AMERICAN THORACIC SOCIETY DOCUMENTS

An Official American Thoracic Society/American College of Chest Physicians Policy Statement: Implementation of Low-Dose Computed Tomography Lung Cancer Screening Programs in Clinical Practice

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This official Policy Statement of the American Thoracic Society (ATS) and the American College of Chest Physicians (CHEST) was approved by the ATS Board of Directors, June 2015, and by the CHEST Board of Regents, April 2015

Rationale: Annual low-radiation-dose computed tomography (LDCT) screening for lung cancer has been shown to reduce lung cancer mortality among high-risk individuals and is now recommended by multiple organizations. However, LDCT screening is complex, and implementation requires careful planning to ensure benefits outweigh harms. Little guidance has been provided for sites wishing to develop and implement lung cancer screening programs.

Objectives: To promote successful implementation of comprehensive LDCT screening programs that are safe, effective, and sustainable.

Methods: The American Thoracic Society (ATS) and American College of Chest Physicians (CHEST) convened a committee with expertise in lung cancer screening, pulmonary nodule evaluation, and implementation science. The committee reviewed the evidence from systematic reviews, clinical practice guidelines, surveys, and the experience of early-adopting LDCT screening programs and summarized potential strategies to implement LDCT screening programs successfully.

Measurements and Main Results: We address steps that sites should consider during the main three phases of developing an LDCT screening program: planning, implementation, and maintenance. We present multiple strategies to implement the nine core elements of comprehensive lung cancer screening programs enumerated in a recent CHEST/ATS statement, which will allow sites to select the strategy that best fits with their local context and workflow patterns. Although we do not comment on cost-effectiveness of LDCT screening, we outline the necessary costs associated with starting and sustaining a high-quality LDCT screening program.

Conclusions: Following the strategies delineated in this policy statement may help sites to develop comprehensive LDCT screening programs that are safe and effective.

Contents

Overview

This policy statement offers pragmatic strategies to assist medical centers and healthcare systems that seek to establish comprehensive low-radiation-dose computed tomography (LDCT) lung cancer screening programs that are safe and effective. The strategies listed herein address the nine core components of LDCT screening programs proposed by the American Thoracic Society (ATS) and American College of Chest Physicians (CHEST) and are consistent with the requirements for coverage of LDCT screening issued by the Center for Medicare and Medicaid Services (CMS; for Medicare beneficiaries) and the U.S. Preventative Services Task Force (USPSTF; for the privately ensured). For each component, we

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summarize multiple successful strategies for programs to consider, allowing individual programs to choose the strategy that best fits their local work environment. We conclude that:

- Implementation of LDCT screening begins with several planning steps, including formation of a multidisciplinary steering committee, engaging and educating primary care providers (PCPs), engaging local leadership, establishing a business model, and marketing the program.
- During the implementation phase, programs should be attentive to establishing systems to screen the right patients at the right time, to performing shared decision making to help eligible patients decide whether to undergo screening, and to standardizing processes for performing LDCT scans, reporting LDCT results, evaluating screen-detected nodules, communicating results to patients and their providers, and managing incidentally detected abnormalities.
- Smoking cessation is a critical corollary to LDCT screening, and LDCT screening programs should either incorporate counseling into the program or refer current smokers and recent quitters to external smoking cessation resources.
- To maintain performance, programs should collect data on patients undergoing LDCT screening in a registry that should be periodically reviewed to ensure the program is achieving quality metrics.

Introduction

The National Lung Screening Trial (NLST) demonstrated that LDCT screening of high-risk individuals can reduce lung cancer death (1). On average, NLST participants had a 1.66% risk of lung cancer death in the next 6.5 years; after three rounds of annual LDCT screening, that risk was reduced to 1.33% (a 20% relative risk reduction). Multiple organizations recommend LDCT screening for individuals at high risk for lung cancer (2–8).

However, LDCT screening may cause harm (Table 1), a salient concern given that most individuals undergoing screening do not have cancer and therefore cannot benefit from screening (9, 10). Moreover, LDCT screening is a complex process requiring careful coordination. The process begins with selecting appropriate candidates for screening and discussing screening trade-offs with patients, includes annual screening LDCT scans, and extends through evaluation of suspicious findings and treatment of screen-detected cancers.

To optimize the balance of benefits and harms at the population level, guidelines recommend LDCT screening be conducted in "effective screening settings" (2). The ATS and CHEST recently issued a statement delineating nine core programmatic components designed to ensure safe, effective screening (Table 2) (11). This companion statement summarizes strategies for designing and implementing comprehensive LDCT screening programs that include these core elements. The proposed strategies are consistent with the coverage requirements from CMS (12) and address the "considerations for implementation" noted by the USPSTF (3), which sets coverage requirements for private insurers (Table 3).

Methods

In developing this statement, we were guided by two implementation science frameworks: the RE-AIM model (13) and the Promoting Action on Research Implementation in Health Services (PARIHS) model (14). The RE-AIM model asserts that to translate evidence into practice in a sustainable way with fidelity to the original intervention, one must consider Reach, Effectiveness, Adoption, Implementation, and Maintenance (Table 2). The PARIHS framework asserts that successful implementation is a function of evidence, context, and facilitation. We drew on several sources of evidence: systematic reviews (10, 15–17) and guidelines (2–8, 18) on LDCT screening, national surveys of clinicians' perceptions about implementation of LDCT screening and formative evaluations of existing LDCT screening programs (19–21), and the expert opinion of our multi-stakeholder committee.

The committee Chair (R.S.W.) and Co-Chair (M.K.G.) convened a team with expertise on LDCT screening, pulmonary nodule evaluation, and/or implementation science, and early adopters of LDCT screening. To understand diverse contexts and facilitation strategies for implementing LDCT screening programs, we selected a multidisciplinary group with representation from primary care, pulmonology/interventional pulmonology, radiology, thoracic surgery, and nursing, from various settings, including academic centers, community hospitals, integrated health systems, and the Department of Veterans Affairs. We also included a patient and a consumer advocate. Conflicts of interest were disclosed and vetted through standard ATS procedures. During moderated sessions the committee discussed strategies to implement the ideal elements of comprehensive LDCT screening programs and iteratively drafted the statement.

Results

We have organized our results into three sections: planning, implementation, and maintenance (Table 2). First we address the

Table 1. Trade-offs of Low-Radiation-Dose Computed Tomography Screening for Lung Cancer*

Potential Benefits	Potential Harms
Mortality benefits	Harms related to test characteristics
20% relative decrease in lung cancer death (from 1.66 to 1.33%, or 3 fewer deaths per 1,000 screened)	Radiation exposure from screening CT
	False reassurance (aggressive cancers may develop in intervals between screening examinations)
7% relative reduction in all-cause mortality	Overdiagnosis of clinically insignificant cancers (15–20% of tumors detected)
Psychosocial benefits and behavioral changes	Harms related to findings of test
Reassurance if normal CT	False positives and other incidental findings
Teachable moment for smoking cessation	Potential harms from downstream evaluation of findings

Definition of abbreviation: CT = computed tomography.
**See* Reference 10.

Table 2. Phases of Program Development, Implementation, and Maintenance, Mapped to Corresponding American College of Chest Physicians/American Thoracic Society Core Programmatic Components of Low-Radiation-Dose Computed Tomography Screening Programs and to Elements of RE-AIM Implementation Science Model

Phase of Program and Associated Activities	CHEST/ATS Core Elements of Comprehensive Screening Program*	Corresponding RE-AIM Model Element and Definition†
Planning phase (formation of steering committee, outreach and education of PCPs, marketing to healthcare community and patients)	8. Patient and provider education	Reach: ensuring the intervention reaches the target population (i.e., patients at high risk of developing lung cancer) Adoption: ensuring the intervention is adopted by the healthcare community (i.e., PCPs and care team involved in evaluation and treatment of lung cancer)
Implementation phase (design and implementation of corresponding CHEST/ATS core elements)	1. Who is offered lung cancer screening 2. How often and for how long to screen 3. How the CT is performed 4. Lung nodule identification 5. Structured reporting 6. Lung nodule management algorithms 7. Smoking cessation 8. Patient and provider education	Effectiveness: designing intervention with fidelity to original intervention shown to be efficacious (i.e., design of LDCT screening programs similar to NLST screening intervention) Implementation: deploying intervention into clinical practice (i.e., operationalizing screening program elements and implementing into practice)
Maintenance phase (ensuring LDCT screening program continues to operate with high quality, safety, and effectiveness; feedback of results to providers and administrators)	8. Patient and provider education 9. Data collection	Maintenance: sustaining programs beyond the initial implementation and into the maintenance phase with high quality, fidelity, and safety

Definition of abbreviations: ATS = American Thoracic Society; CHEST = American College of Chest Physicians; CT = computed tomography; LDCT = low-radiation-dose computed tomography; NLST = National Lung Screening Trial; PCP = primary care physician; RE-AIM = Reach Effectiveness Adoption Implementation Maintenance.
*See Reference 11.
†See Reference 13.

planning steps to consider before launching screening programs (19). We then address each of the CHEST/ATS core elements needed to implement programs with fidelity to the NLST intervention (11). Finally, we discuss how to maintain programs that sustain quality, effectiveness, and safety.

Planning

Multidisciplinary Steering Committee

The experience of the early-adopting LDCT screening programs represented by our committee highlights the importance of considering local context and workflow issues. LDCT screening and evaluation and treatment of screen-detected nodules requires involvement of pulmonology, primary care, radiology, thoracic surgery, interventional radiology, and medical and radiation oncology. All these parties should be represented on a steering committee that plans the screening program. Some programs assembled a steering committee composed of members from an existing lung cancer tumor board, capitalizing on established working relationships, communication channels, and clinical expertise to create a highly functional multidisciplinary team. Steering committees should have clearly defined leaders to act as liaisons and champions for the program (19). A patient member may provide valuable perspective.

Engaging PCPs

A lesson learned from early-adopting LDCT screening programs is the importance of involving and educating PCPs from the outset. Because PCPs are tasked with preventive healthcare and see a broader patient base than specialists, it is critical to obtain PCP support to reach the target population for screening (20). Failure to include PCPs during planning, to solicit PCP concerns about implementation, to incorporate PCP feedback on workflow issues, or to educate PCPs on the trade-offs of LDCT screening may create barriers to implementing a successful program. These may include slow uptake of screening or overzealous uptake with referral of inappropriate patients. Successful programs performed early outreach to PCPs, including educational sessions that emphasized LDCT screening as a tool to improve quality of care and outcomes for individuals at high risk for lung cancer (19, 21).

Engaging Local Leadership and Establishing a Business Model

It is critical to ensure local hospital or healthcare system leadership supports the development of an LDCT screening program (19). Leadership can help spread the word, leverage support of reluctant departments, and provide necessary resources. Comprehensive screening programs require initial and ongoing investment of resources to be sustainable. A business model should be established early. The main costs are personnel related, but equipment and information technology (IT) costs must also be considered (Table 4) (20).

Program Marketing

Finally, marketing can help raise awareness of the screening program among the public as well as clinicians within and outside the health system (20). Some sites have hosted community screening days to provide a

Table 3. Requirements for Coverage by Medicare and Private Insurers

	Medicare (CMS Coverage Decision*)	Private Insurers (USPSTF Guidelines†)
Patient eligibility		
Age	55–77 yr	55–80 yr
Smoking history	⩾30 pack-years, with tobacco use within the prior 15 yr	⩾30 pack-years, with tobacco use within the prior 15 yr
Comorbid conditions	Not specified	No conditions that substantially limit life expectancy
Symptoms	No symptoms suggestive of lung cancer	No symptoms suggestive of lung cancer
Shared decision making	Required: Conducted in office visit by physician or qualified nonphysician (physician's assistant, nurse practitioner, clinical nurse specialist) Use of decision aid(s) Discussion of benefits, harms, follow-up testing and importance of adherence, overdiagnosis, false-positive rate, total radiation exposure, willingness and ability to undergo evaluation and treatment	Recommended
Radiologist eligibility	Current certification with American Board of Radiology (or equivalent) Training in diagnostic radiology and radiation safety Supervision and interpretation of ⩾300 chest CT scans in prior 3 yr Participation in CME as required by ACR	Not specified
Screening facility eligibility	Accredited advanced diagnostic imaging center with training and experience in LDCT screening Use of LDCT with ⩽3.0 mGy for standard size patient Use of standardized reporting with criteria for lung nodule identification and classification Submission of data on all LDCT screening to CMS-approved national registry	Suggest that LDCT screening may be more effective in "clinical settings that have high rates of diagnostic accuracy using LDCT, appropriate follow-up protocols for positive results, and clear criteria for doing invasive procedures"
Smoking cessation counseling	Must be available	Recommended

Definition of abbreviations: ACR = American College of Radiology; CME = continuing medical education; CMS = Center for Medicaid & Medicare Services; CT = computed tomography; LDCT = low-radiation-dose computed tomography; USPSTF = United States Preventative Services Task Force.
*See Reference 12.
†See Reference 3.

needed service and increase awareness of the program. Other marketing strategies include direct-to-consumer advertising, informational websites, and telephone access lines to permit self-referrals (19, 20, 22). Any direct-to-consumer advertising must be clear about the target population (high-risk individuals) and should not be coercive or overly optimistic about potential benefits (23).

Implementation

Establishing Systems to Offer Screening to the Right People at the Right Time

CHEST/ATS Components 1: Who is offered lung cancer screening; 2: How often and for how long to screen

The CHEST/American Society of Clinical Oncology guidelines, endorsed by the ATS (2), suggest that screening be offered to individuals who meet NLST criteria (aged 55–74 yr, who smoked within the past 15 yr, with at least 30 pack-years total, without severe comorbidities that limit life expectancy). However, we recognize that many programs will follow criteria set by payers. Both CMS (12) and the USPSTF (3) follow the NLST criteria but extend the upper age limit: Medicare beneficiaries are covered for LDCT screening through age 77 years and the privately insured through age 80 years. Guidelines recommend offering annual LDCT screening until the individual reaches the upper age limit, has been tobacco-free for more than 15 years, or is no longer healthy enough to benefit from screening (2, 3).

Perhaps the most important question for implementation is how to ensure that screening is provided to appropriate individuals (20–22). The purpose of limiting the scope of screening is to ensure that benefits outweigh harms; individuals at lower risk of lung cancer or with limited life expectancy are less likely to benefit, and therefore the balance of benefits to harms is less favorable (24, 25). How best to incorporate information about how the risk:benefit ratio changes depending on personal characteristics (e.g., comorbidities) has not been resolved but is important to consider when selecting patients for screening or prioritizing resources (26).

Table 4. Program Costs to Be Considered

Personnel/human effort
Core programmatic functions that require human effort; often conducted by a midlevel provider serving as screening coordinator, but sometimes tasked to PCPs or other clinicians
To serve as a point of contact for referring clinicians
To confirm eligibility of patients referred for screening
To maintain the registry of screened patients
To follow up LDCT results and confirm the ordering clinician and/or PCP is aware of these results
To ensure evaluation of any screen-detected nodules is appropriate (either by ordering the next test directly or by checking that the appropriate test is ordered by the treating clinician)
To intervene if the patient does not follow through with evaluation (at a bare minimum by contacting the ordering provider and often by also contacting the patient directly to encourage adherence and to reschedule the test at a time convenient to the patient)
To counsel and communicate with the patient about screening
Initial shared decision making about whether to undergo LDCT screening
Notification of results
Discussion of smoking cessation
Other associated personnel costs
Effort of multidisciplinary steering committee members to govern program
Effort of clinicians surrounding screening itself (e.g., radiology effort to conduct and read LDCT scans)
Effort of program administrator (e.g., to schedule appointments, coordinate mailings)
Equipment costs
LDCT scanner(s)—number needed depends on volume of patients screened
Information technology costs
Costs associated with developing and maintaining registry (database) of screened patients
Costs associated with developing and maintaining any EMR-based tools
Costs associated with integrating structured reporting system
Costs associated with generating periodic reports of quality metrics from registry data
Marketing costs
Costs associated with promoting the program within and outside of the medical center (e.g., grand rounds, direct-to-consumer advertising, telephone access line, website)
Mailing costs
Mailings to patients (e.g., appointment reminders, results letters, educational brochures)
Costs associated with smoking cessation services
Costs to produce (or obtain) and distribute smoking cessation brochures
Training of personnel to deliver smoking cessation interventions (if offered directly through screening program)
Costs associated with downstream evaluation of screen-detected nodules and other abnormalities
PET scanner(s)
Clinic visits directly related to nodule evaluation
Biopsy services (bronchoscopy, advanced bronchoscopic procedures [e.g., endobronchial ultrasound-guided transbronchial needle aspiration], interventional radiology procedures [e.g., transthoracic needle biopsy], surgical biopsy)

Definition of abbreviations: EMR = electronic medical record; LDCT = low-radiation-dose computed tomography; PCP = primary care physician; PET = positron emission tomography.

Electronic medical record tools. Several early-adopting LDCT screening programs with high-functioning electronic medical records (EMRs) have successfully implemented EMR-based tools as a first-pass step to limit screening to individuals who meet eligibility criteria and to reinforce education of referring providers. These include clinical reminders that are only displayed for eligible patients and decision support systems that prompt providers to confirm patient eligibility when ordering a screening LDCT (21, 27). Implementing EMR-based tools requires a commitment from IT to create tools and maintain their performance (19).

Human review. Human review can reinforce (or replace, if insufficient IT capability) EMR-based strategies. In some programs, the screening program coordinator (often a nurse or midlevel provider) confirms eligibility with the patient directly or through chart review as a gate-keeping step (19, 22). An added advantage is that human review can identify comorbidities that might limit cancer treatment or life expectancy—contraindications that cannot be readily detected by EMR-based strategies. Finally, human review is necessary if there is a mechanism for patients to self-refer for screening, as these individuals would be circumventing EMR-based gatekeeping. Human review can also ensure that self-referred patients have an appropriate clinician (e.g., PCP, pulmonologist) to receive the results of the screening LDCT; if the patient cannot identify such a clinician, the screening program should offer to assign one. In many health systems, the onus of human review may fall on PCPs, again highlighting the need for PCP engagement and education.

Strategy for those who do not meet eligibility criteria. Screening individuals at lower risk for lung cancer or individuals with severe comorbidities will likely create an unfavorable balance of benefits to harms

(2, 28). It is critical to educate and reassure low-risk patients and their providers (20). Although verbal counseling may be ideal, some programs use personalized letters supplemented by generic educational brochures (e.g., Consumer Reports/ Choosing Wisely patient page [29]). Targeted feedback should be provided to clinicians who repeatedly refer low-risk individuals for screening.

Deciding Whether to Screen: Shared Decision Making

CHEST/ATS Component 8: Patient and provider education

Guidelines recommend (2–8), and CMS requires (12), shared decision making—discussing the potential benefits and harms of LDCT screening with patients and incorporating patient preferences. The purpose of shared decision making is not to convince every patient to undergo LDCT screening but rather to allow individuals to weigh trade-offs based on their personal risk profiles and make informed choices about whether LDCT screening is right for them. It may be informative for programs to monitor how often eligible individuals are offered shared decision making and how often informed patients accept LDCT screening.

Designating and educating clinicians to perform shared decision making. An important consideration is who will perform shared decision making. Some programs have tasked PCPs with shared decision making at the time of referral for LDCT screening (19). The advantage is that patients have a prior relationship with PCPs that may facilitate these conversations. However, PCPs may be less familiar with the nuances of LDCT screening and have competing demands during visits (21, 33–35). Accordingly, some programs have empowered screening coordinators to perform shared decision making (30). Health educators may help engage patients in shared decision making (31). Of note, CMS requires that shared decision making occur during an in-person visit with a physician, midlevel provider, or clinical nurse specialist (Table 3) (12).

A critical early step is educating the clinician(s) who will conduct shared decision making (20, 22). Clinicians should be well-versed in the benefits and harms of LDCT screening (Table 1) and how trade-offs vary depending on the patient's personal risk profile and comorbidities (24, 26). Important elements to include in a conversation before a screening decision is made (32) are that nodules are commonly found (approximately 25–50% of screening examinations [33]), that most (∼95%) nodules detected by screening are benign (1), and that the detection of a lung nodule and its subsequent evaluation may cause distress, physical complications, or other harms (17, 39–44).

Available tools. Fortunately, there are tools to help clinicians remember the relevant facts during discussions with patients (34), and CMS requires use of such a tool to facilitate shared decision making (Table 3) (12). The American Thoracic Society has developed a patient decision aid, available at http://www.thoracic.org/patients/patient-resources/resources/decision-aid-lcs.pdf. Validated risk calculators (24, 35–41) may be particularly useful to tailor the expected trade-offs of LDCT screening to the individual and have been incorporated into web-based decision tools (Figures 1 and 2). It is reasonable to supplement verbal discussions with plain language materials (21, 24, 25) or video decision aids (42) the patient can review at home. Of note, these tools are still undergoing testing (42, 43), and the best format for decision tools remains unclear (44).

The Screening Process: Standardizing LDCT Screening and Follow-up of Abnormal Findings

CHEST/ATS Components 3: How the CT is performed; 4: Lung nodule identification; 5: Structured reporting

Standardizing several elements can improve quality of care in LDCT screening programs (19).

LDCT performance. To minimize patient harms, protocols to reduce radiation exposure have been developed, such as the technical specifications delineated by the American College of Radiology and Society of Thoracic Radiology (45). Per these specifications, screening scans should be noncontrast helical studies performed with radiation dose less than or equal to 3 mGy for most patients, acquired and viewed at less than or equal to 2.5-mm slice thickness (<1 mm preferred). All technicians responsible for performing screening LDCT scans should be trained in the protocol.

Structured reporting. Because interpretation of LDCT results and recommendations for follow-up can vary between radiologists (46–48), and because radiologists' recommendations are the strongest predictor of nodule evaluation received (49), standardized reports that provide specific recommendations linked to the findings (20–22) may improve care. To facilitate a standardized process, the American College of Radiology developed a structured reporting system similar to that used for mammography: the Lung Imaging Reporting and Data System (Lung-RADS) (50). Lung-RADS categorizes LDCT findings based on likelihood of cancer and links each category with specific recommendations. Although reducing false positives, Lung-RADS may decrease sensitivity compared with NLST criteria, and its effects on clinical endpoints such as lung cancer mortality are unknown (51, 52). Some programs have established similar structured reporting systems based on other nodule evaluation algorithms (21). Structured reports may help promote guideline-concordant nodule evaluation (53). It may be beneficial to perform a quality check using a training set of screening LDCTs to ensure consistent application of the structured reporting system, particularly if radiologists who are not specifically trained in thoracic imaging read screening LDCTs.

Evaluation of screen-detected nodules. CHEST/ATS Component 6: Lung nodule management algorithms

Several guidelines and algorithms have been proposed for pulmonary nodule evaluation (4, 50, 54, 55). Adherence to these algorithms can reduce resource use associated with nodule evaluation and does not appear to worsen clinical outcomes (49, 52). One approach being studied to risk stratify nodules and facilitate evaluation is volumetric analysis (56, 57).

One of the biggest perceived barriers to successful implementation of LDCT screening programs is concern about who will direct evaluation of screen-detected nodules. Although some early-adopting sites defer nodule evaluation to pulmonologists given their expertise, most agreed that the volume could quickly overwhelm pulmonary workload (27). Many early-adopting programs have tasked PCPs with evaluation of small lung nodules (≤8 mm), assisted (often heavily) by automated systems or a screening coordinator trained on nodule evaluation algorithms (19, 58).

Subcentimeter nodules. The majority of screen-detected pulmonary nodules will have a low likelihood of malignancy, and guidelines suggest that

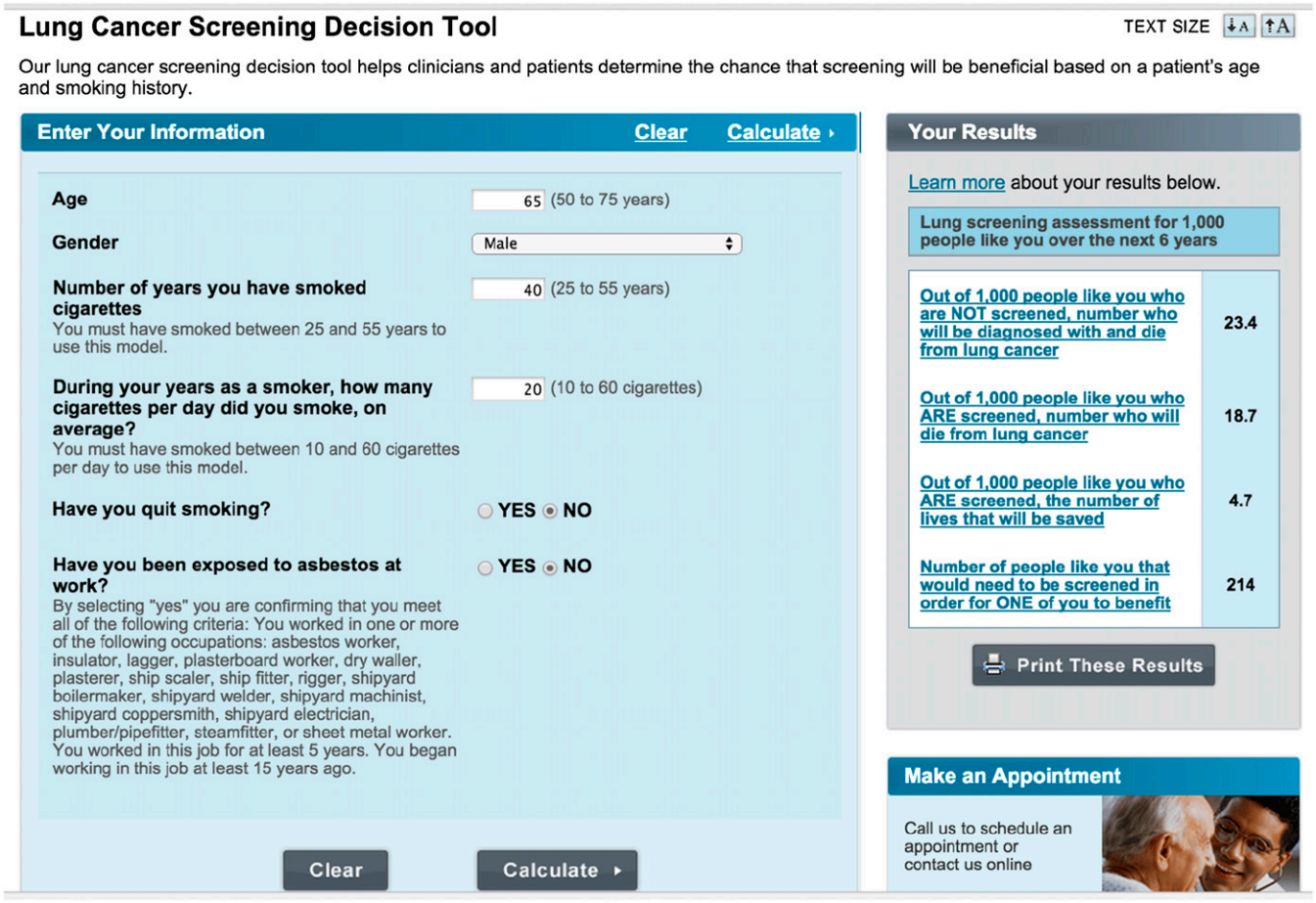

Figure 1. Screen shots of online calculator, developed by the Memorial Sloan Kettering Cancer Center, to predict personalized expected benefits of low-radiation-dose computed tomography screening. This tool is available at http://nomograms.mskcc.org/Lung/Screening.aspx, and the risk prediction model is supported by References 35–37. Reproduced by permission from http://nomograms.mskcc.org/Lung/Screening.aspx.

nodules less than or equal to 8 mm can be safely followed with radiographic surveillance without invasive testing (4, 50, 54, 55). Assuming the nodule does not enlarge during surveillance, guidelines delineate straightforward algorithms of serial LDCT scans at regular intervals, which can be followed by PCPs or other clinicians not specifically trained in pulmonary medicine. Outreach and educational presentations can enhance PCP comfort with nodule evaluation algorithms.

Higher-risk nodules. For larger pulmonary nodules (>8 mm) or small nodules that grow during surveillance, pulmonologists and other specialists often become involved in evaluation to assess the need for invasive testing. Many programs involved a multidisciplinary tumor board, or a dedicated pulmonary nodule review between radiology and pulmonology, to assist in decision making surrounding evaluation of nodules with a higher likelihood of cancer (20–22).

Adherence with follow-up. Regardless of nodule size, it is essential to establish mechanisms to prevent loss to follow-up. Two such strategies are development of registries with data on all patients who have undergone LDCT screening (a CMS requirement [12]) and designation of a screening program coordinator (58, 59).

Registry. Registries help monitor recommended follow-up, whether for repeat screening in 1 year or earlier testing for evaluation of a screen-detected nodule (58, 60). Some programs are facilitating entry of patients into registries via automated methods to identify screen-detected nodules through the EMR and/or by tasking the interpreting radiologist with flagging positive scans (58, 61). However, even the most advanced EMR-based registries require human review to check, maintain, and update the registry (58). The registry should ideally contain information on patient and nodule characteristics, the recommended evaluation, adherence to evaluation, and test results (58). The registry should be maintained in a database that can be sorted to facilitate clinical care and quality monitoring.

Coordinator. Simply maintaining a registry is insufficient to ensure all patients receive appropriate care (62). Thus, it is important to have a clinician who proactively directs, or at least monitors and intervenes on, the screening and evaluation process (58), performing the core programmatic functions in Table 4. Many sites designate a midlevel provider or nurse to perform these activities (63); however, sites may opt to assign these responsibilities to a pulmonologist or other physician with a specific interest in LDCT screening. The coordinator should have unfettered access to the clinical director(s) of the screening program and an established relationship with the specialists responsible for nodule

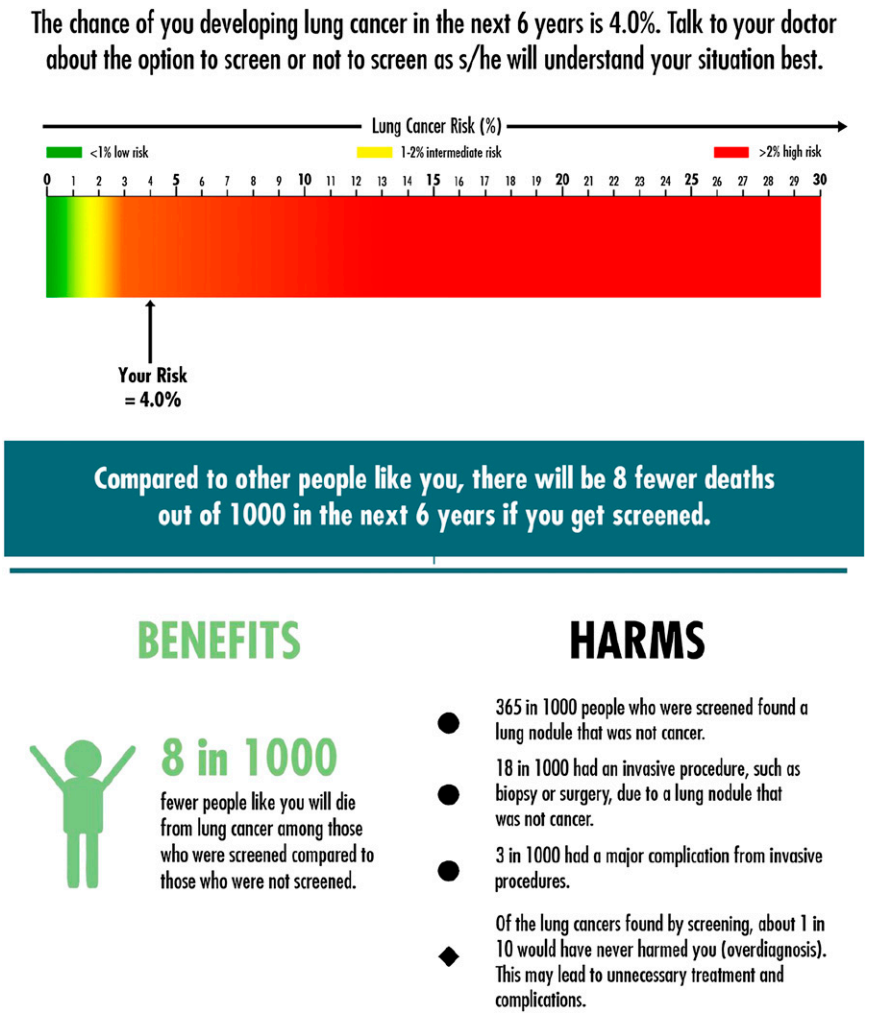

Figure 2. Screen shots of patient decision aid with personalized information about trade-offs of low-radiation-dose computed tomography screening. This tool is available at http://shouldIscreen.com, and its development and validation are described in References 43 and 84. Reproduced by permission from http://shouldIscreen.com.

evaluation and lung cancer care to help advise and troubleshoot any questions that arise.

Communicating results to patients. Timely communication with patients and sensitive delivery of LDCT results is of paramount importance. Patients with both screen-detected and incidental nodules have expressed dissatisfaction with communication that is either vague, offering little information about the nodule or likelihood of cancer, or, conversely, overly technical with medical jargon (21, 40, 42). Standardizing and improving communication of results may improve patient satisfaction and reduce distress (64).

Many screening programs inform patients of normal LDCT results via letter (30). Registries linked to EMRs can facilitate communication by automatically generating templated letters. For patients with indeterminate results (i.e., a nodule that requires evaluation), any written notification of results should be supplemented with a phone call or in-person visit (65), allowing patients the opportunity to ask questions and clinicians the opportunity to allay the immediate distress that an abnormal finding may provoke (17, 64). For patients who have a nodule detected with a moderate or high likelihood of malignancy, communication should occur in person. Information on smoking cessation and a plain-language brochure addressing common questions about LDCT screening and nodule evaluation can be useful; these materials could be provided directly to patients and/or posted on EMR-based patient portals.

Other incidental findings. Of note, LDCT screening can also identify abnormalities outside the lung that may require further evaluation (e.g., thyroid nodules, coronary calcifications). The screening program should ensure PCPs are aware of any incidental findings so that they can be evaluated as indicated following existing guidelines.

Corollary to Screening: Smoking Cessation Counseling

CHEST/ATS Component 7: smoking cessation

Because smoking cessation clearly reduces mortality (66), guidelines recommend (2–8) and CMS requires (12) that smoking abstinence efforts be integrated into LDCT screening programs for all current smokers and recent quitters (who have high recidivism rates). Simply undergoing LDCT screening is not enough to increase abstinence from tobacco; in trials, no differences in smoking cessation or relapse rates were observed between screening and control arms (16). However, the best strategy to optimize smoking abstinence in the setting of LDCT screening is unknown (67, 68).

Written materials on the benefits of smoking cessation with links to online resources (69) and telephone hotlines (e.g., 1-800-QUIT-NOW) may be useful interventions (21, 70). More intensive interventions (e.g., nicotine replacement therapy or other pharmacologic treatments [71], in-person counseling [72, 73], financial incentives [74], mobile technology-based interventions [75]) have been found to be safe and effective in other contexts and are recommended in smoking cessation guidelines (76, 77). Screening programs may offer such interventions directly or provide referrals to an affiliated smoking cessation program. Of note, LDCT screening studies have shown limited use of optional smoking cessation services (67, 78); consequently, some programs require enrollment in smoking cessation programs for current smokers and recent quitters as a condition of LDCT screening.

When is the optimal "teachable moment" for smoking cessation? Although one study suggested smoking cessation interventions were more effective before screening (79), others found that individuals with abnormal findings were more likely to quit than those with normal results (16, 80, 81). Recognizing that tobacco dependence is

a disease that requires repeated interventions, some programs offer interventions at multiple time points: the initial referral for screening, results delivery, and 3 to 4 weeks after results delivery (20, 22).

One promising strategy may be to train clinicians who discuss LDCT screening with patients (e.g., screening coordinators) to deliver tailored smoking cessation interventions (e.g., motivational interviewing, nicotine replacement therapy). Resources are available online to train clinicians in these skills (82). It may be useful to highlight to patients the link between smoking and findings from screening LDCT, analogous to informing patients of their spirometric "lung age" as a tool to promote smoking cessation (16, 83).

Maintenance

CHEST/ATS Component 9: Data collection

Periodic review of quality metrics can help ensure screening programs are operating as intended (58). The ATS and CHEST have proposed quality metrics to be monitored annually, including: (*1*) appropriateness of who is screened (≥90% should meet criteria); (*2*) adherence with structured reporting by the radiologist (≥90% should use structured reports); (*3*) appropriateness of nodule evaluation (tracking of how many patients receive full course of surveillance, how many invasive tests are performed and how many complications occur, how many cancers are diagnosed and their stages); and (*4*) adherence with smoking cessation interventions (how many smokers were offered and participated in interventions) (11). These data can be collected and maintained in the registry. If periodic review of these data reveals deficiencies, the steering committee should make a plan for corrective action. Meanwhile, high performance on quality metrics can serve to reinforce enthusiasm for the program if shared with staff and referring providers (19). Of note, CMS requires that data on all LDCT screening performed at a site be reported to a national registry (12).

Conclusions

We have outlined pragmatic strategies to implement comprehensive programs with fidelity to the LDCT screening intervention shown to be efficacious in the NLST. Recognizing that "one size does not fit all," we have provided guidance on different strategies to achieve the nine core components of effective screening programs (11) to allow sites to tailor programs to fit their local context. Although we have not discussed explicit cost calculations, ensuring adequate personnel and resources are dedicated to the screening program is critical to developing and sustaining high-quality, smoothly functioning programs and should not be underestimated. The experience of early-adopting screening sites demonstrates that the strategies outlined herein can produce effective and successful programs that are consistent with guideline recommendations for LDCT screening (20–22, 58). ■

This official statement was prepared by an *ad hoc* subcommittee of the ATS and CHEST. The committee included representation from several ATS assemblies (Thoracic Oncology, Clinical Problems, Nursing, and Behavioral Sciences and Health Services Research). We also included a patient who underwent LDCT screening (identified through the ATS Public Advisory Roundtable) and a medical consumer advocate representing the Center for Medical Consumers.

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