



Rescue Lung, Rescue Life

Translating the NLST results into clinical practice

Lung cancer is the number one cancer killer of men and women in the United States, responsible for approximately 450 deaths every day.¹ In November of 2010, the National Lung Screening Trial (NLST) was halted after a minimum 20 percent disease-specific mortality benefit was observed in participants undergoing three rounds of annual low-dose thoracic CT (CT lung screening) compared to those undergoing chest X-ray evaluation.² Four years have passed since closure of the NLST, and while more than a dozen national organizations, including the American Cancer Society and the National Comprehensive Cancer Network (NCCN), recommend CT lung screening (Table 1, page 22), the vast majority of high-risk patients have not enrolled in a screening program.³⁻¹¹

The lack of screening enrollment is somewhat surprising given the magnitude of the mortality benefit and published evidence of significant pre-existing interest among primary care physicians in screening patients at high-risk for lung cancer.¹² Possible causes for this slow adoption include unfamiliarity with new published data in support of CT lung screening and absence of widespread insurance coverage. As a result, even qualified individuals may have to pay out-of-pocket for an exam, which can cost hundreds of dollars.¹³ The unavailability of third-party reimbursement may incorrectly suggest to patients and physicians that CT lung screening is either not recommended or of unproven benefit, further weakening enrollment.

In July 2013 the United States Preventive Services Task Force (USPSTF) issued a draft grade “B” recommendation that patients at high-risk for lung cancer undergo annual CT lung screening.¹⁴ The USPSTF defined “high-risk” factors as:

- People ages 55-79
- Those with ≥ 30 pack-year smoking history

- Current or former smokers who have quit within the past 15 years.

The USPSTF grade “B” recommendation was made final on Dec. 30, 2013,¹⁵ with the “high-risk” factors defined as:

- People ages 55-80
- Those with ≥ 30 pack-year smoking history
- Current or former smokers who have quit within the past 15 years.

The Affordable Care Act mandates “first dollar coverage” of preventive services receiving a final USPSTF grade “A” or “B” recommendation.¹⁶

This article discusses our strategy to translate the NLST results into clinical practice in the face of these challenges and presents necessary building blocks for successful, safe, and responsible CT lung screening program development.

Organizational Change: Preparation

Professor John Kotter of Harvard Business School outlined eight steps necessary to bring about organizational change in his seminal work *Leading Change*.¹⁷ Our team closely followed this roadmap to help overcome the numerous, significant challenges as we established a CT lung screening program at Lahey Hospital & Medical Center (LHMC) (see Figure 1, page 22).

During phase 1 of the process, we began by:

- Creating a sense of urgency around the issue
- Forming a powerful coalition of program champions and supporters
- Creating a vision for our CT lung screening program.

Lung cancer has a disappointing 16 percent five-year survival.¹⁸ In the absence of screening, lung cancer is diagnosed at an advanced stage in two out of three cases—typically after a patient has become symptomatic.¹⁹ The NLST showed that diagnosing these patients

in the pre-symptomatic phase of the disease saves lives. In the NLST population, 1 percent of participants were found to have cancer on the initial CT lung screening exam. Other trials have reported even higher prevalence rates.²⁰ As a result, we know that at least 1 in 100 of our patients with a risk profile similar to the NLST already has lung cancer and could benefit from early detection. Extrapolating this experience to the entire U.S. population, we estimate that there are between 9 and 10 million individuals who meet the USPSTF high-risk profile of which approximately 100,000 are currently living with undiagnosed, potentially treatable lung cancer.¹⁴ Making CT lung screening accessible to this population has the potential to save 50 of the 450 lives lost each day to lung cancer.²¹ There is an urgent need to act immediately to rescue these individuals harboring this lethal disease.

Shortly after publication of the NLST, our team at LHMC concluded that eliminating self-pay rates and raising patient and physician awareness about the proven ability of CT lung screening to save lives could unlock the latent need and demand for screening and allow us to begin realizing the mortality reduction promised by the NLST. We did not have any previous experience in CT lung screening (LHMC did not participate in the NLST, I-ELCAP, or other CT lung screening research trials), nor were we able to find any existing models of high-volume clinical CT lung screening to use for guidance. Much work lay ahead for us to begin offering responsible and ethical CT lung screening as a community benefit equally available to all high-risk individuals, regardless of socio-economic status.

In the fall of 2011 physicians, administrators, and staff from the departments of internal medicine, pulmonary and critical care, laboratory medicine, radiation and medical oncology, thoracic surgery, and radiology founded the Rescue Lung, Rescue Life movement at Lahey Hospital & Medical Center with the following mission:

Table 1. Societies Recommending CT Lung Screening

• National Comprehensive Cancer Network
• American Lung Association
• American Thoracic Society
• American College of Chest Physicians
• American Society of Clinical Oncology
• American Association for Thoracic Surgery
• American Cancer Society
• American Association of Bronchology and Interventional Pulmonology
• Society of Thoracic Radiology
• Society of Thoracic Surgeons
• International Association for the Study of Lung Cancer
• Oncology Nursing Society
• European Society of Thoracic Surgeons
• American College of Radiology
• Cancer Care Ontario

Figure 1. Rescue Lung, Rescue Life Implementation of Kotter Model for Organizational Change

<ol style="list-style-type: none"> 1. Create a Sense of Urgency 2. Form a Powerful Coalition 3. Create a Vision 	<p>< PREPARE ></p>	<ol style="list-style-type: none"> 1. Rescue Lung, Rescue Life 2. Steering Committee 3. Hospital Mission
<ol style="list-style-type: none"> 4. Communicate the Vision 5. Remove Obstacles 	<p>< IMPLEMENT ></p>	<ol style="list-style-type: none"> 4. Approval 5. CME Campaign, Demystify, LungRADS, Radiology Infrastructure
<ol style="list-style-type: none"> 6. Create Short-Term Wins 7. Build on the Change 8. Embed the Change into the Culture 	<p>< MANAGE ></p>	<ol style="list-style-type: none"> 6. Quality and Safety Metrics 7. Research 8. Steering Committee Governance

- Save lives through early detection of lung cancer with responsible CT lung screening
- Encourage the government to establish reimbursement for responsible CT lung screening
- Encourage other centers of excellence in the treatment of lung cancer to offer responsible *free* CT lung screening until CMS establishes reimbursement
- Break down barriers and prejudice faced by those at risk for lung cancer
- Raise public awareness of the power of responsible CT lung screening to save lives
- Provide a platform to explore relevant research questions.

To offer CT lung screening as a community benefit, we needed strong support from the numerous clinical and administrative departments touched by the screening process. Common to all clinical CT lung screening programs is the fact that 100 percent of patients interact with the radiology department. A much smaller proportion of screened patients will be seen by interventional radiology for diagnostic and therapeutic procedures.

To achieve cost-effective, decentralized screening, our program

To achieve cost-effective, decentralized screening, our program requires the primary care team and/or referral base to partner with radiology to identify, inform, and follow all eligible patients.

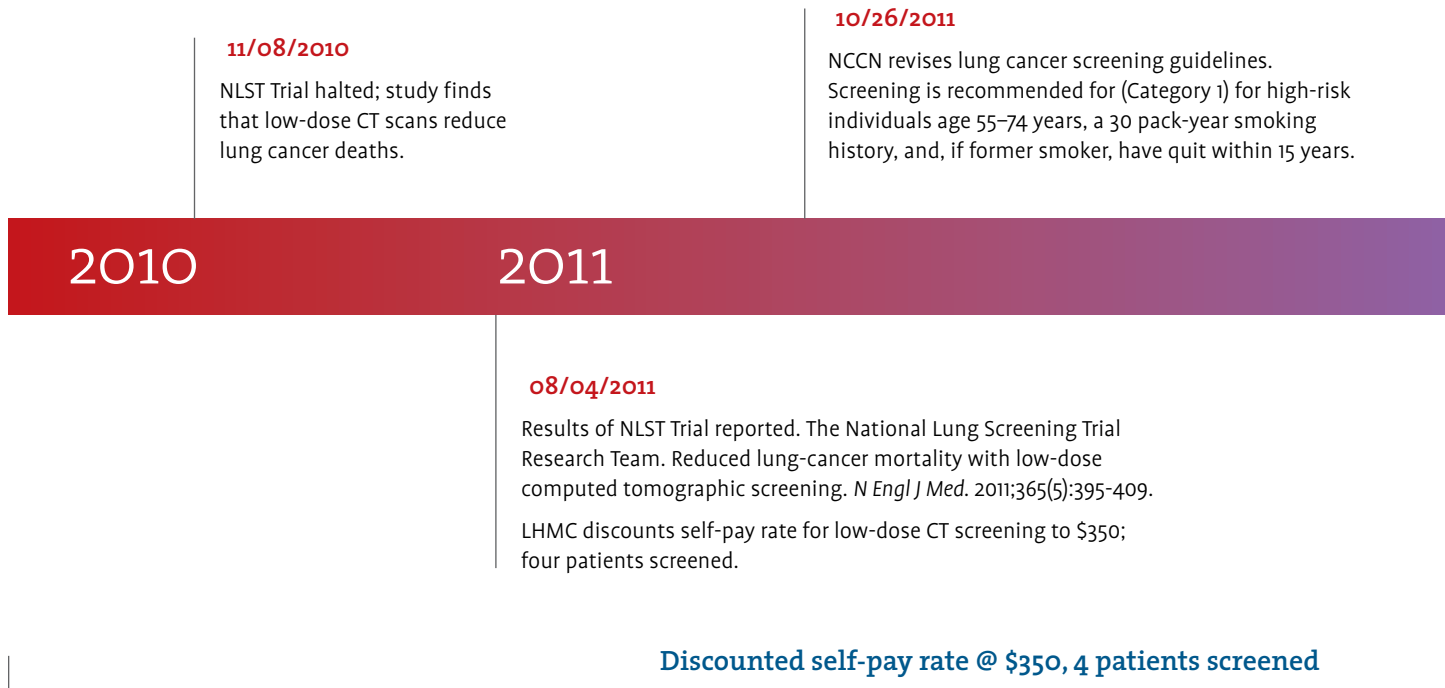
requires the primary care team and/or referral base to partner with radiology to identify, inform, and follow all eligible patients. Patients with suspicious findings—in our experience about 4 to 5 percent of individuals screened—are referred to pulmonary medicine. This department assumes the role of “quarterback” in these cases, directing care escalation with support from our multidisciplinary thoracic oncology group, which includes the departments of pulmonary medicine, pathology, radiology, medical and radiation oncology, and thoracic surgery.²²

For community-based physician-owned practices, equivalent

Figure 2. Rescue Lung, Rescue Life Steering Committee Members

CLINICAL	ADMINISTRATION
Radiology <ul style="list-style-type: none"> • Section Head Thoracic Imaging • Vice Chair Clinical Services • Vice Chair Research • Section Head Interventional Radiology • Chief Resident 	Senior <ul style="list-style-type: none"> • VP Hospital-Based Clinical Services • VP Cancer Services • Associate Chief Nursing Officer
Primary Care <ul style="list-style-type: none"> • Chair General Internal Medicine • Resident Representative 	Radiology <ul style="list-style-type: none"> • Administrative Director • Rescue Lung, Rescue Life Program Coordinator • Department Manager, CT • Department Manager, Nuclear Medicine
Pulmonary Medicine <ul style="list-style-type: none"> • Chair & Chief Medical Officer • Director of Interventional Pulmonology • Residency Director 	Cancer Services <ul style="list-style-type: none"> • Department Manager, Radiation Oncology • Specialty Program Coordinator, Radiation Oncology • Rescue Lung, Rescue Life Program Coordinator
Oncology <ul style="list-style-type: none"> • Chair Radiation Oncology • Cancer Center Medical Director 	Marketing
Thoracic Surgery	Business Development
Laboratory Medicine	Philanthropy

Figure 3. Rescue Lung, Rescue Life Program Development Timeline



alliances between leading subspecialty practices in a geographic area may be formed to serve the same purpose and represent an opportunity for physicians in the community to distinguish themselves as leaders across specialties and build their respective practices. In addition to these clinical specialties our team needed support from finance, compliance, legal, and philanthropy to assess the impact of offering screening as a community benefit prior to the initial rollout of the program.

Senior members of the various involved specialties joined together to form the Rescue Lung, Rescue Life steering committee. This powerful coalition guides program development, provides a common forum to establish consensus, and perhaps most importantly acts in concert to overcome obstacles to program implementation (Figure 2, page 23). We specifically invited members for their proven ability to advocate for patients, design program systems, and support implementation on behalf of their specialty.

A radiology working group was created to manage day-to-day operations within the Radiology Department and to report program metrics and opportunities for program improvement back to the steering committee. Participants included thoracic radiologists, radiology administration, information technology, scheduling, and ad hoc representation by members of our mammography team. All infrastructure and systems developed to manage program implementation were designed in concert by the radiology working group and the steering committee.

Presented with this unique opportunity to fulfill the LHMC mission to save lives, grow, innovate, establish sustainability, and promote teamwork, our senior leadership approved the Rescue

Lung, Rescue Life program to be run as a community benefit. We set a go live date of January 9, 2012, which gave us six weeks (through the holiday season) to begin to fulfill the Rescue Lung, Rescue Life mission of offering CT lung screening at no cost to patients who met the NCCN Lung Cancer Screening Guidelines® high-risk definition and several LHMC criteria:³

- Group 1 (NCCN Category 1 recommendation)
 - ▼ 55-74 years of age, 30 pack-year smoking history, quit < 15 years
 - ▼ Same as NLST study population
- Group 2 (NCCN Category 2B recommendation)
 - ▼ Aged >50 years and older, > 20 pack-year smoking history
 - ▼ Require at least one additional lung cancer risk factor, such as:
 - Personal history of smoking-related cancer
 - History of lung cancer in a first degree relative
 - Chronic lung disease, including IPF (idiopathic pulmonary fibrosis) and emphysema
 - Exposure to several known carcinogens
- Additional LHMC qualification criteria
 - ▼ Asymptomatic at time of screening
 - ▼ Free of lung cancer diagnosis within the past five years
 - ▼ No known metastatic disease
 - ▼ Order for exam from patient’s physician prior to the exam.

Figure 3, above, shows a timeline of Rescue Lung, Rescue Life program development.

12/28/2011

LHMC conducts a CME campaign to educate providers and patients about the benefits of low-dose CT screening.

12/31/2013

By the end of the year, approximately 1,700 patients have received low-dose CT screening.

2012

2013

2014

12/06/2011

LHMC creates a steering committee to look at low-dose CT screening.

01/09/2012

LHMC rolls out its Rescue Lung, Rescue Life program.

2014 and Beyond

How does the oncology community ensure equal access so that the estimated 9 to 10 million at-risk individuals are screened, regardless of their ability to pay?

1,700 patients screened

Organizational Change: Implementation

In phase 2, our team’s goals were to: 1) communicate the vision to all stakeholders, patients, primary care physicians, and the community, 2) remove barriers to implementation, and 3) create short-term wins. Offering CT lung screening as a community benefit mitigated the most formidable barriers to program success, however, significant additional obstacles lay ahead (see Figure 4, page 26).

The Henry Ford Motor Company’s assembly line innovations streamlined automobile production and ushered in an era of efficient and cost-effective manufacturing.²³ In a similar manner, scalable, cost-effective screening requires distribution of work responsibilities among the many involved disciplines to ensure success. For example, primary care physicians (PCPs) are preventive care experts who discuss the risks and benefits of a variety of screening choices with their patients on a daily basis. Armed with knowledge from NLST on the benefits and risks of CT lung screening, PCPs are ideally positioned to guide patients in making a decision to enroll in a CT lung screening program. For high-risk patients this discussion may be integrated into their annual well-patient visit without creating an additional patient encounter. CT lung program staff can work with the primary care base to ensure all referred patients meet high-risk criteria and to provide patients and ordering physicians access to additional lung screening resources as needed. The Program Coordinator and the Program Navigator work directly with physicians and patients to provide the needed resources. We believe that a requirement of centralized specialty and multidisciplinary consultation *prior* to enrollment usurps the role of the primary

care physician and creates additional barriers to patient access by increasing costs and limiting scalability. Therefore, we advise against that model. Decentralizing patient enrollment through primary care well-patient visits with support from CT lung screening program staff eliminates such barriers and puts the screening discussion into the hands of those physicians most experienced and best positioned to advise patients on screening decisions.

Overcoming many remaining identified barriers required special focus in two important domains, a continuing medical education campaign by LHMC cancer services and infrastructure development in radiology. These components have previously been published in the *Journal of the American College of Radiology* and are reviewed below.²²

Primary Care Initiative. We anticipated high patient volumes because our program was the only program in the state offering lung cancer screening at no charge to the patient. Using our current mammography volume as a benchmark and the ratio of the number of U.S. women who qualify for mammography to the number of high-risk individuals who qualify for CT lung screening (6:1), we projected LHMC should perform 100 screening exams per week at a steady state.^{14, 24}

We currently enroll 20 to 30 new patients and perform around 50 total screening exams each week. The vast majority of patients enter our screening program through a direct referral by their PCP. Patients may self-refer for eligibility assessment, but we must receive an order for screening from their physician prior to screening.

To prepare and enable PCPs to have effective screening enrollment discussions with their patients, we needed to dispel

Figure 4. Obstacles to Program Implementation

• Patient Access
• Uninsured Patients
• Patient Anxiety
• Long Debate
• Busy Practices
• Informed Decision Making
• False Positives
• Competing Demands for Funds
• Cost to Society
• Radiation Risk
• Fear of Encouraging Smoking
• PCP Acceptance
• Managing Findings

misconceptions resulting from the decades-long controversial debate over CT lung screening. During the six weeks leading up to our program launch date, steering committee members conducted numerous face-to-face CME events with local PCP groups to present facts from the NLST, detail the risks and benefits specific to CT lung screening, and explain opportunities to integrate smoking cessation counseling. We reassured our PCP base that the program would be modeled after mammography, most importantly using a structured reporting system with clinical recommendations linked to specific findings, and centralized tracking of patient appointments managed through the radiology department. This model was critical in building support. We discussed the medico-legal risk associated with failure to inform high-risk patients of the proven life-saving potential of CT lung screening in light of the growing number of national medical society endorsements.²⁵ Finally we emphasized that undergoing screening at LHMC in no way obligates any patient to return to LHMC for follow-up of any findings on the CT lung screening exam or for any other services provided by LHMC as a result of undergoing the initial screening exam.

Radiology Systems. Prior to program inception, LHMC's Rescue Lung, Rescue Life team created a reporting and data system "LungRADS," modeled after BI-RADS® but specifically adapted for the needs of CT lung screening.²² LungRADS consists

of several elements, including an overall exam assessment score, a nodule lexicon, and a structured reporting system (Figure 5, right). As in mammography, a CT lung screening structured reporting and data system links screening findings with standard guideline recommendations and provides a common language to communicate results among members of the care team. In conjunction with our in-house designed CT lung screening database, LungRADS creates a mechanism to track patients, audit results, and facilitate research and training. LungRADS also helps avoid care escalation in those patients unlikely to have lung cancer by triaging high-risk patients into appropriate risk categories based on their screening exam.

Program Statistics. The radiology working group publishes program statistics regularly for steering committee review.

Weekly reports include:

- New inquiries and orders: NCCN Group 1, NCCN Group 2, and Group 3 (not qualified)
- Patients scheduled
- Patients screened: initial and repeat (annual) and interval.

Bi-monthly reports include:

- Positive screens (LungRADS 3 and 4)
- Suspicious screens (LungRADS 4)
- PET/CT
- Biopsies
- Surgeries
- Pathology
- Significant incidental findings
- Complications.

We benchmark results against the corresponding NLST metrics for quality assurance. Opportunities for process improvement are discussed and important program decisions are made collectively through the steering committee. These measures create short-term wins necessary for program sustainability. Since initiating the clinical CT lung screening program, LHMC has screened over 1,700 unique patients (~20 percent from NCCN Group 2) and initial results are similar to those reported in the NLST.^{2,22}

Organizational Change: Management

In phase 3, our team looked to build on the change and embed the change into the culture.

LHMC now has multiple research projects underway to identify methods to further improve on the process of CT lung screening, as well as maintaining engagement of the various involved departments. The evidence-based structured reporting algorithms developed to administer the lung screening program have been well received. In fact, clinical departments have requested that radiology develop a similar structured approach for other disease sites and applications. Our primary care teams have taken the initiative to

build identifiers within the organization's incoming electronic health record (EHR) to automate and facilitate the identification of high-risk patients, thus facilitating their process during the patient office visit.

To accelerate opening access to responsible CT lung screening throughout the U.S., members of our steering committee have presented the Rescue Lung, Rescue Life program at regional, national, and international scientific meetings. We have also made our screening materials and management systems available online at no cost. To date, over 400 centers from around the world have downloaded the more than 40 available documents. We hope that free sharing of our materials reduces the operational barriers to CT screening program development by other cancer programs.

Lessons Learned

For cancer programs looking to implement a similar CT lung screening program, our team shares these lessons.

Change is hard. The more people that are required to make it happen, the harder the change is to bring about. Following proven frameworks for organizational change can help successfully implement organization-wide initiatives, such as the Rescue Lung, Rescue Life CT lung screening program at LHMC.

CT lung screening program development is a team sport. Individual physicians or disciplines cannot do it alone. A successful CT screening program divides the work among appropriate members of the care team and respects the expertise each team member and discipline brings to the program.

Screening in high volume presents its own set of challenges, which will not become widely recognized until reimbursement barriers are removed. A reporting and data system (e.g., LungRADS) is an absolute requirement to effectively manage a high-volume program.



Dr. McKee confers with LHMC's Chief Therapist.

An integrated IT infrastructure in the imaging department, which allows tracking of findings and facilitation of appropriate patient follow-up, is necessary to perform safe, responsible CT lung screening.

Standardized diagnostic work-up protocols for both operable and medically inoperable patients must be established at screening sites given the relatively high percentage of medically inoperable patients we have observed within the high-risk groups (about 25 percent in our program).

Decentralized access to the screening program is necessary for cost-effective, efficient, high-volume screening.

In the absence of a national education campaign, a local CME campaign is required to engage the organization or geographic PCP base. Our experience has been that once educated about the risks and benefits of screening, high-risk patients do enroll in screening programs.

A well-organized, multidisciplinary CT lung screening program offers an extraordinary opportunity to develop research initiatives directed to optimize the screening process and address the many unanswered questions pertaining to early lung cancer diagnosis.

Figure 5. LungRADS Overall Exam Assessment: Part 1

Lung Cancer Specific Category (BI-RADS® Based)		NCCN-Guidelines® Based Follow-up Recommendation
Category	Assessment	
1	Negative	Routine annual LDCT screen (age < 75)
2	Benign	Routine annual LDCT screen (age < 75)
3	Probably Benign	Interval short-term diagnostic LDCT (1, 2, 3, 6, 12 months)
4	Suspicious	Pulmonary consultation and multidisciplinary clinic review
5	Known Malignancy	PCP and oncology referral

Going Forward

Responsible CT lung screening programs can serve as a model for value-based healthcare delivery as envisioned by the Institute of Medicine (IOM) and Centers for Medicare & Medicaid Services (CMS). The IOM report “Delivering High Quality Cancer Care: Charting a New Course for a System in Crisis” describes a healthcare delivery system in crisis with contributing factors that include an aging population, increasing complexity of cancer care, a shrinking work force, and rising costs.²⁶ The IOM conceptual framework asks healthcare teams and stakeholders to develop care delivery models that engage patients in decision making. Similar to Rescue Lung, Rescue Life, these models:

- Use a coordinated and adequately trained workforce to the highest level of their abilities
- Provide evidenced-based cancer care
- Use informatics for process improvement
- Translate research into clinical practice
- Provide accessible, affordable cancer care to patients.

CMS has developed measure domains intended to focus stakeholders on developing systems to reduce potential for patient harm; provide superior patient and caregiver experiences and outcomes; systematically coordinate complex care; provide better

access to evidence-based strategies proven to reduce mortality and improve outcomes; and develop strategies to improve efficiency and reduce costs.²⁷ Figure 6, below, illustrates the linkage between the CMS measure domains and design elements of our Rescue Lung, Rescue Life CT lung screening program.

Now that the USPSTF recommendation is final—removing the reimbursement barrier—cancer programs interested in CT lung screening will be challenged by their administrators and the physician and patient base to quickly implement delivery systems needed for responsible, safe screening. We hope that LHMC’s Rescue Lung, Rescue Life program can serve as a demonstration of a scalable CT lung screening program design that achieves results similar to those reported in the NLST and paves the way for access to lung cancer screening for the millions of individuals at high-risk not currently enrolled.


By preventing one in five lung cancer deaths in the high-risk population, CT lung screening has the power to rescue tens of thousands of U.S. lives per year. To realize this potential, the medical community must work together to expedite insurance coverage, develop a national education campaign, and build the local program infrastructure needed to make responsible CT lung screening equally accessible to all those at high-risk to develop this deadly disease. 

Figure 6. CMS Measure Domains

DOMAINS	VALUE BASED DELIVERY SYSTEM
Safety	Reduce potential for patient harm <ul style="list-style-type: none"> • Unnecessary testing in LungRADS category 3 group • Wrong screening test • Fabrication of symptoms
Patient and Family Experience and Outcomes	Reduce cost to patient Lower burden of Stage IV disease
Care Coordination	Standardize communication among providers
Clinical Care	Prevention Improved outcomes
Population of Community Health	Reduce healthcare disparities Improved access with PCP involvement Integrated smoking cessation
Efficiency and Cost Reduction	Avoid high-cost, low-quality specialty clinics <ul style="list-style-type: none"> • Centralized specialty clinics that are resource intensive • High marketing costs • Limit litigation risk

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