unrecognized and untreated.[7,8]

One reason may be that access to specialized psycho-oncology providers is limited—even absent in some institutions,[9] placing the responsibility to care for the patient's emotional needs on the medical team, nursing staff, and family caregivers. Among cancer

programs that do monitor for psychological distress and refer to specialized psychiatric providers, few have implemented systematic assessments of depression with validated and reliable tools.[10,11] Accordingly, today's cancer programs have the opportunity to incorporate quality and outcome metrics associated with the screening and management of psychiatric sequelae in the development of specialized psycho-oncology services.[10]

Here's how one ACCC member program in Louisville, Ky., developed the Norton Cancer Institute Behavioral Oncology Program (NCIBOP), a comprehensive, embedded psychiatric program with an emphasis on integrating high-quality psychiatric care to medically complex patients.

An Overview of NCIBOP

The Norton Cancer Institute employs 29 physicians and 28 advanced practice providers (APRN/PAs) in medical, surgical, gynecological, radiation, and behavioral oncology. Norton Cancer Institute is part of the Norton Healthcare System with practice sites at each of the four adult hospitals in Louisville, as well as several other locations within Kentucky and Southern Indiana. As a fully embedded psychiatric program, NCIBOP offers a spectrum of services to help medically complex patients and their families deal with cancer and associated quality of life (QOL) issues.

NCIBOP services include individual therapy, group therapy, couples and family therapy, and pharmacological and non-pharmacological management. The program is comprised of three APRNs, one psychiatrist, a part-time social worker, a nurse, and two administrative staff. NCIBOP providers work collaboratively with oncology providers to deliver holistic care. Consultations are available in both inpatient and outpatient settings, with frequent dialogue among multidisciplinary specialists in both formal settings, such as tumor boards and other clinical meetings, and informal settings. NCIBOP acts as a liaison between patients, providers, and other team members; consistent assessment of patient distress along the cancer trajectory is a foundational component of the program.

Currently, Norton Cancer Institute clinics assess patient distress using the NCCN Distress Thermometer (DT). Patients are screened upon initiation of care at Norton Cancer Institute, followed by ongoing assessment. Similar to the pain scale, this instrument asks patients to rate their current level of distress on a scale of 0 to 10.[12-14] The DT allows for a brief, effective assessment of distress and is easily understood by medically-ill individuals.[15,16] Patients with a score of 4 or greater are offered a referral to NCIBOP. Currently Norton Cancer Institute clinics use this tool to assess distress in 100 percent of patients, as monitored through Quality Oncology Practice Initiative (QOPI) metrics. Regardless of the distress score, providers assess patient needs and refer patients who could benefit from specialized mental health services.

Despite the importance of evidence-based care, few studies have addressed the impact of sequential assessment paired with evidence-based interventions in the cancer patient population.[17] In 2013 NCIBOP implemented quality measures as the result of a quality improvement project for the evaluation of program outcomes. Specifically, NCIBOP used the Patient Health Questionnaire (PHQ-9) as a means to enhance patient-centered measures of care and to measure NCIBOP outcomes. (View the PHQ-9 online at: accc-cancer.org/oncology_issues/MA2016.asp.) In addition to implementation of consistent use of the PHQ-9, NCIBOP also began routine use of the Generalized Anxiety Disorders Questionnaire 7-item (GAD-7) to establish patient outcomes related to anxiety. An overview of the NCIBOP patient population, quality measures using the PHQ-9, a quality study with relevant findings, and program information are discussed below.

Patient Population & Services

NCIBOP providers see approximately 800 new patient visits annually, with 6,000 total patient visits per year. More females (73 percent) seek care through behavioral oncology than males (27 percent). The mean age of patients seen at NCIBOP is 56. Patients are predominantly Caucasian (90 percent), followed by African Americans (8 percent), and other races (2 percent). Outpatient consultations account for the majority of patient contacts, comprising 73 percent of new patient contacts.

On average, patients are seen four days from the time the referral is received for their new patient appointment. Figure 1, right, shows the percentage of patients treated by cancer type. Approximately 6 percent of patients seen through the program are family caregivers. A broad range of psychiatric conditions are noted, including:
- Depressive disorders (36 percent)
- Anxiety disorders (24 percent)
- Adjustment reactions (11 percent)
- Bipolar and related disorders (7 percent)
- Delirium and/or other psychiatric illnesses (22 percent).

In 2013 NCIBOP conducted a clinical microsystem assessment. Chart reviews of patients seen in NCIBOP during 2012 revealed that 59 percent of patients were diagnosed with and treated for a depression spectrum disorder. Consistent with the psycho-oncology literature, depression is a predominant mental health diagnosis seen at NCIBOP. Co-existing conditions include anxiety disorders, substance abuse disorders, and personality disorders.

In addition to NCIBOP's annual 800 new visits, an additional 250 patients are referred for services but decline them or do not keep their appointment. The primary barriers for pursuing psychiatric services include insurance constraints and stigmas associated with accessing mental health services. Patients who choose

Figure 1. NCIBOP Patient Population by Disease Site

- Breast cancer
- GI cancers
- Hematological malignancies
- Lung cancer
- Gynecological malignancies
- Genitourinary cancers
- Neuro-oncology cases
- Head and neck cancers
- Other malignancies
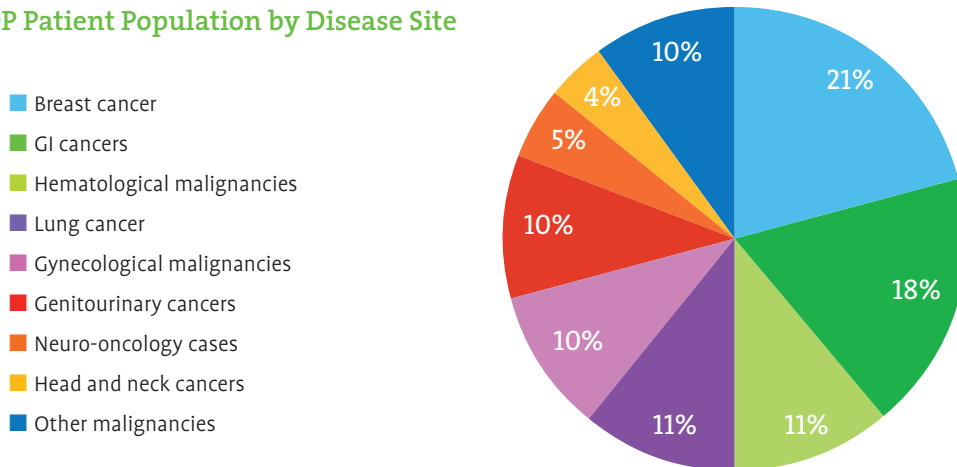
not to access specialized mental health services are offered alternative resources through Norton Cancer Institute's social work team and Cancer Resource Center facilities to ensure patient needs are evaluated and met. The Cancer Resource Centers provide resources such as massage therapy, nutrition counseling, and music therapy. Additionally, nurse navigation staff is available on-site at each Cancer Resource Center to provide access to cancer literature, educational materials, and clinical trial searches. The Cancer Resource Centers also host monthly events to promote physical wellness, emotional well-being, and networking opportunities for patients. Patients have access to free yoga classes, support groups with trained staff, and Tai Chi.

Social service providers and navigation staff are available to any patient seen through the healthcare system free of charge. Patients may be re-identified as needing psychiatric services through these programs and will be accepted into a more appropriate level of care as necessary. When a patient refuses psychiatric care or a barrier to care is identified, NCIBOP makes treatment recommendations to oncology providers to ensure the patient care need is met.

Specialty integration and care is provided through interdisciplinary case collaboration, including medication suggestions. The psychiatric team's presence on-site with the oncology team allows for timely triaging of acute psychiatric care needs and significantly reduces lengthy wait times for the first appointment, which is often typical in the psychiatric community. Providing prompt patient care during times of peak stress maximizes patient benefit and allows for enhanced continuity of care among multiple specialty providers.

NCIBOP Quality Study

In 2014 NCIBOP conducted a quality study to better understand its practice patterns and population; findings are discussed below, including implications for integrated psychiatric care in oncology facilities.

Patient Sample. The study included 41 patients seen for an initial evaluation in the outpatient setting between Jan. 1–Mar. 31, 2013. Study participants were male and female patients, 18 years of age and older, with an oncologic diagnosis. Individuals seen at NCIBOP who did not have a cancer diagnosis (family members or those with benign disorders), inpatient consultations, and individuals seen for fewer than two visits were excluded; 107 patients were excluded based on these criteria.

Intervention. NCIBOP implemented sequential assessment of depression using the PHQ-9. The information technology (IT) team built the PHQ-9 template and synopsis reporting features into the electronic health record (EHR) to enhance data aggregation opportunities. NCIBOP providers entered PHQ-9 scores into the EHR, comparing subsequent scores against baseline data. Evidence-based practice guidelines related to the treatment and management of depression were disseminated to the provider team. Providers used the medications approved for the treatment and management of depression in conjunction with individual psychotherapy. Practice observations and opportunities for enhancing care with evidence-based interventions were shared with providers.

Instrument. The PHQ-9 survey is based on the diagnostic criteria for depression and pairs well with a clinical interview to determine the presence of depressive illness.[18-22] The tool consists of 9 questions (with scores ranging from 0 to 3) to determine the presence and severity of depressive illness. Total scores of 1-5 indicate minimal depression, 6-10 mild depression, 11-14 moderate depression, 15-19 moderately severe depression, and 20-27 severe depression.[18,19,22] Using a cut-off score of 10 or higher, the tool has a high sensitivity (0.93) and specificity (0.85) and acceptable positive and negative predictive values.[23] In addition to demonstrating the capacity to ascertain depression outcomes,[20] the one-page PHQ-9 is cost-effective—with no copyright or distribution restrictions—and easy for patients and clinicians to use.

Figure 2. Psychiatric Diagnostic Characteristics (N=41)

Legend:
- Depression
- Major Depression
- Unspecified Anxiety
- Unspecified Mood Disorder
- Adjustment Disorder with Mixed Features
- Bipolar Disorder

Pie chart values: 37%, 27%, 17%, 10%, 7%, 2%
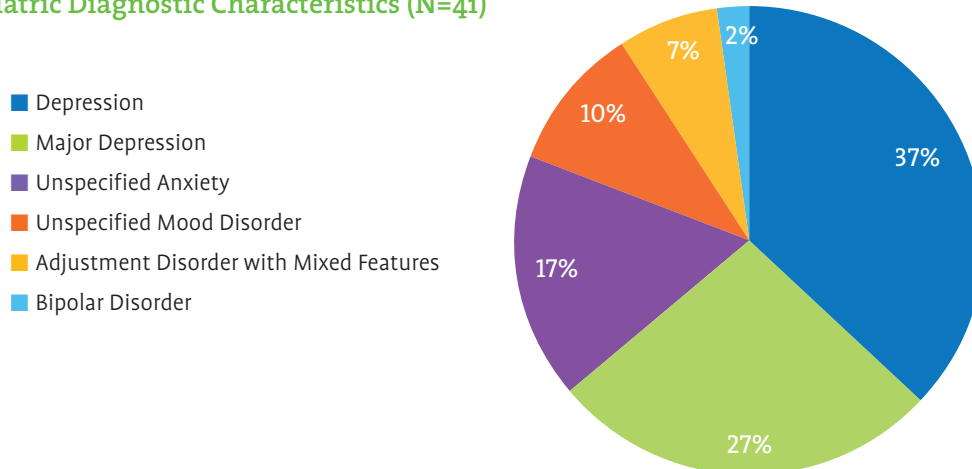
Data Collection. NCIBOP providers reviewed new patient charts for documentation of the PHQ-9 in the EHR. Data was gathered on all newly-referred patients to the NCIBOP who met inclusion criteria from Jan. 1–Mar. 31, 2013. The six-month retrospective chart review concluded Sept. 30, 2013. Data was de-identified to maintain patient privacy.

Data aggregation was an ongoing process. The PI (principal investigator) analyst and the department manager shared responsibility for data collection with quality assurance checks to ensure data integrity. They extracted socio-demographic and clinical data from the patient charts, including age, gender, race, ethnicity, educational level, religious affiliation, marital status, and employment status. Clinical data included cancer type and stage. Provider documentation in the EHR was reviewed for:
- PHQ-9 entry at each visit
- Psychiatric diagnosis
- Treatment plan and rationale, including psychopharmacological interventions and non-pharmacological interventions
- A plan for follow-up care.

Implementation Approval. The Western Institutional Review Board (WIRB) reviewed the study and granted a waiver of authorization (approval #1140717). The Norton Healthcare Office of Research Administration (NHORA) approved the study (NHORA #13-N0160).

Results. The majority of the patient sample was married, Caucasian females. The mean age of participants was 58 (SD=11.3) years of age. On average, patients were seen for 5.5 (SD=3.1) visits. Socio-demographic characteristics are presented in Table 1, right. NCIBOP providers obtained cancer diagnostic and staging variables (Table 2, page 28); however, caution should be taken when interpreting this variable as the medical record did not always clearly describe times of progression or remission. The most frequent diagnosis among participants was breast cancer (34.1 percent). Psychiatric diagnosis was most often reported as unspecified depression (37 percent) or major depression (27

percent). Psychiatric diagnosis among the study participants is found in Figure 2, above.

At the initial evaluation, the PHQ-9 was entered into the EHR 93 percent of the time; at follow-up visits the PHQ-9 was entered 84 percent of the time. Provider documentation review revealed 100 percent of patients received appropriate psychiatric diagnosis based on DSM-5 criteria, 89 percent of patients received approved medication interventions, and 100 percent of notes included rationales for treatment with follow-up planning. All patients received supportive psychotherapy. NCIBOP providers prescribed a variety of medications including:
- Anti-depressants (76 percent)
- Mood stabilizers (22 percent)
- Anxiolytics (49 percent)
- Sleep aids (20 percent).

Some patients received more than one pharmacological intervention.

Patients showed benefit in all areas of PHQ-9, including a statistically significant reduction in overall PHQ-9 score after intervention ($p = 0.0098$). Four specific items on the PHQ-9 showed significant reduction post-intervention including:
- Feeling down, depressed, or hopeless ($p = 0.011$)
- Trouble with sleep ($p = 0.01$)
- Feeling bad about yourself or that you are a failure or have let your family down ($p = 0.006$)
- Difficulty with psychomotor agitation or retardation ($p = 0.054$).

Additional information can be found in Table 3, page 29.

Translating Data into Evidence-Based Practice Interventions

Previous research has identified variances among cancer patients diagnosed with depression and those who receive antidepressants.[24]

Table 1. Socio-Demographic Characteristics of the Study Group

CHARACTERISTIC	n	PROPORTION (%)
Gender		
Male	9	21.90%
Female	32	78.00%
Race		
Caucasian	36	94.70%
African American	2	5.26%
Marital Status		
Married	26	65.00%
Divorced	5	12.50%
Widowed	4	10.00%
Separated	1	2.50%
Never Married	3	7.50%
Partner	1	2.50%
Educational Attainment		
Some High School	4	10.50%
12th Grade	12	31.50%
Some College	11	28.90%
Bachelor's Degree	8	21.00%
Post-graduate Degree	3	7.80%
Employment Status		
Employed	18	45.00%
Unemployed	4	10.00%
Retired	9	22.50%
Disabled	9	22.50%
Religious Affiliation		
Yes	21	72.40%
No	8	27.50%

Table 2. Cancer-Associated Characteristics and Staging

CHARACTERISTIC	n	FREQUENCY (%)
Cancer Diagnosis		
Hematologic malignancy	3	7.30%
GI cancer	1	2.40%
Colon cancer	3	7.30%
Brain tumors	3	7.30%
Breast cancer	14	34.10%
Gynecological cancers	6	14.60%
Lung cancer	4	9.70%
Pancreatic cancer	1	2.40%
Head and neck cancers	1	2.40%
Other	5	12.10%
Cancer Stage		
Stage 0	1	2.40%
Stage I	9	21.90%
Stage II	13	31.70%
Stage III	4	9.70%
Stage IV	12	29.20%
Remission	2	4.80%

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(continued from page 26)

In 2006 the IOM reported fewer than 11 percent of cancer patients received evidence-based interventions.[25] The integrated psycho-oncology program at Norton Cancer Institute is a model for high quality care. Indeed, NCIBOP's evidence-based care far exceeds the national norm described in the IOM report.[25]

Since the release of the 2001 IOM report, *Crossing the Quality Chasm*, emphasis has been placed on ways healthcare systems can improve care. The report identified safety, patient centeredness, effectiveness, timeliness, efficiency, and equality as six overarching aims to better meet patient needs.[26,27] For cancer programs, implementation of processes and structured care interventions in these areas may help improve quality of care, patient quality of life, and ultimately outcomes.[27]

Depression remains one of the most prevalent and treatable mental health disorders.[18] The integration of evidence-based practice guidelines in clinical settings is one approach to minimizing broad variation in care delivery across clinicians.[27-29] One approach to enhance quality in psychiatric practices is through the use of valid and reliable patient questionnaires to assess patient outcomes.[28,30] Among depressed adults, medications and psychotherapy are both evidence-based interventions for treatment and management.[31-35]

Still, Oldham and colleagues have found that psychiatry, as a discipline, struggles to adhere to evidenced-based treatment guidelines.[28] Factors contributing to the under-utilization of clinical practice guidelines include:[28,29]

- Lack of awareness regarding guidelines
- The complexity of bio-psycho-social interactions
- The absence of psychiatric providers in certain regions.

Table 3. Mean Differences in PHQ-9 Total and Item Scores

INDICATOR	PRE-INTERVENTION	POST-INTERVENTION	t-VALUE	p-VALUE
Total PHQ-9 Score	11.34 (± 6.18)	8.43 (± 5.27)	2.71	p = 0.009*
Anhedonia	1.20 (± 1.00)	1.14 (± 0.88)	0.66	p = 0.515
Depressed	1.51 (± 1.07)	1.09 (± 0.88)	2.66	p = 0.011*
Sleep	1.80 (± 1.16)	1.24 (± 1.09)	2.68	p = 0.011*
Fatigue	2.12 (± 0.93)	1.70 (± 0.96)	1.83	p = 0.750
Appetite	1.43 (± 1.02)	1.21 (± 1.15)	1.03	p = 0.311
Failure	1.02 (± 1.25)	0.53 (± 0.83)	2.91	p = 0.006*
Concentration	1.24 (± 1.11)	0.95 (± 1.18)	1.27	p = 0.209
Psychomotor	0.76 (± 0.99)	0.39 (± 0.80)	1.99	p = 0.054*
Suicide	0.17 (± 0.49)	0.07 (± 0.34)	1.16	p = 0.253
Distress Score	3.80 (± 3.68)	0.90 (± 1.78)	5.03	p = 0.000**

Note: *p <0.05. **p < 0.01.

As a result, mental health interventions are often not evidence-based—despite the known importance of delivering effective and scientifically based care.[36]

Screening for Depression Using the PHQ-9

In efforts to improve quality healthcare for mental health conditions, the IOM recommended that clinicians use reliable and valid patient questionnaires routinely to assess progress and outcomes in patients.[25] An extensive database of psychometric scales exists within the field of psychiatry; however, further research is needed within the field to strengthen the recommendation of a single tool.[29] A well-studied, reliable, and valid tool for the measurement of depression is the PHQ-9.[18,37,38] As stated previously, the PHQ-9 is a brief tool that is used with medically complex patient populations, including the cancer patient population.[39-42] Using a cut-off score of greater than or equal to 8, one study found the PHQ-9 to be 93 percent sensitive and 81 percent specific.[42]

There is currently no benchmark data related to use of the PHQ-9 in cancer patient populations. An opportunity exists to establish benchmarks within the field of psychiatry and psycho-oncology. The PHQ-9 is a brief scale by comparison to many other depression measures and consists of the criteria on which the diagnosis of depression is based, meaning this tool partners well with a clinical interview.[18,43] The NQF endorses outcome measurements for mental health, including measures that focus on depression and the use of standardized psychometric scales, specifically the PHQ-9.[21] Epidemiological studies, including NHANES and the Behavioral Risk Factor Surveillance System (BRFSS), use the patient health questionnaire series (PHQ-8/9) for assessment of depression to gather national study data.[44]

Current Practice with Psychometric Scales

Currently broad variability exists among measurements used in psychiatry and psycho-oncology departments. The 2006 IOM report, *Improving the Quality of Health Care for Mental and Substance Use Conditions*, states that as few as 27 percent of studies reviewed showed adherence to clinical guidelines, and as few as 10.5 percent of individuals were found to receive evidence-based interventions.[25] The IOM recommends that cancer programs use patient-centered decision-making to engage patients in their care, including information regarding options for and effectiveness of treatments.[25]

A better understanding of a patient's baseline presentation allows for ongoing assessment of interventions and identifies opportunities to focus on targeted areas for clinical improvement.[28] The methodology and implementation of quality improvement initiatives within the mental health arena is in its very early stage of development. A dearth of information exists within the mental health community with regard to consistently used metrics and benchmarking to assess clinical and functional outcomes.[30,45] A gap remains between clinical care and evidence-based practice guidelines.[25,45] The American Psychiatric Association (APA) endorses pharmacotherapy, supportive psychotherapy, and combined medication management and psychotherapy as

efficacious in depressed patients.[46] After integration of evidence-based practice interventions within programs, anticipated outcomes include improvement in depressive symptoms, reduced recurrence risk, and reduction in depression related to morbidity and mortality.[46]

Importance of Quality

The implementation of quality and process improvement initiatives provides a foundation for aggregating department-specific outcomes. Study data may be helpful for establishing benchmarks internally and with other psycho-oncology practices. Multi-center collaboration studies are needed to better understand the unique needs of specialized patient populations. As the national healthcare agenda continues to evolve, metric-based outcome studies will be necessary to articulate the importance of mental health interventions across cancer settings. With the advent of the medical home and further integration of mental health providers into medical settings, the capacity to fully explain the added value of specialized mental health services and to advocate for these services is more important than ever before.

Systematic Assessment of Depression in Oncology Programs

Cancer clinicians can easily overlook the diagnosis of depression, assuming it to be a reflection of the patient's adaption to illness and thus minimizing the severity of depression.[47,48] Since psychosocial interventions can enhance adaptation to illness, screening individuals to determine the need for a psychiatric referral is an important component of care. Multiple studies have documented the importance of screening for and identifying patients at high risk for emotional distress.[2,3,12-16,49-56] Despite this evidence, screening for distress in cancer patients is still not consistently practiced, with estimates that fewer than half of cancer patients with distress are identified.[3] As few as 10 percent of cancer patients are referred for specialty care with psycho-oncology providers, thus limiting opportunities to improve quality of life, treatment adherence, and potential prognosis.[53,54]

Although there is a significant body of literature supporting the psychological care for cancer patients, there is a gap with respect to program availability and practice.[57-59] There are few specialty-trained providers equipped to address the psychological and emotional needs of cancer patients. In recognition of this need, there are emerging models for enhancing collaboration between mental health and medical health teams.[60,61]

One systematic review of outcomes resulting from screening for depression in cancer patients identified 19 studies that address the accuracy of screening, including one trial evaluating treatment efficacy for major depression. No trials specifically examined changes in outcomes based on the implementation of screening alone.[2] McMillan and colleagues conducted a study that showed

interdisciplinary, standardized, systematic assessment of depression in cancer patients enrolled in hospice care was associated with significant improvement in depression and quality of life.[62] Complicating the issue of systematic assessment in cancer patient populations is the lack of consensus among psycho-oncology providers regarding which psychometric instrument is most appropriate for use in this patient population.

Consequences of Unmet Psychosocial Needs

Left untreated, psychological and emotional sequelae have significant consequences. Psychological impairment and the presence of mental health problems, including depression, anxiety, post-traumatic stress symptoms (PTSS), and post-traumatic stress disorder (PTSD) contribute to:[1,2,8,15,52,54,63-74]

- Role impairment
- Reduced compliance with medical treatments
- Reduced quality of life
- Increased medical costs
- Prolonged hospitalizations
- Higher utilization of medical care
- Greater symptom severity
- Poorer medical outcomes.

In addition, the failure to assess depression in cancer patients ignores depression as a treatable illness and inadequately attributes depression as a possible result of a deeper physiological process that may need further evaluation.[47,48,63,65-67,69]

Depression contributes to impairment in personal, social, occupational, and family functioning.[52,50,75] Untreated distress and lack of available psychosocial support place families at risk for role strain and impaired family functioning.[52,55,76] As distress exists along a continuum, waiting until severe levels of distress occur fails to provide timely care that could prevent catastrophic results.[77] In severe cases, depression may even lead to an enhanced desire for early death or suicide.[24,76,78-82] Cancer patients are at an increased risk for suicide. Many factors contribute to this increased risk, including:[47,83,66]

- Pain
- Physical symptoms
- Advanced illness with poor prognosis
- Depression resulting in hopelessness
- Delirium and disinhibition
- Loss of control and helplessness
- Pre-existing psychopathology
- Suicidal history
- Inadequate social support.

Individuals with cancer and concurrent depression and anxiety have more difficulties with somatic concerns, disabilities, unexplained symptoms, and increased symptom severity.[1,8,24] Co-morbid

psychiatric illnesses have been associated with unhealthy behaviors and reduced adherence to anti-neoplastic treatments.[1,24] Distress can contribute to a reduced level of hope, thus translating to a belief that cancer treatments are not worthwhile and contributing to poor follow-through with potentially curative treatments. Optimism relates to an underlying capacity for resilience, which leads to a greater ability for problem solving, enhanced coping strategies, and an ability to find meaning in illness.[1] The presence of psychological distress reduces these functions and increases the risks of possible long-term complications.[1]

Policy Support for Integrating Psychosocial Assessment & Management

At the national level, the Commission on Cancer (CoC) has tasked oncology programs with finding ways to implement distress screening and referral to specialized psychosocial providers.[11,84,85] Since the 2008 IOM report, efforts have expanded to include the provision of psychosocial screening and the addition of mental health providers to deliver this specialty care. With the support of multiple organizations, including the American Psychosocial Oncology Society (APOS), the National Quality Forum (NQF), the CoC and the American College of Surgeons (ACoS), the International Psychosocial Oncology Society (IPOS), and the ASCO Quality Oncology Practice Initiative (QOPI), the importance of quality mental and emotional health interventions in cancer populations will continue to stay on the national agenda. In addition, current QOPI metrics require the identification and documentation of patients' emotional needs by oncology providers.[86]

Going Forward

Bio-medical approaches to treatment continue to advance, and psychosocial interventions supporting quality of life must keep pace.[1] As the field of psycho-oncology continues to grow, providers will need to support evidence-based psychosocial assessments and psychiatric measures to describe patient and program outcomes. With the inclusion of psychosocial measures for accreditation at the majority of cancer programs nationwide, cancer programs will be pushed to screen for psychological sequelae as a routine part of care.[11, 84, 87] Once patients enter care with specialized psychiatric providers, the ability to measure outcomes is important for describing clinical care, advocating for resources, and sustaining psychiatric programs. Use of the PHQ-9, a reliable and valid measure of depression severity,[18] at routine intervals in specialized cancer mental health settings provides a metric for ongoing analysis of patient outcome data. Evidence supports the use of validated screenings as a way to minimize treatment variability. Combined with comprehensive medication management and psychotherapeutic interventions, patients are likely to have the most optimal outcomes.[21, 31]

Findings from the NCIBOP study suggest that implementation of quality metrics, sequential assessment with validated tools, and the integration of evidence-based treatment guidelines are feasible. Aggregation of patient outcome data showed statistically significant improvement in PHQ-9 scores after intervention with the NCIBOP providers when using evidence-based treatment approaches. With the evolution of healthcare policy and a rising demand for quality, the establishment of standards for care and the inclusion of quality metrics are necessary to measure patient outcomes effectively. **OI**

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Building a
Navigation and Psychosocial
Support Program

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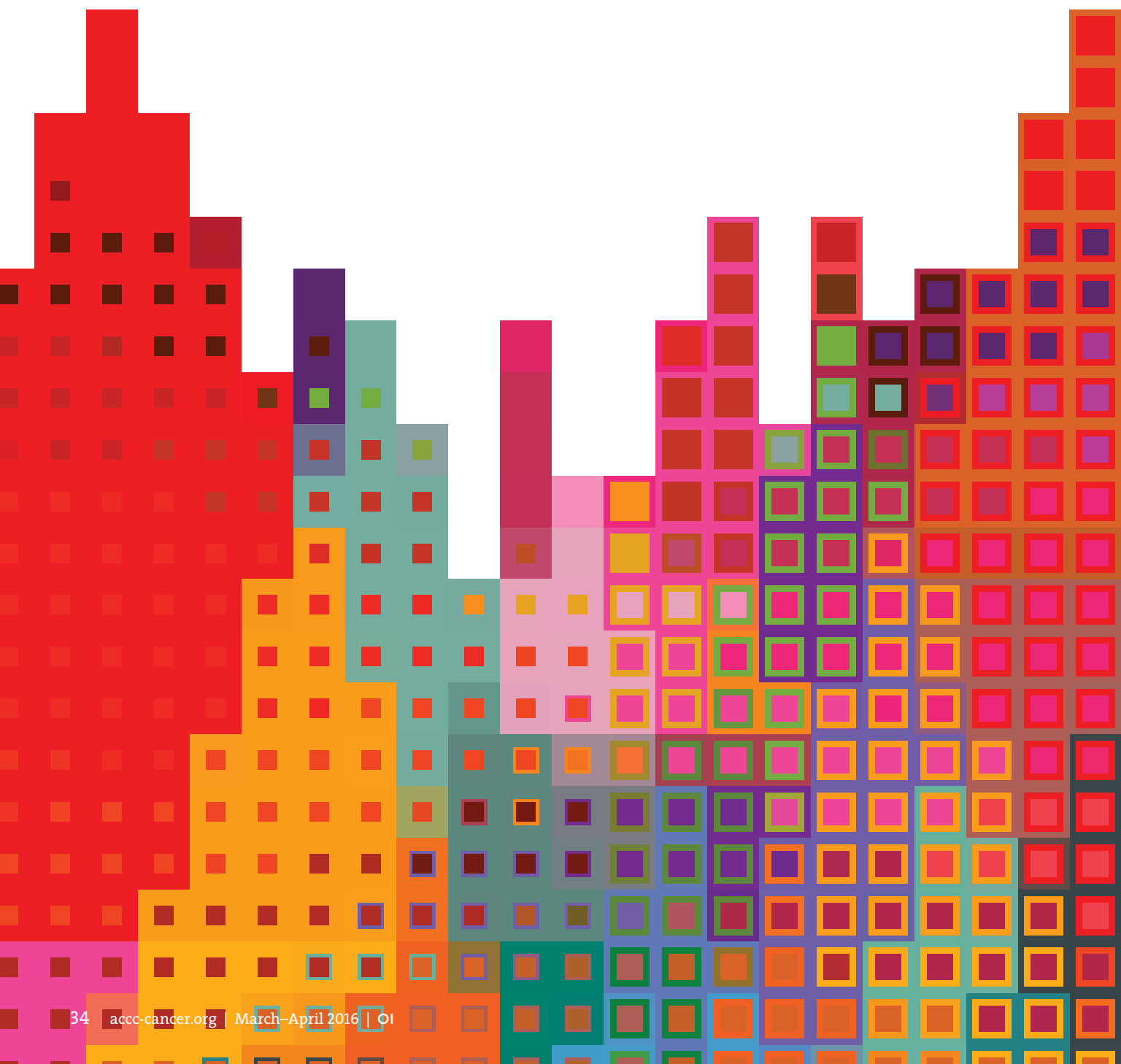
from the Ground Up

I n 2009 Southside Regional Medical Center's administrative team committed to the development of an oncology service line that would not only meet the needs of the community, patients, families, providers, and facility, but also become accredited by the American College of Surgeons' Commission on Cancer (CoC). Identifying the oncology-related needs of the community was critical to this effort. As part of its facility and community health needs assessment, Southside surveyed patients, physicians, and staff to identify needs, barriers, and disparities in the community and within Southside Regional Medical Center. At the same time, Southside formed multidisciplinary oncology teams and reorganized the Cancer Committee to create an Oncology Steering Committee and an Oncology Quality Committee. Using the collected needs assessment data, these two committees developed and oversaw the implementation of the oncology service line plan.

Growing Patient-Centered Services

Two key components of the oncology service line plan were the development of a comprehensive oncology navigation program and a psychosocial program. Southside leadership determined that the best way to accomplish these two goals was to create an oncology nurse navigator role. The Steering Committee was tasked with creating the ideal job description based on identified potential navigator roles and responsibilities, including:

> The role of the oncology nurse navigator was defined as "an individual who is responsible for guiding patients and their families through their cancer journey and identifying and supporting all of their needs at any point along the way."

- Decreasing barriers and/or disparities across the care continuum (i.e., improving patient access to care)
- Acting as patient advocate
- Providing patient education
- Improving care coordination
- Conducting patient assessment, support, and referrals
- Coordinating distress management and psychosocial support.

This new staff position would not only "navigate" our oncology patients, but also act as "the face of Southside's oncology

program" in the community and lead all psychosocial-related services for the oncology program.

In 2011 hospital administration approved the hire of the FTE oncology nurse navigator. A panel of interviewers that included Southside's patient advocate/social worker, radiation oncologist, oncology service line director, and radiology service line director offered a broad perspective to assess the applicants, provided a well-rounded set of interview questions, and identified key attributes of an ideal candidate:

- Compassionate
- Knowledgeable
- Critical thinker and decision maker
- Independent
- Organized
- Flexible.

The Steering Committee's vision was to meet all of the psychosocial and physical needs of patients and families along the entire cancer care continuum. Thus, Southside formally defined its oncology patient navigation services as "assisting our cancer patients and families with everything they may need." The role of the oncology nurse navigator was defined as "an individual who is responsible for guiding patients and their families through their cancer journey and identifying and supporting all of their needs at any point along the way." Of course that is a lot to ask of one staff person, but the Steering Committee determined that initially the oncology nurse navigator could:

- Lead a navigation team
- Coordinate patient assessments, needs, referrals, and resources
- Act as the "go to" person for patients and families.

The Steering Committee identified an oncology nurse as the ideal person to fulfill this role in the startup phase, with a goal to add new staff—social workers, RNs, and/or lay navigators—to the navigation team as it grew. The oncology nurse navigator joined Southside's oncology team in January 2012.

Implementing Patient Navigation

With the oncology nurse navigator on board, the next step was to determine which oncology patients would be navigated (cancer sites and phase of care), which populations of cancer patients or entry sites would be included (inpatient versus outpatient), and which staff would be a part of the navigation team. Southside made the following decisions for its navigation program:

- The navigation program would encompass all actual and potential cancer diagnoses
- The navigation program would provide services in both the inpatient and outpatient settings
- Navigation team members would include navigator(s) and key oncology team and IT staff members.

Next, the Steering Committee defined patient and family needs as "all knowledge, support, or items that a patient is missing or barriers to care that have been identified for each patient and/or family." Southside committed to placing the patient at the center of its program and processes.

The Steering Committee then developed a navigation screening tool (Figure 1, right) that could be used not only by the oncology nurse navigator but also by any staff that has contact with patients. This screening tool is used to identify patients in distress and/or patients who need assistance with unmet needs. Identified patients are then referred to the oncology nurse navigator for further assessment and support as needed.

Another critical tool: Equicare, a software program that was approved and purchased concurrently with the hiring of the oncology nurse navigator. Although Equicare is marketed as a "survivorship" software program, Southside chose the software because it also met the psychosocial, navigation, distress screening, and patient education needs of the cancer program. With finite resources for the new navigation and psychosocial programs, all of this functionality in one software program was critical. The oncology service line director and the oncology nurse navigator

Figure 1. Oncology Navigation Screening Tool

INSTRUCTIONS: Tool should be used for all cancer patients to determine if they would benefit from a referral to our oncology nurse navigator. Check all that apply.

☐ New cancer diagnosis

☐ First visit to Southside Regional Medical Center's oncology program

☐ Experiencing unrelieved pain at any time

☐ Experiencing decreased quality of life and/or suffering

☐ Displaying signs of distress

☐ Change in prognosis and/or treatment plan

☐ Nearing survivorship stage and no survivorship care plan in place

☐ Experiencing psychosocial issues

☐ Needs assistance with end-of-life decisions

☐ Uninsured, underinsured, financial distress

☐ Access to care issues

☐ Difficulty with compliance/follow-up

· ·

FOR A REFERRAL: Call the Oncology Nurse Navigator (NAME) at (NUMBER) or fax this form to: (Number) if the patient or their family meets any of the above criteria.

Date: ....

Patient name: .... DOB: ....

Diagnosis: .... Phone number:...

Physician: ....

Person completing form: .... Phone: ....
                         (please print)

spent several months individualizing the software program to best meet all of Southside's needs. In June 2012 Southside began using Equicare, which resulted in an increase in the amount of time staff was able to spend with patients and reduced time spent on paper charting and manual spreadsheet for tracking data.

Meeting a Growing Need for Services

During the planning and implementation period, providers and patients requested the new (and as yet unadvertised) navigation services more frequently than anticipated. Based on these requests, Southside started offering its psychosocial and navigation services much sooner than expected—and patient volume grew very quickly. During the oncology nurse navigator's first year at Southside Regional Medical Center, she received 120 patient referrals for navigation. These referrals included an unexpected number of referrals for patients in the community who were not diagnosed or treated at Southside, but who were referred by phone to the oncology department, and patients and/or family members who contacted the oncology nurse navigator directly. This demand for services—coupled with the new CoC requirement for distress screening—helped Southside realize early on that the oncology nurse navigator needed help.

The Steering Committee was challenged to think "outside of the box" about how to structure the navigation and psychosocial programs to meet a growing need for services—without adding an additional FTE. In several brainstorming sessions, the Steering Committee and oncology nurse navigator came up with many great ideas, but each had an obstacle the Steering Committee could not overcome—mostly due to financial constraints. All agreed that adding a social worker to the team would help the oncology nurse navigator better meet patient needs; unfortunately, at that time, the cancer program did not utilize social workers.

Finding a Community Partner

A Steering Committee member who is also the hospital patient advocate and an MSW suggested partnering with the Good Neighbor Community Services, a local company committed to offering services to improve the overall health of individuals and families in the community through counseling and group homes. Good Neighbor Community Services had licensed clinical social workers (LCSWs) and psychologists who oversaw masters-level social work interns (MSWs). The patient advocate thought the agency would be open to partnering with Southside Regional Medical Center and using their staff and MSW interns to help meet the psychosocial needs of oncology patients and families. Possible benefits to this partnership for Good Neighbor Community Services included:

- Its staff would receive education and training in oncology care.
- Its staff would work side by side with oncology care providers to meet patient needs.
- The program's MSW interns would gain real-world experience in the outpatient setting of a hospital-based clinic.

The Steering Committee invited Good Neighbor Community Services to meet and brainstorm on how this partnership could benefit both organizations. After this successful meeting, the Steering Committee developed a formal plan that mapped out the partnership, including the distress screening process.

The next step was to sign a formal agreement with Good Neighbor Community Services, which included specifics on how Southside's oncology nurse navigator and Good Neighbor Community Services would work together to develop tasks and oversee the interns during their time at Southside Regional Medical Center. In the end, this partnership allowed Southside to offer additional services even as patient volume increased.

Implementing Distress Screening

When implementing comprehensive distress screening, Southside's goal was to screen patients at time of diagnosis and at other key distress points. Southside Regional Medical Center serves a large community and not all patients are referred to the program at diagnosis, so staff worked to identify other points of entry to the program.

When Southside Regional Medical Center first partnered with Good Neighbor Community Services and began its distress screening in the fall of 2012, staff used the NCCN Distress Thermometer (DT). The team soon realized that patients had difficulty with this tool, so the oncology team and Good Neighbor Community Services worked together to create a simplified tool (Figure 2, right).

In early 2013 Southside was asked to be a beta test site for an upcoming Equicare upgrade, which added a navigation section to the "survivorship software." As a beta test site, Southside was able to electronically implement its oncology distress screening tool across the continuum of care, increasing the number of staff using the tool. Outside of the psychosocial team, nutrition and outpatient infusion center staff most used the distress screening tools. It also gave Southside the capability to quickly compare patients' current distress screenings with previous screenings, allowing staff to identify areas of improvement or concern.

Today, the oncology nurse navigator is housed in the new

Figure 2. Oncology Distress Screening Tool

INSTRUCTIONS: Thank you for taking the time to fill this out. We want to make sure we take care of all of your needs. Please circle the number for each symptom that best describes how you feel now.

(0 = No complaints; 10 = Severe complaints)

How would you rate your overall distress?	0	1	2	3	4	5	6	7	8	9	10
Appetite/Weight	0	1	2	3	4	5	6	7	8	9	10
Sexuality/Fertility	0	1	2	3	4	5	6	7	8	9	10
Sadness	0	1	2	3	4	5	6	7	8	9	10
Anxiety	0	1	2	3	4	5	6	7	8	9	10
Financial Concerns	0	1	2	3	4	5	6	7	8	9	10
Insurance Issues	0	1	2	3	4	5	6	7	8	9	10
Family Concerns	0	1	2	3	4	5	6	7	8	9	10
Sleep Disturbances	0	1	2	3	4	5	6	7	8	9	10
Transportation	0	1	2	3	4	5	6	7	8	9	10
Spirituality	0	1	2	3	4	5	6	7	8	9	10
Pain (specify location)	0	1	2	3	4	5	6	7	8	9	10
_____											
Other (specify condition)	0	1	2	3	4	5	6	7	8	9	10
_____											

. . . .

PLEASE CHECK all of the following oncology team members you would like to speak to

_____ Nurse Navigator   _____ Therapist   _____ Billing

_____ Financial Counselor   _____ Dietitian   _____ Chaplain

Date of last chemotherapy treatment: _____

Name: _____   Date: _____

cancer center that opened January 2014. Specifically, the oncology nurse navigator is located in the lobby of the radiation therapy department, with easy access to one of Southside's two private medical oncology practices located one floor up. This physical proximity has streamlined distress screening, bringing together key staff to assist in the process.

The distress screening process continues to change and evolve, depending on work load and patient acuity. At present, the radiation therapy nurse completes the first distress screening at the patient's first consult visit. The oncology nurse navigator reviews completed forms with patients, identifying needs and making referrals to appropriate services and resources as necessary. This process allows radiation therapy patients to meet the oncology nurse navigator (the main point of contact for navigation and psychosocial support) at their first appointment—if they have not had the opportunity to meet prior to consult.

As follow-up and to identify any new areas of distress, patients are assessed again midway through their radiation therapy treatment and other times as needed. The midway re-assessment was established in order to assist patients at what appears to be one of the more critical points in their radiation treatment. The staff noticed that patients who had previously scored 3 or below on the screening tool may have increased distress due to symptom management needed from side effects of treatment or billing and/or financial issues that emerge as patients move through the treatment schedule. Re-assessment is determined by patients that verbalize or have signs and symptoms of increased distress, as well as those patients that score consistently greater than 3 on the 0-10 scale. This approach allows patients to easily access navigation staff at any point during their daily treatments. Once treatment is complete, staff lets patients know that they can contact the navigation team at any time via phone or in person.

The team also assists patients through distress screening via referral from medical oncology physicians and nurses in their practice settings, at their staff's discretion; other patients are referred to the distress screening program by radiologists and inpatient providers.

Outcomes

Patients and families often verbalize their needs differently to different disciplines. When patients and families communicate their distress or needs to a physician, radiation technician, nurse, or any other team member, they quickly refer the patient and/or family to the oncology nurse navigator. Staff is very aware that the navigation team is an integral part of the oncology team and that the oncology nurse navigator is the point of contact to assist patients with their needs. Southside physicians have championed navigation and psychosocial support services for patients and families. They recognize patients and families have distress that requires a multidisciplinary approach and often refer patients directly to the oncology nurse navigator at key points, noting that the navigation and psychosocial team is easily accessible.

Good Neighbor Community Services has counseled several patients in the oncology nurse navigator's office. Further, having the Good Neighbor Community Services interns available on site has allowed the navigation team to meet increased demand for services and allowed patients access to social work services.

An active member of many local and national oncology-related organizations, the oncology nurse navigator goes out to the community, staffing exhibit booths at health fairs and distributing information to community partners to help them guide patients and families to the new navigation and psychosocial services. Southside's Patient, Family, and Community Resource Center (housed within the cancer center) and its support of local public libraries' Healthy Living and Learning Centers also help to increase community awareness of these new patient-centered services.

In addition to meeting the needs and expectations of patients, the new navigation and psychosocial programs helped Southside Regional Medical Center meet CoC standards for oncology program accreditation, specifically, navigation, psychosocial services, psychosocial distress screening, palliative care, survivorship, cancer committee membership, and quality improvements. It is also believed that Southside's navigation and psychosocial program helped to increase referral sources and resources, which, in turn, helped the cancer program meet additional CoC standards related to community outreach, prevention and screening, clinical trials, rehabilitation, nutrition, public reporting of outcomes, risk and genetic assessments, and quality studies. As of May 2015, the team has grown by adding another FTE nurse navigator to focus on lung cancer patients, education, and low-dose CT screening for lung cancer.

Figures 3-6, pages 41-44, offer a summary of the navigation and psychosocial services delivered in 2015, including patient populations served, referrals made, and outcomes. To view Southside Regional Cancer Center's 2015 disparities priorities and key agency referrals, go to: accc-cancer.org/oncology_issues/MA2016.asp. ◙

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Figure 3. 2015 Navigation Summary of Identified Issues

Identified Need and/or Issue	Disparity	Barrier	Resource Gap	Related Initiative	Care Phase	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	YTD
Financial status	Yes	Yes	Yes	Yes	All	26	22	29	19	96
Addictive behaviors	Yes	Yes	Yes	Potential	All	19	17	36	20	92
Level of education	Yes	Yes	Yes	No	All	12	10	14	10	46
Patient & family education	Yes	Yes	Yes	No	All	94	94	99	82	369
Distress & psychosocial	No	Yes	Yes	Yes	All	94	94	99	82	369
Mental health	No	Yes	Yes	Yes	All	7	2	4	5	18
Transportation & gas	No	Yes	Yes	No	All	8	16	10	14	48
Uninsured	Yes	Yes	Yes	Yes	All	11	6	7	5	29
Underinsured	Yes	Yes	Yes	Yes	All	24	27	36	25	112
Medication payment assistance	Yes	Yes	Yes	Yes	All	6	3	5	6	20
Housing	No	Yes	Yes	No	All	1	5	2	1	9
Family support	No	Yes	Yes	No	All	12	21	38	27	98
Physical disabilities	Yes	Yes	No	Yes	All	5	4	6	4	19
Physical support	Yes	Yes	Yes	No	All	1	3	4	4	12
Nutrition & food	No	Yes	Yes	Yes	All	21	27	42	36	126
Bariatric & weight loss	Yes	Yes	No	Yes	All	0	0	0	0	0
Fertility & sexuality	No	Yes	Yes	Yes	All	24	26	42	28	120
Spiritual	No	Yes	No	No	All	17	12	24	22	75
Vocation & school	No	Yes	Yes	No	All	6	8	16	12	42
Smoking cessation	No	Yes	Yes	Yes	All	26	17	36	20	99
Legal assistance	No	Yes	No	No	All	2	4	6	2	14
Rehabilitation & activity	No	Yes	Yes	Yes	All	12	4	7	3	26
Pain control	No	Yes	Yes	Yes	All	15	28	66	56	165
Home assistance	No	Yes	No	No	All	6	8	10	7	31

Figure 3. Navigation Summary

Identified Need and/or Issue	Disparity	Barrier	Resource Gap	Related Initiative	Care Phase	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	YTD
Palliative care	No	Yes	Yes	Yes	All	12	18	21	15	66
End-of-life & hospice	No	Yes	No	Yes	End-of-life	6	10	8	8	32
Symptom management & medical support	No	Yes	Yes	Potential	All	94	94	99	82	369
Genetic counseling	No	Yes	Yes	Yes	All	0	0	3	1	4
Abuse	No	Yes	Yes	No	All	0	1	0	0	1
Oncology specialist(s)	No	Yes	No	Yes	All	0	3	2	2	7
Non-oncology provider	No	Yes	No	No	All	0	5	3	3	11
Medical equipment	No	Yes	No	No	All	5	2	5	3	15
Prevention & screening	Yes	Yes	Yes	No	All	0	30	0	95	125
Support of children	No	Yes	Yes	No	All	0	0	3	0	3
Obtaining medical information	No	No	No	No	All	0	2	2	1	5
Support group	No	No	Potential	No	All	94	94	99	82	369
Total # of Needs Identified						660	685	785	688	2,130
Total Referrals						1,025	1,085	1,312	1,011	2,110

Figure 4. 2015 Patient Navigation QA & Outcomes

Measure	Goal	1st QTR	2nd QTR	3rd QTR	4th QTR	YTD
Percentage of navigation patients compared to the number of analytic cases	50%	78%	59%	57%	52%	61.5%
Patient satisfaction	95%	100%	100%	100%	100%	100%

Figure 5. 2015 Patient Navigation Summary of Patient Population Served

GENDER	Male	Female
1ST QTR	42	52
2ND QTR	48	46
3RD QTR	50	49
4TH QTR	40	42
YTD	180	189

AGE	18-35	36-50	51-60	61-74	75+
1ST QTR	2	10	13	55	14
2ND QTR	3	11	19	36	25
3RD QTR	0	8	21	45	24
4TH QTR	0	7	22	36	17
YTD	5	36	75	172	80

DIAGNOSIS	Breast	Lung	Prostate	Colorectal	GYN	Lymphoma	Head & Neck	Multiple Myeloma
1ST QTR	30	15	24	6	1	1	4	1
2ND QTR	23	17	27	2	2	3	7	1
3RD QTR	17	31	24	7	1	3	4	2
4TH QTR	30	14	13	2	1	2	6	0
YTD	100	77	88	17	5	9	21	4
DIAGNOSIS	Glioblastoma	Skin	Bladder	Sarcoma	Pancreas	Testicular	Esophageal	Other
1ST QTR	1	4	1	1	0	1	2	2
2ND QTR	2	6	1	0	0	0	3	0
3RD QTR	2	2	0	2	1	0	2	1
4TH QTR	0	6	2	0	0	0	3	2
YTD	5	18	4	3	1	1	10	7

PHASE OF CARE CONTINUUM	At Diagnosis	Treatment Planning	Treatment	Survivorship	End-of-Life	Expired	Refused
1ST QTR	2	17	41	27	6	1	0
2ND QTR	3	11	36	36	5	3	0
3RD QTR	2	16	44	28	5	3	1
4TH QTR	2	12	34	26	6	2	0
YTD	9	56	155	117	22	9	1

Figure 6. 2015 Patient Navigation Summary of Referrals

	Pain Control	Symptom Management	Palliative Care	Spiritual Care	Distress Management	Fertility Care
1st QTR	15	94	12	17	94	4
2nd QTR	18	94	18	12	94	0
3rd QTR	14	99	14	18	99	0
4th QTR	16	82	12	22	82	0
YTD	63	369	56	69	369	4

	Hospice Care	Financial Counseling	Home Health Care	Oncology Specialist	Non-Oncology Provider	Medical Equipment
1st QTR	3	73	3	0	0	5
2nd QTR	8	62	2	3	5	2
3rd QTR	6	68	5	2	3	3
4th QTR	8	58	4	2	3	3
YTD	25	261	14	7	11	13

	American Cancer Society	Support Group	Rehabilitation & Exercise	Education Program	Nutrition Support	Smoking Cessation
1st QTR	52	94	0	0	21	26
2nd QTR	46	94	0	0	27	17
3rd QTR	53	99	2	1	30	20
4th QTR	42	82	3	1	36	20
YTD	193	369	5	2	114	63

	Transportation	Prevention & Screening	Dental	Social Work	Look Good, Feel Better	
1st QTR	8	0	4	94	52 invited (5 attended)	
2nd QTR	16	0	6	54	46 invited (3 attended)	
3rd QTR	10	0	4	18	49 invited (2 attended)	
4th QTR	14	0	6	36	42 invited (2 attended)	
YTD	48	0	20	202	189 invited (12 attended)	

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ACCC
Association of Community Cancer Centers

Association of Community Cancer Centers
These programs are a benefit of membership.

BY RYAN LANGDALE, MBA,
AND ALEX GLONEK

DEVELOPING
an Oncology IT Strategy

Cancer has become a disease characterized by its data. Insurance companies demand cost and utilization data, searching for a meaningful way to optimize value. Patients request test results, lab values, and physician notes, seeking to become shared decision-makers in their care. Researchers, pharmaceutical manufacturers, and others seek clinical data in an effort to further our biological understanding of the disease and provide clinicians with novel treatment compounds and decision support. Everyone wants cancer data, and yet the demand for quality oncology data far outstrips the provider community's ability to collect and deliver such data.

This data deficiency is driven, in part, by healthcare organizations' pattern of adopting one-size-fits-all approaches to information technology (IT), expecting generic ambulatory systems to support the complex specialty that is oncology. The resulting landscape has been one of physician frustration, poor EHR (electronic health record) utilization, error-prone workflows in chemotherapy orders and administration, disengaged patients, and ultimately, a lack of quality cancer data. However, some healthcare organizations have taken the opposite approach, recognizing that superior outcomes, improved patient experience, and value-based readiness in oncology can only be achieved through a measured, tailored approach to information technology.

> Oncology's multimodal, multidisciplinary nature makes it a healthcare specialty with a tremendous amount to gain from a fully coordinated, data-sharing IT ecosystem.

This article reviews the keys to developing a successful oncology-specific IT strategy in a continuously changing IT environment. Included is a description of the process that successful healthcare organizations have followed and the pitfalls and best practices uncovered along the way, offering a path forward for those who would follow their example.

Leadership & Project Support
The prerequisite for any successful oncology IT strategy is enlightened leadership. Oncology is a highly complex specialty and is not well served by many standard healthcare information systems. Leadership understands that a combination of high-toxicity biologicals, complex treatment plans and infusion regimens,
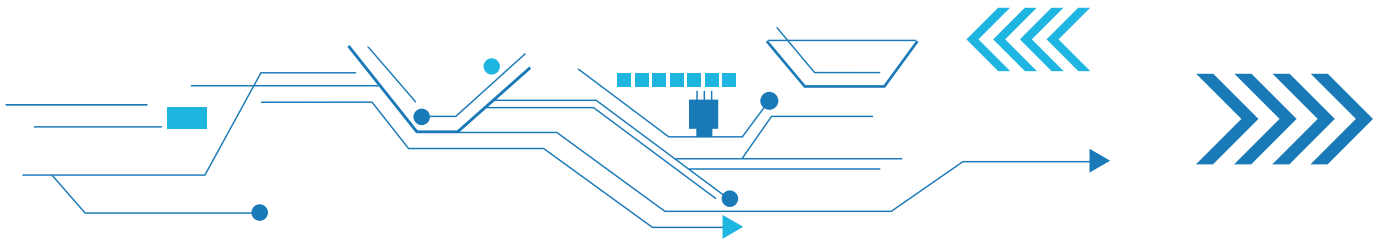
varying dose schedules, lifetime radiation dosages, and clinical trials often make oncology resistant to the efficiencies and improvements typically gained in large-scale technology deployments. Conversely, oncology's multimodal, multidisciplinary nature makes it a healthcare specialty with a tremendous amount to gain from a fully coordinated, data-sharing IT ecosystem.

With this understanding, enlightened leaders should begin IT strategy exploration by engaging a team with a robust oncology perspective, including representation from medical, surgical, and radiation oncologists and allied health professionals. This team is charged with assessing the gaps in the current environment and identifying a set of solutions that can deliver an exceptional oncology experience, integrated with the enterprise's broader delivery network.

Enlightened leadership also recognizes and guards against the temptation to jump directly to solutions. The process of developing a robust IT strategy in oncology requires a deliberate approach (Figure 1, below), which often includes a months-long process

of strategic discovery, market evaluation, and eventual vendor solicitation and evaluation. While this timeline may seem like a luxury, the guiding principle should be to preserve a process that allows sufficient time for proper analysis of current and future oncology environments prior to shopping for solutions.
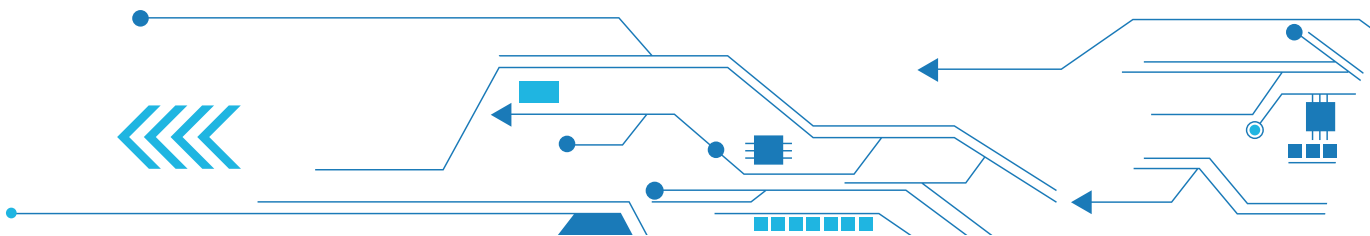
Phase I. Discovery

An oncology IT strategy should begin with an understanding—at an expert level—of how technology influences clinical decisions and the workflow of all stakeholders in the cancer value chain. This will change within each environment, as unique workflow concerns, systems limitations, and physician preferences make the knowledge highly specific. For that reason, discovery is the first phase of oncology IT strategy development. This can be segmented into the following steps.

Engaging Stakeholders. The primary key to success—fully engaged stakeholders—is to enlist an engaged Steering Committee. Composed of physicians, allied professionals, and revenue cycle

Figure 1. Sample IT Project Timeline

Q2 2016 PHASE I	PHASE II	PHASE III Q2 2017
Formation of Oncology IT Steering Committee	Formal IT requirements for oncology solution set(s)	Preparation and distribution of RFP(s) to target vendors
Inventory of all IT systems deployed in oncology environments	Workshop to refine requirements and target vendors	Onsite vendor demonstrations and use-case scenarios
Workflow mapping with key oncology constituents	Market scan of oncology-specific IT solutions	Site visits to deployed environments for final evaluation
Interviews with oncology constituents	Matrix of vendors and solutions with high-level workflow and IT deployment considerations	Selection and negotiation of solution(s)
Development of synthesized oncology gap analysis	Evaluate solution sets with Oncology IT Committee	
Determination of future-state oncology business architecture		

and IT leadership, the committee should be right-sized to the organization. Likely members include medical oncology, infusion, radiation oncology, pharmacy, pathology, radiology, surgery, inpatient nursing, billing, and IT. The Steering Committee should meet monthly, at a minimum, and review the timeline and deliverables associated with each phase of the IT strategy.

Defining a Common Vocabulary. Discovery is best facilitated with the Steering Committee and other key stakeholders speaking the same language. For this reason achieving early buy-in on a common vocabulary for clinical workflow and IT concepts is critical. Often dissonance in conversations around oncology IT is caused by confusion in terminology. Which care environments are covered under "oncology?" What is an "IT system" and what does it affect or enable? How does the "technology architecture" support the requirements of the "business architecture," including clinical and administrative workflow?

Ecosystem and Workflow. The next step is to thoroughly understand the existing cancer care environment(s). This involves documenting "current state" clinical and operational workflows and noting all key touch points with information technology—both hardware and software. Typically this discovery process will uncover a host of complaints and process breakdowns that will need to be remedied, which should be documented as part of the exercise. The detailed review of systems and workflow allows the Steering Committee to capture the nuances of each care environment and begin the process of designing a more optimal solution for workflow and information capture requirements.

Creation of an Oncology IT Gap Analysis. The aggregation of current state information typically produces a litany of process breakdowns, wish-list items, and needs being underserved by existing system capabilities. In addition to current-state information, the Steering Committee must extrapolate beyond what was heard in the interviews and consider the current system's ability to handle challenges on the horizon. What likely future challenges may arise as further digitization, data-intensive workflows, cost

Table 1. Gap Analysis Categories	
DATA INTEGRATION	In many healthcare systems a "best of breed" IT strategy requires a significant amount of work to create data connectivity. Gaps tend to revolve around lack of clinically relevant information available at the point of care, as well as deficiencies in data governance, or physicians calling the same data different names across multiple systems.
PATIENT & PHYSICIAN EXPERIENCE	Gaps are typically perceived between the current care process and what the team envisions as a personalized, intuitive approach to care that leverages modern technology so that patients and families can be engaged in the care process, rather than passive bystanders. Care experience gaps are often bundled into categories like way-finding, efficiency, patient engagement, access, safety, and personalization.
ONCOLOGY FUNCTIONALITY	Perceived gaps in workflow often relate to functional limitations of the software in place, or lack of education on existing software capabilities. For medical oncologists, this feedback often involves pain points in the EHR (e.g., redundant data entry, multiple clicks, buried screens, and disparate abilities).
DATA CAPTURE & REPORTING	Many healthcare organizations are increasingly interested in tracking and reporting on outcomes, cost of care, adherence to clinical pathways, operational efficiencies, and other metrics related to accreditations and marketing efforts for centers of excellence in oncology. The ability to aggregate and dissect this data is usually a major gap, and requires an IT strategy that emphasizes oncology-specific analytics.
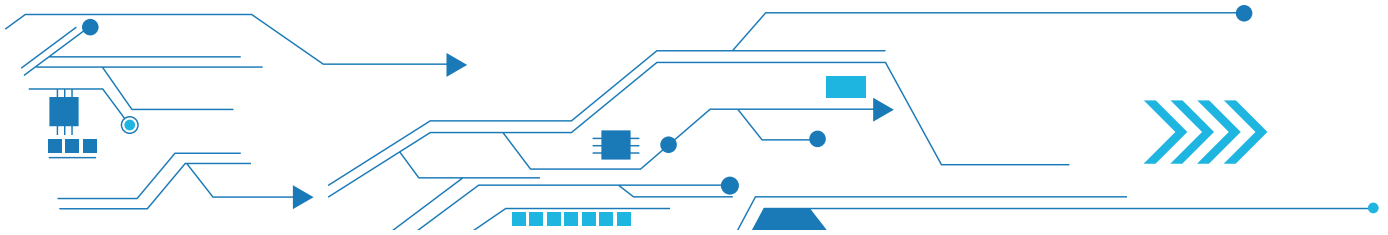
pressures, or government mandates emerge? Ideally the gap analysis is proactive in anticipating emerging trends, and not just reactive to current-state deficiencies. At a high level, gaps can be categorized along the continuum highlighted in Table 1, page 49.

> The most critical component of Phase II is ensuring that the EHR is specific to oncology—both in form and function. The oncology EHR is the central nervous system of the cancer center and drives the flexibility or inflexibility of system architecture and downstream workflow.

Defining Future State Workflow and Business Architecture.
The end goal for discovery is to develop a "future state" architecture that will enable the cancer program to operate efficiently and safely and support positive patient outcomes. Many organizations fail at this, allowing their existing IT architecture to drive the processes in their cancer center, rather than designing the optimal cancer program and then searching for solutions that support their vision. Beware of this trap in the process and use the gap analysis to design optimal workflow and business processes before moving forward. Successful business architectures:

- Tell the story of the cancer program, including its mission, resources, and future aspirations
- Focus the Steering Committee and key stakeholders on important IT needs
- Drive vendor requirements
- Maintain focus on an oncology IT strategy that is uniquely tailored and uncompromising in its vision.

Phase II. Market Scan

This phase involves a process of developing requirements and soliciting vendors. Healthcare organizations commonly have trouble staying true to the vision within the constraints of market solutions, as well as managing the project timeline. To stay on track, the Steering Committee must translate the future state workflow and business needs into a set of functional requirements, i.e., a comprehensive list of your program's wants and needs. The

gaps in the architecture may drive a focus on functionality provided by an oncology-specific EHR, patient navigation software, data analytics, or a cancer patient portal. It may also focus on "next-gen" capabilities that rely on unstructured data capture, natural language processing, real-time decision support, or risk stratification. Whatever the need, the Steering Committee should scan the market for all available solutions, looking at both "best fit" and "best of breed" solutions, and evaluate them at a high level for harmony with the future state architecture and the health system's interoperability and performance standards.

Navigating the landscape of oncology IT software can be complex, but broadly consider if the vendor(s):

- Offer specific functionality that meets the needs of the future state architecture
- Meet requirements of accreditations and Meaningful Use
- Rank highly in industry reports, e.g., Black Book, KLAS, Truven
- Support workflow and deployment efforts consistent with organizational needs
- Fit within the broader hospital and/or healthcare system's IT strategy
- Have a proven base of customers that can serve as references in the evaluation stage.

The most critical component of Phase II is ensuring that the EHR is specific to oncology—both in form and function. The oncology EHR is the central nervous system of the cancer center and drives the flexibility or inflexibility of system architecture and downstream workflow. The EHR landscape is filled with software platforms that market a specialized ambulatory approach and, in actuality, have varying degrees of oncology-specificity, interoperability, and clinical effectiveness. Identifying an appropriate solution requires a broad cancer perspective on the requirements that can be met within the crowded solution set. Those vendors that meet the requirements should be short-listed and included in the request for proposal (RFP) invitation.

Phase III. System Selection

The final phase of the IT strategy involves system evaluation and selection. During this phase, the Steering Committee and clinical users, e.g., physicians, oncology nurses, radiation therapists, should drive the evaluation as to whether the solution set meets the needs and vision expressed in the future state architecture.

Phase III begins with issuing an RFP. The RFP should elicit an honest self-assessment from vendors about their ability to meet the functional requirements and their commitments to customer service, implementation support, and product upgrades.
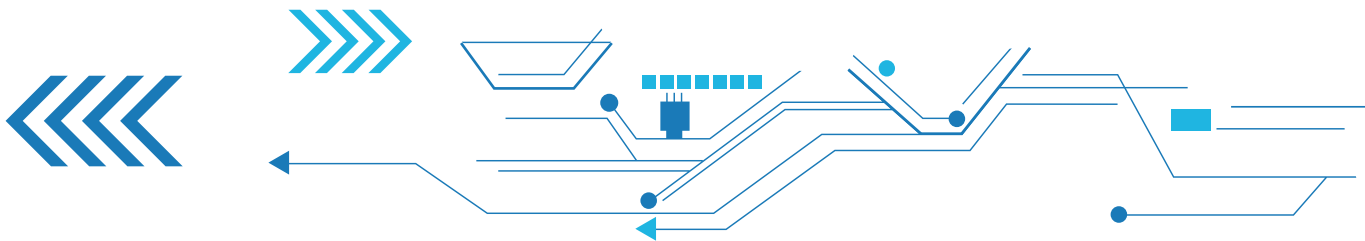
While these items may be dictated by service agreements, it is useful to understand the companies' philosophies and gauge their desire to grow with the cancer program, anticipate future program needs, and offer products that adapt to cancer industry trends.

After reviewing the RFPs, conduct remote and onsite demonstrations to test the validity of the vendors' self-assessments and to observe functionality first hand. The demo process is the most cumbersome portion of the IT strategy engagement, but also the most indispensable in terms of ensuring that system selection aligns with the cancer program's long-term vision. It is critical to prep the vendor with specific use-case scenarios that mimic real-life clinical oncology situations to discourage vendors from showcasing only their strongest features.

The final step in the evaluation process involves short-listing the vendors of interest and organizing site visits to environments where the solution(s) are deployed. At this point, the steering committee should be armed with all available knowledge and be prepared to make a purchase decision. The final system selection will often be driven by clinical champions, but in some cases may be facilitated by a selection algorithm that weighs various organizational priorities. Figure 2, below, shows an example of such an algorithm.

With vendors selected, the purchasing department can now take the reins and begin the process of negotiating the scope of work, service level agreements, and pricing with the vendor.

Wrap-Up

Some cancer programs around the country have successfully designed IT systems that align with best-practice patient experience and clinical outcomes. For many other cancer programs, IT remains a roadblock, rather than a facilitator. A key distinction between these two scenarios is the development of a vision, the recruitment of a committed group of stakeholders, and the perseverance to truly define and adhere to an IT roadmap for the organization. Oncology will continue to be defined by its data, and technology will continue to be a moving target, but healthcare systems equipped with robust IT strategies will be nimble, proactive, and far more effective in providing exceptional care to their patients. **OI**

Ryan Langdale, MBA, is partner, and Alex Glonek is a senior consultant at Oncology Solutions, Decatur, Ga.

Figure 2. IT Vendor Selection Algorithm

$$\text{VENDOR SCORE} = \text{Corporate Culture Score (weighted at 15\%)} + \text{Functionality (weighted at 25\%)} + \text{Business Risk (weighted at 25\%)} + \text{Price (weighted at 20\%)} + \frac{\text{Customer Base}}{\text{Number of Users (weighted at 15\%)}}$$

Note: Weighting will vary depending on institutional procurement requirements, but using an algorithm can drive some impartiality in that selection process

BY SARAH HALL

Investigating Radiodynamic Therapy to Treat The Untreatable

Fox Chase Cancer Center, Philadelphia, Pa., is in the process of acquiring advanced technology that is not available elsewhere in North America. This technology is based on a specialized accelerator known as a Racetrack Microtron, which delivers radiation at very high energies, offering treatment to a patient population that is often receiving only palliative care. Treatment consists of high-energy (45 MV) photon beams, in conjunction with a photosensitizing drug, which serves as the activation agent. Over the past few months, Fox Chase Cancer Center has been working with the manufacturer, Top Grade Medical, to install the Microtron equipment and begin the process of acquiring FDA approval for radiodynamic therapy (RDT) treatment of this new technology. Clinical trials to evaluate its therapeutic potential to treat patients who have previously exhausted other radiation treatments are in the initial stages.

A History Primer

A microtron is a combination of an electron accelerator and a cyclotron and was first developed in the early 1970s by Scanditronix, which also produced the first 50 MeV Racetrack Microtron.[1] The technology was established to destroy tumors at a higher energy, but it never quite lived up to its promise. After being sold a few times, the technology was purchased by a company called Top Grade Medical in Beijing, China.

The company discovered that the microtron (now referred to as the Racetrack Microtron LA45) could be paired with a photodynamic agent and used to target both bulky tumor volumes as a locoregional treatment or metastatic cancers as a systemic treatment, providing a new focus for this technology. For the purposes of this article, the Racetrack Microtron will be referred to as simply the Microtron.

> While we cannot force a photon to distinguish between normal and healthy tissue, we can use the methods described in this article to potentially arrive at the equivalent of a "smart bullet" for cancer therapy.

A Deep Dive into This Technology

The Microtron produces a range of photon energies from 5 to 45MV. While this system can be used for both conventional and advanced radiotherapy treatments, such as IMRT, the truly innovative treatment modality this unit affords is known as radiodynamic therapy (RDT). It is well known that certain tumors have an affinity for specific molecules

or compounds. These molecules can be tagged with or incorporated in certain non-carriers and substrates to form photosensitizers (e.g., 5-ALA, porphyrins) and injected into the patient. Following a site- and patient-specific time for tumor uptake, the Racetrack Microtron can be used to deliver a relatively low dose (several cGy for systemic treatment to several Gy for locoregional treatment) to the tumor as traditionally defined during the simulation process, which uses CT, MRI, PET, etc. (Gy, or gray, is basically defined as one unit of a radiation dose.) The oxygen component of the photosensitizer can be activated (become radioactive) by the photon energy. As the oxygen decays, the immediately adjacent cell structures (tumor cells have 10-20 times higher uptake of these photosensitizers) are irradiated and damaged, e.g., damage to mitochondria, DNA, and/or cell membranes.

Additionally, the photons generated can be detected using the gamma cameras of a PET scanner. Immediate image acquisition

on a PET/MRI scanner following irradiation allows for highly accurate soft tissue definition and a record of dose deposition. This data can be used to evaluate treatment delivery accuracy and/or to assess treatment effects, e.g., monitoring the changes in biochemical environment, such as hypoxia and metabolism.

Given the existing basic science departments at Fox Chase and their continued development of the aforementioned molecules or "markers," significant changes in how we treat cancer are possible. While we cannot force a photon to distinguish between normal and healthy tissue, we can use the methods described above to potentially arrive at the equivalent of a "smart bullet" for cancer therapy.

The name Microtron, itself, sounds like a science fiction character; however, Microtron is basically an intimidating name for a machine that accelerates electrons in a circular pattern (see Figure 1, left). A Racetrack Microtron is a Microtron that uses two magnets to stretch this circular pattern out resulting in what looks like a "racetrack pattern." The racetrack shape allows for a straighter path, which produces greater control when accelerating electrons (see Figure 2, right). For example, you have more control over a car when you are driving straight than when you are maneuvering corners. The repeated circular pattern allows for the electron acceleration to reach higher energies.

This technology differs from a standard linear accelerator, which accelerates electrons in a straight path (see Figure 3, page 54). The energy is gained by the electrons riding on the electromagnet waves, like surfing along the trajectory. Limited space restricts the amount of acceleration possible on a basic linear accelerator. In other words, if you had a linear accelerator the length of a bowling alley, you might be able to rev the engine up to 45 MeV, but the circular pattern generated by the Racetrack Microtron makes it less costly and more efficient.

When a 45 MeV electron beam hits a metal target, it generates a spectrum of photons with energies between 0 and 45 MeV, which is nominally called a 45 MV photon beam. Such high-energy photon beams have been found to be effective in activating photosensitizing drugs for RDT.

The Racetrack Microtron provides both the control and acceleration of electrons in order to reach higher MeV within a small space.

Photosensitizers & Photodynamic Therapy
Although the theory behind this technology is very complex, photodynamic therapy (PDT) has been around for more than 100 years.[3] These photosensitizing agents are taken into a patient's system and absorbed 10 to 20 times more by tumor cells than by normal tissues and metabolized similar to glucose. It is interesting to note here that cancer cells love sugar. These tumors are insatiable, sucking up anything that resembles sugar. Many tumor cells that absorb the photosensitizing agents also absorb glucose, and can

Figure 1. The Particle Trajectory of a Microtron

In this figure, the source is represented by the blue dot. The magnetic cavity, shown in gray, delivers small pulses which accelerate the electrons.[2] These electrons are contained by the magnetic field in orange, forcing it to move in a circular pattern until the optimal energy is gained, and delivered to the patient.
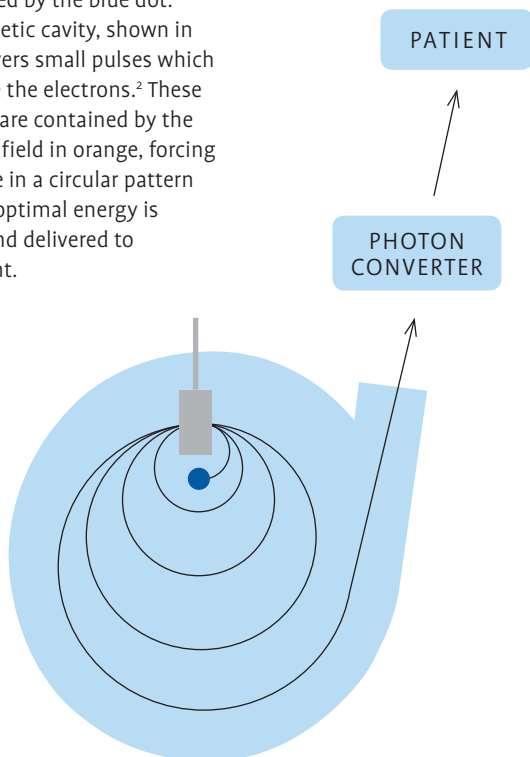
therefore be picked up by a PET scan. Anything visible on a PET also potentially absorbs photosensitizing agents and will automatically be targeted by the high-energy radiation in RDT.

In order to achieve the best therapeutic ratio, it is important to deliver the radiation dose when the photosensitizing agent has left the normal cells, but remains in the cancer cells. The therapeutic ratio is the ratio of tumor damage to normal tissue damage. The high-energy photon beams can be arranged in such a way that only the targeted treatment volume will receive a tumoricidal dose while sparing the nearby normal tissues.

There are a number of drugs that are used with PDT including 5-aminolevulinic acid (5-ALA) and Photofrin, which is currently being considered for use with RDT. 5-ALA is FDA-approved as a topical cream or lotion that is applied directly to the skin and typically used in conjunction with skin cancers. Photofrin is a type of porfimer sodium and is given intravenously and approved to treat esophageal and some lung cancers.[4]
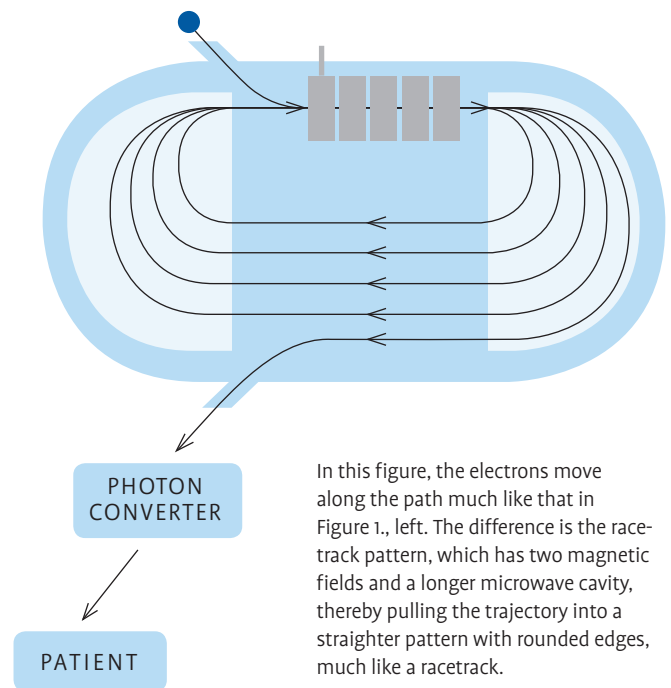
The Role of PET

A PET scanner is typically used in conjunction with fluorodeoxyglucose (FDG), which pinpoints any cell that is over utilizing or underutilizing glucose. As mentioned earlier, cancers need glucose. This means the tumor "glows" on a PET scan. Anything visible on a PET is also likely to absorb photosensitizing drugs more effectively than normal tissues and therefore will be targeted by the high energy radiation in RDT. This allows the physician to pinpoint the exact location of the tumor in order to develop a more precise dose distribution to destroy the tumor mass while minimizing side effects.

Providers use PET/FDG to find out where the tumor targets are located and then combine photosensitizing drugs, like 5-ALA, with high energy photon beams to destroy those tumors.[5] The differential 5-ALA absorption of metastatic tumor cells makes them easy targets when exposed to high-energy photon radiation. For bulky tumors, advanced treatment delivery techniques, such as IMRT, can be used to conform the high-energy photon radiation to the tumor volume, allowing higher radiation doses to be employed to those tumor cells that cannot reach ultimate drug concentration because of poorer circulation.

Treatment Implications

The literature indicates that the optimal time for the patient to receive RDT treatment is about 4 to 6 hours after the initial photosensitizing drug injection.[6] The total radiation dose varies from a few cGy for systemic treatments of metastases in the entire body, to several Gy for local or regional treatment of bulky tumors. The radiation rays hit the tumor cells, which have absorbed a heavy dose of the photosensitizing agent. Once exposed to these high energy waves, these agents will produce a collection of free radicals, including singlet oxygen that kill the cancer cells.

Figure 2. The Electron Trajectory of a Racetrack Microtron

In this figure, the electrons move along the path much like that in Figure 1., left. The difference is the racetrack pattern, which has two magnetic fields and a longer microwave cavity, thereby pulling the trajectory into a straighter pattern with rounded edges, much like a racetrack.

Historically, PDT could only treat tumors that could be reached by light. This means PDT was only effective on a surface about a few millimeters deep, restricting the treatment to skin cancers or the lining of organs. The Microtron unit allows radiation particles to penetrate the skin, tissues, and bones to activate photosensitizers in areas deep within the body, much like conventional radiation, except with the results of PDT.

This technology has great potential to open up entirely new treatment options. Now cancer patients receiving palliative care and those with minimal to no treatment options will be able to receive systemic, as well as loco-regional treatments, and, if international studies can be duplicated, see impressive results.

Side Effects

Side effects for RDT in general are minimal, similar to those with PDT. As mentioned earlier, photosensitizers make the patient very sensitive to light. This light sensitivity can continue for several weeks post-treatment and can affect the eyes and skin. Patients should remain away from harsh light, such as direct sunlight. Patients could potentially experience burning, swelling,

Figure 3. The Particle Trajectory of a Linear Accelerator

In this figure, the source, in blue, sends electrons that move in a wavelike pattern accelerated by oscillating charges created by the gray high-powered microwave.[2] Although there is more control of the electrons with a linear accelerator, there is only one straight path to accelerate. Therefore, the energy gained by an electron is limited, which is proportional to the path length.
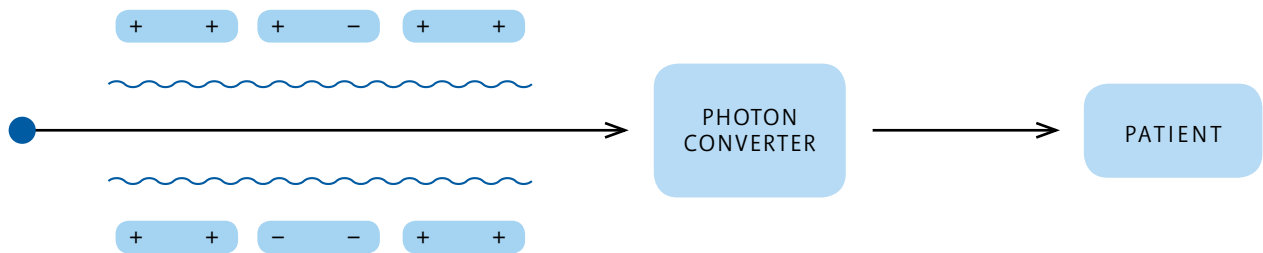
pain, scarring, or trouble swallowing, but minimal long-term effects or complications to healthy tissues overall.[4]

Study Outcomes

Microtron's clinical results emerging from China are promising for patients with late stage cancers of the brain, head and neck, breast, lung, liver, colon, prostate, and GYN cancers. At this point, no research has been published, so definitive data is not available. The technology is shown, however, to be very effective in animal studies. Tumors showed a significant response on PET within a week.[7] If these findings can be replicated in ongoing human trials, this technology could be an enormous game changer for the cancer community. It is anticipated that the research from China will be published within the year. **OI**

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BY TRACY C. WYANT, RN-BC, MSN, AOCN®, CHPN

Exploring the Issue of Cancer Drug Parity

Understanding the magnitude and underlying considerations surrounding the multidimensional and controversial issue of cancer drug parity is important for evaluating the value of cancer treatments and the impact of related legislative efforts. This article offers a snapshot of where we are today on the issue of cancer drug parity, including implications for patient care.

Oral Therapies to Treat Cancer

Innovative discoveries in cancer treatment have led to the development and approval of more than 40 orally administered anticancer agents in the U.S. While many cancer therapies continue to be administered by infusion and injection, oral agents have indications to treat more than 50 types of cancer.[1,2] Experts estimate between 25 and 50 percent of oncolytics currently being studied are orally administered "smart" or targeted agents.[2,3-6] While targeted oral therapies are cutting-edge advancements in personalized healthcare, creating more treatment options for refractory and recurrent disease, their use increases the complexity of treatment and is not without controversy.

With the focus on patient-centered care, the decision to treat cancer with oral agents greatly impacts shared decision making due to physical, psychosocial, economic, and organizational factors. The value of treatment across each of these domains is important to consider.[2,7,8] Physically and psychosocially, oral antineoplastics are widely perceived to enhance patient quality of life due to convenience in self-administration, lower work absenteeism, and increased survivorship. However, home administration highlights concerns related to patient self-reporting of side effects, the potential for incorrect self-dosing, and safe handling issues for agents with hazardous characteristics.[2,4,5,6,9] Furthermore, most of these agents are novel targeted biotherapies, costing more to develop. These oral agents are priced higher than those administered by other routes, traditional chemotherapy, and drugs with generic equivalents, and they fall into the highest formulary cost tiers.[2-6, 9-12]

> Policymaker recognition of the rapid rise in patient financial responsibility for cancer treatments is promising, yet more aggressive advocacy and cost management are needed.

The economic issue is complicated by the multiple payment, reimbursement, and incentivization channels in the U.S., which vary depending on care setting. Dispensing oral therapies typically occurs in a pharmacy while injected treatments are administered in a clinical care setting. As a result, injected antineoplastics are usually covered through medical health plans, while orally administered cancer therapies are often covered by prescription drug plans. When compared to medical plans, cost-sharing may be substantially higher for agents with no generic equivalent and paid through prescription drug plans. The most expensive oral

cancer treatments carry high compulsory cost-sharing.[2-6,9,10,12] Some plans require up to a 30 percent cost-sharing rate.[2,4,8] The difference in dispensing settings and cost has created disproportionate payment for patients by some insurance plans.

Cancer Drug Parity Legislation

"Parity" refers to equality in cost-sharing between different routes of medication administration. Many states have addressed this issue by enacting oral parity laws. According to the Patients Equal Access Coalition (PEAC), as of January 2016, 40 states plus the District of Columbia have enacted cancer drug parity legislation, with 5 more states actively working to pass similar legislation. State fact sheets can be viewed and printed to share with community oncologists on the PEAC website: peac.myeloma.org.

Essentially, state-based oral parity laws affect insurance pricing to the consumer; pricing set by drug companies is not restricted.[3,5,6] State rulings affect only plans already offering coverage for antineoplastics, requiring equal cost-sharing for oral cancer therapies as for cancer drugs administered by other routes.[2-6,9,10,12] In a few states parity laws differ, placing out-of-pocket caps on expenditures.[13] Additionally, cancer drug parity laws prevent insurers from adjusting costs of injected cancer drugs to balance increased coverage of oral therapies.[2-6,9,10,12]

It is important to note that state cancer drug oral parity legislation primarily affects private, small group, and state-based insurance policies. These laws do not apply to patients covered by the Employee Retirement Income Security Act of 1974 (ERISA) or by Medicare. (Patients need to opt into Medicare Part D for outpatient prescription drug coverage.) Traditionally, Medicare reimburses for drugs administered in a clinical setting. Reimbursement for self-administration is limited to certain agents, diseases, and situations. Strict criteria determine whether oral anticancer agents are reimbursed, and prior authorization is required.[3,4,6,9,12] Furthermore, the Medicare threshold price for many anticancer drugs is quickly reached in regimens with multiple treatment cycles.

Federal Initiatives

As stated above, cancer patients insured by federal health plans are not covered by oral parity laws enacted at the state level.[13] Thus, action at the federal level is still needed. The most recent Congressional activity involves the bipartisan Cancer Drug Coverage Parity Act of 2015 introduced by Congressman Leonard Lance (R-NJ), Congressman Brian Higgins (D-NY), Senator Mark Kirk (R-IL), and Senator Al Franken (D-MN). Supporters believe that enacting cancer drug parity at the federal level will equalize coverage to include federal insurance recipients, and will benefit states without parity legislation. The outcomes of this parity bill are aimed at group and individual insurers to require equal or "no less favorable" coverage for all prescribed antineoplastics

meeting guidelines for clinical necessity and appropriateness regardless of administration route or setting. Similar to state acts, the bill proposes to ban insurers from creating situations of noncompliance and from imposing increased cost-sharing or limitations on other anticancer medications to counterbalance the oral drug costs. According to Leslie Brady, Health Policy Advisor to Rep. Higgins, the bill is hoped to be a starting point that eventually includes a re-evaluation of federal insurance plans specific to anticancer agents.[14,15]

> Some experts question the value and convenience of newer oral cancer therapies due to the higher cost being transferred to consumers upon drug approval, referring to this as "financial toxicity."[7,8,19]

Collaboration for Change

Policymaker recognition of the rapid rise in patient financial responsibility for cancer treatments is promising, yet more aggressive advocacy and cost management are needed. Patients and providers must be able to measure the value-based benefits of therapeutic agents and understand cost stipulations to facilitate collaborative treatment decision-making. As discussed above, the quality and value of care are impacted by underlying factors that determine the rapid rate of therapy development, importance of treatment compliance, and appropriateness of treatment regimens in vulnerable populations. Delving deeper into these factors may assist in improving collaborative advocacy efforts pushing for drug parity in cancer care.

Accessibility & Cost Control

The Institute for Healthcare Improvement (IHI) approaches optimizing the health system based on the "Triple Aim." The framework pursues improvement of the patient experience (quality and satisfaction), improvement in population health, and reduction in healthcare costs.[16] The Affordable Care Act (ACA) includes provisions that medical treatments are accessible and affordable with expanded drug coverage, decision-making is shared, and therapies are based on clinical necessity. Access to innovative therapies, such as biologic oncolytics, includes a time-sensitive pathway for development of generic medications. The ACA also expands incentives to enable hospitals

to obtain cancer treatment medications for their formularies at discounted prices.[17]

While both the Triple Aim and ACA set forth general provisions to limit treatment costs, specific metrics for determining accessibility and affordability are lacking. New oncologic agents may not be universally covered. Consumer pricing is addressed with varying details of out-of-pocket cost capping. Determining treatment necessity is unclear with the exception that decisions are not based on life expectancy. Lastly, discount pricing for hospitals does not apply to private oncology practices.[18] These issues generate concern and are partially driving state drug parity initiatives.[2,18]

While some insurers and a few state cancer drug parity laws limit consumer cost-sharing, no capping or benchmark pricing exists for costs set by pharmaceutical companies in the U.S. The price of a drug is dependent on who may use it and the market share based on patient volume. Greater volume initiates lower pricing and lesser cost to the patient. Most innovative cancer therapies are biologic agents, costing more to develop than traditional therapies. Some experts question the value and convenience of newer oral cancer therapies due to the higher cost being transferred to consumers upon drug approval, referring to this as "financial toxicity."[7,8,19] While drug companies offer payment assistance programs aimed to alleviate cost burdens for patients, many of these programs are not comprehensive, are difficult to navigate, and have time-intensive application processes.[20,21] ACCC has developed two key resources to help meet these challenges: the *2016 Patient Assistance and Reimbursement Guide* (accc-cancer.org/PatientAssistanceGuide) and the Financial Advocacy Network (accc-cancer.org/FAN).

Reimbursement is another cost-controlling issue that is increasingly dependent on and incentivized based on prescribing of standard of care treatments. Pharmacies and healthcare organizations are often offered discounted drugs that may have less efficacy but are more affordable.[1,2,5,8,9,22] Recently, two large U.S. managed care pharmacies removed specific drugs from formulary after pharmaceutical companies denied requests for price cuts. Provider complaints then resulted in pharmaceutical companies lowering drug prices to attain formulary status once again.[6] Also, the growing use of specialty pharmacies may impact price negotiations and the work of traditional retail pharmacies.[23]

Patient Outcomes & Quality of Life

Cancer patients and their families have healthcare expectations, including treatment standards based on efficacy, quality of life, safety, and financial considerations. Patients routinely desire to receive treatment considered to have the best outcomes, sometimes regardless of cost or side effects. Most standard regimens include quality-of-life data in post-marketing studies; however, economic data is rarely collected. Treatment standards do not consider

value of options, such as cost of care, influence of disparities and culture, patient preference, or compliance issues. Furthermore, life expectancy is not considered in most treatment standards.[1,2,7,10]

Lastly, many parity advocates believe oral agents offer greater quality of life, including the convenience of at home self-administration, decreased travel expense, fewer work hours lost, and avoidance of infusions with potential risk for infection and extravasation.[4,5,9,12,20] However, in some cases, convenience of oral agents and infusion risks are not true issues, as there may be no other choice for treatment, or no equivalent administration route options.[2,20] Travel and time may be a priority depending on patient performance status, work and home life, and geographic location. Clear communication is critical to addressing quality of life issues when considering appropriate route of administration.[3,20,21]

Patient Safety, Compliance & Satisfaction

Safety issues in managing oral drug therapy include monitoring treatment adherence and compliance; reporting, assessing, and managing toxicities; assessing for drug interactions; and safe handling of hazardous oral agents.[5,12,24,25] Adherence issues are most problematic because of complex dosing schedules. Survival and well-being may depend on precise administration, and studies indicate up to 80 percent of patients do not take oral oncolytics as prescribed. This overuse, underuse, or misuse may result in greater risk for complications and treatment failure.[2,8]

At home administration requires specific, intense, and ongoing educational efforts to optimize patient self-reporting of complications and other issues that may arise. Community or home-based caregivers may be needed. Staff availability and training to triage incoming calls and monitor electronic communication from patients must be considered as the use of oral agents increases with or without cancer parity legislation.[3,6] Patient involvement in planning care and follow-up is vital to success.[3,20,21]

Proponents & Opponents of Cancer Drug Parity

Proponents of cancer drug parity legislation primarily focus on easing the cost burden for patients whose best treatment option includes an oral agent. Simply put, without parity laws some patients cannot afford to pay for cancer treatment. As a result, providers may not be able to prescribe optimal therapies based on clinical guidelines and considered standard of care.[1,2]

Opponents believe the issue is important but needs to include stipulations related to the value of treatment and cost of drugs assessed by pharmaceutical companies.[6,8,9,26] Concerns also exist related to the increased use of oral antineoplastics, specifically safety and care related to adherence and proper use.[5,12] With parity legislation, many insurers face a surge in cost for oral cancer drugs; use of treatments with higher costs are usually

Table 1. Key Stakeholder Position Statements Related to the Cost of Cancer Care

- **American Society of Clinical Oncology (ASCO).** The healthcare system is "not integrated, is poorly coordinated, and values clinical interventions, the uses of advanced technology, and cognitive care in markedly different ways."[27]

- **Association of Community Cancer Centers (ACCC).** The Association advocates for quality comprehensive cancer care for all, including passing legislation at the state and federal level that would require health insurance plans to cover orally administered chemotherapy at the same rate as IV-infused counterparts.[28]

- **The Institute of Medicine (IOM).** Providers must supply patients with "understandable information at key decision points on such matters as cancer prognosis, treatment benefits and harms, palliative care, psychosocial support, and costs of care."[7]

- **The Oncology Nursing Society (ONS).** Posits that healthcare should be accessible and affordable with coverage that "includes consumer choice and control, including providing the patient with information about the cost of treatment options and allowing for informed treatment decisions."[29]

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dissuaded by most payers.[4] However, without parity legislation, increased care costs may be incurred due to less effective treatment options that lead to recurrence or complications.[20]

Various organizations have tackled the issue of treatment cost as it relates to information-sharing, patient engagement in decision-making, and quality outcomes. Table 1, above, offers excerpts from key position statements that help guide professional standards, including ethical considerations for quality care.

Advocating for Change

Advocating for cancer drug parity legislation with amendment recommendations from community cancer centers may bolster support for the issue at the federal level. Based on the evidence and literature in support of cancer drug parity, amendments may include:

- Accountability for and measurement of implementation, evaluation, and compliance processes
- Resources for determination of medical necessity and clinical appropriateness for the entire treatment plan
- Incentives for compliance and sanctions for noncompliance
- A timeline with tools and resources to address healthcare literacy with participant notification.

Alternative or additional proposals to consider based on information presented include:

- Measures and stipulations regarding cost-sharing limits
- Inclusion of adequate supplying of supportive care agents

- Immersion of economic disparities in clinical guideline development
- Recommendations for service coding changes
- Negotiations, price caps, and benchmarks for pharmaceuticals
- Timeline development changes for generic equivalents.

Interest in passing oral parity legislation at the federal level remains high and is expected to move forward in 2016. ◖◗

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action

ACCC Launches Metastatic Breast Cancer Education Project

An estimated 150,000 to 250,000 women in the U.S. are currently living with metastatic breast cancer—an incurable condition. These individuals have few treatment options, and their median survival is three years. In fact, the number of number of women dying from metastatic breast cancer has remained steady at about 40,000 annually since the 1970s.[1] While breast cancer is a high-profile disease, receiving significant private and public research funding and focused awareness and prevention initiatives, patients with metastatic breast cancer face unique challenges. According to the Metastatic Breast Cancer (MBC) Alliance "public messaging about the [breast cancer] 'cure' and survivorship is so pervasive that people diagnosed at stage IV with metastatic breast cancer can be stigmatized by the perception that they've failed to take care of themselves or undergo annual screening."[2] In addition, many metastatic breast cancer patients face a number of communication challenges, including:

- A perception that their cancer is curable, driven in part by a low-level of engagement during conversations with providers
- Providers who use overly vague or overly technical medical language
- Providers who may "minimize" the severity of the disease, perhaps in efforts to reduce patient distress or help patients stay positive, engaged, and compliant with treatment recommendations.

Project Deliverables

With this education project, ACCC seeks to address these challenges. Specific project goals: 1) to expand the current breast cancer conversation to address gaps between early and metastatic disease and 2) to improve the treatment and management of metastatic breast cancer in the community setting. Project deliverables include:

- An environmental scan of the current state of metastatic breast cancer treatment and patient management
- Site visits to programs that exhibit effective practices in metastatic breast cancer treatment and patient management
- Access to Cancer Support Community's Cancer Experience Registry: Metastatic Breast Cancer
- Education materials geared towards the multidisciplinary cancer care team
- A project-specific webpage and app
- A workbook to educate members of the multidisciplinary cancer care team about effective practices for this unique patient population.
- And—in 2017—development of operational pathways to help ACCC member programs improve the treatment and management of individuals with metastatic breast cancer.

A Call to Action

If your cancer center has strong support programs in place to meet the unique needs of metastatic breast cancer patients, or if you would like to participate in the development of effective practices and operational pathways to improve the management and treatment of this patient population, email mgandee@accc-cancer.org. Be a part of effecting positive change today!

ACCC is pleased to partner with the MBC Alliance (mbcalliance.org) and the Cancer Support Community (cancersupport-community.org) on this education project. Stay tuned for more information! ◼️

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views

Bike Loud

BY DAVID MARGOLIES

I n the fall of 2014, seven boy scouts and six leaders from Troop 845 of Chapel Hill/Carrboro, North Carolina, decided that the next summer we were going to accomplish our long-standing, ambitious goal of cycling across the United States—without vehicle support. While the ride has been a troop tradition for more than a decade, it's more than just a custom. The ride has always been completed on behalf of a cause that makes the 4,000 miles of hard pedaling worthwhile! Our group believed that there was no better cause than the *Be Loud! Sophie Foundation* (beloudsophie.org) to represent and promote as we made our way from Florence, Oregon, to Wrightsville Beach, North Carolina, in the summer of 2015.

Meet Sophie

Be Loud! Sophie Foundation is a non-profit inspired by Sophie Steiner who at the age of 14 was diagnosed with a rare form of germ cell cancer. While undergoing intensive treatment at UNC Health Care, Sophie remained incredibly positive and brave. In and out of the hospital, Sophie and her parents made great efforts to maintain a sense of normalcy and not let Sophie's condition impede her participation in the activities she loved so much. The Steiner family spent weekends at the beach, arranged for Sophie to meet her favorite band (The Avett Brothers), made sure she could attend her big sister's high school graduation, and much more. Sophie even took the strength and initiative to walk the length of a marathon by doing 700 laps within the halls of the bone-marrow unit at UNC Hospitals.

Despite treatments and the best efforts of everyone involved, Sophie Steiner passed away in the summer of 2013. Before she died, however, Sophie expressed a desire to help adolescents and young adults diagnosed with cancer and their families. She specifically wanted to help young cancer patients stay true to their authentic selves in the face of overwhelming illness. Too often, teen and young adult cancer patients are treated in pediatric hospitals designed with young children in mind, or in adult hospitals alongside elderly cancer patients. These patients often feel like they are receiving treatment in a "no man's land" where their particular needs are not supported. *Be Loud! Sophie Foundation* was created to address this need.

Meet Lauren

The Steiners decided that the best way to make Sophie's dream a reality was to have a person at the hospital entirely dedicated to meeting the unique needs of adolescent and young adult cancer patients, helping them to maintain their identity, to keep in touch with their friends, and to be treated as the emerging adults they are. Through the efforts of the Steiner family and many supporters, UNC Hospitals hired a full-time teen and young adult liaison. Lauren Lux, MSW, is a licensed, experienced social worker who firmly believes in the cause she is working for. Together with Don Rosenstein, MD, the director of UNC's Lineberger Comprehensive Cancer Support Program, and Stuart Gold, MD, chief of Pediatric Oncology at UNC Children's Hospital, Lauren is building a research-

based support program designed to advance our national understanding of how best to meet the unique needs of patients in this diverse age group.

Bike Loud!

As we biked our way across the continent, many of the people we encountered asked the simple question: *"Why?"* Why would seven boys want to spend their summer away from home on the back roads and in the small towns of America? Out on the road there was no shortage of time for each of us to contemplate the underlying reasons behind our motivation for getting up and biking in the heat, wind, and rain, going to sleep, and doing it all again the next day. As the initial excitement of being out on the road faded, the true colors of "Bike Loud" began to emerge. Despite not knowing Sophie well, our crew members felt that a part of her was ingrained in each one of us. For example, we knew that in seventh grade, Sophie wrote a poem that read in part:

> *"...Be loud*
> *And move with grace*
> *Explode with light*
> *Have no fear..."*

Sophie's poem matched her personality. She was fearless, funny, direct, soulful, compassionate, adventurous, creative, headstrong, and, most of all, brave. Sophie wanted to create a lasting legacy to help others, and helping that cause was the unifying factor and motivation behind our "Bike Loud" trip. In short, the trip was for Sophie.

The Sophie Effect

As we stopped in small towns across the country for food, rest, or both, our team fielded many questions about what we were doing—most likely because of our bright yellow shirts. When we explained our trip, the mission of the *Be Loud! Sophie Foundation*, and our goal to raise $100,000 for the foundation, incredible things happened. People would randomly give donations to the Foundation in cash, pick up our tab at a restaurant, or even let us stay in their home. The *Be Loud! Sophie Foundation* had a very powerful effect on people. The cause touched the hearts of almost everyone we met and prompted so much generosity. Our bike trip helped spread the message of the *Be Loud! Sophie Foundation* across America and create a newfound sense of awareness about adolescent cancer, and what can be done to reduce the toll it takes on patients and their families.

It is often said that the brightest flames burn quickest, and Sophie Steiner was one of those flames. Although her life was short, she inspired the creation of an extremely meaningful charity that will continue to help adolescent and young adult cancer patients for years to come. Myself (David Margolies), Will Owen, Brian Richardson, Max Morgan, Sam Billings, Andrew De Figueiredo, and Alex Broz, and our leaders, Ed Billings, Dean Broz, Karl Murphy, John De Figueiredo, David Hardy, and Steve Rothwell, are honored to be fortunate enough to be a part of this incredible cause. To date, we have raised more than $40,000. To help us reach our goal of $100,000, and to read more about our "Bike Loud" trip please visit us at bikeloud.org. ◙

David Margolies is 16 years old and attends East Chapel Hill High School in Chapel Hill, N.C. He plans to continue cycling and will pursue studies in business at college.

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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.