ONCOLOGY ISSUES

The Journal of the Association of Community Cancer Centers
January | February 2015

Molecular Testing in the Community Oncology Setting

GRANIX™
(TBO-FILGRASTIM)
Injection

Take a bite out of G-CSF acquisition costs*

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

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

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

†Biologics License Application.
‡As of February 2014.

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

Indication

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

Important Safety Information

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

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

For more information, visit GRANIXhcp.com.

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

TEVA Oncology

GRANIX™
(TBO-FILGRASTIM)
Injection

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

SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Splenic Rupture

Splenic rupture, including fatal cases, can occur following administration of human granulocyte colony-stimulating factors. In patients who report upper abdominal or shoulder pain after receiving GRANIX, discontinue GRANIX and evaluate for an enlarged spleen or splenic rupture.

5.2 Acute Respiratory Distress Syndrome (ARDS)

Acute respiratory distress syndrome (ARDS) can occur in patients receiving human granulocyte colony-stimulating factors. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving GRANIX, for ARDS. Discontinue GRANIX in patients with ARDS.

5.3 Allergic Reactions

Serious allergic reactions including anaphylaxis can occur in patients receiving human granulocyte colony-stimulating factors. Reactions can occur on initial exposure. The administration of antihistamines, steroids, bronchodilators, and/or epinephrine may reduce the severity of the reactions. Permanently discontinue GRANIX in patients with serious allergic reactions. Do not administer GRANIX to patients with a history of serious allergic reactions to filgrastim or pegfilgrastim.

5.4 Use in Patients with Sickle Cell Disease

Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disease receiving human granulocyte colony-stimulating factors. Consider the potential risks and benefits prior to the administration of human granulocyte colony-stimulating factors in patients with sickle cell disease. Discontinue GRANIX in patients undergoing a sickle cell crisis.

5.5 Potential for Tumor Growth Stimulatory Effects on Malignant Cells

The granulocyte colony-stimulating factor (G-CSF) receptor through which GRANIX acts has been found on tumor cell lines. The possibility that GRANIX acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which GRANIX is not approved, cannot be excluded.

6 ADVERSE REACTIONS

The following potential serious adverse reactions are discussed in greater detail in other sections of the labeling:

- Splenic Rupture [*see Warnings and Precautions (5.1)*]
- Acute Respiratory Distress Syndrome [*see Warnings and Precautions (5.2)*]
- Serious Allergic Reactions [*see Warnings and Precautions (5.3)*]
- Use in Patients with Sickle Cell Disease [*see Warnings and Precautions (5.4)*]
- Potential for Tumor Growth Stimulatory Effects on Malignant Cells [*see Warnings and Precautions (5.5)*]

The most common treatment-emergent adverse reaction that occurred at an incidence of at least 1% or greater in patients treated with GRANIX at the recommended dose and was numerically two times more frequent than in the placebo group was bone pain.

6.1 Clinical Trials Experience

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

GRANIX clinical trials safety data are based upon the results of three randomized clinical trials in patients receiving myeloablative chemotherapy for breast cancer (N=348), lung cancer (N=240) and non-Hodgkin's lymphoma (N=92). In the breast cancer study, 99% of patients were female, the median age was 50 years, and 86% of patients were Caucasian. In the lung cancer study, 80% of patients were male, the median age was 58 years, and 95% of patients were Caucasian. In the non-Hodgkin's lymphoma study, 52% of patients were male, the median age was 55 years, and 88% of patients were Caucasian. In all three studies a placebo (Cycle 1 of the breast cancer study only) or a non-US-approved filgrastim product were used as controls. Both GRANIX and the non-US-approved filgrastim product were administered at 5 mcg/kg subcutaneously once daily beginning one day after chemotherapy for at least five days and continued to a maximum of 14 days or until an ANC of ≥10,000 x 10^6/L after nadir was reached.

Bone pain was the most frequent treatment-emergent adverse reaction that occurred in at least 1% or greater in patients treated with GRANIX at the recommended dose and was numerically two times more frequent than in the placebo group. The overall incidence of bone pain in Cycle 1 of treatment was 3.4% (3.4% GRANIX, 1.4% placebo, 7.5% non-US-approved filgrastim product).

Leukocytosis

In clinical studies, leukocytosis (WBC counts > 100,000 x 10^6/L) was observed in less than 1% patients with non-myeloid malignancies receiving GRANIX. No complications attributable to leukocytosis were reported in clinical studies.

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The incidence of antibody development in patients receiving GRANIX has not been adequately determined.

7 DRUG INTERACTIONS

No formal drug interaction studies between GRANIX and other drugs have been performed.

Drugs which may potentiate the release of neutrophils, such as lithium, should be used with caution.

Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting bone-imaging results.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

There are no adequate and well-controlled studies of GRANIX in pregnant women. In an embryofetal developmental study, treatment of pregnant rabbits with tbo-filgrastim resulted in adverse embryofetal findings, including increased spontaneous abortion and fetal malformations at a maternally toxic dose. GRANIX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

In the embryofetal developmental study, pregnant rabbits were administered subcutaneous doses of tbo-filgrastim during the period of organogenesis at 1, 10 and 100 mcg/kg/day. Increased abortions were evident in rabbits treated with tbo-filgrastim at 100 mcg/kg/day. This dose was maternally toxic as demonstrated by reduced body weight. Other embryofetal findings at this dose level consisted of post-implantation loss, decrease in mean live litter size and fetal weight, and fetal malformations such as malformed hindlimbs and cleft palate. The dose of 100 mcg/kg/day corresponds to a systemic exposure ($AUC_{0\text{-}24}$) of approximately 50-90 times the exposures observed in patients treated with the clinical tbo-filgrastim dose of 5 mcg/kg/day.

8.3 Nursing Mothers

It is not known whether tbo-filgrastim is secreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when GRANIX is administered to a nursing woman. Other recombinant G-CSF products are poorly secreted in breast milk and G-CSF is not orally absorbed by neonates.

8.4 Pediatric Use

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

8.5 Geriatric Use

Among 677 cancer patients enrolled in clinical trials of GRANIX, a total of 111 patients were 65 years of age and older. No overall differences in safety or effectiveness were observed between patients age 65 and older and younger patients.

8.6 Renal Impairment

The safety and efficacy of GRANIX have not been studied in patients with moderate or severe renal impairment. No dose adjustment is recommended for patients with mild renal impairment.

8.7 Hepatic Impairment

The safety and efficacy of GRANIX have not been studied in patients with hepatic impairment.

10 OVERDOSAGE

No case of overdose has been reported.

TEVA Oncology

Manufactured by:
Sicor Biotech UAB
Vilnius, Lithuania
U.S. License No. 1803

Distributed by:
Teva Pharmaceuticals USA, Inc.
North Wales, PA 19454

Product of Israel
GRX-40189 January 2014

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

insightful cancer data
at your fingertips

CHAMPS insight$_2$oncology™

Transform your cancer data into actionable information for strategic planning, operational and financial decisions with CHAMPS Oncology's new web-based system.

insight$_2$oncology™ provides you with a new perspective of your current market position and the unique insight to manage and improve your cancer services.

i$_2$o™ allows you to collaborate with CHAMPS to analyze and interpret your cancer data in order to identify gaps, retain and attract patients, and make informed decisions with confidence.

"CHAMPS i$_2$o™ is changing the way our healthcare system is managing its practices both operationally and strategically," said one i$_2$o™ beta tester.

CHAMPS Oncology

select client launch - 2015 | insight2oncology.com

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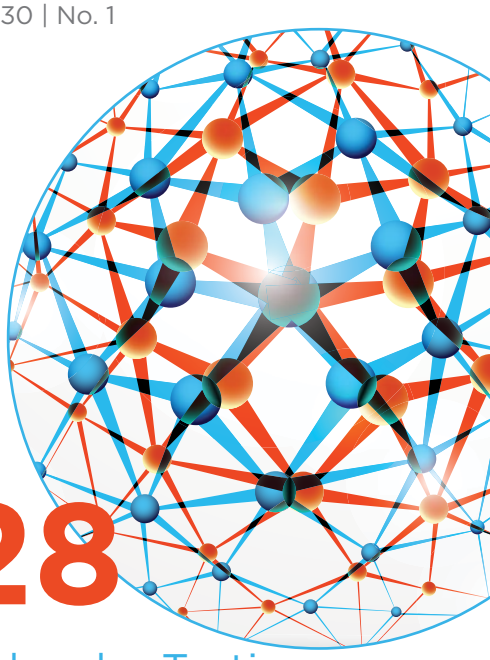

DEPARTMENTS

ACCC
Association of Community Cancer Centers

ONCOLOGY ISSUES

The Journal of the
Association of Community Cancer Centers

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

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

FROM THE EDITOR

Try It On For Size

BY CHRISTIAN DOWNS, JD, MHA

When I first started in healthcare 20 years ago, I worked for a mid-sized health system made up of a large teaching hospital and several rural facilities. When I would visit the rural locations, a common refrain I would hear is "We don't do that here; we send those patients to the 'big' hospital." Now on one level, I understood why that made sense. Clearly the "big" hospital had facilities, skills, and resources that were not practical, effective, or perhaps even possible to offer at one of our rural, more remote locations. But I also felt that this response was sometimes used as a default position when either the "big" hospital or the rural program did not *want* to do something.

Fast forward 20 years and the healthcare landscape is vastly different. Today, cancer patients, their caregivers, and even their insurers expect a great many cutting-edge services to be provided close to the patient's home—regardless of where the patient lives.

In this edition of *Oncology Issues*, we focus on some initiatives and services that a few years ago might only have been found at a "big" hospital, but which are now commonly offered at small and/or rural programs.

First, Joseph Kim looks at the state of molecular testing in the community setting. In his article, Dr. Kim shows how eight community cancer programs were able to identify process improvements for molecular testing for their non-small lung cancer (NSCLC) patients. These improvements came after the cancer programs participated in experiential learning labs, where multidisciplinary teams came together to brainstorm key areas for improvement and potential action items.

Staying with the molecular testing theme, Lawrence Wagman, MD, and colleagues share information about a pilot program that used lean methodology to improve molecular testing processes in advanced NSCLC. On pages 38-41, the authors share their "hybrid value stream maps." Combining traditional process mapping tools and lean value stream map components allowed this cancer program to visualize the processes, progression, waste, and value of its molecular testing program.

Next *Oncology Issues* showcases a 2014 ACCC Innovator Award Winner, Oncology Specialists, SC. In part one of her two-part article, Sigrun Hallmeyer, MD, talks about the history and current state of cancer survivorship care plans (SCPs) in the U.S. Then, in a companion article, Dr. Hallmeyer describes how her practice is leveraging its electronic health record (EHR) in the creation of survivorship care plans so that the clinician workload is reduced, even while the program's delivery of patient-centered care is enhanced.

Our next feature circles back to lung imaging, and focuses on development and evolution of an incidental lung lesion program—a huge "hot topic" with ACCC members, judging by the number of posts on this topic on ACCCExchange. Authors Esther Muscari Desimini, Patricia Aldredge, and Kimberly Gardner share the story of how their program evolved, starting with looking at the number of patients who came into their emergency department—for whatever reason—who were then found to have an incidental lung lesion on their CT scans. To ensure that these patients received adequate follow-up, this cancer program developed a quality improvement initiative that improved both the patient experience and the communication between the emergency department, cancer program, and primary care physicians (PCPs).

Finally, on a related topic, Stephen Cattaneo, MD, and colleagues discuss how their Rapid Access Chest and Lung Assessment Program (RACLAP) helps ensure that patients receive timely follow-up, diagnosis, and treatment. (FYI: Anne Arundel Medical Center won a 2012 ACCC Innovator Award for this program.)

So while there will always be some services and technologies that are only (and should only be) available at the "big" hospital, more and more community cancer programs are asking, "Can we do that *here*?" and stepping up to make it happen. So go ahead, try it on for size. And remember, ACCC is here to help. OI

PRESIDENT'S MESSAGE

Happy New Year!

BY BECKY L. DEKAY, MBA

Welcome to 2015! I always like to think of the New Year as a time for new beginnings, but sometimes my mood falls short. As I write this column, the temperature is cold outside, which says a lot for Louisiana. The skies are also gray and mostly dreary. It is dark when I get to work in the morning and dark when I leave at night. The festivities of the holidays are behind us, and seemingly there is nothing "to do"—at least not until the end of February when Mardi Gras hits. As my mother used to say, "The best time to have surgery is January or February because you won't miss anything."

If you're thinking similar thoughts going into 2015, you're in luck! There is a big "to do" for all of us and that's making sure our cancer programs are adhering to the new Medicare rules that went into effect on January 1. What fun! But at least ACCC works to make understanding what's new in the 2015 rules a little less painful for us all.

First, starting on page 9 of this *Oncology Issues*, Cindy Parman's "Compliance" column offers a comprehensive 2015 coding update—for both hospitals and practices. She distills the hundreds of pages that comprise the Hospital Outpatient Prospective Payment System (OPPS) and Physician Fee Schedule (PFS) final rules down to 14 pages, highlighting all of the changes that will affect your cancer program (and your patients). If you have not yet been lucky enough to hear Ms. Parman speak at one of ACCC's Regional Oncology Reimbursement Meetings, her "Compliance" column is a must read!

Second, you can go to ACCC's website to access a concise summary of the 2015 HOPPS final rule (www.accc-cancer.org/advocacy/Hospitals.asp) and 2015 PFS final rule (www.accc-cancer.org/advocacy/Physicians.asp). ACCC has compiled new information that radiation oncology providers should pay particular attention to as they face some significant changes in 2015.

Third, as an ACCC member, you can log in and listen to a recording of ACCC's November 18 members-only conference call on the 2015 OPPS and PFS final rules, which highlights key details in both. A link to the archived call can be found on the webpages referenced above.

Finally, you can start making plans to attend the ACCC 41st Annual Meeting, CANCERSCAPE, March 16-18, in Arlington, Va. With a focus on legislative and regulatory changes and marketplace trends impacting the cancer care landscape—ACCC's Annual Meeting offers insight on the areas most likely to affect care delivery in the near and long-term future. Plan to attend ACCC's Capitol Hill Day, which kicks-off the meeting on March 16. The next day, on March 17, hear keynote speaker Charlie Cook, from the Cook Political Report. He will offer his perspective on the policy direction of the current administration, as well as on the 2015 Congressional agenda in light of the mid-term elections. Then, listen to a panel of experts discuss value-based cancer care and provider efforts for integrating value into their programs and practices. And my presidential theme—measuring, demonstrating, and communicating quality to key stakeholders—will be explored through the effective use of Big Data and EHRs. There will also be sessions centered on legal issues that impact care delivery, how to successfully navigate the latest developments in healthcare reform, an update on the 340B Drug Pricing Program, and strategies for minimizing financial toxicity for your cancer patients.

So you see, you do have plenty to focus on during the winter doldrums of January and February. I look forward to seeing many of you in March for ACCC's Capitol Hill Day and Annual Meeting (www.accc-cancer.org/CANCERSCAPE). Happy New Year to all! OI

Coming in Your 2015 *ONCOLOGY ISSUES*

- The Journey to Cultural Competence
- Cancer Clinical Trials: Enhancing Infrastructure & Accrual
- A Value-Driven Symptom Management Clinic
- Closing the Gap: An Outpatient Nutrition Clinic
- Capturing Quality Data to Improve Palliative Care
- From Distress Screening to Solutions: Patient-Centered Support
- An Innovative Patient Companion Program
- Closing the Loop with a Post-Biopsy Breast Clinic
- Implementing Oncology Inpatient Bedside Scheduling
- CoC Accreditation—The REAL Story
- A Patient Tracking System Helps Transition Patients to a Multi-disciplinary Nurse Care Model
- NCQA's Patient-Centered Specialty Practice Program
- An Oncology Nurse Navigator-Led Psychosocial Program

more online @
www.accc-cancer.org

fast

SURVEY

Immuno-Oncology Survey

This new area of cancer research and treatment looks to harness the body's own immune system to fight cancer. Let us know what you want to learn about immuno-oncology and how ACCC can assist your program with implementation of immuno-oncology by taking our short survey: www.surveymonkey.com/s/ICLIO_ACCC.

SPEAK UP

ACCC's 2015 Capitol Hill Day

Speak up for access to quality care during visits with your Congressional representatives on Monday, March 16, 2015, and discover how much stronger the cancer care community is when we come together to advocate for our common goals. Register and learn more at: www.accc-cancer.org/CANCERSCAPE.

INFO

Final 2015 OPPS and PFS Rules

Did you miss ACCC's call on the 2015 final rules? Log onto mynetwork@accc-cancer.org and go to the Members Resource Library to hear everything you missed.

HOST

Immunotherapy Education Series

ACCC seeks host centers for 60-minute, live teleconferences and webcasts on "Principles and Application in Immunotherapy of Cancer." Learn the core principles of immunotherapy and review issues related to the clinical application of these therapies in specific tumor types—melanoma or lung cancer. Interested in this opportunity? Email resources@accc-cancer.org and include "PAIC" in the subject line, along with the name and contact information for your cancer program.

Oncology Issues is published bimonthly at the Association of Community Cancer Centers, 11600 Nebel St., Suite 201, Rockville, MD 20852. Editorial correspondence, changes of address, manuscripts, and letters to the editor should be addressed to: Managing Editor, Oncology Issues, 11600 Nebel St., Suite 201, Rockville, MD 20852-2557. Author's instructions available at www.accc-cancer.org.

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

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

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

"Doc Fix" Medicare Legislation Could Cost $144 Billion Over 10 Years

Source. CBO. Medicare's Payments to Physicians: the Budgetary Effects of Alternative Policies. www.cbo.gov/sites/default/files/cbofiles/attachments/49770-SGR-Menu.pdf.

Want to Avoid a RAC Audit? Try These Tips

1. Avoid copy-and-paste documentation—While it is acceptable to use templates, your documentation must be patient-specific.
2. Benchmark your E&M coding against your peers—AAPC offers national E&M coding averages by specialty: www.aapcps.com/resources/em_utilization.aspx.
3. Focus on medical decision making—Do not use a higher-level code when the complexity is not there, regardless of your documentation.
4. Four eyes are better than two—Have a certified professional coder review several chart notes for every provider, every year, for appropriate coding and documentation.
5. Document medical necessity—When ordering a test or procedure, make sure you document why it is needed.

Source. Roberts LW. Six Ways to Avoid a RAC Audit. Physicians Practice. www.physicianspractice.com.

facts

What's Behind the Rapid Growth in the 340B Program?

A whitepaper identifies four historical drivers of substantial growth in the 340B Program that will continue to underpin future expansion during the next five years:

1. **Increase** in 340B enrolled disproportionate share hospitals (DSH). Newly-enrolled DSH hospitals account for about half of total 340B drug spending in 2013. DSH hospitals purchase the vast majority—more than **80%**—of 340B drugs.
2. **Acquisition** of satellite clinics by DSH hospitals. Between 2009 and 2012 these hospitals have acquired at least 140 community oncology practices; an almost 120 percent increase in 340B oncology drug utilization followed these acquisitions.
3. **Contract** pharmacy arrangement expansion. Almost two-thirds of all 340B DSH hospitals have at least **5** contract pharmacies; many have more than **50.**
4. **Impact** of the Affordable Care Act. The ACA established new eligibility categories in the 340B Program for pediatric hospitals, critical access hospitals, sole community hospitals, rural referral centers, and freestanding cancer centers. To date, more than **1,100** of these entities have enrolled in the 340B program.

Source. Vandervelde A. *Growth of the 340B Program: Past Trends, Future Projects*. www.thinkbrg.com/media/publication/524_Vandervelde_340B_GrowthDrivers_WhitePaper_20141202_FINAL.pdf.

Uninsured Americans Decline by 10.6 Million

The number of uninsured non-elderly adults fell an estimated **10.6** million between Sept. 2013-Sept. 2014 as the un-insured rate fell from **17.7%** to **12.4%**. Most of the gain in coverage was among low- and middle-income adults specifically targeted by the ACA.

Source. Long SK, et al. Taking stock: health insurance coverage under the ACA as of September 2014. *Health Reform Monitoring Service*. http://hrms.urban.org/briefs/Health-Insurance-Coverage-under-the-ACA-as-of-September-2014.html.

Biosimilar Drugs Could Create $44 Billion in Savings in 10 Years

Source. The RAND Corporation. "The Cost Savings Potential of Biosimilar Drugs in the U.S." www.rand.org/pubs/perspectives/PE127.html.

A Look Ahead to 2015

BY LEAH RALPH

The last few months have brought big changes to Washington, D.C. The 2014 midterm elections dealt a sweeping victory to Republicans in Congress, giving the party a 54-seat majority in the Senate and its biggest majority in the House since 1928. As we start the New Year, both chambers are now under GOP control. The parties are reorganizing and, importantly, the legislative agenda is shifting. While it's still anyone's guess whether new leadership will mean less political infighting in 2015, issues like trade, energy, and tax reform are early contenders for potential areas of compromise.

The ACA (Affordable Care Act), on the other hand, will be top of the list for a different reason—in the 114th Congress you can count on Republicans to look for every opportunity to take the legs out from under President Obama's signature achievement. Although full repeal is unlikely, as it would face an all-but-guaranteed presidential veto, expect the new majority to focus their efforts on introducing a series of stand-alone bills targeting the most unpopular provisions of the law.

How non-ACA related healthcare legislation will fare is a harder question. Healthcare fatigue still looms large among legislators, making issues like oral parity, sequestration, and a long-term fix to the Sustainable Growth Rate (SGR) more of an uphill climb. Yet new leadership, a renewed vow to work across the aisle, and palpable public dissatisfaction with the status quo are bringing new energy to Congress—and ACCC is committed to focusing attention on these issues by sharing your experiences and bringing real-world perspectives to the table.

Make a New Year's resolution to add your voice on these important issues. Join us March 16, as ACCC holds its third annual Capitol Hill Day, meeting with legislators on issues that are critical to ensuring access to quality cancer care. Specifically, we will remind Congress (once again!) that the time is ripe to pass a long-term fix to the SGR. In 2014 we saw what seemed to be the best opportunity in years to finally fix the fundamentally flawed formula used to calculate physician payments in Medicare: Congress came to agreement on a bipartisan bill that had a relatively low price tag. While the bill did not come to a vote and will need to be reintroduced in the new Congress, finding consensus on policy is a promising sign for this year. Physicians have now seen 17 (seventeen!) patches that, if added together, cost far more than the comprehensive approach lawmakers are considering today. This year, ACCC members will be on Capitol Hill just before the current "doc fix" expires on March 31.

Passing a national oral parity law continues to be a top priority for ACCC membership. Oral parity efforts are gaining momentum: 34 states and D.C. have now passed oral parity laws, and several other states are ramping up their grassroots efforts for 2015. With an estimated 25 to 35 percent of all therapies in the oncology pipeline only available in pill form, the need for comprehensive, federal oral parity legislation is increasingly critical to patient access. Although many states have passed state-level legislation, lawmakers need to understand that federal legislation would ensure consistency in oral parity laws across the country and would include plans that fall outside the purview of state regulation.

This is the time to make your voice heard on these and other issues important to cancer care. Join us for Hill Day, and stay for the ACCC 41st Annual Meeting, CANCERSCAPE, which will follow March 17–18 in Arlington, Va. Meeting attendees will hear healthcare policy experts discuss issues such as recent developments in the 340B Program, emerging oncology payment and delivery models in Medicare, the economics of pharmaceutical pricing, how to put quality initiatives to work for your program, and much more. Learn more and register today at: www.accc-cancer. org/cancerscape.

If you have additional questions or would like to get involved another way, please contact me at lralph@accc-cancer.org. OI

Leah Ralph is ACCC's manager of provider economics & public policy.

Oncology Reimbursement Update 2015

BY CINDY PARMAN, CPC, CPC-H, RCC

Change is inevitable—except from a vending machine.

ROBERT C. GALLAGHER, BUSINESSMAN AND FORMER DIRECTOR OF THE GREEN BAY PACKERS

That quote is never more accurate than when final regulations, code updates, and other oncology reimbursement changes occur at the end of each year. And this year we have challenges with physicians and hospitals scrambling to update their respective chargemasters, fee schedules, and other reimbursement documents because in 2015 there are different procedure codes reported based on the radiation oncology setting.

New & Revised Procedure Codes

Each year the Centers for Medicare & Medicaid Services (CMS) releases new codes, revised codes, and updates to its coding guidelines. For 2015, there is only one change to the Evaluation and Management (E/M) Guidelines: "military history" has been added as one of the items included in social history. Many physicians already document this history element, so this may not be a significant change for oncologists. In addition, two new codes have been created for advance care planning, including completion of advance directive. This service is frequently provided by oncology physicians, but it must be completely documented in the medical record in order to report the following codes:

- **99497**: Advance care planning, including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified healthcare professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate.
- **99498**: This code is for each additional 30 minutes and should be listed separately and in addition to the code for the primary procedure (**99497**, listed above).

CMS will not pay separately for this service in calendar year (CY) 2015, but it will consider separate payment in subsequent years.

There has also been an update to add a HCPCS Level II code for lung cancer screening, which was effective Oct. 1, 2014.

- **S0832**: Low dose computed tomography for lung cancer screening. (Note: CMS published the code as "S8032" in its Transmittal, but the HCPCS File for 2015 lists the code as **S0832**.)

CMS has indicated its intention to pay for this service, but with specific patient criteria, radiologist criteria, and facility criteria.

Teletherapy & Brachytherapy Isodose Planning

The three existing codes for simple, intermediate, and complex teletherapy isodose plans (**77305**, **77310**, and **77315**) have been deleted and been replaced with two new codes for simple and complex teletherapy isodose plans; these new codes include basic dosimetry, which means code **77300** will *not* be reported in addition to these computer plans. The two new codes are:

- **77306**: Teletherapy isodose plan; simple (1 or 2 unmodified ports directed to a single area of interest), includes basic dosimetry calculation(s).
- **77307**: Teletherapy isodose plan; complex (multiple treatment areas, tangential ports, the use of wedges, blocking, rotational beam, or special beam considerations), includes basic dosimetry calculation(s).

The three existing codes for brachytherapy isodose plans (**77326, 77327,** and **77328**) have also been deleted. They have been replaced by three new codes that define the levels for remote afterloading brachytherapy in terms of channels rather than sources; like the new teletherapy isodose plan codes, these plan codes also include basic dosimetry:

- **77316**: Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s).
- **77317**: Brachytherapy isodose plan; intermediate (calculation[s] made from 5

to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s).
- **77318**: Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s).

Treatment Delivery, Image Guidance & Motion Tracking

While the new CPT procedure codes for treatment planning will be used in all practice settings (hospitals, freestanding cancer treatment centers, and physician offices), there are different Medicare treatment delivery and image guidance codes for hospitals and freestanding radiation centers for calendar year 2015.

For hospital billing on the UB-04 claim form, the existing IMRT treatment delivery codes (**77418**, **0073T**) were deleted and replaced by two new codes for simple and complex treatment delivery, both of which include image guidance and motion tracking (when performed). This means that IGRT (e.g., cone-beam CT, CT on rails, stereoscopic imaging, US guidance) and intra-fraction motion tracking will no longer be separately coded by the hospital when IMRT treatment is performed. Instead hospitals will report these two new codes:

- **77385**: Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple (prostate, breast, compensator-based).
- **77386**: Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex (all other sites, non-compensator-based).

The existing Category III code for intra-fraction localization and tracking (**0197T**), code **77421** (Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy), and code **76950** (Ultrasonic guidance for placement of radiation fields) were deleted. Effective Jan. 1, 2015, hospitals will report this new code when patients receive standard external beam therapy (e.g., this code is *not* reported with IMRT treatment):

- **77387**: Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed.

The radiation treatment delivery codes billed by the hospital were also restructured for CY 2015. There is still a single code for superficial and orthovoltage treatment, but there are now only three codes for treatment delivery at any dose greater than or equal to 1 MeV (previously there were 12 codes based on both the complexity and the MeV.) The following codes were deleted:

- **77403**, **77404**, and **77406** for simple treatment delivery.
- **77408**, **77409**, and **77411** for intermediate treatment delivery.
- **77413**, **77414**, and **77416** for complex treatment delivery.

Starting in CY 2015, hospitals will now bill these new codes:

- **77401**: Radiation treatment delivery, superficial and/or orthovoltage, per day.
- **77402**: Radiation treatment delivery, >1 MeV; simple.
- **77407**: Radiation treatment delivery, >1 MeV; intermediate.
- **77412**: Radiation treatment delivery, >1 MeV; complex.

Starting in CY 2015, physician practices and freestanding centers (claims submitted on the CMS1500 form) will not report any of the new CPT treatment delivery or image guidance procedure codes for Medicare patients. Instead, these entities will report HCPCS Level II codes, which have the same definitions as the deleted CPT codes (see Table 1, page 11). Of importance, while Medicare requires the HCPCS Level II codes identified in Table 1, physician practices and freestanding cancer centers may be required to report the new CPT procedure codes (**77401**, **77402**, **77407**, and **77412**) for their other payers.

The physician will continue to report the professional charge for image guidance performed in conjunction with IMRT treatment, when all documentation requirements are met. While the technical component of IGRT is part of the new IMRT treatment delivery codes for hospital billing (and for freestanding centers that report codes **77385** and **77386** to non-Medicare payers), the professional component can be separately charged.

HCPCS Level II Codes & Modifiers

No modifiers were deleted or revised, but the following new HCPCS Level II modifiers were added for calendar year 2015:

- **PO**: Services, procedures, and/or surgeries provided at off-campus provider-based outpatient departments.
- **XE**: Separate encounter, a service that is distinct because it occurred during a separate encounter.
- **XP**: Separate practitioner, a service that is distinct because it was performed by a different practitioner.
- **XS**: Separate structure, a service that is distinct because it was performed on a separate organ/structure.
- **XU**: Unusual non-overlapping service, the use of a service that is distinct because it does not overlap usual components of the main service.

Modifiers XE, XP, XS, and XU are intended to replace modifier 59 for Medicare patients. Each Medicare contractor will post information on when and how these modifiers are to be applied.

New, Revised & Deleted Drug Codes

Here are the new, revised, and deleted codes for drugs, biologicals, radiation sources, and radiopharmaceuticals.

Two new codes for CY 2015 include:

- **A9606**: Radium Ra-223 dichloride, therapeutic, per microcurie.

(*continued on page 13*)

Table 1. 2015 Treatment Delivery and Image Guidance Codes Reported by Physician Practices and Freestanding Cancer Centers

2014 CPT CODE	2015 HCPCS CODE	DESCRIPTION
76950	**G6001**	Ultrasonic guidance for placement of radiation therapy fields
77421	**G6002**	Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy
77402	**G6003**	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks; up to 5 MeV
77403	**G6004**	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks; 6 – 10 MeV
77404	**G6005**	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks; 11 – 19 MeV
77406	**G6006**	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks; 20 MeV or greater
77407	**G6007**	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks; up to 5 MeV
77408	**G6008**	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks; 6 – 10 MeV
77409	**G6009**	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks; 11 – 19 MeV
77411	**G6010**	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks; 20 MeV or greater
77412	**G6011**	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; up to 5 MeV
77413	**G6012**	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 6 – 10 MeV
77414	**G6013**	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 11 – 19 MeV
77416	**G6014**	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 20 MeV or greater
77418	**G6015**	Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session
0073T	**G6016**	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensators, convergent beam modulated fields, per treatment session
0197T	**G6017**	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating, 3D surface tracking), each fraction of treatment

Table 2. CY 2015 Q-codes for Epoetin Beta

2015 CODES	DESCRIPTION	DELETED 2014 CODES	DESCRIPTION
J0887	Injection, epoetin beta, 1 microgram (for ESRD on dialysis)	**Q9972**	Injection, epoetin beta, 1 microgram (for ESRD on dialysis)
J0888	Injection, epoetin beta, 1 microgram (non-ESRD use)	**Q9973**	Injection, epoetin beta, 1 microgram (non-ESRD use)

Table 3. CY 2015 Codes for Clotting Factors

2015 CODES	DESCRIPTION	DELETED 2014 CODES	DESCRIPTION
C9136	Injection, factor viii, fc fusion protein, (recombinant), per iu		
J7181	Injection, factor xiii a-subunit, (recombinant), per iu		
J7182	Injection, factor viii, (antihemophilic factor, recombinant), (Novoeight), per iu		
J7200	Injection, factor ix, (antihemophilic factor, recombinant), Rixubis, per iu	**C9133**	Factor ix (antihemophilic factor, recombinant), Rixubis, per iu
J7201	Injection, factor ix, fc fusion protein (recombinant), per iu		
		C9134	Factor xiii (antihemophilic factor, recombinant), Tretten, per 10 iu
		C9135	Factor ix (antihemophilic factor, recombinant), Alprolix, per iu

Table 4. CY 2015 Drug Code Changes for Testosterone

2015 CODES	DESCRIPTION	DELETED 2014 CODES	DESCRIPTION
J1071	Injection, testosterone cypionate, 1mg	**J1070**	Injection, testosterone cypionate, up to 100 mg
		J1080	Injection, testosterone cypionate, 1 cc, 200 mg
		J1060	Injection, testosterone cypionate and estradiol cypionate, up to 1 ml
J3121	Injection, testosterone enanthate, 1mg	**J3120**	Injection, testosterone enanthate, up to 100 mg
		J3130	Injection, testosterone enanthate, up to 200 mg
		J0900	Injection, testosterone enanthate and estradiol valerate, up to 1 cc
J3145	Injection, testosterone undecanoate, 1 mg	**C9023**	Injection, testosterone undecanoate, 1 mg
		J3140	Injection, testosterone suspension, up to 50 mg
		J3150	Injection, testosterone propionate, up to 100 mg

(*continued from page 10*)

- **C2644**: Brachytherapy source, Cesium-131 chloride solution, per millicurie.

For CY 2015, the Q-codes for epoetin beta have been replaced with J-codes (Table 2, page 12).

Starting in CY 2015, there are five new codes, one revised code, and three deleted codes for clotting factors (Table 3, page 12). There is one clotting factor code with a revised description for 2015:

- **J7195**: Injection, factor ix (antihemophilic factor, recombinant) per iu, not otherwise specified.

Replacement codes were created for two chemotherapy drugs. For CY 2015, CMS deleted code **J9265** (Injection, paclitaxel, 30 mg) and replaced it with code **J9267** (Injection, paclitaxel, 1 mg). Similarly, CMS deleted code **C9021** (Injection, obinutuzumab, 10 mg) and replaced it with code **J9301** (Injection, obinutuzumab, 10 mg). In addition to these chemotherapy drugs, CMS deleted codes **Q9970** (Injection, ferric carboxymaltose, 1 mg) and **C9022** (Injection, elosulfase alfa, 1 mg), replacing them with codes **J1439** (Injection, ferric carboxymaltose, 1 mg) and **J1322** (Injection, elosulfase alfa, 1 mg), respectively.

For CY 2015 CMS created two new codes for chemotherapy drugs:

- **C9027**: Injection, pembrolizumab, 1 mg
- **C9442**: Injection, belinostat, 10 mg.

Other new drug HCPCS codes effective Jan. 1, 2015, include:

- **C9443**: Injection, dalbavancin, 10 mg.
- **C9444**: Injection, oritavancin, 10 mg.
- **C9446**: Injection, tedizolid phosphate, 1 mg.
- **C9447**: Injection, phenylephrine and ketorolac, 4 ml vial.
- **J7327**: Hyaluronan or derivative, monovisc, for intra-articular injection, per dose.

Table 4 (above) shows CY 2015 drug code changes for various forms of testosterone.

In addition to the codes listed in this article, there are a number of changes to HCPCS quality measure codes, diagnostic imaging agents, and other medical supplies. Finally, remember that the existence of a procedure or supply code does not guarantee reimbursement; payment for a service depends on the patient's insurance policy, medical necessity, and other determining factors. OI

Hospital Regulatory Update

The Hospital Outpatient Prospective Payment System (OPPS) is not intended to be a fee schedule, in which separate payment is made for each coded line item. Instead, the OPPS is currently a prospective payment system that packages some items and services, but not others. CMS' overarching goal is to make payments for all services covered under OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule. For CY 2015, CMS will continue base payments on geometric mean costs. Under this methodology, claims are selected for services paid under the OPPS and matched to the most recent cost report filed by the individual hospitals represented in the claims data.

CMS estimates that total payments, including the beneficiary cost share, to the approximately 400 facilities paid under OPPS will be approximately $56.1 billion in CY 2015, an increase of just over $5.1 billion compared to CY 2014 payments. Outpatient hospital payment rates will increase by 2.2 percent and CMS will continue the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements. The CY 2014 conversion factor of $72.672 rises to $74.144 with the 2.2 percent increase, but for hospitals that fail to meet the OQR (Outpatient Quality Reporting) requirements, the conversion factor will drop to $72.661 in 2015.

CMS will also continue the policy of providing additional payments to the 11 designated cancer hospitals so that the hospitals' payment-to-cost ratio, with the adjustment, is equal to the weighted average for the other OPPS hospitals. And last, CMS will continue to make an outlier payment that equals 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC (ambulatory payment classification) payment amount when both the 1.75 multiple threshold and the final fixed-dollar threshold of $2,775.00 are met.

Packaged Services

For CY 2015, CMS will continue to unconditionally or conditionally package the following five categories of items and services:

- Drugs, biologicals, and radiopharmaceuticals used in a diagnostic test or procedure
- Drugs and biologicals when used as supplies in a surgical procedure
- Certain clinical diagnostic laboratory tests
- Procedures described by add-on codes
- Device removal procedures.

In CY 2014 CMS proposed the packaging of ancillary services, but decided further study was needed. The agency finalized this proposal for CY 2015, and included the following provisions:

- Ancillary service APCs with a geometric mean cost of $100 or less will be conditionally packaged.
- Status indicator X (ancillary service) will be deleted; services formerly assigned status indicator X will be converted to status Q1 (STV-packaged) or S (Procedure or service, not discounted when multiple).
- Status Q1 services will continue to be paid separately when not performed with status S, T, or V services.
- Preventive services (including bone density studies, glaucoma screening, AAA screening, EKG for IPPE, and obtaining Pap smear) will be excluded from this policy even though they are under the $100 cutoff.
- Certain psychiatry and counseling services are also excluded.
- Low-cost drug administration services are excluded as CMS is current looking at alternative ways to pay for drug administration.

CMS continues to state that given the frequency of drug administration services in the hospital outpatient department and their use in such a wide variety of different drug treatment protocols for various diseases in all types of hospitals, further study of the payment methodology for these services is warranted. According to CMS, the agency is "examining various alternative payment policies for drug administration services, including the associated drug administration add-on codes." Last, CMS continues to emphasize that "hospitals should report all HCPCS codes for all services, including those for packaged services, according to correct coding principles."

Comprehensive APCs

To improve the accuracy and transparency of payment for certain device-dependent services, CMS finalized the policy to establish 28 comprehensive APCs (ambula-

tory payment classifications) to prospectively pay for the most costly hospital outpatient device-dependent services, and will implement this policy in CY 2015. A comprehensive APC, by definition, will provide a single payment that includes the primary service and all adjunct services performed to support the delivery of the primary service. For services that trigger a comprehensive APC payment, the comprehensive APC will treat all individually reported codes on the claim as representing components of the comprehensive service, resulting in a single prospective payment for the comprehensive service. This means that hospitals will continue to report procedure codes for all services performed, but will receive a single payment for the total service. According to the 2015 OPPS final rule:[1]

For CY 2015, we [will] convert the following existing APCs into C-APCs: APC 0067 (Single Session Cranial Stereotactic Radiosurgery) and APC 0351 (Level V Intraocular Surgery). C-APC 0351 only contains one procedure – CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens). We also proposed to assign the CPT codes for IORT (CPT codes 77424 and 77425) to C-APC 0648 (Level IV Breast and Skin Surgery) because IORT is a single session comprehensive service that includes breast surgery combined with a special type of radiation therapy that is delivered inside the surgical cavity but is not technically brachytherapy. The HCPCS codes that we proposed to assign to these C-APCs in CY 2015 would be assigned to status indicator "J1."

This means that single-fraction stereotactic radiosurgery will be reimbursed through a single payment and intraoperative radiation therapy will be included in the payment for the surgical procedure beginning in CY 2015.

Off-Campus Provider-Based Departments

In the CY 2014 proposed rule, CMS solicited comments regarding a potential new claims modifier or other data element that would designate services furnished in an off-campus provider-based department (PBD). According to CMS, research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resulting increase in the delivery of physician services in a hospital setting. When a Medicare beneficiary receives outpatient services in a hospital, the total payment amount for outpatient services made by Medicare is generally higher than the total payment amount made by Medicare when a physician furnishes those same services in a freestanding clinic or in a physician's office.

For physician and/or practitioner professional claims, CMS has decided to implement new place of service (POS) codes rather than a modifier. For hospital claims, CMS will proceed with the modifier requirement. The new modifier is PO (Services, procedures, and/or surgeries furnished at off-campus provider-based outpatient departments). Reporting of the modifier will be voluntary until CY 2016, at which point it will become mandatory.

Providers will append the modifier to every code for all outpatient hospital services furnished in an off-campus provider-based department of a hospital. CMS defines the campus as "the physical area immediately adjacent to the provider's main buildings, other areas, and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus."

The modifier should not be used on services performed at remote locations of the hospital, satellite facilities of the hospital, or emergency departments. A remote location is defined as "a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider." CMS states that questions about whether a particular location requires the modifier should be referred to the CMS regional offices.

Quality Measures & EHRs

CMS continues to align measures across the Hospital OQR and ASCQR (Ambulatory Surgical Center Quality Reporting) Programs, and is finalizing the addition of one outcome-based measure for the CY 2018 payment determination and subsequent years for both programs. In addition, CMS is excluding one previously adopted measure from the measure set for the CY 2016 payment determination and changing this measure from required to voluntary for the CY 2017 payment determination and subsequent years for both the Hospital OQR and ASCQR Programs. Facilities will not be subject to payment reductions while the measure is voluntary. Additionally, for the Hospital OQR Program, CMS is:

1. Removing two "topped-out" prophylactic antibiotic surgery measures
2. Clarifying data submission requirements for one measure
3. Noting a delayed data collection for two colonoscopy measures.

Also, for the Hospital OQR Program, CMS is formalizing a review and corrections period for chart-abstracted measures, and updating validation procedures. Specifically, hospitals will only be eligible for random selection for validation if they submit at least 12 cases to the Hospital OQR Program Clinical Data Warehouse during the quarter with the most recently available data. Hospitals will also have the option to submit validation data using electronic methods and must identify the medical record staff responsible for submission of records to the designated CMS contractor.

New Code Process Changes

In the 2015 proposed OPPS rule, CMS outlined plans for changing the way it handles new procedure codes and this plan was adopted as proposed. Beginning with the 2016 rulemaking process, CMS will

publish APC assignments for new codes as part of the proposed rule, as long as the codes are received in time. Otherwise, CMS will establish HCPCS Level II G-codes equivalent to the prior year's CPT codes and require providers to use those G-codes, rather than the new CPT codes, until the following year's rulemaking. CMS states:[1]

Therefore, beginning with the CY 2016 OPPS update, we will publish proposed APC and status indicator assignments for any new and revised CPT codes for January 1, 2016, that are publicly released by the AMA in time for us to consider them for inclusion in the OPPS/ASC proposed rule. After review of the public comments received on the proposed rule, we will finalize the status indicator and APC assignments for those new and revised CPT codes in the CY 2016 OPPS/ASC final rule. Because the APC assignments would be final, we would no longer request comments in the OPPS/ASC final rules for these new and revised CPT codes that are included in the proposed rule. For any new and revised codes released too late for us to consider them for inclusion in the CY 2016 OPPS/ASC proposed rule, we will create HCPCS G-codes that reflect the same description(s), and APC and status indicator assignments, as their predecessor codes. These HCPCS G-codes will be used during CY 2016, and then we will include proposals for the corresponding new and revised codes and APC and status indicator assignments in the CY 2017 OPPS/ASC proposed rule.

CMS states that it anticipates the use of the G-codes "will be largely a temporary solution or may not be necessary in the OPPS." With the Medicare Physician Fee Schedule (PFS) CMS has to wait for RUC recommendations in order to determine the RVUs for the code. Under OPPS this is not necessary, so CMS states that even if G-codes are created for the PFS, they may not need to be used for OPPS billing.

Radiation Oncology Services

CMS also included a discussion of APC assignments and valuation issues for specific services in this final rule.

- Stereotactic body radiation therapy (code **77373**) will continue to be assigned to APC 0066, which will be renamed to "Level V Radiation Therapy."
- C-APC 0067 for stereotactic radiosurgery (codes **77371** and **77372**) will be renamed to "Single Session Cranial Stereotactic Radiosurgery."
- Radiosurgery HCPCS codes **G0173** and **G0251** were deleted effective Dec. 31, 2014.
- HCPCS Level II codes **G0339** and **G0340** are not used for hospital billing, but will not be deleted since these codes will continue to be used under PFS.
- Hospitals will continue to report codes **77371**-**77373** for radiosurgery and stereotactic body radiotherapy.
- Last, CMS plans to re-evaluate the APC assignments for all of the radiosurgery codes as part of the 2016 rulemaking.

Beginning in CY 2008, CMS began providing a single payment allowance under a Composite APC for low-dose rate (LDR) prostate brachytherapy. At least two procedure codes are used to report the composite treatment service because there are separate codes that describe placement of the needles (code **55875**, transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and the application of the brachytherapy (code **77778**, interstitial radiation source application, complex). These codes are generally present together on claims for the same date of service and the same operative session. For CY 2015, CMS will continue to pay for LDR prostate brachytherapy using APC 8001.

CMS also finalized the proposals affecting the proton beam therapy services for CY 2015 as follows:

- CPT code **77520** is reassigned from APC 0664 to APC 0412
- CPT code **77522** is reassigned from APC 0664 to APC 0667
- CPT codes **77523** and **77525** are reassigned to APC 0667
- APC 0664 is deleted
- APC 0667 is re-named to "Level IV Radiation Therapy."

According to the final rule[1]:

The three CPT codes, 77522, 77523, and 77525, are similar clinically. All three of these CPT codes describe procedures that involve proton beam therapy delivery services with a continuum of complexity. The procedure described by CPT code 77520 is the least complex. The procedure described by CPT code 77522 is more complex than the procedure described by CPT code 77520, and the procedure described by CPT code 77523 is more complex than the procedure described by CPT code 77522. The procedure described by CPT code 77525 is the most complex procedure of the series proposed to be reassigned to APC 0667. We proposed to reassign CPT code 77520 from APC 0664 to APC 0412 because of the resource comparability with respect to the other procedures involving proton beam therapy delivery services assigned to APC 0412, not based on the clinical dissimilarity with respect to the procedures assigned to APC 0664. In regard to the remaining three procedures involving proton beam therapy delivery services (the procedures described by CPT codes 77522, 77523, and 77525), we believe that these procedures are clinically similar, but each has a slightly varying level of complexity relative to the others. The proposed configuration of APC 0667 only contains the three proton beam therapy delivery services described by CPT codes 77522, 77523, and 77525, and does not include any other service codes. APC 0667 is the most clinically homogeneous APC under the OPPS to assign these services that would ensure adequate payment, with the exception of single service APCs. With regard to the resource comparability of the procedures described by CPT codes 77522, 77523 and 77525, the lowest geometric mean cost among these procedures is associated with the procedure.

CMS continues to package all image guidance under the OPPS, and made minor APC changes to low-dose rate intracavitary and interstitial code placement, as well as hyperthermia codes.

Medical Oncology & Hematology Services

Based on the final rule, for CY 2015, payment for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status continue to be set at the statutory default of average sales price (ASP)+6 percent. In addition, CMS finalized the proposed policy to continue to establish payment rates for blood and blood products using a blood-specific cost-to-charge methodology.

Section 1833 of the Social Security Act permits CMS to make pass-through payments for a period of at least two, but not more than three years after the product's first payment as a hospital outpatient service under Medicare Part B. The longstanding practice has been to provide pass-through payment for a period of two to three years, with expiration of pass-through status proposed and

finalized through the annual rulemaking process. Table 5 (below) lists the drugs for which pass-through status expired on Dec. 31, 2014.

In addition to drugs and biologicals with expired pass-through status, other medications and substances were approved for pass-through during CY 2015. Payment for drugs and biologicals with pass-through status under the OPPS is currently made at the physician's office payment rate of ASP+6 percent. If ASP data are not available for a radiopharmaceutical, CMS will provide pass-through payment at Wholesale Acquisition Cost (WAC)+6 percent. And, if WAC information is also not available, CMS will provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent Average Wholesale Price (AWP). Table 6 (page 18) lists the drugs and biologicals that continued or were granted pass-through status as of January 2015.

CMS estimates that total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2015, including those devices, drugs, and biologicals that first become eligible for pass-through during CY 2015 will be approximately $82.8 million (approximately $61.0 million for device categories and approximately $21.8 million for drugs and biologicals), which represents 0.15 percent of total projected OPPS payments for CY 2015.

Ambulatory Surgical Center (ASC) Update

There are approximately 5,300 Medicare-participating ASCs paid under the ASC payment system. For CY 2015, CMS is increasing payment rates under the ASC payment system by 1.4 percent. Based on this update, CMS estimates that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2015 will be approximately $4.147 billion, an increase of approximately $236 million compared to estimated CY 2014 Medicare payments. The 2015 ASC conversion factor is $44.071 for centers that meet the quality reporting requirements and $43.202 for those facilities that do not meet quality reporting requirements.

In the CY 2013 OPPS/ASC final rule with comment period, CMS finalized the proposal to establish the ASC payment rate for LDR prostate brachytherapy services based on the OPPS relative payment weight applicable to APC 8001 when CPT codes **55875** and **77778** are performed on the same date of service in an ASC. For CY 2015, the ASC will continue to report HCPCS Level II code G0458 instead of the CPT codes to describe this service. Last, ASC payment for brachytherapy sources mirrors the payment policy under the OPPS. Both hospitals and ASCs are paid for brachytherapy sources provided integral to covered surgical procedures at prospective rates adopted under the OPPS.

CMS added code **19296** (Placement of radiotherapy afterloading expandable catheter, on date separate from partial mastectomy) to the list of procedures permanently designated as an office-based procedure (e.g., performed more than 50 percent of the time in a physician's office). Few comments were received on any CMS proposal regarding inclusion or exclusion of procedure codes in the ASC site of service and update of ancillary services; proposals were generally finalized without modification.

Table 5. Drugs & Biologicals for Which Pass-Through Status Expired Dec. 31, 2014

CY 2015 HCPCS CODE	CY 2015 LONG DESCRIPTOR	FINAL CY 2015 SI	FINAL CY 2015 APC
C9290	Injection, bupivicaine liposome, 1 mg	N	N/A
C9293	Injection glucarpidase, 10 units	K	**9293**
J0178	Injection, aflibercept, 1 mg vial	K	**1420**
J0716	Injection, centruroides (scorpion) immune f(ab)2, up to 120 mg	K	**1431**
J9019	Injection, asparaginase (erwinaze), 1000 iu	K	**9289**
J9306	Injection, pertuzumab, 1 mg	K	**1471**
Q4131	EpiFix, per square centimeter	N	N/A
Q4132	Grafix core, per square centimeter	N	N/A
Q4133	Grafix prime, per square centimeter	N	N/A

Table 6. Drugs & Biologicals with Pass-Through Status in CY 2015

CY 2014 HCPCS CODE	CY 2015 HCPCS CODE	CY 2015 LONG DESCRIPTOR	FINAL CY 2015 SI	FINAL CY 2015 APC
A9520	**A9520**	Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries	G	**1463**
N/A	**A9586**	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	**1664**
C9021	**J9301**	Injection, obinutuzumab, 10 mg	G	**1476**
C9022	**J1322**	Injection, elosulfase alfa, 1 mg	G	**1480**
C9023	**J3145**	Injection, testosterone undecanoate, 1 mg	G	**1487**
C9025	**C9025**	Injection, ramucirumab, 5 mg	G	**1488**
C9026	**C9026**	Injection, vendolizumab, 1 mg	G	**1489**
N/A	**C9027**	Injection, pembrolizumab, 1 mg	G	**1490**
C9132	**C9132**	Prothrombin complex concentrate (human), Kcentra, per iu of Facto IX activity	G	**9132**
C9133	**J7200**	Factor IX (antihemophilic factor, recombinant), Rixubus, per iu	G	**1467**
C9134	**J7181**	Injection, Factor XIII A-subunit, (recombinant), per iu	G	**1746**
C9135	**J7201**	Injection, Factor IX, fc fusion protein, (recombinant), per iu	G	**1486**
N/A	**C9136**	Injection, Factor VIII, fc fusion protein, (recombinant), per iu	G	**1656**
C9441	**J1439**	Injection, ferric carboxymaltose, 1 mg	G	**9441**
N/A	**C9349**	FortaDerm, and FortaDerm Antimicrobial, any type, per square centimeter	G	**1657**
N/A	**C9442**	Injection, belinostat, 10 mg	G	**1658**
N/A	**C9443**	Injection, dalbavancin, 10 mg	G	**1659**
N/A	**C9444**	Injection, oritavancin, 10 mg	G	**1660**
N/A	**C9446**	Injection, tedizolid phosphate, 1 mg	G	**1662**
N/A	**C9447**	Injection, phenylephrine and ketorolac, 4 ml vial	G	**1663**
C9497	**C9497**	Loxapine, inhalation powder, 10 mg	G	**9497**
J1446	**J1446**	Injection, tbo-filgrastim, 5 micrograms	G	**1477**
J1556	**J1556**	Injection, immune globulin (Bivigam), 500 mg	G	**9130**
J3060	**J3060**	Injection, taliglucerase alfa, 10 units	G	**9294**
J7315	**J7315**	Mitomycin, ophthalmic, 0.2 mg	G	**1448**
J7316	**J7316**	Injection, Ocriplasmin, 0.125 mg	G	**9298**
J7508	**J7508**	Tacrolimus, extended release, oral, 0.1 mg	G	**1465**
J9047	**J9047**	Injection, carfilzomib, 1 mg	G	**9295**
J9262	**J9262**	Injection, omacetaxine mepesuccinate, 0.01	G	**9297**
J9354	**J9354**	Injection, ado-trastuzumab emtansine, 1 mg	G	**9131**
J9371	**J9371**	Injection, vincristine sulfate liposome, 1 mg	G	**1466**
J9400	**J9400**	Injection, Ziv-Aflibercept, 1 mg	G	**9296**
Q4121	**Q4121**	Theraskin, per square centimeter	G	**1479**
Q4122	**Q4122**	Dermacell, per square centimeter	G	**1419**
Q4127	**Q4127**	Talymed, per square centimeter	G	**1449**

Physician & Freestanding Center Regulatory Update

Since 1992, Medicare has paid for the services of physicians, non-physician practitioners, and certain other providers under the Medicare Physician Fee Schedule (PFS). For reimbursement purposes, relative values are assigned to each of more than 7,000 services to reflect the amount of work, the direct and indirect (overhead) practice expenses, and the malpractice expenses typically involved in furnishing that specific service. After applying a geographic practice cost indicator, the resulting relative value units (RVUs) are summed for each service and multiplied by a fixed-dollar conversion factor to establish the payment amount for each visit or procedure.

The Sustainable Growth Rate (SGR) is a formula adopted by the Balanced Budget Act of 1997 to determine the conversion factor that may result in steep across-the-board reductions in fee schedule reimbursement. The CY 2015 conversion factor (CF) will remain at $35.80 from January 1 through March 31 as mandated by the Protecting Access to Medicare Act. Without a change in the law, effective April 1, 2015, the conversion factor will be $28.22 representing a 21.2 percent decrease. The President's budget calls for averting these cuts and finding a permanent solution to this annual problem. Table 7 (below) shows estimated CY 2015 payment increases or decreases by specialty (without considering the potential conversion factor change).

Radiation Vault

CMS did not finalize its proposal to remove the radiation treatment vault from the direct Practice Expense (PE) input and treat it as part of the infrastructure. The 2015 Final Rule states:[2]

Table 7. Estimated CY 2015 Payment Increases or Decreases by Specialty*

SPECIALTY	ALLOWED CHARGES (MILLIONS)	IMPACT OF WORK RVU CHANGES	IMPACT OF PE RVU CHANGES	IMPACT OF MP RVU CHANGES	COMBINED IMPACT
Hematology and Oncology	$1,811.00	0%	1%	0%	1%
Radiation Oncology	$1,794.00	0%	0%	0%	0%
Radiation Therapy Centers	$57.00	0%	0%	0%	1%

1. Specialty: The Medicare specialty code as reflected in the physician/supplier enrollment files.
2. Allowed Charges: The aggregate estimated PFS allowed charges for the specialty based on CY 2013 utilization and CY 2014 rates.
3. Impact of Work RVU Changes: The estimated CY 2015 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to new, revised, and misvalued codes.
4. Impact of Practice Expense (PE) RVU Changes: The estimated CY 2015 impact on total allowed charges of the changes in PE RVUs, including the impact due to new, revised, and misvalued codes and miscellaneous minor provisions.
5. Impact of Malpractice (MP) RVU Changes: The estimated CY 2015 impact on total allowed charges of the changes in the MP RVUs, which are primarily driven by the required five-year review and update of MP RVUs.
6. Combined Impact: The estimated CY 2015 combined impact on total allowed charges of all the changes in the previous columns.

* Does not consider the potential conversion factor change.

In previous rulemaking, we indicated that we included the radiation treatment vault as a direct PE input for several recently reviewed radiation treatment codes for the sake of consistency with its previous inclusion as a direct PE input for some other radiation treatment services, but that we intended to review the radiation treatment vault input and address whether or not it should be included in the direct PE input database for all services in future rulemaking. Specifically, we questioned whether it was consistent with the principles underlying the PE methodology to include the radiation treatment vault as a direct cost given that it appears to be more similar to building infrastructure costs than to medical equipment costs.

CMS stated that it understands the essential nature of the vault in the provision of radiation therapy services and its uniqueness to a particular piece of medical equipment, but the agency is not convinced that either of these factors leads to the conclusion that the vault should be considered medical equipment for purposes of the PE methodology under the PFS. Although, CMS did not finalize the proposal at this time, the agency "intends to further study the issues raised by the vault and how it relates to our PE methodology."[2]

Off-Campus Provider-Based Departments

CMS had proposed creating a new modifier to be reported on all services performed in an off-campus provider-based department (PBD), but based on comments received, it has decided to use a new place of service (POS) code for physician claims and a new modifier for hospital claims. This means that CMS will delete POS code 22 (outpatient hospital department) and request two new POS codes from the POS Workgroup. One will be for outpatient services furnished in on-campus, remote, or satellite locations of a hospital. The other will be for services in an off-campus hospital PBD setting that is not a remote location of a hospital, a satellite location of a hospital, or a hospital emergency department. The new POS codes must be used as soon as they are available, but CMS does not expect this to be until July 1, 2015. Providers will be notified prior to the implementation date.

Potentially Misvalued Codes

Consistent with amendments made by the Affordable Care Act (ACA), CMS has been engaged in a vigorous effort over the past several years to identify and review potentially misvalued codes and make adjustments where appropriate. CMS and the RUC (Relative Value Update Committee) have taken several steps to improve the review process, examining potentially misvalued services in the following seven categories:

1. Codes and families of codes for which there has been the fastest growth
2. Codes and families of codes that have experienced substantial changes in PEs
3. Codes that are recently established for new technologies or services
4. Multiple codes that are frequently billed in conjunction with furnishing a single service
5. Codes with low relative values, particularly those that are often billed multiple times for a single treatment
6. Codes which have not been subject to review since the implementation of the Resource-based Relative Value Scale (RBRVS, the so-called "Harvard-valued codes")
7. Other codes determined to be appropriate by the Secretary.

Section 220(c) of the Protecting Access to Medicare Act of 2014 further expanded the categories of codes to be examined by adding nine additional categories:

1. Codes that account for the majority of spending under the PFS
2. Codes for services that have experienced a substantial change in the hospital length of stay or procedure time
3. Codes for which there may be a change in the typical site of service since the code was last valued
4. Codes for which there is a significant difference in payment for the same service between different sites of service
5. Codes for which there may be anomalies in relative values within a family of codes
6. Codes for services where there may be efficiencies when a service is furnished at the same time as other services
7. Codes with high intra-service work per unit of time
8. Codes with high PE RVUs
9. Codes with high cost supplies.

After considering the comments received, CMS stated that it is appropriate to finalize the high-expenditure screen as a tool to identify potentially misvalued codes. However, given the resources required over the next several years to revalue the services with global periods, CMS will concentrate its efforts on these valuations. Therefore, the agency is not finalizing the codes identified through the high-expenditure screen as potentially misvalued at this time. This means that codes **77263** (Complex clinical treatment plan), **77334** (Complex treatment device), **96372** (Therapeutic injection), **96375** (Therapeutic intravenous push, each additional drug), **96401** (Chemotherapy injection, non-hormonal antineoplastic), and **96409** (Chemotherapy push, each additional drug) will not be reviewed at this time. CMS will re-run the high-expenditure screen at a future date, and at that time will propose the specific set of codes to be reviewed that meet the high expenditure criteria.

After publication of the CY 2014 Physician Fee Schedule final rule with comment period, CMS was made aware that, due to a clerical error, the clinical labor type for CPT code **77293** (Respiratory Motion Management Simulation [list separately in addition to code for primary procedure]) was entered as L052A (Audiologist) instead of L152A (Medical Physicist), which has a higher cost per minute. CMS has corrected the clinical labor type for this service.

Stereotactic Radiosurgery

In the CY 2014 PFS final rule, CMS summarized comments received about whether CPT codes **77372** and **77373** would accurately reflect the resources used in furnishing the typical SRS delivery if there were no coding distinction between robotic and non-robotic delivery methods. SRS services furnished using robotic methods were billed in the non-hospital setting using contractor-priced HCPCS Level II G-codes **G0339** (Image-guided robotic linear accelerator based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment) and **G0340** (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment). Last year, CMS indicated that it would consider deleting these codes in future rulemaking. However, after considering comments regarding the appropriate inputs to use in pricing the SRS services, CMS concluded that it lacks sufficient information to make a determination about the appropriateness of deleting the G-codes and paying for all SRS/SBRT services using the CPT codes. Therefore, CMS will not delete the G-codes for CY 2015, but will instead work with stakeholders to identify an alternate approach and again reconsider this issue in future rulemaking.

Establishing RVUs

CMS is going to adopt a new process for publicly sharing the proposed values for new and revised procedure codes prior to implementation, but this process will not begin until CY 2016. To allow an opportunity for public input into the values for the 2015 CPT code sets for radiation therapy, CMS will not adopt these new codes under the PFS until CY 2016. CMS describes the implementation of the new process as follows:[2]

As suggested by some commenters, we will use CY 2016 as a transition year. In the PFS proposed rule for CY 2016, we will propose values for the new, revised, and potentially misvalued codes for which we receive the RUC recommendations in time for inclusion in the CY 2016 proposed rule. We will also include proposals for the two code sets delayed from CY 2015 in the CY 2016 proposed rule, as discussed above. For those new, revised, and potentially misvalued codes for which we do not receive RUC recommendations in time for inclusion in the proposed rule, we anticipate establishing interim final values for them for CY 2016, consistent with the current process. Beginning with valuations for CY 2017, the new process will be applicable to all codes. In other words, beginning with rulemaking for CY 2017, we will propose values for the vast majority of new, revised, and potentially misvalued codes and consider public comments before establishing final values for the codes; use G-codes as necessary in order to facilitate continued payment for certain services for which we do not receive RUC recommendations in time to propose values; and adopt interim final values in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive RUC recommendations in time to propose values.

This means that while hospitals will use the new CPT procedure codes for radiation treatment delivery and image guidance, physicians and freestanding radiation treatment centers will use HCPCS Level II G-codes referenced in Table 1, page 11. CMS further states:[2]

There is substantial work to be done to assure the new valuations for these codes accurately reflect the coding changes. Accordingly we are delaying the use of the revised radiation therapy code set until CY 2016 when we will be able to include proposals in the proposed rule for their valuation. We are maintaining the inputs for radiation therapy codes at the CY 2014 levels. [Note: Due to budget neutrality adjustments and other system-wide changes, the payment rates may change.] Since the code set has changed and some of the CY 2014 codes are being deleted, we are creating G-codes as necessary to allow practitioners to continue to report services to CMS in CY 2015 as they did in CY 2014 and for payments to be made in the same way. All payment policies applicable to the CY 2014 CPT codes will apply to the replacement G-codes. The new and revised CY 2015 CPT codes that will not be recognized by Medicare for CY 2015 are denoted with an "I" (Not valid for Medicare purposes). [Table 1, page 11] *lists the G-codes that we are creating and the CY 2014 CPT codes that they are replacing.*

CMS also finalized the interim RVUs for hyperthermia and HDR brachytherapy, and increased the equipment time from 86 minutes to 104 minutes for codes **77373** (SBRT), **77422**, and **77423** (neutron treatment). Last, the RUC made a recommendation regarding the practice expense inputs for digital imaging services. CMS accepted the RUC recommendations to remove the film supply and equipment items and to allocate minutes for a desktop computer as a proxy for the PACS (Picture Archiving and Communication System) workstation as a direct expense. This policy impacts new brachytherapy isodose plan codes **77316**, **77317**, and **77318**.

Locum Tenens

In the 2015 proposed PFS rule CMS indicated concern about the operational and program integrity issues that result from the use of substitute physicians to fill staffing needs or to replace a physician who has permanently left a medical group or employer. There are concerns that a physician who has left a group may still have claims filed in his or her name and NPI (national provider identification) number, as well as the SSA requirement for the locum tenens identifying information to be submitted with each claim. As a result, CMS solicited comments on the policy for substitute physician billing arrangements. Through this solicitation, the agency hoped to understand better current industry practices for the use of substitute physicians and the impact that policy changes limiting the use of substitute physicians might have on beneficiary access to physician services. CMS received a few comments on the issues raised in this

solicitation and will carefully consider these comments in any future rulemaking on this subject.

Concerns with the 10-day and 90-day Global Packages

CMS supports bundled payments as a mechanism to incentivize high-quality, efficient care. Although on the surface, the PFS global codes appear to function as bundled payments similar to those Medicare uses to make single payments for multiple services to hospitals under the Inpatient and Outpatient Prospective Payment Systems, CMS believes that these global codes function significantly differently than other bundled payments. Another concern is that payment for the PFS global packages relies on valuing the combined services together. This means that there are no separate PFS values established for the procedures or the follow-up care, making it difficult to estimate the costs of the individual global code component services. After consideration of all the comments received regarding this proposal, CMS finalized the proposal to transition and revalue all 10- and 90-day global surgery services with 0-day global periods, beginning with the 10-day global services in CY 2017 and following with the 90-day global services in CY 2018. Medically reasonable and necessary visits would be billed separately during the pre- and post-operative periods outside of the day of the surgical procedure. This change will affect some brachytherapy procedures and related surgical services.

Open Payments Update

The Open Payments program establishes a system for annual reporting and increasing public awareness of financial relationships between drug and device manufacturers and certain healthcare providers. The Open Payments program requires applicable manufacturers to report payments or other transfers of value they make to physicians and teaching hospitals to CMS. In its final rule, CMS finalized four changes to this program:[2]

1. CMS is deleting the definition of "covered device" as it is duplicative of the definition of "covered drug, device, biological, or medical supply," which is already defined in regulation.
2. CMS is deleting the Continuing Education Exclusion in its entirety. According to CMS, eliminating the exemption for payments to speakers at certain accredited or certifying continuing medical education (CME) events will create a more consistent reporting requirement, and will also be more consistent for consumers who will ultimately have access to the reported data.
3. CMS will require the reporting of marketed name and therapeutic area or product category of the related covered drugs, devices, biologicals, or medical supplies, unless the payment or other transfer of value is not related to a particular covered or non-covered drug, device, biological, or medical supply.
4. CMS will require applicable manufacturers to report stocks, stock options, or any other ownership interest as distinct categories. This will enable the collection of more specific data regarding the forms of payment made by applicable manufacturers.

Based on public comments and manufacturers' need to update their systems according to the new requirements, these changes will be implemented for data collection in CY 2016.

Other Issues

In addition to the specific topics listed above, CMS also provided details on the Physician Compare Website, the Electronic Health Record Incentive Program, the Medicare Shared Savings Program, value-based modifiers, the Physician Self-Referral Prohibition, and Physician Quality Reporting Systems. OI

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Approved Drugs

- The U.S. Food and Drug Administration (FDA) has approved **Avastin® (bevacizumab solution for intravenous infusion)** (Genentech, Inc., www.gene.com) in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for the treatment of patients with platinum-resistant, recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

- The FDA has granted accelerated approval for **Blincyto (blinatumomab)** (Amgen Inc., www.amgen.com) for the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (R/R ALL).

- The FDA has approved **Cyramza® (ramucirumab)** (Eli Lilly and Company, www.lilly.com) for use in combination with paclitaxel for the treatment of patients with advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma whose cancer has progressed on or after prior fluoropyrimidine- or platinum-containing chemotherapy. In April 2014, Cyramza was approved as a single agent for the treatment of patients with advanced gastric or GEJ adenocarcinoma refractory to or progressive following first-line therapy with platinum or fluoropyrimidine chemotherapy.

  The FDA has also approved Cyramza for use in combination with docetaxel for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with disease progression on or after platinum-based chemotherapy.

- Merck (www.merck.com) announced that the FDA has approved **Gardasil® 9 (Human Papillomavirus 9-valent Vaccine, Recombinant)** for the prevention of certain diseases caused by nine types of Human Papillomavirus (HPV). Gardasil 9 now has the potential to prevent approximately 90 percent of cervical, vulvar, vaginal, and anal cancers.

- AstraZeneca Pharmaceuticals (www.astrazeneca.com) announced that the FDA has granted accelerated approval to **Lynparza™ (olaparib)** for women with advanced ovarian cancer associated with defective *BRCA* genes, as detected by an FDA-approved test. Lynparza is a poly ADP-ribose polymerase (PARP) inhibitor that blocks enzymes involved in repairing damaged DNA. It is intended for women with heavily pretreated ovarian cancer that is associated with defective *BRCA* genes.

- Ipsen Biopharmaceuticals, Inc. (www.ipsen.com), an affiliate of Ipsen, announced that **Somatuline® Depot® (lanreotide) Injection**, 120 mg, was approved by the FDA for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs) in adult patients with unresectable, well, or moderately differentiated, locally advanced or metastatic disease to improve progression-free survival.

Drugs in the News

- Advaxis, Inc. (www.advaxis.com), announced that the FDA has cleared its Investigational New Drug (IND) application to conduct a Phase 1/2 clinical study of **ADXS-HPV (ADXS11-001)** alone or in combination with MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, for the treatment of advanced, recurrent or refractory HPV-associated cervical cancer and HPV-associated head and neck cancer. The trial is expected to begin patient enrollment in early 2015.

  The company also announced that it has submitted an IND to the FDA to conduct the first-in-human study of **ADXS31-142** for the treatment of metastatic castration resistant prostate cancer (mCRPC). ADXS31-142 is the company's lead Lm-LLO immunotherapy designed to specifically target prostate-specific antigen (PSA). Pending FDA acceptance of the IND submission, the proposed Phase 1/2 protocol is designed to evaluate the safety and efficacy of ADXS31-142 as monotherapy and in combination with Keytruda® (pembrolizumab).

- The FDA has granted orphan drug designation to BerGenBio's (www.bergenbio.com) **BGB324** for the treatment of acute myeloid leukemia (AML). BGB324 is a first-in-class, highly selective small molecule inhibitor of the Axl receptor tyrosine kinase. It blocks the epithelial-mesenchymal transition (EMT), which is a key driver in drug-resistance and metastasis.

• Genentech (www.gene.com) announced the company has submitted a new drug application (NDA) to the FDA for **cobimetinib** for treatment, in combination with Zelboraf® (vemurafenib), for people with BRAF V600 mutation-positive advanced melanoma.

• Cellectar Biosciences, Inc. (www.cellectar.com) announced that the FDA has granted orphan drug designation to **I-131-CLR1404** for the treatment of multiple myeloma.

• The FDA has granted orphan drug designation to Juno Therapeutics, Inc.'s (www.junotherapeutics.com) **JCAR015**, a chimeric antigen receptor product candidate. The designation was granted for treatment of acute lymphoblastic leukemia. JCAR015 Phase I trials are currently underway at Juno's collaboration partner, Memorial Sloan Kettering Cancer Center.

• Merrimack Pharmaceuticals, Inc. (www.merrimackpharma.com) announced that the FDA has granted fast track designation to **MM-398 (nanoliposomal irinotecan injection)**, also known as "nal-IRI," for the treatment of patients with metastatic adenocarcinoma of the pancreas who have been previously treated with gemcitabine-based therapy.

• The FDA has granted fast track designation Momenta Pharmaceuticals, Inc.'s (www.momentapharma.com) **necuparanib**, as a first-line treatment in combination with Abraxane® and gemcitabine in patients with metastatic pancreatic cancer. Momenta recently announced the successful completion of Part A of the Phase I/II study and has initiated the Part B (Phase II proof-of-concept) study.

• Radius Health, Inc. (www.radiuspharm.com) announced that the FDA has accepted the Company's IND application for its investigational drug **RAD1901**, a tissue-selective estrogen receptor degrader (SERD) being developed for potential use in metastatic breast cancer. The Phase I study that is the subject of the IND is a multi-center, open-label, two-part, dose-escalation study of RAD1901 in postmenopausal women with advanced estrogen receptor positive and *HER2*-negative breast cancer, designed to determine the recommended Phase II dose and include a preliminary evaluation of the potential anti-tumor effect of RAD1901.

Devices in the News

• GI View Ltd. (www.giview.com), announced that it has received FDA 510(k) clearance for the **Aer-O-Scope™ Colonoscope System** for colorectal cancer screening. Market introduction is expected in the U.S. in early 2016.

• **Narrow Band Imaging® (NBI)** (Olympus, www.medical.olympusamerica.com), has received FDA 510(k) clearance for targeting of biopsies not seen under white light and improved visualization of tumor boundaries in non-muscle-invasive bladder cancer patients.

• RaySearch Laboratories AB (www.raysearchlabs.com) has received 510(k) clearance from the FDA for version 4.5 of its treatment planning system **RayStation®**. The new version includes a wide range of new features that will help cancer centers improve their treatment planning process and also enable them to take adaptive planning a step further, including ultrafast and robust optimization for proton and photon treatments, boosted dose calculation, automated breast planning, and biomechanical deformable registration using the unique MORFEUS technology.

• **SoftVue™** (Delphinus Medical Technologies, Inc., www.delphinusmt.com) has received another 510(k) clearance from the FDA. This additional regulatory clearance was granted less than a year after obtaining the first 510(k). Powered with circular, volumetric transducer technology, SoftVue is engineered with a proprietary process of ultrafast 360 electronic sequencing, enabling transducer elements to both send and receive signals. SoftVue captures reflection echoes from all directions around the breast and gathers transmitted signals coming through the breast.

Genetic Tests and Assays in the News

• Myriad Genetics, Inc. (www.myriad.com) announced that it has received approval from the FDA for **BRACAnalysis CDx** to be used as the only companion diagnostic in conjunction with AstraZeneca's drug Lynparza™ (olaparib). Lynparza is a poly ADP-ribose polymerase (PARP) inhibitor for patients with germline mutations in *BRCA*1/2 advanced ovarian cancer who have had three or more lines of chemotherapy. BRACAnalysis CDx is a highly accurate molecular companion diagnostic test that identifies deleterious or suspected deleterious mutations in the *BRCA*1 and *BRCA*2 genes, using DNA obtained from a blood sample. OI

spotlight

Ann B. Barshinger Cancer Institute at Lancaster General Health, Lancaster, Pa.

The Ann B. Barshinger Cancer Institute (ABBCI) at Lancaster General Health is a new state-of-the-art facility that exhibits a model of integrated care, with prevention, screening, treatment, education, and survivorship care all under one roof. Every feature of the 100,000-square-foot outpatient facility, which opened its doors in the summer of 2013, has been carefully considered to contribute to the physical and spiritual well-being of patients. "We are a community hospital that feels, as part of our community, it's a privilege to take care of the people we know. I think the community defines the programs" said Randall Oyer, MD, medical director of the Cancer Institute.

The program is built on the National Cancer Institute (NCI) model, which recognizes that 85 percent of cancer care is delivered in the community setting, and therefore a strong partnership with an academic organization is crucial. LG Health maintains a close relationship with the University of Pennsylvania and the Penn Cancer Network, and involves the university in their quality initiatives, treatment planning, research, clinical services, and other programs. The Cancer Institute also utilizes many of the NCI tools available online for program development, quality improvement, and patient education.

The program also represents a unique and successful combination of multiple specialties into a single multi-specialty clinic run by the Cancer Institute. Hospital-employed physicians, private practice, and faculty from Penn Medicine all practice in the same space and specialties include hematology oncology, radiation oncology, GYN oncology, breast surgery, colorectal surgery, hepatobiliary surgery, and palliative care. Creation of this model was only possible after all parties agreed to work in the best interest of the patient, which required adopting a single clinical team, a single scheduling system and EMR, and a single billing system, all in a central location.

Building a Center for the Community

While the new facility was under construction, a diverse advisory committee of current patients, former patients, family members of patients, and representatives of local support organizations met over a period of six months. The group addressed issues related to care access, parking difficulties, the check-in process, and availability of clinical offerings.

The unified message that came from this group of stakeholders was that while the quality of care was high, the delivery of care was fragmented. The resulting cancer center design houses all care services under one roof.

The Cancer Institute's consolidated registration and check-in process, recently highlighted at an Epic User Group Meeting, allows patients to register only once for any future hospital or professional services. Check-in at a kiosk is a quick process that can also provide patients with a monthly appointment schedule.

The building has two floors, but with a unique design of three concentric arcs. The patient exam rooms are along the outer arc lined with windows. The innermost arc is a circulation corridor that connects each department. The middle corridor separating the two is an inner hallway where the staff has offices, equipment, and supplies.

The first floor is dedicated to patient-physician appointments, including initial consultation, diagnosis, follow-up, and check-ups. The exam rooms that ring the outside are divided into five pods with eight rooms. The rooms are clustered around a nursing station and a collaboration zone where the physicians, nurses, genetic counselors, and social workers can work in a single space side by side to collaborate on the care of patients. The zone functions as the working clinic hub for a patient session and contains four built-in computers and a large conference table.

A larger family consultation room, with a sofa and chairs rather than an exam table, is also available for longer visits, bigger families, or more relaxed discussions.

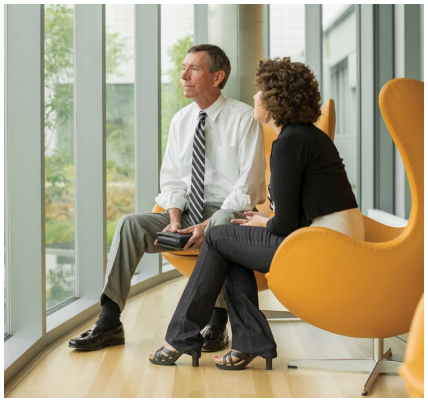
Robust Supportive Care

The Cancer Institute has specialized nurse navigators in breast, GI, urology, lung, gynecologic oncology, and leukemia and lymphoma. Two dietitians act as navigators for the head and neck cancer patients. Navigators are always available at a time of crisis; at diagnosis; when there is a change in condition; or by physician, patient, or family request.

The Image Recovery Center on the second floor is a boutique run by a licensed cosmetologist, two certified mastectomy fitters, an acupuncturist, and a massage therapist. The center has wigs, lymphedema-sleeve fittings, custom garments,





mastectomy fittings, and skin care products, and offers haircuts, nail services, and wig stylings for patients.

The upper level also houses the education center. The main education room seats 144 people, and has video-conferencing capabilities, allowing the Cancer Institute to connect with their care affiliates. The education center hosts tumor boards as well. Breast and lung tumor boards meet every week; GI, hematologic malignancy, head and neck, GYN, and urology boards meet monthly.

Also on the upper level are a healthy food café and a tranquil healing garden. The Cancer Institute itself is constructed around the garden.

The Cancer Institute's survivorship and supportive care program are funded through community philanthropy to "help patients as they navigate the complexities of their treatment, get extra support, provide a soft landing, and help them recover from the fog of treatment," said Dr. Oyer. Staff members include an oncology-specialized chaplain, three oncology-certified social workers, a full-time financial counselor, and a certified full-time behavioral medicine counselor.

Another supportive care offering at the Cancer Institute is a symptom management clinic. Same-day appointments are available for patients experiencing pain, shortness of breath, fever, nausea, and other side effects. Patients see a physician's assistant working in coordination with the Cancer Institute's physicians.

Cutting-Edge Technology

Cancer treatment takes place on the second floor of the Cancer Institute, which features the program's new CyberKnife M6. The Radiation Oncology Department offers a full range of treatment modalities, including Tomotherapy, Gamma Knife, HDR and LDR brachytherapy, respiratory gating, 4D imaging, radionuclide therapy, orthovoltage radiation, and TrueBeam linear accelerators.

The Infusion department is located on the second level, and has 31 infusion bays, all individual and private. Each bay has customizable lights, music, and window shades in addition to TV featuring on demand movies for relaxation, education, or entertainment.

The dedicated oncology pharmacy is staffed by oncology-certified pharmacists and oncology-specialized technicians. The pharmacy created a patient education video to show patients all the lengthy safety steps involved to make their chemotherapy and what it takes to calculate doses and mixes. Watch it online at: www.youtube.com/watch?v=izFEX_NMFe4.

The Cancer Institute is an American College of Surgeons Commission on Cancer (ACoS-CoC) accredited cancer program and NAPBC (National Accreditation Program for Breast Centers) accredited, as well as a Breast Imaging Center of Excellence. The Cancer Institute has also been awarded American College of Radiology (ACR) Breast MRI Accreditation and American College of Radiation Therapy (ACR) Accreditation. OI

Select Support Services

- Behavioral counseling
- Chaplaincy
- Dietitian services
- Financial counseling
- Genetic Counseling
- Lymphedema therapy
- Navigation
- Social Work

Number of new analytic cases seen in 2013: 1,979

Molecular Testing in the Community Oncology Setting

MOLECULAR TESTING

Resources & Tools for the Multidisciplinary Team

The evolution of biomarker-driven medicine is having an impact on oncology patient care—both diagnostically and therapeutically. Recent research suggests that actionable mutations are found in 62 percent of patients with lung adenocarcinoma.[1] To ensure that cancer programs are optimizing molecular testing processes, the Association of Community Cancer Centers (ACCC), in collaboration with Pfizer Oncology, launched a multi-phased initiative in 2012 titled, "Molecular Testing in the Community Oncology Setting."[2] Phase I consisted of member surveys and a published report that summarized key findings from the survey and outlined effective strategies to overcome common barriers.

BY JOSEPH KIM, MD, MPH

Learning Lab Participants

In 2013, ACCC proceeded with Phase II, Learning Labs for Process Improvement, a program for member institutions that focused on improving molecular testing at the system level through experiential learning labs. Eight member centers were selected to participate in this project:

1. Anne Arundel Medical Center, DeCesaris Cancer Institute, Annapolis, Md.
2. IU Health Goshen Center for Cancer Care, Goshen, Ind.
3. Riverside Health System, Riverside Cancer Care Center, Newport News, Va.
4. Shawnee Mission Medical Center, Shawnee Mission, Ks.
5. Southside Regional Medical Center, Petersburg, Va.
6. St. Vincent's HealthCare, Jacksonville, Fla.
7. The Methodist Hospitals, Oncology Services, Merrillville, Ind.
8. The Thomas Johns Cancer Hospital, Richmond, Va.

Each program identified an administrator and a physician champion who helped to gather baseline data, schedule the learning lab workshop, and hold follow-up meetings with staff to monitor progress as they proceeded in the process-improvement journey.

Collecting Baseline Data

Participating programs gathered baseline performance data on molecular testing in lung cancer at the start of the project to assess their current clinical practices and workflows. The process of collecting this information involved working with their cancer registry teams to review patient charts and interview clinicians to gather feedback on key workflow issues.

The 8 programs offered 12 months of recent de-identified, aggregated, data from their cancer registries and patient charts which indicated:

- The total number of lung cancer patients
- The population of lung cancer patients who had adenocarcinoma compared with other histology subtypes
- The number of lung adenocarcinoma patients by disease stage
- The breakdown of lung adenocarcinoma patients by disease stage who had *EGFR* or *ALK* molecular testing.

Additionally, programs were asked to review their current clinical workflow processes and answer questions on issues such as:

- What types of steps occur in the patient flow when someone has a suspected lung mass and requires a biopsy?
- How often are lung biopsies performed by radiologists compared with pulmonologists? Compared with surgeons?
- How do physicians performing lung biopsies communicate with pathologists about the need for molecular testing?
- What are key reasons why some lung cancer patients are not receiving molecular testing?

By reviewing its data and existing workflows, each program had a starting point to engage its team members in an open dialogue about the current state of molecular testing in lung cancer at that center and about some potential opportunities for improvements.

> ... each program is taking a personalized approach to their process improvement plan based on their staffing resources, organizational structure, relationships with physician groups, and other factors.

Tailored Workshops

Based on each program's baseline data, tailored learning lab workshop materials were prepared and ACCC scheduled learning lab workshops. Participants at these two-hour workshops included cancer center administrators, senior executive leaders, physicians (medical oncologists, pulmonologists, pathologists, radiologists, radiation oncologists, and surgeons), nurses, patient navigators, quality improvement professionals, cancer registrars, and other members of the multidisciplinary cancer care team.

During the workshop, attendees:

- Reviewed the 2013 College of American Pathologists/International Society for the Study of Lung Cancer/Association of Molecular Pathologists guidelines on molecular testing in lung cancer[3]
- Discussed key opportunities for process improvement
- Explored how to proceed with implementing some of those changes.

Learning lab attendees were also introduced to the Plan-Do-Study-Act (PDSA) cycle for improvement. At the conclusion of each workshop, attendees were asked to schedule a follow-up meeting to discuss and prioritize areas for improvements and corresponding action items.

PDSA Framework

Each program held a follow-up meeting to outline two to three improvement plans and applied the PDSA cycle for improvement to develop specific action items, agree on progress metrics, and document the changes over a three-month period. Table 1, right, summarizes key areas for improvement and potential action items that were identified by the learning lab participants. (For more information, go to www.accc-cancer.org/molecculartesting.)

Three-Month Follow-Up

Three months after the learning lab workshops, the eight programs were asked to evaluate their progress and provide an update on the improvement plans based on the PDSA framework. The following areas for improvement emerged as top priorities in several programs:

- Biopsy samples insufficient for molecular testing
- Molecular tests not ordered for eligible patients
- Lack of pathology-driven reflexive molecular testing.

However, each program is taking a personalized approach to its process improvement plan based on staffing resources, organizational structure, relationships with physician groups, and other factors. Centers had performed root cause analyses to determine why certain issues were problematic and had held several meetings or formed committees to discuss improvement strategies. This article describes how the different programs made improvements in these three areas. To learn how programs approached other areas for improvement, go to www.accc-cancer.org/molecculartesting.

Biopsy samples insufficient for molecular testing. The majority of lung needle biopsy procedures are performed either by radiologists who use computed tomography (CT)-guidance or by pulmonologists who perform a bronchoscopy.[4] Needle biopsy methods generally include: 1) fine-needle aspiration (FNA), which may be performed by radiologists or pulmonologists and 2) core-needle biopsy (CNB), which is only performed by radiologists. In some cases, tissue can be obtained from thoracic surgeons, who acquire tissue samples from lung cancer patients using minimal to fully invasive techniques (i.e., aspiration, needle, incisional and excisional biopsies, open surgeries, and resection).

In general, CNB yields larger segments of tissue (histology) that are better for molecular testing.[5] FNA yields fluid and cells (cytology) and when the sample is adequate, the pathologist can create a cell block for molecular testing analysis.[6]

Several learning lab participants found that their radiologists strongly preferred using FNA over CNB, so there was an opportunity to educate these radiologists about the importance of using CNB when it is safe and appropriate. One center performed an internal review and assessment of its CT-guided biopsies to compare complication rates between FNA and CNB and found improvements in biopsy sample adequacy with CNB and no significant differences in complication rates between FNA and CNB.

Some programs found that their physicians were only obtaining minimum amounts of biopsy tissue for diagnosis and were not aware of the importance and relevance of molecular testing in lung cancer. These programs offered further education to these physicians, improved communication between the pathologists, and provided feedback to ensure that additional biopsy samples were being obtained.

> When programs realized that sometimes a physician may forget to order molecular tests on lung cancer patients, they focused their efforts on building or improving their reflex molecular testing pathway.

Molecular tests not ordered for eligible patients. During the learning lab workshops, some attendees were puzzled when the discussion led to the following question: "Some of our eligible lung cancer patients did not receive molecular testing on their biopsies. Why was molecular testing not performed?" This question provided an opportunity for each team to perform a root cause analysis to better understand why those patients did not receive molecular testing and the teams identified these reasons:

- The amount of biopsy tissue was inadequate for testing
- The physician forgot to order the molecular test
- The patient decided not to receive any further treatment
- The physician did not feel that the test would change treatment options.

When biopsy samples are extremely limited in quantity, it becomes increasingly important to communicate the priority of molecular testing to the pathologist who will be processing the biopsy material. Several pathologists shared how they would handle the biopsy

(continued on page 32)

Table 1. Key Areas for Improvement and Potential Action Items

IDENTIFIED AREAS FOR IMPROVEMENT	POTENTIAL ACTION ITEMS
Biopsy samples insufficient for molecular testing	✔ Reach out to programs with effective endobronchial ultrasound (EBUS) procedures and request to let team observe ✔ Improve fine-needle aspiration (FNA) biopsy results by scheduling meeting with radiologist, pulmonologist, and pathologist to review literature on FNA and discuss the optimal approach ✔ Review how radiologists are performing CT-guided lung biopsies and identify opportunities to standardize, make improvements in techniques, and increase appropriate use of core needle over FNA ✔ Compare adequacy rates of core needle biopsy samples vs. FNA
Molecular tests not ordered for eligible patients	✔ Review individual charts to determine why patients were not tested ✔ Discuss findings with team and consider ways to make improvements for future patients ✔ Review how disease staging impacts reflexive molecular testing process ✔ Create a reflexive molecular testing process
Lack of pathology-driven reflexive molecular testing	✔ Develop and implement a reflexive molecular testing pathway ✔ Update process and policy to include: • Simultaneous testing for *EGFR* & *ALK* • Documentation of why *EGFR* & *ALK* were not completed • Create process and tools for monitoring
Clinicians not capturing and documenting key quality measures for reporting	✔ Add molecular testing results to cancer registry as structured data fields ✔ Improve documentation around specific National Quality Forum (NQF), American Society of Clinical Oncology (ASCO), Quality Oncology Practice Initiative (QOPI) or other validated quality measures ✔ Revise progress notes templates or add tabs, fields, and/or sections so that nurses and physicians are consistently documenting information in EHR ✔ Include document of completion for molecular testing, along with test results ✔ Define process or create a template to assure inclusion of documentation of the reason for not completing testing
Lack of standardized reporting formats for molecular test results	✔ Standardize the application of the College of American Pathologists (CAP) lung biomarker reporting template in the EHR system
Difficulty using the cancer registry to measure molecular testing quality	✔ Add *EGFR* and *ALK* test results into cancer registry as a structured data field which will allow periodic review of molecular testing rates in an easier, more efficient manner ✔ Develop more uniform approach for entering NSCLC information into registry
Lack of an established pathway when evaluating a suspicious lung mass	✔ Monitor lung cancer patient data obtained from imaging reports, pathology reports and surgical reports, to include size of lesion, location of lesion, and mode of biopsy to see if there are patterns that drive mode of biopsy decisions ✔ Include information about a lung "hotline" to report abnormal chest x-ray and CT scan reports for radiology charts ✔ Include lung "hotline" information on patient instruction forms for chest X-ray or CT scan
Delays when ordering molecular tests for inpatients due to the CMS "14 Day" rule	✔ Working with senior administration to develop an approved center policy for molecular testing for inpatient diagnosis; educating staff and physicians about policy

(continued from page 30)
sample differently and preserve tissue for molecular testing if they knew that molecular testing was a priority. These discussions led some programs to create new policies designed to improve communication between the physician performing the biopsy and the pathologist. Other programs even modified their pathology requisition form to include more clinical information about the patient and the priority for molecular testing.

When programs realized that sometimes a physician may forget to order molecular tests on lung cancer patients, they focused their efforts on building or improving their reflex molecular testing pathway.

Lack of pathology-driven reflexive molecular testing. Programs agreed that a pathology-driven reflexive molecular testing pathway reduces delays and ensures that a greater percentage of appropriate biopsy samples will undergo molecular testing. (Note: reflex testing is a testing policy that does not require a separate clinician order for each case, is appropriate if agreed on by the lung cancer care team, and may help ensure expedited and consistent routing of specimens for molecular testing.) Most programs agreed that a lung needle biopsy sample that has an adenocarcinoma component should undergo *EGFR* and *ALK* testing at a minimum. Some programs felt that additional mutation markers could be actionable based on the 2014 NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer.[7] Programs also felt that the pathologist should not wait for disease staging information before sending the sample for molecular testing.

Programs that developed and implemented a pathology-driven reflexive pathway formed an interdisciplinary task force to evaluate options and make recommendations to their leadership team. Programs that already had a reflexive molecular testing pathway agreed that they needed to further refine the process to ensure that biopsies were not being missed.

In Closing

This education project helped participating programs apply process improvement methodologies that improved molecular testing in lung cancer patients. Programs relied heavily on a physician to effectively champion these change processes and to work with administrators and other staff members to identify key issues and barriers, as well as ways to overcome them. Every participating program remarked how this project was beneficial because it was able to identify actionable opportunities to make specific process changes that led to improved workflow and patient care. For more information about this project report go to: www.accc-cancer.org/moleculartesting.

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Advisory Committee

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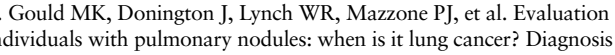

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How Lean Methodology Can Improve Molecular Testing Processes in Advanced NSCLC

BY LAWRENCE D. WAGMAN, MD, FACS; RAYMOND CASCIARI, MD; JOHN MAURICE, MD; PEGGY J. CRABTREE, MBA, RN; AND RUSLAN HORBLYUK, PHD, MBA

The demand for molecular testing services has grown at an enormous rate in recent years, as molecularly-targeted therapies have revolutionized the approach to cancer treatment and challenged the ability of molecular testing facilities to keep pace.[1] In addition, the efficiency of molecular testing processes is increasingly becoming an operational concern for healthcare providers as it relates to the initiation of therapy and in the cost-containment environment driven by reduced reimbursement.[2] Targeted therapies with molecular testing requirements are a prime example of processes that contain natural gatekeepers in their operational flow. Process improvement techniques can help identify the underlying inefficiencies that are delaying or deterring patients from receiving treatment they require.

An example of such a process improvement technique is "lean" methodology, which was developed by Toyota to improve flow and minimize waste.[3,4] In the healthcare setting, lean methodology aims to maximize value to the customer—typically patients—while minimizing any activity that is not valued (i.e., "waste") to provide a streamlined, valued-added service through five simple principles:[3,4]

1. Identify the value
2. Map the value stream and identify waste
3. Create a constant flow of value and eliminate waste
4. Pull patients along their journey
5. Aim to continually improve the patient journey.

Although lean methodology has only been applied in the healthcare industry for a decade, its tools have been used in manufacturing and other industries for more than a century. Clinical laboratories began adopting lean methodology some time ago, resulting in improved turnaround time and workflow, despite high test volumes.[5]

In U.S. healthcare systems, interest in the use of lean process improvement has increased since the passage of the Affordable Care Act (ACA).[6,7] Healthcare providers, payers, and pharmaceutical companies alike are tasked with finding opportunities to reduce cost, improve efficiency, reduce waste, and improve the patient experience at all levels of their organizations—with the ultimate aim of reducing the national expenditure on healthcare and maintaining quality measures. Implementation of lean interventions has the potential to reduce the cost of services incurred by providers and to improve the timeliness of treatment initiation.[5] For example, use of lean methodology in the design of new clinics has been found to improve patient volume, lead time, and satisfaction, while reducing operating costs.[7]

> ...the efficiency of molecular testing processes is increasingly becoming an operational concern for healthcare providers...

Current clinical guidelines in lung cancer treatment recommend that molecular testing results be available within 10 working days of receipt of tissue.[8] Some of the focus that has been given to developing the molecular tests themselves must now turn to improving performance on the front end of the molecular diagnostic testing cycle, from when patients first enter the provider setting and throughout the remainder of their care journey.

Lean in Practice: A Pilot Study

To see how lean methodology could be used to evaluate current molecular testing processes, identify waste, and design an improved process for advanced non-small cell lung cancer (NSCLC) in the community setting, a pilot study was conducted at St. Joseph Hospital, Orange, Center for Cancer Prevention and Treatment (SJH), located in Orange County, Calif. The study also evaluated the applicability of any improved processes to other disease sites within the organization and to the St. Joseph Health System as a whole. The study focused on NSCLC adenocarcinoma (which accounts for about 40 percent of all NSCLC cases),[9] for which two targeted therapies were available at the time the study was conducted: erlotinib for patients with epidermal growth factor receptor (*EGFR*) mutation and crizotinib for patients with anaplastic lymphoma kinase (*ALK*) gene rearrangement and metastatic disease. These actionable mutations occur in relatively small

numbers of patients; *EGFR* mutations are estimated to occur in 10 to 15 percent of Caucasian patients and 40 percent of Asian patients with adenocarcinoma and *ALK* rearrangement in 2 to 7 percent of all patients.[10] These percentages raised the question of how the common bottlenecks and barriers that exist in a tertiary community cancer center impact the ability of clinicians to achieve optimal efficacy in identifying a small number of patients for potential targeted treatment.

> ...applying lean methodology could streamline the care process and ultimately create value for patients through a more timely and protocol-driven molecular testing process...

SJH is a National Cancer Institute (NCI)-designated Community Cancer Center at which an estimated six to eight new cases of NSCLC are treated each month. Within SJH's Thoracic Oncology Program, a comprehensive multidisciplinary team is dedicated to patient care. Supplementing the traditional physician team (medical oncologists, pathologists, pulmonologists, radiologists, radiation oncologists, and thoracic surgeons) are nurse navigators, genetic counselors, registered dietitians, social workers, pain managers, and other nursing and radiology staff. The Thoracic Oncology Program also offers other services, such as computed tomography (CT) screening, video- and robotic-assisted thoracic surgery, radiofrequency ablation, high-dose-rate brachytherapy, pulmonary rehabilitation, an outpatient infusion center, a lung cancer support group, and smoking cessation classes, as well as access to clinical trials to stay at the leading edge of research and innovation. Moreover, SJH is considered a lean organization, and many of its leaders have been trained in lean techniques.

Within the pilot study, the patient journey focused on the subset of patients diagnosed with biopsy-confirmed NSCLC adenocarcinoma of stage IIIb or higher who underwent molecular testing and ultimately received targeted treatment. (Per National Comprehensive Cancer Network [NCCN] guidelines prior to 2014, NSCLC adenocarcinoma of stage IIIb or higher was eligible for molecular testing; 2014 NCCN guidelines recommend that only stage IV tumors be tested.[11]) Researchers involved in the SJH pilot study hypothesized that applying lean methodology could streamline the care process and ultimately create value for patients through a more timely and protocol-driven molecular testing process by eliminating or reducing existing process inefficiencies.

Mapping the Value Stream

Within the SJH pilot study, the key lean principle used was a value stream map (VSM) to assess the current state and design the ideal future state of the care process. To better visualize the processes, progression, waste, and value, the researchers developed an innovative "hybrid value stream map" that combined traditional process mapping tools and lean VSM components.

Researchers conducted semi-structured one-on-one interviews with stakeholders about the current state of the care process and the physician experience at SJH. Group consensus about the current state map was reached with the dedicated multidisciplinary team through the use of lean tools and process mapping. Researchers then worked with the team members to develop the future-state molecular testing process and metrics to support this process. The researchers and selected physician leaders devised an action plan for implementing the monitoring of the metrics, developing a molecular testing protocol, and finalizing the future-state process map.

Major themes of the interviews included:

- Utilization of the molecular testing process
- Tissue insufficiency post-biopsy
- Patient experience
- Utilization of guidelines and protocols
- Communication across the care team
- Reference lab processes
- Reimbursement and cost
- Overall efficiency of the care process.

The interviews showed that the existing protocols for initiating molecular testing at SJH were being used inconsistently, with a high degree of variability that was mostly due to differing perspectives on when reflex testing should be done. Multidisciplinary team members who were aware of the protocol recognized that it was used on a limited basis. Perceived delays in obtaining authorizations for molecular testing and insufficient quantities of tissue were all cited as reasons for further testing delays. Indeed, in some cases it was not apparent from whom authorization should be sought. The interviews also identified the challenges associated with the hospital resources responsible for data collection at the center. Previously, data collection had focused on diagnostics, cancer volumes, and treatments delivered, including cancer registry metrics. Under healthcare reform, however, data collection must now include data to monitor patient experience, access, outcomes, and patient throughput in order to demonstrate value. At the same time that the pilot project was being conducted, simultaneous development of a centralized process within the St. Joseph Health System also improved the accession of these data.

Evaluating the Current State of the Care Process

The next stage of lean implementation was a two-hour session between researchers and the multidisciplinary team to evaluate the current state of the care process, in order to understand all the processes, inputs, outputs, and suppliers and lay them out visually in a hybrid value stream map. Five key components of the care process were built into the framework:

1. ***Patient access:*** all areas through which the patient enters the process (e.g., the hospital or an outpatient setting) and diagnostic testing
2. ***Tissue collection:*** the various points and providers responsible for the biopsy
3. ***Histologic diagnosis:*** evaluation of biopsy tissue by the pathology team for definitive diagnosis and adequacy of tissue for further studies
4. ***Clinical and molecular diagnosis:*** assessment by the oncology team of the pathology diagnoses and determination of appropriate care, including the need for molecular testing
5. ***Treatment:*** determination by the medical oncologist and multidisciplinary team of the most appropriate course of treatment (targeted therapy, chemotherapy, or other).

Several waste elements were identified and highlighted within the hybrid value stream map (see Figure 1, pages 38-39). There was group consensus on the need for primary care physician (PCP) education on patient flow with regard to molecular testing, as well as on lung cancer as a whole. Suggestions included raising PCP awareness that SJH offers molecular testing to better identify and treat advance-stage cancers, that a lung cancer diagnosis is not always fatal, and that referral pathways do exist. In turn, education could lead to wider support among PCPs for lung cancer screening to aid early detection. However, the key to reaching PCPs may be through patient education and social media to prompt patients to initiate discussion and question their PCPs.

Another potential area of waste was the approval process for biomarker testing in the various payer venues, including managed-care, commercial, low-income third-party, and traditional Medicare. The anxiety over possible front-end delays in the process with multiple types of health insurance, each with unique and occasionally arcane regulations, was emphasized. However, the medical oncologists who typically submit the authorizations differed widely in their view of this process and its impact as a barrier in the molecular testing process.

There was significant focus on clinical processes for obtaining appropriate tissue quantity and quality during biopsy. Given the past struggles with quantity and/or quality not being sufficient (QNS) for molecular and other testing, the thoracic oncology team had already moved away from fine-needle aspiration and begun focusing more on core-needle biopsies. Despite this, the interviews indicated that up to 40 percent of samples are QNS for molecular testing, frequently requiring re-biopsy that resulted in a delay in treatment. The current-state discussions again highlighted uncertainty among members of the multidisciplinary team as to whether the oncologist or pathologist was responsible for ordering molecular testing when clinical history and histologic diagnosis confirms a "known" stage IV NSCLC. This led to high variability and process waste in practice and execution.

Another identified area of waste was developing the packet of information on patients referred into SJH during their biomarker evaluation process journey. Although referrals from PCPs or non-specialists to specialists are standard practice, gathering the requisite information (medical history, imaging studies, histologic diagnosis, remaining tissue, consultations with specialists) typically created a bottleneck. In order for the multidisciplinary team to provide the referred patient with the highest quality care, a number of authorizations, medical history reviews, and course of action reviews were required before an appropriate treatment plan could be implemented.

There were also functional delays in identifying, screening, and accruing patients for clinical trial research. The current infrastructure for patient data mining was cumbersome due to the de-centralization of the data sources, thereby causing delays in enrolling patients in appropriate clinical trials at the time of histologic diagnosis. Operational delays as simple as office hours, clinical trial biopsy requirement, and patient access to the informed-consent process exacerbated the delays.

Lastly, timeliness of cross-functional communication across the multidisciplinary team members was identified as an overarching area for improvement throughout the care process.

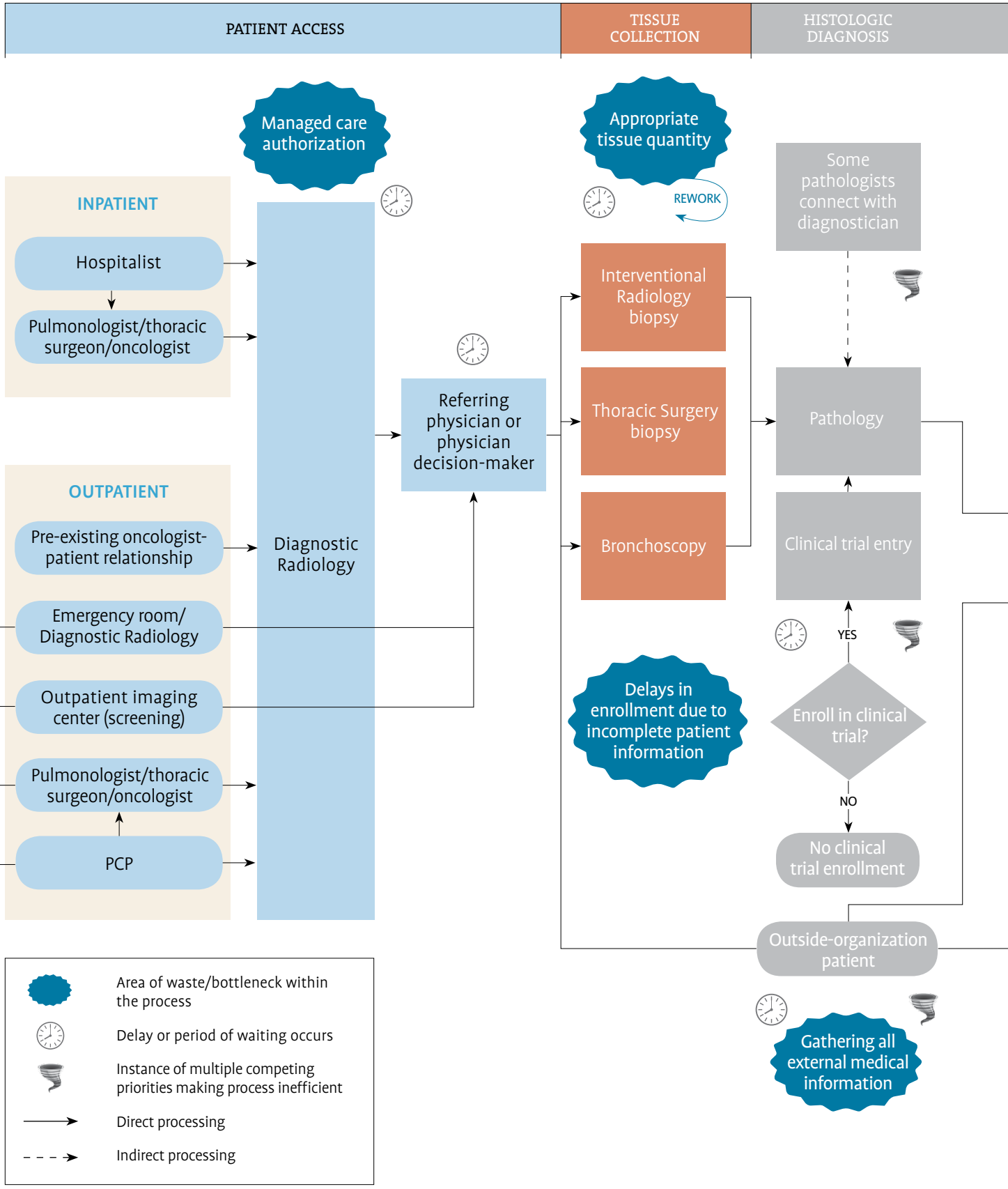
Determining the Ideal Future State of the Care Process

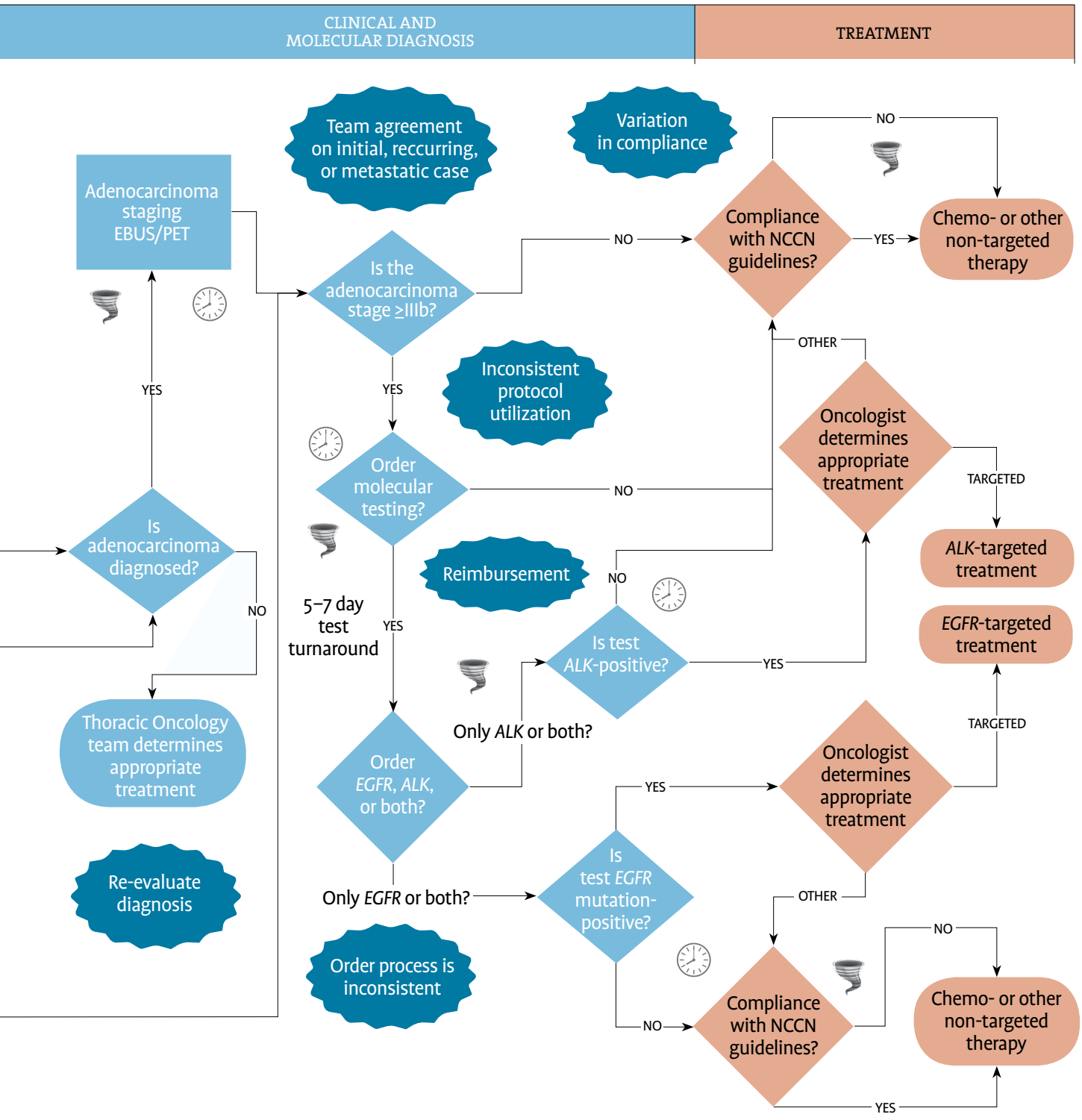
Upon consideration of the current state, physician leaders highlighted that the strength of SJH's thoracic oncology team was its use of a multidisciplinary conference that meets weekly to discuss specific oncology cases. (About 45 members of the multidisciplinary team, including pulmonologists, pathologists, radiation oncologists, medical oncologists, thoracic surgeons, interventional radiologists, and nurse navigators attend these conferences.) The physician leadership viewed this process improvement as a baseline for developing a streamlined blueprint for future innovations and developments within a new, value-added process that could be scaled up to include other sites (e.g., breast or colorectal cancer) within SJH. Additionally, best practices could be provided to other cancer centers.

Walking through the different components of the care process, the team modified pathways to eliminate barriers, areas of confusion, duplicate processes, and areas of rework to assure a streamlined future state that provides optimal value to patients

(continued on page 42)

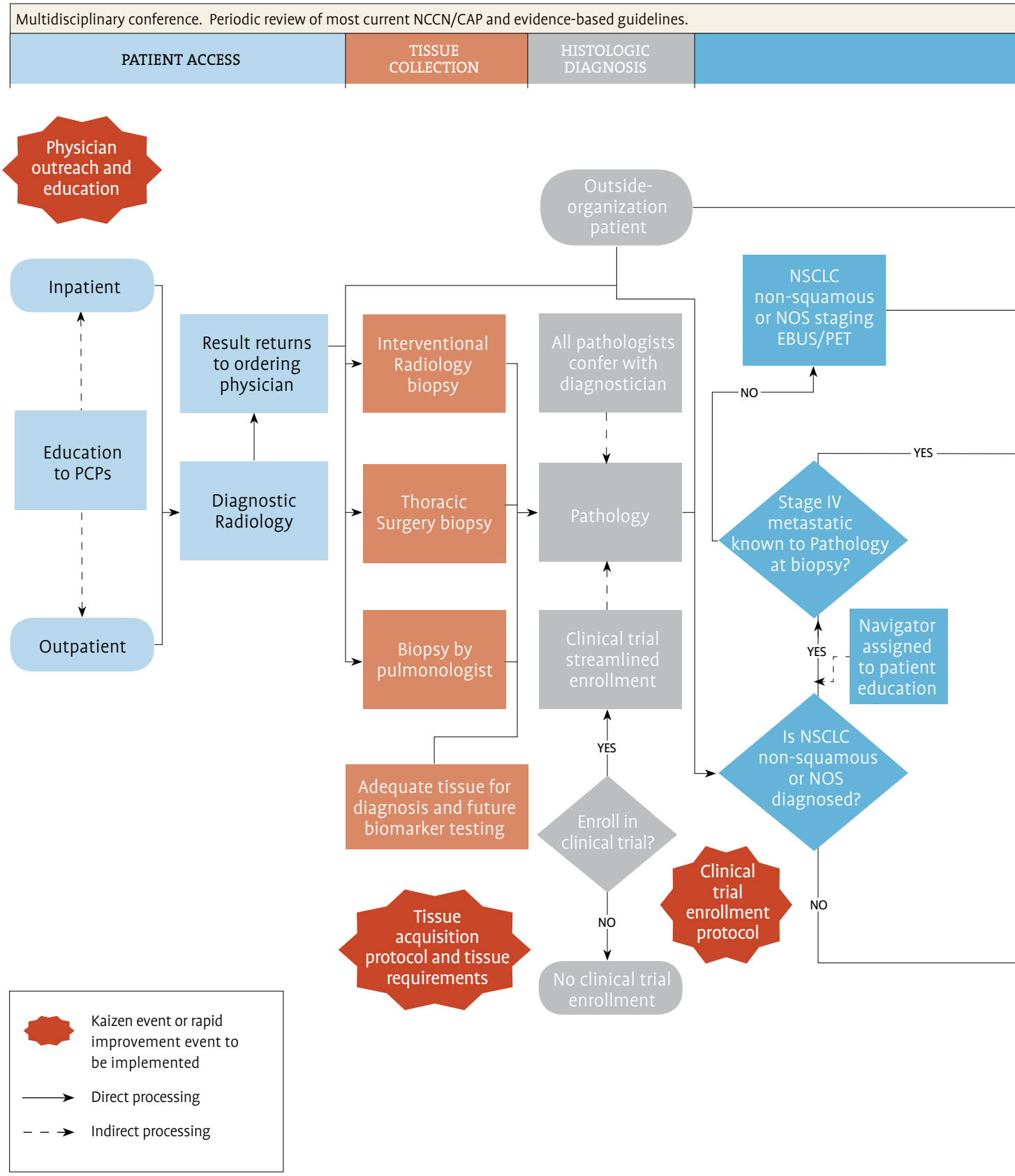
Figure 1. Hybrid Value Stream Map for the Current State of the Care Process

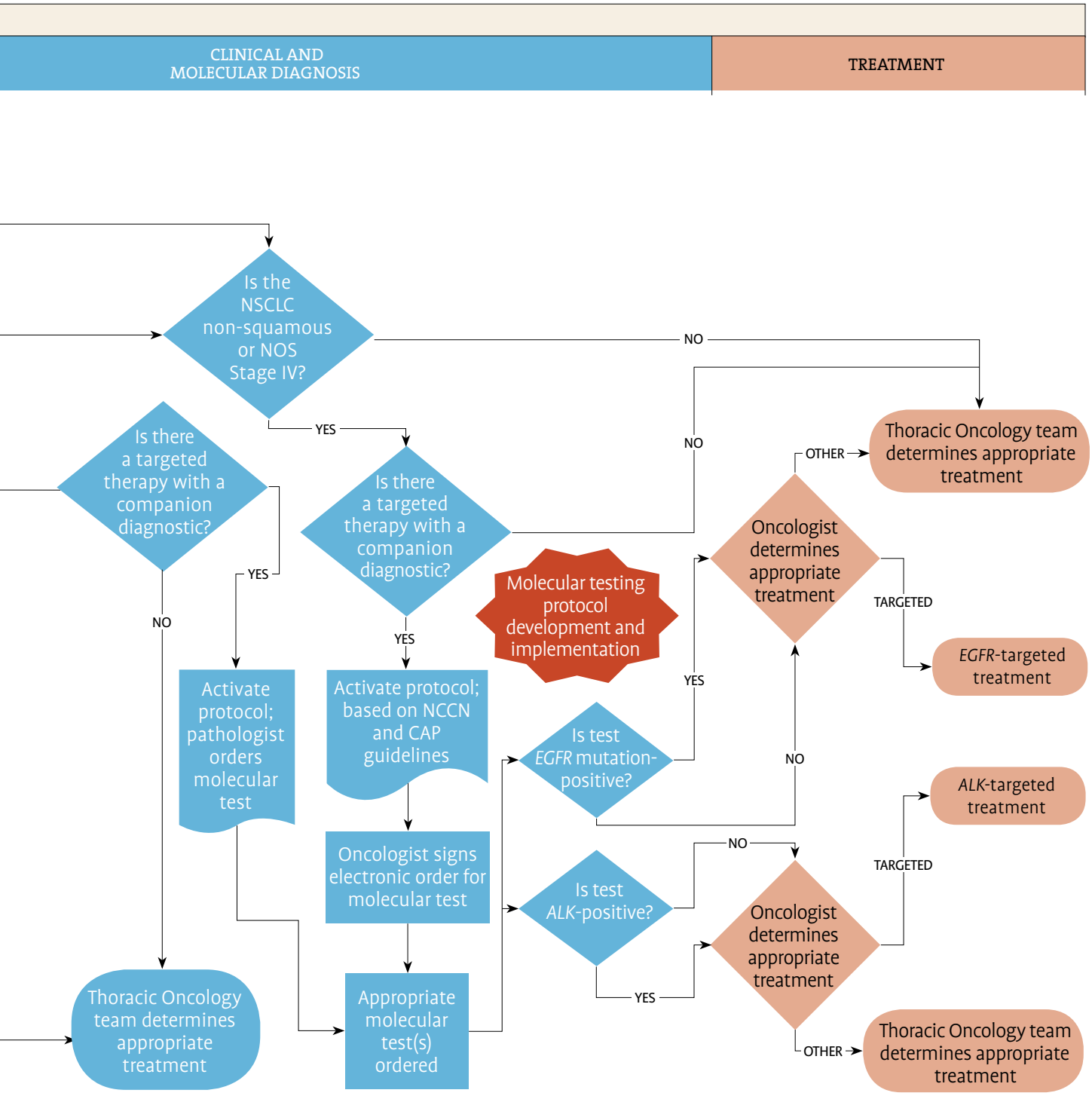




Glossary. *ALK*: anaplastic lymphoma kinase; EBUS: endobronchial ultrasound; *EGFR*: epidermal growth factor receptor; NCCN: National Comprehensive Cancer Network; PCP: primary care provider; PET: positron emission tomography.

Figure 2. Hybrid Value Stream Map for the Ideal Future State of the Care Process





Glossary. *ALK*: anaplastic lymphoma kinase; CAP: College of American Pathologists; EBUS: endobronchial ultrasound; *EGFR*: epidermal growth factor receptor; NCCN: National Comprehensive Cancer Network; NSCLC: non-small cell lung cancer; NOS: not otherwise specified; PCP: primary care provider; PET: positron emission tomography.

(continued from page 37)

Table 1. Action-Oriented Rapid Improvement Events

Physician Outreach and Education

- Town hall meetings with PCPs to discuss thoracic oncology issues
- Inclusion of select PCPs in multidisciplinary thoracic oncology meetings
- One-on-one educational sessions with PCPs on thoracic oncology treatment options and use of molecular testing

Tissue Acquisition Protocol and Tissue Requirements

- Assigning criteria for tissue sample extraction by modality (i.e., needle size, biopsy extraction method, etc.)
- Defining specific minimal biopsy tissue requirements that are sufficient for testing but also patient- and system-friendly

Molecular Testing Protocol Development and Implementation

- Protocol for the responsibilities of ordering molecular testing through use of future-state process criteria (pathologist or oncologist)
- Protocol compliance tracking
- Development of automatic triggers for testing based on clinical status

and stakeholders (see Figure 2, page 40-41). The team outlined three key action-oriented events (in lean terms, "kaizens") to rapidly address areas of inefficiency (see Table 1, above). Participants also agreed that information-sharing stages within the multidisciplinary team, as well as with other program leaders and the SJH administration, should be incorporated throughout the care process.

Two subsequent meetings were held with the multidisciplinary team to review and finalize potential metrics for tracking the adoption of the future state by the SJH Thoracic Oncology Program and to assure the long-term sustainability of the initiative. In the first meeting, participants brainstormed metrics that could be tracked within SJH's current data infrastructure. Among the metrics suggested were variability of cycle times, biopsy QNS rate, cost impact, patient treatment preferences, and protocol compliance.

The study sponsors (the cancer center director, the chief medical officer, and the Thoracic Oncology Program director) were then tasked with selecting the top six metrics to be implemented in the pilot.

In the second meeting these metrics were revisited, and consensus was reached on the final list of metrics:

1. Re-biopsy rates
2. Percent of patients tested with biomarkers who received targeted therapy
3. Number or percent of patients with adequate tissue at time of biopsy to complete biomarker testing
4. Percent of various techniques yielding adequate tissue
5. Aggregated cost of performing test (i.e., scheduling, biopsy, procedure, pathology)
6. Measurement of adherence to protocol
7. Cycle time (time from biopsy order to receipt of results).

Once the metrics were finalized, the participants tasked a work group with determining the granular components needed to support the metrics and assigning accountability for implementation. The stakeholder departments involved in this ongoing implementation effort are the cancer registry, decision support, information technology, quality, and cancer center medical and administrative leadership.

Future Steps

The SJH pilot study successfully employed lean methodology and identified areas of improvement for the molecular testing process in a subgroup of patients with advanced NSCLC. Program evaluation is underway to quantify the impact of this initiative. Through active buy-in of leadership into the pilot process and ongoing engagement through the challenges of transition to the future-state design, the potential for improved efficiency and

Disclosures

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The SJH pilot study successfully employed lean methodology and identified areas of improvement for the molecular testing process in a subgroup of patients with advanced NSCLC.

patient access, and reduced operation costs (e.g., re-biopsy, excessive diagnostic testing, professional fees, cost from ineffective pharmaceutical prescriptions, etc.) may be realized. It is anticipated that this will result in improved timeliness, quality of care, and overall patient satisfaction.

The scalability of the pilot study may, however, be limited, as other cancer programs may be structured differently or operate in a different setting (for example, physician group practice versus integrated delivery network), although modular areas within the flow diagram can be swapped in and out to customize for other user groups. Evaluation of the current state revealed that the SJH System is culturally a lean healthcare organization, and was therefore particularly adaptable to implementation of lean methodology. Additional process improvement training may be required in organizations that have not participated in change efforts in the past.

Key to the success of the post-pilot interventions is the presence of committed physician and hospital leadership and the clinical commitment of the multidisciplinary team to ensure compliance. These concepts have already been achieved with NCCN guidelines and evidence-based protocols. Thus, introduction of additional guidelines and locally developed algorithms is likely to be successful. Future evaluation of the qualitative and quantitative impacts of the pilot study interventions and the sustainability of those efforts is recommended. This will, in turn, facilitate the advancement of other technological evolutions, such as single testing, parallel testing, and whole-genome sequencing.[12] OI

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1975 1985 1995 2005 2015 2025

A History of Cancer Survivorship Plans

BY SIGRUN HALLMEYER, MD,
AND NAVEED CHEEMA, DO

A generation ago cancer care consisted of diagnosis, active treatment, and resigned palliation. Today, advances in cancer care have increased the number of people surviving a cancer diagnosis leading to a new dimension of care—cancer survivorship. The health, psychological, and social needs of cancer survivors are still in the process of being thoroughly understood by the cancer care community. A tool offered up as a means to facilitate survivorship care is the survivorship care plan (SCP). In this *Oncology Issues* we offer a history of SCP development and outline the current state of SCPs in the cancer care community. In part two of our article, we describe our process for developing and using a survivorship care plan, concluding with how this effort fits within the larger context of SCPs throughout the cancer care community and where we intend to focus future efforts. (Editor's Note: Oncology Specialists, SC, Park Ridge, Ill., received a 2014 ACCC Innovator Award for its "EMR-Driven Approach to Survivorship Care Plans." Read more about these efforts starting on page 52.)

Cancer detection, treatment, and management of cancer-related complications have improved greatly in the past 40 years. Accordingly, both the rates of five-year and longer-term survival have also improved. The National Cancer Institute's 2011/2012 Cancer Trends Progress Report, which covered data collected for the year of 2009, found that there were more than 12.6 million cancer survivors in the U.S.[1] The majority of these were prostate, female breast, and colorectal cancer survivors; with five-year survival rates for prostate cancer and female breast cancer being the most robust, standing at 99 percent and 89 percent respectively as of 2003.[1] Across all cancers, the five-year survival rate was estimated at 67 percent in 2003.[1] The number of longer-term survivors, alive at least 20 years after diagnosis, was estimated to be more than 2 million in 2009.[1]

Of these millions of cancer survivors, each has his or her own associated medical, personal, psychosocial, and economic challenges related to individual disease status that must be accounted for in ongoing care. Faced with this evolving and largely overlooked dimension of care, various organizations have issued mandates and statements addressing the cancer care community's collective responsibility to these cancer survivors. Most notably, in 2005, the Institute of Medicine (IOM) released its report, "From Cancer Patient to Cancer Survivor: Lost in Transition."[2] The report notes that cancer survivors "move from an orderly system of care to a non-system in which there are few guidelines to assist them through the next stage of their life or help them overcome the medical and psychosocial problems that may arise."[2]

Cancer survivors "move from an orderly system of care to a non-system in which there are few guidelines to assist them through the next stage of their life or help them overcome the medical and psychosocial problems that may arise.'"

2005 IOM REPORT

The Role of SCPs

As part of this effort, the IOM recommended the use of survivorship care plans as a step towards standardization of survivorship care and provided a general outline of the requirements of such a plan. In general terms, an SCP is a document to be provided to a cancer survivor, which summarizes his or her diagnosis, treatment, associated short- and long-term toxicities, expected course of recovery, signs of late effects or recurrence, follow-up plan, and information to support the survivor through potential complications.[3]

The IOM's recommendation divides SCPs into two sections: record of care and standards of care. Aimed at ensuring that cancer survivors have an accurate understanding of the

events they have undergone in that "orderly environment" of active cancer care, the record of care includes at a minimum the following:[2]

- Diagnostic tests performed and results
- Tumor characteristics
- Dates of treatment initiation and completion
- Therapies provided (surgery, chemotherapy, radiotherapy, transplant, hormonal therapy, gene therapy, clinical trial, or any other therapies) along with indicators of treatment response and toxicities experienced
- Psychosocial, nutritional, and other supportive services provided
- Full contact information on treating institutions and key individual providers
- Identification of a key point of contact and coordinator of continuing care.

The standards of care portion stipulates that on discharge from cancer treatment, every patient and his or her primary healthcare provider should receive a written follow-up care plan incorporating available evidence-based standards of care and should include at a minimum:[2]

- The likely course of recovery from treatment toxicities, as well as a need for ongoing health maintenance and adjuvant therapy.
- A description of recommended cancer screening and other periodic testing and examinations, and the schedule on which these should be performed (and who should provide them).
- Information on possible late and long-term effects of treatments and symptoms of such effects.
- Information on possible signs of recurrence and second tumors.
- Information on the possible effects of cancer on marital and partner relationship, sexual functioning, work, and parenting, and the potential future need for psychosocial support.
- Information on the potential insurance, employment, and financial consequences of cancer and, as necessary, referral to counseling, legal aid, and financial assistance.
- Specific recommendations for healthy behaviors. When appropriate, recommendations that first-degree relatives be informed about their increased risk and the need for cancer screening.
- As appropriate, information on genetic counseling and testing to identify high-risk individuals who could benefit from more comprehensive cancer surveillance, chemoprevention, or risk-reducing surgery.
- As appropriate, information on known effective chemoprevention strategies for secondary prevention.
- Referrals to specific follow-up care providers, support groups, and/or the patient's primary care provider.
- A listing of cancer-related resources and information.

According to the IOM, even though this proposal of SCP use was not preceded by validating studies or evidence, the potential benefits and minimal harm justified its introduction to clinical practice.[3,4] As a result, interest in and support for SCP use began to develop among key oncology organization, notably ASCO, ACS, and the LIVE**STRONG** Foundation.

In 2012 the Commission on Cancer (CoC) updated its Cancer Program Standards (S3.3), requiring accredited cancer centers to include a comprehensive SCP and treatment summary for each patient by 2015. (Approximately 30 percent of U.S. hospitals have achieved CoC accreditation, a widely-recognized seal of quality. These hospitals treat nearly 80 percent of newly-diagnosed cancer patients each year.[5]) However, in September 2014, the CoC revised and amended 3.3, in response to its findings that accredited cancer centers were showing significant lack in readiness for the new standard. The CoC revision now calls for a phased-in approach over five years for adjuvant patients only, allowing for special recognition to cancer centers that attain the standard requirement sooner.

The Current State of SCPs

Overall, the oncology community has made tangible progress in fulfilling a legitimate need for survivorship care plans. However, various studies have illustrated the need for a standardized method of survivorship care. Salz et al. published a two-part study in July 2013 consisting of a comprehensive review of literature investigating the content and use of SCPs from the perspective of patients and providers and a quantitative survey to 53 NCI-designated cancer centers on SCPs in breast and colorectal cancer survivors up to July 2009.[3]

Patient needs. From the patient perspective, there are problems with survivors being both under- and over-informed. Several studies reported patients who were "unsure of their diagnosis and treatment, particularly the less salient details such as presence of metastasis and which diagnostic tests were used."[3,6-11] On the opposite end of the spectrum, other studies reported that [patients] "received too much information when they could not focus on it properly."[3,12,13] Related to the issue of level of detail in SCPs, breast cancer survivors surveyed on the ASCO treatment summary and care plan "felt the language was too technical and preferred more detail about managing their own care."[3,7,12]

These findings bring to light the special nature of information delivery in oncology care. Clearly a record of information is a basic patient need. Simple transmittal of the information is not enough, however, as the psychological stress from cancer diagnosis and treatment can have varying effects on the patient's already

...most oncology providers have "bought into" the idea of SCPs and recognize their utility; however, logistical concerns about resources and time remain.

difficult task of interpreting complex medical information. An effective survivorship care program has an SCP that can succinctly simplify medical jargon for the patient and then has a delivery method nuanced enough to verify whether a patient has indeed understood the information.

In the review by Salz et al., other significant conclusions from the patient perspective were that patients rated highly a desire to be "alerted to and informed about potential psychological issues" related to survivorship.[3,7,12,14,15] Patients also "valued the SCP for its role in involving their PCP in their survivorship journey."[3,6-8,16-18] Finally, not all patients believed that receiving the SCP at the end of treatment was the most beneficial strategy, with preferences for timing of receipt ranging from at the start of treatment to after the end of treatment.[3,8,19]

Provider needs. Compared to oncology providers, primary care providers (PCPs) identified different needs. Various physician surveys showed that only roughly half of surveyed PCPs have confidence in their ability to provide ongoing cancer survivorship care to breast and colorectal cancer patients. This finding was especially true when asked about their confidence in being responsible for cancer recurrence, with 84 percent unsure about type, frequency, or duration of surveillance tests for breast and colorectal cancer.[3,20-21] Because of their varying other clinical responsibilities, it is not unreasonable that PCPs are not intimately familiar with cancer survivorship guidelines and recommendations. In fact, one survey found that over 90 percent of PCPs did not know of the 2005 IOM report regarding SCPs and the needs of cancer survivors. When asked about receiving SCPs from oncology providers, PCPs favored this as tool as a means to improve care for cancer survivorship through written guidelines.[3,12,16,20,22]

Oncology providers are the key stakeholder in the process of implementing SCPs. Evidence seems to suggest that most oncology providers have "bought into" the idea of SCPs and recognize their utility; however, logistical concerns about resources and time remain. Barriers highlighted by oncology providers include choosing an optimal format; allocating time, resources, and personnel to the production of an SCP for each patient; and lack of an adequate reimbursement process for the SCP production and delivery appointment.[3,12,23,24]

A pilot study reviewed by Salz et al. found that it takes 60 to 90 minutes for a research assistant to complete an SCP for a colorectal cancer survivor, which then needs to be reviewed by a nurse. The patient appointment dedicated to SCP delivery took an average of one hour.[3,16,25] Meanwhile, oncology providers surveyed felt that a reasonable amount of time to devote to SCP production was about 20 minutes.[3,12] Of note, two studies found that an EMR-driven tool that allows for automated completion could reduce the oncology provider's workload.[3,23,24]

Lastly, a lingering question remains regarding the effectiveness of SCPs on influencing tangible outcomes. Most of the literature on survivorship care to date is qualitative rather than quantitative. Whether SCPs actually improve either patient-related endpoints (improved compliance with follow-up, earlier detection of secondary toxicities, etc.) or provider-related outcomes (better adherence to standardized surveillance guidelines, among others), remains to be seen. While qualitative studies paint a picture of the needs an SCP may meet, quantitative studies are needed to evaluate if this is indeed being accomplished.

SCPs at NCI-Designated Cancer Centers

The second part of the study by Salz et al. discusses a quantitative survey of 53 NCI-designated cancer centers. The survey focused on SCPs for breast and colorectal cancer survivors, evaluating how often these were being used, their content, degree of adherence to the IOM framework, and time and method of SCP delivery, up to July 2009. The survey found that only 43 percent of centers reported using SCPs for breast cancer survivors, colorectal cancer survivors, or both. Somewhat encouragingly, of the centers that reported not using SCPs, 50 percent said SCPs were in planning or development.

Content evaluation revealed very inconsistent adherence to IOM guidelines. Only 1 of the 23 SCPs that were evaluated included information on psychosocial services received by the patient, and none included history of other supportive services used.[3]

The SCPs evaluated did only slightly better on follow-up plans, with breast cancer SCPs generally better developed than those for colorectal cancer. In both instances, more than half of the SCPs included basic recommendations for ongoing care, but less than 20 percent explained which provider would perform follow-up testing. While 40 percent of breast and 17 percent of colorectal cancer SCPs described potential late effects associated with therapy, very few (20 percent breast, 0 percent colorectal) provided descriptions of other non-therapy related medical and psychological issues that may arise. Signs of recurrence or secondary malignancy were included in 65 percent of breast cancer SCPs, but none of the colorectal cancer SCPs included this information. The potential need for psychosocial support was noted in almost half of all SCPs (50 percent breast cancer, 40 percent colorectal cancer), in

keeping with the qualitative data from part one of the study by Salz et al. in which patients expressed desire for more psychosocial support. However delineation of the psychosocial burden of cancer survivorship was not well addressed, with concerns such as impact on marital issues, sexual dysfunction, parenting difficulties, insurance, employment, legal, and financial assistance details being low (0 to 33 percent, depending on disease and type of psychosocial issue).[3]

Regarding SCP delivery, most centers (71 percent) indicated varying timing of plan delivery within their institution, usually impacted by when patients were referred (self- or provider-driven) to the survivorship program. They were unable to estimate what percent of actual treating clinicians were part of the SCP production and implementation process, but clearly it was not uniform since many of the survivorship programs within the same institution functioned separately from the treating clinician. Among institutions that were able to provide information on SCP delivery statistics, 52 percent stated that less than half of survivors were receiving SCPs.[3]

Salz et al. conclude that SCP use has general support and potential benefit as evidenced by qualitative reviews. However, uptake of SCP implementation among NCI-designated cancer centers is inconsistent, and even among programs that use SCPs, content and delivery is still largely suboptimal. Highlighted deficiencies include lack of psychosocial support information and lack of a key contact person for patients to refer to. Barriers seem to involve financial resources, time, and lack of institutional commitment. Salz and colleagues also hypothesized that part of the variation in SCPs may be due to the actual IOM guidelines, which are essentially a vague and wide-based framework. Additionally, in attempting to address two different audiences (survivors and PCPs), the SCP may lose its effectiveness and fall short of satisfying the needs of either party.[3]

More Inconsistent Use of SCPs

Since the work by Salz et al., other studies have been published that echo their results and also highlight a few other key points. Further supporting the still infrequent use of survivorship care plans, in 2014, Blanch-Hartigan et al. published a study using data obtained from a 2009 nationwide poll of over 1,020 PCPs and 1,130 oncologists, the Survey of Physician Attitudes Regarding the Care of Cancer Survivors. They examined four variables:

1. Whether oncologists gave written SCPs to patients
2. Whether oncologists discussed SCPs with patients and delineated a responsible party for follow-up
3. Whether oncologists performed both of the previous two roles
4. Whether PCPs discussed the SCP and provider follow-up responsibilities with survivors.

They found that while 64 percent of oncologists "always or almost always" discussed issues of survivorship, when it came to regulated use of an SCP, the results were considerably worse. Less than 10 percent of oncologists "always or almost always" provided a written SCP; about 30 percent of oncologists discussed both the SCP and provider responsibilities; and less than 5 percent regularly did both tasks. Only 12 to 34 percent of PCPs regularly participated in discussions of survivorship recommendations or delineation of provider responsibilities of cancer care and other medical care, depending on the task. Two notable findings were that oncologists who were trained in long-term effects of cancer were twice as likely to discuss in detail survivorship care, and that PCPs who received treatment summaries and follow-up plans from oncologists were nine times as likely to discuss survivorship care. Time was again cited as a major barrier.[26,27]

Barriers to SCP Use

The barriers to progress suggested in the study by Salz and colleagues were reiterated by Birken et al. in their 2013 study on SCP prevalence and barriers to use through a 12-point survey sent to 71 member programs of the South Atlantic Division of the American Cancer Society. Their findings regarding prevalence were no better than those of Salz et al., with 76 percent of survey recipients responding that 25 percent or less of their institution members were using SCPs. The majority of reported barriers were the usual suspects: 75 percent reported insufficient organizational resources such as time, staff, money, and training. Other barriers included lack of systems to streamline SCP use, with open-ended responses, including lack of EMR and SCP integration. An interesting finding that speaks to the importance of professional society adoption of SCP use is that 61 percent of respondents reported that their programs began SCP use because of professional society recommendations; 62 percent reported a lack of a professional society accreditation requirement for SCP as a barrier.[28]

SCPs Outside the U.S.

To assess the state of SCP use outside of the U.S., Daudt et al. reviewed 16 SCPs from Canada, the U.K., New Zealand, and Australia on content, method of delivery, and self-evaluation of results after implementation. Most SCPs were delivered by nurses or nurse practitioners at face-to-face meetings. Regarding content, the findings of Daudt and colleagues were similar to the 2009 findings of Salz et al.; survivorship care plans do not all follow IOM guidelines, especially with regards to psychosocial aspects of survivorship and clear designation of a key clinical contact person for follow-up.

Daudt and colleagues did uncover a potentially useful point regarding timing of delivery. They noted in qualitative feedback

> ...oncologists who were trained in long-term effects of cancer were twice as likely to discuss in detail survivorship care and...PCPs who received treatment summaries and follow-up plans from oncologists were nine times as likely to discuss survivorship care.

that patients wished they had been given information earlier in their disease course. When evaluating the U.K.'s National Cancer Survivorship Initiative (NCSI), the authors found a unique approach to intent of SCP and timing of delivery. Unlike most SCPs, which are delivered at the end of treatment, the NCSI plan encompassed the entire cancer timeline. The NCSI SCP began with continuous nurse assessments based on validated tools: the Distress Thermometer and the Sheffield Assessment Instrument. As treatment approached completion, the care team adopted a "risk stratified pathway," in which they categorized patients into different types of care plans determined by the level of their needs thus far based on the validated assessment tools. At the end of treatment, based on the continuously developing care plan already in place, an SCP was generated and also distributed to the PCP. The NCSI's self-evaluation of this process shows that this broad and dynamic approach to care plans improves patient satisfaction, patient confidence in self-managing their health, and cost effectiveness, and decreases need for acute medical care.[29]

The Big Picture

An evaluation of the state of survivorship care plans reveals a developing process. IOM and CoC standards have undoubtedly increased SCP use. However, due to the vagueness of these guidelines, interpretative freedom has allowed an organic growth process for SCPs. This has resulted in progress as well as "growing pains." In summary:

- Adoption of SCP implementation remains inconsistent among the oncology care community.
- Where SCP adoption has taken root, there remains a lack of standardization of the components (as identified by the IOM) and in SCP delivery.
- Two IOM SCP features are under-represented in plans: psychosocial aspects of survivorship and a key point of contact for continuing care.
- Barriers to progress thus far are resource related: time, money, and lack of ability to provide dedicated staff time to this effort.

Remaining issues that need further study include whether SCP implementation is truly cost effective and ultimately useful. Intuitively, a plan that facilitates better preventive care during survivorship should theoretically minimize needs for acute care, as seen by the NCSI. Studies to date have not demonstrated cost savings with SCP use.[30] However, these results were obtained on SCPs as they stand currently. As SCPs themselves improve in content and use, future studies may yield different results in terms of cost effectiveness and utility. Validated metrics are also needed to accurately evaluate SCPs, as well as patient satisfaction, as we move forward in their evolution. At this point in their trajectory, SCPs are recognized as a yet unproven but flexible tool with potential to aid in providing holistic and patient-centered care to cancer survivors. OI

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BY SIGRUN HALLMEYER, MD,
AND NAVEED CHEEMA, DO

An EMR-Driven Approach to Survivorship Care Plans

In order to minimize the challenges of time and resource allocation, Oncology Specialists, SC, set out to create a survivorship care plan (SCP) using its electronic medical record (EMR) as a tool to ease the clinician's workload and time commitment, while still delivering patient-centered care at the end of treatment. We modeled our care plan after the IOM format in an effort to remain true to its varied components. Due to the range in health literacy among end-users (from patients and families to PCPs), we use language that is generic but still informative. Our original plan was to supply a comprehensive SCP to all patients completing therapy (including adjuvant and curative intent, as well as advanced and stage IV disease completing one-line of therapy) by January 2015. However, we have revised our efforts and are currently limiting this process to patients completing neo-adjuvant therapy only following the recent revision in the CoC standards (see page 46).

From EMR to SCP

Our EMR facilitates SCP creation through the ability to:

1. Auto populate appropriate data points, including diagnosis, stage, treatment regimen, and associated physicians.
2. Easily "copy and paste" patient-specific individualized information that does not lend itself to auto population—thus minimizing time spent free-filling the form. Examples of this category include freely-texted MD or RN documentation located in other parts of the EMR chart.
3. Format in such a way that patient-specific data only needs to be marked as present if applicable to that patient. If unmarked, it does not apply to the patient. A significant amount of generic language was added explaining the common trajectory of any cancer patient following the completion of adjuvant therapy and addressing fears and common concerns associated with diagnosis and treatment of cancer (i.e., toxicities, effects on relatives, genetic testing, effects of financial and insurance future, available local resources, among many others). Non-applicable information can be easily deleted. Throughout the SCP, text is carefully selected to address the reader using 6th grade reading level language to assure best possible patient comprehension.

> The documents, coupled with a dedicated care plan delivery meeting, provide a detailed summary of the care provided and contain a personalized road map for each patient for the next five years and beyond.
>
> PAGE 57

Our SCP Components

Our SCP has four components: a treatment summary (Figure 1, page 54), a surveillance section, a health maintenance section (Figure 2, page 55), and a five-year follow-up plan (Figure 3, page 56).

Treatment Summary (IOM: Record of Care). This section indicates the patient's diagnosis, date of diagnosis, whether or not there was recurrence or metastasis and, if so, when and to which anatomic location(s). It lists hormonal, genetic, or molecular results, as well as relevant prognostic markers. The next portion of the treatment summary lists all modalities of treatment.

The chemotherapy section provides the regimen and individual drug names, in addition to specific delineation of chemotherapy

(continued on page 56)

Figure 1. Your Survivorship Care Plan

Your survivorship care plan is a summary of your recent cancer treatment and our recommendations for follow-up care. It provides you with some information about what to expect and where you can find answers.

TREATMENT SUMMARY

The Treatment Summary is a brief record of major aspects of your recent cancer treatment. It includes some information about your diagnosis, treatments used to treat your disease, and side effects that you have encountered.

New diagnosis date: _____ **Recurrence date:** _____

Diagnosis:

<All Primary Diagnoses with Stage> [^Primary – 174.4 – Malignant neoplasm of upper-outer quadrant of female breast, Diagnosed Apr 2014 (Active) Stage IIB, T2, N1, M0, G3^]

Hormone/genetic/molecular results and other prognostic markers (e.g., *BRAF*, *KRAS*) (must be manually entered)

Location of metastasis or recurrence (if applicable): _____

Cancer Therapies

1. **Surgery:** ☐ No ☐ Yes Type: _____
2. **Radiation:** ☐ No ☐ Yes Where: _____
3. **Chemotherapy:** Clinical Trial: ☐ No ☐ Yes Trial: _____

Chemotherapy Intent: ☐ Curative/Adjuvant ☐ Neo-Adjuvant ☐ Disease/Symptom Control

Regimen Given: ☐ First Line ☐ Other, specify: _____

Dose Sense-AC-P

Drugs: _____ Dose: _____ Frequency: _____

Dose Reductions: ☐ No ☐ Yes Reason: _____

Performance Status at the End of Treatment: [<Performance Status> [^0 – Fully active, able to carry on all pre-disease activities without restrictions. (ECOG)^]

Reason for Ending Chemotherapy: ☐ Completed ☐ Progression ☐ Toxicity

Response to Chemotherapy: ☐ Complete ☐ Partial ☐ Stable disease ☐ Progression ☐ Not measurable

Major Side Effects from Chemotherapy (Grade 3-4 Toxicities):

☐ Hair Loss ☐ Nausea/vomiting ☐ Diarrhea ☐ Neuropathy ☐ Low blood counts ☐ Fatigue ☐ Pain

☐ Menopause symptoms ☐ Mucositis ☐ Cognitive impairment ☐ Cardiac ☐ Weight changes ☐ Other: (Specify)

_____

4. **Hormone Therapy:** ☐ No ☐ Yes

Line of Therapy: _____

Intent: ☐ Curative/adjuvant ☐ Disease/Symptom control

Drug/dose: _____

Referrals Provided during Treatment

Physicians: _____

☐ No "Referrals to" exist for this patient

☐ Nutritionist ☐ Psychologist ☐ Physical Therapist ☐ Geneticist ☐ Survivorship Center

☐ Other (Please Identify): _____

Figure 2. Your Follow-up Plan

With any cancer diagnosis, there is a possibility your cancer could return. The chance of this happening depends on the stage and grade of the original tumor. A recurrence could occur locally, which means that the tumor may come back in or near the same area where it was originally located. There is also a chance that the cancer cells from the original tumor could travel to sites farther away from the original tumor, including organs like the lungs, liver, or bones. Part of your follow-up care may include specific exams, blood work, and scans to check for presence of recurrence of your cancer.

5-YEAR POST-TREATMENT PLAN FOR CANCER FOLLOW-UP (medications [e.g., hormones], scans, labs, exams)

Immediate Plan: _____

_____

1- to 5-Year Plan: _____

_____

Treatment for ongoing or long-term side effects (list ongoing side effects and treatment, including PT/medications, etc.):

Many of the side effects from your treatment occur during and a short time after you receive your treatment. Most of these side effects eventually resolve over days or in a few cases months after you complete your treatment. Sometimes, there may be long-lasting side effects that do not completely resolve. You will be closely monitored for long-lasting side effects, and we will discuss additional interventions with you if your recovery is slower than expected.

☐ Side effects have resolved ☐ Side effects persist and are listed below (please describe)

_____

_____

Many cancer treatments have a small risk of causing long-term problems. Some treatments can affect your kidneys, heart, or lungs. They may also cause lifelong numbness or tingling, hearing loss, brittle bones (osteoporosis), thyroid problems, swelling in an arm or leg, diabetes, and other cancers. Some people may have trouble getting pregnant or be unable to get pregnant. You will be followed closely by your doctors for possible long-term effects from your cancer treatment. We want you to discuss any changes in your usual state of health with your healthcare provider team. Many of these problems would be found as part of your routine follow-up and surveillance, but some would require specific testing.

List any known long-term effects that should be monitored based on agents given:

_____

_____

Other Possible Life Effects from Your Cancer Diagnosis:

A cancer diagnosis is always life changing. Along with the physical effects of treatment, your cancer diagnosis and your treatment may have other effects (for example):

- *It may affect your body image, your physical relationships, and your sexual function.*
- *It may impact your personal relationships or you may feel more stressed at work or with your family.*
- *It may impact on your ability to obtain life insurance and may influence your employment.*
- *But, there is help and support available at our Cancer Survivorship Center* [phone number] *or talk to your healthcare provider about your concerns.*

Concerns for Your First-Degree Relatives (children, sisters, brothers, parents):

Most cancers are not related to a genetic predisposition. But, some cancers can occur in families and may be associated with a known genetic mutation. Your genetic risk was assessed by your oncologist and a genetic referral was found to be:

☐ Indicated ☐ Not Indicated

Your Genetic Mutation is:

Your diagnosis of cancer may have implications on your family members even if a genetic mutation is not found. Please tell your first-degree relatives to inform their healthcare providers of your diagnosis and to undergo screening tests for [Fill in the type of cancer].

_____

(continued from page 53)

intent (curative, adjuvant, neo-adjuvant, or palliative). Reasons for ending chemotherapy (completion, progression, or toxicity) are listed, as well as the patient's response to chemotherapy (complete, partial, stable disease, progression, or not measurable). Common grade 3-4 toxicities from chemotherapy are listed and can be selected and explained as applicable to the patient.

Additional supportive therapies used are detailed in the referrals portion included, along with a listing of additional physicians and healthcare providers that the patient was referred to (nutritionists, psychologists, physical therapists, geneticists, etc.).

Surveillance Section (IOM: Standards of Care). This section contains generic language addressing: the short- and long-term toxicities commonly encountered with cytotoxic therapy; how the patient will be monitored for these toxicities; and what to expect in terms of recovery from any current and listed toxicities. Additionally, risk for disease recurrence and monitoring for disease recurrence is addressed here. We also discuss the risk of the patient's malignancy to affect his or her blood-related relatives and include screening recommendations for them, as applicable. Lastly, we address the need for genetic counseling and testing and document whether these options were recommended and/or performed and whether these options should or should not be pursued at this time.

Health Maintenance. This section aims to promote survivorship through identification of resources that the patient can use to incorporate healthy behaviors. The first part of this section is a reference to a separate document, the Health Maintenance Form, which outlines early prevention and standard cancer screening recommendations. The SCP contains a field to ensure that the Health Maintenance Form is explained and delivered to the patient. This explanation is followed by specific recommendations from the oncologist regarding healthy behaviors, such as smoking cessation, exercise, diet and weight loss, stress and psychosocial support, and financial counseling. Any ongoing chronic medical conditions that require follow-up with the PCP are also outlined, as these auto-populate from the medical problems/diagnoses list captured in the EMR.

Figure 3. Your Health Maintenance

With the completion of this treatment, it is a good time to re-establish your relationship with your primary care physician for general health follow up. Health maintenance is very important and a form has been provided to you for a reference. Some of the prevention tests will be ordered by your primary care physician and others may be ordered by your oncologist. Share this form with all your physicians.

Health Maintenance form reviewed and copy given to patient

☐ Yes ☐ No (If no, explain why not): _____

Recommendations from your oncologist

Healthy living is important now that you are through treatment. This may include smoking cessation, diet modification, sunscreen use, weight-bearing exercise, stress reduction, or other behaviors that would enhance your well-being.

☐ Smoking cessation ☐ Diet modification ☐ Sunscreen use ☐ Stress reduction/psychosocial support

☐ Exercise program ☐ Financial counseling ☐ Weight loss ☐ Other: _____

Other ongoing chronic conditions that need follow-up with your primary care physician:

_____

_____

If you have not done so, please make an appointment with your primary care physician.

Resources are available:

As you continue your life as a survivor, you may have more questions or concerns. There is help for you! Here are a few suggested resources:

- *Your physicians and other members of your healthcare team.*
- *The Cancer Survivorship Center, 1999 Dempster Street, Park Ridge, IL 60068, (phone) 847.723.5650*
- *The American Cancer Society, www.cancer.org, (phone) 800.782.7716.*
- [List other resources, as applicable.] _____

Five-Year Follow-Up Plan. This section contains a disease-specific follow-up plan detailing the frequency of planned doctor visits, and scheduled laboratory and imaging tests, as applicable, in their frequency and duration (i.e., how often, for how many years). Additionally, reference is made to the need for continued follow-up with other physicians and healthcare providers involved in the individual's cancer treatment. These plans were developed following ASCO and NCCN guidelines for appropriate post-treatment cancer patient surveillance and are disease-specific. Where no such guideline exists (less-common cancer conditions), the treating oncologist develops a surveillance plan based on his or her experience and expertise.

Our SCP Generation Process

As treatment nears completion, the chemotherapy RN who has been thus far responsible for the patient's therapy delivery generates a draft of the SCP. This process was intuitive in our practice as we have a primary nurse model, where all chemotherapy nurses are assigned to their patient at the start of therapy and will follow that patient through the entire trajectory of treatment. At the start of SCP creation, auto-populated and generic content is automatically transferred into the plan. Thereafter, the RN, who is the clinician with the most familiarity and experience with the patient's treatment course, records information on treatment timings, toxicities, dose reductions, delays, etc., into the SCP. Upon completion of therapy, the RN forwards the document to the treating oncologist who is then responsible for finalizing all of the information. In addition, the physician is also responsible for generating the detailed five-year surveillance plan.

Our SCP Delivery

A dedicated clinic visit for delivery of the SCP and supporting documents is scheduled within three to eight weeks after the last treatment cycle. The patient first spends 20 minutes of this visit with the treating oncologist who presents and explains the major components and structure of the SCP, including the five-year surveillance plan.

Immediately after the MD visit, the patient then meets with the primary chemotherapy RN who reviews the entire care plan in detail. This step is vital as it provides an opportunity for patients to clarify any questions about the documents with a clinician with whom they are comfortable and familiar.

The finalized survivorship care plan and its supporting documents are then printed and given to the patient, as well as uploaded to the electronic patient portal. A copy is also sent to the physicians associated with the patient's care (PCP, radiation oncologist, surgeon, and others, as applicable).

Our Results

The composite of the SCP, health maintenance form, and five-year surveillance plan is a comprehensive treatment summary and care plan. Using our EMR, all documents are easily customized to each individual patient, diagnosis, and treatment. The language used throughout all documents is carefully selected to be easily understood and highly-informative for all involved parties—from providers to patients and their families. The documents, coupled with a dedicated care plan delivery meeting, provide a detailed summary of the care provided and contain a personalized road map for each patient for the next five years and beyond. Finally, by sharing these documents with the patient's other providers, all care partners are involved in the patient's survivorship.

Cancer Survivorship Care Plan development team at Oncology Specialists, SC. (L to R) Anna Shew, RN, OCN, BA; Sigrun Hallmeyer, MD; Abigail Dillon, RN, BSN, OCN; Susie Sultan, RN, BSN, OCN; Susan Kelby, RN, OCN, MSN; and Marybeth Mardjedko, RN, MN (practice manager).

Our Process within the Context of SCPs Today

We hope that some of the deficiencies surrounding SCPs in use throughout the U.S. cancer care community have been addressed in our effort, including variation in content and variation in delivery timing, which we sought to standardize. Our SCP has been modeled on the IOM framework and remains consistent with its requirements. Addressing the barriers to SCPs regarding their use of time and straining of limited resources reported in literature, our EMR-driven process allows for efficient generation of the care plan in terms of both time and effort.

In our experience thus far, the estimated RN time and oncologist time required for generation of the SCP are 15 to 30 minutes and 15 minutes respectively. The delivery meeting involving the treating oncologist and RN whom the patient has grown familiar with, serves as a reinforcing step to ensure any ambiguous parts of the documents are sufficiently explained to and understood by the patient.

The feedback we have received since implementation of this process has been overwhelmingly positive. Patients appreciate the opportunity to understand and reflect on their diagnosis and treatment course. The implementation of the survivorship care plan provides patients a measure of reassurance about what lies ahead. We have learned that the opportunity to ask questions about the disease, treatment, and the upcoming survivorship

Patient-centered discussion and review of the Cancer Survivorship Care Plan.

surveillance schedule is important to patients, especially at the end of treatment when the initial stress and anxiety surrounding a cancer diagnosis is no longer strongly preventing the patient from comprehending and absorbing complex information.

Future Direction

Through our survivorship care plan generation and delivery process, we have created a resourceful tool that provides description of care and continuation of support. Our employment of the SCP is a significant tool in providing holistic and patient-centered care to our cancer survivors rather than abandoning them to an unregulated environment once they leave the highly-ordered realm of cancer treatment. We have been able to demonstrate that the IOM guidelines and updated CoC standards for SCPs are attainable in a busy community oncology practice. We hope that our EMR-driven process is one that can be replicated by other oncology practices in the community.

We have noted to our own surprise that there is great variation within our group of physicians regarding the recommendation and implementation of our five-year surveillance plans. As a result, we aim to standardize these plans (based on national or expert consensus guidelines, when available) and are in the process of developing standardized disease- (and if applicable stage-) and treatment-specific surveillance plans for all diagnoses encountered in our institution.

Now that the need for SCPs has been made clear by some of the literature cited previously (see pages 44-50), and these plans are slowly gaining more traction in terms of use, we recognize further steps are needed to improve their utility. In line with this finding, we hope to study the effectiveness of our SCP and quantify patient feedback so that necessary changes can be made. Currently, patients provide feedback at the time of the survivorship care plan discussion meeting. In the future we plan to contact a sample size of patients post-meeting and ask that they fill out a specific questionnaire. While our SCP is being fully implemented, studied, and modified for patients in the adjuvant and curative treatment setting, we hope to develop survivorship care plans for patients with advanced disease moving onto their next therapy, including all stage IV patients completing a first course of therapy. We strongly believe that this group of patients (and their associated healthcare providers) will also greatly benefit from the information provided. OI

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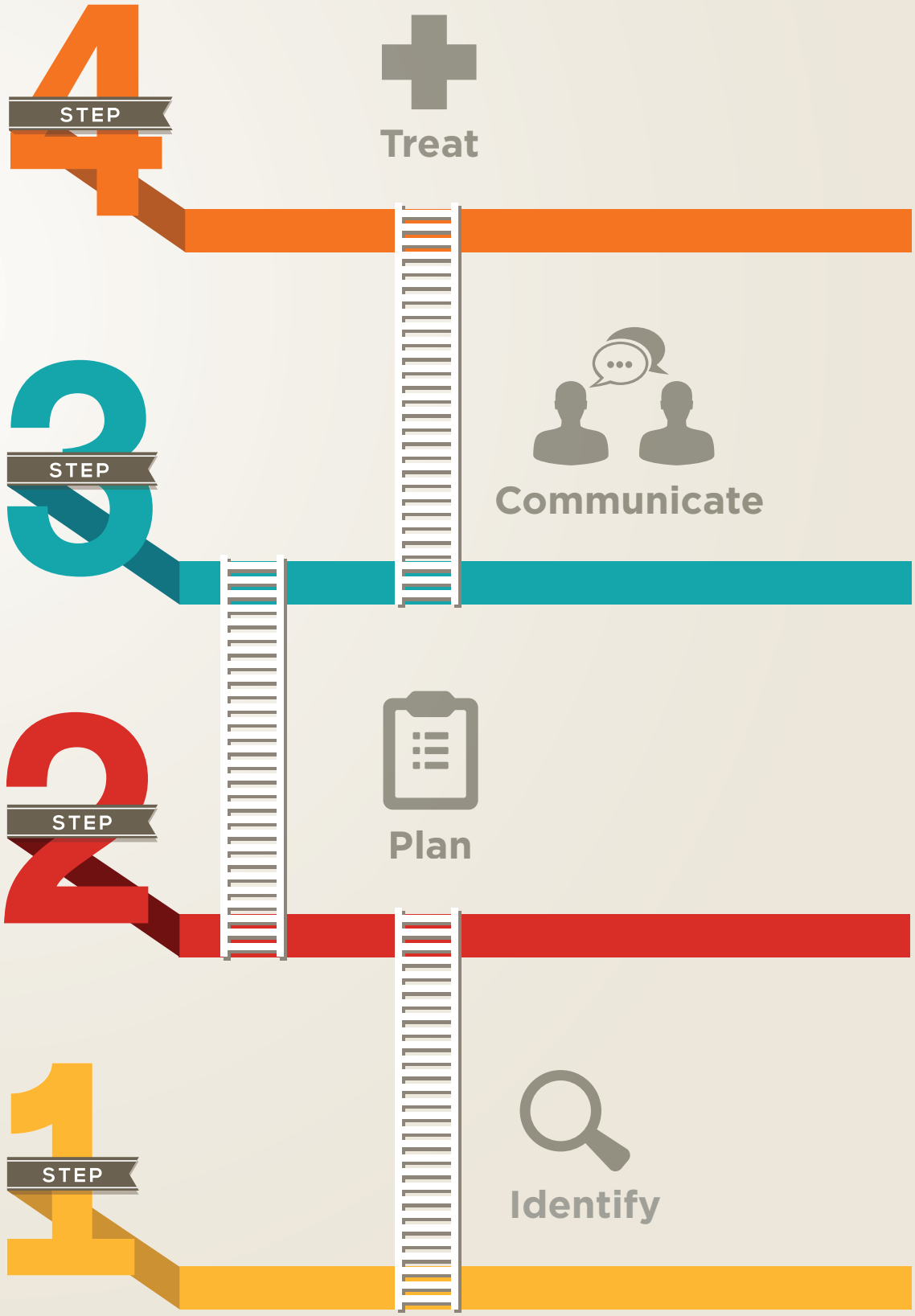
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PATRICIA ALDREDGE, RN, MSN, ANP-BC; AND
KIMBERLY GARDNER, RN, MSN, ACNP-BC

Development & Evolution of an Incidental Lung Lesion Program

Unexpected radiologic findings in the lungs (incidental lung lesions) on a diagnostic CT pose a risk of lack of follow-up and follow through for patients. (Note: incidental findings can be defined as "any abnormality not related to the illness or causes that prompted the diagnostic imaging test."[1])

This risk is particularly true for patients presenting in the Emergency Department (ED), where ED visits often result in discharge rather than hospitalization after a work-up. The challenges facing hospitals:

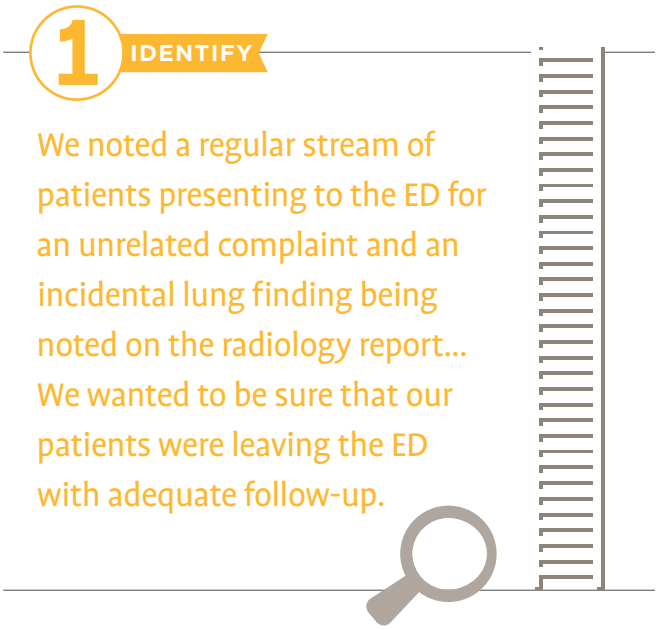
- Identifying the incidental lung lesion and the significance of the finding
- Developing the necessary follow-up plan
- Communicating this information to both the patient and his or her primary care provider (PCP).

Literature Review

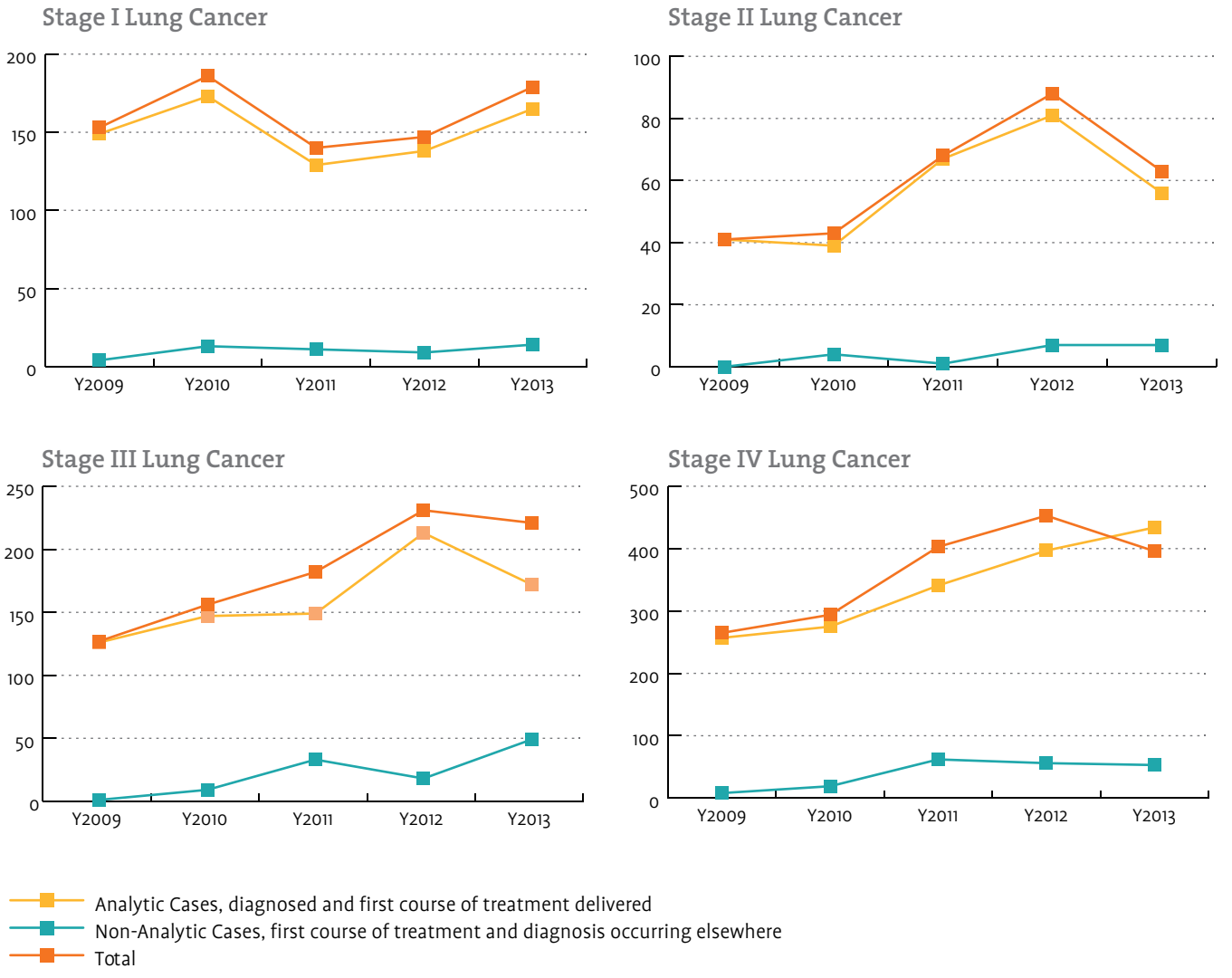
Little research has been done on the occurrence, clinical significance, additional diagnostic testing for, and clinical outcomes of patients with incidental findings. Although incidental findings can occur with other diagnostic imaging, CT provides a wider field of view with greater organ and tissue visualization, resulting in a higher probability of occurrence of additional findings. With this advanced imaging technology, hospitals must now improve how they identify these patients and how they communicate with these patients and their referring physicians to ensure appropriate proper follow-up.

Incidental lung lesions can be noted in the lung bases captured on an abdominal CT for a patient with gastrointestinal symptoms or in 10 to 20 percent of individuals undergoing cardiac CT examination.[2] Indications for CT scans have evolved from a set of differentials not necessarily associated with a lung lesion, therefore an unexpected radiologic notation of a lung nodule is at risk of being overlooked by the ordering PCP or not followed up on by the patient. The greatest concern is that an incidental lung finding on a CT may represent a lung cancer.

When screening the smoking, high-risk population in the National Lung Cancer Screening Trial, 27.3 percent of patients were noted to have an incidence of pulmonary nodules, with 3.6 percent developing a lung cancer diagnosis in the five-year follow-up.[3] Identifying the rates of incidental lung finding occurrence in the general population is more challenging, with reports ranging from 19.8 percent to 56.3 percent.[4-8] The wide variation is due to the type of CT scan performed, the quality of CT technology utilized, radiologist expertise and consistency, and the established system for reporting and following up on findings.



Figures 1–4. Cancer Registry: Division by Lung Cancer Stage of Diagnosis Review



The Henrico Doctors' Hospital Experience

When Henrico Doctors' Hospital reviewed its cancer registry data, we noted a large number of lung cancer patients being diagnosed with later stage disease (see Figures 1-4, above). Next we reviewed the locations and referral patterns of patient presentation, which led us to the Emergency Department. We noted a regular stream of patients presenting to the ED for an unrelated complaint and an incidental lung finding being noted on the radiology report. Often the ED visit was due to gastrointestinal or abdominal symptoms and the physician ordered an abdominal CT or X-ray. Our medical staff was concerned about the potential for patients to get lost in the transition. We wanted to be sure that our patients were leaving the ED with adequate follow-up. To do so, we would need to develop quality and process improvement protocols to create a follow-up loop for these patients.

In emergency departments across the nation, follow-up after an ED visit can be very time intensive and is an area of high liability.[9] Although most hospitals have put measures into place

to ensure primary care physicians receive copies of reports of diagnostic workups performed in the ED and a discharge summary, gaps in care and communication can occur, placing patients at risk.[10] Many steps must be completed to ensure PCPs receive the information necessary to adequately follow-up and care for their patients (see Table 1, below).

As Henrico Doctors' Hospital reviewed its current ED experience with incidental lung findings found on CT scans, we realized that there was variation in both the frequency of findings and follow-up. Although ED notes documented that patients with incidental findings were informed about the need to follow up with their primary care provider for possible further testing, when our nurse navigator contacted patients, many either reported hearing this information for the first time or did not have a sense of urgency or seriousness for follow-up.

When the nurse navigator reached out to PCPs regarding findings noted in a patient's report, physicians were grateful for the call. On occasion PCPs acknowledged not having noted the incidental finding as they were focused on the diagnostic results. Literature reports of follow-up are consistently low regardless of the patient population reviewed retrospectively; some reports indicate only 20 percent of patients having follow-up.[11,12]

Program Goals

At the same time that we were looking to improve the processes in the Emergency Department, our multidisciplinary lung cancer

2 PLAN

The high-quality CT technology allowed our physicians to identify smaller and smaller lesions, so the lung cancer team established a set of goals to improve both the patient experience and communication with primary care physicians. Being part of a large healthcare system, we decided to implement these changes at one hospital, refine our processes, and then move the changes into our imaging centers and sister hospitals.

Table 1. Necessary Elements for Emergency Department-PCP Communication

PATIENT RESPONSIBILITY	ED PHYSICIAN/STAFF	PRIMARY CARE PHYSICIAN/STAFF
Inform ED of correct PCP name	Notify PCP of ED visit	Inform ED physician of past medical history
Inform ED of complete past medical history	Call or fax diagnostic reports and discharge summary to PCP office and ensure receipt of summary	Inform ED physician of patient's baseline
Inform ED of presenting signs and symptoms	Review discharge instructions with patient, including follow-up expectations	Review results and discharge summary from ED visit and schedule timely follow-up
Follow up with PCP as recommended by ED physician	If information is obtained after patient discharge from ED, call or fax results to PCP	Notify patient of scheduled follow-up visit and ensure compliance
Comply with recommendations for follow-up testing	Notify patient of results and follow-up expectations	

Table 2. Recommendations for Follow-up and Management of Nodules Smaller than 8mm Detected Incidentally at Non-screening CT[13]

NODULE SIZE (MM)*	LOW-RISK PATIENT†	HIGH-RISK PATIENT‡
≤4	No follow-up needed§	Follow-up CT at 12 mo; if unchanged, no further follow-up¦
>4–6	Follow-up CT at 12 mo; if unchanged, no further follow-up¦	Initial follow-up CT at 6–12 mo then at 18–24 mo if no change¦
>6–8	Initial follow-up CT at 6–12 mo then at 18–24 mo, dynamic contrast-enhanced	Initial follow-up CT at 3–6 mo then at 9–12 mo and 24 mo if no change
>8	Follow-up CT at around 3, 9, and 24 mo, dynamic contrast-enhanced CT, PET, and/or biopsy	Same as for low-risk patient

Note—Newly-detected indeterminate nodule in persons 35 years of age or older.

* Average of length and width.
† Minimal or absent history of smoking or other known risk factors.
‡ History of smoking or other known risk factors.
§ The risk of malignancy in this category (<1%) is substantially less than that in a baseline CT scan of an asymptomatic smoker.
¦ Non-solid (ground-glass) or partly solid nodules may require longer follow-up to exclude indolent adenocarcinoma.

program was reviewing community needs and the experience of our patients. The high-quality CT technology allowed our physicians to identify smaller and smaller lesions, so the lung cancer team established a set of goals to improve both the patient experience and communication with primary care physicians. Being part of a large healthcare system, we decided to implement these changes at one hospital, refine our processes, and then move the changes into our imaging centers and sister hospitals.

Fortunately, we had experience in developing a network connecting our mammography centers across 75 miles, and we used that experience to consider what we could construct across our Emergency Departments. For example, mammography dictation is standardized through specific software, which in turn triggers nurse navigator involvement. Using this same concept, our team developed the following initial goals:

1. Establish an automated system to identify patients with incidental findings on CT scans.
2. Connect automatically every incidental finding to the thoracic oncology nurse navigator/nurse practitioner.
3. Communicate with every patient having an incidental finding in the ED, confirming the patient's knowledge of the incidental finding and the follow-up plan.
4. Communicate with every referring provider whose patient had an incidental finding in the ED, ensuring that the provider was informed about the incidental finding.

Development Process

Initially in the pilot facility ED, staff set aside imaging reports for the thoracic oncology nurse navigator/nurse practitioner to review. After review, if a finding was noted by the radiologist, the thoracic oncology nurse navigator would reach out to the patient's PCP to ensure he or she was aware of the report. If a PCP was not identified in the ED note, the thoracic oncology nurse navigator would reach out to the patient to inform him or her of a finding that required follow-up and help the patient connect with a PCP who could then oversee the necessary follow-up. (At the start of the pilot, about 35 percent of patients did not have an identified PCP).

Next, cancer center leadership developed a multispecialty Thoracic Advisory Board made up of the:

- Thoracic oncology nurse navigator
- Cancer center leadership
- A thoracic surgeon
- A pulmonologist
- A radiologist
- A radiation oncologist
- A medical oncologist
- An information technologist.

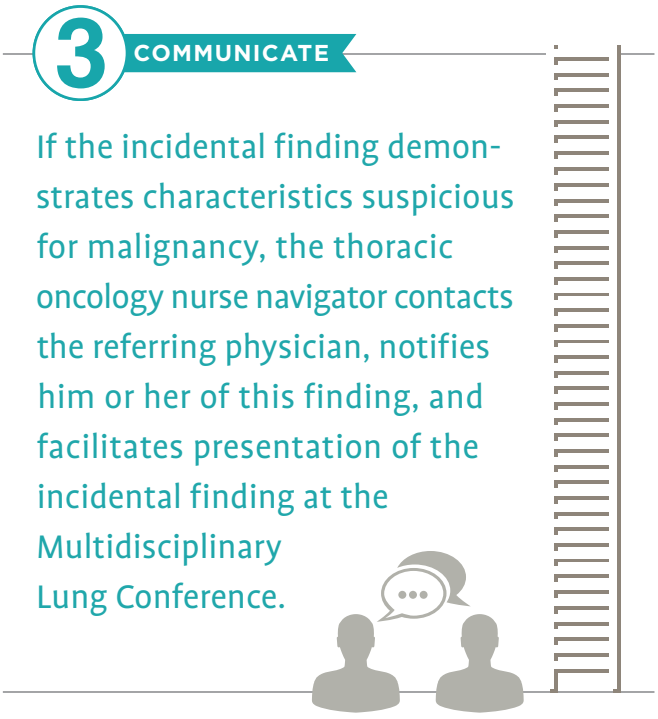
The Thoracic Advisory Board would ensure quality within the Thoracic Oncology Program by:

- Reviewing hospital registry data
- Establishing quality metrics
- Developing a program and process to ensure that incidental findings were identified and followed up according to Fleischner's Guidelines (Table 2, page 64).[13] The Thoracic Advisory Board agreed that these standards and guidelines would provide a framework and structure necessary to guide the PCP and ensure quality in follow-up recommendations based on the patients' risk. (The Fleischner Society developed its guidelines in 2005 to provide recommendations for follow-up and management of pulmonary nodules detected on non-screening CT scans. Fleischner's Guidelines direct the recommended follow-up of identified nodules based on the patients' risk.)[13]

Using key search terms that are within the radiology report or impression, our IT&S (Information, Technology & Systems) created a way to identify patients who require further follow-up. Initially, to ensure that the thoracic oncology nurse navigator was alerted to all CT scans with incidental findings, radiologists agreed to use the key phrase "Recommend dedicated Chest CT" in the body of the report or in the impression to trigger the need for follow-up. However, after implementation, the thoracic oncology nurse navigator noted that while this phrase may alert the PCP to order additional imaging, there was no way for the thoracic oncology nurse navigator to know what actions (if any) were taken. Our hospital wanted feedback that all patients were being appropriately followed for their incidental findings.

The Thoracic Advisory Board next decided to use the search terms "nodule" and "Fleischner," and IT&S used these key search terms to create a non-procedural report that was pulled from the electronic health record. These reports spool to the thoracic oncology nurse navigator's printer each morning for review. After further experience with these search terms, the thoracic oncology nurse navigator determined that the key search term "nodule" was not capturing actual incidental findings, but instead pulling in reports where the term nodule had been used by the radiologist indicating "no nodules present."

Based on this new data, the Thoracic Advisory Board decided to continue to use the key search term of "Fleischner" and to create a phrase within the powerscribe dictation system entitled "cc Nurse Navigator." This would allow radiologists to alert the thoracic oncology nurse navigator of the need for further follow-up. The powerscribe feature within the dictation system simplified the process for radiologists, allowing them to check a box during dictation to insert this phrase into the dictated imaging report so that the information would be pulled into the non-procedural report. Once this process was established, we rolled out this quality improvement measure at each hospital facility and outpatient imaging center. The nurse navigators at each location were trained to review the non-procedural reports and imaging studies, the Fleischner Society Guidelines, and recommendations for follow-up.



Radiologist Role

To ensure the capture of all incidental findings, radiologists were actively engaged in the process. The challenge for our radiology group is that it is comprises more than 50 radiologists across our healthcare network. At the pilot hospital alone, each month 8 to 10 radiologists rotate the reading of the imaging studies. The radiologist is crucial in deciding whether or not an image is normal or requires follow-up. The radiologists' recommendations are naturally influenced by the knowledge that many incidental findings are insignificant and they are trying to balance unnecessary testing for a disease that might cause morbidity and mortality, along with its own risks, emotional burdens on the patient, and related costs.[1] We used email communications, information presented at the routine radiologist meetings, and signage at each radiologist work station to continuously educate all radiologists about the incidental lung lesion quality improvement initiative.

Nurse Navigator/Advanced Practice Role

An advanced practice nurse serves as the thoracic oncology nurse navigator and is able to assess risk, suggest evidence-based interventions, and facilitate collaboration between the hospital and

physicians in the community.

The thoracic oncology nurse navigator reviews an average 10 to 15 search-criteria-generated reports weekly. If incidental findings are noted, she completes a thorough search of the available patient history to help determine risk.[3] The National Lung Screening Trial (NSLT) and the National Comprehensive Cancer Network (NCCN) have both identified risk factors to use to categorize individuals by risk.[14] As noted in earlier studies, applying patient history and risk factors to the incidental findings helps the thoracic oncology nurse navigator determine a level of significance for follow-up.[1,2]

The risk factors that should be utilized to determine risk are age, smoking history, work exposures, personal history, and family history. Often this information is incomplete in the ED record and the thoracic oncology nurse navigator is unable to determine risk status. Fleischner Society recommendations are used for individuals older than age 35 to determine appropriate follow-up based on the size of the lung nodule identified on the CT scan and the individual's risk factors. The thoracic oncology nurse navigator reviews these abnormal scans with a member of the multidisciplinary lung team—either a pulmonologist or thoracic surgeon. Because risk factors are often not readily available to the team, letters are mailed to the patient's primary care physician or ordering physician to notify them of the incidental finding and allow them to further assess the patient's risk and final determination of needed follow-up.

If the incidental finding demonstrates characteristics suspicious for malignancy, the thoracic oncology nurse navigator contacts the referring physician, notifies him or her of this finding, and facilitates presentation of the incidental finding at the Multidisciplinary Lung Conference. The multidisciplinary lung team meets biweekly to discuss cases; review radiologic images, patient presentation, risk factors, and pathology if biopsied; and provide follow-up or treatment recommendations to the referring physician. This forum can also be used for ED patients without a primary care physician. For patients without a PCP, after presentation at the Multidisciplinary Lung Conference, the thoracic oncology nurse navigator notifies the patient about the incidental finding and team recommendations, offers patient education, and helps the patient identify a primary care physician for follow-up.

Next Steps

In hopes of ensuring that all incidental findings are captured, the initial pilot facility has expanded to include all types of CTs, as well as chest imaging, in the non-procedural report. The Thoracic Advisory Board has also expanded the list of key search terms, and is slowly deleting those search terms that prove unnecessary. The thoracic oncology nurse navigator will continue to maintain data reports to show if the expansion of these studies and key search terms provides a larger catchment of incidental lung findings. Further, because some patients who present to the ED do not have a primary care physician, the Thoracic Advisory Board added an additional goal: to consistently provide patients with PCP options and available appointments.

Program Evaluation & Outcomes

Evaluation is ongoing as we continue to refine the search process for automating incidental finding notification.

The quality improvement effort has increased patient volume. We have had positive feedback from our patients, referring physicians, and community urgent care centers, resulting in lung clinic case growth and subsequent diagnostic CT imaging. A major reason for lung clinic growth has been the opportunity to have incidental findings evaluated by the multidisciplinary lung team. Many of the local urgent care centers have included the lung clinic in their standardized orders when CT scans that have been ordered by their physicians result in incidental findings.

Despite the fact that our documentation of patient awareness in discharge paperwork is higher than literature-reported rates of 9.8 to 27 percent, we have found that our patients did not have a sense of urgency about follow-up. We recognize that we need to assist patients with incidental lung lesions to make follow-up appointments and tests and then document that follow-up in their medical record. We continue to work on this issue with our community primary care physicians.

One of the most unexpected findings was the wide variation among our sites in patients without PCPs. At one of our sister hospitals that is in the process of instituting the Incidental Lung

Lesion Program, more than 50 percent of patients in the community use the local urgent care facility as their primary care provider. This scenario poses additional challenges for this particular community.

The cost savings per life-year saved with early detection of lung cancer is estimated at less than $19,000, which is similar to the savings associated with breast, colorectal, and cervical cancer screening.[15] Using Fleischner's Guidelines provides a high level of evaluation since the patient's risk is thoughtfully incorporated.

We realize that we have a significant opportunity to improve the identification process since our incidental rate for all CTs is less than the literature reported rate of 33 percent.[4] This may be due to the search terms we are using, but we are also considering consistency of practice across all of our radiologists. In other words, we need to ensure that the appropriate staff is aware of the Incidental Lung Lesion Program, including the consistent use of Fleischner's Guidelines within the dictations, so that clinical leaders have the opportunity to alert the thoracic oncology nurse navigator about these patients.

The Incidental Lung Lesion Program is a component of our Thoracic Oncology Program. It is a quality patient service that is good for the patient and good for the hospital. Just as low-dose CT lung cancer screening is an access point for people at high-risk, our program is another means for people to be cared for at the earliest possible time, possibly even prior to lung cancer symptoms. OI

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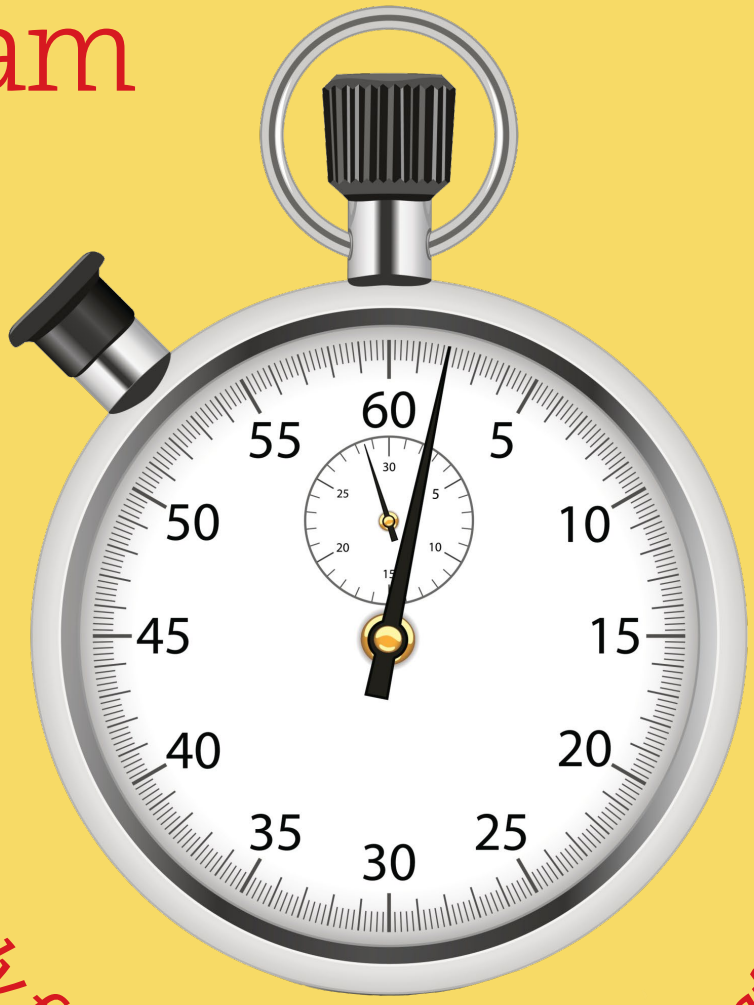
The *Rapid Access* Chest and Lung Assessment Program



Ensuring timely follow-up, diagnosis & treatment

BY STEPHEN CATTANEO, MD; BARRY MEISENBERG, MD; CATHY BRADY-COPERTINO, BSN, MS, OCN; MARIA CHRISTINA GERONIMO, RN, MSN, MBA; AND TERESA PUTSCHER, RN, BSN, OCN

Non-specific abnormalities found on chest imaging can present a clinical dilemma for physicians in terms of management and may also cause anxiety for patients. Despite the existence of professional society guidelines for management and follow-up, non-adherence and gaps in management of patients with abnormal findings occur often.[1,2] Take, for example, the case of PM, a 52-year-old former smoker who presented to her primary care office after multiple episodes of bronchitis. Additional symptoms included wheezing, DOE (dyspnea on exertion), cough, night sweats, and loss of appetite. A diagnostic CT [ordered by the primary care provider] demonstrated enlarged subcarinal and right hilar adenopathy and a right posterior basilar segment lesion measuring 2 x 3.5 cm in size. The patient had made an emergency department visit two years earlier with mild chest symptoms. A CT scan performed at that time had revealed a solitary lung lesion measuring 1.4 x 3.1 cm in size, consistent with a clinical stage IB tumor. The CT scan on page 70 shows a representative view of these findings.

Despite an accurate reading of the films and the radiologist's documented call to PM's primary care provider, no follow-up occurred until the patient became much more symptomatic as described above. Subsequent workup after the new scan led to a diagnosis of stage IV infiltrating poorly-differentiated lung adenocarcinoma. While the reason for lack of further investigation or follow-up is not entirely clear, presumably better communication, vigilance, and adherence to established recommendations would have benefitted this high-risk patient.

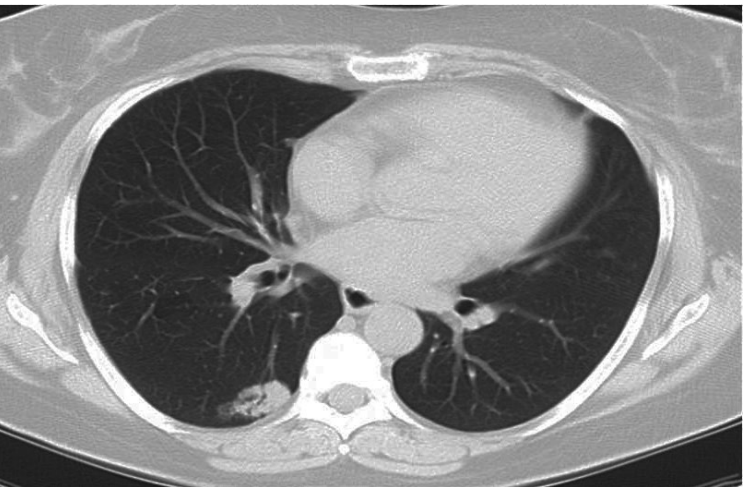
To respond to these potential gaps in care, in 2010 Stephen Cattaneo, MD, formed a thoracic oncology working group and implemented the Rapid Access Chest and Lung Assessment Program (RACLAP) at Anne Arundel Medical Center (AAMC) in Annapolis. RACLAP is a multidisciplinary rapid assessment team whose primary objective is to quickly identify, evaluate, and manage patients with abnormal findings on chest imaging while keeping in close communication with a patient's primary care provider. Additionally, RACLAP strives to have patients evaluated by an appropriate specialist within a week of abnormal finding with the understanding that rapid evaluation can help decrease a patient's anxiety. AAMC's Rapid Access Chest and Lung Assessment Program received an ACCC Innovator Award in 2012.

RACLAP is a multidisciplinary rapid assessment team whose primary objective is to quickly identify, evaluate, and manage patients with abnormal findings on chest imaging while keeping in close communication with a patient's primary care provider.

Life before RACLAP

In 2003 AAMC established a weekly multidisciplinary Thoracic Tumor Board comprising thoracic surgeons, medical oncologists, radiation oncologists, pulmonologists, pathologists, radiologists, nurses, and social workers. Two years later, AAMC created a new staff position—the thoracic nurse navigator—to provide physicians, patients, and families with one point of contact in the healthcare system, allowing for a seamless, patient-centered experience. The nurse navigator's responsibility is to facilitate the patient's care for diagnostic testing and physician appointments, as well as to act as a patient advocate and liaison while the patient is receiving care. The thoracic nurse navigator is the central facilitator for the RACLAP program, caring for approximately 300 patients yearly.

Prior to the implementation of RACLAP no standard patient flow existed for thoracic patients. Often lung findings were managed by primary care providers based on recommendations made by the radiologists in imaging reports. However, radiologists



A CT scan of a solitary lung lesion consistent with stage IB tumor.

do not always follow published recommendations, such as Fleischner Society guidelines[3] and lack of management standardization for lung findings potentially leads to delays [in treatment] and excess resource utilization.

Primary care physicians, pulmonologists, surgeons, or oncologists managed these patients. However, without an established management paradigm, variance in timeliness, imaging follow-up, and diagnostic interventions was common. Prior to the creation of RACLAP in 2010, the time from a suspicious chest X-ray or CT to diagnosis was 2 to 10 days for inpatients. Unfortunately for outpatients, the time to diagnosis could vary from 12 days to 4 months.

Various international studies seem to suggest that this problem (i.e., variation in timelines) is widespread. In a Canadian study, the median time from development of symptoms to commencement of therapy was 138 days and the authors concluded that lung cancer patients experienced substantial delays to treatment.[4] In Northern India, a published study found that the median time from symptom to therapy was 185 days but that patients were also inappropriately treated with anti-tubercular treatment first, which significantly prolonged the delay.[5] Finally, in Brazil, outpatients waited an average of 58.2 days from their first appointment until surgery, while inpatients waited an average of 34.9 days.[6]

Current State

RACLAP's overarching goal is rapid referral to the appropriate specialist via increased centralization of care. Collaboration with various specialties to create an individualized care strategy for patients allows for judicious resource utilization while decreasing time to evaluation and management.

RACLAP provides same-day phone consultation with the thoracic nurse navigator via a centralized and well-publicized phone number. Imaging is reviewed by a combination of thoracic radiologists, pulmonologists, and thoracic surgeons to determine whether expedited referral to a particular specialist or diagnostic procedure is the best initial step. More complicated patient cases are presented initially at AAMC's weekly Thoracic Tumor Board. Referring providers and primary care providers are continually updated about the patient's care plan and results. AAMC's thoracic nurse navigator, social worker, therapists, and other allied professionals assist with concurrent patient and family education to prepare patients for decisions regarding management options and what to expect throughout treatment as well as providing one-on-one support as deemed necessary.

Building & Promoting RACLAP

The initial step in developing RACLAP began with a literature search on evidence-based practices related to building a coordinated thoracic program. Support from hospital administration and collaboration with all the major stakeholders—radiology, pulmonology, thoracic surgery, medical and radiation oncology, and pathology—was key to program development (see Figure 1, right).

RACLAP has a single, direct phone number, which is managed by the thoracic nurse navigator who is responsible for returning calls by the next business day. All inpatient and outpatient providers are encouraged to refer patients to the program. Not surprisingly, radiologists have been the largest referral base since they have initial access to imaging abnormalities. The referral criteria include, but are not limited to:

- Solitary and multiple lung and chest wall lesions
- Mediastinal adenopathy or masses
- Large pleural effusions (particularly unilateral effusions).

All patients with abnormal imaging are eligible for enrollment in RACLAP, including inpatients, outpatients, and emergency department patients.

Once a referral to RACLAP is received, the thoracic nurse navigator contacts the patient's healthcare provider, explains the purpose of RACLAP, and obtains consent to enroll the patient in the program. However, providers are not obligated to enroll patients in RACLAP and may choose to manage the imaging abnormality personally. Once the patient is enrolled, the case is then reviewed to determine the next course of action—direct referral to a specialist or diagnostic intervention and/or presentation at our multidisciplinary Thoracic Tumor Board. The thoracic nurse navigator communicates the plan of care to both the referring provider and the patient and then assists with scheduling additional testing and appointments.

With the program's structure in place and a dedicated phone

line established, RACLAP was promoted throughout the institution at medical staff meetings and through print ads, videos, and the health system's intranet. AAMC also disseminated information to primary care providers, local urgent care centers, and radiology practices in its market.

Benefits & Barriers

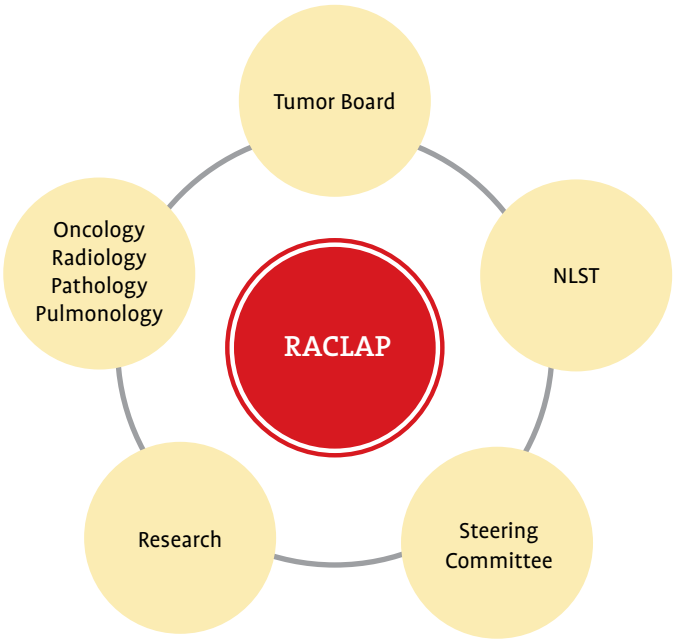
The benefits of enrolling the patient in RACLAP include improved centralization of care and patient satisfaction due to decreased stress from timely diagnosis and by minimizing unnecessary procedures and referrals. Additionally, providers with patients in RACLAP benefit from close, evidenced-based follow-up of patients with expert guidance. By eliminating unnecessary referrals or low-value imaging tests and speeding the appropriate work-up, RACLAP reinforces AAMC's goals of population health, including its accountable care organization in which high quality and lower cost processes are valued.

Currently at AAMC, RACLAP is also integrated with the hospital's lung cancer screening program, which is modeled after the National Lung Screening Trial's (NLST) practice of screening high-risk patients for lung cancer with low-dose CT. All screening participants have their results communicated to their primary care provider. If their CT has suspicious findings, patients are automatically enrolled in RACLAP with the consent of both the patient and their primary care provider.

The United States Preventive Services Task Force (USPSTF) endorses adherence to quality standards for low-dose chest CT, as well as establishing protocols to follow-up on abnormal results. Additionally, it recommends a system be in place to ensure adherence to these standards in order to achieve the mortality benefit of lung cancer screening seen in the NLST. RACLAP provides seamless integration with diagnostic low-dose CT screening so that quality is not compromised and the positive benefits are more readily achieved in a regional setting.

Some of the barriers to full implementation of RACLAP include already established-referral patterns and limited awareness of the program among a large number of radiology providers in the community most of whom do not work at AAMC. Thoracic nurse navigator resources are also stretched by the growth of the program.

Figure 1. Integration of RACLAP



Up-to-Date Analysis

Currently, RACLAP data is managed via a desktop spreadsheet by the thoracic program coordinator. One future goal is to establish an IRB-approved registry that is both capable of generating data reports and adept at managing patients who need close follow-up for their lung nodules to ensure timely follow-up and re-evaluation.

RACLAP data was recently published. This analysis was done over a 27-month period in which 238 patients were referred to the RACLAP program—227 patients had an abnormal finding on chest imaging and 11 patients were excluded from data analysis due to various reasons. Of these patients 171 (75 percent) enrolled in the program. Other findings:

- Radiologists were the most frequent referrers
- Patients and primary care providers were contacted within a median of two days after imaging
- The median time from imaging to diagnosis of lung cancer was 16 days.

The authors concluded that the program provided rapid and evidence-based evaluation and management of patients resulting in a short time-to-diagnosis. Table 1, page 72, shows the disposition of the patients who were referred to RACLAP.

We noted a statistically significant shift to a lower cancer stage (IA-IIB 39 percent) compared to patients who were diagnosed with lung cancer; concurrent controls 25.7 percent and historic controls 27.9 percent (see Table 2, page 72).

The Future of RACLAP

Providers who have referred patients to RACLAP were given the opportunity to express any comments, questions, and concerns

(continued on page 73)

Table 1. Disposition of RACLAP Patients in Published Data Analysis

DISPOSITION OR DIAGNOSIS	NUMBER	PERCENTAGE
Lung cancer	72	31.7
In follow-up surveillance	44	19.4
Other diagnoses	34	15
Primary physician declined; patient followed elsewhere	30	13.2
Issue resolved with follow-up	21	9.2
Unable to contact the patient	18	7.9
Patient declined assistance	8	3.5

Table 2. Lung Cancer Stage in Patients Diagnosed in RACLAP Compared with Controls

	RACLAP N-72		Concurrent Controls Diagnosed During the Same Period Outside of RACLAP N=378		Historic Controls Diagnosed in the 24 Months Prior to RACLAP N=458	
STAGE	NUMBER	PERCENT	NUMBER	PERCENT	NUMBER	PERCENT
0	0	0	1	0.3	0	0
IA	15	20.8	55	14.5	83	18.1
IB	13	18.1	30	7.9	37	8.1
IIA	4	5.6	23	6.1	8	1.7
IIB	5	6.9	15	4.0	24	5.2
IIIA	6	8.3	59	15.6	65	14.2
IIIB	7	9.7	22	5.8	47	10.3
IV	22	30.6	165	43.5	176	38.4
Unknown	0	0	8	2.1	18	3.9

(continued from page 71)

through a brief survey. While physician satisfaction with the program was high, the survey results revealed that areas of potential improvement include educating providers about the program and providing feedback to referring providers in a timelier manner. These issues are being addressed through continued education of providers about the program and improved follow-up. In the future, it will be important to also survey the enrolled patients regarding their level of satisfaction. Other goals include adding new radiology sites that are not directly contracted by AAMC as a referral base and using dedicated thoracic radiologists to review all chest imaging.

In the four years since implementation of RACLAP, more than 530 patients have been managed by the program. There are numerous instances in which patients were rapidly assessed and diagnosed after enrollment. One example is ML, a 72-year-old female. In 11 days, she went from abnormal CXR through rapid referral, PET/CT, and bronchoscopy with biopsy to confirm stage IIIA lung cancer. At the other end of the spectrum is patient NJ, a 57-year-old woman who was enrolled in the program following abnormal CT imaging and was followed with serial surveillance imaging based on low-risk thereby averting unnecessary biopsy and further workup.

RACLAP is able to provide evidence-based evaluation and management of patients with imaging abnormalities in a timely, coordinated way. This benefits both providers who may not feel comfortable managing abnormal findings on chest imaging and patients who may feel anxiety about what the results may mean. RACLAP has also demonstrated that the program can help in diagnosing lung cancers at earlier stages. As healthcare systems continue to search for ways to provide high quality low-cost care, a program similar to RACLAP may be an inexpensive solution to providing expert, timely care.

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OUR PROGRAM-AT-A-GLANCE

Founded in 1902, Anne Arundel Medical Center (AAMC) is a 384-bed regional referral center located on a 57-acre campus in Annapolis, Md. AAMC has a medical staff of more than 1,000 providers and nearly 30,000 inpatient admissions and 95,000 emergency department and 100,000 outpatient visits annually. AAMC includes a not-for-profit hospital, a 200-provider employed medical group, a substance use center, and five regional pavilions with multispecialty services. AAMC also contracts with local physician groups, including radiology, anesthesia, emergency medicine, and pulmonary/critical care medicine. AAMC operates five diagnostic imaging facilities that together perform 159,000 imaging studies annually.

Since 2007, AAMC has experienced steady growth in both its primary and extended market particularly in cardiology, colorectal oncology, and thoracic surgery. More specifically, over the past seven years, the number of new analytic cancer cases evaluated at AAMC has increased 50 percent to a total of 1,800, making AAMC one of the largest cancer programs in the state.

AAMC serves an area of more than 1 million people and is the state's third busiest hospital based on inpatient discharges. AAMC is the recipient of numerous awards and certifications and recently achieved Magnet® recognition by the American Nurses Credentialing Center.

Think Tank Takeaways

Supported by a grant from Genentech, ACCC hosted a series of "Think Tanks" at its 2014 National Oncology Conference. These 45-minutes sessions focused on four hot topics in oncology: the Healthcare Marketplace, Lung Cancer Screening, Molecular Tumor Boards, and Personalized Medicine

Healthcare Marketplace

- ***Growing need for patient navigation.*** Many first-time insurance purchasers need help navigating the process of signing up for healthcare coverage; they remain confused about terms like deductible, co-pay, co-insurance, and out-of-pocket maximum. To meet these needs, ACCC has developed a set of resources around cancer patient navigation and patient assistance programs, as well as the Financial Advocacy Network with resources for both clinicians and administrators.
- ***Many new patients remain "functionally" uninsured.*** As a result of the Medicaid expansion, approximately 10.5 million new patients will receive health insurance coverage. However, many of these patients will remain "functionally" uninsured because they will lack access to providers who are accepting new Medicaid patients.
- ***"Value" in oncology.*** The "value" of healthcare can be difficult to measure in oncology. The measurement of subjective clinical endpoints can be challenging when cancer patients are dealing with symptoms such as severe nausea or vomiting, fatigue, or pain. Cancer programs and oncology clinicians are also noting the growing importance of focusing on patient satisfaction scores, since these metrics directly impact reimbursement.
- ***Other key factors that impact the oncology landscape.*** These include the 340B Drug Pricing Program, consolidation and acquisition of oncology practices, and creative models for patient-centered care.

Lung Cancer Screening

Lung cancer screening programs are necessary, since lung cancer is the leading cause of cancer-related mortality in the United States. Today, most lung cancer patients are diagnosed with advanced disease, but effective screening would allow these patients to get diagnosed and treated earlier in their disease. Regardless of coverage, cancer programs need to be prepared to offer LDCT and ensure proper follow-up for patients who have non-negative screening results. One model: multidisciplinary lung nodule clinics that provide ongoing follow-up to a large number of patients who have a non-negative screening test. And because some patients who undergo LDCT or who get diagnosed with lung cancer may not want to quit smoking, cancer programs will need to integrate robust smoking cessation interventions into their lung cancer screening programs.

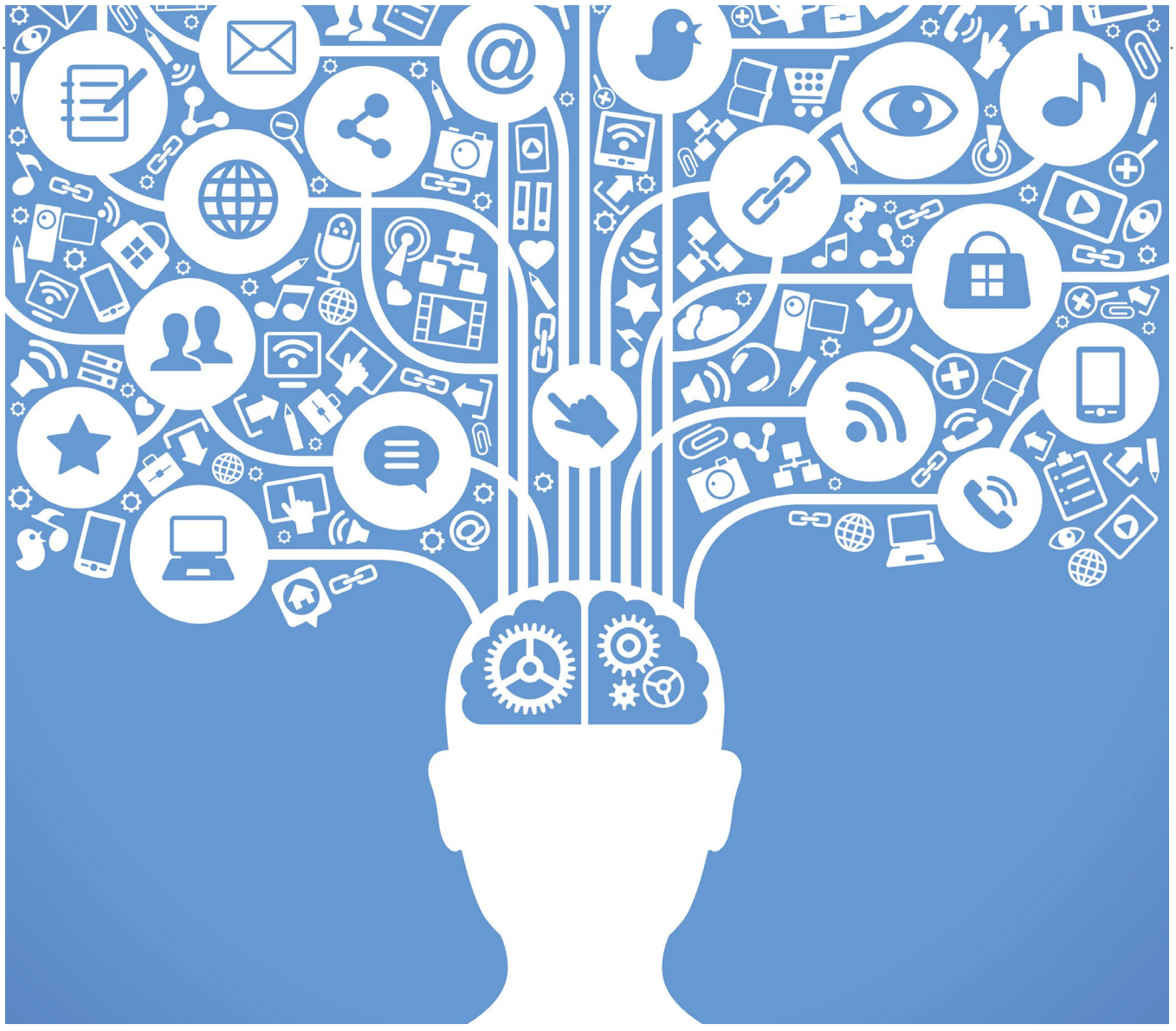
Molecular Tumor Boards

In an era of molecular testing, genomic analysis, and personalized medicine, the "molecular tumor board" is emerging as a way to get input from additional members of an expanded multidisciplinary team that includes experts in the field of molecular pathology, bioinformatics, tumor genetics, and basic science research. These discussions can help guide oncologists in clinical decision-making as they interpret results from genetic mutation panels. Some cancer programs are reserving comprehensive biomarker testing for patients who have not responded to first- or second-line therapies; others are instituting molecular tumor board discussions about patients even before first-line therapies are selected to see if patients should be referred for clinical trials. Key considerations: the patient's ability to enroll and access clinical trials, the patient's level of interest in participating in clinical trials, and the cancer program's ability to interpret molecular test results and make appropriate treatment recommendations.

Personalized Medicine

Personalized medicine in oncology has been defined as "the use of molecular diagnostics and genome analysis to select targeted therapies designed to treat cancer." Some refer to this as "precision" medicine; others call this "genomic" personalized medicine.

- ***Targeting treatments with precision.*** Predictive biomarkers are being used to identify cancer patients who may respond to certain targeted therapies or to identify patients who may be resistant to other therapies. This allows oncologists to focus their treatment strategies by using drugs that have been approved by the FDA based on biomarker test results or companion diagnostic studies.



- ***The key role of biopsy.*** To perform highly-specialized molecular testing on cancer biopsy samples, pathology labs must have adequate tissue. This continues to be a major challenge in the community setting because many physicians performing diagnostic biopsies are still only obtaining enough tissue to establish a diagnosis and are not getting extra tissue for molecular mutation testing. To further complicate matters, health insurance companies do not always reimburse for certain mutation tests.
- ***Academic partnerships.*** Community cancer programs are forming collaborations with academic research centers so that they can gain access to experts trained in tumor genetics, translational science, and bioinformatics. These discussions are providing guidance around molecular test result interpretation, care pathways, clinical trial recruitment, and much more.
- ***Big data analytics.*** Some academic research centers are even exploring the use of supercomputers like IBM Watson to analyze data and outline a personalized approach to treatment. One example is the Memorial Sloan Kettering-IBM Watson Collaboration where oncologists are working with Watson to go through massive quantities of clinical data and published research to form actionable pathways for certain cancers. The New York Genome Center (NYGC) IBM Watson collaboration is looking at ways to leverage genomic research as a tool to help oncologists accelerate how they may more effectively deliver personalized care to patients with brain tumors.

As the landscape of oncology practice evolves, ACCC continues to develop innovative ways for its members to openly share ideas and have dialogues about creative ways they are addressing these key topics and ideas for future improvements. Read more on these Think Tanks at: www.accc-cancer.org/acccbuzz-thinktank.

action

FREE! ACCC Oncology Reimbursement Meetings

April 16, 2015
Chicago, Ill.
Embassy Suites Hotel

April 28, 2015
Raleigh, N.C.
Doubletree Raleigh Brownstone

May 19, 2015
Scottsdale, Ariz.
The McCormick Scottsdale

Register today at:
www.accc-cancer.org/meetings/ReimbursementMeetings.asp.

SAVE THE DATES!

March 16–18, 2015
ACCC 41st Annual Meeting
CANCERSCAPE
Hyatt Regency Crystal City
Arlington, Va.

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

Oct. 21–24, 2015
ACCC 32nd National Oncology Conference
Portland Marriott Downtown Waterfront
Portland, Ore.

ADVERTISER'S INDEX

What Do We Do When We (or Our Staff) Become the Patient?

BY SHIRRAY GABRIEL, MHA

Cancer doesn't discriminate. It doesn't care about age, gender, sexual orientation, political preference, race, or religion. When someone is diagnosed with cancer, it not only affects their life, it affects everyone around them—their family, friends, and even co-workers. So what happens when someone in your work family is diagnosed with cancer? How will this affect your co-workers, staff, and the organization as a whole? Are you prepared for how a cancer diagnosis will change the workplace?

My Story

I am fortunate to have been healthy all of my life. I am a daughter, sister, mother, aunt, grand-aunt, and cancer program administrator—like many of you reading this article today. In my 32 years in the healthcare field (approximately eight of those in oncology) I never thought that I would become a cancer statistic.

Visualize sitting in a doctor's office during a routine visit. Nothing out of the ordinary—just a simple check-up for tonsillitis. Next, imagine the doctor coming back and telling you he wants a scan done because you might have cancer.

On Oct. 21, 2010 (my 45th birthday), I received that news, and it changed my life—as well as the lives of everyone who knows me—forever. That was the day I was diagnosed with stage IV head and neck/tonsillar cancer. That was the day, I became a cancer patient. Now, I was on other side of the patient-provider equation, experiencing firsthand the patient care my program was delivering. One would think that the transition from employee to patient would be simple, and it can be. Still, for all involved, it is important to know how to handle this delicate situation. Steps can and should be taken to protect both the employee and the organization.

When someone in your work family receives a cancer diagnosis and transitions from co-worker to patient, colleagues' initial reaction may be one of shock and sympathy. Some key points to keep in mind during this transition are privacy and respect, expectations, employee versus patient, and understanding versus policy and support.

Privacy & Respect

A patient's privacy is extremely important. Because we interact with our co-workers every day, we may tend to forget that this individual is now our patient and, as such, is entitled to and deserving of the same respect, treatment, and privacy as other patients.

There can be a fine line between being supportive and invading someone's privacy. When someone we know has something bad happen to them, our instinct may be to wear our "hearts (and emotions) on our sleeves," conveying our concern and support. Some may want the patient to feel as if he or she can discuss the situation, and start asking questions. Not all patients want to discuss their personal lives, however, so wait until your co-worker wishes to discuss the issue. Depending on your relationship, you may have a sense of how best to approach your co-worker. My advice: do not ask direct questions unless your co-worker approaches you or asks for advice. Answering questions from a co-worker who is now your patient can be difficult. Do you answer them from a professional point of view or from a friend's point of view? And what is the difference?

When employees receive treatment at the center where they work, co-workers must remember to respect their privacy and not discuss their results with anyone else. Unless we are the treating physician or our co-worker has given specific consent, we cannot review any results or reports—even if the results are sent to us in error.

Workplace Expectations

Now that your co-worker is your patient, should workplace expectations change? From an institutional perspective, they should not. Staff should maintain the same level of professionalism in their work interactions, treating all co-workers fairly and equally—no matter what the illness. In other words, as long as your co-worker is employed, he or she should perform daily job functions, as well as maintain attendance per corporate policy.

Co-Worker vs. Patient

The delineation between these roles seems simple enough, but can be more complicated than it first appears. There are definitive lines for how we treat our co-workers and how we treat our patients. During a cancer journey, the lines may get crossed, and this can be detrimental to both the employee and the healthcare organization.

Staff has access to their co-workers' medical records, so it is important to review and then uphold company policy regarding accessing records. Of course, there are

exceptions. For example, information from the medical records may be needed to complete reports. Even then staff should take great care not to violate company policy. Often administration must make a decision (and communicate to staff) on how your co-worker's medical records will be maintained with the privacy they deserve.

And what about appointments? From a management perspective, are there better (or worse) times for employees to schedule their provider visits and treatment appointments? In the end, employee appointments need to be scheduled and documented just like any other patient. For example, workplace conversations may take place during which the patient's need to see a certain provider may be mentioned. This should by no means be considered "notifying the patient of an appointment." Do not allow co-workers to reschedule appointments to accommodate another patient. If in doubt, ask yourself, would you do the same for any other patient?

Understanding vs. Policy

We empathize with our co-worker, understanding what he or she faces with a cancer diagnosis. We want to help and to accommodate our co-worker's needs during this difficult journey. That said, as professional colleagues working for the same healthcare organization, we must abide by company policies, particularly time off and leave policies.

Encourage your co-worker to speak to the HR department about FMLA (Family and Medical Leave Act) and other types of leave or absence that may be available.

Further, as cancer care providers, we should understand our company's healthcare benefits. For example, if our plan has a high deductible, we need to understand that some of our co-workers may find it difficult to afford treatment. Personally, I was floored when I was told that my co-payments would be between $250 and $400 for prescriptions needed every three weeks. It made me wonder how many patients choose not fill their prescriptions and tell the physicians that they do? This perspective encouraged me to advise my staff to be honest with their physicians. Do not be ashamed to admit if a prescription is too expensive. There may be a more affordable generic version or an alternative.

We should also understand our legal rights. Title I of the Americans with Disabilities Act (ADA) of 1990 prohibits private employers, state and local governments, employment agencies, and labor unions from discriminating against qualified individuals with disabilities in job application procedures, hiring, firing, advancement, compensation, job training, and other terms, conditions, and privileges of employment. The U.S. Equal Employment Opportunity Commission enforces the employment provisions of the ADA. Cancer can be considered a disability and is therefore protected under the ADA. Accordingly, cancer program administrators need to ensure they adhere to the guidelines outlined by the ADA. Any wavering from these guidelines could result in a serious fine for the healthcare organization.

Patient Support

Cancer patients rely heavily on their support systems. Support from co-workers can make the workday easier. Co-workers who face cancer need to know that the organization is behind them. Don't assume that your co-worker will know where to go for support and resources. From the moment your co-worker heard the three words, "You have cancer," they went from an employee with years of knowledge and experience to a patient. Educate your co-worker as you would any other patient and provide them with the same tools for this journey.

Reality Check

You may ask why I shared my personal story with cancer. I did so for one simple reason: no matter how much we think cancer will not happen to us or anyone we know, it is a reality I—along with my employers, physicians, and staff—continue to face. It is a reality none of us expected or could have predicted.

Throughout my transition from co-worker to patient, my co-workers have seen firsthand what being diagnosed and treated for cancer has done to me physically, mentally, and emotionally. I freely admit that I count on my co-workers to keep me in check—to make sure I still perform my job as I always have and to the same high standards as I expect from them. And I also acknowledge that I struggled at first with ensuring my office ran smoothly, while not sacrificing my health.

My hope is that this article can help other cancer programs prepare for a similar workplace situation. With in-house training, steps can be taken to protect co-workers who have cancer and their healthcare organization.

Just the other day I read an interesting article entitled, "Would You Want to be a Patient in Your Office?" It caused me to ponder my situation. First, because I never expected to be in this situation; second, because I never had a reason to doubt my cancer program. The reality is that when I became a cancer patient, I had to ask myself these tough questions. Did I really trust and believe in the technology, physicians, and cancer care team I ask my patients to believe in? Did I believe my privacy would be respected and protected? Would everyone in my organization know I was being treated for cancer and would this put my job in jeopardy? I urge you today to ask those same questions of yourself and your staff. If any of your answers are "No," your task should be to identify the reasons for this answer and what you can do to help make improvements to change it. OI

ShirRay Gabriel lost her battle with cancer just after her 49th birthday. She was regional administrator, 21st Century Oncology, Inc., Jacksonville, Fla.

References

1. Schardt TL. Would you want to be a patient in your office? Available online at: www.ncbi.nlm.nih.gov/pmc/articles/PMC1325286. Last accessed Jan. 5, 2015.

FINANCIAL ADVOCACY NETWORK Forum

Financial Advocacy - A Growing Field

Join the discussion at the Financial Advocacy Forum online discussion group on ACCC's MyNetwork to exchange information and discuss financial counseling and patient advocacy issues in real time with your colleagues.

STAY CONNECTED!

http://mynetwork.accc-cancer.org

FAST FACTS

90%
of cancer programs now offer financial assistance services.

84%
of programs employ "financial specialists" on staff.

68%
of respondents say that their program has a foundation or philanthropic organization to help meet their patients' financial needs.

ASK QUESTIONS

What should I know about ICD-10?

How do I make a case for hiring a financial advocate?

How can I improve processes to leverage copay programs?

Are there strategies to help maximize reimbursement?

ACCESS RESOURCES

Job descriptions.

Flow charts to help streamline financial advocacy services.

Resources to help with payer issues, including denials, pre-authorizations, and appeals.

Staffing models.

Financial tracking & reporting tools.

ACCC
Association of Community Cancer Centers

GRANIX™
(TBO-FILGRASTIM)
Injection

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

SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Splenic Rupture

Splenic rupture, including fatal cases, can occur following administration of human granulocyte colony-stimulating factors. In patients who report upper abdominal or shoulder pain after receiving GRANIX, discontinue GRANIX and evaluate for an enlarged spleen or splenic rupture.

5.2 Acute Respiratory Distress Syndrome (ARDS)

Acute respiratory distress syndrome (ARDS) can occur in patients receiving human granulocyte colony-stimulating factors. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving GRANIX, for ARDS. Discontinue GRANIX in patients with ARDS.

5.3 Allergic Reactions

Serious allergic reactions including anaphylaxis can occur in patients receiving human granulocyte colony-stimulating factors. Reactions can occur on initial exposure. The administration of antihistamines, steroids, bronchodilators, and/or epinephrine may reduce the severity of the reactions. Permanently discontinue GRANIX in patients with serious allergic reactions. Do not administer GRANIX to patients with a history of serious allergic reactions to filgrastim or pegfilgrastim.

5.4 Use in Patients with Sickle Cell Disease

Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disease receiving human granulocyte colony-stimulating factors. Consider the potential risks and benefits prior to the administration of human granulocyte colony-stimulating factors in patients with sickle cell disease. Discontinue GRANIX in patients undergoing a sickle cell crisis.

5.5 Potential for Tumor Growth Stimulatory Effects on Malignant Cells

The granulocyte colony-stimulating factor (G-CSF) receptor through which GRANIX acts has been found on tumor cell lines. The possibility that GRANIX acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which GRANIX is not approved, cannot be excluded.

6 ADVERSE REACTIONS

The following potential serious adverse reactions are discussed in greater detail in other sections of the labeling:

- Splenic Rupture [*see Warnings and Precautions (5.1)*]
- Acute Respiratory Distress Syndrome [*see Warnings and Precautions (5.2)*]
- Serious Allergic Reactions [*see Warnings and Precautions (5.3)*]
- Use in Patients with Sickle Cell Disease [*see Warnings and Precautions (5.4)*]
- Potential for Tumor Growth Stimulatory Effects on Malignant Cells [*see Warnings and Precautions (5.5)*]

The most common treatment-emergent adverse reaction that occurred at an incidence of at least 1% or greater in patients treated with GRANIX at the recommended dose and was numerically two times more frequent than in the placebo group was bone pain.

6.1 Clinical Trials Experience

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

GRANIX clinical trials safety data are based upon the results of three randomized clinical trials in patients receiving myeloablative chemotherapy for breast cancer (N=348), lung cancer (N=240) and non-Hodgkin's lymphoma (N=92). In the breast cancer study, 99% of patients were female, the median age was 50 years, and 86% of patients were Caucasian. In the lung cancer study, 80% of patients were male, the median age was 58 years, and 95% of patients were Caucasian. In the non-Hodgkin's lymphoma study, 52% of patients were male, the median age was 55 years, and 88% of patients were Caucasian. In all three studies a placebo (Cycle 1 of the breast cancer study only) or a non-US-approved filgrastim product were used as controls. Both GRANIX and the non-US-approved filgrastim product were administered at 5 mcg/kg subcutaneously once daily beginning one day after chemotherapy for at least five days and continued to a maximum of 14 days or until an ANC of ≥10,000 x 10^6/L after nadir was reached.

Bone pain was the most frequent treatment-emergent adverse reaction that occurred in at least 1% or greater in patients treated with GRANIX at the recommended dose and was numerically two times more frequent than in the placebo group. The overall incidence of bone pain in Cycle 1 of treatment was 3.4% (3.4% GRANIX, 1.4% placebo, 7.5% non-US-approved filgrastim product).

Leukocytosis

In clinical studies, leukocytosis (WBC counts > 100,000 x 10^6/L) was observed in less than 1% patients with non-myeloid malignancies receiving GRANIX. No complications attributable to leukocytosis were reported in clinical studies.

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The incidence of antibody development in patients receiving GRANIX has not been adequately determined.

7 DRUG INTERACTIONS

No formal drug interaction studies between GRANIX and other drugs have been performed.

Drugs which may potentiate the release of neutrophils, such as lithium, should be used with caution.

Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting bone-imaging results.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

There are no adequate and well-controlled studies of GRANIX in pregnant women. In an embryofetal developmental study, treatment of pregnant rabbits with tbo-filgrastim resulted in adverse embryofetal findings, including increased spontaneous abortion and fetal malformations at a maternally toxic dose. GRANIX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

In the embryofetal developmental study, pregnant rabbits were administered subcutaneous doses of tbo-filgrastim during the period of organogenesis at 1, 10 and 100 mcg/kg/day. Increased abortions were evident in rabbits treated with tbo-filgrastim at 100 mcg/kg/day. This dose was maternally toxic as demonstrated by reduced body weight. Other embryofetal findings at this dose level consisted of post-implantation loss, decrease in mean live litter size and fetal weight, and fetal malformations such as malformed hindlimbs and cleft palate. The dose of 100 mcg/kg/day corresponds to a systemic exposure ($AUC_{0\text{-}24}$) of approximately 50-90 times the exposures observed in patients treated with the clinical tbo-filgrastim dose of 5 mcg/kg/day.

8.3 Nursing Mothers

It is not known whether tbo-filgrastim is secreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when GRANIX is administered to a nursing woman. Other recombinant G-CSF products are poorly secreted in breast milk and G-CSF is not orally absorbed by neonates.

8.4 Pediatric Use

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

8.5 Geriatric Use

Among 677 cancer patients enrolled in clinical trials of GRANIX, a total of 111 patients were 65 years of age and older. No overall differences in safety or effectiveness were observed between patients age 65 and older and younger patients.

8.6 Renal Impairment

The safety and efficacy of GRANIX have not been studied in patients with moderate or severe renal impairment. No dose adjustment is recommended for patients with mild renal impairment.

8.7 Hepatic Impairment

The safety and efficacy of GRANIX have not been studied in patients with hepatic impairment.

10 OVERDOSAGE

No case of overdose has been reported.

TEVA Oncology

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Sicor Biotech UAB
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Product of Israel
GRX-40189 January 2014

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

GRANIX™
(TBO-FILGRASTIM)
Injection

Take a bite out of G-CSF acquisition costs*

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

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

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

†Biologics License Application.
‡As of February 2014.

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

Indication

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

Important Safety Information

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

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

For more information, visit GRANIXhcp.com.

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

TEVA Oncology