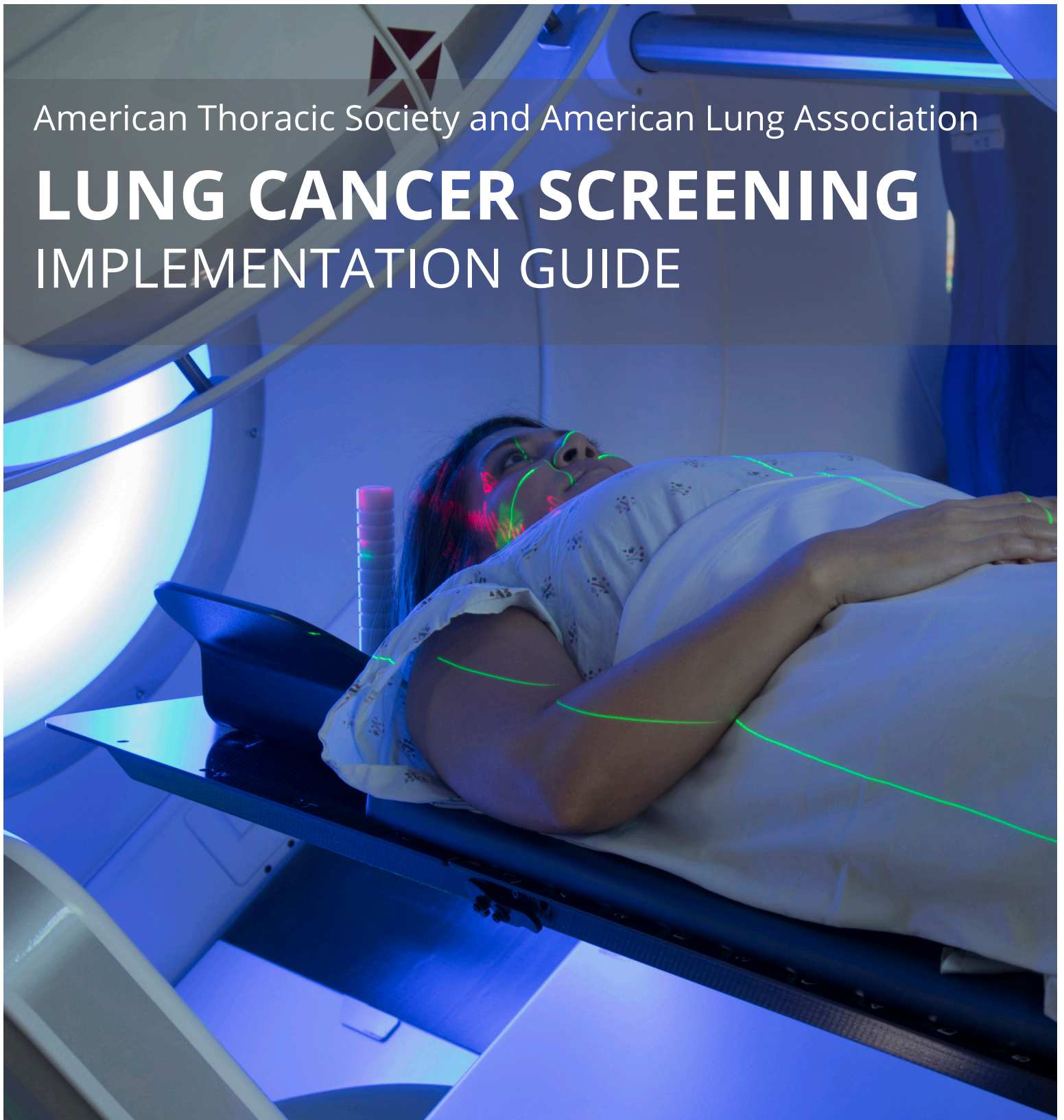


American Thoracic Society and American Lung Association

LUNG CANCER SCREENING IMPLEMENTATION GUIDE



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Preface

The American Thoracic Society and the American Lung Association joined forces to develop a guide for implementation of lung cancer screening (LCS) programs. The aim of this document is to provide a pragmatic guide and toolkit of how to design, implement, and conduct an LCS program based on a survey of experts in LCS representing a diversity of institutions throughout the United States. Members from the American Lung Association and American Thoracic Society known for their involvement in LCS activities, were selected to participate in the project. A panel of experts in the areas of research, behavioral sciences, quality improvement, nurse navigation, patient advocacy and clinicians involved in leading and performing lung cancer screening in the fields of pulmonary, radiology, interventional pulmonary, primary care, oncology, and thoracic surgery was assembled. The panel developed a document using information gathered from a clinical practice survey that aimed to address how participating members approached common problems encountered in clinical LCS and program implementation. *This is not a guideline or position statement of the American Lung Association or the American Thoracic Society.*

The panel reached consensus for the document to be formatted in question and answer format. Participants were polled for questions they are commonly asked by others performing or contemplating performing screening services. Questions were pooled together and organized under three categories. Members and questions were divided into one of the three working groups and questions distributed for answers. All members were given an opportunity to respond to every question. Not all participants responded to all questions and for some questions several gave the same response, which was indicated. The survey addresses practice approaches to challenges in LCS for which guideline or consensus statements may not exist. There are a variety of different screening models in practice today and therefore different responses are provided within this document. Some of the approaches are different and some may be in apparent conflict. No attempt was made to reach consensus on approaches because the goal was to report on actual practice patterns from diverse settings. Responses from individual members were collated and presented at an all-group in-person meeting. Following an initial draft, a second in-person meeting of several panel members took place resulting in this implementation guide for LCS programs.

The survey is meant to allow individuals to search specific participant responses. For example, if a reader's center is most similar in organizational structure to a center like Cleveland Clinic, then the Cleveland Clinic responses are available for that reader to implement. Other centers may be more interested in the Kaiser responses, or the VA responses. This is why we have structured the document in this fashion. The responses are the viewpoints of the authors only and NOT reflective of the entire organization. The document is not meant to be read cover to cover, but rather for individuals to skip around to specific sections as they are tackling a particular issue along the course of their program development. Page numbers for the various sections allow this sort of usability, and ultimately the website will facilitate this functionality at a higher level.

Key summary recommendations are not possible in a practice survey such as this as some responses may be in contradiction to others. The reason for the survey format is to specifically avoid making summary recommendations as there are currently no available agreed upon screening quality metrics to allow comparisons across screening methods to state that one method is superior to another.

We begin by summarizing existing LCS criteria statements, the LCS implementation policy statements of the ATS/ACCP, and the general structure in which the panelists participate (Sections 1, 2). Next, we cover topics that should be considered when planning an LCS program (Section 3), review considerations essential to running a successful LCS program, including issues that arise before the LCS study, i.e., identifying and counseling eligible patients (Section 4), during the LCS exam, i.e., performing the scan and reporting the results (Section 5), and after the LCS study, i.e., ensuring proper surveillance and follow-up of screen-detected findings (Section 6). We also cover the parallel process of providing smoking cessation interventions (Section 7), a corollary to LCS that should be incorporated at multiple points in the LCS process to maximize the potential to reduce lung cancer and other smoking-related deaths. Finally, we provide resources and links to helpful tools for implementing LCS programs and performing required elements of the process (Section 9). The forthcoming web-based toolkit will provide links for direct access to these and many other resources.

How to use this manual

To use this manual most effectively, read Section 1 and 2 first. Section 3 is the Question and Answer section outlined in the index. You may want to move to specific sections based on your questions and use the index as a guide. You may want to read this section by reading the responses from the panelists who work at the center most similar to your own. You can identify those by reading Table 3 to identify the center and panelists most similar to your organization and looking for those as you move through Section 3. We would urge you to look at all responses under the content areas of most interest to you given that many of the responses are relevant to any center.

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Section 1: Implementing an LCS Program

All major medical organizations, including the United States Preventive Services Task Force (USPSTF) and the Centers for Medicare & Medicaid Services (CMS), recommend annual LCS for individuals at high-risk of developing lung cancer, with only one exception.¹⁻⁹ There is near uniform consensus among these organizations that LCS is appropriate for the population studied in the National Lung Screening Trial (NLST), which enrolled healthy adults who were current and former (quit < 15 years) cigarette smokers aged 55-74 with at least a 30 pack-year smoking history. Many of these organizations including the USPSTF, CMS, American Association for Thoracic Surgery (AATS), and the American College of Chest Physicians (ACCP) now recommend expanding LCS coverage beyond the NLST criteria to capture others at high-risk of developing lung cancer (Table 1).

Table 1. Organizational LCS Eligibility Recommendations

	Year	Age	Pack-Years	Quit	Other
AAFP¹	2013	Ins. Ev.	Ins. Ev.	Ins. Ev.	None
AATS Tier 1²	2012	55 - 79	≥ 30	No Limit	None
AATS Tier 2²	2012	50-79	Over 20	No Limit	Cumulative 5% chance of developing lung cancer in next 5 years
AATS Tier 3²	2012	Any	Any or None	No Limit	Personal History of Lung Cancer and 4 years NED
ACS³	2013	Over 50	≥ 30	≤ 15	"Relatively good health"
ACCP⁴	2017	55 - 77	≥ 30	≤ 15	None
ALA⁵	2017	55 - 80	≥ 30	≤ 15*	None
ASCO/ATS⁶	2015	55-74	≥ 30	≤ 15	None
CMS⁹	2015	55 - 77	≥ 30	≤ 15	None
NCCN Group 1⁷	2017	55 - 74	≥ 30	≤ 15	None
NCCN Group 2⁷	2017	Over 50	Over 20	No Limit	At least one additional lung cancer risk factor or at least 1.3% chance of lung cancer diagnosis within 6 years
USPSTF⁸	2014	55 - 80	≥ 30	≤ 15	None

AAFP = American Association of Family Physicians, AATS = American Association of Thoracic Surgery, ACS = American Cancer Society, ACCP = American College of Chest Physicians, ASCO = American Society of Clinical Oncology, ATS = American Thoracic Society, ALA = American Lung Association, CCO = Cancer Care Ontario, NCCN = National Comprehensive Cancer Network, USPSTF = United States Preventive Services Task Force, CMS = Center for Medicare and Medicaid Services

Year = year recommendation was published, Ins. Ev. = insufficient evidence to recommend for or against screening

Other = additional considerations for groups to screen beyond the core recommendation:

ALA – urges consideration of risk prediction, suggests standard criteria given insurance coverage, * = not forced to exit screening after reaching 15 year quit mark



In addition to these clinical practice guidelines, the ACCP and American Thoracic Society (ATS) have issued policy statements to ensure that benefits of LCS outweigh harms as LCS advances from the clinical trial setting to implementation in real-world practice. (Table 2). Multiple other LCS implementation guidelines are available.^{7,10-12}

Table 2. Recommendations of ATS/ACCP policy statements on implementation of LCS

Core LCS domain ¹³	Policy recommendations & metrics for high-quality LCS programs ¹³	Implementation strategies ⁶
Who is screened, how often, and for how long?	<p>Policy recommendation:</p> <p>LCS programs should collect data on all enrolled subjects related to the risk of developing lung cancer.</p> <p>Associated quality metrics:</p> <ul style="list-style-type: none"> • The LCS program must confirm that there is a policy about who will be offered screening. While this is up to each individual program, insurance agencies will often mandate that they are in keeping with USPSTF recommendation. • At least 90% of all screened subjects must match the program's stated policy, excluding those enrolled in clinical trials.gov registered screening research protocols. • The LCS program must confirm that there is a policy about the frequency and duration of screening that is in keeping with the recommendations. 	<ul style="list-style-type: none"> • Education of referring clinicians on eligibility criteria • EMR-based clinical reminders • Human review (e.g., LCS coordinator) • Targeted feedback to PCPs who repeatedly refer patients for LCS who do not meet eligibility criteria
How the CT is performed	<p>Policy recommendations:</p> <ol style="list-style-type: none"> 1. A low-dose LCS CT should be performed based on the ACR-STR technical specifications. 2. LCS programs should collect data to ensure the mean radiation dose is in compliance with ACR-STR recommendations. <p>Associated quality metric:</p> <p>The LCS program must confirm that there is a policy about the technical specifications for performing low-dose CT screening that is in keeping with the ACR-STR technical specifications and credentialing criteria.</p>	<ul style="list-style-type: none"> • Protocols for CT technician • Training of CT technicians



Table 2. Recommendations of ATS/ACCP policy statements on implementation of LCS (continued)

Core LCS domain ¹³	Policy recommendations & metrics for high-quality LCS programs ¹³	Implementation strategies ⁶
Structured reporting	<p>Policy recommendations:</p> <ol style="list-style-type: none"> 1. LCS programs should use a structured reporting system, such as Lung-RADS™. 2. LCS programs should collect data about compliance with the use of the structured reporting system. <p>Associated quality metrics:</p> <ul style="list-style-type: none"> • The LCS program is using Lung-RADS™ as their structured reporting system, or uses a structured reporting system with similar elements (communication tool, identification of positive findings, lung nodule management recommendations). • The selected structured reporting system is being used for at least 90% of the CT screen reports. 	<ul style="list-style-type: none"> • Use of templated structured reporting system (e.g., Lung-RADS™) • Training of radiologists in use of reporting system



Table 2. Recommendations of ATS/ACCP policy statements on implementation of LCS (continued)

Core LCS domain ¹³	Policy recommendations & metrics for high-quality LCS programs ¹³	Implementation strategies ⁶
Lung nodule management algorithms	<p>Policy recommendations:</p> <p>LCS programs must:</p> <ol style="list-style-type: none"> 1. Include clinicians with expertise in the management of lung nodules and the treatment of lung cancer, 2. Have developed lung nodule care pathways, 3. Have the ability to characterize concerning nodules through PET imaging, non-surgical and minimally invasive surgical approaches, 4. Have an approach to communication with the ordering provider and/or patient, 5. Have a means to track nodule management, and 6. Collect data related to the use of, and outcomes from, surveillance and diagnostic imaging, surgical and non-surgical biopsies for the management of screen detected lung nodules. <p>Associated quality metrics:</p> <ul style="list-style-type: none"> • The LCS program has designated clinicians with expertise in lung nodule management, the performance of non-surgical biopsies and minimally invasive surgical biopsies, and lung cancer treatment. The following specialties should be represented: radiology (diagnostic, interventional), pulmonary medicine, thoracic surgery, medical oncology, radiation oncology. • The LCS program has designated an acceptable lung nodule management strategy, such as the use of available published evidence-based algorithms and/or care pathways. • The LCS program can describe the lung nodule communication and nodule management tracking system being used by their program. • The LCS program must be capable of reporting on: <ul style="list-style-type: none"> ◦ the number of surveillance and diagnostic imaging tests, ◦ non-surgical and surgical biopsies that are performed for malignant and benign screen-detected nodules, ◦ the number of cancer diagnoses, and ◦ the number of procedure-related adverse events (e.g., hospitalization, death). 	<ul style="list-style-type: none"> • Formation and regular meetings of multidisciplinary LCS steering committee with clear leadership structure • Multidisciplinary lung cancer tumor board to advise on evaluation of nodules at high-risk of malignancy • Adoption of nodule evaluation algorithm • Clear allocation of responsibility for nodule evaluation between primary care and specialists, via EMR or direct communication • LCS coordinator to oversee and coordinate nodule evaluation between primary care and specialists • Registry of LCS patients, used to track nodule evaluation and other quality metrics



Table 2. Recommendations of ATS/ACCP policy statements on implementation of LCS (continued)

Core LCS domain ¹³	Policy recommendations & metrics for high-quality LCS programs ¹³	Implementation strategies ⁶
Smoking cessation	<p>Policy recommendations:</p> <ol style="list-style-type: none"> 1. LCS programs must be integrated with a smoking cessation program. 2. LCS programs should collect data related to the smoking cessation interventions that are offered to active smokers enrolled in screening. <p>Associated quality metrics:</p> <ul style="list-style-type: none"> • The LCS program has integrated smoking cessation services. • The LCS program will report on the portion of active smokers who are offered, and who participate in, a smoking cessation intervention. 	<ul style="list-style-type: none"> • Written materials with links to smoking cessation resources • Evidence-based interventions: nicotine replacement, pharmacotherapy, counseling • Interventions at multiple time points (before, after LCS)
Patient and provider education	<p>Policy recommendations:</p> <ol style="list-style-type: none"> 1. LCS programs should educate providers so that they can adequately discuss the benefits and harms of screening with their patients. 2. LCS programs should develop or use available standardized education materials to assist with the education of providers and patients. 3. LCS programs are responsible for the oversight and supplementation of provider-based patient education. <p>Associated quality metrics:</p> <ul style="list-style-type: none"> • The LCS program will list the educational strategies used to educate ordering providers about the key components of LCS. • The LCS program demonstrates the availability of standardized patient and provider educational material. 	<p>Provider education:</p> <ul style="list-style-type: none"> • Grand round presentations • Audit and feedback to individual providers <p>Patient education / shared decision-making:</p> <ul style="list-style-type: none"> • Designate who will conduct shared decision-making (e.g., referring clinician, LCS coordinator) • Patient decision aids (generic or personalized) available at point-of-care, or mailed to patients in advance



Table 2. Recommendations of ATS/ACCP policy statements on implementation of LCS (continued)

Core LCS domain ¹³	Policy recommendations & metrics for high-quality LCS programs ¹³	Implementation strategies ⁶
Data collection	<p>Policy recommendations:</p> <ol style="list-style-type: none"> 1. LCS programs must collect data on all enrolled patients related to the quality of the program, including those enrolled in registered clinical research trials. Data collection should include elements related to each of the other 8 components of an LCS program (as above). In addition, data collection should include the outcomes of testing (complications, cancer diagnoses), and a description of the cancers diagnosed (histology, stage, treatment, survival). 2. A review of the data and subsequent quality improvement plan should be performed at least annually. 3. An annual summary of the data collected should be reported to an oversight body with the authority to credential screening programs. Standards set forth in the above policy statements should be used by the oversight body to judge areas of compliance and deficiency. <p>Associated quality metrics:</p> <ul style="list-style-type: none"> • The LCS program must collect data related to each component of an LCS program, the outcomes of testing, as well as the cancers diagnosed, and report this data annually to an oversight body. • The LCS program should respond to concerns from the oversight body in order to maintain accreditation. 	<ul style="list-style-type: none"> • LCS registry to facilitate data collection • LCS coordinator tasked with maintaining registry • Regular feedback of quality metrics data to LCS steering committee • Regular feedback of quality metrics data to referring providers



Section 2: Strategies for Implementation— Program Structure and Panel Profiles

Program Structure

The structure of each LCS program will depend on available resources, the type of institution and practice, and the skills and interests of the individual providers. Often new LCS programs will build upon or arise from pre-existing multidisciplinary lung cancer clinics and/or tumor boards. Most LCS programs fit within one of three general categories.

At one end, a centralized LCS program actively recruits eligible patients, conducts education and shared decision-making visits, assists in smoking cessation, and schedules, orders, performs, and interprets all screening studies. The program also arranges consultations, schedules follow-up studies, and tracks all clinical and outcome data. The centralized LCS program communicates results and plans to the patient and referring provider. This model requires significant resources including a dedicated LCS coordinator, clinical leadership, and an integrated multidisciplinary program team.

At the other end, a **decentralized LCS program** performs the LCS exam and interpretation and leaves the referring provider responsible for all other functions.

In between the extremes of a completely centralized and a completely decentralized program are many examples of **hybrid LCS programs** with some centralized processes and other aspects decentralized, i.e., deferred to the primary care provider.

Please refer to Table 3 (page 17) of Planning an LCS Program section that lists the panel profiles and organizational structure.



Section 3: Planning an LCS Program

Starting a successful and effective clinical LCS program is a complex endeavor that requires careful coordination of many clinical and administrative activities. General elements required for program initiation have been previously described (Table 2). However, as with any complex process, the details are important. There are many questions which arise in planning an LCS program that are incompletely addressed in the published guidelines referenced earlier. The answers to the questions below provide practical guidance to commonly encountered implementation issues and are answered by the panel. Participating panelists from centers around the country are outlined in Table 3, which allows the reader to understand the environment the panelist is working in and how their program may differ from those at another institution.

3A. Engaging Local Leadership and Establishing a Business Plan

3B. Forming a Governance Structure and Multidisciplinary Team

3C. Forming a Radiology Working Group, Credentialing and Radiologist Training

3D. Establishing Radiology and Program Quality Metrics

3E. Insurance and Reporting Requirements

3F. Outreach and Education of Providers

3G. Marketing to Healthcare Community and Patients



Table 3. Participating LCS Center Profiles and Panelists

Institution/Panel Member	Brief description of organization and LCS program	Describe program structure:	What is your program governance structure?	Type of tracking system	Unique populations served by program
Boston Medical Center Renda Soylemez Wiener (RSW) Katrina Steiling (KS)	Boston Medical Center is an academically affiliated urban tertiary care center and the largest safety-net hospital in New England	Hybrid program: Decentralized ordering/centralized tracking	Multidisciplinary steering committee Pulmonary and Radiology	Database for registry /tracking	Minority, inner city poor
Christiana Care Health System Albert Rizzo (AR)	Christiana Care Health System, headquartered in Wilmington, Delaware, is one of the country's largest health care community teaching hospitals	Centralized: SDM and orders performed by dedicated LCS program personnel	Pulmonary/ Thoracic Surgery Pulmonary with close partnership with Radiology	In-house developed tool	Minority representation We participate in the state's Screening for Life Program for the uninsured
Cleveland Clinic Peter Mazzone (PM)	The Cleveland Clinic health system is an academic multi-specialty group practice	Centralized: SDM and orders performed by dedicated LCS program personnel	Pulmonary Pulmonary with close partnership with Radiology	Internal registries implementing a purchased patient management software package	N/A



Table 3. Participating LCS Center Profiles and Panelists (continued)

Institution/Panel Member	Brief description of organization and LCS program	Describe program structure:	What is your program governance structure?	Type of tracking system	Unique populations served by program
Kaiser Permanente Southern California Michael Gould (MKG)	Kaiser Permanente Southern California (KPSC) is a fully integrated health care system that provides comprehensive care to over 4.4 million members at 14 hospitals and over 200 medical offices in the southern California region	Decentralized: SDM and orders by PCP with limited centralized verification, scheduling or tracking	Radiology Pulmonary Primary Care input	We have a robust infrastructure at regional headquarters and individual medical centers to support data analytics and tracking	Minority representation The KPSC membership reflects the diversity of the source population in southern California, with large numbers of Hispanics (>30%) and African Americans (11%)
Lahey Hospital and Medical Center Andrea McKee (AM) Andrea Borondy Kitts (ABK) Brady McKee (BM) Carla Lamb (CL) Shawn Regis (SR)	Lahey Hospital & Medical Center is an academically affiliated multispecialty group practice accountable care organization	Hybrid program Decentralized ordering/ centralized tracking	Multidisciplinary steering committee Radiology Radiation Oncology	Commercially available LCS patient tracking database	



Table 3. Participating LCS Center Profiles and Panelists (continued)

Institution/Panel Member	Brief description of organization and LCS program	Describe program structure:	What is your program governance structure?	Type of tracking system	Unique populations served by program
Mount Auburn Hospital Carey Conley Thomson (CCT) Kaitlyn Kelley (KK)	Mount Auburn Hospital is a community based academic center associated with Harvard Medical School and a part of a long-standing accountable care organization	Hybrid program Decentralized ordering/ centralized tracking	Centralized governance Radiology Pulmonary	EMR-based registry and manually entered databases	Minority representation We are located in Cambridge, MA and serve immigrant populations of a number of countries as well as an African-American and homeless population
Mount Sinai Health System Charles A Powell (CAP) Andrea Wolf (AW)	Mount Sinai Health System includes seven teaching hospitals and the Icahn School of Medicine at Mount Sinai. It is an Accountable Care Organization (ACO)	Centralized: SDM and orders performed by dedicated LCS program personnel	Radiology	As of 2000, we use the I-ELCAP database which we developed to capture background data, and CT information and images	African-American, Hispanic, and other minority and immigrant populations



Table 3. Participating LCS Center Profiles and Panelists (continued)

Institution/Panel Member	Brief description of organization and LCS program	Describe program structure:	What is your program governance structure?	Type of tracking system	Unique populations served by program
Northwestern Medicine Eric M Hart (EMH)	Northwestern Medicine (NM) is an integrated healthcare system anchored by our downtown Chicago academic hub providing primary- quaternary medical care throughout Chicago and its northern and western suburbs through our network of regional medical groups and facilities. NM consists of a multispecialty academic hub and multiple regional community practices	Hybrid program: Decentralized ordering/ centralized tracking The exact structure varies slightly by region	We have multidisciplinary steering committees in each region that cooperate on overall strategy Radiology Other: The clinical LCS program is managed in radiology in the central and north regions, and in oncology in the west region	Patient and outcomes tracking are regionally supported by tools developed within the institution	With its regional presence, NM serves a broad spectrum of Chicagoland patients, from urban to suburban to exurban



Table 3. Participating LCS Center Profiles and Panelists (continued)

Institution/Panel Member	Brief description of organization and LCS program	Describe program structure:	What is your program governance structure?	Type of tracking system	Unique populations served by program
New York University - Langone Health Gaetane Michaud (GM)	New York University Langone Health is a health network consisting of 5 hospitals, Tisch (academic private hospital), Bellevue Hospital (public city hospital), NYU Brooklyn (large community hospital in Brooklyn), Winthrop (large community hospital on Long Island) and Manhattan VA. Screening is currently only being offered at Tisch, however there are plans to expand the program to both NYU Brooklyn and Winthrop Hospital over the next 6-12 months		Pulmonary We have a steering committee consisting of thoracic radiologists (3), thoracic surgery (2), Medical IT (1), Pulmonology (5)	We have a commercially available database	Minority representation



Table 3. Participating LCS Center Profiles and Panelists (continued)

Institution/Panel Member	Brief description of organization and LCS program	Describe program structure:	What is your program governance structure?	Type of tracking system	Unique populations served by program
The Ohio State University Derrick Herman (DH) Edwin Jackson (EJ)	<p>The Ohio State University is a tertiary care center with two screening sites. The first is the State University Wexner Medical Center and the second is in our community outreach hospital on the East side of Columbus (UHE).</p>	<p>Hybrid program: Decentralized ordering/centralized tracking and Centralized: SDM and orders performed by dedicated LCS program personnel</p>	<p>Pulmonary</p> <p>Pulmonary Medicine, Thoracic Radiology and Medical Oncology establish policies and procedures. Continuous monitoring of their proper implementation is done by a multidisciplinary group (Oncology, Thoracic Surgery, Interventional Radiology, Radiation Oncology and Hospital Administration) lead by Pulmonary Medicine</p>	EMR-based registry	<p>Minority representation</p> <p>65% of patients screened at UHE are recipients of Ohio Medicaid and 40 percent are African-American. Operations at each clinic are identical</p>
PrimaCARE PC Carolyn Fruci (CF)	<p>PrimaCARE PC is a large, ~150 physician, multi-specialty group practice in Fall River, MA. We are affiliated with but not owned by a local community hospital</p>	<p>Hybrid program: Decentralized ordering/ Centralized tracking</p>	<p>Multidisciplinary steering committee</p> <p>Pulmonary</p>	Manually tracked by our program coordinator	Large percent from Portugal, Azores



Table 3. Participating LCS Center Profiles and Panelists (continued)

Institution/Panel Member	Brief description of organization and LCS program	Describe program structure:	What is your program governance structure?	Type of tracking system	Unique populations served by program
Rush University Medical Center James Mulshine (GM)	Rush University Medical Center is an academic medical center, affiliated with Rush University. It is a not-for-profit healthcare education, and research enterprise comprising of Rush University Medical Center, Rush University, Rush Oak Park Hospital, Rush Health, and Rush Copley Hospital	Hybrid program: Decentralized ordering/ Centralized tracking	Radiology Medical Oncology Shared-governance	EMR-based registry, the ACR registry, and self-made commercially available non-dedicated spreadsheet	Military Minority representation 4% of our patient population is African American 1% is of Asian descent 7% of our patient population is of unknown ethnicity
UC Davis Health David T Cooke (DTC)	UC Davis Health is an academic health system that is part of the University of California, Davis (UC Davis)	Hybrid program: Decentralized ordering/ Centralized tracking	Multidisciplinary team Led by Radiology	EMR-based registry, ACR Registry	Rural Minority representation Multiple minority populations
Seattle Cancer Care Alliance/ University of Washington Medical Center David K Madtes (DKM)	The Seattle Cancer Care Alliance / University of Washington Medical Center is a multidisciplinary group practice accountable care organization	Hybrid program: Decentralized orders/SDM Centralized: tracking and smoking cessation performed by dedicated LCS personnel	Radiology Pulmonary Multidisciplinary LCS Oversight Committee	Commercially available LCS software	Minority representation Socio-economically disadvantaged patients

**Table 3. Participating LCS Center Profiles and Panelists (continued)**

Institution/Panel Member	Brief description of organization and LCS program	Describe program structure:	What is your program governance structure?	Type of tracking system	Unique populations served by program
VA Portland Health Care System Christopher G Slatore (CGS) Mark Deffebach (M.D.)	VA Portland Health Care System; Level 1A VA facility in the Pacific Northwest	Centralized: SDM and orders performed by dedicated LCS program personnel	Pulmonary	EMR-based registry	Rural Military Minority representation
Vanderbilt University Medical Center Kim L Sandler (KLS)	Vanderbilt University Medical Center is an academic institution providing multidisciplinary care in Nashville, TN	Centralized: SDM and orders performed by dedicated LCS program personnel	Radiology		Minority representation

Panelists are identified by their initials, so that their specific comments can be tracked in the Question and Answer portions of the following sections.



3A. Engaging Local Leadership and Establishing a Business Plan

LCS programs generate activity across multiple departments throughout an organization. Accounting for these diverse sources of downstream revenue can be challenging but necessary when seeking to secure resources for program implementation. Additional considerations for engaging senior leadership beyond the proven mortality benefit to the high-risk population are addressed by the following questions and responses.

1. How did you gain support from your administration when setting up your LCS program?

AM: Armed with the ground-breaking results from the NLST and the newly-released NCCN LCS guidelines, physician and administrative members of our multidisciplinary steering committee educated our senior administration about the net benefit of LCS for the high-risk population at various time points and settings including one-on-one conversations and formal group presentations. We highlighted the power of LCS to save lives and decrease morbidity while simultaneously mitigating our institutional legal liability. We also provided our senior administration with a forward looking business analyses projecting potential hospital activity/volume resulting from LCS under a variety of scenarios.

CCT/AR: Our program leaders worked with senior leadership in oncology, radiology, and pulmonary to synthesize the evidence and evaluate the financial impact of such a program on the organization. We assessed ACO financial data on the lung cancer diagnosis as well as therapies and evaluated leaks from our program with a plan for improved retention of patients from the point of screening forward utilizing a multidisciplinary team and navigator. We also used evidence of the risk of loss to follow-up and the need for a surveillance system in addition to an LCS program. This is a huge area of concern for primary care and ordering providers across the organization and our screening program was proposed in conjunction with a robust mechanism to track incidental lung nodules as well and to provide surveillance.

CF: Making the case to provide an LCS program through our practice was a challenge. We met with administrations and reviewed the data regarding LCS to establish a need for such a service. We are a large multispecialty group affiliated with but separate from a local hospital system. The sources of “downstream” revenue for our group are limited, i.e., we do not directly provide chemotherapy, radiation therapy, or receive the facility fee for surgeries. However, there is a strong incentive for administration to prevent “leakage” of patients from the practice. We were able to get backing by emphasizing that a program was the right thing to do for our patients, to ensure that screening is discussed and offered to appropriate high-risk patients, and also to ensure that patients without a clear benefit are not unnecessarily exposed to the risks of screening. It was also emphasized that if we did not offer an internal screening program our PCP’s would still need to discuss LCS with appropriate patients and if screening was to be pursued it would require referring them to a program outside our practice and our affiliated medical center.



3B. Forming a Governance Structure and Multidisciplinary Team

Development of a Multidisciplinary Steering Committee can serve as a powerful coalition to guide program development, provide a forum to establish consensus, and promote a team-based approach to overcome obstacles to program implementation. The following descriptions derive from a survey sample of project panelists.

2. Provide a description of your program, including its structure and governance.

AM: The Rescue Lung, Rescue Life LCS program at Lahey Hospital & Medical Center is a **hybrid program with decentralized referral and centralized tracking**. It is managed by a multidisciplinary steering committee consisting of representatives from radiology, radiation oncology, pulmonary medicine, thoracic surgery, medical oncology, internal medicine, pathology, marketing, philanthropy, and administration. Co-chairs of the steering committee are from the departments of radiology and oncology. The steering committee responsibilities are to set high-level program structure, define roles and responsibilities of personnel, define high-risk populations, garner administrative and service line support, define quality metrics, oversee outreach initiatives, agree on policies for medically inoperable patients, and work together to remove barriers to increase patient access. Since the program's inception in 2012, we have performed over 13,000 exams on 5,000 high-risk individuals. We currently perform 60 LCS exams per week, with full capacity estimated to be ~100 scans per week.

AR: The Lung Health Screening program at Christiana Care Health System began enrolling eligible patient in the spring of 2015. This was done in a joint effort with the state of Delaware's Screening for Life Program that was already performing screening for the uninsured in the areas of colon, breast and prostate. Other healthcare facilities in the state worked in concert as well. The program is **centralized** and all orders and shared decision making are conducted by the program. The steering committee consists of leaders in radiology, pulmonary, thoracic surgery, IT/statistician, primary care representatives, smoking cessation counselor, along with the nurse navigator. The responsibilities of the steering committee are to set high-level program structure, define roles and responsibilities of personnel, define high-risk populations, garner administrative and service line support, define quality metrics, oversee outreach initiatives, agree on policies for medically inoperable patients, and work together to remove barriers to increase patient access. Currently with about 2,000 enrolled over the past two years and it will grow as needed.

CCT/KK: The Mount Auburn Hospital LCS and Nodule Management program is a **hybrid program with decentralized referral and centralized management** and tracking of findings. Providers can elect to refer directly to the program for evaluation and entry into the program in a centralized manner. The electronic health record (EHR) triggers a best practice advisory for eligible patients and the order is



placed by the provider following SDM and smoking cessation counseling. Eligibility is verified centrally. The program is managed by a multidisciplinary steering committee consisting of key experts in pulmonary, diagnostic and interventional radiology, radiation oncology, thoracic surgery, oncology, pathology, and coordination through a nurse navigator. The program is supported by monthly review of key metrics by an Oncology Steering Committee led by the hospital CEO with members including chairs of medicine, radiology, and chiefs of oncology, radiation oncology, pulmonary, and representation from surgery, development, and fiscal management. Central program staff includes a medical director, radiology director, a nurse navigator, and key support from operations in radiology and IT. A smaller steering committee exists for our LCS program and includes the director and assistant director of the program, the radiology screening program director, the nurse navigator, and the chief of oncology. This group develops major initiatives and opportunities for quality control and growth. Logistic and operational issues and registry reporting requirements are discussed among these individuals with supporting personnel from radiology, quality, and IT where needed. We also identify areas for quality improvement and research. The director of chest imaging manages the radiology requirements and Lung-RADS™ training, reporting process, surveillance letters, and oversees the processes in radiology for verification of screening criteria with each order. We have a direct notification system through our EMR to the ordering provider, primary care physician (PCP), and lung nodule program. If there is a Lung-RADS™ 3 or 4 finding, the program navigator speaks directly to the ordering provider's office to offer an appointment for management. All suspicious findings are discussed at our multidisciplinary clinical team meetings. We currently screen approximately 1,000 patients per year and have shifted the curve to early stage of diagnosis following close to three years of the program.

CF: The PrimaCARE program is a **hybrid program with decentralized referral and centralized tracking**. Operations are managed by the pulmonary division. We have a steering committee that includes pulmonary (medical director and navigator), thoracic surgery, radiology, primary care, and administration at our practice and oncology and interventional radiology at our local hospital system. The committee meets regularly to review data and discuss strategy going forward. The steering committee reviews data and quality metrics and identifies areas for improvement, assesses PCP participation in LCS and barriers to participation, opportunities for education, and sets goals. We also review finances and discuss opportunities for complying with LCS CMS requirements in a fiscally responsible manner. Staff and physicians in the pulmonary office manage the day-to-day operations of the LCS center. Shared decision-making, and, where applicable, smoking cessation counseling is provided initially by the PCP. Patients also receive educational material at the time of their scan. We currently have approximately 600 patients enrolled. Full capacity is likely over 5,000.



PM: The Cleveland Clinic's LCS program is a **centralized program** accessible throughout our health system. Any provider can refer patients to the program. Patients are pre-screened for eligibility then scheduled for a counseling and shared decision-making (SDM) visit as well as low-dose CT at one of seven sites blanketing Northeast Ohio. The multi-specialty and inter-disciplinary team has developed a standardized SDM visit, documentation including structured reporting, communication tools, and management algorithms for nodule and common non-nodule findings. Program personnel are trained to provide smoking cessation guidance. Multidisciplinary team led by pulmonary with close partnership with radiology. Data collection and reporting are assisted by internal registries. Approximately 2,500 patients have been screened with further growth anticipated.

RSW/KS: The LCS program at Boston Medical Center has a hybrid structure to its program. There is the option of **either decentralized referral (PCP conducts SDM and places LCS order) or centralized referral (PCP refers patient to an LCS/Pulmonary Nodule clinic** for SDM visit and decision whether to proceed with screening; if yes, the sub-specialty clinic provider places LCS order). A coordinator notifies the referring provider directly and the referring provider communicates these results to the patient. Screen-detected findings can either be managed in a decentralized fashion by the referring provider (i.e., PCP orders follow up testing and referrals) or through the centralized LCS/pulmonary nodule clinic. The program has centralized tracking of the LCS results and follow up is managed by a multidisciplinary steering committee with co-chairs from pulmonary medicine and radiology. The program is additionally staffed by an LCS program coordinator who is a nurse practitioner and a patient navigator. Since March 2015, over 1,200 individuals have undergone baseline LCS. We currently screen about 90-120 patients per month.

The steering committee meets quarterly to review LCS program metrics such as volume, proportion meeting eligibility criteria, Lung-RADS™ distribution, cancer outcomes, etc. We also discuss challenges that have arisen during implementation and day-to-day operations of the program, e.g., rolling out an EPIC best practice alert, increasing data capture from referrals outside the BMC system, etc.

MKG: The program at Kaiser Permanente Southern California (KPSC) is **decentralized**. The SDM and LCS orders are placed by the PCP with limited centralized verification, scheduling or tracking. LCS exams at KPSC are ordered by primary care providers and pulmonologists using a standardized order set in the electronic health record. Providers are required to check boxes to confirm that the patient is asymptomatic, meets eligibility criteria, has undergone shared decision making, and has been referred for tobacco cessation treatment (TST), if a current smoker.

The program is run by clinical chiefs of service in the radiology and pulmonary medicine, with input from primary care. We have a robust infrastructure at regional headquarters and individual medical centers to support data analytics and tracking.



We perform approximately 4,000 LCS exams per year. The eligible population includes as many as KPSC 30,000 members.

CAP/AW: The Mount Sinai LCS program is a **centralized** program. It is governed by radiology through the International Early Lung Cancer Action Program (I-ELCAP). This has been an ongoing screening program since 2010. We have used a protocol since starting screening in 1992 at the Weill Cornell Medical Center and have continuously updated it, with references, on our website (IELCAP.org). We have a database of 80,000 screening participants worldwide. At the Icahn School of Medicine, we are providing screening at all the clinical sites of the Mount Sinai Health System. The program will continue to expand as CT scanners are added with American College of Radiology (ACR) certification. Scheduling, reading, and tracking are done centrally by the ELCAP staff. Shared decision-making and smoking cessation sessions are provided by the faculty or a nurse practitioner. Smoking cessation has been part of our program since our initial publication on smoking cessation (in the context of CT screening) in 2001. We have a database of 80,000 screening participants worldwide. We are currently screening participants who are covered by Medicare/Medicaid and those who meet the expanded criteria.

EMH: Northwestern Medicine (NM) is the clinical enterprise affiliate of Northwestern University Feinberg School of Medicine. NM consists of three regions (central, north, and west), each of which runs a **hybrid clinical LCS program with decentralized referral and centralized tracking**. In our central and north regions, the multidisciplinary LCS steering committee is centered in the radiology department, a continuation of our NLST structure. In our west region, the multidisciplinary LCS steering committee is centered in the oncology department. The regions cooperate on overall program strategy and quality initiatives. Since 2013, we have performed initial screens on approximately 2,200 individuals in our three regions. We anticipate our capacity for the three regions to be approximately 6,000 enrollees.

GM: The NYU program is a **centralized referral and tracking program**. Patients are referred to the program internally via EPIC referral or by calling 1-800-NYU-LUNG. Once referred, the patient is contacted by the patient coordinator to set up an appointment. The CT scan is ordered and placed on hold until after the initial visit. In the initial visit, the patient is seen by the nurse practitioner and pulmonary attending physician to have a physical exam and further identify if they meet criteria for LCS. During the clinic visit, the patient's individual lung cancer risk is determined. In addition, smoking cessation counseling is provided. A balanced discussion of individualized risk and benefit of CT screening for lung cancer occurs and documented in the patient's chart. If the patient meets criteria, they have the CT scan the same day and follow up is scheduled according to the CT reading. The NYU LCS Program provides recommendations and appropriate follow-up for pulmonary nodules as well as close collaboration with referring providers with any abnormal findings that require closer follow up or invasive procedure. Patient demographic, clinical and screening data is captured and logged into our secure, commercially-



available database. We have a steering committee consisting of thoracic radiologists (3), thoracic surgery (2), medical IT (1), pulmonology (5). We currently have more than 900 patients actively involved in our screening program. We are currently expanding to two additional sites. Our maximum capacity has not yet been established.

EJ: The Ohio State University Early Lung Cancer Detection Clinic (ELCDC) is a combination of a **decentralized referral with centralized** SDM and orders for LCS and tracking. It is a novel all-inclusive screening lung cancer and smoking cessation program that is managed by pulmonary medicine in conjunction with medical oncology. Following patient referral dedicated nurses call each patient, ensure eligibility and schedule patients in one of two separate screening locations. LCS operations consist of a same-day 90 minute 4 step processes which are outlined here. During the first appointment, each patient will take part in a three-step shared decision-making process with a pulmonologist or pulmonary and critical care fellow. Once the decision to screen is made, the patient will then be immediately screened with a low-dose chest CT.

Low-dose computed tomography will be obtained immediately following the initial screening visit. The CT scanner is conveniently located on site making the transition from ELCDC clinic to radiology seamless.

Positive screens are discussed by our multidisciplinary tumor board consisting of interventional pulmonary, pulmonary medicine, medical oncology, radiation oncology, thoracic surgery, interventional radiology and pathology. Establishment of policies and continuous monitoring of their proper implementation is owned by The Ohio State University James Cancer Center and Division of Pulmonary Medicine. The program is projected to perform 650 LCS scans this academic year (July 2017-2018). We have two locations. Both sites screen 6-8 patients per week.

JM: The LCS program at Rush University Medical Center (RUMC) and Rush Oak Park Hospital (ROPH) is a **decentralized referral and centralized tracking program**. It is managed by a multidisciplinary team consisting of two thoracic radiologists, thoracic surgeons, a pulmonologist, multiple CT techs, and two program nurse coordinators (LCSC RN). Once the exam is ordered, the LCSC nurse will confirm the patient is eligible for their exam. Once a patient is confirmed eligible, they will complete their screening appointment at either RUMC or ROPH. After a patient has finished their exam, an LCSC RN will meet with them to address any questions regarding the exam, discuss smoking cessation and available smoking cessation resources if applicable, and invite the patient to participate in a research study being conducted by the medical center. After the exam appointment is complete, a thoracic radiologist will read and interpret the screening. Once the screening has been resulted, if the patient's exam results in a lung RADS 4 exam finding, the thoracic radiologist will notify patient's ordering provider, who will notify the patient of their results, and choose a treatment plan for the patient. After a patient's exam has been resulted, if a patient has a negative exam or a Lung-RADS™ 3 reading, an LCSC RN will manually result the screening within the patient's EMR to send to the



ACR for tracking, and a result letter will generate from the EMR to be sent to the patient. The LCSC RN will then remind patient to come back for their exam annually. If a patient has a Lung-RADS™ 4 result, once the patient's ordering physician has been notified by the thoracic radiologist, an LCSC RN will contact the ordering provider to offer navigation services, to help the patient schedule an appointment with thoracic surgery. The ordering physician may refuse the navigation service if they prefer another form of treatment. Lung-RADS™ 4 exams will be presented at a weekly MDC Chest Conference where a multi-disciplinary team of providers can view the scan and offer opinions for treatment. The LCSC RN oversees registry submission of all screening patients to the ACR, following patients and updating the ACR for one year after screening. The LCSC RN's are also in charge of generating program metrics and promoting program growth. Since 2015, we have 504 patients enrolled in our screening program and 629 exams have been completed. Of the 629 exams completed, we have found 18 lung cancers and seven other cancers. Our goal is to grow the volume of our program by 5 percent in the next year, accruing at least 25 more screening patients to our program by November 2018.

DTC: The UC Davis Comprehensive LCS Program (CLSP) is a **hybrid program with decentralized referral and centralized tracking**. It is a multidisciplinary collaborative for comprehensive LCS. To serve our patients in the program, we use a multidisciplinary team of radiologists, thoracic surgeons, pulmonologists, pathologists, medical oncologists, primary care doctors, smoking cessation experts and radiation oncologists to develop a best-practice, patient-centered plan. The program is led by a screening task force through a task force chair. The CLSP offers an LCS Shared Decision-Making Tool Kit to assist the referring provider at the point of care. Smoking cessation assistance is also offered through a myriad of patient centered tools.

DKM: The LCS Program at the Seattle Cancer Care Alliance/University of Washington Medical Center offers the option of **either decentralized referral (PCP conducts SDM and places LCS order) or centralized referral (PCP refers patient to the LCS Program)** for SDM counseling and LCS order. The program has **centralized verification, tracking of results, and smoking cessation counseling**. It is managed by a multidisciplinary steering committee with representatives from pulmonary medicine, radiology, primary care medicine, thoracic surgery, marketing and administration. Central program staff in radiology and pulmonary medicine manages day-to-day operations with a dedicated commercially available LCS database. Over 750 individuals have undergone baseline screening with diagnosis of 24 asymptomatic lung cancers. The program estimated full capacity patient population is 2,300.

CGS: The VA Portland Health Care System (VAPORHCS) LCS Program is a **centralized program** with orders performed by dedicated LCS personnel. It is a multidisciplinary collaboration of primary care, pulmonary, radiology, informatics, and thoracic surgery. Currently, about half of our primary care clinics are equipped to refer



patients to our program, about 40,000 patients served by these clinics.

KLS: The Vanderbilt University Medical Center is a **centralized program and is governed by a multidisciplinary team**. All patients undergo shared decision-making visits prior to their CT exam, most often performed by our clinical coordinator, a nurse practitioner with specialized training in LCS and smoking cessation. Since 2013, 1,000 screening CT examinations in more than 800 patients have been completed. We currently have approximately 700 patients enrolled in the program and estimate full capacity to be 3,000 patients enrolled. We have diagnosed more than 25 cancers, the vast majority of which have been early stage disease.

3. Do you believe that an LCS program should be based in a specific department or practice, such as imaging, pulmonary, surgery, or oncology?

MD: An LCS program should have a “home,” but at the same time it must be multidisciplinary. A home within imaging or pulmonary often makes sense; the core of LCS is based on imaging, and most evaluations that result from screening include small indeterminate nodules that are most often managed by pulmonary. Some institutions establish free-standing programs, while others establish programs within the context of other cancer screening, such as mammography.

CL/AM: While this may be institution specific, the home base for the program seems the best fit in imaging with a multidisciplinary team having specifically defined roles and work flow, and most importantly a reliable navigator to maintain accountability for study results and confirmation of appropriate action and communication of those results. A decentralized system may provide easier access to the program, but will require a centralized system for tracking of mandatory reporting elements.

CCT/KK: This is institution specific, although having a central home with coordination and tracking from that point between all members of the team and for the patient is crucial in running a successful program. Radiology defines the necessary elements of the study itself and assesses eligibility criteria for the study prior to performing it. There needs to be a centralized mechanism to intervene on suspicious findings through a multi-disciplinary team, and to maintain standards for quality as well as to track the many required data elements for registry reporting and program specific quality metrics. The home in our institution is in pulmonary given the need to follow pulmonary nodules over time and decide when intervention is necessary, review imaging with patients, and the management of non-malignant pulmonary conditions that lead to pulmonary nodules. This is also a good opportunity to perform shared decision making and smoking cessation counseling. Follow up frequency also requires more knowledge of the patient than the nodule characteristics seen on imaging. Referrals to diagnostics and treatment come from the pulmonologist who communicates with the navigator for care coordination and discussion with the multi-disciplinary team. Most alternate diagnoses are also managed by pulmonary, which allows the patient to connect with a caregiver for longitudinal care as well.



There should also be a robust centralized surveillance system for follow-up of findings on the screening study, as well as criteria for ongoing annual follow-up. This is an area of risk to the patient and to the providers caring for these patients. A centralized process and a navigator are essential to this.

4. Do you believe that an LCS program needs to have a program navigator?

AM: Yes, we could not manage a population health program of this nature at our organization without program navigation.

MD/RSW/KS: Most experienced programs have concluded that it is essential to have a program coordinator. High quality LCS requires attention to details, such as ensuring that only eligible patients are being screened and that patients actually get their screening studies, and any evaluation that comes from an abnormal study. Reimbursement is often dependent on a proper sequence of events—for example, shared decision-making visits must occur before screening studies. All this requires ongoing attention to details, most likely utilizing a data management tool. Without a program coordinator, these details can be overlooked. In addition, abnormal screening studies must be followed up. Nodules detected through screening that are not followed up only to later reappear as a more advanced lung cancer are a serious liability. The coordinator might be shared with other related activities. Some programs have a coordinator support the LCS program as well as an incidental lung nodule program.

CCT: A program navigator is essential to provide care coordination for patients, to ensure education of providers and the community, and to assist with data management. Many navigators also work to ensure appropriate surveillance and reduce loss to follow up. In our program the navigator provides care coordination, outreach, smoking cessation, survivorship visits, and is the “glue” to patient care coordination efforts. She also manages the data collection of clinical care, and maintains educational materials on the program, tracks all diagnostic and treatment strategies, provides resources on nodules and lung cancer, as well as on shared decision making and smoking cessation.

AR: Yes, preferably one who has clinical background (RN, LPN) with appropriate clerical/administrative support.

CF: Yes. Our navigator’s work coordinating the program has been essential to our success. With appropriate coaching and scripting she has been able to do this exceptionally well despite not being an RN or LPN. Our program navigator reviews all referred individuals for appropriateness of screening, schedules exams, collects results and brings to lung cancer program physician for review, contacts patients and PCP’s by phone and mail regarding results, schedules necessary follow-ups, including pulmonary consults for positive scans, and communicates directly with PCP offices regarding patient results and compliance with screening. In addition to the navigator, the program director provides guidance and education to PCP offices.



5. Who manages your program database and patients? Clinical or non-clinical? Nurse navigators from the cancer center, radiology assistants, pulmonary NPs, or other?

CCT: Clinical staff who are familiar with the medical terminology and follow appropriate protocols and guidelines manage our databases. In our program, a nurse navigator manages the flow of patients in and out of the database and tracks necessary follow-up. She also tracks all clinical diagnostic and therapeutic care provided and follows process measures related to access and diagnostics. She intersects with other staff members in radiology, oncology, radiation oncology, and thoracic surgery who track oncologic diagnosis, stage, and outcome and transfers necessary information into the LCS program database. A surveillance database also maintained for the purposes of tracking annual follow-up of LCS studies. This database also houses follow-up for incidentally found nodules and nodules found on diagnostic chest imaging.

SR/BM: This will vary from site to site. With the amount of work involved in managing a screening program, this would ideally be done by someone who is dedicated full-time to the program and not doing it in addition to their other responsibilities. In our program, we have two non-clinical positions dedicated to the program due to our high volume; we did not want to create a bottleneck by having all patients see a clinical navigator prior to screening. However, if the volume allows, having a clinical navigator can be advantageous for shared decision making, smoking cessation, discussion of results, etc. What department the position comes from will also vary, though it should be noted that this is a radiology program above all else, as roughly 90 percent of patients will remain in the annual/interval imaging cycle and never see specialist services.

CF: Our program coordinator, who is not a nurse, manages our database. We have pre-templated letters that we send out to patients, depending on CT result, and we also pre-scripted and coached our program director on phone calls to patients regarding results and follow-up needed based on CT result (after physician review of each case). We do have a goal of getting a nurse navigator so that they could do the shared decision making and smoking cessation counseling.

6. How do the various personnel involved in your LCS program communicate with each other?

AM/CL: Communication occurs through different methods. For an individual patient direct communication between providers and program navigators is required. For program management and oversight, every other month steering committee meetings, where radiology working group report outs and research committee report outs, are standing agenda items. Weekly program statistics are reported to the steering committee members through steering committee distribution list e-mail communication. Multidisciplinary weekly conference is an additional forum for communication to discuss Lung-RADS™ 4 findings and to develop consensus



recommendations. These are then relayed to the ordering provider either directly (physician-to-physician) or with the nurse navigator in oncology to close the communication loop.

MD/RSW/KS: Communication with the specialists involved in LCS, as well as patients and referring providers, is one of the most important functions of a screening program. Communication with referring providers and patients is often part of the screening coordinators role. Communication among the other components can occur in a variety of settings. Some programs have regular meetings of the screening radiologist, coordinator, and the key providers engaged in nodule management, often pulmonary or thoracic surgery, reviewing studies that might require extra follow-up or evaluation. One large program has found that these meeting are only needed every other week, can take as little as 20 minutes, are very instrumental in keeping the program cohesive and responsive, and can help expedite evaluations. Another forum for communication could be a regularly scheduled lung cancer conference or tumor board, where concerning screening studies are reviewed as a multidisciplinary group.

CCT/KK: Communication occurs daily through specialists and the nurse navigator. The nurse navigator also visits patients receiving treatment and maintains relationships with each of these patients. Our team meetings include review of concerning new nodules and each element of their referrals and work-up to date including imaging, pathology, and therapy. Recommendations are communicated back to the managing provider. Our clinical database is another source of communication and monthly, year to date, and yearly comparisons are reported monthly at our Oncology Steering Committee meeting with key leaders in the organization, in oncology meetings, and in our steering committee multidisciplinary meetings.

AR: Team communicates internally and with referring sources as well as with the state's program by way of fax and EMR flags.

CF: Personnel communicate primarily through EMR messaging but also through secure texting and email. In addition to our quarterly steering committee meetings, the program director and program navigator meet weekly or biweekly to review any problematic issues. All positive scans are also reviewed monthly at our tumor board.

7. Are there models for LCS in rural areas with limited access to specialists experienced in lung cancer and LCS?

MD: Very few LCS programs have included rural areas. To be most successful, LCS should be multidisciplinary and many areas may lack some of the key specialists such as pulmonary, thoracic surgery, and radiologists with experience in screening and thoracic imaging. Some programs have approached this by having a local nurse coordinator and imaging, filling the gaps by developing a specialized network of providers with regular teleconferencing with ability to review images together.



This network can support the rural program through telemedicine visits with patients traveling to tertiary centers when needed for procedures and other highly specialized care. The principles of LCS remain the same: careful patient selection using accepted criteria, low-dose CT imaging, structured interpretation and reporting, and multidisciplinary management of pulmonary nodules and suspected cancers.

8. Does your LCS program have a research committee?

AM/CL/RSW/KS/CCT: Yes, it consists of all colleagues interested in program research initiatives. The research committee meets monthly and works to manage, coordinate, and assist one another with research activities relative to program and program database. The committee also updates stakeholders on research activities and identifies opportunities for future LCS progress. The research group serves to assist with prioritizing research within the institution and partnering with other institutions in collaboration. It also assists with reducing redundancy in project endeavors among a wide group of interests.

CCT/KK: Yes, the program director leads a research and quality improvement team that evaluates priority questions and conducts projects along with residents interested in QI or lung cancer. The project consists of process, access, outcome, and surveillance questions important in LCS and care and meets 2-4 times per month.

AR: Yes. Some of this is done in conjunction with the University of Delaware, especially around smoking cessation. There are also projects from our Value Institute looking into methods and effectiveness of SDM visits among PCPs.

CF: As a program based in a community setting, not affiliated with an academic institution, we do not have a research committee at this time, although we would be open to developing one if the resources become available. In addition, we are collecting data that we would be happy to share.



3C. Forming a Radiology Working Group, Radiologist Credentialing and Training

The Lung-RADS™ system is not consistently taught in radiology residency programs and requires radiologists undergo additional training to use the reporting methodology appropriately and effectively. Competent use of a standardized radiology reporting system can help keep LCS patients safe by avoiding unnecessary care escalation in the LCS population. Integrating an LCS program within the myriad activities of a radiology department requires careful coordination between clinical and administrative staff. Survey solutions to these issues can be found below.

9. If your program has a radiology working group, what are their responsibilities?

AM/CCT: The radiology working group sets the scanning protocols, ensures appropriate radiologist training, ensures program navigator, CT technologist and scheduler training, selects database, oversees day-to-day program functions and questions. The radiologist in charge handles daily questions on individual case level. The radiology working group is essential to work through our day-to-day issues, identify areas for improvement, and problem solve. At our center, the radiology working group consists of a lead radiologist, program navigators, CT scheduler lead, and radiology lead administrator.

CCT: Yes, there is a radiology working group run by the director of the radiology portion of the LCS program. This group reviews criteria for low-dose CT screening, reviews eligibility criteria following the EHR order, and tracks volume and quality metrics within radiology. The director of the LCS program within radiology also communicates key program communication and reporting standards and sits on the steering committee. She trains other radiologists in standardized Lung-RADS™ reporting. The radiology director also coordinates without outreach efforts, educational programming for providers, and collaborates with the LCS program leadership to implement structured radiology reporting through the EHR system.

CF: We started by getting agreement on a standardized report for all individuals undergoing LCS. Once consistent compliance with this was achieved, we revisited the concept of Lung-RADS™, the need for submission of data to an approved registry (tied to reimbursement) and the fact that currently only the ACR registry, which requires Lung-RADS™ is approved by CMS. With this, and assistance from radiology administration in the building of templates, compliance with standardized interpretation of LCS exam with use of Lung-RADS™ has moved forward rapidly with almost 100 percent compliance at this point.

10. Do you have a specific internal credentialing process for the radiologists reading the LCS exams? If so what is the process?

SR/BM: We have specific requirements for all radiologists interpreting LCS exams.



Each new radiologist must be board certified and have completed an online commercially available LCS training course with a simulated workstation to report over 100 actual LCS cases. Following successful completion of the course, each radiologist is trained by one of the credentialed LCS readers on the appropriate use of the dictation templates and macros to construct the report with standard language. Once credentialed each reader must interpret 150 LCS exams per year to maintain credentialing.

CAP: As of 2000 we use the I-ELCAP database, which we developed to capture background data and CT information and images. Our centralized system allows for dual reading and other training methods for radiologists and coordinators.¹⁴

KLS: At our center, all LCS examinations are read centrally at the University Medical Center by a Radiologist with specialty training in thoracic imaging. Additionally, radiologists interpreting LCS examinations undergo additional one-on-one training specific for interpretation of LCS examinations including the use of Lung-RADS™.

CCT: Our director of chest radiology is an integral partner in the LCS program. She works with us closely to ensure that radiologists meet the requirements of the ACR to read LCS studies. This includes that all reading radiologists have read or been involved in reading or supervising at least 300 chest CT exams in the prior three years. She reviews reports and is a day-to-day resources for interpretation of LCS exams.

11. What metrics do you review to assess the performance of the radiologists interpreting the exams, how often do you make that assessment, and what benchmarks should be used?

BM/SR: We review radiologist performance quarterly. Exams read by each radiologist are broken down by Lung-RADS™ result (including S positive results) and percentages are compared among all radiologists. Positive predictive value (PPV), suspicious predictive value (SPV), and cancer detection rate (CDR) are determined for each radiologist as well but require at least a three month follow-up period from the last interpreted exam to allow for adequate workup of suspicious findings. Existing benchmarks include metrics reported by the NLST and I-ELCAP research studies and limited reports from clinical LCS programs.

RSW/KS/AR: We use quarterly review by the steering committee of breakdown by Lung-RADS™ results, aggregate data. There are no benchmarks in place to-date.

DTC: A systematic review of radiology reports is reviewed by the task force. Recommendations for reporting improvement are then taken back and disseminated to faculty by the radiology director of LCS who is a member of the task force.

CCT/KK: The program systematically reviews radiology reports for report of nodules, recommendations, and follow-up by the patient. Feedback is given to the radiology director of the LCS program and the chief of radiology. A quality report is developed



by the program in conjunction with radiology and pulmonary.

CF: All reports are reviewed by an LCS program physician (pulmonologist). Any concerns with interpretation are reviewed with program director immediately, who communicates with radiology director. Concerns are also reviewed with steering committee periodically.



3D. Establishing Which Quality Metrics Will Be Followed In the Program

The effectiveness of an LCS program is dependent upon multiple factors. Similar to mammography, regular assessment that quality metrics and objectives set forth by the steering committee are met and deficiencies are addressed in a timely fashion is necessary. Examples of approaches to these issues from various institutions are found below.

Quality Metrics Care Escalation

Access	<ul style="list-style-type: none"> • Number Referred¹ • Number Qualified • Number Scanned • Number Enrolled • Number Discharged • Referral Source²
Smoking	<ul style="list-style-type: none"> • Number Current • Number Former • Number Quit¹ • Number Relapsed¹
Radiology	<ul style="list-style-type: none"> • Lung-RADS™ Category³ • S Positive³ • Coronary Calcs³ • Emphysema³
Cancer Detection Rate	<ul style="list-style-type: none"> • Stage • Histology • Presumed⁴
Non-invasive Procedures	<ul style="list-style-type: none"> • Pulmonary Consults • PET/CT
Invasive Procedures	<ul style="list-style-type: none"> • Percutaneous Biopsy • Bronch w/Biopsy • Surgery • Benign Disease⁵

1 Overall and by provider

2 How heard about program

3 Overall and by radiologist

4 PET positive, growth and multidisciplinary consensus

5 Per procedure type



12. What data are collected by your LCS program? To whom are the data reported—internally and externally?

AM: The steering committee evaluates the number of referrals by primary care provider, qualified rate, best practice advisory (BPA) activity, how patients access program, patient satisfaction surveys, time between referral and exam date, no-show rate, program discharge rate, demographic and racial inequities, smoking cessation rates, and program outreach efforts. This data is collected through dedicated LCS database, which is derived from radiology information system and electronic health record and is reported annually to the steering committee. Program navigators are responsible for collating and ensuring data entry is performed accurately. Data is reported to the steering committee, reading radiologists, and to a CMS approved registry. Navigators oversee electronic submission of data to a CMS approved registry. Cancer detection rate, qualified rate, patient enrollment, discharges, and program outreach activities are sent out weekly to steering committee and reviewed in person at steering committee meetings every other month.

CCT/KK: There are two major areas of data that are tracked by our program. Those metrics necessary for reporting to the CMS registry is one major area. The other group of metrics is those related to quality of our program and providing excellent patient care. The program tracks the number of patients referred to the program, the number of screening CTs, eligibility criteria, access times for each diagnostic and therapeutic step, number and percentage of each therapeutic area, and number of patients cared for outside of our system. We also have a prospective and retrospective surveillance program, which tracks follow-up and provides outreach to patients and providers for overdue follow-up. Data is collected by radiology, oncology, thoracic surgery, our screening program, and nodule program. We review program related metrics internally through our steering committee and through the oncology steering committee. Externally, data is reported to the ACR registry, as well as specific registries associated with oncology and radiation oncology, and thoracic surgery.

AR: Because of previous experience with ELCAP,¹⁵ we collect for Mount Sinai registry/Delaware registry and all ACR data points for Medicare and additional public health data fields for the state program.

13. What data must be collected to submit to an LCS registry?

CF/BM/SR/DTC/RSW/KS/CCT: CMS established reimbursement criteria for LCS exams. Included in those requirements is that specific data must be submitted to an approved clinical practice registry.⁹

Currently there is only one approved CMS registry which has additional data elements required/requested and requires use of Lung-RADS™.^{16,17}

**Required Elements****Exam details:**

Facility ID number, patient name, exam date

General:

Smoking status in pack years

Smoking cessation counseling

Documentation of shared decision making

Height, weight, comorbidities, cancer history

Radiologist name, ordering provider and NPI

Indication for the exam

Exam modality, manufacturer, radiation exposure

CT exam results by Lung-RADS™ category

Other abnormalities- CT exam result S modifier

Prior history of lung cancer and years since diagnosis

Follow-up within 1 year

Documentation of an exam anytime within prior 12 months and date

Follow-up diagnostic for tissue:

Tissue Diagnosis

Tissue diagnosis method

Location from which sample was obtained

Histology

Stage- Clinical or pathologic

Overall stage

T, N, M status

Period of follow-up for incidence (in months)

Additional Risk Factors:

Education level, radiation exposure, occupational exposures, history of cancers associated with a higher risk of lung cancer, lung cancer in first-degree relative, other family history of lung cancer, COPD, pulmonary fibrosis, secondhand smoke exposure.

Name of person performing data collection for the exam, submission date.



14. Who collects quality metrics for your program? What specific metrics are collected, how are they shared, and who reviews the metrics?

BM/SR: Program coordinator and patient navigator collect quality metrics. Specific metrics are reported to the steering committee every week, including number of qualified patients, number of scans performed, number of baseline scans performed, number of Lung-RADS™ 4 exams, number of patients discharged, net enrollment, and cancers diagnosed. Other metrics, such as percent breakdown of Lung-RADS™ results, PPV, and breakdown of diagnoses/staging are reported on an ad-hoc basis.

RSW/KS: LCS physician director and screening coordinator collect metrics; LCS physician director presents summary metrics to LCS multidisciplinary steering committee at quarterly meeting. Metrics: number screened/month (baseline and annual), percentage screened that did not meet eligibility criteria, breakdown of screened by Lung-RADS™ category, cancers diagnosed and their stages, and ad hoc reporting on invasive procedures and complications.

CF: Program coordinator/patient navigator collects information and enters into database. Metrics are reviewed with LCS physician director monthly and with the steering committee quarterly.

CCT/KK: Quality metrics are collected in many areas of our program. Radiology metrics are collected within radiology and include screening studies and eligibility criteria with an evaluation by radiology of those indications, quality reporting of Lung-RADS™, biopsy number, results and complications, and CMS metrics that fall under radiology; the navigator who sits in pulmonary collects all clinical evaluation data, process measures related to referral patterns and access, clinical results, therapies, and outcome; thoracic surgery collects data on thoracic surgery volume, technique, diagnosis, and complications; and oncology collects data on cancer diagnosis, stage, and clinical therapies including radiation therapy and chemotherapy, as well as outcome. Quality and outcome data is presented monthly at our oncology steering committee meeting.



3E. Understanding and Following Insurance Requirements and Mandates

The insurance landscape for LCS is complex. The Affordable Care Act mandates all private insurers must provide no co-pay coverage for all USPSTF Grade A and B recommendations, including LCS for the USPSTF defined high-risk population. Unfortunately, the CMS and USPSTF high-risk groups are slightly different, often leading to confusion when determining patient eligibility. Further complicating the matter are society recommendations which expand the high-risk group beyond the USPSTF and CMS eligibility criteria. These issues and others are addressed by the responses below.

15. What is required for reimbursement for LCS?

AM/SR: An overview of insurance requirements for Group 1 and Group 2 criteria is summarized in this table.

REQUIREMENTS FOR CT LUNG CANCER SCREENING

GROUP 1—COVERED BY INSURANCE WITH NO CO-PAY

INSURANCE	MEDICARE	MEDICAID	PRIVATE
AGE	55–77	55–77	55–80
TOBACCO HISTORY	30-PACK YEARS	30-PACK YEARS	30-PACK YEARS
SMOKING STATUS	Smoked within the Last 15 Years	Smoked within the Last 15 Years	Smoked within the Last 15 Years
SYMPTOMS OF LUNG CANCER	Asymptomatic	Asymptomatic	Asymptomatic
SHARED DECISION MAKING	REQUIRED (FACE TO FACE) BILLABLE CODE: G0296	REQUIRED (PHONE OR VISIT) BILLABLE CODE: G0296	REQUIRED (PHONE OR VISIT) NOT BILLABLE

Symptoms of Lung Cancer

Persistent cough
Worsening of chronic cough
Coughing up blood
Constant chest pain
Persistent hoarseness
Unintentional weight loss >10% of baseline weight

GROUP 2—NOT COVERED BY CMS/MEDICAID. MAY REQUIRE PRE-AUTH FROM PRIVATE INSURANCE.

INSURANCE	MEDICARE	MEDICAID	PRIVATE
AGE	N/A	N/A	≥ 50
TOBACCO HISTORY	N/A	N/A	20 PACK YEARS
One Additional Risk Factor For Lung Cancer	N/A	N/A	Yes

RISK FACTORS

Radon Gas—Documented History

Occupational Exposure—

Silica, Arsenic, Nickel, Cadmium, Beryllium, Asbestos, Chromium, Diesel fumes, Soot, Coal smoke
NOTE: Most people who have had occupational exposure are aware of what substance they were exposed to

LUNG DISEASE—

COPD, Emphysema, Pulmonary Fibrosis

HISTORY OF CANCER—

Lung, Head, Neck, Lymphoma

LUNG CANCER IN 1st DEGREE FAMILY MEMBER—

Parent, sibling, children

SCAN COSTS APPROX \$300 OUT OF POCKET AT SCCA/UW

ADDITIONAL CONSIDERATIONS FOR SCREENING

Are they willing to have surgery for curative intent?	YES	Proceed with screening
Are they healthy enough for lung resection surgery? —Poor lung function? Chronic supplemental O2?	NO	Do Not Screen
Was the patient previously screened and now falls outside of the eligibility criteria?	YES	May Continue—Case by Case Basis May Require Pre Auth From Insurance
Have they had primary lung cancer in the past?	YES	May Screen if >5 Years Since Completing Surveillance

SCAN COSTS APPROX \$300 OUT OF POCKET AT SCCA/UW

ADDITIONAL CONSIDERATIONS FOR SCREENING

Are they willing to have surgery for curative intent?	YES	Proceed with screening
Are they healthy enough for lung resection surgery? —Poor lung function? Chronic supplemental O2?	NO	Do Not Screen
Was the patient previously screened and now falls outside of the eligibility criteria?	YES	May Continue—Case by Case Basis May Require Pre Auth From Insurance
Have they had primary lung cancer in the past?	YES	May Screen if >5 Years Since Completing Surveillance

CCT: It is important to understand each of these requirements by insurance provider to ensure reimbursement. Required elements for documenting eligibility are hard coded into the LCS exam order within the EHR. These criteria are verified at the time of imaging by the radiology center using standardized forms.



GM/CCT: Specific requirements were outlined by Medicare and documented in a summary written by Carly Carlson in March 2016.¹⁸ (page 98)

Below is a practical summary of the rules for performing and billing for these screening services.

BEGIN REVISED TABLE

Codes and payment levels* for LDCT screening			
Description	Code	Professional component	Global payment
Counseling visit to discuss need for screening with LDCT	G0296	\$28.64	\$28.64
LDCT scan for LCS	G0297	\$51.56	\$254.93

**Fees used for illustration are from the national Medicare fee schedule, using the 2016 conversion factor. Medicare applies a geographic adjustment to develop actual fees paid in each area of the country.*

Summary of LDCT LCS Reimbursement Provisions in CY 2018 HOPPS Final Rule.¹⁹

16. What are the differences in criteria for screening between private insurance, Medicare and Medicaid?

GM: LCS coverage varies widely depending on the plan. The most common plans are outlined in the accompanying table including criteria for coverage, cost-sharing i.e., fees paid by the plan member as well as additional costs such as physician or facility fees. It is recommended to contact the insurer directly for coverage questions in advance of providing LCS services and obtain a pre-authorization to ensure reimbursement.

Insurance Plan:	Eligibility Criteria	Cost Sharing	Additional Costs	Additional Information
Employer-Sponsored Plan	Age 55-80 30 pack-year smoking Current smoker or quit within 15 years	No co-pay, co-insurance or deductible	*May be additional costs associated with screening (e.g., facility fees)	*If plan grandfathered under Affordable Care Act then coverage not required



Insurance Plan:	Eligibility Criteria	Cost Sharing	Additional Costs	Additional Information
Medicare	Ages 55-77 30 pack-year smoking Current smoker or quit within 15 years No signs or symptoms of lung cancer	No co-pay, co-insurance or deductible	*May be additional costs associated with screening (e.g., facility fees)	
Medicare Advantage Plan	Ages 55-77 30 pack-year smoking Current smoker or quit within 15 years No signs or symptoms of lung cancer	*May charge co-pay, coinsurance or deductible if out-of-network	No additional costs associated with screening	*May cover beyond age 77 depending on plan
State Health Insurance Marketplace Plan	Age 55-80 30 pack-year smoking Current smoker or quit within 15 years	No co-pay, co-insurance or deductible	May be additional costs associated with screening (e.g., facility fees)	
Medicaid	*Criteria varies by state	*May charge co-pay, coinsurance or deductible	*May be additional costs associated with screening (e.g., facility fees)	*Coverage varies by state (see Medicaid.gov) May be pre-determined facility or providers
Individual Private Plan	Age 55-80 30 pack-year smoking Current smoker or quit within 15 years	No co-pay, co-insurance or deductible	*May be additional costs associated with screening (e.g., facility fees)	*If plan grandfathered under Affordable Care Act then coverage not required
TRICARE	Age 55-80 30 pack-year smoking Current smoker or quit within 15 years	No co-pay, co-insurance or deductible	No additional costs associated with screening	

*Contact plan directly to verify coverage



3F. Outreach and Education of Providers

Most programs have a process of education and outreach to inform the provider community about eligibility criteria, the process for ordering an LCS study, or the referral process to the LCS program including who will subsequently manage the shared decision making discussion, CT scan, and subsequent management and follow up of exam findings.

17. How is the provider community engaged in the LCS program?

JM: Education can take many forms: grand rounds presentations, visits to offices, newsletters, web overviews and decision aids, on-hold messages, health fairs, and journal articles are examples. Education efforts should be multifaceted and repeated over time, particularly early in a program's existence. The primary care champion for the program can provide guidance about the most effective means of communication with the primary care group. Automated reminder systems can be built into many EHRs that can serve to educate the ordering provider.

AM: We began by assisting primary care through an education campaign consisting of face-to-face meetings with PowerPoint presentations to inform practitioners of the characteristics of patients who are at high-risk for lung cancer. During these visits, we provided office materials that could be used by medical assistants to identify the high-risk population as well as shared decision-making tools to assist in performing these conversations.

PM/RSW/KS/CCT: Our program focused on educating the community of providers who will refer patients for screening. Education can take many forms: grand rounds presentations, visits to offices, newsletters, web overviews and decision aids, on-hold messages, health fairs, and journal articles are examples. Education efforts should be multifaceted and repeated over time, particularly early in a program's existence. The primary care champion for the program can provide guidance about the most effective means of communication with the primary care group. Similar education and marketing efforts targeting potentially eligible patient populations should also be considered. Patient education tools in the form of pamphlets, call-lines, internet resources, and letters can be considered in conjunction with marketing experts.

CF: The screening program educates PCPs regularly regarding criteria for eligibility, components of shared decision making and smoking cessation counseling. This is done twice a year at regular group meetings which most of our PCPs attend and also plan for the program director to do site visits to individual PCP offices to provide education. We have a brochure that we provide to PCP offices for patients as well.

18. How do you address physician concerns about LCS at your site?

ABK/CCT:

- Provide information and tools to address physician concerns.
- Educate clinicians on time involved with shared decision-making discussion.



- Provide decision aid.
- Review screening results in NLST and your program.
- Provide false positive rate in your program with ACR Lung-RADS™ (12 percent at baseline decreases to 5-6 percent on additional screening rounds).³⁶
- Inform clinicians of rate of invasive intervention for benign disease.
- Review potential for over-diagnosis based on Patz study 3 percent when BAC excluded.²⁰
- Describe referring MD involvement to follow-up for incidental findings.
- Discuss radiation exposure for follow-up imaging.
- Review cost potential for follow-up tests and interventions.
- Address AAFP lack of endorsement for screening.
- Assist PCPs through EHR and office work-flow to identify high-risk population.
- Prepare primary care to conduct shared decision-making discussion.
- Review evidence of screening results across disease sites.
- Show broad society support for LCS.

CF:

- Education (as noted above under 3F), including site visits to offices to review purpose and process and answer questions.
- Examples of shared decision making tools provided, as well as links to online tools.
- Educational video. One of our PCP's made a video that patients can watch and then discuss with their provider.
- PCPs encouraged to contact program directly with any questions or concerns.
- Emphasize LCS program commitment to make sure ordering provider aware of all abnormal results that need followup even if not a positive lung cancer screen.

19. How do you promote LCS with physicians?**ABK/CCT:**

- Screening program personal visits PCP, pulmonary, cardiology, and ob/gyn practices.
- Grand rounds, noon conferences, and medical leadership presentations.
- Regular bulletins with program quality metrics and latest updates to referring physician practices.
- Emphasize additional health benefit for increased smoking cessation and reduced relapse rates for those in an LCS program.
- Having a resource or "go to" person that is readily responsive for PCP support.
- Hospital newsletter write-up.



- Provide informational materials for exam rooms and handing out, including emergency rooms, urgent care sites, radiology, PFT lab, pulmonary and cardiac rehab, inpatient rooms (see Resource Section).
- PCP representative on LCS steering committee and lung nodule team.

DKM:

- CME credited video on LCS e.g., MorningCME.com (use search term “lung cancer screening”).²¹
- Hospital-wide e-mail on pertinent topics each month including LCS.

DTC:

- Physician outreach via grand round presentations for various specialties, visits to primary care sites.
- Website and postings on our health system’s provider intranet.
- 0.5 credit CME educational video that we have distributed to care providers.

RSW/KS:

- Grand rounds presentations at BMC and affiliated community health centers.
- LCS Program website. The website includes general information, patient education materials, and a healthcare provider information page with links to background reading (e.g., original research articles, LCS guidelines), instructions for ordering LCS, local resources, and contact number for further information.
- EPIC best practice alert to remind healthcare providers when a patient is eligible for LCS, with associated instructions for how to order LCS (e.g., reminder about eligibility criteria, shared decision-making).

CF:

- Working with administration to generate a list of potentially eligible patients from our EMR that will be provided to PCP’s with emphasis on the importance of determining true eligibility and engaging in a shared decision making discussion regarding screening with appropriate patients. This list can also be used to identify patients that need smoking cessation counseling, regardless of risk for lung cancer.
- Making sure PCP’s aware of reimbursement for shared decision making and appropriate billing codes.



3G. Marketing to Healthcare Community and Patients

20. How do you raise awareness about LCS in your community?

CCT: Education is the key to marketing to the healthcare community and to patients. Educational materials which include information about the program, team members, contact information, referral and follow-up process, eligibility criteria should be developed and targeted to the provider community. These can be delivered through educational sessions and through mail, in-person delivery, and posters/emails. Patient education tools in the form of pamphlets, call-lines, internet resources, and letters can be considered in conjunction with marketing experts.

Automated reminder systems can be built into many EHRs to market the program to the provider community at the point of care. Many programs have a navigator who can visit practices and engage with providers and the community through health fairs and community events.

ABK/KK/CCT:

- Attend community events—table with pamphlets and giveaways.
- Attend health fairs for the community.
- Connect with community leaders.
- Public service announcements.
- Meet and greet with legislators.
- Newspaper ads.
- Presentation to high-risk populations (e.g., group homes).
- Facebook ads.
- Craigslist ads.
- Ads on public transit, buses, trains, subway.



Section 4: Before the Screening—Identifying Eligibility Criteria and Providing Pre-Screening Counseling

Determining who to screen may be one of the first decisions you make after deciding to start an LCS program. CMS and USPSTF upper age eligibility limits are different and will need to be considered in the eligibility process. How does your program consider those recommendations to screen individuals beyond CMS and USPSTF eligibility? Shared decision making is required by CMS. What are good ways to go about making sure patients are informed of the risks and benefits? These questions and more need to be answered up front when setting up your program and are addressed in our survey of LCS experts below.

4A. Deciding Who to Screen

4B. Establishing Systems to Offer Screening to the Right People at the Right Time—Eligibility

4C. Deciding Whether to Screen—Shared Decision-Making

4D. Scheduling the Screening Study

4A. Deciding Who to Screen

A review of recommendations based on policy statements and guidelines including summaries of these guidelines are presented in Table 1 of Section 1.

1. Are medically inoperable patients eligible for screening at your institution?

AM: The steering committee must determine if medically inoperable patients will be considered for screening. In our program, individuals with a life expectancy of greater than two years are offered LCS. In clinical practice, determining who is or is not medically fit for lobectomy or segmental resection is often debated amongst even the specialty care team and not something readily assessed by primary care; therefore most programs will encounter this scenario. It is important to have high-level program agreement on how to manage these individuals so that patients can be protected from unnecessary procedures and treatments.

PM/RSW/KS/CCT: Should medically inoperable patients be considered for screening? Would you consider SBRT for medically inoperable patients? Would you consider screening patients who are unable to tolerate a diagnostic biopsy? These are very difficult questions to provide evidence-based answers. Much of our understanding of the favorable balance of benefit to harms was provided by the results of the National Lung Screening Trial. The population enrolled in this trial was seen to be somewhat healthier, with a higher education level, and lower proportion of active smokers than the general population of eligible patients. Survival rates for those participating in the trial were much higher than population estimates for this group (95 percent vs. 89 percent five-year survival). This is largely felt to be a result of a



healthy patient bias, reflecting the characteristics of those most likely to participate in clinical trials. Exclusion criteria for the NLST were not prohibitive—treatment for cancer within the past five years (other than non-melanoma skin cancer and carcinoma in situ), a history of lung cancer, a history of removal of any portion of the lung, the requirement for home oxygen supplementation, metallic implants or devices in the chest or back, unexplained weight loss of more than 15 pounds in the past 12 months, recent hemoptysis, pneumonia treated with antibiotics in the 12 weeks prior to assessment, and a chest CT examination in the 18 months prior to assessment. With these exclusion criteria in place, 347 patients were diagnosed with stage I lung cancer during the baseline and incident screening rounds of the NLST. Of these 347, only seven (2.0 percent) were treated with radiation alone, suggesting the population was largely capable of tolerating curative intent lung resection. With the understanding that the benefit of LCS has largely been shown in a population capable of tolerating curative intent resection, it is difficult to extrapolate these findings to at-risk populations who are not well enough to tolerate resection of a screen detected early stage cancer. The at-risk group with more health issues than present in the NLST population may be at higher risk for complications from the evaluation of lung nodules and treatment of early stage cancer. Survival after curative intent treatment may be lower, as may all-cause survival. Despite these concerns, it is very difficult to determine who is too ill to benefit from screening, particularly at the time of the screening visit when testing required to make this determination may not be available. Criteria similar to those used in the NLST (above) are reasonable to apply. Some of the programs allow SBRT eligible patients to enroll despite these concerns. Those who are not well enough to even tolerate a diagnostic biopsy should be excluded from screening. Collaborative discussions with relevant specialists connected to your program (e.g., pulmonary, cardiology) about potential exclusion criteria based on comorbidities is advised. Additional research in this field is required.

DTC: It is difficult to determine who is medically inoperable without consultation from an American Board of Thoracic Surgery eligible/certified general thoracic surgeon. Many patients who might appear medically inoperable may actually be eligible for potentially curative surgery via minimally invasive approaches, sub-lobar resection, or resection of upper lobe tumors in the setting of heterogeneous upper zone predominant emphysema. In addition, patients who are truly high-risk for surgery may have potential for cure after treatment with stereotactic body radiotherapy (SBRT). Patients who are marginal performance status but found to have a worrisome Lung-RADS™ score after CT screening are discussed in our multidisciplinary tumor board.

CCT: Yes, any patient who could be eligible for any therapy would be offered screening. Some patients will reveal “up front” that they would not pursue therapy but wish to know if they could have a lung cancer. Often, once they are diagnosed with a lung cancer and meet with specialists involved with treating lung cancer, they



do decide to proceed with therapy. Many patients don't have the understanding of modern therapy for cancer or that we don't give chemotherapy for stage 1 lung cancer. These misconceptions can impact their initial response to screening and should be considered in the shared decision-making visit along with the medical comorbidities that would preclude screening.

AR: We try to avoid this by trying to increase education among referring sources.

CF: We follow same philosophy as above (CCT). I would also add that some patients who do not wish to pursue treatment still want to be screened because they feel the information provided has value to them. Additionally, as noted above and depending on the results, someone who initially does not want treatment might change their mind after the cancer is diagnosed and treatment options are discussed. Given multiple non-surgical options for treatment of cancer, individuals are not denied screening based on medically inoperability.

2. Can patients with prior malignancy be enrolled for screening in your program?

EMH/CCT: Yes, if their ordering provider believes their prior malignancy won't limit their lifespan such that screening becomes meaningless for that individual. Patients with metastatic disease are, however, excluded from screening.

BM/SR: We consider known metastatic disease and lung cancer diagnosis within the preceding five years exclusion criteria for our program. Patients with known or prior malignancies not meeting these exclusion criteria can be enrolled. In fact, a history of smoking-related cancer(s) is considered an additional risk factor in NCCN Group 2 high-risk patients.

CF: We evaluate on a case-by-case basis but agree a program should have a set policy. We use a five-year disease-free cutoff.

GM: It is important to have a baseline definition of screening and surveillance for your prior lung cancer patients.

DTC: As part of the ordering clinician education process, ordering providers are advised that patients who have had prior malignancy within five years and would benefit from cancer survivorship surveillance of previous malignancy with a diagnostic scan that will cover the chest, should not undergo LCS with low-dose CT scan.

AR: Patients need to be five-year disease-free, except for basal cell skin cancer.

3. Will you enroll a new patient in your screening program and complete a screening CT if they have recently had a diagnostic CT?

EMH: If the patient had a chest CT within the last 12 months, the answer is no. We would take the opportunity to direct them to return for initial screening 12 months after the prior chest CT (as appropriate), or into the correct short-term follow-up or



further diagnostic evaluation (as needed), based on that CT exam result.

BM/SR/CF/DTC: Among other reasons, a patient is considered symptomatic if (s) he is currently being followed for lung nodules. If the recent CT shows new nodules or recommends follow-up of the nodules, the patient would need to wait until that follow-up is resolved before entering a screening program. If the recent CT shows resolution/stability, the patient can be enrolled and his/her baseline screening exam should be one year from the recent CT.

CCT: If the patient has had a diagnostic CT within the past 12 months that would essentially count as a baseline study and you would delay starting a low-dose CT screening study for 12 months.

AR: Yes, but after 12 months.

CF: We will enroll with first LCT 12 months after diagnostic CT if no other indication for follow up diagnostic CT identified on current diagnostic CT. We re-confirm eligibility for LDCT at 12 months, prior to scheduling.

4. What do you do if a patient enrolled in your program becomes symptomatic with respiratory symptoms and is due for screening?

BM/SR/DTC/CCT/CF: Patients who become symptomatic should undergo a diagnostic evaluation and have any upcoming screening exam delayed until resolution of the symptoms. If any interval CTs are done as part of the work up for those symptoms, these should be considered when determining when the next screening exam should be. They should not be discharged from the program unless diagnosed with lung cancer (or something else makes them ineligible).



4B. Establishing Systems to Offer Screening to the Right People at the Right Time—Eligibility

5. How does your program identify patients who may be eligible for LCS?

PM/RSW/KS/CCT: Strategies should be developed to identify patients who meet the program's screening criteria. The most important strategy is education of the community of providers who will refer patients for screening, as indicated in Section 3G. The primary care champion for the program can provide guidance about the most effective means of communication with the primary care group. Similar education and marketing efforts targeting potentially eligible patient populations should also be considered. Patient education tools in the form of pamphlets, call-lines, internet resources, and letters can be considered in conjunction with marketing experts.

The EHR can be useful in creating best practice advisories for appropriate patients for LCS. In our EHR, we have created a best practice advisory (BPA), a pop-up alert for patients meeting criteria, and embedded the appropriate order for an LCS exam in the order window. Alternatively, if a provider orders an LCS exam on their own, criteria for inclusion can be funneled into a hard stop, as well as smoking cessation and shared decision-making criteria answered prior to the system allowing the order. EHRs could also provide the means for a program to mine patient data with the goal of identifying potentially eligible patients. The quality of the smoking history within the EHR impacts the success of these approaches. Order sets can be built to include reminders about the accepted screening criteria within them.

AM: High-risk individuals can be identified through primary care offices. We began educating primary care providers through a campaign consisting of face-to-face meetings with PowerPoint presentations describing the characteristics of patients who are at high-risk for lung cancer. During these visits, we provided office materials that could be used by medical assistants to identify the high-risk population as well as shared decision-making tools to assist in performing these conversations. High-risk patients are now identified through an EHR best practice alert.

! Your patient qualifies for a lung cancer screen and has not had one in the past year. Please place your order below.

Acknowledge reason:

☐ Add to unsigned orders: CT Lung Screening Request - Burlington/Peabody Only

☐ Add to unsigned orders: CT Low Dose Lung Screening WO Contrast-Addison Gilbert/Danvers Only



CF: The screening program regularly educates all our providers, with a special emphasis on PCPs, regarding criteria for eligibility, components of shared decision making and smoking cessation counseling. We primarily rely on our PCPs and pulmonary providers to identify eligible patients, perform shared decision-making and enroll appropriate patients in the screening program. Administration assists PCPs with identifying potentially eligible patients in their practice with whom screening should be addressed by pulling smoking history data from our EHR. The screening program confirms eligibility before the CT is scheduled.

CCT: Education and inclusion of LCS for eligible patients are keys to finding and enrolling patients. After forming our multi-disciplinary team, we developed educational packets for primary care providers. These were hand delivered to every office and the team nurse navigator provides in-person outreach to primary care practices. Our team presented at medical staff meetings, through primary care meetings, in medical grand rounds, and through our nurse navigator visiting offices. Outreach to the community with pocket cards in key locations through the facility and visits by our navigator to leadership meetings, health fairs, and community organizations were other methods. We worked with our EHR analysts to develop a best practice advisory that would be included in the key area for health care maintenance and pop up when a patient was eligible for screening. Inclusion criteria are included in this resource as is shared decision-making information.

6. In your program, how do you reach out to eligible patients?

ABK/KK/DKM/CCT:

- Identify eligible patients via electronic medical record.
 - EHR best practice advisory alert to physician that patient may be eligible for screening. These can be included in the area of health maintenance frequented by primary care providers as well as pop ups for patients meeting criteria via structured data fields by age and smoking history.
 - Note to physician in patient's chart to address at next visit.
- Send letter or email to patient with information on LCS from physician office.
- Reach out to community programs and those populations at high-risk for lung cancer.
- Administer tobacco use survey by intake office to identify patients who might qualify for screening or tobacco cessation counseling.
- Provide information on LCS to patients in PFT labs, emergency rooms, radiology, urgent care, pulmonary, cardiology, pulmonary rehab, and primary care offices.

KS:

- Schedule SDM counseling visit and screening CT appointment for same day to enhance adherence.



- Hospital emergency room smoking history collection trigger a discussion of LCS for eligible patients.
- Include discussion about LCS during hospital in-patient smoking cessation counseling.

KK/DKM/CCT:

- Provide a fact sheet of eligibility criteria for physicians and patients for use at point of care (either print or electronic medium)—include a range of costs for screening (Figure, [page 103](#)).

CF:

- Educating PCP about at risk population and the need to discuss lung cancer screening with appropriate patients.
- LCS program brochures.

7. Does your program confirm that patients meet your eligibility criteria for screening? If so, how?

AM: Yes, we rely on primary care providers to identify eligible patients during their office visit, but our CT schedulers also speak with the patients to verify their high-risk criteria. Demographic data is entered into a data tracking system by the program navigators. Navigators call patients prior to the exam to determine if they remain asymptomatic and answer questions prior to screening.

GM: We have a centralized program. Patients are referred for LCS to the program only in order to meet compliance for eligibility criteria, shared decision making, follow-up, and to communicate results.

KLS: Referring providers should be aware of the USPSTF guidelines and only order/refer patients who meet criteria. We include the criteria in the electronic health record (EHR) CT order set that is visible to clinicians while ordering the LCS CT. LCS program or radiology staff members then validate the criteria on the day of the shared decision-making visit and CT scan. The shared decision-making discussion and the CT scan order are done in the same visit.

MKG: Kaiser Permanente Southern California uses a standardized order set for an LCS CT that includes mandatory yes/no questions to document that the patient meets eligibility criteria for age, smoking history and is asymptomatic.

CF: All LCS CTs are scheduled through the LCS program. The LCS program navigator confirms eligibility before the CT is scheduled.

CCT: A best practice advisory prompts the ordering provider based on eligibility criteria as documented in the EHR. To order an LCS CT, there are mandatory yes/no questions that must be answered regarding shared decision making and smoking cessation counseling. Any provider can order an LCS study; thus, this is a decentralized access program. However, centrally, a radiology technician screens all orders for eligibility and will cancel orders that do not meet criteria or change the



order to a diagnostic CT after conferring with the ordering provider. This mechanism assists with ensuring that only eligible patients are being screened and that insurance will reimburse the study.

8. When a patient does not meet eligibility criteria but has an order and will pay out of pocket, what do you do?

AM: This situation is rarely encountered when an educated and engaged primary care base is involved with your program. If individuals outside the program's defined high-risk criteria are insistent on a CT screen, they must pay out-of-pocket for service and are not tracked or entered into the LCS program.

CCT: This is rare, but when it does occur the results are tracked in our program.

AR: The scan is done as a screen with lower cost but is not part of the program. Follow up is dependent on the PCP and patient.

CAP: We are currently screening participants who are covered by Medicare/Medicaid and those who meet the expanded criteria. For those not meeting the Medicare/Medicaid requirements, a low-dose screening CT scan is offered at \$150.



4C. Deciding Whether to Screen—Shared Decision-Making (SDM)

9. Do you coordinate the shared decision-making visit and LCS exam?

AM: Primary care provides SDM and smoking cessation interventions during annual office visits using decisions aids supplied by the LCS program. This is the customary time for prevention interventions to be discussed.

KS: SDM and smoking cessation counseling are both performed by the radiology nurse practitioner immediately prior to the LCS CT unless previously documented by the requesting provider. Our order set defaults to a request that includes the SDM visit and LCS CT scan; however, clinicians may choose to only order the CT exam if they would prefer to perform the SDM visit themselves.

DTC: Built into our electronic health record order is a hard stop attestation requirement for SDM. The ordering physician has to select that they performed SDM before they can complete the order. The order also has a link to a PDF of our program's SDM tool kit that can be printed out and assist with SDM during the point of care.

CL: In the pulmonary clinic the SDM visit is often synchronized with the placement of the order for the next LCS scan. For example, the patient presents to the clinic to review the actual screening CT scan and then SDM is ongoing to determine continuation for next screening scan with an order placed at that time.

CCT: In every office a best practice advisory will notify the provider of their patient's eligibility for LCS. The EHR will pop up with structured fields regarding shared decision-making and smoking cessation counseling prior to an order for LCS CT order being accepted. In the nodule program, appointments with patients are paired with review of the CT finding such that shared decision-making and smoking cessation counseling occur prior to ordering the next study.

10. What are the barriers to shared decision making from a physician perspective?

ABK/RSW/KS/CCT: We heard from our physicians that time, lack of training, and lack of organization support and appropriate decision aids were barriers to SDM as we were developing our program. AHRQ identified common themes on barriers to shared decision making for providers:²²

- Time
- Already do it
- Not applicable—patients don't want it
- Lack of organizational support
- Lack of decision aids



11. What are the perceived barriers to shared decision making from a patient perspective? And, what barriers may be specific to minority populations?

ABK: We have found fear of lung cancer death and stigma to be significant barriers to SDM for patients. AHRQ literature review identified common themes on barriers to shared decision making for patients to include the following:²²

- Not aware of option for shared decision making
- Health literacy
- Cultural Issues
- Demographic or geographic issues
- Rural
- Advanced age
- Language

Patients need knowledge AND power.²³ Knowledge about:

- Disease conditions and outcomes
- Options
- Personal values and preferences
- Power
- Perceived influence on decision making encounter, e.g., be invited to participate
- Confidence in own knowledge
- Self-efficacy in using shared decision-making skills

African Americans face additional challenges:

- Healthcare provider implicit bias²⁴
- Double stigma—smoking and race
- Racial differences trust and perceptions physician communication²⁵
- Lack of consideration of racial differences in design and validation of decision aids
- Higher lung cancer mortality in African American males (1.2X White males)
- Higher risk lung cancer despite not meeting LCS criteria
- Lower health literacy



EJ: The National Lung Screening Trial (NLST) found a significant reduction in mortality among high-risk patients screened annually LDCT. A sub-group analysis of this trial by Tanner et al. showed that while patients in the screening arm experienced lower all-cause and lung-cancer associated mortality, this effect was even larger in African American participants.²⁶ However, the availability of LCS among minority and socioeconomically disadvantaged populations is limited. National medical associations have called for the implementation of LCS services in minority communities; however, the realization of these programs has been challenging. We have identified four barriers to LCS in underserved minority populations along with strategies to overcome these obstacles. The following recommendations can be used for any racial/ethnic group, African Americans are highlighted as this is the population that our clinic treats.

A. Access to screening: The disparity in lung cancer morbidity and mortality with in the African American community is well described.^{27,28} LCS has the potential to worsen this disparity if African Americans are not screened at the same rates as other high-risk groups. One of the major obstacles to successful LCS for minority patients is lack of access. The Ohio State University has two full service screening locations, one of which is located in an area that densely populated with minority patients as well as the medically underserved of all races. This location not only provides access to LCS services but also serves as an access point to other medical services for underserved populations.

- Develop access points for screening underserved patient.
- Screening within rural communities is also challenging. The future use of mobile lung CT units have been used in some areas and can provide cancer screening to rural communities, eliminating the transportation, financial, and resource barriers.

B. Patient and Provider identification: African-American patients are less likely to be screened for lung cancer compared with non-African American patients.²⁹ Many patients and providers are not aware of current LCS eligibility guidelines.

- Educational outreach to primary care providers (PCP) with a goal of assessing baseline understanding of LCS.
- Explain LCS rationale, guidelines and provide PCP offices with printed materials.
- In centralized programs ensure that PCPs know that the LCS program will follow positive screens.
- Identification of high-traffic locations: grocery stores, churches, barbershops, and beauty salons.
- Develop local relationships and provide information to organizations that empower minority communities such as the NAACP and National Urban League.

C. Relationship with health professionals: An effective strategy to enhance minority patient's participation in LCS is matching patients and healthcare provider's ethnic and cultural backgrounds. Minority providers are more



successful in engaging minority patients and building lasting relationships, while fostering a therapeutic alliance between patients and providers.³⁰

- Recruit African-American physicians, nurses and medical assistants.
- Invest in the patient's overall health.
- Openly discuss mistrust of traditional medicine, fear of cancer and fatalism regarding cancer.
- Clearly explain how early detection and smoking cessation can save lives.
- Use personal testimonies from minority patients who were screened and have survived lung cancer.

D. Community engagement: Community engaged programming may be more acceptable to communities that are historically distrustful of researchers or academic institutions.

- Recruit lay health educators from the community.
- Develop local relationships and provide information to organizations that empower minority communities such as the NAACP and National Urban League.
- Face-to-face patient education events give patients an opportunity to ask questions, meet with LCS staff and build relationships with care providers.
- CCT: In our program the nurse navigator provides outreach to a number of community programs and health fairs.

12. What does CMS require for shared decision making for LCS and what decision aide tools are available to assist with this?⁹

CCT: CMS specifically outlines the requirements for shared decision-making visit and the elements within that discussion that meet the definition.

CF: Must include all of the following elements:

- Determination of beneficiary eligibility including age, absence of signs or symptoms of lung cancer, a specific calculation of cigarette smoking pack-years; and if a former smoker, the number of years since quitting.
- Shared decision-making, including the use of one or more decision aids, to include benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure.
- Counseling on the importance of adherence to annual lung cancer LDCT screening, impact of co-morbidities, and ability or willingness to undergo diagnosis and treatment.
- Counseling on the importance of maintaining cigarette smoking abstinence if former smoker; or the importance of smoking cessation if current smoker and, if appropriate, furnishing of information about tobacco cessation interventions
- If appropriate, the furnishing of a written order for lung cancer screening with LDCT.



ABK: There are several LCS risk calculators that can assist in shared decision making including key features, strengths and weaknesses and links to the calculator. The validity of these tools is unclear at this time and they should be used as a guide and not an absolute.

- Counseling on the importance of adherence to annual LCS, impact of comorbidities and ability or willingness to undergo diagnosis and treatment.

Specific information related to NLST findings³¹:

- A 20 percent reduction in lung cancer mortality with LCS in eligible patients following three rounds of LCS CT with 6.5 years of follow-up.
- There was a 6.7 percent reduction of all-cause mortality.

The harms include:

- Less than 1.5 mSv radiation exposure.
- 26.6 percent false positive rate baseline scan—reduced to 12.8 percent in a retrospective analysis with ACR Lung-RADS™.³²
- Less than 0.5 percent intervention for benign disease.
- Estimated 3 percent over-diagnosis once the 15 percent incidence of carcinoma in situ (bronchioloalveolar cell carcinoma) is removed.²⁰

13. How do you document the shared decision-making visit?

ABK: Primary care SDM visits include elements required for Medicare/Medicaid reimbursement as indicated above. Written orders for both initial and subsequent LCSs include the following information, which must also be appropriately documented in the beneficiary's medical records for CMS reimbursement:

- Beneficiary date of birth.
- Actual pack—year smoking history (number).
- Current smoking status, and for former smokers, the number of years since quitting smoking.
- Statement that the beneficiary is asymptomatic (no signs or symptoms of lung cancer).
- National Provider Identifier (NPI) of the ordering practitioner.

ABK/CCT: These can be documented in EMR as part of the order for the scan, as indicated in the screen shot (Figure, page 98). These can be “hard coded” into the EMR and required to order the LCS study.

KK/DKM/CCT:

- Document on patient chart in EMR using “Smart Text” template.
- EHR pop up documents this in a structured field when attempting to order an LCS exam.
- Document in LCS database.
- Paper template filled out and scanned into patient chart (Figure, page 99).

**CF:**

- To order LDCT for lung cancer screening, ordering provider must attest to shared decision being done and documented.
- Requirement for actual documentation not clear. Some of our PCP's document the shared decision making discussion in detail, some just document that it was done. They are encouraged to reference the shared decision making tool used especially if they do not go into detail in their note as to what was discussed.

14. Who does the shared decision-making discussion in your program?

ABK: Primary care physician or a pulmonologist most commonly conducts the SDM in our program.

KS: Primary care physician's office, advanced practice registered nurse (APRN) or other qualified healthcare professional, qualified healthcare professional at the screening site, or dual SDM-provider first followed by second discussion with a screening coordinator. The center can bill both visits if done on separate days.

DTC: Shared decision-making occurs through two possible pathways: 1) conducted by primary care providers with material and educational support provided by the central program staff and 2) conducted by a dedicated LCS central program APRN. Built into our electronic health record order there is a hard stop attestation requirement for shared decision making. The ordering physician has to select that they performed SDM before they can complete the order. The order also has a link to a PDF of our program's SDM tool kit that can be printed out and assist with SDM during the point of care.

CCT/KK/RSW/KS: In our center, any physician can order an LCS exam and he or she must conduct the SDM visit prior to ordering this. A best practice advisory will alert the provider to the possibility that their patient may meet criteria for LCS. An LCS exam can't be ordered without documentation of the SDM visit and smoking cessation counseling.

Section 4

Before the Screening—Identifying Eligibility Criteria and Providing Pre-Screening Counseling



CT Lung Screening Low Dose

Expected-3/6/2018, Expires-3/6/2019, Routine, Ancillary Performed

Status: Expected: Expires:

Priority:

Class:

Reason for Exam:

Reason for Exam (Free Text):

☐ Have you engaged the patient in shared decision making?

☐ Smoking cessation counseling performed?

☐ Does the patient show any signs or symptoms of lung cancer?

☐ Is there documentation of shared decision making?

☐ Is this a low dose CT or a routine CT?

15. How do you ensure reimbursement for the counseling and shared decision making visit at your site?

ABK/CCT: The shared decision-making visit has a separate Healthcare Common Procedure Coding System (HCPCS) billing code that can be generated in the face-to-face visit and is distinct from the CT scan, which is billed through radiology.^{33,34} The two codes are listed below. At least 11 elapsed months must pass between screenings (billing for G0297). Medicare coinsurance and Part B deductible are waived for this service.^{33,34}

- G0296 – LDCT-LCS Shared Decision-making session.
 - Counseling visit to discuss need for lung cancer screening (LDCT) using low-dose CT scan (service is for eligibility determination and shared decision making).
 - APC 582.
- G0297 – Low-dose CT (LDCT) scan for lung cancer screening.
 - APC 552.

Services must be billed with ICD-10 diagnosis codes:

- Z87.891 for former smokers (personal history of nicotine dependence).
- F17.2 for current smokers (nicotine dependence).

**16. What can a PCP say about screening if they have <5 minutes for the discussion?**

ABK: Have the patient review a decision aid before physician visit:

- iPad in office.
- Brochure in office or sent to home.
- Letter or email with link to online decision aid.

DM: Key elements for a five-minute discussion between provider and patient regarding LCS (Figure, [page 106](#)).

CF:

- Review shared decision making tool prior to appointment.
- View a video made by one of our PCPs. Others are available online.



4D. Scheduling the Screening Study

17. Who orders and/or schedules your LCS exams?

CCT: Any provider can order and schedule an LCS study. They are ordered and scheduled in a decentralized manner. The EHR includes a best practice advisory which triggers consideration of an LCS study based on age and smoking history. Once an exam is ordered, the eligibility criteria are then assessed by radiology in a centralized way. If the criteria are not met, the radiologist will query the ordering provider and either cancel the study or change it to a diagnostic CT where appropriate. Each office has a different workflow for scheduling the study with radiology. In most offices administrative staff or medical assistants obtain prior authorization for the exam where necessary and schedule the study following approval.

EMH: We started off having orders for LCS routed through central scheduling and switched to an EHR-based distributed model. The distributed EHR model is only as good as the vendor and IT implementation team allow it to be, however, and we are progressing back towards a centralized model. In our system, a central scheduling model seems to offer us the best chance of order success. I anticipate this will change again when we complete a system wide EHR migration project in the near future.

SR/BM: All LCS exams are scheduled by one of our two program coordinators. LCS exams are not scheduled through central scheduling due to potential pre-authorization requirements.

CF: In general, primary care physicians and pulmonologists enroll patients into the screening program. All orders for LCS studies are processed through our LCS program coordinator and vetted for appropriateness. To the extent that our EHR is able, patients who may qualify for LCS are identified and their provider is notified. The LCS study is ordered through the EHR as “lung cancer screening CT.” We originally had the order as “Low dose CT for lung cancer screening” and physicians would use the order for non-eligible patients because they liked the idea of low-dose. In addition, when ordered, a box comes up where the ordering provider has to check boxes to confirm eligibility criteria, confirm that they have performed and documented shared decision making, and confirm that they are enrolling the patient in the LCS program. The order is transmitted to radiology and the LCS program. The LCS program navigator confirms insurance coverage details, contacts the patient, confirms their understanding of out of pocket costs, and schedules the CT.

KS: The Vanderbilt University Medical Center referring providers may order the LCS study as they order other imaging tests and patients are then scheduled by the imaging center. We only perform these studies at our outpatient imaging facilities, which allow us greater control of scheduling (do not have to involve the main hospital ordering system). The imaging center schedules a consult appointment



with the radiology nurse practitioner immediately prior to the LCS appointment. This allows the nurse practitioner to confirm eligibility criteria and perform a shared decision-making visit if necessary.

CL: Program navigators, after reviewing for initial and continuing eligibility, will send an EMR in-basket message to the healthcare provider with a reminder of the patient's eligibility, so that timely orders can be activated by the provider. It would be equally important to provide ordering providers prompts or reminders when patient eligibility has ended, so that imaging beyond the guidelines does not occur.

CCT: Any office can schedule an LCS study once an order has been placed. Radiology will then review the eligibility criteria to ensure that the patient is eligible. Reporting requirements are maintained through the EHR within the ordering fields with mandated questions regarding shared decision making and smoking cessation counseling.

RSW/KS: Our program is a hybrid. There is the option of either decentralized referral (PCP conducts SDM and places LCS order) and ordering of the study or centralized referral (PCP refers patient to an LCS / Pulmonary Nodule clinic for SDM visit and decision whether to proceed with screening; if yes, the sub-specialty clinic provider places LCS order).

MKG: LCS studies are ordered by primary care providers and pulmonologists using a standardized order set in the electronic health record. Providers are required to check boxes to confirm that the patient is asymptomatic, meets eligibility criteria, has undergone shared decision making, and has been referred for tobacco cessation treatment (TST), if a current smoker.

JM: LCS studies are ordered through a trigger in the patient's electronic medical record (EMR) which triggers a clinical reminder for their physician to order a CT chest screening. The clinical reminder is based on patient's age and smoking history. If a physician chooses to order a CT chest screening, they then perform a shared decision-making session with the patient to discuss the risks and benefits of CT chest screenings. Once the exam is ordered, the patient can call radiology to schedule their exam.

CGS: The VA Portland Health Care System is a centralized program where SDM and orders are performed by dedicated LCS program personnel.

PM: Any clinician in our health system can place an order for a consult to our LCS program. Our program administrator screens the order for patient eligibility. If the patient is eligible an order for the SDM visit and coordinated CT scan is placed, then signed by our program navigators.

18. How do you ensure the correct initial LCS exam is ordered?

SR/BM: We created an LCS request order that has no CPT code attached (and therefore cannot be scheduled/billed) that we ask physicians to place when they are



ordering a screening exam. This request also falls onto a work queue and is changed to the correct order by a program coordinator based on the patient's most recent exam.

GM: We have an order that requires the completion of criteria eligibility questions. It then goes to a work queue for review by our NP who places the actual order.

CCT: Any LCS order can only be placed in the EHR after the provider completes questions related to symptoms, shared decision making, and smoking cessation counseling for eligible patients. These are sent to radiology and screened to make certain the patient meets criteria prior to the study being performed. In the ordering process the baseline vs. follow-up examination are options and this is verified centrally in radiology. The order is changed where necessary.

EMH: No system is perfect in this respect. We use a mix of distributed and central ordering with downstream checks to try to maximize adherence to recommended screening criteria. A robust IT implementation including hard stops for adherence to individual criteria is very helpful in this respect.

19. Do you pre-screen patients for insurance coverage prior to scheduling?

SR/BM: Yes. Non-CMS patients will also require pre-authorization.

CF: Yes, in particular some patients with private insurers have a large co-pay as some plans are grandfathered and are not obligated to fully cover LCS despite its Grade B recommendation. We try to identify the patient cost and share this with them prior to the scan being scheduled.

CCT: Yes, all patients will have an insurance pre-authorization where needed and any large co-pay or denial of coverage would be relayed to the physician and the patient prior to scheduling the exam.

20. How do you ensure the correct order is placed for follow up exams (to indicate it is an LCS follow-up) rather than a diagnostic chest CT when the next annual LCS is ordered?

EMH: An annual lung cancer screen should not be considered a “follow up” exam. Annual rescreening is the expected result for most patients undergoing LCS. Our EHR currently makes no distinction between first and subsequent lung cancer screens; annual exams are simply ordered as LCS. For short-term follow-up chest CT exams (three-month or six-month, as directed by Lung-RADS™ category), the exam is typically ordered as a non-contrast chest CT at the appropriate interval. In the exam protocoling stage the technical parameters for the exam are prescribed to be concordant with best practices for LCS and nodule follow-up.

CCT: In terms of follow-up examinations, ensuring LCS exam vs. other forms of CT scanning is challenging. Radiology reports should indicate which form of examination is appropriate for follow-up based on the initial findings. If there are no findings, the



patient is returned to annual LCS exam. In our EHR, the orders specify initial low-dose screening or follow-up low-dose screening. All screening orders are reviewed for appropriate study classification in radiology prior to the exam being completed and changed if necessary.

SR/BM: We have a separate section of our database to help catch incorrectly ordered exams before the patient arrives so we can fix them if necessary. We have an alert board that, among other things, informs us of patients in the screening program who have a regular (not screening-related) chest CT scheduled within the next two weeks. If this CT was incorrectly ordered and should be either a screening exam or a follow up to a screening exam, we can make the change at that time so the exam will be tracked appropriately.

CF: All LSC exam reports are transmitted to LCS program in addition to the ordering provider. The LCS program physician reviews all reports and confirms appropriate follow-up (annual or otherwise) with respect to lung with the program navigator. The program navigator enters an alert into the EHR to be trigger a few weeks prior to scan due date. Eligibility for the LCS exam is reconfirmed prior to the follow-ups being ordered.

21. What steps do you take in your program prior to an annual LCS exam to ensure the patient is asymptomatic?

BM/SR: Prior to a patient's annual screening exam, our database searches the patient's record for any chest imaging (CTs or chest chest radiographs) the patient has had in the 12 weeks leading up to the screening exam. Often times chest imaging is ordered due to upper respiratory symptoms so this can cue us in if the patient is symptomatic. Further, patients receive a reminder phone call two days prior to their appointment where they are reminded that they should reschedule the exam if they have new or worse cough or shortness of breath, unintentional weight loss, or are coughing up blood.

RSW/KS: Defer to PCP (or other ordering provider) to ensure patient remains an appropriate candidate for screening.

CF: LCS program coordinates annual follow-up. Patients receive reminder letter and are called by LCS program navigator to confirm appointment. Patients are screened for symptoms by navigator using symptom screen form at time of call. Any symptoms are reviewed with LCS program doctor prior to scheduling scan.

GM: We have a script that is given to the program coordinator. She performs a basic screen at the time of the appointment reminder call.

DTC/CCT: As a part of the electronic health record order, there is a built-in hard stop attestation that the patient does not have symptoms. If that hard stop attestation is not completed, the order cannot move forward. Additionally, patients are queried at the time of their screening study as to any respiratory symptoms. If the patient is



symptomatic, the ordering provider will be notified and the study may be changed to a diagnostic rather than screening CT; the study may alternatively be deferred if the symptoms are believed to be due to a URI, etc.



Section 5: During the CT: Reporting

5A. Screening Process—Standardizing LCS

5B. Structured Reporting

5C. Incidental Findings

5D. Communication of Results to Patients and Providers

5A. Screening Process—Standardizing LCS

1. How do you dose modulate for patients of different size in your program?

SR/BM: We use a fixed milliamperage (mA) for all LCS exams. For very large patients we increase the mA by 10 and for small patients we decrease the mA by 10. This decision is at the discretion of the technologist performing the exam.

EMH: We screen at multiple sites using a variety of CT equipment. We use both fixed mA and variable mA approaches to minimize patient dose, depending on the site and equipment used. The most important thing is that all sites adhere to the dose limitations required by CMS, optimizing for individual patient size as needed.

2. How do you identify/track orders for LCS patients in your EHR?

KK/CCT: Many programs utilize radiology databases for tracking orders and results. Transferring data into other management systems for surveillance is also a method to ensure tracking orders and completion of orders. Manual review of the database is often required to ensure this occurs. EHR systems can be programmed to create critical results for lung nodules that are sent to the ordering provider and the multidisciplinary team managing lung nodules at the institution. In our program we have a critical result reporting function, a notification to the nodule program, and a movement of these patients into a registry for management by the team. If a patient does not show for a follow-up or an order is not completed, the navigator can follow-up to ensure its completion or the reason why it was not followed if not clinically indicated. The team manages the removal of patients from the registry when follow-up is no longer indicated or a diagnosis is made.

SR/BM/CCT: We have two order codes that are specific to LCS. One order is for the initial and annual screening exams and has the G0297 CPT code attached to it. The second is for follow-up low-dose CTs that stem from screening exams and has the 71250 CPT code attached. These exam codes fall onto a work queue in our EHR to be reviewed, pre-authorized, and scheduled; they also migrate into our LCS patient database.

MG: Screening exams are tracked in the Radiology Information System by using unique exam codes.



5B. Structured Reporting

3. How are the results of the LCS exam reported by the radiologist?

CF: Our radiologists use Lung-RADS™. There was some resistance at first due to lack of familiarity with format. This was overcome by education by the LCS program (run by pulmonary at our practice), providing a template in radiology reporting software, and current need for this format for data submission to an approved registry (required for reimbursement by CMS).

CCT/RSW/KS: Our program reports findings of all LCS studies in a structured reporting system utilizing Lung-RADS™. Results are then tracked by the navigator of the program.

EMH: LCS studies are reported in a standardized fashion using the ACR Lung-RADS™ classification system to categorize results and recommended follow up. We currently use institutionally developed tracking systems but are in the market for a commercial system to be shared among all regions.

EJ: CT scans are interpreted using Lung-RADS™ within 25 minutes to allow for same day review of the results with patients.

MKG: Most exams are interpreted by general radiologists, using a standardized template that conforms to Lung-RADS™ categories. Follow-up is arranged by the ordering provider.³⁵

4. What do you recommend for patients with suspicious findings (Lung-RADS™ 4A/B/X)?

EMH: This will be local practice specific; the radiologist should provide direction to the ordering provider though, especially if that person is an APN/PA/PCP.

SR/BM: In our program, all patients with a Lung-RADS™ 4 lesion are recommended to be seen by a pulmonologist. It is important to note that these patients remain in the screening program, as the majority of them will end up back in the screening cycle. Patients are followed until they are no longer a Lung-RADS™ 4 (i.e., either downgraded due to imaging stability or benign pathology and returned to annual screening, or found to have lung cancer), and during this time all appointments related to the abnormal finding are tracked (i.e., specialist consults, PET/CTs, percutaneous/trans bronchial/excisional biopsies, etc.).

CCT: All Lung-RADS™ 4 cases in our program are called to the ordering provider and the nodule program for referral to a pulmonologist in the program within 24 working hours. The navigator then discusses this option with the ordering provider whom either calls the patient themselves with the appointment information (the typical course of action) or asks our program to call the patient. The patient is then tracked within the program and their care navigated. If a work up is completed and the patient is no longer a Lung-RADS™ 4, they are returned to the screening population.



RSW/KS: For patients with findings suspicious for lung cancer, (Lung-RADS™ 4A, 4B, 4X), the LCS Program Coordinator notifies the referring provider directly, and the referring provider communicates these.

CF: All screened individuals with Lung-RADS 4A/B/X are seen in consultation by a pulmonologist to develop a plan for further evaluation as indicated.

5. If a patient had a Lung-RADS™ 4 exam for slowly growing part-solid nodule and a follow-up is performed three month later which shows the part-solid nodule is unchanged from the immediate prior exam, what do you assign as the Lung-RADS™ overall exam assessment?

SR/BM/CCT: Regardless of short-term stability, if a solid or part-solid nodule has documented growth in comparison to older prior exams, it is suspicious and will result in an overall exam assessment of Lung-RADS™ 4 in our program until such time that it is resolved, resected or treated. Non-solid nodules of any size will have annual surveillance recommended until development of a solid component is suspected.

EMH: The answer to this depends on whether the initial result was Lung-RADS™ 4A or 4B. If it was a 4A, the new result becomes a Lung-RADS™ 2 (by Lung-RADS™ definition) and the recommendation becomes a return to screening in 12 months. If it was initially a 4B, we would likely discuss the case at multidisciplinary conference for a consensus opinion on next action.

6. Do you ever recommend a PET-CT to follow-up a suspicious finding on an LCS exam?

SR/BM: We recommend a formal pulmonary consultation for suspicious exams and allow the pulmonologist to determine based on that consultation if a PET-CT is needed and be available to help the patient interpret the findings on the PET-CT once it is performed. Using this method, 50 percent of patients in our program with suspicious findings undergo PET-CT, more than half of which (54 percent) are eventually diagnosed with lung cancer.

CCT: All suspicious nodule findings are referred to the nodule program and the ordering provider is notified. The ordering provider can decide not to refer the patient, which is a very rare occurrence. The pulmonologist then decides whether a PET CT or other evaluation is warranted.

EMH: For some Lung-RADS™ 4 nodules, yes. It is the interpreting radiologist's discretion as to what to recommend based on their assessment of the identified nodule.

CF: As above, all patients with Lung-RADS 4A/B/X are seen by a pulmonologist with plans for further evaluation and management determined at that visit.



5C. Incidental Findings

7. How do you define a “significant incidental finding” in LCS?

SR/BM: In our program, significant incidental findings are unexpected findings which are either new or unknown and require some form of clinical or imaging investigation before the next recommended LCS study. Coronary artery calcifications and emphysema are highly prevalent, expected findings in this population and should be reported on every exam separate from this category. The rate of significant incidental findings in the NLST was 10.2 percent at baseline and 7.5 percent overall³¹ and as such could not have regularly included either coronary artery calcifications or emphysema of any level based on the prevalence of these findings in this patient population.

EMH: Significant incidental findings in NLST were left to the discretion of the radiologist, and so undoubtedly did include some degree of emphysema and coronary artery calcification (CAC), although only in select patients. This is quite a complex issue and will vary by radiologist depending on their own unique sensitivity/specificity, and their need for certainty (follow-up) on specific items. We also report all emphysema and CAC routinely (as well as aortic calcification, another predictor of downstream cardiovascular risk); however, if a 55-year-old has what looks like a 3000 CAC score, we'll make that an S and recommend noninvasive cardiovascular risk assessment (like Framingham) if it hasn't been done before. Similarly, emphysema disproportionate to age and smoking history will generally get called out for specific follow-up. We are using the ACR thyroid white paper to minimize thyroid evaluations; kidneys are the biggest problem issue we see, due to noise.

JM: At Rush the presence of moderate to severe coronary calcification is reported. The frequent finding of coronary artery calcification in the screening setting has been widely reported and discussed and findings from the NHLBI MESA studies and other sources suggest that preventative interventions such as enhanced smoking cessation efforts, diet and life style intervention, statin directed therapy should be considered. In regard to COPD, there is no uniform opinion in the radiological community as to how the findings of coronary artery calcification or emphysema, both representative of smoking-related disease, identified on LCT should be interpreted. Most commonly these are interpreted as incidental findings; alternatively these can, and some believe should, be viewed as opportunistic findings.^{36,37} The importance of the reporting of emphysema may also lead to the earlier identification, diagnosis, and treatment of COPD; for example, because COPD may be underdiagnosed in up to 80 percent of patients who meet diagnostic criteria for airway obstruction on spirometry, the reporting of emphysema on LCT may lead to an earlier investigation for COPD than otherwise sought. For example, one study demonstrated that although 31.6 percent of patients who underwent LCT screening were diagnosed with COPD, a higher percentage of patients demonstrated emphysema and bronchial wall thickening, at 50.6 percent and 39.4 percent, respectively. This earlier identification of incidental



findings may lead to an earlier diagnosis and subsequent treatment with smoking cessation and inhaled bronchodilators with or without inhaled corticosteroids. This may ultimately result in less exacerbations and hospitalizations for COPD, greatly reducing the burden to society and the healthcare system.³⁶

CF: Significant findings are defined as those that require further evaluation or treatment prior to the next scheduled screening exam.

8. How are incidental findings communicated to the provider?

CF: For scans with other significant findings (S) the PCP is contacted directly by LCS program to confirm they are aware of scan results.

CCT/RSW/BM: Incidental findings are documented in the radiology report. Concerning incidental findings that would fall into criteria for an unexpected or urgent finding are reported with a flag in the EHR and if there is a significant concern it is called personally to the ordering physician.

EMH: Incidental findings are flagged in the report. Potentially significant unexpected or urgent findings are communicated directly to the ordering provider.

PM: Incidental findings are reported in the structured radiology report. We have partnered with specialists in fields relevant to the most commonly identified incidental findings (e.g., thyroid nodules, coronary artery calcification) to develop algorithms for management of these findings. Our program navigator will follow these algorithms in guiding patient management. These results and the evaluation plan are communicated to the referring providers within the EMR or directly by phone. We have found that approximately one in seven patients require additional testing related to incidental findings, and one in eight require a specialty consult. Approximately half of the payment to the institution in the year following the initial screen has been related to management of incidental findings.



5D. Communication of Results to Patients and Providers

9. How are the results of the LCS exam communicated by the radiologist to the providers and patients?

ABM: All Lung-RADS™ 1, 2, and 3 exams and S positive exams are communicated via Lung-RADS™ and S positive category specific patient letters. Program navigators ensure appropriate letters are sent according to Lung-RADS™ category. The reading radiologist reports S positive exams to the urgent finding notification system so that the ordering physician is aware that a finding is being followed through the program.

Lung-RADS™ 4 exams are all double read by radiology. The exam result and recommendations are communicated via direct conversation between one of the reading radiologists and the ordering provider. The ordering provider is expected to contact the patient directly with next steps, which in our program is a referral to pulmonary medicine. Lung-RADS™ 4 patients are not sent a notification letter. Program navigators follow clinical activity in the patient chart for Lung-RADS™ 4 and S positive exams. All patients are called after three weeks to ensure patients are receiving appropriate clinical follow-up, answer questions, inquire about the patient experience and reinforce smoking cessation.

CCT: Lung-RADS™ 1,2 are reported through the EHR to the ordering provider and to the LCS program. A letter is sent to the patient as well. Lung-RADS™ 3 and 4 results are called to the ordering provider and the LCS program navigator for referral to the multi-disciplinary team program.

KLS: Lung-RADS™ 1 and 2 results are communicated to the patient by phone within one business day; the referring provider is notified electronically in the EHR or the results are faxed to providers at outside facilities after the patient is contacted. Reports are also immediately available to providers within the EHR and to patients within a few days on a secure online access system. For Lung-RADS™ 3 and 4 lesions, our program nurse practitioner communicates the findings to the ordering provider and asks their preference as to whether they would like to communicate the findings to the patient or if they would prefer the screening program communicate findings.

CCT: All nodules are reported through the EHR to the ordering provider or care team, the primary care provider, and the nodule program for either surveillance or intervention. If there is a concerning nodule, the radiologist also calls the ordering provider to confirm the finding is communicated and the nurse navigator of the program reaches out immediately to the ordering provider to offer a nodule program appointment within 24 working hours. In most cases, the ordering provider notifies the patient of the finding and offers the appointment in the program. In some cases, they ask that our program call the patient directly. The program tracks all diagnostic evaluations, stages, therapies, and outcomes. The patient receives a written report from radiology as well as reminders of annual LCS CT when the



surveillance period recommends this.

EMH: In the ideal world, it would go to both at the same time, although in almost all cases the ordering provider will have first access electronically or as a result of a phone conversation. The order in which this occurs and who discusses things with the screened individual are important questions that sites may want to individualize.

DTC: Currently we are only screening patients that are part of our health system. Therefore, results are communicated automatically to the patient's ordering physician and/or PCP via the electronic health record.

CF: Reports are sent to PCP/ordering provider and LCS program navigator. LCS program doctor reviews all reports. All screened individuals receive a letter tailored to their Lung-RADS™ category. Individuals with Lung-RADS™ category 3 or greater are contacted and scheduled for a consult with LCSP doctor (pulmonologist in our practice) usually within two business days of scan completion (this mandatory consult was negotiated with our PCPs as part of enrolling a patient in the LCS program). For scans with other significant findings (S) the PCP is contacted directly by LCS program to confirm they are aware of scan results. As with usual CT, any urgent findings are directly communicated by Radiology to the ordering provider.

CCT: Results are sent to the ordering provider and primary care provider. Any lung nodule is also sent to the lung nodule program through the navigator. Concerning incidental findings are called to the ordering provider by radiology in addition to the EHR notification.

RSW/KS: Screen-detected findings are communicated to patients and their referring providers by the LCS program coordinator and patient navigator using a Standard Operating Protocol (SOP). Briefly, for patients with benign or likely benign findings (Lung-RADS™ 1-3), letters are sent to the patients and referring provider summarizing the results and recommendations. For patients with findings suspicious for lung cancer, (Lung-RADS™ 4A, 4B, 4X), the LCS Program. Lung-RADS™ 4A, 4B, 4X), the LCS program coordinator notifies the referring provider directly, and the referring provider communicates these.



Section 6: After the Screening Study— Surveillance and Follow-up

1. Does your program track patients with missed exams and send reminder letters to patients who missed or no-showed their baseline exam?

KK/CCT: Programs should develop and implement a follow-up notification program that includes patients and providers. This can be accomplished with a database in radiology that includes a date of follow-up and automatic letters for missed follow-up appointments. Notification should also be sent to the ordering provider. A system-wide tracking mechanism for previously identified nodules in need of follow-up is a safety net for ensuring follow-up. If a follow-up is overdue then an outreach call to the provider can be performed and follow-up tracked from there as well. Certified letters to patients should be provided from the provider's office or from the nodule team if a follow-up is not completed.

BM/SR: Any patient who ever had a scheduled exam or a recommended follow-up date will fall into our reminder cycle. Thus, a patient who schedules a baseline exam and then misses it for some reason will get their first reminder letter 30 days from that date. If a patient never schedules a baseline exam, there is no date to base the reminder letters on so they don't fall on the reminder list. If a patient missed or never scheduled a follow-up appointment for the recommended date, a reminder letter is sent to the patient 30 days thereafter. This letter informs the patient that they were due for their CTLS on or around a given date and that they should call a patient navigator to reschedule their exam, if they have any questions, or if they no longer wish to be in the program.

At 60 days past the missed appointment, the same reminder letter is sent to the patient and to the ordering health care provider (HCP). This letter notifies the HCP that the patient missed their CTLS appointment and that the program was not able to reach them to reschedule.

At 90 days past a missed appointment, a final letter is sent to both the patient and the HCP informing them of the missed appointment and again encouraging the patient to reschedule; however, it also notes that this is the final reminder. The patient is discharged for non-adherence once the 90-day letter was issued.

CF/AR: Patients are called and receive a reminder letter. If they decline rescheduling or miss a rescheduled exam, their PCP is notified.

CCT: For patients who miss appointments that are scheduled, formal attempts by telephone and in writing will be made at 30, 60 and 90 days, with the patient's primary care provider informed and other avenues of reaching them sought. If the patient is not responding, a certified letter is then delivered to their home at 90 days indicating the attempts to reach them and encouraging their follow-up.



Recommendations for tracking annual exams and assessing adherence:

AM/CCT:

- Use a dedicated database and screening navigation to track patient appointments.
- Schedule an annual follow-up appointment as soon as the window of pre-authorization opens.
- Send reminder letters 30, 60 and 90 days after screening due date to patients and physicians.
- Create ease of scheduling for desired location, and date and time for screening exam.
- Send order for future activation to the PCP 30 days before the annual date. PCP can accept the order or decline the order if the patient is not eligible anymore.

DKM:

- Send a courtesy reminder letter to patient and provider 30 days prior to the screening CT anniversary date (Figure, [page 109](#)).

KK/ABK/CCT:

- Conduct outreach calls to PCP offices if screening is overdue and track completion of follow-up exams.
- Fill in a postcard with patient's name, address and date of screening, and file by month. Once a month, send out the next annual prefilled reminder postcards from the file.

RSW/KS:

- The patient navigator sends reminder letters to patients and their referring providers one month in advance of the recommended follow-up testing.

2. Who is responsible for managing the abnormal findings on the LCS exam?

AM: Program navigators track and manage follow up for Lung-RADS™ categories 1-3. All Lung-RADS™ category 4 cases are recommended to have formal pulmonary consultation with multidisciplinary team back-up. S positive findings are managed by the ordering clinician and tracked through program navigation.

KS: The radiology nurse practitioner coordinates follow-up imaging and referrals to Lung Nodule Clinic in concert with the referring provider. Ultimately the LCS program is responsible for ensuring necessary follow-up appointments are scheduled.

The referring provider is notified first and given the option to manage the findings or refer to the Lung Nodule Clinic for management, which the radiology nurse practitioner coordinates. Other incidental findings are managed by the referring provider.



CF: The ordering provider is ultimately responsible. To help with buy-in from our PCPs, we committed to an LCS program doctor reviewing all reports, confirming results and making sure PCPs were made aware of positive scans and any other concerning findings.

CCT: The ordering provider is ultimately responsible. The abnormal finding is relayed to the program and the ordering provider/PCP are contacted as well by the nodule program. While the program offers an appointment with the nodule program, approximately one to three percent of the time the PCP declines this and manages the evaluation themselves. Regardless of the next step, all diagnostic and therapeutic care clinical is tracked by the program. Overdue follow-up imaging is tracked and the patient's providers are notified of the need for follow-up.

AR: Non-nodular findings are referred back to the PCP. Nodule abnormalities are entered into the pulmonary nodule clinic or the MDC clinic.

3. How should abnormal findings be managed? Lung nodules? Other findings?

SR/BM: We use Lung-RADS™ and the referenced document for Lung-RADS™ gaps and use of guidelines for S positive and non-S positive incidental findings.¹⁶

CF: Radiology calls the ordering provider with any perceived urgent findings. CT reports are also reviewed by the LCS program physician (pulmonologist). If positive, an automatic consult with a pulmonologist in the LCS program is scheduled within three days, if possible. If negative, but there are other significant pulmonary findings, a pulmonary consult is recommended. The provider office is contacted directly for a referral. If significant non-pulmonary findings are noted, non-urgent but further evaluation is needed and the provider office is contacted by the LCS program to confirm they are aware. If urgent findings are noted, the ordering provider is directly notified (and/or other appropriate provider, if indicated), action taken and documented. This last step may be duplicative as radiology has already likely called but kept in to make sure the communication loop is completed.

CCT: Abnormal findings of nodules are reported by radiology using Lung-RADS™, as well as abnormal findings but not urgent, and urgent findings. Non-urgent findings that are not nodules are reported through the EHR to the ordering provider for follow-up as indicated. An urgent finding would include both notification through the EHR and a call to the ordering provider.

4. Does your LCS program staff track the downstream workup of the patient with findings suspicious for lung cancer (Lung-RADS™ 4)?

BM/SR: Yes. These patients have the highest odds of being diagnosed with lung cancer and therefore need to be followed to resolution whenever possible to ensure they are receiving the proper follow-up and care. In addition, the presence of absence of cancer as a result of downstream Lung-RADS™ 4 workup is required to



assess important program metrics including positive predictive value, false positive rate, and false discovery rate. Any complications arising as a result of the workup of LCS exam findings should be collected and reported to the steering committee.

RSW/KS: Yes. The screening coordinator should monitor the work-up of these patients and make recommendations as needed to ensure the patient receives appropriate workup and doesn't fall through the cracks.

CF: Yes. All patients with Lung-RADS™ 3 or 4 are seen by LCS MD (pulmonary doctor or thoracic surgeon) for review of results and planning of follow-up (in coordination with PCP).

DTC: We encourage PCPs who have patients with Lung-RADS™ 3 or 4 to be seen by either the pulmonologist or thoracic surgeon as part of LCS provider clinic. Either way, for all patients who have undergone LCS, the results of downstream diagnostic and therapeutic algorithms are recorded. This includes invasive radiology, interventional pulmonary, and thoracic surgical diagnostic procedures. Also, we track therapeutic thoracic surgery, as well as chemotherapy and radiation oncology treatment.

CCT: Yes, the program tracks every aspect of diagnostic and therapeutic care for every patient with Lung-RADS™ 3 and 4. The program sees more than 95 percent of these patients, and manages the evaluation and care as well.

5. How is data submitted to a registry?

CCT: A guide to registry reporting is found here and can assist with this function:

<https://nrdrsupport.acr.org/support/solutions/articles/11000033721>

CCT: In our program, findings from the screening CTs are sent to the program nurse navigator so that each is catalogued. Those reporting elements specific to the low-dose scan technique, Lung-RADS™ reporting, and number of each level of Lung-RADS™ nodule, as well as documentation of eligibility criteria, shared decision-making and smoking cessation counseling are collected by the radiology section of our program. Those elements that are specific to diagnostic and therapeutic care, staging, and outcome are tracked by our oncology, radiation oncology, thoracic surgery and interventional radiology sections, and each of those areas are kept in a central database for the program by the nurse navigator.

AR: An electronic commercially available non-dedicated spreadsheet is used or data submission to a registry.

6. What protocol do you follow in discharging patients from your LCS program?

BM/SR/CCT: An individual may be discharged for several reasons. Anyone who informs the program staff or PCP that he or she no longer wishes to participate in the screening program will be discharged. The program will notify the PCP of the



reason for discharge, if given, and will document the time and date of the request for discharge in the database. Reasons for discharge include moving out of the area, inability to obtain a follow-up order from their provider, and undergoing screening or treatment elsewhere. Patients who exceed the upper age limit of the program will also be discharged.

Patients will be notified of the discharge in the examination results letter and told the program will contact them if the upper age limit for eligibility is increased. For patients who miss appointments, formal attempts by telephone and in writing will be made at 30, 60 and 90 days, with the PCP informed at 60 and 90 days. If, despite these efforts, no contact can be established with the patient, the patient will be discharged. The 90-day letter notifies the patient and PCP of the delinquency, documents all previous efforts to contact the patient, and states that the program will make no further efforts to contact the patient to reschedule the appointment. The letter also encourages the patient to contact the program at any time if they choose to re-engage in the screening process.

CCT/CF: For patients who miss appointments, formal attempts by telephone and in writing will be made at 30, 60 and 90 days, with the PCP informed at each of these intervals. If the patient is not responding, a certified letter is then delivered to their home at 90 days indicating the attempts to reach them and encouraging their follow-up.

AR: The patient will receive three calls prior to being un-enrolled if the patient no-shows or if they develop co-morbidity that makes surgical treatment an issue.



Section 7: Smoking Cessation

1. When do you offer smoking cessation counseling in your program?

AM/CCT: Smoking cessation is discussed at the point of care when the LCS exam is ordered. Educational materials for smoking cessation counseling are developed during office visits (see Resource Section). Smoking cessation is reinforced at multiple additional time points through program navigators and CT technologists.

CL: Smoking cessation counseling is provided at the SDM visit prior to ordering the LCS CT. For a new patient, pulmonary function studies will be ordered if not previously performed to provide an opportunity to optimize overall lung health and establish a diagnosis of COPD if not previously assessed.

DTC: Smoking cessation resources and access to the Living Tobacco-Free Smoking Cessation Program are made available through the screening process.

CF: Whenever the opportunity presents! At visits with PCP, all patients actively smoking will be referred to pulmonary.

2. What are ways to promote clinician intervention through education, resources and feedback?

ABK/AR: Although the optimal strategy for delivering smoking cessation advice and intervention in an LCS setting is unknown at this time, prior research suggests that integrating smoking cessation into LCS programs represents a teachable moment for smoking behavior change.

Screening provides multiple opportunities to personalize the health risks of persistent smoking. Smoking cessation is part of the shared decision-making discussion and resources for smoking cessation can be provided at the SDM discussion, at screening site at the time of the scan, in the appointment confirmation patient letter, with the patient results letter and with patient appointment reminder letters. Physicians have teachable moments at the SDM discussion and when discussing scan results regardless of the result.

These opportunities present themselves on an annual basis in a screening program. This is important as interventions as brief as three minutes have been shown to increase cessation rates significantly.³⁸

In one Mayo Clinic study, a dose response between false positive findings and improved quit rates was observed. Patients receiving one positive, two positive or three positive screening results had a 19.8 percent, 28 percent, and 41.9 percent quit rate.³⁹ A similar dose response for the impact of positive findings on smoking status was observed in the NLST.⁴⁰



Smoking cessation and relapse rates in a large clinical LCS program were better than general population rates:⁴¹

- Point prevalence quit rate 20.8 percent (141/678).
- Annualized rate 14.5 percent vs. 5 percent general population.
- Relapse rates 10 to 20 percentage points lower than the general population.

In the first successful randomized trial of its kind, researchers have provided preliminary evidence that telephone-based smoking cessation counseling given to smokers shortly after undergoing LCS can be effective at helping people stop smoking.⁴²

Surgeon General 2014 Report:⁴³

- Quitting smoking improves the prognosis of cancer patients.
- All-cause and cancer-specific mortality is improved by smoking cessation.
- Smoking cessation decreases risk of secondary malignancies.

Other Facts:

- Sustained smoking cessation improves wound healing, reduces hospital LOS, and reduces readmission rates.⁴⁴⁻⁴⁶
- COPD and lung cancer are the fourth and seventh leading cause of death worldwide.⁴⁷
- 90 percent of lung cancer and COPD are attributable to smoking.^{48,49}
- 36 percent risk reduction in cardiac mortality associated with smoking cessation (Critchley et al. 2003).

3. How can patient tobacco use status and tobacco use history be determined and tracked?⁵⁰

ABK:

- Patient reports during SDM discussion with healthcare provider, captured in LCS exam order and in patient medical record: packs/cigarettes per day, years smoked and years quit if former smoker. We also capture other tobacco use, including cigars, pipe, snuff, hookah and other.
- Patient reports to lung cancer exam scheduler and reported in the LCS database: packs/cigarettes per day, years smoked and years quit if former smoker. We also capture other tobacco use: cigars, pipe, snuff, hookah and other.
- Patient is asked about current smoking status at every screening exam by CT scan technologist and data entered into PACS.
- There is an algorithm to mine data from EHR.



4. How do you track that smoking cessation was provided in your program?

ABK/CCT:

- Document in the EHR as part of the order for the scan. (EHR Meaningful Use Specification Sheet for Eligible Professional—Record Smoking Status).⁵¹
- Document in LCS relational database.
- Track Quality Metrics.
- Tobacco use screening:
 - number of individuals screened for tobacco use (numerator).
 - number of individuals who present to an LCS program screening site (denominator).
- Tobacco use treatment provided or offered at the time of LCS.
- The number of individuals who received and refused practical counseling to quit (numerators).
- The number of individuals who received and refused FDA-approved cessation medications (numerators).
- The number of individuals identified as current tobacco users (denominator).
- Tobacco use assessment annually, at each LCS appointment.
- Reassessment of smoking cessation at the time of annual repeat LCS.
- Reassessment of smoking status at the time of follow-up of positive study.

MG: Robust options for TST include phone-based and web-based instruction, as well as in-person classes.

5. What resources are available for physicians to help patients quit smoking?

ABK/CCT/KK: Consistent with the U.S. Public Health Service Clinical Practice Guidelines for Treating Tobacco Abuse and Dependence, the brief tobacco treatment model emphasizes five key steps:

- Ask each patient about tobacco use.
- Advise patient to quit.
- Assess quit readiness.
- Assist with quitting.
- Arrange follow-up.

Provide list and links for physicians to hand to patients:

- <https://betobaccofree.hhs.gov/basic-information/index.html>.
- American Lung Association series of robust resources available nationwide, providing information and resources about quitting available at: <http://www.lung.org/stop-smoking/how-to-quit/>.



- CDC quit smoking resources https://www.cdc.gov/tobacco/quit_smoking/
- National QuitLine: 1-800-QUIT-NOW
- Smokefree.gov free website <https://smokefree.gov/>
- BecomeAnEx.org <https://www.becomeanex.org/>
- Text messaging: Sign up for text message reminders and encouragement at <http://smokefree.gov/smokefreetxt>
- iPhone and Android app: Livestrong My Quit app (free smartphone app that allows you to track your quitting and cravings, and offers encouragement through the quitting process)
- Free online smoking cessation support group <https://quitnet.meyouhealth.com/#/>
- Mindfulness smoking cessation program based on a successful program developed at Yale—web and app based <https://www.cravingtoquit.com>.

National organizations and websites⁵²⁻⁵⁵ are included in the resource section.

6. What are ways to dedicate staff and/or resources to providing smoking cessation treatment and follow-up for people in LCS programs? How do you incorporate smoking cessation support in the screening program?

ABK/CCT:

- Send all current smokers smoking cessation resource lists with patient letters.
- LCS program navigator/coordinator calls all current smokers in the program and discusses smoking cessation options.
- Navigator or other provider conducts smoking cessation counseling with all smokers.
- Hospital/medical center smoking cessation program manager contacts all current smokers in the screening program to discuss smoking cessation options.
- Programs offering screening program participants:
 - American Lung Association Freedom from Smoking® group clinics.
 - Telephone counseling.
 - Individual in-person counseling.
 - Group counseling.
 - Online support groups.



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Section 9: Resources

SECTION 3 Planning an LCS program

Example Governance Structure

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



Invite participation

McKee, *Oncology Issues*, March 2014 p20-29

Insurance

REQUIREMENTS FOR CT LUNG CANCER SCREENING

GROUP 1—COVERED BY INSURANCE WITH NO CO-PAY

INSURANCE	MEDICARE	MEDICAID	PRIVATE	Symptoms of Lung Cancer
AGE	55–77	55–77	55–80	Persistent cough
TOBACCO HISTORY	30-PACK YEARS	30-PACK YEARS	30-PACK YEARS	Worsening of chronic cough
SMOKING STATUS	Smoked within the Last 15 Years	Smoked within the Last 15 Years	Smoked within the Last 15 Years	Coughing up blood
SYMPTOMS OF LUNG CANCER	Asymptomatic	Asymptomatic	Asymptomatic	Constant chest pain
SHARED DECISION MAKING	REQUIRED (FACE TO FACE) BILLABLE CODE: G0296	REQUIRED (PHONE OR VISIT) BILLABLE CODE: G0296	REQUIRED (PHONE OR VISIT) NOT BILLABLE	Persistent hoarseness
				Unintentional weight loss >10% of baseline weight

GROUP 2—NOT COVERED BY CMS/MEDICAID. MAY REQUIRE PRE-AUTH FROM PRIVATE INSURANCE.

INSURANCE	MEDICARE	MEDICAID	PRIVATE	RISK FACTORS
AGE	N/A	N/A	≥ 50	Radon Gas —Documented History
TOBACCO HISTORY	N/A	N/A	20 PACK YEARS	Occupational Exposure — Silica, Arsenic, Nickel, Cadmium, Beryllium, Asbestos, Chromium, Diesel fumes, Soot, Coal smoke <i>NOTE: Most people who have had occupational exposure are aware of what substance they were exposed to</i>
One Additional Risk Factor For Lung Cancer	N/A	N/A	Yes	LUNG DISEASE — COPD, Emphysema, Pulmonary Fibrosis
				HISTORY OF CANCER — Lung, Head, Neck, Lymphoma
				LUNG CANCER IN 1st DEGREE FAMILY MEMBER — Parent, sibling, children

SCAN COSTS APPROX \$300 OUT OF POCKET AT SCCA/UW

ADDITIONAL CONSIDERATIONS FOR SCREENING

Are they willing to have surgery for curative intent?	YES	Proceed with screening
Are they healthy enough for lung resection surgery? —Poor lung function? Chronic supplemental O2?	NO	Do Not Screen
Was the patient previously screened and now falls outside of the eligibility criteria?	YES	May Continue—Case by Case Basis May Require Pre Auth From Insurance
Have they had primary lung cancer in the past?	YES	May Screen if >5 Years Since Completing Surveillance

Codes and payment levels* for LDCT screening

Description	Code	Professional component	Global payment
Counseling visit to discuss need for screening with LDCT	G0296	\$28.64	\$28.64
LDCT scan for LCS	G0297	\$51.56	\$254.93

**Fees used for illustration are from the national Medicare fee schedule, using the 2016 conversion factor. Medicare applies a geographic adjustment to develop actual fees paid in each area of the country.*

Required Reporting Elements**Exam details:**

Facility ID number, patient name, exam date

General:

Smoking status in pack years

Smoking cessation counseling

Documentation of shared decision making

Height, weight, comorbidities, cancer history

Radiologist name, ordering provider and NPI

Indication for the exam

Exam modality, manufacturer, radiation exposure

CT exam results by Lung-RADS™ category

Other abnormalities- CT exam result S modifier

Prior history of lung cancer and years since diagnosis

Follow-up within 1 year

Documentation of an exam anytime within prior 12 months and date

Follow-up diagnostic for tissue:

- Tissue Diagnosis

- Tissue diagnosis method

- Location from which sample was obtained

- Histology

- Stage- Clinical or pathologic

- Overall stage

- T, N, M status

- Period of follow-up for incidence (in months)

Additional Risk Factors:

Education level, radiation exposure, occupational exposures, history of cancers associated with a higher risk of lung cancer, lung cancer in first-degree relative, other family history of lung cancer, COPD, pulmonary fibrosis, secondhand smoke exposure.

Name of person performing data collection for the exam, submission date.

Marketing To Healthcare Community And Patients



Lung Cancer Screening Program

Cleveland Clinic Chest Cancer Center

What is screening?

Screening means that a test is done to look for a disease, in someone at risk of developing the disease, before the disease has advanced enough to cause symptoms. The goal of screening is to reduce the number of people who die from the disease by detecting the disease early in its course, when it is easier to treat, with minimal harm to those who are screened.

Benefits of lung cancer screening

You can be screened for lung cancer using a low-dose computed tomography (CT) scan. CT scans combine X-ray views from multiple angles, creating a two-dimensional, cross-sectional image of your lungs. Having a lung cancer screening chest CT reduces the chance of dying from lung cancer in those at very high risk of developing lung cancer.

Eligibility for lung cancer screening

To be a candidate for lung screening, an individual must be:

- 55 to 77 years old.
- A smoker or a person who quit smoking less than 15 years ago.
- Have a smoking history of at least 30 pack-years. (A pack year is a way of determining how many cigarettes a person has smoked during his or her lifetime. One pack year is equal to smoking 20 cigarettes, or one pack, every day for one year.)
- Have no new symptoms that could be related to lung cancer;
- Be healthy enough to tolerate curative intent treatment for early stage lung cancer; and,
- Have not had a chest CT in the last 12 months

Drawbacks to consider

Screening for lung cancer with a chest CT can find small spots in the lungs of at least 25 percent of all people who get the scan. These spots are called lung nodules. Only three or four out of 100 lung nodules found are cancer. The rest are small scars that will never affect your health.

There is no way to tell if many of these small lung nodules are scars or lung cancer without further tests. CT scans are usually done over time to see if the lung nodule grows. You might need a biopsy if the lung nodule is large enough.

Therefore, many people who are screened will have further tests without actually having lung cancer. The lung cancer screening program will talk with you about whether or not you need more tests.

Lung cancer screening CTs use a very small dose of radiation to take pictures of your lungs. The dose of radiation is quite low (five times less than a standard chest CT scan). The effects of radiation from lung cancer screening are not known. The benefits are thought to outweigh any consequences.

Quitting smoking

If you smoke, you can cut your risk of dying from lung cancer by quitting. We advise all smokers to quit. You can find help from your doctor or through counsellors within the screening program.

Components of our Lung Cancer Screening Program

1. Participants selected according to current national health guidelines.
2. In-person discussion about the benefits and harms of lung cancer screening to help make informed choices.
3. Standardized low-dose chest CT.
4. Chest CT interpretation by radiologists with expertise in chest imaging.
5. Lung nodule evaluation care pathway.
6. Tobacco treatment experts integrated with the program.
7. Cutting-edge research to improve tomorrow's outcomes.
8. Experts in the treatment of lung cancer.
9. Central call-in number for questions.

Questions?

If you have any questions about our Lung Cancer Screening Program, please call 1.216.445.3800 or visit clevelandclinic.org/lungcancerscreening



Lung Cancer Screening Program

Cleveland Clinic Chest Cancer Center

GOAL:

Lung cancer screening aims to reduce the number of people who die from lung cancer by detecting the disease early in its course when it is easier to treat, with minimal harm to those who are screened.

BENEFITS:

Screening for lung cancer with a low-dose chest CT has been shown to lower the risk of dying from lung cancer in active or former smokers age **55 to 77 years old**, who have smoked at least **30 pack years** (for example, 1 pack per day for 30 years or 2 packs per day for 15 years).

ELIGIBILITY:

To qualify for lung cancer screening, a person must:

- Be **55 to 77 years old**
- Be a **smoker, or a person who quit smoking less than 15 years ago**
- Have a **smoking history of at least 30 pack years**
- Have **no new symptoms that could be related to lung cancer**
- Be **healthy enough to tolerate treatment intended to cure early-stage lung cancer**
- Have **not had a chest CT in the last 12 months**

Lung Cancer Screening Program

Cleveland Clinic Chest Cancer Center

WHAT TO CONSIDER:

- The low-dose chest CT can find small spots on the lungs called nodules in at least 25 percent of all people who get the scan.
- Typically three or four out of 100 lung nodules found are cancer.
- The low-dose chest CT uses a very small dose of radiation (equivalent to about 280 hours of air travel time) to take pictures of your lungs.

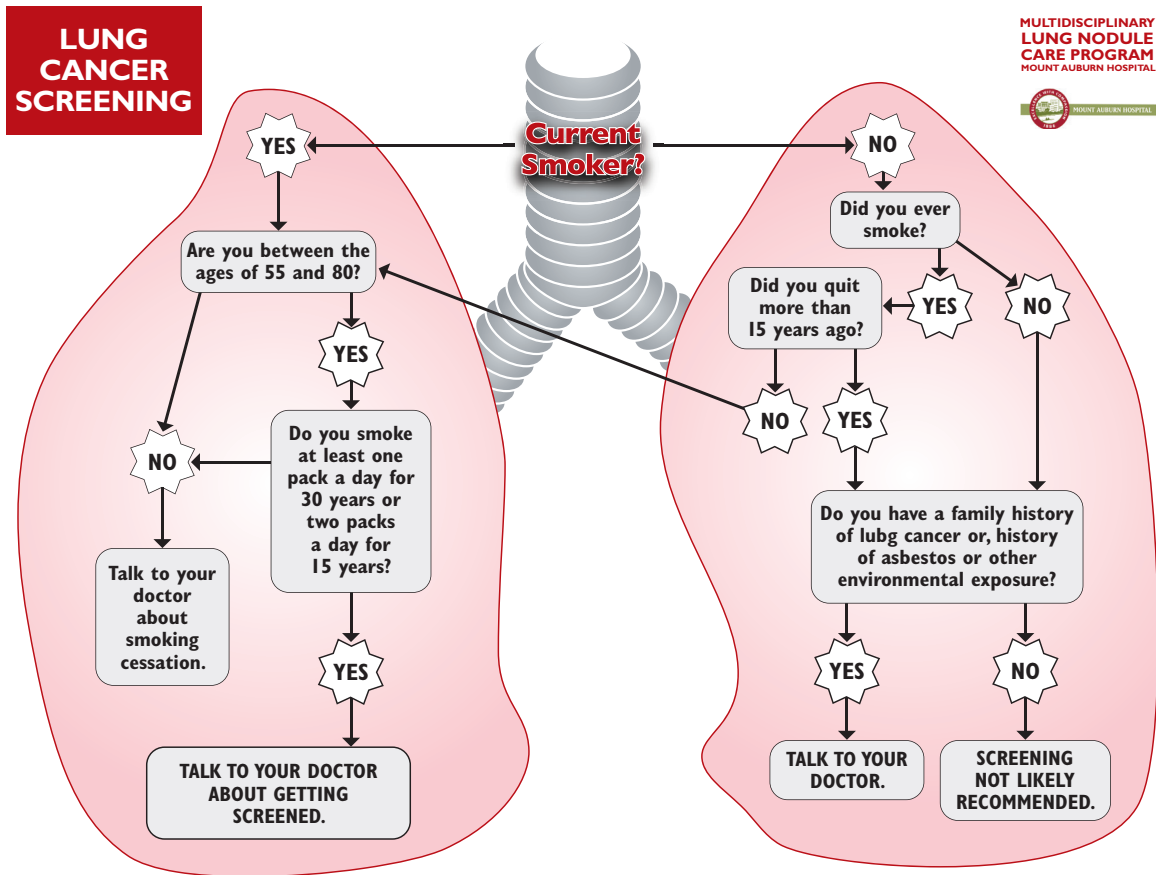
WHY CHOOSE CLEVELAND CLINIC?

- Participants selected according to current national health guidelines
- In-person counseling on the benefits and harms of lung cancer screening to help you make an informed choice
- Standardized low-dose chest CT
- Chest CT interpretation by radiologists with expertise in chest imaging
- Standardized lung nodule evaluation
- Integrated tobacco treatment program
- Cutting-edge research to improve tomorrow's outcomes



QUESTIONS?

For questions, and to see if you qualify for our Lung Cancer Screening Program, please talk to your doctor, call the Lung Cancer Screening Program at **216.445.3800** or visit our website at clevelandclinic.org/lungcancerscreening.

14-RAD-1722



Section 4: Eligibility For Screening, Clinical Decision Support and Shared Decision Making

CT Lung Cancer Screening Order Form				
Scheduling Tel: (206) 606-1434		Scheduling Fax: (206) 606-6729		
Patient Name: _____		Date of Birth: _____		
Patient Phone: _____		Exam: <u>Lung Cancer Screening CT</u>		
Age: _____		Reason for exam: <u>Lung Cancer Screening</u>		
Height: _____		Weight: _____		
<input type="checkbox"/> Current Smoker		<input type="checkbox"/> Former Smoker: Quit Year: _____		
<input type="checkbox"/> Maximum Packs per day: _____		<input type="checkbox"/> Years Smoking: _____		
<input type="checkbox"/> Pack Year History: _____				
<p>By signing this order, you are certifying that (Please check below):</p> <ul style="list-style-type: none"> <input type="checkbox"/> The patient is between the ages of 55-77 for Medicare/Medicaid insurance and 55-80 for private insurance. <input type="checkbox"/> The patient is a current or former smoker with at <u>least</u> a 30 pack year history AND has smoked within the last 15 years. <input type="checkbox"/> The patient is asymptomatic for lung cancer (patients that have symptoms for lung cancer should typically receive a diagnostic CT). <input type="checkbox"/> The patient is willing to undergo lung resection surgery should a lung cancer be found. <input type="checkbox"/> The patient does not have any co-morbidities that would preclude a lung resection surgery such as poor lung and cardiac function or chronic supplemental oxygen use. <input type="checkbox"/> The patient was informed of the importance of smoking cessation and/or maintaining smoking abstinence, including the offer of tobacco cessation consulting services, if applicable. <input type="checkbox"/> A fax of the most recent clinic note has been sent to: Radiology Scheduling at (206) 606-6785 <p>A one-time shared decision-making session, discussing the risks and benefits associated with screening (using one of the decision aids below), has been completed for initial scan only: <input type="checkbox"/> YES / <input type="checkbox"/> NO</p> <ul style="list-style-type: none"> • University of Michigan lung cancer risk calculator: www.shouldscreen.com • American Thoracic Society: https://www.thoracic.org/patients/patient-resources/resources/decision-aid-lcs.pdf • American Lung Association: www.lungcancerscreeningsaveslives.org <hr/> <p>Additional Information:</p> <ul style="list-style-type: none"> • Some insurers may recognize NCCN Group 2 criteria for lung cancer screening which expands the high risk population to those who are: Greater than or equal to 50 years old, have at least a 20 pack year smoking history, and have one additional risk factor for lung cancer. Additional risk factors for lung cancer can include: family history of lung cancer, occupational exposure, history of lung disease, or prior history of head/neck/thoracic cancer. Please have the patient contact their insurer to verify eligibility. https://www.nccn.org/patients/guidelines/lung_screening/ <p>Informational Handouts:</p> <ul style="list-style-type: none"> • American Cancer Society: https://www.cancer.org/health-care-professionals/american-cancer-society-prevention-early-detection-guidelines/ • Lung Cancer Alliance: http://www.lungcanceralliance.org/Educational%20Materials/LCA_Risk_Brochure_2015.pdf • National Comprehensive Cancer Network: https://www.nccn.org/patients/guidelines/lung_screening/ 				
PHYSICIAN SIGNATURE: _____		ORDERING/ATTENDING PRINTED NAME: _____		NPI CODE: _____
REQUIRED		REQUIRED		REQUIRED
PHONE NUMBER: _____		FAX NUMBER: _____		
TEAM NAME PT NO DOB		<div style="text-align: center;">  Seattle Cancer Care Alliance </div> <div style="text-align: center;">  <small>*SRAD016</small> </div>		
PLACE EPIC LABEL HERE		RAD016 (10/17)		
CT LUNG CANCER SCREENING ORDER FORM				



To refer a patient to the Lung Cancer Screening Program at Cleveland Clinic, please complete the following form and either email it to lungcancerscreening@ccf.org or fax it to 216.445.8794.

If you have any questions, please call the Lung Cancer Screening Program at 216.445.3800.

Patients must meet all the following criteria to be eligible for the screening.

- Have at least a 30 pack year history of smoking (cigarettes only)
- Ages 55-77
- Have smoked within the past 15 years
- Have no signs or symptoms of cancer
- Healthy enough and willing to undergo curative intent treatment

Lung Cancer Screening Program

Patient name: _____

Patient date of birth: _____

Patient phone number: _____

Referring provider name: _____

Referring provider phone: _____

Referring provider fax: _____

How many years has the patient been a smoker? _____

On average, how many packs per day has the patient smoked? _____

Is the patient an active smoker? ☐ Yes ☐ No

Has the patient has a chest CT scan within the last year? ☐ Yes ☐ No

Does the patient show any signs or symptoms of lung cancer? ☐ Yes ☐ No

Please check the location you'd like your patient to have the screening:

- ☐ Cleveland Clinic main campus
- ☐ Cleveland Clinic Akron General Medical Center
- ☐ Cleveland Clinic Richard E. Jacobs Health Center, Avon
- ☐ Cleveland Clinic Beachwood Family Health and Surgery Center
- ☐ Cleveland Clinic Strongsville Family Health and Surgery Center
- ☐ Cleveland Clinic Twinsburg Family Health and Surgery Center

Best Practice Advisory in the Electronic Record:

⚠ Your patient qualifies for a lung cancer screen and has not had one in the past year. Please place your order below.

Acknowledge reason:

☐ Add to unsigned orders: CT Lung Screening Request - Burlington/Peabody Only

☐ Add to unsigned orders: CT Low Dose Lung Screening WO Contrast-Addison Gilbert/Danvers Only

Key elements for a five-minute discussion between provider and patient regarding LCS

Healthcare experts recommend LCS for individuals at high-risk for developing lung cancer. The goal of LCS is to detect lung cancer early to save lives. Without LCS, lung cancer is usually not found until a person develops symptom, and at that time, it is more difficult to treat. LCS is performed using a lower radiation version of a chest CT scan, taking an image of your lungs and surrounding structures. This is a 10-minute test that is performed as an outpatient.

Eligibility criteria:

- As a Medicare or Medicaid patient, you are eligible for LCS if you are age 55 to 77, have smoked the equivalent of one pack of cigarettes per day for at least 30 years, and are a current smoker or quit smoking within the past 15 years.
- As a private health insurance patient, you are eligible for LCS if you are age 55 to 80, have smoked the equivalent of one pack of cigarettes per day for at least 30 years, and are current smoker or quit smoking within the past 15 years.
- It is important that you have no signs or symptoms of lung cancer including: persistent cough, worsening of chronic cough, coughing up blood, constant chest pain, persistent hoarseness or unintentional weight loss of greater than 10 percent of baseline weight. If you have any of these symptoms, then a different type of diagnostic evaluation is required.

Potential benefits:

The major benefit of LCS is preventing death from lung cancer.

- A large national study called the National Lung Screening Trial has shown that LCS with a low-dose CT scan can decrease lung cancer deaths by 20 percent in high-risk individuals. In other words, CT screening resulted in three fewer lung cancer deaths for every 1,000 individuals screened.
- CT screening for lung cancer is at least as effective in preventing lung cancer deaths in high-risk individuals as mammography is in preventing breast cancer deaths and colonoscopy is in preventing colon cancer deaths.
- If you are concerned about the possibility of having lung cancer, a normal screening CT scan can be reassuring.

Potential harms:

There are several potential harms to a screening that you should consider:

- Radiation risk:
 - The screening CT scan will expose you to a low level of radiation, equivalent to six months of background radiation exposure or 50 coast-to-coast round-trip flights in a commercial airplane.
 - This is considered a very low risk.
- Anxiety risk:
 - One in four patients may have a lung nodule or “spot” found on screening CT.

The number of false positive findings or “false alarms” outnumber cancers by 25 to one.

- One in 10 patients may have an abnormality other than a lung nodule(s) found on the scan that is not causing any symptoms but may require evaluation.
- **Complication risk:**
 - Sometimes a finding on the screening CT leads to the need for additional testing such as a biopsy or surgery that can cause harm in individuals that do not have cancer.
 - The risk for a major complication from invasive procedures is three for every 1,000 individuals undergoing such additional testing.
- **Overdiagnosis risk:**
 - There is a possibility that a lung cancer could be diagnosed by screening that would never cause a problem because it is very slow growing.
 - One in 10 lung cancers found by CT screening will never cause a problem for the patient.

Cost:

As an eligible Medicare or Medicaid patient, the screening CT scan will not cost you anything out of pocket.

As an eligible private health insurance patient, the screening CT scan will not cost you anything out of pocket nor be charged to your deductible.

Screening Modality:

- The 20 percent decrease in lung cancer deaths found in the large national study was through screening with low-dose CT scan.
- A separate large national study showed that routine chest x-ray is of no benefit for LCS.

Patient Commitment:

- Like mammography, LCS is not a one-time test. You should be willing to undergo yearly screening as long as you continue to meet the eligibility requirements.
- In addition, you should be willing to undergo surgery to treat an early stage lung cancer detected by screening.

Smoking Cessation:

- Smoking cessation remains the most effective way to prevent lung cancer as a current smoker, we want to help you quit smoking for good.
- CT screening for lung cancer is most effective in decreasing your risk of death from lung cancer when combined with smoking cessation.

Clinical Decision Support Tools

Decision Aid	Source	Media	Individualized risk assessment	Criteria for positive scan	Link
Should I Screen	University of Michigan	Web - Interactive	Yes	NLST	http://www.shouldiscreen.com/
LCS with Computerized Tomography (CT)	American Thoracic Society	Print	No	NLST	https://www.thoracic.org/patients/patient-resources/resources/decision-aid-lcs.pdf
Is LCS Right for Me?	Agency for Healthcare Research and Quality	Web & Print. Limited interactive features	No	NLST	https://effectivehealthcare.ahrq.gov/decision-aids/lung-cancer-screening/home.html
LCS Benefits, harms of chest CT scans	Health Decision	Web – Interactive	Yes	NLST	https://www.healthdecision.org/tool.html#/tool/lungca
Lung Cancer: Should I Have Screening?	Healthwise	Web – Interactive and print	No	NLST	https://www.cigna.com/healthwellness/hw/medical-topics/lung-cancer-abq5042
LCS: Yes or No	Options Grid - Dartmouth Institute	Web interactive and print	No	Lung-RADS™	http://optiongrid.org/option-grids/grid-landing/8
LCS	Center for Clinical Management Research, Ann Arbor VHA	Web-interactive	Yes	NLST	https://lungdecisionprecision.com
Lung cancer Project	Genentech	Web – Interactive and print	No	NLST & Lung-RADS™	https://www.thelungcancerproject.org/screening
LCS Saves Lives	American Lung Association	Web – Interactive and print	No	?	http://lungcancerscreeningsaveslives.org/

Section 6: Surveillance And Follow Up

INSERT LOGO

PTNAME
PTADDRESS

DATE:
MRN: PTMRN

Dear PTNAME:

This letter is a courtesy reminder that you are due for a CT lung screening exam on or around FOLLOWUPDATE. Please contact your doctor to discuss whether lung cancer screening continues to be right for you and ask your doctor to order the screening exam. Please call (XXX) XXX-XXXX to schedule the CT lung screening appointment. If you have decided you do not want this study, performed or are receiving your care elsewhere, please let us know at your earliest convenience so we can update our records.

Here are important points you should know:

- THE SCREENING DOES NOT OBLIGATE YOU TO RETURN TO XXXX FOR ANY FURTHER SCREENINGS, FOR FURTHER EVALUATION OF ANY FINDINGS, OR FOR ANY OTHER SERVICES THAT XXXX PROVIDES THIS SAME POINT HAS BEEN EMPHASIZED IN OUR CORRESPONDENCE WITH YOUR REFERRING PHYSICIAN.
- Your full low-dose Chest CT report will be sent to your health care provider. Your exam report and images will be kept on file at: XXXX as part of your permanent record and will be available for your continuing care.
- Although low-dose chest CT is very effective at finding lung cancer early, it cannot find all lung cancers. If you develop any new symptoms such as shortness of breath, chest pain, or coughing up blood, please call your doctor.
- Please keep in mind that the best way to reduce the risk of getting lung cancer is to stop smoking.

If you have any questions about this letter or have difficulty in contacting your health care provider please call our scheduling department at (XXX) – XXX-XXXX.

Thanks for allowing us to help in meeting your health care needs.

We look forward to seeing you on your next visit.

Sincerely,
The Imaging Department at XXXX

Cc: Referring Provider

Section 7: Smoking Cessation

National organizations and websites

Centers for Disease Control and Prevention

Office on Smoking and Health

Free quit support line: 1-800-784-8669 (1-800-QUIT-NOW)

TTY: 1-800-332-8615

Website: www.cdc.gov/tobacco

The quit support line offers information on smoking and health as well as help with quitting. Languages and range of services vary by your state of residence.

Nicotine Anonymous (NicA)

Toll-free number: 1-877-879-6422 (1-877-TRY-NICA)

Website: www.nicotine-anonymous.org

For free information on their 12-step program, meeting schedules and locations, print materials, or information on how to start a group in your area.

QuitNet

Website: www.quitnet.com

Offers free, cutting-edge services to people trying to quit tobacco.

National Cancer Institute

Free tobacco line: 1-877-448-7848 (1-877-44U-QUIT) (also in Spanish)

Direct tobacco website: www.smokefree.gov

Quitting information, quit-smoking guide, and counseling are offered, as well as referral to state telephone-based quit programs (if needed for special services).

American Heart Association

Toll-free number: 1-800-242-8721 (1-800-AHA-USA-1)

Website: www.americanheart.org

Quitting tips and advice can be found at www.everydaychoices.org or by calling 1-866-399-6789.

Environmental Protection Agency (EPA)

Telephone: 202-272-0167

Website: www.epa.gov

Has advice on how to protect children from secondhand smoke, a Smoke-free Homes Pledge, and other tobacco-related materials on the direct website, www.epa.gov/smokefree, or at 1-866-766-5337 (1-866-SMOKE-FREE).

American Lung Association

Toll-free number: 1-800-LUNGUSA

Website: www.lung.org

Printed quit materials are available, including Spanish materials. Also offers an online quit smoking program Freedom From Smoking® Plus at www.FreedomFromSmoking.org; in-person group clinics at www.lung.org/ffs and telephonic services at 1-800-LUNGUSA.

