

Shared decision-making conversations and smoking cessation interventions: critical components of low-dose CT lung cancer screening programs

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Abstract: Lung cancer remains the world's deadliest cancer despite efforts to decrease smoking rates. Lung cancer screening (LCS) with low-dose computed tomography (LDCT) was shown to reduce lung cancer deaths by 20%. Screening with LDCT comes with potential harms including a high rate of false-positive test results, subsequent follow-up procedures, and radiation exposure. For some patients, the potential benefits associated with screening may be outweighed by the harms. The decision to screen must therefore take into consideration patients' risk of developing lung cancer, comorbidities that may prevent diagnostic procedures or curative surgery, and their values and preferences regarding the benefits and harms of screening. A process called shared decision-making (SDM) is recognized as a crucial feature of LCS. SDM is a patient-centered approach where healthcare providers provide best clinical evidence and then work together with patients to discern if the screening process aligns with the patient's values and preferences. Unfortunately, clinician SDM skills are often of poor quality which can lead to patients making uninformed decisions. Decision support tools that help patients make informed decisions and increase SDM on LCS are available. In 2015, the Centers for Medicare & Medicaid Services issued a coverage memo for LCS that contained an unprecedented requirement: an initial patient counseling and SDM visit with the use of at least one decision aid must occur for screening services to be reimbursed. This review focuses on SDM and suggests ways to increase the prevalence and effectiveness of SDM in LCS programs. Stopping smoking greatly reduces a person's risk for developing lung cancer, and smoking cessation messages in LCS guidelines from major medical organizations and interventions in LCS programs are explored. LCS has come of age; so too has SDM as it is an integral part of LCS programs.

Keywords: Decision aids; lung neoplasms; screening; shared decision-making (SDM); smoking cessation

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Introduction

Every year, more deaths occur from lung cancer than from colon, breast, and prostate cancers combined. Lung cancer is the most common cancer worldwide, accounting for 1.8 million new cases and 1.6 million deaths in 2012 (1). Lung

cancer is often diagnosed at an advanced stage, resulting in a 5-year survival rate of 16% (2). Screening and detection of earlier-stage disease has improved the survival of patients with the aforementioned non-lung cancers; an effective screening method for lung cancer was lacking until recently.

In the words of the lung cancer screening (LCS) and surveillance task force of the American Association for Thoracic Surgery (AATS), “...at this time and for the first time in medical history, we can say, ‘lung cancer screening—the time has come.’” (3). This statement stems from the evidence that annual screening for lung cancer with low-dose computed tomography (LDCT) can reduce lung cancer mortality in high-risk individuals. However, LDCT lung screening is not without harms and patients need to be educated about the potential benefits, harms, and limitations of screening to make informed decisions about LCS.

This review provides: (I) a brief summary of a large randomized controlled trial (RCT) on LDCT LCS that has changed the screening landscape; (II) various LCS guidelines established by professional and medical organizations, with particular attention given to smoking cessation and shared decision-making (SDM); and (III) SDM definitions and evidence of its ability to increase patient-centered care, with tools for SDM. The paper also suggests implementation strategies for incorporating SDM for LCS in clinical settings.

Overview of the evidence for LCS with LDCT

Given the public health burden of lung cancer, an effective screening strategy that detects early-stage disease has been sought for decades. Earlier screening tests, i.e., sputum cytology and chest radiographs, were able to detect small, earlier stage tumors. However, screening with these modalities did not decrease the number of deaths from lung cancer nor the number of advanced lung cancers (4). Thus, they are not recommended for LCS.

RCTs and observational studies have shown that LCS with LDCT reduces deaths from lung cancer (4-6). Two small European trials, the Detection and Screening of Early Lung Cancer by Novel Imaging Technology and Molecular Essays (DANTE) (7,8) and the Danish Lung Cancer Screening Trial (DLCST) (9) were underpowered enrolling 2,472 and 4,104 individuals, respectively, and considered of fair-quality. Another European trial, the Multicentric Italian Lung Detection (MILD), is considered of poor quality due to concerns about the adequacy of randomization (10). The National Lung Screening Trial (NLST), published in 2011, is the largest RCT and showed LDCT for LCS reduced lung cancer-related deaths by 20% (11). The NLST randomized 53,454 current and former smokers to three annual screenings (baseline, 1 year and 2 years after baseline) with LDCT or chest radiography with a median

follow-up of 6.5 years. The NLST had 90% power to detect a 21% decrease in lung cancer-specific mortality in the LDCT group compared to the control group. Greater reduction in lung cancer-specific mortality with LDCT may have been seen if the control group received no screening or if annual LDCT examinations continued beyond 3 years.

To save one life, about 320 people would need to be screened based on the NLST data (11). In the systematic review on the benefits and harms of LDCT LCS by Bach *et al.*, the authors conclude that “screening a population of individuals at a substantially elevated risk of lung cancer most likely could be performed in a manner such that the benefits that accrue to a few individuals outweigh the harms that many will experience.” (4). This statement attests to the fact that LCS is not without harms, such as false-positive results, which can lead to invasive procedures and potential complications (4,6). In the NLST, 96.4% of positive screening results were false positives, and most cases were resolved with one follow-up LDCT scan (12). Only about 1.9% of NLST participants had to undergo biopsy to determine if abnormalities on imaging identified by screening were in fact cancer (12). Other harms include overdiagnosis (the diagnosis of a cancer that would never have caused harm in a person’s lifetime), overtreatment, false-negative results, incidental findings, and radiation exposure.

Guidelines on LDCT LCS and attention to SDM and smoking cessation

In 2014, the U.S. Preventive Services Task Force (USPSTF) issued a grade B recommendation for annual LCS with LDCT for individuals that meet the criteria listed in *Table 1* (14). The USPSTF found that LDCT had a net benefit, albeit moderate, when performed annually in patients who are at high risk for lung cancer based on pack-year smoking history, age, and years since quitting smoking; the available evidence for the efficacy of LDCT screening in decreasing lung cancer mortality was deemed of moderate certainty. Many major medical and professional societies have endorsed LCS with LDCT, including the American Cancer Society (15), American College of Chest Physicians (16,17), American Thoracic Society (16), Society of Thoracic Surgeons (18), American College of Radiology (19), American Society of Clinical Oncology (20), and the American Lung Association (21). The American Academy of Family Physicians concluded there is currently insufficient evidence to recommend for or against screening for lung cancer with LDCT among high-risk individuals (22).

Table 1 Lung cancer screening eligibility criteria

Criteria	U.S. Preventive Services Task Force	Centers for Medicare & Medicaid Services ^a
Relevant group	Persons with private health insurance	Medicare and Medicaid beneficiaries
Age (years)	55–80	55–77
Smoking status		Current or former ^b smoker
Smoking history		≥30 pack-years ^c
Lung cancer signs		Asymptomatic (no signs of lung cancer)
Screening frequency		Yearly
When to stop screening	The patient exceeds upper age criterion, has not smoked for more than 15 years, and/or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative surgery	

Source: adapted from *Lung Cancer Screening: A Summary Guide for Primary Care Clinicians* (13).^a, CMS requires that the beneficiary receive a written order for LDCT by a physician or non-physician practitioner, as outlined in CMS policies for initial or subsequent LDCT lung cancer screening; ^b, former smokers must have quit within the last 15 years; ^c, number of pack-years = (average number of packs smoked per day) × (years smoked). Note there are 20 cigarettes in one pack. CMS, Centers for Medicare & Medicaid Services; LDCT, low-dose computed tomography.

In 2015, the Centers for Medicare & Medicaid Services (CMS) issued a coverage determination for LCS with LDCT (23). After reviewing relevant clinical evidence and soliciting public comments, CMS found sufficient evidence to add LDCT lung screening as a preventive service benefit under the Medicare program. While annual screening is covered for beneficiaries who meet the criteria outlined in *Table 1*, an unprecedented prerequisite must occur: an LCS counseling and SDM visit using one or more decision aids. The beneficiary must receive a written order for LDCT LCS during a counseling and SDM visit provided by a physician, physician assistant, nurse practitioner, or clinical nurse specialist. The SDM and counseling visit is coded and reimbursed separately from the annual LDCT LCS to emphasize the importance of patient selection.

SDM components of various professional organizations are highlighted in *Table 2*. Benefits of screening need to be discussed, which include early detection of disease and potential reduction in treatment-related morbidity compared to late-stage cancer therapy, and reduced lung cancer-specific mortality. Potential harms must also be addressed which include the high false-positive rate of LDCT and the associated follow-up testing and procedures, overdiagnosis, and radiation exposure. Other harms must be taken into consideration, including anxiety from indeterminate results and the work up of incidental findings (e.g., coronary artery disease and emphysema), and financial concerns. Thus, the SDM process must integrate the knowns and unknowns of lung screening, along with patients' values, preferences, health and functional status,

and eligibility for screening, for them to make informed decisions on LCS.

The counseling requirements of the visit include emphasizing the commitment to annual LDCT screening until patients no longer meet screening criteria, discussion of patients' comorbidities and their ability or willingness to undergo diagnosis and treatment, and providing information on smoking cessation. While the initial LDCT lung screening service must include the counseling and SDM visit, subsequent annual screening does not require one.

Although CMS outlines components of the SDM and counseling visit, major uncertainties exist. Specific decision aids were not mentioned and CMS has not issued an "approved" decision aid. Smoking cessation counseling and interventions are emphasized during routine primary care visits as part of the counseling visit before screening, and CMS lists eligibility criteria for imaging facilities to "make available" smoking cessation interventions; however, no specific details are provided on type, intensity or duration of interventions which should be provided.

Guidelines from major organizations also highlight the need for smoking cessation interventions in LCS programs (*Table 2*). Some guidelines briefly mention smoking cessation, while others like the USPSTF recommendation statement go into greater detail. Smoking cessation is the most effective way of decreasing one's risk of lung cancer. For instance, Halpern *et al.* found that with increasing age, adults who quit smoking between the ages of 30 to 49 years had only a slightly higher risk of dying from lung cancer compared to nonsmokers, while those who quit between

Table 2 Statements from professional organizations on smoking cessation and shared decision-making

Organization	Smoking cessation (SC) excerpts	Counseling/SDM excerpts
United States Preventive Services Task Force (14)	Screening cannot prevent most lung cancer-related deaths, and SC remains essential	The National Cancer Institute has developed a patient and physician guide for SDM for LCS based on the NLST (website given)
	SC substantially reduces a person’s risk for developing and dying of lung cancer	SDM is important for persons within the population for whom screening is recommended
	Current smokers should be informed of their continuing risk for lung cancer and offered cessation treatments	The decision to begin screening should be the result of a thorough discussion of the possible benefits, limitations, and known and uncertain harms
	Screening with LDCT should be viewed as an adjunct to tobacco cessation interventions	
	[Many resources are suggested including a CDC website on SC, information on quit lines, counseling services (often provided at no cost to users; can be tailored to individual clients), and medications]	
National Comprehensive Cancer Network (24)	Cessation of tobacco smoking decreases the risk for lung cancer	The risks and benefits of LCS should be discussed with the individual before a screening LDCT scan is performed
	Smokers, including those undergoing LCS, should always be encouraged to quit smoking tobacco	Shared patient/physician decision-making may be the best approach before deciding whether to do LDCT lung screening, especially for patients with comorbid conditions. SC counseling is recommended
	(Website for NCCN guidelines for SC is given)	SDM aids may assist when determining if screening should be recommended. In addition, risk calculators may be used to assist with decision-making for group 2 in the NCCN Guidelines
	Former smokers should be encouraged to remain abstinent	Before recommending LCS, shared patient/physician decision-making is recommended so that patients have a full understanding of all risks and benefits related to screening with LDCT
	LCS is not a substitute for SC	
	Programs using behavioral counseling combined with medications that promote SC (approved by the FDA) can be very useful in helping individuals to quit smoking	
American Association of Thoracic Surgery (3)	LDCT provides an opportunity for a “teachable moment” for tobacco cessation	Not mentioned
	It is most desirable to create a program for lung cancer screening that also supports SC	

Table 2 (continued)

Table 2 (continued)

Organization	Smoking cessation (SC) excerpts	Counseling/SDM excerpts
American Cancer Society (15)	SC counseling remains a high priority for clinical attention in discussions with current smokers, who should be informed of their continuing risk of lung cancer	A process of informed and SDM with a clinician related to the potential benefits, limitations, and harms associated with screening for lung cancer with LDCT should occur before any decision is made to initiate LCS
	Screening should not be viewed as an alternative to SC	Eligible patients should make the screening decision together with their health care provider. Helping individuals to clarify their personal values can facilitate effective decision-making
	Numerous studies have demonstrated that SC measurably reduces the risk of developing and dying from lung cancer compared with continuing smoking	Many clinicians are not experienced in or prepared to guide patients through the SDM process around screening. Developing this competency is a rapidly emerging obligation for the primary care clinician and their clinical teams
	Vigorous SC efforts must accompany LDCT screening for adults who are current smokers, and further investigations are warranted to determine best practices for promoting cessation among smokers seeking LCS	Cancer control organizations and specialty societies must devote resources to ensuring that clinicians are prepared to distinguish those patients who are eligible for screening from those who are not, and to support SDM
American College of Chest Physicians (17)	Screening for lung cancer is not a substitute for stopping smoking. The most important thing patients can do to prevent lung cancer is not smoke	Counseling should include a complete description of potential benefits and harms, so the individual can decide whether to undergo LDCT screening
		If primary-care physicians are asked to play the primary role in counseling patients about whether they should be screened as well as in the interpretation of results, a major educational effort is needed
		How individuals view the risk of cancer and risk of radiation or invasive interventions can also vary. It is important that these individual decisions are made rationally and not out of fear. We suggest a good (screening) program offers risk assessment and counseling
American Thoracic Society (16)	The mortality reduction that could be achieved by SC exceeds that from LCS	Providers must... be capable of helping their patients make value-based decisions about being screened
	A LCS program must be integrated with a SC program	A LCS program should educate providers so that they can adequately discuss the benefits and harms of screening with their patients
	A LCS program should collect data related to the SC interventions that are offered to active smokers enrolled in the screening program	A LCS program should develop or use available standardized education materials to assist with the education of providers and patients
American Society of Clinical Oncology (4)	Screening for lung cancer is not a substitute for stopping smoking. The most important thing patients can do to prevent lung cancer is not smoke	Counseling should include a complete description of potential benefits and harms... so the individual can decide whether to undergo LDCT screening
	SC should be considered a valuable component of any screening program	The fear and anxiety that patients can experience once there is even a slight suspicion of lung cancer highlights the need for careful education of LDCT participants
American Academy of Family Physicians (22)	In the words of the NLST authors: " <i>The cost-effectiveness of low-dose CT screening must also be considered in the context of competing interventions, particularly smoking cessation.</i> "	A SDM discussion between the clinician and patient should occur regarding the benefits and potential harms of screening for lung cancer

SDM, shared decision-making; LCS, lung cancer screening; LDCT, low-dose computed tomography; NLST, National Lung Screening Trial; NCCN, National Comprehensive Cancer Network; CDC, Centers for Disease Control and Prevention; FDA, U.S. Food & Drug Administration.

the ages of 50 to 64 years retained the risk attained at the time of cessation (25). While LDCT LCS is an important means of reducing lung cancer mortality, smoking cessation or continued abstinence for past smokers is of primary importance.

Guidelines vary in eligibility requirements and risk factors for lung cancer. CMS largely utilizes the NLST inclusion criteria to identify eligibility for LCS in high-risk smokers (≥ 30 pack-year history of smoking, current smokers or recently quit within the past 15 years, no clinical symptoms of lung cancer, age 55–74 years); CMS increased the upper age limit to 77 (23). The National Comprehensive Cancer Network (NCCN) panel recommends LDCT lung screening for two groups of individuals at high risk of developing lung cancer: (I) smokers or former smokers who meet the same criteria (i.e., age, pack-year history, and smoking status) as in the NLST and (II) individuals age 50 years or older (no upper age limit) with a 20 or more pack-year smoking history and with one additional risk factor (24). The AATS advises screening up to age 79 in ever smokers regardless of time since quitting (3). The USPSTF recommendation also increased the upper age limit (80 years) after review of Cancer Intervention and Surveillance Modeling Network (CISNET) modeling studies which still showed benefit among older adults in appropriately selected populations (14).

The NCCN and AATS consider other risk factors (e.g., occupational exposure to carcinogens like asbestos and coal smoke, history of chronic obstructive pulmonary disease) that, in addition to smoking, may synergize to increase risk of lung cancer. Finally, some guidelines acknowledge that absolute risk factor(s) may not be adequate to define eligibility as 2/3 of lung cancer diagnoses would not have met LCS criteria (26). Thus, NCCN suggests risk-based assessments (27) using a risk calculator may help determine a patient's risk of developing lung cancer and can be used during SDM visits (28).

The role of primary care providers in LCS

The primary care provider is central to implementing a high-quality LCS program. The USPSTF outlined six components of a structured LCS program: (I) identify eligible patients; (II) engage in SDM; (III) refer to certified LCS centers; (IV) follow-up on abnormal findings; (V) manage other health problems during cancer treatment; and (VI) provide tobacco treatment services (29). The literature shows that there are challenges to implementing the first

three components.

One study found that only 33% of providers identified eligible patients for LCS (30). A contributing factor may be the lack of awareness or knowledge about the recommendations for LCS. There is variation in the awareness of the guidelines for LCS, ranging from 0% to 89% (30–35). The wide range could be due to the timing of the data collection in relation to when the guidelines were released, confusion due to various guideline eligibility requirements, and the practice setting. For instance, in a qualitative study, none of the primary care providers (N=10) in New Mexico were aware of the new guidelines for LCS (31). They were interviewed from February to September of 2014, which overlapped with the release of the USPSTF recommendations. In contrast, in the study where 89% of the primary care providers (N=36) were aware of the guidelines, they were all from an academic medical center and the data were collected in 2015 after the release of the USPSTF recommendations (35). A larger study with 350 primary care providers found that 86% reported being somewhat or very familiar with the USPSTF guidelines (29). However, many providers do not know the specific eligibility criteria for LCS (32). Only 11 of 36 providers could correctly identify the NLST eligibility criteria for age and smoking history (35). The failure to engage patients in SDM is discussed later in this article.

Although providers may discuss LCS, few are referring patients for screening. An analysis of the National Health Interview Survey showed that in 2015, only 6% of smokers were being screened and chest X-rays were still being ordered for LCS (36). In a study by Duong and colleagues, 27 of the 36 primary care providers reported they discussed LCS and 21 ordered a LDCT for LCS (35). In a study by Lewis and colleagues (37), only 12% of the providers ordered a LDCT. In a more recent survey of providers, 52% ordered LDCT for LCS but only 21% referred patients in the past 12 months (33). A survey study of 350 family medicine providers found that more than half (56%) planned to refer patients for LCS, but only about a quarter (26%) referred patients to a certified LCS center (30). Many providers report assessing for smoking behaviors. However, few are referring patients to formal cessation services (32). More than half (66%) of providers from Texas reported following up on abnormal findings (30). This same study found that nearly 83% of providers manage other health problems during treatment. A recent qualitative study reported that providers had little time for counseling and SDM (32).

Table 3 Shared decision-making questions for patients and health care providers: comparison of cancer screening decisions

Cancer type	Screening decision making questions for patients and health care providers				
	Yes/no?	When to start?	When to stop?	What interval?	Which modality?
Lung	√	–	–	–	–
Colorectal	–	√	√	–	√
Breast	√*	√	√	√	–
Prostate	√	√	√	√	–

Based on screening recommendations in the U.S. *, for women under 50, depending on guideline.

What is SDM?

Attention to SDM in healthcare continues to rise. In the U.S. in 1982, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research called for a more equal doctor-patient relationship (38). SDM was advocated as an ethical ideal for patient-professional relationships. The 2009 Institute of Medicine (IOM) Report on Comparative Effectiveness Research defined the purpose of comparative effectiveness research as providing evidence to assist consumers (and by extension patients) to make informed decisions about their care (39).

The landmark IOM Report on “Delivering High-Quality Cancer Care” identified essential components of the healthcare system for cancer patients (40). Two specific recommendations from the IOM address the component about engaging patients in cancer care. Recommendation 1 focuses on information and decision support tools, and Recommendation 2 focuses on improving end of life care through patient-centered approaches, such as clinician training, use of advance care plans, and support and referral to hospice. The goal is to provide patients with high quality information about their care, including use of tools such as decision aids, and training of the care team in providing information.

The Agency for Healthcare Research and Quality (AHRQ) defines SDM as a model of patient-centered care that enables and encourages people to play a role in the medical decisions that affect their health. It operates under two premises: first, consumers armed with good information can and will participate in the medical decision-making process by asking informed questions and expressing personal values and opinions about their conditions and treatment options. Second, clinicians will respect patients' goals and preferences and use them to guide recommendations and treatments. The aim of SDM is to

ensure that patients understand their options and the pros and cons of those options, and patients' goals and treatment preferences are used to guide decisions (www.ahrq.gov).

In cancer screening, SDM is relevant for a variety of decisions. For LCS, the most recent cancer screening context where SDM is recommended, the primary focus is on the decision to be screened given the potential benefits and known harms. Guidelines indicate an upper age limit at which screening should stop, or when a patient has not smoked within the past 15 years. Guidelines are also clear about the need for annual screening and that LDCT is the only approved screening method. The decision is complex because of the tradeoffs between harms and benefits. In contrast, screening for colorectal cancer includes questions about when to start, when to stop, and which screening modality should be selected (*Table 3*). Breast cancer screening involves uncertainty about when to start screening and the appropriate screening interval. Finally, prostate cancer screening involves questions about whether or not to be screened, plus when to start, stop, and what interval is appropriate.

SDM is poorly performed

One of the classic studies in informed decision-making was conducted by Clarence Braddock in the mid to late 1990s (41). Braddock's group audio-recorded 1,057 encounters among 59 primary care clinicians and 65 general and orthopedic surgeons. The audio-taped discussions were analyzed for seven elements of informed decision-making, reflecting 3 levels of decision complexity: (I) basic decisions (high consensus decision with minimal impact on patient): discuss patient has a role in decision making, and the nature of the decision; (II) intermediate decisions (some uncertainty about options, moderate impact on patient): adds discussion of alternatives and pros/cons of

alternatives; and (III) complex decisions (great uncertainty about options, major impact on patient): further adds discussion of uncertainty associated with decision, assesses patient's understanding, and explores patient's preferences. Overall, clinicians were doing a very poor job addressing all the elements of informed decision-making. For basic decisions, 17% of encounters met all criteria, while none of intermediate decisions and only one of the complex decisions met all criteria. Elements that were rare included discussing alternatives, pros and cons, the patient's desired role in decision making, and uncertainties about the choices.

The DECISIONS study, which was conducted by the University of Michigan between November 2006 and May 2007, showed that patients are making uninformed decisions, despite feeling informed, for prostate, colorectal, and breast cancer screening (42). The DECISIONS study surveyed 1,082 adults from the general U.S. population who were 50 years of age or older and had discussed cancer screening with their healthcare provider. Aside from prostate cancer screening, fewer than half of eligible adults reported being asked about their preferences for colorectal (41% for men and 31% for women) and breast cancer (45%) screening. Discussions about the benefits of cancer screening were very common, while discussions of the harms were not. Patients reported that doctors discussed harms of screening for prostate cancer about 30% of the time, colorectal cancer 27% of the time for men and 26% for women, and breast cancer screening 19% of the time. It seems as though there has been little progress since the earlier studies conducted by Braddock's team.

Strategies for promoting SDM

SDM can be enhanced through the use of patient tools or decision aids, training for clinicians, the use of other members of the clinical team to serve as "decision coaches," changes in reimbursement for encounters, and redesigning practices to better accommodate opportunities to engage patients in discussions about their healthcare choices. LCS is unique in that CMS reimburses a patient counseling and SDM visit separately from coverage for the actual screening (23). Aside from decision aids, the other strategies have not been explored to any great extent in the context of LCS.

By far, the most widely tested interventions for promoting SDM involve the use of patient decision aids. Patient decision aids are interventions designed to help people make deliberative choices about their healthcare options using the best available evidence. They provide

balanced information about options, and help patients construct, clarify, and communicate what is important to them in making values-based choices with their healthcare providers (43,44). The most recent Cochrane systematic review of decision aids for people facing health treatment and screening decisions includes 105 RCTs involving over 31,000 subjects (43). Studies of screening decision aids are common (e.g., prostate cancer, colorectal cancer), but no trials have been conducted on LCS decision aids through April of 2015, the end date for the systematic review.

A model of SDM

Elwyn and colleagues offered a generic, pragmatic model of SDM that can be applied to the LCS decision (45). The "talk" model is meant to support deliberation between clinicians and patients through three steps and lead to informed preferences and shared decisions. We have adapted the model for LCS decisions (*Table 4*). Any healthcare provider can engage the patient in the SDM process, which is an important consideration for feasibility of the approach in real world clinical settings. Note that CMS has specific criteria for approved non-physicians providing the patient counseling and SDM visit.

Step 1 is the "Choice Talk" and involves helping the patient understand that LCS is a decision where the patient can choose to be screened or choose not to be screened. It may be done in person, but can also be accomplished before a visit through educational material or a decision aid. Step 2, the "Option Talk", is a more detailed discussion of LCS, including the possible benefits and harms associated with LDCT screening. Again, a decision aid can be helpful in guiding this discussion and providing information expressed in lay terms about benefits and harms. At this point, techniques such as the "teach-back" method can be used to check the patient's comprehension of the information and understanding that LCS is a decision. Finally, the "Decision Talk" focuses in exploring the patient's values and preferences for screening, and making a decision which can include the option of deferring the final decision to a later time.

Tools to support SDM

LCS decision aids can support the process of SDM about initiation of LCS. In general, the use of patient decision aids improves the quality of decisions through increased knowledge, more accurate risk perceptions,

Table 4 A shared decision-making model for deliberation about lung cancer screening

Step 1. Choice talk: help patient understand a decision needs to be made about lung cancer screening
Describe lung cancer screening as a choice for patients
Emphasize that the patient's preferences matter
Check readiness to make a decision
Offer to describe lung cancer screening in more detail
Step 2. Option talk: provide more detail about the lung cancer screening decision
Check the patient's understanding of lung cancer screening, including the harms and benefits
Clearly state the options are to be screened annually or not be screened
Present information about the magnitude of the benefits and harms. Use decision support tools
Check patient's understanding using the teach-back method
Step 3. Decision talk: consider the patient's preferences and decide together about screening
Explore issues of importance to the patient in making the decision
Ask if the patient is ready to make a screening decision
Offer more information or more time if the patient isn't ready to decide
Note that the decision to be screened can be reviewed again at a later time

Adapted from Elwyn *et al.*, three-step model of shared decision-making (45).

reduced decisional conflict, improved patient-provider communication, and a better match between what patients' value and the choices they make (43). Five decision aids are described below; information on these and other decision aids can be found in *Table 5*. All the decision aids below offer information regarding: lung cancer, LCS process, benefits and harms of LCS, and smoking cessation importance. We will highlight some distinguishing features of each.

Lung Cancer Screening Decision Aid (LuCaS DA)

LuCaS DA is a decision aid created in response to concerns that most individuals will not take into consideration the potential risks of LCS (54). LuCaS DA includes three main sections: knowledge, empowerment and value clarification. In the knowledge section, screening eligibility and personal risk assessment calculators are included, which follow the NCCN and USPSTF guidelines. The empowerment section aims at improving SDM by developing patients' deliberative skills. The values clarification section helps patients make decisions consistent with their personal values and preferences. Preliminary results of a study comparing the National Cancer Institute's (NCI) webpages on LCS with LuCaS DA show that LuCaS DA improves some behavioral outcomes, but is not consistently better

than the NCI webpages. Participants with elevated risk of lung cancer (N=50; from Kentucky and SE Florida, USA) were randomized to view the NCI webpages or LuCaS DA webpages and were surveyed after two weeks. LuCaS DA had a high level of acceptability among participants. Increases in knowledge of LDCT and LCS guidelines were shown at the 2-week follow-up (e.g., 33% of DA viewers and 20% of NCI website viewers correctly answered questions concerning mortality reduction). Increases in objective knowledge were not uniformly larger.

shouldiscreen.com

shouldiscreen.com is an online decision aid which provides information about lung cancer and screening, benefits and harms of LCS, comparison with screening for other cancers, and reducing risk of lung cancer presented in texts, graphics, and hyperlinks (48). The site offers an interactive component in which patients calculate pack-years of smoking. Additionally, patients can calculate their personal chance of developing lung cancer in the next 6 years by answering basic demographic and risk factor information. The calculator results also prompt the patient to consider if their personal screening benefit is enough to justify their risk and the reasons for their decision.

Table 5 Overview of patient decision aids for lung cancer screening

Name of aid; developers; date of release/publication	Format of aid	Availability	Overview of content	Evaluation data
LuCaS DA; Jamie L. Studts, University of Kentucky; Under testing (study start date: March 2016)	Interactive, web-based aid	Not yet available	Includes the following sections: Knowledge: potential benefits and risks and personal risks assessment; Empowerment: encourages active communication of patients with clinicians; Value clarification: informs patients how they relate to the screening personally (46)	Increased knowledge of LDCT and LCS guidelines from initial to the 2-week follow-up Mean decisional conflict decreased from 39.3 (SD, 13.5) to 34.4 (SD, 11.1) Percentage of participants stated to have made a decision about screening increased from 32.7% to 37.5% LuCaS DA improves some behavioral outcomes, but not consistently better than the NCI webpages (47)
shouldscreen.com (www.shouldscreen.com); University of Michigan; October 2015	Interactive, web-based aid	Available online	Information about lung cancer and LDCT Costs and benefits of screening Comparison with other screening tests for other cancers Personalized estimates of baseline lung cancer risk and benefit and risks of being harmed by screening	Knowledge increased after navigating the DA (P<0.001) 82% (n=49) thought the DA included enough information to help making decisions on screening Mean decisional conflict scale score was 46.33 (SD, 29.69) prior to viewing the tool, and 15.08 (SD, 25.78) after (P<0.001) Concordance between a participant's preference to screening and the USPSTF recommendation improved (24% to 59%, P<0.001) (48)
"Lung Cancer Screening: Is it right for me?"; Robert J. Volk, The University of Texas MD Anderson Cancer Center; June 2012	Video-based patient decision aid in DVD format or web-enabled video	Copies available to patients at MD Anderson Cancer Center	Eligibility criteria Overview of screening Visual display of magnitude of harms and risks Value clarification Visual display of smoking cessation message	Currently under evaluation with results expected in 2018
CHOICE: Should I start having yearly screening for lung cancer; Daniel S. Reuland, UNC Lineberger Comprehensive Cancer Center; May 2015 (Pilot Study Start Date)	Interactive, web-based decision aid	Not yet available	Review of lung cancer and LCS Visual display of benefits and harms of LDCT (e.g., false-positives, radiation, stress/anxiety) (49) Value clarification Screening choices Smoking cessation messaging	The percentage of participants (n=41) having intentions to initiate LCS decreased from 66% to 54%, (95% CI, -0.09%, 33%) Greater knowledge was marginally associated with lower screening intent [OR, 0.68 (95% CI, 0.46, 1.00)] (50)
Is Lung Cancer Screening Right for Me? A Decision Aid for People Considering Lung Cancer Screening with Low-Dose Computed Tomography (https://effectivehealthcare.ahrq.gov/decision-aids/lung-cancer-screening/patient.html); Agency for Healthcare Research and Quality; March 2016	Interactive, web-based aid	Available online	Eligibility criteria Facts and possible symptoms of lung cancer Reviews of LDCT and benefits and harms of screening Smoking cessation information Value clarification	The effectiveness of the DA has not been evaluated (51)

Table 5 (continued)

Table 5 (continued)

Name of aid; developers; date of release/publication	Format of aid	Availability	Overview of content	Evaluation data
Yearly Lung Cancer Screening: Is It Right for Me? (https://siteman.wustl.edu/wp-content/uploads/2016/04/Lung-Cancer-Screening-20160427_rev.pdf); Mary C. Politi and Pamela Samson, Washington University Siteman Cancer Center; April 2016	Brochure	Available online	Evidence-based summary of LCS vs. no screening Screening eligibility Pros and cons of screening choice Symptoms of lung cancer Smoking cessation information Estimates of baseline lung cancer risk	The effectiveness of the DA has not been evaluated (52)
HealthDecision Chest CT for Lung Cancer- Lung Cancer Screening Decision Support Tool (https://www.healthdecision.org/tool.html#/tool/lungca); HealthDecision; December 2017 (version 4.0.5)	Interactive, web-based aid	Available online	Personalized lung cancer risk estimates for patients that: Collects patients' risk factors data; Shows lung cancer risks and eligibility; Compares options of LDCT scans and smoking cessation; Instructs patients and clinicians to make decisions as appropriate	The effectiveness of the DA has not been evaluated
Decision Aid for Lung Cancer Screening with Computerized Tomography (CT) (https://www.thoracic.org/patients/patient-resources/resources/decision-aid-lcs.pdf); American Thoracic Society Thoracic Oncology Assembly; June 2015	Brochure	Available online Copies available for order	Lung cancer and screening information Smoking cessation information Screening choices Benefits and harms of LCS Value clarification Deliberation to healthcare provider	The effectiveness of the DA has not been evaluated
Printable Shared Decision-Making Aids (https://www.emmc.org/Lung-Cancer-Screening/Printable-Shared-Decision-Making-Aids.aspx); Eastern Maine Medical Center; 2015	Web-based aid	Available online	Estimates for individual risk of lung cancer for current or former smokers Benefits and potential risks of LCS	The effectiveness of the DA has not been evaluated
Lung Cancer Screening Decision Tool (http://nomograms.mskcc.org/Lung/Screening.aspx); Peter Bach, Memorial Sloan Kettering Medical Center; June 2013	Web-based prediction tool	Available online	Online questionnaire that asks about lung cancer risk factors (e.g., age and smoking history, occupational exposure to asbestos) Results help clinicians and patients determine the chance that screening will be beneficial	Estimates are calculated from 2 models: one predicts the chance that a person will die of lung cancer in a year, and the other yields the chance that a person will die of another cause (53) The former model has been validated The latter model was found to be undercalibrated for the frequency of deaths from other causes. However, recalibration did not alter the estimates to a meaningful degree

DA, decision aid; LDCT, low-dose computed tomography; LCS, lung cancer screening.

In 2014, a before-and-after study was conducted to determine the effectiveness of this decision aid on patient-reported outcomes. The results show that knowledge increased and decisional conflict decreased after patients navigated the decision aid. The decision aid had a high level of acceptability, with 97% of the decision aid viewers recognizing it as likely useful for making decisions about LCS (48).

LCS: is it right for me?

“Lung Cancer Screening: Is it right for me?” is a video decision aid designed to influence screening behaviors of high-risk smokers, and facilitate informed decision-making. It consists of four main components: eligibility criteria, an overview of screening, visual display of the magnitude of harms and risks, and values clarification. Additionally, it conveys the important message of smoking cessation and includes a vivid display of pack-years of smoking. An evaluation study of the decision aid has recently been completed and will be reported in 2018.

CHOICE: should I start having yearly screening for lung cancer?

The LCS decision aid CHOICE (Communicating Health Options through Interactive Computer Education) is compliant with the CMS Decision Memo on LCS with LDCT (49). For the evaluation of the decision aid, patients from a diverse population participated in a single-site (academic primary care practice) pre-post pilot study. Participants viewed the 6-minute decision aid video and were instructed to consider their preferences and values. Preliminary results from the pilot study showed the association of viewing the decision aid with greater knowledge about the harms of LCS. The influence of the decision aid on patients’ preparedness for screening and decisional conflict needs further investigation.

Is LCS right for me? A decision aid for people considering LCS with LDCT

The Effective Healthcare Program of the AHRQ developed decision aid tools for patients and healthcare professionals (<https://effectivehealthcare.ahrq.gov/decision-aids/lung-cancer-screening/home.html>). The aid includes smoking cessation information with a quit smoking line. Information is presented in text, infographics, and interactive tools. A

pack-year calculator is provided in the eligibility criteria section. In the benefits and harms section, factors such as overall mortality benefits, risks from radiation, major complications and overdiagnosis are communicated. This decision tool includes a value clarification section as an interactive survey that helps high-risk smokers make decisions about screening consistent with their preferences. Another component assesses patients’ knowledge of screening and asks their “decision about lung cancer screening” follows the information. Additional guidance on deliberation with a question prompt list, hyperlink for approved LCS centers, and information on insurance coverage are included.

Implementing SDM for LCS

To be effective, interventions to promote SDM must be implemented in routine clinical care. There are many barriers to implementing SDM that cross patient, provider, and practice levels. LCS is becoming a test case for SDM as it is the first preventive healthcare service that requires a visit to discuss harms and benefits of screening for screening to be reimbursed by CMS.

There are several settings where patients and healthcare providers can work together to make informed decisions about LCS. Mazzone and colleagues (16,55) at the Cleveland Clinic developed a centralized model for providing SDM and smoking cessation counseling (Table 6). Their initial strategy was to have primary care providers identify eligible patients and perform SDM in the primary care setting. The approach proved untenable and evolved to a referral model where primary care physicians (PCPs) referred patients to a central LCS program run through a pulmonology clinic. In the LCS program, patients are assessed for eligibility, watch a brief narrated slideshow about LCS, and complete the shouldscreen.com online patient decision aid to obtain an estimate of their lung cancer risk. Patients and LCS center providers then have a discussion about LCS, make a screening decision, and smokers are connected with local smoking cessation resources. The SDM conversation is delivered by a nurse practitioner, physician assistant, or physician. The program is structured so that interested patients can complete LCS on the same day as the SDM visit. An evaluation of the program showed high acceptability by patients, and gains in knowledge after the SDM visit. Few patients (under 3%) declined screening after the visit, likely due to these patients having accepted a referral for another visit to discuss LCS.

A second approach is to conduct the patient counseling

Table 6 Cleveland clinic approach to patient counseling and shared decision-making visit for lung cancer screening (LCS)

Task	Cleveland clinic approach
Assess patient eligibility	Follow LCS eligibility criteria
Provide overview of benefits and harms	6-min narrated slideshow developed internally
Decision aid	shouldiscreen.com
Prepare patient for results, ask questions	Discuss likely findings
	Stress annual screening
	Discuss how results will be communicated
Incorporate smoking cessation counseling	Connect to local resources
	Train personnel
Documentation and reporting	Templated note with extractable elements

Adapted from Mazzone *et al.*, Chest 2017 (55).

and SDM visit in the primary care setting. This approach is clearly consistent with the USPSTF recommendation and the reimbursement decision from CMS. Yet, very little is known about how best to implement SDM in busy clinical settings. Previous surveys of PCPs show that many are not familiar with the NLST results, have incomplete information about eligibility for LCS, incorrectly endorse chest radiography as an accepted screening approach, and are somewhat skeptical about the evidence supporting screening (30,31,37,56).

A study of 350 primary care clinicians conducted after the USPSTF recommendations were released assessed current screening practices and implementation needs (30). About 10% of respondents' practices had a formal LCS program at the time of the survey and less than half (44%) of providers reported engaging patients in SDM prior to referral for LCS. Their implementation needs were as follows: (I) clarity about guidelines/recommendations; (II) information about eligibility criteria; (III) clarity about insurance coverage; (IV) help finding accredited referral centers; (V) SDM tools for patients; (VI) training programs for healthcare providers; and (VII) strategies for integrating screening programs in electronic health records.

An implementation toolkit for LCS in the primary care setting

The Eisenberg Center of the AHRQ released in March

2016, the "Lung Cancer Screening Tools for Patients and Health Care Professionals". In developing this online toolkit, AHRQ focused on four design goals: (I) providing clinicians with a concise summary of the current evidence and recommendations; (II) providing a way to ensure the patient counseling and SDM visit is consistent with CMS beneficiary eligibility criteria; (III) recognizing that a high-quality patient decision aid was not enough to ensure SDM occurs; and (IV) creating decision support tools in multiple formats and for use in multiple ways to support deliberation between patients and clinicians. The resulting multi-component implementation toolkit can be found here: <https://effectivehealthcare.ahrq.gov/decision-aids/lung-cancer-screening/home.html>.

The toolkit contains four components which are readily downloadable for viewing and printing. First is the 2-page "A Summary Guide for Primary Care Clinicians" that provides a summary of the NLST findings including the magnitude of benefits and harms of screening, eligibility criteria for screening, an overview of beneficiary eligibility criteria from CMS, smoking cessation resources, a link to finding accredited imaging centers, and points to discuss with patients. The second tool is the "Lung Cancer Screening: A Clinician's Checklist" (see *Figure 1*). The checklist is structured around activities that occur before, during, and after the clinical encounter. The pack-year formula is given with the eligibility criteria. The content of the conversation with the patient about screening harms and benefits, and information about smoking cessation is included. Finally, there is guidance on making a referral and noting the visit in the medical record. The back page of the checklist includes tips on promoting SDM, talking points, and teach-back examples.

There is also a 4-page patient decision aid, "A Decision Aid for People Considering Lung Cancer Screening". The aid is meant to be reviewed by the patient before a visit with a healthcare provider to discuss LCS. Features include information about eligibility, messaging about smoking cessation and abstinence, use of icon arrays to describe the magnitude of benefits and harms of LCS, a visual depiction of radiation exposure from LDCT compared to other exposures (see *Figure 2*), questions to help clarify the patient's values, questions for the doctor, and information about insurance coverage and other costs. Finally, there is a 2-page abbreviated summary to be used during visits when screening is discussed titled "A Decision-Making Tool for You and Your Health Care Provider".



Lung Cancer Screening: A Clinician's Checklist

This checklist was developed to help clinicians meet the Centers for Medicare & Medicaid Services (CMS) criteria for a lung cancer screening counseling and shared decisionmaking visit. All of the criteria listed below must be met for the screening to be covered as a preventive service benefit under Medicare.

Before...

The Clinical Encounter

Determine patient's eligibility.
This checklist may be completed with the assistance of a nurse, physician assistant, or other medical assistant.

- » Is the patient 55 to 77 years old? Yes No^a
(55 to 80 years old for patients with private insurance)
- » Is the patient a current smoker or former smoker who has quit within the past 15 years? Yes No^a
- » Does the patient have at least a 30 pack-year smoking history? (See the calculator below.) Yes No^a
- » Is the patient asymptomatic for lung cancer with no personal history of lung cancer? Yes No^{a,b}
- » Is the patient healthy enough to have lung surgery? Yes No^a
- » Is the patient willing to receive potentially curative treatment? Yes No^a

Calculate Pack-Years
(20 cigarettes = 1 pack)

×=

Number of years smoked
Average number of packs smoked per day
Pack-years

During...

The Clinical Encounter

Complete all of the following activities.

- Documented all elements in the patient's medical chart.**
 - » Used a decision aid
- Discussed potential benefits of lung cancer screening:**
 - » Reduced mortality from lung cancer
- Discussed potential harms of lung cancer screening, including:**
 - » False-positive results
 - » Followup testing if an abnormality is found (and the possible complications of invasive testing)
 - » Overdiagnosis
 - » Total radiation exposure (screening and diagnostic testing, cumulative)
- Discussed other issues:**
 - » The impact of comorbidities on screening (the benefit of screening is reduced in patients with poor health)
 - » The patient's ability or willingness to undergo invasive diagnostic procedures and treatment
- Counseled about:**
 - » The importance of adherence to annual lung cancer screening
 - » The importance of maintaining cigarette smoking abstinence or smoking cessation, as applicable
 - » Tobacco cessation interventions (provided information, if appropriate)

After...

The Clinical Encounter

- Establish the next steps.**
 - » If the patient would like screening, provide a written order for the lung cancer screening visit with the following elements:
 - » Patient's date of birth
 - » Actual pack-year smoking history
 - » Current smoking status; for former smokers, the number of years since quitting
 - » Statement that the patient is asymptomatic
 - » National Provider Identifier (NPI) of the ordering practitioner
 - » If the patient declines screening, document the discussion and the patient's decision in his or her medical record.
 - » If the patient is unsure about screening or wants more time, consider scheduling a followup visit to discuss the patient's screening decision.
 - » For all patients, reinforce the importance of smoking cessation and abstinence.

^aScreening is not recommended. If the patient is a current smoker, encourage smoking cessation and provide resources. If the patient is a former smoker, encourage continued abstinence and provide additional support if needed.
^bSymptomatic patients may need followup and diagnostic testing, but not screening. Patients with a history of lung cancer need surveillance, but not screening.



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Figure 1 Lung cancer screening checklist for primary care clinicians, from the Agency for Healthcare Research and Quality (<https://effectivehealthcare.ahrq.gov/decision-aids/lung-cancer-screening/clinicians-checklist.html>).

The future of SDM for LCS

Here we highlight a few key challenges and opportunities for improving the decisions patients make about LCS. First, implementation of SDM for LCS is key. Successful implementation will go well beyond making high quality decision aids available to healthcare providers and patients. Briefer tools seem appropriate for the LCS context as decisions need to be made between patients and healthcare providers. Involving other members of the clinical team is a promising strategy that may offset some of the burden on already busy physicians. SDM training for other members of the clinical team could build on highly successful models for certifying personnel in tobacco cessation interventions.

Second, there exist huge gaps between what the current evidence about LCS tells us and what patients find important and want to know. These gaps have the potential to undermine SDM if patients feel the issues of importance to them are not reflected in the evidence they review with their healthcare providers. Some of these gaps are depicted in *Table 7*. The challenge comes from the constraints of large, randomized trials with limited follow-up periods to assess the outcomes of cancer screening interventions. Modeling studies may be the only strategy for addressing these gaps (57), but there remain methodological issues that must be addressed if modeling is to be used to inform individual patient decisions about screening.

Finally, there is growing interest in tailoring screening

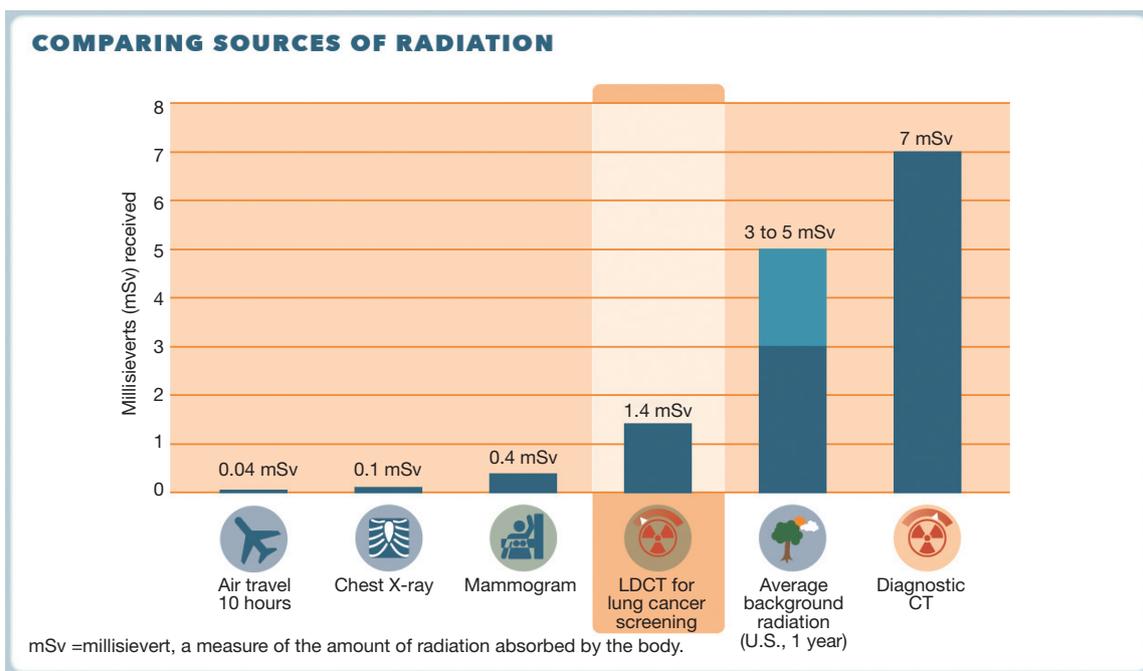


Figure 2 Sources of radiation exposure compared to low-dose CT. From the patient decision aid “Is Lung Cancer Screening Right for Me?” developed by the Agency for Healthcare Research and Quality (<https://effectivehealthcare.ahrq.gov/decision-aids/lung-cancer-screening/patient.html>). LDCT, low-dose computed tomography.

Table 7 Gaps in evidence about lung cancer screening and patient-centered questions

What the evidence tells us:

- ❖ High-risk smokers who are screened annually for 3 years have a 20% reduced chance of lung cancer death within an average 6.5-year follow-up period compared to high-risk smokers screened with standard chest X-ray over the same period of time

What the patient wants to know:

- ❖ I’m 55. If I get screened every year will it save my life?
- ❖ What happens if screening shows something in my lungs?
- ❖ Can screening miss cancer? How often does that happen?
- ❖ What about all the radiation if I get screened every year?

to groups most likely to benefit. The advantages of risk tailoring for LCS include: (I) limiting screening to those at highest risk of lung cancer, thereby limiting harms; (II) informing decisions about when to start and stop screening, and how often screening should occur; and (III) providing individualized estimates of benefits and harms to provide a

more personalized discussion with the patient. Currently, the role of risk tailoring in supporting SDM in the LDCT LCS context is unclear and worthy of further investigation.

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Footnote

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